Comparing alumina-reduced and conventional surface grit-blasted acetabular cups in primary THA: early results from a randomised clinical trial

Ronald Veldstra 1, Annemarie van Dongen 2,3, Eric C. Kraaneveld 4

1 Orthopedic Department, Geminizeidenhuis, Den Helder - The Netherlands
2 Department of Nuclear Medicine, Medical Center Alkmaar, Alkmaar - The Netherlands
3 Department of Nuclear Medicine, Westfries Gasthuis Hoorn, Hoorn - The Netherlands
4 Orthopedic Department, Westfries Gasthuis Hoorn, Hoorn - The Netherlands

ABSTRACT: Alumina grit-blasted implants have been widely used in cementless total hip arthroplasty (THA). However, alumina particles can become embedded in the implant surface, leading to deposition in periprosthetic tissues and implant wear. We hypothesised that the alumina-reduced surface BICON-PLUS NT acetabular cup would improve implant fixation and clinical outcomes over the conventional surface BICON-PLUS cup.

In a randomised controlled, double-blind study, patients with primary or secondary osteoarthritis requiring primary arthroplasty were randomly assigned to THA with either the BICON-PLUS or BICON-PLUS NT cup. All cups were combined with the SL-PLUS stem. In addition to clinical and radiographic assessments, dual-energy X-absorptiometry (DEXA) was performed preoperatively and at regular intervals during a planned 2-year follow-up period to measure bone mineral density as a marker of implant fixation.

At 1 year, there were no differences in bone mineral density, or in clinical or radiographic outcomes between the BICON-PLUS and BICON-PLUS NT groups were identified, leading to early termination of the study. Both groups showed excellent clinical improvement and there were few complications. Both the alumina-reduced and conventional surface acetabular cups can be used with confidence in primary THA for osteoarthritis, although longer-term studies are required to confirm these findings.

KEY WORDS: Total hip replacement, Uncemented cup, Surface, DEXA, Randomised clinical trial

Accepted: February 27, 2012

INTRODUCTION

The success of cementless total hip arthroplasty (THA) relies on a stable bone-implant interface (1), central to which is the establishment of osseointegration, which is dependent on implant material, design, implant finish, status of the bone, surgical technique, and implant loading conditions (2). Modification of the implant finish by grit-blasting the surface with aluminium oxide (alumina) can achieve excellent osseointegration (1, 3-6).

However, alumina blasting leads to embedding of grit particles into the surface, with coverage of hip stems with alumina particles ranging from 23% to 42% (7-9). Retrieved alumina grit-blasted THA prostheses have demonstrated that alumina particles are found in periprosthetic tissues (10-12), leading to immune reactions (11, 12), and can cause wear at loosened implant interfaces (11, 12). These findings have led to attempts to devise methods to remove alumina particles from grit-blasted implant surfaces (7, 8).
The alumina grit-blasted BICON-PLUS threaded acetabular cup (Smith & Nephew Orthopaedics AG, Baar, Switzerland) was first implanted in 1993 and was based on the cementless threaded Zweymüller cup. With a thin-walled, conical titanium shell and thin, lamellar threads, the original cup was designed to match the elasticity of natural bone (13). The redesigned BICON-PLUS version requires reduced bone resection due to the less bulky, double conical shape, thus improving the cutting potential of the modified threads and allowing more medial placement of the cup. Combined with the SL-PLUS stem (Smith & Nephew Orthopaedics AG), it has been associated with high medium-term survivorship and durability, and low rates of osteolysis (14, 15).

The BICON-PLUS NT (Smith & Nephew Orthopaedics AG) has an alumina grit-blasted surface with exactly the same geometry as the BICON-PLUS cup. The only difference is in the treatment of the surface after the blasting process. Following alumina blasting, the surface undergoes a combined chemical–mechanical treatment comprising pickling by short immersion in an etching bath and dry-ice blasting with non-abrasive carbon dioxide pellets. This reduces the alumina surface coverage by chemically loosening and mechanically removing the embedded particles by up to 96%. This is achieved without altering the surface micro-topography or significantly reducing the surface roughness (Fig. 1).

This study aimed to assess any possible differences in hip bone mineral density (BMD) between patients receiving the alumina-reduced acetabular cup and the standard acetabular cup during primary THA. Secondary objectives of the study were the assessment of differences in the prevalence of radiolucent lines and differences in clinical performance between the alumina-reduced acetabular cup and the standard acetabular cup.

MATERIAL AND METHODS

After pre-treatment evaluation to ascertain eligibility and gather baseline data, fifty patients with primary or secondary osteoarthritis who required primary THA aged 50–70 years at the time of surgery were enrolled between March 2007 and October 2008. Exclusion criteria were a diagnosis of rheumatoid arthritis, body mass index greater than 35 m/kg² and revision surgery. Immediately after informed consent, patients were randomised in a double-blind fashion using numbered opaque envelopes to primary THA using either a BICON-PLUS acetabular cup with a conventional surface (control intervention) or a BICON-PLUS NT acetabular cup with an alumina-reduced surface (study intervention). Block randomisation with variable block size was used. Both cups were combined with the SL-PLUS stem, and the articulation was a polyethylene insert with a 28-mm ceramic BIOLOX forte femoral head (Ceramtec, Plochingen, Germany). All prostheses were implanted by one of the two senior surgeons (RV, EK) at a single study site using the surgical technique described by the manufacturer, employing a standard lateral transgluteal exposure. Postoperatively, patients were allowed to start full

![Fig. 1 - Effect of surface treatment on device topography and surface roughness. A) Topography before surface treatment; B) Topography after surface treatment.](image-url)
RCT comparing two acetabular cup surfaces in primary THA

weight-bearing immediately, but were instructed to use crutches for six weeks. Dual-energy X-ray absorptiometry (DEXA), which is a sensitive technique for assessing BMD and for quantifying bone remodelling induced by insertion of a prosthesis (16-18), was performed preoperatively, within 1 week of the THA procedure, and at 8 weeks, 6 months, and 12 months. All scans were evaluated by a single radiologist (AVD), and four regions of interest (ROIs) as described by Wilkinson (18) were employed (Fig. 2).

Clinical evaluation using the Harris Hip Score (HHS) (19), and Western Ontario and McMaster Universities (WOMAC) Index (20), were carried out preoperatively and at 12 months follow-up. Anteroposterior and lateral X-rays were taken preoperatively, postoperatively, after 8 weeks, and after 12 months. All findings, including the presence of radiolucent lines, were documented at the point of observation.

The sample size calculation was based on that employed in a study by Korovessis et al (21), which used the same cup design. The null hypothesis is that the new surface treatment is inferior to the standard treatment. Non-inferiority limit was chosen at 0.30 g/cm2. A sample size of 19 gives a two-group 0.05 one-sided t-test the power to reject the null hypothesis. In order to compensate for patients being lost to follow-up and/or dropping out, it was intended that an initial sample size of 25 patients would be enrolled in each group. The Student-t or Mann-Whitney U test was used to determine any differences between intraoperative continuous variables and for univariate comparison of postoperative continuous parameters. Fisher’s exact test was used to determine differences between categorical variables. The primary hypothesis was tested using the Westlake version of an equivalence test with known and fixed delta (22). Further exploration of the treatment effect was based on linear mixed models (23). Inferences on the random effect structures were based on the restricted maximum likelihood and for the fixed effect structure on standard maximum likelihood. Stepwise backward elimination was used throughout. Two-tailed tests were used throughout. Two-sided p values of <0.05 were considered to indicate significance. Stata 11.2 (StataCorp, College Station, TX) was used for the analysis.

Prior to the commencement of the study, the approval of the regional ethics committee was sought. All patients provided informed consent prior to study inclusion. All patient data were anonymised. The study performed in accordance with the Helsinki Declaration of 1975.

RESULTS

A total of twenty four patients were assigned to the BICON-PLUS acetabular cup and twenty six received the BICON-PLUS NT cup (Fig. 3). One patient was erroneously allocated to the NT group. As a consequence, study groups were not perfectly balanced with regard to sample size. The study was terminated after just 1 year of follow-up as there were no differences observed between the two study groups.

One patient refused to attend the 1 year follow-up. One case needed explantation of the material after 6 months due to a confirmed infection. One case had recorded dislocations at both the 8-week and 1-year follow-ups. One case of bursitis was observed at the 1-year follow-up. All complications occurred in patients who received the BICON-PLUS NT. None of the complications were thought to be associated with the modified device surface.
The median Harris Hip Score increased from 62 (interquartile range (IQR): 56-70) preoperatively to 93 (79-98) at 1 year in the control group and from to 65 (62-71) preoperatively to 89 (71-94) at 1 year in the study group. The difference at 1 year was not statistically significant (p = 0.291).

WOMAC rose from 55 (50-70) preoperatively to 80 (60 – 95) at 1 year in the control group and from 55 (40-68) preoperatively to 85 (75-100) at 1 year in the study group, the difference not being statistically significant. Measurements of periprosthetic bone mineral density revealed no difference between the two groups after 1 year. The equivalence test, with a delta of 0.30 g/cm², refuted the null hypothesis of non-equivalence with p-values of 0.02 and < 0.01 in Zone 1, <0.01 for both tests in zone 2, zone 3 and zone 4.

In the multilevel models, DEXA BMD was consistently lower for the NT group, but except at the 6 months’ time interval in zone 1, the difference was not statistically significant and it already existed at the first postoperative measurement. BMD decrease was largest for Zone 2. Model based (adjusted) values are presented in Table II. All model-based values are adjusted for age sex, age by sex, as well as BMI. Radiological analysis indicated did not show any abnormal findings in terms of radiolucent lines or loosening between the BICON-PLUS and BICON-PLUS NT cups. None of the cups demonstrated macroscopic evidence of migration.

For the sensitivity analysis we performed an intention to treat evaluation, leaving the patient who erroneously received a BICON-PLUS Standard implant in the originally randomised group. The analysis showed a marginal difference and the outcome is omitted from this paper.

---

**TABLE I - DEMOGRAPHIC CHARACTERISTICS**

<table>
<thead>
<tr>
<th></th>
<th>BICON-PLUS</th>
<th>BICON-PLUS NT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, years</td>
<td>62.4 ± 5.4</td>
<td>61.7 ± 7.0</td>
</tr>
<tr>
<td>Weight, kg</td>
<td>80.3 ± 17.4</td>
<td>76.7 ± 14.0</td>
</tr>
<tr>
<td>Height, cm</td>
<td>171.3 ± 9.8</td>
<td>170.2 ± 9.5</td>
</tr>
<tr>
<td>BMI, kg/m²</td>
<td>27.4 ± 5.6</td>
<td>26.4 ± 4.1</td>
</tr>
<tr>
<td>Female sex, n (%)</td>
<td>14 (58.3)</td>
<td>18 (69.2)</td>
</tr>
</tbody>
</table>

BMI: body mass index.

**TABLE II - ADJUSTED RESULTS FOR THE BMD VALUES OVER TIME**

<table>
<thead>
<tr>
<th></th>
<th>Standard</th>
<th>NT</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Postop.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Zone 1</td>
<td>1.58 (1.45 – 1.70)</td>
<td>1.52 (1.40 – 1.64)</td>
<td></td>
</tr>
<tr>
<td>Zone 2</td>
<td>1.43 (1.31 – 1.54)</td>
<td>1.35 (1.24 – 1.46)</td>
<td></td>
</tr>
<tr>
<td>Zone 3</td>
<td>1.19 (1.08 – 1.30)</td>
<td>1.16 (1.06 – 1.26)</td>
<td></td>
</tr>
<tr>
<td>Zone 4</td>
<td>0.96 (0.87 – 1.04)</td>
<td>0.94 (0.86 – 1.02)</td>
<td></td>
</tr>
<tr>
<td>8 weeks</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Zone 1</td>
<td>1.60 (1.47 – 1.72)</td>
<td>1.51 (1.39 – 1.63)</td>
<td>0.34</td>
</tr>
<tr>
<td>Zone 2</td>
<td>1.35 (1.23 – 1.47)</td>
<td>1.24 (1.13 – 1.35)</td>
<td>0.51</td>
</tr>
<tr>
<td>Zone 3</td>
<td>1.13 (1.02 – 1.23)</td>
<td>1.08 (0.97 – 1.18)</td>
<td>0.68</td>
</tr>
<tr>
<td>Zone 4</td>
<td>0.95 (0.86 – 1.03)</td>
<td>0.91 (0.83 – 0.99)</td>
<td>0.49</td>
</tr>
<tr>
<td>26 weeks</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Zone 1</td>
<td>1.56 (1.43 – 1.68)</td>
<td>1.42 (1.30 – 1.54)</td>
<td>0.02</td>
</tr>
<tr>
<td>Zone 2</td>
<td>1.27 (1.15 – 1.39)</td>
<td>1.11 (1.00 – 1.23)</td>
<td>0.11</td>
</tr>
<tr>
<td>Zone 3</td>
<td>1.09 (0.99 – 1.20)</td>
<td>1.02 (0.91 – 1.12)</td>
<td>0.32</td>
</tr>
<tr>
<td>Zone 4</td>
<td>0.91 (0.83 – 1.00)</td>
<td>0.89 (0.81 – 0.97)</td>
<td>0.68</td>
</tr>
<tr>
<td>52 weeks</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Zone 1</td>
<td>1.55 (1.43 – 1.67)</td>
<td>1.48 (1.36 – 1.60)</td>
<td>0.60</td>
</tr>
<tr>
<td>Zone 2</td>
<td>1.24 (1.12 – 1.36)</td>
<td>1.16 (1.04 – 1.27)</td>
<td>0.85</td>
</tr>
<tr>
<td>Zone 3</td>
<td>1.11 (1.00 – 1.22)</td>
<td>1.03 (0.93 – 1.14)</td>
<td>0.34</td>
</tr>
<tr>
<td>Zone 4</td>
<td>0.95 (0.87 – 1.04)</td>
<td>0.91 (0.82 – 0.99)</td>
<td>0.33</td>
</tr>
</tbody>
</table>

---

![Fig. 3 - Flow chart of study participants.](image-url)
DISCUSSION

Results from studies on the periprosthetic tissue absorption of alumina particles and increased wear of articular surfaces imply that the reduced alumina surface of the BICON-PLUS NT acetabular cup might lead to improved osseointegrative and clinical outcomes. In a previous study using rabbit models, a process to reduce alumina particles on grit-blasted, cementless titanium endoprosthetic devices by 96% was associated with a significantly increased bone–implant contact area compared with conventional grit-blasted implants, and uncompromised biocompatibility, with the potential to reduce aseptic loosening and extend implant life (24). Zweymüller et al reported 99.3% survivorship at 10 year follow-up using the standard grit-blasted version of the cup (14). This implies that the grit-blasting not a major concern for this prosthesis design. In addition, we do not believe the generalised postoperative loss of bone mineral density influences implant longevity.

However, results from our double-blind, randomised controlled trial comparing the BICON-PLUS NT cup and the BICON-PLUS in patients with primary or secondary osteoarthritis requiring primary arthroplasty revealed no differences in outcomes, and the study was halted after just 1 year of follow-up. Although BMD scores decreased across ROIs during follow-up, there were only slight differences between the two study populations, thus supporting our initial study hypothesis. There were few complications, all of which occurred in the BICON-PLUS NT group. These complications were not caused by the modified surface. HHS and WOMAC Index scores increased substantially in both the BICON-PLUS and BICON-PLUS NT groups, showing excellent clinical outcomes. There were only minor differences between the two study groups on both scores. Our findings suggest that, while the presence of alumina particles on the surface of prostheses has a histologically observable impact on surrounding tissues and leads to surface wear in vivo, it has no discernible effect on measures of implant fixation and clinical and radiological outcomes. Our study had some important limitations. We acknowledge that the equivalence limit (0.3 g/cm²) in the sample size calculation was not based on prior knowledge. Reduction of the equivalence limit (i.e. to half of the standard deviation) would have led to an inability to reject the null in the equivalence tests, hence to a situation of insufficient evidence due to too little power (25). The relatively low sample size also increases the probability of random differences between the two study groups, hence leaving the possibility for confounding factors open. We consider the consequent lower level of baseline BMD values in the BICON-PLUS NT group a result of these random baseline differences. We also acknowledge that larger studies with longer follow-up are required to determine the long-term effect of the surface modification. Despite the randomisation error in one single case, we found our results robust whether analysed per protocol or on an intention to treat basis.

We conclude that the presence of alumina particles on the surface of implants for THA has no effect on outcomes and safety in the short term, and that both conventional surface and alumina-reduced surface acetabular cups can be used with confidence in patients with primary or secondary osteoarthritis requiring primary arthroplasty.

Financial support: This paper has received funding from Smith & Nephew Orthopaedics AG, Baar, Switzerland.

Conflict of interest: The authors have no significant financial interest or other conflict of interest relating to this paper.

Address for correspondence:
Ronald Veldstra
Gemini-Ziekenhuis
Huisduinerweg 3
1782 GZ Den Helder, The Netherlands
r.veldstra@hotmail.com

REFERENCES


学霸图书馆
www.xuebalib.com

本文献由“学霸图书馆-文献云下载”收集自网络，仅供学习交流使用。

学霸图书馆（www.xuebalib.com）是一个“整合众多图书馆数据库资源，提供一站式文献检索和下载服务”的24 小时在线不限IP 图书馆。

图书馆致力于便利、促进学习与科研，提供最强文献下载服务。

图书馆导航：
图书馆首页  文献云下载  图书馆入口  外文数据库大全  疑难文献辅助工具