Effect of Sliding-Taper versus Composite-Beam Femoral Prosthesis Loading Regime on Periprosthetic Bone Mass and Turnover after Total Hip Arthroplasty: A Randomized Clinical Trial

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INTRODUCTION:
Current designs of cemented femoral prostheses may be classified by design philosophy. ‘Shape-closed’ designs, such as the Charnley prosthesis (DePuy Ltd, Leeds, UK), have a bonded prosthesis-cement interface. The prosthesis-cement-bone construct functions mechanically as a composite-beam, and transfers load principally at the level of the femoral diaphysis. Force-closed designs, such as the polished, double-tapered Exeter prosthesis (Stryker Ltd, Stanes, UK) and the polished, triple-tapered C-stem prosthesis (DePuy Ltd, Leeds, UK), have a non-bonded prosthesis-cement interface and act mechanically as a taper-slip. It is proposed that taper-slip loading sets up hoop stresses in the proximal cement mantle resulting in more proximal femoral loading than occurs with a prosthesis that acts as a composite-beam. Whilst finite element analysis modelling data suggest that this loading regime may reduce bone loss through strain-adaptive remodeling at the proximal femur, there is no clinical, randomized trial data to confirm that this results in preservation of bone mass in patients.

The aims of the study were two-fold: Firstly, to determine whether changes in regional bone mineral density (BMD) and systemic biomarkers of bone turnover differ after THA using sliding-taper versus a composite-beam femoral prostheses; and secondly to determine whether the number of tapers (double versus triple) within sliding-taper designs affects change in regional BMD or biomarkers.

METHODS:
Study design: Single centre, randomized clinical trial of 120 patients undergoing primary unilateral cemented THA. The study was approved by the local research ethics committee. Recruitment & Randomisation: Inclusion criteria: Subjects aged >60yrs undergoing unilateral THA for primary or secondary osteoarthritis of the hip. Femoral neck BMD was measured pre-operatively using standard protocols to determine whether there were any underlying between-group differences in BMD. Exclusion criteria: Subjects with known disorders of bone metabolism, systemic inflammatory disorders; use of drug medications known to affect bone metabolism in the past year, and any past bisphosphonate therapy.

Subjects were randomly allocated, by sealed envelope opened at surgery, to receive a non-tapered (Charnley) prosthesis, a double-tapered (Exeter) prosthesis, or a triple-tapered (C-stem) prosthesis. All procedures were made via the same antero-lateral approach, and all subjects received a standard, cemented, Charnley LPW cup and a metal femoral prosthetic head. Subjects were mobilised fully weight-bearing at post-operative baseline, and at weeks 12, 26, 52, and 104 post-operatively. A Harris hip score was also measured at these time-points. Urine and serum samples were collected between the hours of 8 and 10am after an overnight fast at pre-operative baseline, and at weeks 6, 12, 26, and 52. Urinary n-telopeptides of type I collagen (NTX) was measured by electo-chemiluminescent immunoassay (Ortho-Clinical Diagnostics, High Wycombe, UK), and expressed as a ratio to urinary creatinine. Serum osteocalcin (OC) was measured by electro-chemiluminescent immunoassay (Roche Diagnostics Ltd, Burgess Hill, UK). Femoral prosthesis migration was measured over 1 year in a subset of 60 subjects to confirm that each prosthesis migration pattern was true to its design philosophy. Statistical analyses were performed 2-tailed with a critical p value of 0.05 using SPSS statistical software (SPSS, Chicago).

RESULTS:
One hundred and eight subjects completed the 104-week study. Four subjects died from unrelated conditions, 4 withdrew from the study, 3 commenced drugs known to affect bone turnover, and 1 sustained a pathological femoral fracture. The baseline characteristics of the subjects group were similar (Table 1). P>0.05, all comparisons).

Baseline Characteristics

<table>
<thead>
<tr>
<th></th>
<th>No taper (n=38)</th>
<th>Double taper (n=40)</th>
<th>Triple taper (n=42)</th>
</tr>
</thead>
<tbody>
<tr>
<td>*age at surgery (years)</td>
<td>72±6</td>
<td>72±6</td>
<td>71±7</td>
</tr>
<tr>
<td>**Female:Male</td>
<td>24:14</td>
<td>21:19</td>
<td>20:22</td>
</tr>
<tr>
<td>*BMI (kg/m²)</td>
<td>28.6±4.6</td>
<td>29.2±3.9</td>
<td>29.1±5.1</td>
</tr>
<tr>
<td>+BMD (g/cm²)</td>
<td>0.91±0.17</td>
<td>0.91±0.14</td>
<td>0.88±0.16</td>
</tr>
</tbody>
</table>

Table 1: Characteristics of study subjects. *ANOVA, **χ²-test

DISCUSSION:
Our results indicate that theoretical differences in loading regime between sliding-taper and composite-beam designs of cemented femoral prosthesis do not influence strain adaptive remodelling of the proximal femur after THA. We suggest that the difference in elastic modulus between prosthesis and bone is of such magnitude that between-prosthesis differences in loading regime have a negligible impact on strain adaptive remodelling. Differences in the long term survival between composite-beam and taper-slip prostheses are more likely accounted for by differences in prosthesis surface roughness, resultant particle generation, and mechanical behaviour of the construct in the presence of a cement mantle fracture, than by differences in strain adaptive remodelling related to the load-transfer regime.

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Subjects in all 3 study groups underwent similar improvements in functional outcomes (Figure 3).

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Figure 1. Change in net proximal femur BMD and Gruen zone 7 BMD over 108 weeks

Changes in both the osteocalst activity marker NTX-I and the osteoblast marker OC were similar between the composite-beam prosthesis and the sliding-tapers, and was independent of taper number (Figure 2). ANOVA P>0.05, all comparisons.

Figure 2. NTX and OC change over 52 weeks

Subjects in all 3 study groups underwent similar improvements in Harris hip score during the study period (P>0.05), and each implant design showed a distal migration pattern that was consistent with its design philosophy (Figure 3).

Figure 3. Change in Harris hip score over 108 weeks and prosthesis migration over 52 weeks