Thigh Pain in Primary Total Hip Arthroplasty

The Effects of Elastic Moduli

Carlos Lavernia, MD,* Michele D’Apuzzo, MD,* Victor Hernandez, MD,* and David Lee, PhD†

Abstract: Thigh pain after uncemented total hip arthroplasty (THA) remains a controversial topic. Our objective was to assess the effect of material composition in the development of thigh pain after primary THA. A cohort of 241 primary THAs was followed for a minimum of 2 years. All patients received identically shaped tapered cementless femoral components; the first half received a Cr-Co-Mo implant and the other half an identical implant made of Ti-6Al-4V. There were no statistically significant preoperative differences in the 2 component groups except that the percentage of blacks in the Cr-Co-Mo group was larger than in the Ti-6Al-4V group (26% vs. 14%; P < .05). The overall 1- and 2-year incidence of thigh pain was 9.5% and 8.7%, respectively. Implant composition was unrelated to reported thigh pain 1 and 2 years postoperatively. However, patients receiving larger versus smaller stems irrespective of material composition were more likely to report thigh pain at year 1 (relative risk = 4.68; 95% confidence interval = 1.41, 15.50). Thigh pain reported at year 2 was also higher in patients with larger versus smaller implants; however, this difference was not statistically significant (RR = 1.73; 95% CI = 0.68, 4.43). Material composition of this tapered stem design is unrelated to the incidence of thigh pain.

Key words: thigh pain, cementless total hip arthroplasty, stem composition.

Thigh pain is a recognized problem after cementless primary total hip arthroplasty (THA). The incidence of thigh pain reported in the literature ranges from 1.9–40.4% [1]. Factors that have been associated with the occurrence of thigh pain after THA include bone type, larger stem size, uncemented femoral components, straight femoral stem design, stem material composition, femoral component instability, and loosening [2–8]. After other causes have been ruled out (i.e., infection, stress fracture and spinal problem), the most accepted hypothesis for thigh pain in well-fixed cementless femoral components is a mismatch in flexural rigidity between the bone and the stem [3,9]. The flexural rigidity (EI) of a stem is related to both stem morphometry as well as material composition. Both of these factors have been postulated as the primary etiology of thigh pain.

The senior author (CJL) started using the Tri-Lock stem design (DePuy, Warsaw, IN) in 1997; initially the implant was made of cobalt-chrome-molybdenum (Cr-Co-Mo). In the year 2000 the manufacturer introduced a new version of the same...
stem made out of titanium-aluminum-vanadium (Ti-6Al-4V). Our unit started to exclusively use Ti-6Al-4V implants at that time and we continue to follow patients receiving both types of implants. Our objective in the present study is to assess the effects of material composition in the development of thigh pain after primary cementless total hip arthroplasty in a tapered stem series.

**Methods**

The initial study group consisted of 241 consecutive patients each of which underwent cementless primary total hip replacement using the Tri-Lock prosthesis (DePuy, Warsaw, IN). This design is a triple-tapered, straight, collarless, proximally coated stem that comes in 11 sizes ranging from 6.3 cm to 22.5 cm. All study patients received identically shaped components; the first half received a Cr-Co-Mo implant and the other half an identical implant made of Ti-6Al-4V. All procedures were done consecutively between November 1997 and June 2001 by the senior author. The average age of patients was 59.7 years (range, 18–93). There were 141 women and 100 men; 114 operated hips were performed using a 10-point visual analog scale from none (0) to severe (10). We used the definition of Barrack et al. [14] in which thigh pain was present only if a pain drawing showed that the shaded area was on the anterior view and below the inguinal area. The shaded area over the posterior thigh or gluteal region alone was not considered thigh pain, nor was pain that radiated all the way to the toes. Chi-square and Student’s t-test were used to compare group differences (SPSS, Chicago, IL). A P value < .05 was considered statistically significant. Relative risks (RR) and corresponding 95% confidence intervals (CI) were used to estimate the association between implant characteristics and risk of thigh pain.

**Results**

As can be seen in Table 1, there were no statistically significant presurgical differences among patients receiving Cr-Co-Mo versus Ti-6Al-4V stems with the exception of the higher percentage of blacks in the Cr-Co-Mo stems (26% vs. 14%; P < .05). Six patients died and 3 were revised (6 with Ti-6Al-4V and 3 with Cr-Co-Mo stems), 1 for infection and the other for failure of both components before the 1 year follow-up. One patient with a titanium stem had a periprosthetic fracture. These patients were not included in subsequent analyses. Follow-up information was not available for 19 (7.8%) patients (10 who received Cr-Co-Mo and 9 who received Ti-6Al-4V implants). Patients lost to follow-up had significantly higher preoperative WOMAC pain scores relative to patients with 1-and/or 2-year follow-up information (mean = 15.5 vs. 13.1; t = 2.25, P < .05). Baseline QWB scores were also significantly lower in patients lost to follow-up (mean = 0.48 vs. 0.52; t = −2.2, P < .05).

There were also no significant differences in preoperative bone quality in patients receiving Cr-Co-Mo versus Ti-6Al-4V stems, the majority of which were judged to have type A bone (Table 2). The I Moment of Inertia was identical in both groups (2.75); Spotorno Index scores were also similar in the Cr-Co-Mo and Ti-6Al-4V groups (2.95 vs. 2.87). There was no statistically significant difference in the distribution of stem size implanted in the 2 patient groups.
At year 1, 20 patients (9.5%) reported thigh pain; a slightly lower percentage of patients reported thigh pain at year 2 (8.7%). However, among the 192 patients with 1- and 2-year follow-up information, only 9 patients (4.7%), reported thigh pain at both assessments. Average VAS pain intensity levels at year 1 and at year 2 were 1.30 and 1.37, respectively. Identical rates of thigh pain (9.5%) were reported at the 1-year follow-up among patients receiving cobalt-chrome and titanium stems (Fig. 1). Rates of thigh pain were also similar in these 2 groups at the 2-year follow-up (7.5% and 9.5%). This difference in rates was not statistically significant (RR = 1.21; 95% CI = 0.50–2.95). Mean rating of the VAS pain intensity reported in the lower extremities at years 1 and 2 are 1.58 versus 1.03 and 1.53 versus 1.20, for the Co-Cr-Mo and Ti-6Al-4V implant groups, respectively ($t = 1.51$; $t = 0.91$).

Table 3 shows that 1- to 2-year postoperative radiological assessment of stem position and stem fixation were similar in the Co-Cr-Mo and Ti-6Al-4V groups. The distribution of neutral, valgus, and varus stems were not different between the 2 groups. The mean stem size was 6.6 (range 5.5–8.8) for Co-Cr-Mo and 6.7 (range 5.5–8.8) for Ti-6Al-4V.

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Cobalt (n = 110–118) Mean / %</th>
<th>Titanium (n = 106–123) Mean / %</th>
<th>Test Statistic†</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>57.92</td>
<td>61.38</td>
<td>−1.71</td>
</tr>
<tr>
<td>% Female</td>
<td>55.1%</td>
<td>61.8%</td>
<td>0.29</td>
</tr>
<tr>
<td>% Black</td>
<td>25.9%</td>
<td>14.2%</td>
<td>5.06‡</td>
</tr>
<tr>
<td>OA</td>
<td>56.8%</td>
<td>53.7%</td>
<td>4.26</td>
</tr>
<tr>
<td>AVN</td>
<td>21.2%</td>
<td>22%</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>16.1%</td>
<td>11.4%</td>
<td></td>
</tr>
<tr>
<td>RA</td>
<td>5.9%</td>
<td>13%</td>
<td></td>
</tr>
<tr>
<td>WOMAC</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain</td>
<td>13.12</td>
<td>13.24</td>
<td>−0.26</td>
</tr>
<tr>
<td>Stiffness</td>
<td>3.72</td>
<td>3.39</td>
<td>1.05</td>
</tr>
<tr>
<td>Function</td>
<td>47.12</td>
<td>48.81</td>
<td>−1.08</td>
</tr>
<tr>
<td>Total</td>
<td>63.97</td>
<td>65.48</td>
<td>−0.72</td>
</tr>
<tr>
<td>Visual analog-Intensity</td>
<td>8.62</td>
<td>8.4</td>
<td>0.67</td>
</tr>
<tr>
<td>Visual analog-Frequency</td>
<td>8.95</td>
<td>9.3</td>
<td>−0.66</td>
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<tr>
<td>Quality of well being</td>
<td>0.512</td>
<td>0.519</td>
<td>−0.75</td>
</tr>
</tbody>
</table>

Abbreviations: OA, osteoarthritis; AVN, avascular necrosis; RA, rheumatoid arthritis; WOMAC, Western Ontario and McMaster University Osteoarthritis Index.

*Sample sizes varied due to missing data on selected measures.
†Student’s t-test or chi-square.
‡P value < .05.
and varus stem positions were similar in the 2 groups. The presence of spot welds was slightly higher in the Co-Cr-Mo versus Ti-6Al-4V patient groups (76% vs. 68%); this difference was not statistically significant. One patient in the Co-Cr-Mo group had evidence of a Pedestal.

Given the lack of association between material composition and thigh pain incidence, we undertook a secondary analysis to determine whether any of our pre- and postoperative measures outlined in Tables 1–3 were predictive of thigh pain at years 1 and 2. Only stem size was associated with thigh pain incidence. We plotted thigh pain incidence at both years by stem size and determined that there was a generally marked increase in thigh pain incidence in stem sizes 11.3 cm or larger (Fig. 2). Patients were divided into 2 groups based on this cutpoint. Incidence of thigh pain at year 1 was 3.2% in patients receiving smaller stems (sizes from 6.3 cm to 10 cm); 14.8% of patients who were implanted with larger stems reported thigh pain (sizes from 11.3 cm to 22.5 cm) (Fig. 3). This difference was statistically significant (RR = 4.68; 95% CI = 1.41, 15.50). Thigh pain reported at year 2 was also higher in patients with larger versus smaller implants (10.8% vs. 6.3%); however, this difference was not statistically significant (RR = 1.73; 95% CI = 0.68, 4.43). There were also no differences in the overall intensity of pain reported at years 1 and 2 among participants with larger versus smaller implants, respectively (1.56 vs. 0.99; t = −1.57; 1.44 vs. 1.29; t = −0.42).

Discussion

Thigh pain after cementless total hip arthroplasty continues to be a source of concern for surgeons who use biological fixation for the stem in total hip replacement. Published reports have associated this pain to implant instability and fixation failure [2,7]. However, multiple other reports have clearly established a group of patients with severe thigh pain in

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Cobalt (n = 63–92)*</th>
<th>Titanium (n = 75–92)*</th>
<th>Test Statistic†</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stem position</td>
<td>Mean / %</td>
<td>Mean / %</td>
<td></td>
</tr>
<tr>
<td>Neutral stem</td>
<td>47.8%</td>
<td>50.0%</td>
<td>0.90</td>
</tr>
<tr>
<td>Valgus stem</td>
<td>37.0%</td>
<td>37.0%</td>
<td></td>
</tr>
<tr>
<td>Varus stem</td>
<td>15.2%</td>
<td>13.0%</td>
<td></td>
</tr>
<tr>
<td>Stem fixation</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Presence of spot welds</td>
<td>76.2%</td>
<td>70.7%</td>
<td>0.56</td>
</tr>
<tr>
<td>Presence of Pedestal</td>
<td>1.6%</td>
<td>0%</td>
<td>N/A</td>
</tr>
</tbody>
</table>

*Sample sizes varied due to incomplete x-rays.
†Student’s t-test or chi-square; all P values > .05.
Well-fixed, adequately aligned and correctly sized uncemented femoral components [6,15]. The precise etiology for the pain in patients with well-fixed implants continues to be controversial. The most accepted hypothesis for the development of thigh pain in well-fixed uncemented THR is that abnormal high bone stresses at the tip of the femoral component are the primary cause of the problem. These high stresses result as consequence of a mismatch in the flexural rigidity between the patient’s bone and the stem [3,5,8,9].

The flexural rigidity (EI) of a structure is equal to the elastic modulus (E) of the component multiplied by the section’s area moment of inertia (I) about the axis of bending. The elastic modulus is an inherent property of the stem. The area moment of inertia is solely dependent on the cross-sectional area of the stem. In a circular cross-section it is defined as: \((d_1^4-d_2^4)/64\) [16]. A noncylindrical design is strongly dependent on the amount of material and how its distributed with relation to the loading axis. In our study all patients received stems of identical design, therefore eliminating this potential factor from our thigh pain analysis.

Ti-6Al-4V was introduced into the hip arthroplasty world by Sivash in the 1970s. The principal rationale for the introduction of this material for hip stems was the lower elastic moduli of this alloy when compared to the conventionally used Cr-Co-Mo and stainless steel stems used by most of the manufacturers at that time in history. Mechanical compatibility between stem and bone was cited by most manufacturers when promoting their titanium stem.

Namba et al. studied the effects of the modulus of elasticity (E) on the stresses around two femur-stem composite stems (Co-Cr and a Ti alloy) using a cylindrical design and a natural femur using finite element analysis [5]. They reported a significant decrease in femoral stress at the stem tip with the titanium implant when compared to a Co-Cr implant in the anterior (14 MPa vs. 20 MPa) and posterior (49 MPa vs. 62 MPa) cortices. No differences were reported between the materials on the axial normal stress values at the stem tip in the medial and lateral cortices. The directionality in their model may partially explain why most thigh pain is perceived to be located in the anterior aspect of the thigh in most patients. We found no difference in the incidence of thigh pain in patients receiving Ti-6Al-4V versus Co-Cr-Mo stems at years 1 (RR = 1.00) and 2 (RR = 1.21). Our results clearly demonstrate that the theoretical differences in femoral stress as a function of implant material reported by Namba et al. [5], has little clinical significance for the particular cross-sectional geometry used in the Tri-Lock.

The effects of stem size on the incidence of thigh pain was reported by Vresilovic et al. [8]. They correlated the incidence of thigh pain with device size. They reported that, in general, thigh pain increased with stem size. They used a stem with almost the identical cross-section to the one we used. Additionally, this group associated thigh pain to femoral stem area moment of inertia (I). They postulated that increased flexural rigidity creates a more abrupt transition in the bending of the femur-stem composite at the tip of the component. Our results validate these findings because at the 1-year mark patients with a stem larger than 10 cm were more likely to report thigh pain relative to those with smaller stems (RR = 4.68; 95% CI = 1.41, 15.50). The strength of this association diminished considerably at year 2, but still suggested a continued increased risk of thigh pain associated with stem sizes larger than 10 cm (RR = 1.72; 95% CI = 0.68, 4.43).

Cylindrical fully coated cementless femoral stems depend on distal fixation are mostly fabricated from cobalt chrome. Anatomic stems may be fabricated from titanium or cobalt chrome alloy, while most tapered stems are made of titanium alloy. Both of these designs rely on proximal bone ingrowth and ongrowth. Skinner et al. reported that stems such as the proximally fixed Multilock had flexural stiffness 30% lower than those of the bone they were implanted in distally, but had greater stiffness proximally [3]. The variability in design and fixation modalities of the cementless stem used in the stud-
ies published to date make it difficult to study the specific interaction of design and modulus in the etiology of thigh pain. Comparing clinical differences in the incidence of this problem with different stems further confounds the issues. In our study we were able to eliminate fixation modality and area moment of inertia as potentially confounding variables. Our data show that for this tapered design the elastic modulus of the stem has no effect on the presence and intensity of thigh pain.

Some of the initial studies in uncemented total hip replacement used the porous-coated anatomic (PCA) stem (Howmedica, Rutherford, NJ) and the anatomic medullary locking (AML) stem (DePuy, Warsaw, IN). These are cylindrical stems with large cross-sectional areas (high moment of inertia) both proximally and distally, as well as high modulus of elasticity Co-Cr-Mo. This partially explains the high incidence of thigh pain (12–27%) [1] reported in these series. Anatomic Ti-6Al-4V designs like the Harris-Galante Porous femoral stem (Zimmer, Warsaw, IN) were also associated with incidences of thigh pain as high as 17% [17,18]. Furthermore, in this particular design (HGP-I), the lack of circumferential coating produced loosening rates of as high as 25% [17] at 4–6 years. It is highly probable that early reports of thigh pain with this design occurred due to loose devices that could not be identified radiologically.

Multiple reports of uncemented femoral fixation with tapered stems have demonstrated excellent survival and minimal thigh pain. Designs such as the Mallory-Head (Biomet, Warsaw, IN) [1,19,20] and the Tri-Lock have yielded an incidence of thigh pain of 3% [21–24]. These stems depend on proximal fixation and have cross-sectional geometries that taper distally with a concomitant decrease in area moment of inertia (I). Our results confirm the low incidence of thigh pain with a tapered stem and are similar to those previously reported. We had an incidence of thigh pain of 9.5% at year 1 and 8.7% at year 2; only 4.7% of patients reported thigh pain at both the 1- and 2-year follow-up.

Several study limitations should be noted. First, we have incomplete follow-up information on nearly 8% of our cohort. These patients scored higher on the WOMAC pain subscale and reported lower quality of life relative to patients with available follow-up information. It should be noted, however, that patients lost to follow-up were approximately evenly divided across the 2 component groups. It is therefore unlikely that incomplete follow-up biased our central conclusion that thigh pain incidence is not associated with component composition. We also reported that there was no pre- or post-operative radiological evidence of differences in the 2 component groups, although this comparison was limited by incomplete x-rays.

To summarize, we used the same tapered stem design in all patients, with the elastic modulus of the stem being the only difference between cohorts. We found no clinical or statistically significant difference in patients with Co-Cr-Mo stems and Ti-6Al-4V stems, in terms of presence of thigh pain or in the overall intensity of the pain among patients who were followed for at least 2 years. Instead we found a positive association between thigh pain and the larger stem sizes for both materials. Our data shows that the modulus of elasticity has no role in the development of thigh pain with this tapered, proximally coated stem design.

References

measurement for evaluation research and policy analysis. Health Psychol 1:61, 1982