A randomised study of peri-prosthetic bone density after cemented versus trabecular fixation of a polyethylene acetabular component

The ideal acetabular component is characterised by reliable, long-term fixation with physiological loading of bone and a low rate of wear. Trabecular metal is a porous construct of tantalum which promotes bony ingrowth, has a modulus of elasticity similar to that of cancellous bone, and should be an excellent material for fixation.

Between 2004 and 2006, 55 patients were randomised to receive either a cemented polyethylene or a monobloc trabecular metal acetabular component with a polyethylene articular surface. We measured the peri-prosthetic bone density around the acetabular components for up to two years using dual-energy x-ray absorptiometry.

We found evidence that the cemented acetabular component loaded the acetabular bone centromedially whereas the trabecular metal monobloc loaded the lateral rim and behaved like a hemispherical rigid metal component with regard to loading of the acetabular bone. We suspect that this was due to the peripheral titanium rim used for the mechanism of insertion.

An ideal acetabular component should provide long-term fixation, physiological loading of bone and a low rate of wear. While wear and fixation have been extensively studied, bone loading has not, although it is of primary importance as the best results of revision surgery are obtained in the presence of adequate bone stock.1,2

Finite-element analysis and computer-simulated remodelling studies have predicted that retroacetabular bone mineral density (BMD) decreases after total hip replacement (THR).3,4 When the acetabulum is resurfaced with a construct which is stiffer than the native subchondral plate, the mismatch in elasticity focuses contact stress at the peripheral zones of the host-implant interface.1,5,6 A greater portion of the weight-bearing load is transmitted to the peripheral cortex of the ilium than non-cemented acetabular components and uncremented press-fit implants using DEXA and CT-assisted osteodensitometry has shown that cemented acetabular components are better at preventing loss of cancellous bone than uncemented press-fit implants.19-21

Comparison of the bone density adjacent to cemented acetabular components and uncemented press-fit implants using DEXA and CT-assisted osteodensitometry has shown that cemented acetabular components are better at preventing loss of cancellous bone than uncemented press-fit implants.19-21

Recently, there has been considerable interest in trabecular metal which has a three-dimensional structure and more closely resembles the physical and mechanical properties of cancellous bone than any other prosthetic metal component. Levine, Della Valle and Jacobs24 have reported that porous tantalum may be used as an alternative metal for the components for total joint arthroplasty and
that it offers several unique properties. It is fabricated using elemental tantalum metal and a vapour deposition technique. Its high volumetric porosity (70% to 80%) and low modulus of elasticity (3 MPa) allow bone ingrowth two to three times greater than that of conventional porous coating and double the interface shear strength. Its high strength-to-weight ratio and low modulus of elasticity permit physiological loading and in theory minimise stress shielding. Furthermore, tantalum has excellent biocompatibility and is safe to use in vivo. Its compressive strength and elastic modulus are similar to those of bone. Its high frictional characteristics make it conducive to biological fixation. Finite-element analysis has shown that a porous tantalum monobloc component loads the acetabular bone in a similar way to a cemented all-polyethylene component, with load effectively transferred to the superomedial portion of the acetabulum as occurs physiologically. Our aim was to determine whether a monobloc trabecular-backed polyethylene acetabular component loaded the pelvis in a similar physiological manner to that of a cemented polyethylene component. Our null hypothesis was that there would be no difference between the bone density around an acetabular component whether fixed by cement or trabecular metal.

Patients and Methods

Between 2004 and 2006, 55 patients were randomised to receive either a cemented polyethylene or a monobloc trabecular-backed polyethylene acetabular component. Approval of the Ethical Committee was obtained and informed consent was given by all patients participating in the study. A total of 29 patients (17 women and 12 men) were allocated to the cemented group and 26 (20 women and six men) to the trabecular monobloc group. The mean age of the cemented group was 72 years (59 to 83) and that of the trabecular group 71 years (63 to 81). Surgery was performed through a posterior approach in all patients. The trabecular component was a monobloc design with a polyethylene liner moulded to a trabecular shell (TMT Acetabular cup; Zimmer, Warsaw, Indiana). It has an elliptical shape which provides an interference fit of 2 mm at its periphery with the outer diameter 2 mm greater than the polar dome. The flanged contemporary cemented cup (Stryker UK Ltd, Newbury, United Kingdom) was inserted using fourth-generation cementing techniques with Palacos cement (Heraeus Kulzer, Newbury, United Kingdom). The native acetabulum was reamed to 2 mm greater than the actual size of the polyethylene component to give a cement mantle of 2 mm. The subchondral bone was removed and five to seven 5 mm diameter drill holes were made in the acetabular roof and one or two in the pubic and ischial areas, respectively. The femoral component was a double-tapered polished stem (Exeter; Stryker) and was inserted again using a fourth-generation cementing technique. A cobalt-chromium modular head of 28 mm diameter was used. Assessments were performed pre- and post-operatively at six weeks and at one and two years. The clinical outcome was assessed by an arthroplasty research nurse using the Oxford hip score (OHS),27 the Western Ontario and MacMaster Universities osteoarthritis index (WOMAC),28 the Harris hip score (HHS)29 and Short-Form 12 (SF-12) score.30 Radiological assessment was performed by one author (KP) using plain anteroposterior (AP) pelvis and AP and lateral hip radiographs, standardised for magnification using the 28 mm femoral head as a marker. The radiographs were reviewed at six weeks, and at one and two years along with DEXA scans. The distribution of cement around the acetabular component was classified according to the three zones described by DeLee and Charnley,31 with respect to the width of the radiolucent lines, their location in the three zones and any progressive osteolysis. This allowed like-to-like assessment of the cemented and uncemented components to be made keeping the assessment uniform to both groups.

The primary outcome of the peri-prosthetic BMD was assessed by DEXA scanning. A GE Lunar Prodigy scanner (GE Medical, Waukesha, Wisconsin) was used for all the BMD scans which were performed by an independent medical technical officer (BW). The scanner operated in ‘orthopaedic’ scanning mode from about 2.5 cm distal to the tip of the femoral component up to about 2.5 cm proximal to the anterior aspect of the pelvic rim. The BMD was assessed within specific regions of interest (ROIs).

Given the different shapes and sizes of the pelvis and femur, the assignment of standard-sized ROIs was not thought to be appropriate and therefore ROI templates were individually adjusted as described. The scan for each patient at six weeks post-operatively was used to assign individual peri-prosthetic ROIs in the pelvis and the zones of Gruen, McNeice and Amstutz32 around the femur. These patient-specific ROIs were then applied to all the scans performed on the same patient. The Lunar analysis software had a facility to apply ROI templates to scans other than that used to define them. These templates defined by the user were automatically augmented by a template following the pelvic/femoral outline and could then be projected over a new scan and rotated or translated to align the pelvic or femoral outlines of the original and new scans. In this way, the templates could be easily overlaid over different scans of the same patient in a reproducible way.

The pelvic ROIs extended from the lower border of the ischium to the upper aspect of the iliac spine as shown in Figure 1. The Lunar analysis software only allowed a template of up to ten ROIs to be defined at any one time and therefore the pelvis was divided into lower, middle and upper areas to allow more than ten ROIs to be defined overall. Lower pelvis (Fig. 1a). The vertical distance from the centre of rotation of the femoral head to the inferior border of the ischium was measured using the ruler facility in the analysis software. This distance was divided by four and gave the height for ROIs 1 and 2 while ROI 3 was twice this height.
The upper margin of ROI 1 was aligned with the position of the centre of rotation. The lateral aspects of ROI 1 and ROI 2 were drawn around the profile of the acetabular component leaving a gap of approximately 2 mm in the case of the cemented prosthesis to minimise the effect of the cement on the measurement of the BMD. The medial boundary of ROI 1 was defined by the medial aspect of the acetabular rim (tear drop) while the medial aspect of ROI 2 was drawn vertically in line with the lateral aspect of the obturator foramen. ROI 3 lay directly below ROI 2 and encompassed the lateral ischial region, while ROI 4 included the more medial ischial region delineated by vertical projections through the lateral and medial boundaries of the obturator foramen. ROI 5 encompassed the section of pubic bone between the same projections.

**Middle pelvis (Fig. 1b).** The vertical distance from the centre of rotation to the lower limit of the ipsilateral sacroiliac joint was measured and divided by four to give the height of all the ROIs in this template. ROI 1 was sited medial to the centre of rotation with its lower margin level with the middle of the femoral head. The lateral margin was defined by the medial border of the acetabular component (plus 2 mm for a cemented component) while the medial border of the ROI was extended to the iliopectineal line. The other nine ROIs were stacked in a $3 \times 3$ matrix with ROI 3 directly above the mid-point of the centre of rotation and the whole matrix was angled so that the more lateral ROIs encompassed similar areas of bone as the medial ROIs. ROI 3 and ROIs immediately above it had a fixed width of 2.5 cm. The width of the ROIs to either side was extended to the bone-soft-tissue boundary. The border of the acetabular component defined the lower borders of the lower ROIs, that is ROIs 2, 3 and 4 (and occasionally 6). Here again a gap of approximately 2 mm was left around a cemented component (Fig. 2).

**Upper pelvis (Fig. 1c).** The distance from the lower limit of the ipsilateral sacro-iliac joint to the upper aspect of the pelvic rim vertically was measured and divided by three to give the height of all the ROIs in this template. A $3 \times 3$ matrix of ROIs was aligned to 'sit upon' that for the middle pelvis. As with the middle pelvic templates, the central ROIs were 2.5 cm wide. Those to the lateral side extended to the bone-soft-tissue boundary while those on the medial side were limited to 2.5 cm.

In this way most of the hemipelvis could be assigned to tailor-made ROIs.
Kendall rank correlation test was used. When examining the correlations between the variance and the Mann-Whitney U tests were used as parametric testing throughout to identify significant differences. Therefore, the Friedman two-way analysis of variance was thought to be more appropriate to use non-parametrically as assessed by the Shapiro-Wilk test; indicated that many of the BMD distributions were not normally distributed.

When comparing the two groups of patients the BMD findings for the ROIs were expressed as the percentage BMD change relative to the pre-operative BMD at the same ROI. This was done to help to eliminate gender bias in the BMD given that, in general, the BMD in men is greater than that in women and the fact that the two groups contained different proportions of men and women. However, when looking for changes in the BMD after the operation, the results expressed as g/cm² were used since the patients acted as their own control group and gender bias was expected to be less of a problem.

The BMD of the contralateral total hip and of the L2-4 vertebrae and the corresponding T-scores were analysed as per standard GE Lunar protocols. The T-score for a specific site is expressed as the difference between a patient’s BMD at that site and the mean BMD for young, healthy adults of the same gender at the same site, divided by the SD for the young healthy adult population. The identification of normal, osteopenic or osteoporotic status was obtained from the total hip and/or the L2-4 T-scores.

**Statistical analysis.** Preliminary analysis of the BMD data indicated that many of the BMD distributions were not normally distributed as assessed by the Shapiro-Wilk test; thus, it was thought to be more appropriate to use non-parametric testing throughout to identify significant differences. Therefore, the Friedman two-way analysis of variance and the Mann-Whitney U tests were used as appropriate. When examining the correlations between the BMD in individual ROIs relative to the total hip BMD, the Kendall rank correlation test was used. The results were expressed as the median (interquartile range) unless otherwise stated.

Finally, the chi-squared test was used when assessing possible gender bias or bias due to differing systemic bone status, (normal, osteopenic or osteoporotic) in the two groups. A p-value ≤ 0.05 was considered to be significant. All the statistical analyses were performed using Unistat 4 (Unistat 4, London, United Kingdom) statistical software.

**Results**

**Clinical.** One patient from the trabecular metal group died on the tenth post-operative day after a pulmonary embolism and cerebrovascular accident, leaving 26 patients in this group for analysis. No hip was revised in the first two years after operation.

Although the two groups contained different numbers of men and women, there was no significant gender bias between them (chi-squared test, p = 0.148). Similarly, there was no significant bias between the groups in terms of systemic bone status as defined by the DXA BMD analysis of the hip and lumbar spine (chi-squared test, p = 0.16).

The clinical results of improvement in the OHS, WOMAC, HHS and SF-12 scores for both groups were analysed. The SF-12 score was the least sensitive to clinical improvement while the HHS appeared to be the best clinical indicator by a small margin closely followed by the OHS. The scores tended to improve for up to one year post-operatively with no significant difference subsequently between the first- and second-year results. There were no significant differences between the results for cemented or trabecular fixation for any of the clinical scores at any time up to two years after operation (Table I).

**Radiological findings.** In relation to the zones of Delee and Charnley in the cemented group, there were two defects in zone 1, one in zone 1 and 2 and one in zones 1, 2 and 3 at six weeks, which at one year had progressed to five in zone 1, one in zone 1 and 2 and one in zone 1, 2 and 3. These remained unchanged at the follow-up at two years and none of the patients had any related symptoms. In the trabecular metal group, there were two defects in zone 1, six in zone 2, four in zone 1 and 2 and four in zones 1, 2 and 3 of less than 2 mm at six weeks. These changes reduced to two in zone 2 at the follow-up at one year and there were no defects found at two years.
Figure 3 shows the frequency of radiological abnormalities as a function of time in zones 1, 2 and 3. There were marked differences between the groups. In zone 1, the frequency for the group with the cemented component increased to approximately 40% at one year and then stabilised while that for the group with a trabecular metal component decreased post-operatively to less than 10% at one year. At both one and two years, there was a significant difference between the groups in terms of the incidence of radiological abnormalities (chi-squared test, p < 0.001). For zone 2, the incidence of radiological abnormality was significantly higher for the trabecular metal group at six weeks (chi-squared test, p < 0.001), but at one and two years the intergroup differences were not significant since the incidence for the trabecular metal group decreased with time while that for the cemented component group increased (Fig. 3). The results for zone 3 were less dramatic in that there was no intergroup difference at six weeks and two years while the cemented group had a marginally higher incidence at one year (chi-squared test, p = 0.047).

With respect to the femoral zones\textsuperscript{35}; at six weeks there were four femoral components with lucency in zones 1 and 2. By one year only two showed lucency in zones 1 and 2 and at two years none had a lucency in any zones. Three components had migrated by 2 mm at two years.

**DEXA findings**

These are given in Figures 4 to 8.

**Lower pelvis custom ROIs L1 to L5.** For L1 and L2, the ROIs closest to the acetabular component, there was a significant reduction in the BMD at six weeks for the trabecular metal group, being more marked for L1 than L2, a loss of BMD of 15% as opposed to less than 10%. No further changes occurred up to two years. The BMD in the same ROIs for the cemented group showed no significant change with time. For L1, there was a significant difference between the groups, but not for L2.

For L3 and L5, both groups showed significant reductions in BMD at six weeks with little or no change thereafter up to two years. There were no significant differences between the groups.
For L4, there were no significant changes in the BMD with time with the exception of a decrease for the cemented group at one year. There were no significant differences between the groups.

**Mid pelvis custom ROIs U1 to U10.** For U1, the pattern was similar to that of the immediately lower L1 with significant reduction in BMD for the trabecular group at six weeks continuing up to two years, while there was no significant change for the cemented group. Intergroup differences were significant from six weeks up to two years.

For U2 and U3, the cemented group showed an increase in the BMD from six weeks up to two years, while the trabecular group showed a decrease post-operatively. The difference between the groups was significant at all times post-operatively. The apparent increase in the cemented group could be artefactual because of the infiltration of cement.

For U4, there were no significant differences in the BMD either with time or between the groups.

For U5, there were significant increases in the BMD at all times post-operatively for the cemented group, but no change for the trabecular group with time. Intergroup differences were significant from six weeks to two years post-operatively.

For U6, there were significant increases in the BMD for the cemented group from six weeks to two years with a minor, but significant reduction in the BMD for the trabecular group at one and two years. From six weeks to two years, there were significant differences between the groups.

For U7, there was a minor decrease in the BMD for the cemented group at six weeks which was not sustained at one and two years. The BMD for the trabecular group was increased at one and two years. There were intergroup differences at six weeks up to two years.

For U8 to U10, there were no changes in BMD or intergroup differences.

**Upper pelvis custom ROIs P1 to P9.** There were no significant intergroup differences for any of the P1 to P9 ROIs. For P3, the BMD in the trabecular group showed a significant increase at two years consistent with the pattern shown for U7, also on the lateral border of the pelvis. There was a significant reduction in the BMD at P5 for both groups at one year with some evidence of recovery at two years.

**Femoral zones.** When considering each group separately, there was an increase in apparent BMD relative to preoperative baseline for many zones post-operatively, presumably due to the infiltration of cement. However, there were also significant consistent increases (Freidman two-way ANOVA, p < 0.04) in Gruen zones 3 and 4 from six weeks to one year for both groups with no further changes out to two years. Gruen zone 5 also showed a significant increase from six weeks to one year for the cement group only, while just failing to reach significance for the trabecular group (p = 0.06). Therefore, for both groups there is some evidence of bone increase in Gruen zones 3, 4 and 5 between six weeks and one year. No significant BMD decrease was noted for any Gruen zone to two years.

Despite the above BMD increases noted for both groups, there were no significant intergroup differences for BMD changes in any Gruen zone post-operatively. Although it is a reasonable assumption that some of the apparent BMD increases at six weeks were largely due to cement infiltration, the fact that ongoing increases are seen from six weeks to one year for Gruen Zones 3, 4 and 5 indicates that, in these zones, there was a real increase in BMD over this time period.

Given that the femoral component was the same for both groups, it is not surprising that there was no significant intergroup difference in peri-prosthetic bone stock post-operatively.

Excellent positive correlations (p ≤ 0.02) were observed between total hip BMD and preoperative BMD at L1-5, U1-10 and P1-3 indicating that poor bone quality in the THR is consistent with poor bone quality in the adjacent pelvic and femoral areas.

**Discussion**

The porous tantalum monobloc component has been shown to load the acetabular bone similarly to the cemented all-polyethylene component according to finite-element analysis, implying that the loading pattern of both components was similar on DEXA studies. Our findings indicated that the cemented acetabular component behaved in the expected manner, but that in the trabecular group there was a general reduction in the BMD in the surrounding bone. No cemented component was
radiologically loose by two years, but these findings could represent the difficulty in routinely producing a consistent acetabular cement mantle. The radiological analysis of the trabecular group showed that six of the components (23%) were not completely seated at implantation. This is in keeping with other studies and is considered to be due to the rim fit of the trabecular metal component.\(^{36}\) A reduction in the width of these gaps has been reported with time.\(^ {37}\) Our data suggested that this may have been an apparent filling-in with bone or possibly an optical illusion secondary to stress shielding reducing the sclerotic appearance of the subchondral plate.
The excellent correlations between the total hip BMD and that of the custom ROIs in the pelvis and also the Gruen zones in the femur highlight the robust nature of custom ROI analysis, but more importantly confirm that the finding of bone of poor quality at the total hip location, which is the optimal site for estimating the systemic bone status, suggests that there is also bone of poor quality at the sites of the bone-prosthesis interface and beyond.

With regard to the primary outcome measures (Fig. 9), the DEXA analysis confirmed that in the imme-
In the immediate peri-prosthetic region of the acetabulum, there was a general reduction in the BMD in the trabecular implant group. In some cases the decrease in the immediate peri-prosthetic region may have been due to absent bone because of surgical intervention. By contrast, the cemented group showed an apparent increase in the BMD which may, at least partly, have been an artefact caused by the infiltration of cement beyond the safety zone of 2 mm allowed when drawing the peri-prosthetic ROIs. The other main difference between the groups was the increase in the BMD for the trabecular group relative to the cemented group at the lateral aspect of the pelvis suggesting that in the trabecular group this area was responding to a new post-operative stress. There were

Fig. 7

Graphs showing the percentage change in the bone mineral density (BMD) relative to the baseline for the upper pelvis (P1 to P5). The data points are medians while the error bars define the upper and lower quartiles. * indicates a significant difference between the pressfit and cemented group at that particular time post-operatively.
parallel reductions in the BMD in the two groups in the pubic and ischial bones and also in the iliac fossa in keeping with the predictions of finite-element analysis.

The presence of an acetabular component affects the physiological loading of the pelvis. Retroacetabular stress shielding reflects a remodelling response with decreased stress on the regional pelvic bone and may simply represent the successful adaptation of the local bony architecture to its functional requirements. However, there is a theoretical concern that peri-prosthetic stress shielding could eventually lead to the loosening of the component if the stress shielding proves to be progressive and this at the very least would compromise the result of any revision. Previous finite-element analysis has suggested that the press-fit fixation of hemispherical acetabular components increases rim stress and intensifies transmission of the weight-bearing force to the peripheral cortex of the ilium as a result of the generation of hoop stress at the acetabular rim and decreases the area of host implant contact in the region of the dome. The application of computer-simulated theory has predicted that there is resultant attenuation of the bone density behind the acetabular dome.

Kroger et al reported that cemented acetabular components showed a bimodal nature of bone loss with recovery around two years resembling the remodelling seen with cemented femoral components. One possible explanation is

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**Fig. 8**

Graphs showing the percentage change in the bone mineral density (BMD) relative to the baseline for the upper pelvis (P6 to P9). The data points are medians while the error bars define the upper and lower quartiles.
the preservation of the bone mass because of the similarity in the elastic modulus between the polyethylene components, cement and the bony pelvis. They did not examine the effect of the thickness of the cement mantle on the change in the BMD since the distribution of cement is not uniform and estimates based on the mean thickness are felt to be unreliable. Other studies on the DEXA scans of pelvic remodelling after cemented hip replacement were limited with differences in the mapping of the region of interest, but with bone loss ranging from 6% to 17% as reported by Digas et al.

It should be noted that the trabecular metal acetabular component although a monobloc design is not entirely comprised of trabecular metal since there is a circumferential titanium ring for its insertion. This may increase the rigidity on the construct and contribute to the increase in the rim loading, with consequential stress shielding behind the component. This decrease in bone density will reduce the subchondral sclerosis and visually reduce the obvious gap behind the medial aspect of the component without formation of bone. A trial using quantitative CT would be necessary to confirm this, but our data identified a decrease in bone density in this medial region.

Our study further refined the technique of measuring the BMD by increasing the ROIs to 24. This gave more anatomically detailed information in determining the effects of cement on the BMD and the loading pattern of the acetabulum.

Recently, CT-assisted osteodensitometry has been used to evaluate the bone density. It is a new technique and has the advantage of allowing differentiated three-dimensional analyses of cortical and cancellous bone structure compared with the two-dimensional methods used by DEXA. However, our study was begun before the technique became popular.

In summary, comparing the cemented versus trabecular metal press-fit acetabular fixation, the significant differences in the BMD in the peri-prosthetic region were due partly to the artefactually raised BMD in the cemented group and the true decreases in the BMD in the trabecular metal group. Additionally, there was an increased BMD in the trabecular group relative to the cemented group along
the lateral cortical bone of the pelvic rim and a significant reduction in the BMD for both groups in the upper pelvis in keeping with the predictions of finite-element analysis.

We conclude that the trabecular metal monobloc acetabular component has a loading pattern consistent with that of a rigid cementless press-fit component rather than of a cemented one. Therefore although there may be excellent bony ingrowth, stress shielding will still be produced. We believe that this is due to the quality of the rim fit which creates the initial stability and the presence of the peripheral titanium ring which stiffens the construct.

Supplementary material

A figure showing the percentage change in bone mineral density relative to baseline for L2-5 is available with the electronic version of this article on our website at www.jbjs.org.uk.

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