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Bone remodelling around HA-coated acetabular cups

A DEXA study with a 3-year follow-up in a randomised trial

Received: 7 December 2005 / Revised: 23 February 2006 / Accepted: 13 March 2006 / Published online: 8 June 2006
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Abstract This study was designed to investigate bone remodelling around the cup in cementless THA. Previous studies indicate an advantage of better sealing of the bone-prosthesis interface by HA/TCP coating of implants, inhibiting polyethylene-induced osteolysis. One hundred patients gave informed consent to participate in a controlled randomized study between porous coated Trilogy versus Trilogy Calcicoat (HA/TCP coated). The cup was inserted in press-fit fixation. The femoral component was a cementless porous coated titanium alloy stem (Bi-Metric), with a modular 28-mm CrCo head. The Harris Hip Score (HHS) and bone mineral density (BMD) determined by DEXA scanning were used to study the effect. Measurements revealed no difference between the two groups after 3 years either in the clinical outcome or in terms of periprosthetic bone density. Patients with a body mass index above normal regained more bone mineral than patients with normal weight. This finding supports the assumption that load is beneficial to bone remodelling.

Résumé Cette étude a pour but d'analyser le remodelage osseux autour des cupules sans ciment dans l'arthroplastie totale de hanche. Cent patients ont accepté de participer à une étude randomisée utilisant une cupule trilogie « porous coated versus calcicoat » (avec revêtement HAP). La cupule a été mise en place en press-fit. Le composant fémoral était un composant sans ciment en titane (bi métrique)

avec une tête CrCo de 28 mm. Les résultats ont été analysés avec le score de Harris et une étude de la densité osseuse déterminée par scanner DEXA. Les mesures n'ont pas montré de différence entre les deux groupes pendant 3 ans, ni de différence dans le devenir clinique de ces patients en terme de densité osseuse. Les patients présentant une surcharge pondérale ont une densité osseuse supérieure aux patients sans surcharge pondérale. Cette attitude nous montre que la charge est le facteur principal du remodelage osseux.

Introduction

Worldwide more than 1 million hips are replaced each and every year, and the number of procedures is still on the increase. Generally, results are good, but aseptic loosening and the development of periprosthetic osteolysis offers great challenges for new developments in THA. For a decade, advances in the understanding of bone remodelling around hip arthroplasties have concentrated on the femoral components. Bone loss of 10–21% within the first postoperative year has been demonstrated, followed by a steady state until eventual loosening of the stem facilitates further bone loss [1, 3–5]. Little attention has been paid to the acetabular side, although two thirds of all revisions for aseptic loosening include an exchange of the cup [6].

From experimental studies in animals, we expect a positive effect from HA-coatings in terms of gap-healing and sealing of the bone-implant interface. HA might thus be the solution to the prevention of debris particles from producing osteolysis and aseptic loosening [12, 16].

HA-coated femoral stems always perform better in terms of migration [8, 17].

Roentgen stereophotogrammetric analysis (RSA)-controlled studies of the performance of HA-coated acetabular components have indicated that HA improves results by a more complete ingrowth of bone and a better sealing of the interface at 2- and 5-year follow-up [13, 18, 19].

Finite element studies (FEM) predict bone loss medial and inferior to the acetabular implant [11].

This work was supported by Zimmer Scandinavia, who produced the Trilogy Calcicoat prostheses.

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Our study was designed to compare the changes in bone mineral density around a specific cementless cup with and without HA coating and to describe the pattern of bone remodelling around hemispherical cementless press-fit acetabular cups in general.

Patients and methods

From October 1998 to May 2000, we performed 247 unilateral cementless total hip arthroplasties at our clinic. One hundred thirty-nine patients with primary osteoarthritis had no competing medical conditions and had pure press-fit fixated cups implanted without additional screw-fixation. One hundred of these gave informed consent to participate in this controlled randomised study (Fig. 1).

The procedure was approved by the local committee of scientific ethics. Informed consent was obtained prior to the operation.

Demography

All patients suffered from primary osteoarthritis. None of them had previously had surgery on the hip. The mean age at surgery was 60 years (range: 33–78); there were 47 females and 54 males. The mean BMI was 29 (range 18–44), and the mean Harris hip score preoperatively was 51 (22–72). The group of 39 patients who refused to participate had a mean age of 64 years old (32–78) and comprised 17 females and 22 males [BMI 28 (20–41); preoperative HHS 49 (9–85)]. We found no significant differences between this group and our two treatment groups. Patients with metabolic diseases or cerebral dysfunction were excluded. No patients entered the study with two problem hips.

Surgery

Surgery was performed in an operating room with laminar airflow. Single dose prophylactic methicillin of 1 g was given i.v. preoperatively. Anaesthesia was provided with spinal infusion of a single dose local anesthetic. During the operation, patients were fixed in a lateral decubitus position, allowing exposure of the hip joint through a posterior approach. The bony bed of acetabulum was prepared for cup insertion by reaming away residual cartilage and bone excrescences, whilst maintaining the subchondral bone plate. Cup size was chosen 2 mm larger than the last reamer used, i.e., press-fit fixation [15]. Mobilisation commenced on the first postoperative day, although weight bearing was restricted for 6 weeks using two crutches.

Prosthesis

Envelope randomisation was performed in the operating room after the reaming procedure. The standard cup was the porous coated Trilogy (Zimmer, Warsaw, IN). The core is manufactured of titanium alloy (Ti-6Al-4V), and it is covered with a fibre mesh of technically pure titanium.

The study cup was identical to the standard, but a supplementary layer of absorbable calcium-phosphate (Calcicoat) was plasma-sprayed to its outer surface to a thickness of approximately 70 µm. Calcicoat is approximately 65% calcium hydroxyapatite and 35% tricalcium phosphate (HA/TCP) that is 50% crystalline and 50% in a soluble phase.

We used a standard polyethylene liner (not highly cross-linked) with a 10-degree elevated rim. The femoral component was a cementless plasma-sprayed coated titanium alloy design (Bi-Metric, BiometMerck, Warsaw, IN) with a modular 28-mm CrCo femoral head.

DEXA scanning

Wilkinson et al. performed the first studies on acetabular periprosthetic BMD measurements. They concluded that a model with four regions of interest (ROI) – ‘the Wilkinson regions’ – offered the highest precision in BMD measurements [21].

We went further in testing the reproducibility and quantifying of the model and concluded that it would be useful in detecting periacetabular osteolysis [9, 10].

Measurements were performed with a dual energy X-ray absorptiometer (Norland XR-36 Bone Densitometer) as previously described [9, 10]. We performed calibration daily, with two different phantoms, according to the instructions from the manufacturer. The scanner reported an internal precision CV% ranging from 0.41 to 0.71 during the years of this study.

Fig. 1 Inclusion diagram

Regions of interest

Patients were placed supine on the scanner table in the position yielding the best reproducibility according to previous studies [10, 20, 21]. Four regions of interest (ROI) were used, modified from the regions defined by Wilkinson et al. (Fig. 2) as previously described [10].

Data collection

Patient data were recorded on admission, and the Harris Hip Score preoperatively and after 1 and 3 years. DEXA scanning was performed within 1 week operation and after 3, 6, 9, 12 and 36 months.

Statistics

The hypothesis to test was expressed as follows:

H_0 : there is no difference between the two treatment groups in any of the four regions of interest concerning BMD change during the evaluation period. A significance level of $P < 0.05$ was selected.

Sample size was chosen to find differences exceeding BMD 0.25 g/cm^2 (least relevant difference: $\delta = 0.25$; $SD = 0.4$), with a risk of type 1 error: $\alpha = 0.05$ (5%); $\beta = 0.2$ (20%); statistical power = risk of type 2 error = $1 - \beta = 80\%$. The statistical table sample size had 43 patients in each group. We chose 50 patients in each group to accommodate for drop-outs. Differences between groups were evaluated by calculating the 95% confidence limits of the changes in BMD.

Results

One patient died of an unrelated cause a few months after the operation. Ten patients (4 HA; 6 standard) had

Fig. 2 Modified Wilkinson regions of interest

insufficient clinical examinations or unprocessable DEXA scans after 3 years, leaving 89 (46 HA; 43 standard) patients with a complete set of data.

There were no revisions or recurrent dislocations in the study period (nor in the ten-patient group with insufficient data).

The Harris Hip Score rose from 53 to 92 in the study group and from 48 to 93 in the control group (ns). The group of 39 patients who could have entered the study but refused was not called for routine follow-up after 3 years, but their 1-year follow-up HHS data rose from 49 to 94.

Measurements of periprosthetic bone mineral density revealed no difference between the two groups after 3 years (Fig. 3). In ROIs 1 and 2 there was an initial decrease, followed by a restoration of bone density in the following years. In ROI 3 we observed a very slight decrease during the whole period. In ROI 4 density rose from the beginning to the end of the investigation.

When stratifying for body mass index into the groups normal $18\text{--}24.9 \text{ kg/m}^2$; overweight $25\text{--}29.9 \text{ kg/m}^2$ and obese $30\text{--}\infty \text{ kg/m}^2$, and not taking the treatment group into consideration, we found a clear tendency of better bone regeneration in the overweight and obese groups, compared to the normal weight patients. This difference was significant ($P < 0.05$) only in the ROI 3 (Fig. 4).

Discussion

In this controlled study randomised between HA and non-HA coated cups, we found no differences after 3 years concerning the bone mineral density (BMD) or clinical outcome. We observed an initial decrease and subsequent partial regaining of BMD during the 3-year observation period. The reasons for BMD changes could be stress-shielding, osteolysis, physiological age-dependent changes or medical/pharmacological causes.

Osteolysis is not likely to occur within this short time span, nor should age-dependency cause any relevant loss. Patients taking any medication that could affect bone mineral density were not included in the study, and none of the patients commenced such treatment in the course of the study.

Knowledge of osseointegrated porous-coated implants has mostly been obtained from retrieval studies that have contributed substantially to the basic understanding of the histological and radiographic durability of biological fixation. Other autopsy studies are indicative of the benefits from load transmission showing bone apposition primarily around the peripheral rim and at the peaks of the threads of screw cups [2]. From this study, we can bring in the effect of weight bearing – the heavier the load transferred to the implant, the more bone will grow in the bone-implant interface.

The use of a finite element model to examine stress-related bone changes in the acetabular region has predicted the distribution of bone density throughout the natural pelvis and after the insertion of two designs of cementless metal-backed acetabular cups. The simulations with fully

Fig. 3 Bone mineral density changes in the different regions of interest. No significant differences between treatment groups

Fig. 4 Influence of body mass index on bone mineral changes. Similar differences in all regions, significant in ROI 3

fixed bone-implant interfaces predicted extensive loss of bone density medial and inferior to the prosthetic components. These results predict that acetabular components with full bony ingrowth may induce significant stress-related bone remodelling due to an altered transfer of load [11]. Our results are different, with almost no changes in ROI 3 and an increase in ROI 4, and question the reliability of the FEM simulations.

Previously, the term stress shielding was reserved for bone mineral loss in the proximal femur with distally fixed stems. Now we have to consider what happens in the acetabulum exposed to implantation of a press-fit device. A bone mineral decrease in the short-term follow-up after press fit fixation of acetabular implants has been described in a CT study. Wright and co-workers propose that the changes represent a response to a decrease in regional bone stress induced by the presence of the press-fit implant, and this might be considered as *retro-acetabular stress shielding* [22].

The immediate benefit from our study is the contribution to comprehension of bone remodelling around the press-fit hemispherical acetabular cup.

A preliminary study on periacetabular bone mineral density around press-fit threaded cups by DEXA scanning was reported using the original DeLee and Charnley regions. After 2 years they found demineralisation in the medial and distal ROIs, whereas BMD in the proximal ROI was practically unchanged [14]. Wilkinson and co-workers, who introduced the DEXA model for BMD measurements employed in our studies, found similar changes in a few patients followed up for 13 months [20, 21]. In our study we found a very different remodelling pattern: a BMD decrease for 6–12 months in ROIs 1 and 2 to a steady state for the rest of the observation time, practically no changes in ROI 3, and a BMD increase during the whole period in ROI 4! Furthermore, our study elucidates an interesting difference between normal and overweight/obese patients – we venture to suggest that the reason for the better remodelling pattern among these groups is a response to the higher load transfer to the bone-implant interface. Our findings could be relevant to early weight-bearing without restrictions, a regimen recently shown to have no adverse effects to implant stability [3, 7].

Conclusion

We found no difference with regard to bone mineral density changes or clinical outcome in 100 patients followed up for 3 years after randomisation between HA or standard porous coated cups inserted with the press-fit technique.

Acknowledgements The authors were awarded consultancy from the Research society for Western Danish Health Sciences. They introduced us to Associate Professor Malene Højbjerg and Associate Professor Søren Lundbye-Christensen, Statistical Laboratory, Institute of Mathematical Sciences, Department of Mathematical Sciences, Aalborg University, Denmark; we wish to thank both of them for invaluable statistical guidance.

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