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Original article

Liner type has no impact on bone mineral density changes around a 3D printed trabecular titanium acetabular component

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Background: Three-dimensional printing of implants allows the ability to produce implants and interfaces which theoretically better mimic “normal” bone behaviour, leading to a possible reduction in stress shielding thus maintaining bone mineral density (BMD). This issue was not investigated in vivo using bone scan and different bearings; therefore, we did a prospective study aiming to answer: 1) is there a loss of BMD around the 3D printed trabecular titanium cup, when compared to the native hip; 2) does liner type influence the BMD changes around the acetabulum when a 3D printed trabecular titanium cup is used?

Hypothesis: BMD changes around the acetabulum are not influenced by the liner type, and the cup will be associated with a reduction in BMD when compared to the native hip.

Material and methods: This is a prospective observational study of patients receiving a primary total hip arthroplasty. A 3D printed trabecular titanium uncemented acetabular component was used in all cases. All patients received a ceramic femoral head, with either a ceramic or polyethylene acetabular liner. BMD measurements using DXA were performed at 6 weeks, 6, 12 and 24 months after surgery to evaluate remodeling changes. The 3 acetabular regions of interest (ROI) of DeLee and Charnley were used for serial comparisons of peri-acetabular BMD. The study was powered as a non-inferiority study with the principle variables compared using a two-step repeated analysis of variance.

Results: A total of 48 consecutive patients were included in the study, with all patients completing their 2 year follow-up. There were no failures, revisions or complications within this cohort. We found no statistically significant difference in the BMD change scores between the operated and the native hip in any of the 3 ROI zones. We found no differences in BMD scores when comparing ceramic to polyethylene acetabular liners, head sizes and BMI.

Discussion: This study shows a similar pattern of BMD behaviour around a 3D printed cup when compared to the contralateral native hip. We were unable to show a clinical or radiological difference between the bearing material, head size, or BMI when used with this type of acetabular component.

Level of evidence: III; prospective comparative study.

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1. Introduction

The engineering and manufacturing of Total Hip Arthroplasty (THA) components continue to evolve and improve [1]. Whilst these components can look similar to previous implants, they have been manufactured by a very different engineering process. The method of additive manufacturing (also referred to as 3D printing) is one of these technological changes gaining popularity [2]. It has attractive features, both clinically [2] and financially [3,4]. In THA, 3D printed acetabular components are becoming more common. They can produce complex 3D shapes and provide a trabecular-looking outer morphology.

Whilst there are a number of femoral stems which have remained unchanged for many years due to their long successful track history, acetabular components have changed more frequently. It is the acetabular component which remains a limiting factor in the longevity of the arthroplasty [5,6]. How these components are manufactured, with apparent subtle changes in...
techniques and morphology should continue to be evaluated [2]. Peri-acetabular bone remodeling assessment using DXA can be used to evaluate early fixation of acetabular implants as well as the later effects of bone remodeling and stress shielding. In the short-term, a big loss of BMD around the cup may be indicative of subsequent fixation failure of the component [7] due to a lack of osseointegration [8].

Cup liner wear and aseptic loosening remain the leading causes of long-term acetabular failure after THA [9]. These have been associated with micromotion in modular components and non-fixation at the bone-implant interface [5,6,10]. There is also concern that retro-acetabular stress shielding can potentiate this, and that changes in BMD are variable between different types of acetabular components [11]. Bone mineral density varies between populations and over time. It is affected by several factors, including smoking [12], BMI [13] and the underlying cause of native joint failure [14] and may influence the surgeon’s decision deciding on the type of arthroplasty used [15]. Loss of bone density around the implant [16] may affect short and long-term fixation and may in time lead to loosening of the component [17]. The changes around a loose cup affect the type of revision performed [18]. Although DXA is an established assessment technique in the proximal femur [7], there are relatively few reports of BMD changes in the acetabular region following total hip arthroplasty, especially considering the number of acetabular components available. The previous studies that have investigated BMD of the acetabulum following THA showed a reduction in bone density over time [7,19]. Radiostereometric analyses of cup migration between different liners have been performed [20]. It remains unclear how liner types influence the BMD changes around the acetabulum. Furthermore, the cup assessed in this study is a 3D printed cup – it remains unclear if a cup manufactured with this technology mimics the bone in an improved manner. Therefore, we performed a prospective observational study to evaluate clinical outcomes and the peri-acetabular BMD changes around this new style (3D printed trabecular titanium) of acetabular component that is becoming more popular in THA. We asked the following questions: 1) is there a loss of BMD around the 3D printed trabecular titanium cup, when compared to the native hip?; 2) does liner type influence the BMD changes around the acetabulum when a 3D printed trabecular titanium cup is used? We hypothesized that BMD changes around the acetabulum are not influenced by the liner type, and the cup will be associated with a reduction in BMD when compared to the native hip.

2. Patients and methods

2.1. Patients

This is a registered prospective, observational study. Two senior authors recruited consecutive patients during 2014 and 2015. All patients provided informed consent for participation in the study. Surgery was performed by either of the two senior authors who are fellowship-trained hip surgeons using the posterior approach. The inclusion criteria for the study were: primary osteoarthritis of the hip, male or non-pregnant female between the ages of 18–75, BMI 18–40, ASA I–III and understanding and willingness to participate in the study and in the follow-up. Exclusion criteria were active infection, fracture, previous surgery around the hip, osteonecrosis of the femoral head, secondary osteoarthritis, presence of malignancy in either of the hip joints, patients who were judged by the recruiting surgeons to be incompetent to understand the study process and follow-up, neuromuscular deficit interfering with gait, and patients with chronic systemic illnesses that would significantly impact the outcome, such as rheumatoid arthritis. Patients using oral corticosteroids or bisphosphonates were excluded due to the potential impact on bone remodeling.

The study was designed as a non-inferiority study. Using an alpha of 0.05 and a beta of 90%, with a limit equal to the standard deviation of BMD of 0.4, 36 patients in total, 18 in each group, were necessary to show non-inferiority. We estimated loss to follow-up at 10% and further 20% of patients either having a contralateral THA or undergoing a contralateral THA during the study period, thus becoming lost to follow-up for the native and operated acetabulum comparison. The final number needed was, therefore, 48.

3. Methods

All patients received an uncemented DELTA-T cup (LimaCorporate, Villanova di San Daniele del Friuli, Italy). It is a 3D printed, hemispheric, trabecular titanium (Ti6Al4V) cup. The scaffold in the trabecular titanium has a high open porosity (65%) and a mean pore diameter of 640 μm [21]. The cup diameters range from 44 to 66 mm. The stem used was either a cementless H-MAX S (LimaCorporate) or cemented Friendly (LimaCorporate). The native acetabulum was reamed line-to-line, and press-fitted. All patients received a 32- or 36-mm ceramic head (Bioflex Delta, LimaCorporate) and either a highly cross-linked polyethylene (X-Lima) or ceramic liner (Bioflex Delta, LimaCorporate). The choice of the liner material was performed during the consent process, taking into account patient’s preferences.

3.1. Methods of assessment

Data including patient gender, age at surgery, body mass index (BMI) and American Society of Anesthetist’s (ASA) score. Patients received a plain pelvis AP X-ray and lateral hip view as well as dual energy X-ray absorptiometry (DXA) bone mineral density (BMD) measurements at 6 weeks, 6, 12 and 24 months of both the operated and non-operated side. Where the native hip underwent a THA during the study period further DXA scans of the native hip were not performed after this. The BMD measurements were performed using a Lunar Bravo DXA device (General Electric, Boston, MA, U.S.). Scans were performed with a resolution of 0.5 line pair/mm and a speed of 2 mm/sec. The dose of radiation was 20 μSv per examination. Calibration of the machine was performed weekly with an encapsulated phantom, and a quality assurance phantom was scanned at the time of each clinic. Calculations were performed using enCORE (General Electric). The patient was placed on the DXA plinth in a supine position with a positioner placed at the knee and ankle to ensure standardization of the leg position at each visit. The distal tip of the femoral prosthesis was ascertained, and the machine was repositioned to start 5 cm below this, scanning to 5 cm above the acetabular component. All measurements were repeated twice, with the second measurement performed after repositioning of the patient. At baseline, patients were scanned for possible osteoporosis or osteopenia at the neck of femur. The acetabular regions of interest (ROI) were defined according to DeLee and Charnley [22] into Regions 1, 2, and 3 (Figs. 1 and 2). We compared the acetabular changes in BMD around the implanted cup and the native hip within each patient. We also compared the acetabular BMD changes between cups with a ceramic liner and the PE liner. Furthermore, the presence of radiolucent lines in ROI were evaluated according to DeLee and Charnley [22]. We assessed the cup inclination as the angle between the line connecting the most caudal points of the ischium and the line parallel to the cup. The clinical follow-up included the Oxford Hip Score (OHS) preoperatively, at 6 weeks, 6, 12 and 24 months.

3.2. Statistical analysis

Normality of data was tested using the Shapiro–Wilk Test. Continuous, normally distributed data is reported using the mean
(± standard deviation) and was compared using the *t*-test. Non-normally distributed variables are reported using the median [range] and compared using the Mann–Whitney U test. Categorical variables were compared using Chi² test. The precision of BMD measurements for each ROI was calculated as the coefficient of variation, calculated using the formula $\text{CV} = 100 \times \left( \frac{\delta}{\mu} \right)$ with $\delta$ being the standard deviation of the difference between the two measurements and $\mu$ being the overall mean of all BMD measurements for each region. The differences in BMD of the acetabulum were compared using the two-step repeated analysis of variance. The assumption of sphericity was assessed using the Mauchly’s test. If the assumption was not met, the difference in the interaction was assessed using Greenhouse–Geiser Epsilon correction with the significance ($p$) reported. Pearson correlation was used to analyze the correlation between BMD and clinical outcomes and BMI and BMD. Data were analyzed using SPSS 24.0 (IBM, Armonk, NY, U.S.). Statistical significance was set at $p < 0.05$.

4. Results

There were 50 patients included in the study. Two patients were excluded at their own request. This left 48 patients in the study that were followed throughout. Twenty-four patients received a ceramic liner and 24 received a PE liner, shown on the Flow Chart in Fig. 3. Twenty-nine patients received a 32 mm diameter head, 19 patients received a 36 mm diameter head. Three patients received a cemented stem, 1 in the ceramic group and 2 in the polyethylene group, all others received an uncemented stem. Before the beginning of the study, 7 patients had a THA in the contralateral hip and were not included in the contralateral hip DXA measurements. Of the remaining 41 patients, 11 had early osteopenia on DXA scanning at the femoral neck of the native hip at baseline. The mean $T$-score of the group at baseline was zero (range −2.2−1.5). Over the study period, 5 patients underwent a THA on the contralateral side. Their contralateral DXA measurements were not performed at

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**Fig. 1.** DeLee and Charnley zones [22] in the native acetabulum.

**Fig. 2.** DeLee and Charnley zones [22] in the operated acetabulum.

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**Fig. 3.** Flow Chart of patient inclusion and exclusion for two main study questions; the numbers adjacent to the timeline represent the number of patients available for comparison at that follow-up within that group.
subsequent follow-up. Two patients were excluded from this analysis at the 6-month follow-up, three at the 24-month, final follow-up.

Mean age at surgery was 60.9 ± 11.5 years. There were 26 women and 22 men. Mean BMI was 28.4 kg/m² (± 4.3). Fourteen patients were former smokers, and an additional 3 patients were smoking during the study period. Most patients were ASA 2 [1–3]. One surgeon performed 17 cases, the other 31 cases. At baseline, there was no statistical difference between the ceramic and PE groups in any of the above variables (Table 1), except in the distribution of head sizes between the groups. Stratifying for head size (32 vs. 36 mm) showed no correlation to BMD changes in any of the Regions over time (p = 0.705, p = 0.982, p = 0.829). Mean cup inclination in the cohort was 39.9 ± 5.9, without a difference between the groups, Table 1. Radiolucent lines were not observed in any of the zones. The median preoperative OHS of 19.0 [9–38] increased to 47.0 [27–48] at 2 years (p < 0.001). After a mean clinical follow-up of 5.2 ± 0.5 years, the cumulative survivorship was 100%.

The mean BMD of the native hip at baseline in all 3 regions was 1.76 g/cm² ± 0.44. The precision of measurement for all regions was a coefficient of variation between 1 and 2%. Table 2 and Fig. 4 show the changes in BMD over time of each of the zones for the operated and non-operated acetabulum. The repeated measures ANOVA showed no significant difference in BMD between the native and operated hip in any of the zones over time. Zone 1 (p < 0.001), zone 2 (p = 0.035) and zone 3 (p < 0.001) failed the Mauchly’s test of sphericity, suggesting slight differences in the behavior of the bone remodeling between the native and the operated hip, but at no stage was there a significant difference.

Table 2 and Fig. 5 show the changes in BMD over time for each of the zones of interest for the ceramic and PE liner groups. The repeated measures ANOVA showed no significant difference between the BMD in any of the regions over time. ROI 1 and 3 failed the Mauchly’s test of sphericity (p < 0.001), whereas region 2 did not (p = 0.732), suggesting a trend in the behavior of the bone remodeling between the liners, but at no stage was there a significant difference. BMD was not correlated to the change in BMD (p = 0.561, subsequent follow-up. Two patients were excluded from this analysis at the 6-month follow-up, three at the 24-month, final follow-up.

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Fig. 4. Changes in BMD over time for the operated and native hip in the zones of interest.

Fig. 5. Changes in BMD over time for the ceramic and polyethylene in the zones of interest.

$p = 0.965, p = 0.355)$. The only significant correlation between BMD and clinical outcomes was observed at 6 weeks follow-up in zone 3, $p = 0.046, r = -0.293$ (Table 4).

5. Discussion

Bone mineral density changes around the acetabular cup after THA are a known phenomenon [2]. Additive manufacturing might mitigate these changes. The behavior of acetabular cups manufactured with this technology as well as potential differences between liner types has not been investigated. This study shows good clinical and radiological outcomes with the Delta TT (Trabecular Titanium) 3D printed acetabular component with no early failures. It showed that changes in BMD around the acetabulum following THA using this specific cup do not significantly differ from those changes in the native acetabulum with respect to BMD in all three DeLee and
Charnley ROI in the first 2 years post THA. We found no difference in peri-acetabular BMD changes between liner material (ceramic and PE), head size (32 mm and 36 mm), between patients with differing BMI and no correlation of BMD to clinical outcomes.

Previous studies looking at peri-acetabular BMD changes around different acetabular components have shown different changes over time with varying components. Sabo et al. [27] evaluated a titanium threaded cup and observed reduced BMD of 27.9% at 6 months and 17% in region 2 at 2 years postoperative. In region 2, we observed a reduction of 7.5% at 6 months and 12.5% at 2 years in the THA group compared to 4.3% loss at 6 months and 4.9% loss at 2 years in the native hip. Adding coatings does not seem to create a significant difference. Laursen et al. [24] compared the BMD between 2 types of porous titanium cups, one with a hydroxyapatite-coating and one without, and found no difference in the reduction of BMD at 3 years. At 8 years, there was still no difference [25]. A systematic review found no difference in terms of survival, when hydroxyapatite-coating is used [26]. Some studies do note an almost complete return to normal at 2 years. Salemyr et al. [27] have recently compared a 3D porous trabecular-like titanium shell with a porous-coated titanium shell. Comparing baseline values to two-year values, they observed an almost complete return to baseline in both groups. The more significant initial loss in mineralization was observed in superior 2 regions due to rim loading that initially occurs. The increase in inferior regions, observed by Salemyr et al. [27], was not observed in our study in the operated hip in region 3. Baad–Hansen et al. [28] compared the BMD loss in 50 patients between a trabecular metal tactalum cup and a titanium fiber-mesh cup. They found a loss of BMD of up to 0.33 g/cm² at 2 years postop in superior regions and up to 0.13 g/cm² in the inferior regions with both acetabular components.

The rigidity of ceramic compared to any polyethylene liner was believed to cause increased osteolysis for these bearings due to increased stress and microseparation on the implant-bone interface [29,30]. The clinical evidence on occurrence of this phenomenon is limited. Schmidt et al. [31] performed a matched pair analysis of polyethylene and alumina liners and found no difference in loosening at 5 years. Zhou et al. [20] randomized 61 patients to either ceramic on ceramic bearing or CoCr on cross-linked polyethylene bearing and found no difference in cup migration between the groups, measured with radiostereiosmetric analysis at 2 years. This study corroborates these findings using DXA while, at the same time, reporting a similar pattern of BMD changes compared to the native hip. The BMD and its change are reflected by a number of demographic factors [13]. We have not observed any correlation with BMI. BMI has been shown to increase some complication rates after THA [32], including osteolysis [23]. Our results suggest that this phenomenon does not occur during the first two years after THA. Since the effect of femoral reaming has been reported to have a positive effect on BMD [33], the cup reaming might also have an impact, one that is currently not investigated.

Several limitations to this study must be noted. We were unable to randomize for the polyethylene and ceramic liners within the acetabular shells due to the constraints with ethical approval. In the wake of the metal-on-metal era, our surgical consenting process has had to incorporate discussion and a patient-orientated decision on the bearing surface. However, the baseline characteristics between these 2 groups show no difference. The 6-week postop DXA BMD was used as our baseline for future changes due to the logistics and location of the DXA scan. At the 6 weeks mark, all patients were off crutches and fully weight bearing. Prior to this, there was a variance in achieved weight bearing status and use of walking aids between patients. We expected any changes in BMD between a preop and 6 week DXA was likely to represent this variable weight bearing status and intraoperative surgical factors rather than the acetabular component [34] and would be minimal.

More advanced analytical methods, such as texture analysis, would have allowed for a more detailed analysis [35]. The variability in head size was a feature of differing external diameters of the acetabular component and the liner choice. The 36 mm ceramic head could only be used with a ceramic liner. Not all contralateral hips were native and some were converted to THA during the study period. This prevented comparisons to the native hip BMD in subsequent follow-ups. A 5-year follow-up might have revealed further changes among the BMD or even some failures. We were however unable to design the study with a longer follow-up.

6. Conclusions

This study shows similar patterns of peri-acetabular BMD behavior around this 3D printed trabecular titanium cup when compared to the contralateral hip. Liner material, head size, gender and BMI did not significant affect peri-acetabular BMD.

Disclosure of interest

Two of the authors certify that they (AB, BF) have received research support and teaching fees from LIMA Australia Ltd. The other authors declare that they have no competing interest.

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Contribution

AB, BF and IH initially designed the study; all coauthors gathered the data. BF and AB performed the surgeries. AK and BF analyzed and interpreted the data. AK drafted the article; BF, AB and IH revised it. All authors approved the final version of the manuscript.

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