Results of Prospective, Randomized Clinical Trials Comparing Standard and High-flexion Posterior-stabilized TKA: A Focused Review

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**abstract**

High-flexion total knee arthroplasty (TKA) designs have been available for several years for patients desiring a greater postoperative flexion. We conducted a focused review on published results of prospective, randomized clinical trials that compared a standard posterior-stabilized TKA with a high-flexion posterior-stabilized TKA design. Follow-up ranged from 1 to 2.7 years. None of the articles included in the review showed a statistical difference between the standard and high-flexion designs in clinical flexion or range of motion. Mean postoperative flexion ranged from 106° to 130° for the standard design and 110° to 128° for the high-flexion design.

Based on currently available literature, high-flexion cruciate-substituting TKAs do not appear to provide increased flexion in the short term. The downsides of these designs, such as increased cost, increased bone resection, and early femoral loosening, need to be weighed against the potential long-term improvement in polyethylene wear due to increased conformity in high flexion. Continued follow-up to document these findings will be important.
Although several high-flexion total knee arthroplasty (TKA) designs have been commercially available for the past decade, the benefits of these designs with regard to increased postoperative flexion are still being debated. Available designs include fixed-bearing and mobile-bearing versions, often including cruciate-retaining and cruciate-substituting options. In addition, some manufacturers have produced high-flexion designs that are considered sex-specific. Currently available studies have compared some but not all of these designs. This article focuses on the published results using a fixed- or mobile-bearing posterior-stabilized TKA.

**MATERIALS AND METHODS**

On April 7, 2011, articles were selected using a PubMed search for prospective, randomized clinical trials comparing a standard and a high-flexion TKA device with postoperative knee flexion or range of motion (ROM) as a primary outcome measure. Studies of high-flexion devices that are cruciate-retaining or sex-specific were excluded. The search terms “high-flex knee randomized” yielded 7 results. The search terms “high-flexion randomized” yielded 14 results. Excluded from the review were 2 articles that reported on cruciate-retaining designs, 2 that reported on sex-specific devices, and 2 that were meta-analyses. Another 10 PubMed query results were either repeated in both queries, did not study a high-flexion device or have knee flexion as a primary outcome, were commentaries, were in press and unavailable, or did not include a sample size calculation as part of the study design. The 5 articles that met all of the criteria are summarized in Table 1.

**RESULTS**

In the 5 clinical trials, 3 different standard and high-flexion posterior-stabilized TKAs were studied. One system is mobile-bearing and 2 are fixed-bearing. Publication dates ranged from 2005 to 2011, and the studies were conducted in Canada, Korea, Scotland, and the United States (Table 1). Follow-up ranged from 1 to 2.7 years. Sample size ranged from 28 patients per group to 85 patients per group. Some studies reported no statistical difference in age or body mass index (BMI), but others did not mention the difference. The majority of studies had a greater percentage of female patients enrolled. This difference was most pronounced in the 2 studies from Korea.

None of these prospective, randomized studies showed a statistical difference in maximum postoperative flexion or ROM (Table 2). Mean flexion ranged from 106° to 130° for the standard device and 110° to 128° for the high-flexion device. Kim et al reported that ROM was 135.8° and 138.6° for the standard and high-flexion devices, respectively, implying higher flexion measurements than the other studies. Range of motion was defined as flexion minus extension in this study.

Patellar crepitus, the continuous grinding sensation observed during knee extension, is not an uncommon diagnosis following a cruciate-substituting TKA. Hamilton et al reported a statistically significant difference in patellar crepitus between the standard group and the high-flexion group (P=.017), with a higher rate of crepitus in the high-flexion group. To further explore the relationship between patellar crepitus and maximum flexion and also between patellar crepitus and implant size, the t test and Mann-Whitney test were used. There was no difference for maximum flexion, but the P value was .05 for femoral component size. Patients with larger femoral components exhibited a trend toward developing patellar crepitus.

We also calculated the incidence of femoral, tibial, or patellar radiolucencies using Fisher’s test. Only femoral radiolucencies showed a trend toward a differ-

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**Table 1**

<table>
<thead>
<tr>
<th>Publication Date</th>
<th>Authors</th>
<th>Country</th>
<th>Follow-up, y</th>
<th>No. Patients</th>
<th>Mean Age, y</th>
<th>Mean BMI</th>
<th>No. F:M</th>
</tr>
</thead>
<tbody>
<tr>
<td>2011 (in press)</td>
<td>Hamilton et al</td>
<td>US</td>
<td>1</td>
<td>71</td>
<td>62.5</td>
<td>30.1</td>
<td>42:27</td>
</tr>
<tr>
<td>2010</td>
<td>Choi et al</td>
<td>Korea</td>
<td>2.3</td>
<td>85</td>
<td>70.1</td>
<td>26.5</td>
<td>71:3</td>
</tr>
<tr>
<td>2009</td>
<td>McCalden et al</td>
<td>Canada</td>
<td>2.7</td>
<td>50</td>
<td>72</td>
<td>32.1</td>
<td>25:25</td>
</tr>
<tr>
<td>2008</td>
<td>Nutton et al</td>
<td>Scotland</td>
<td>1</td>
<td>28</td>
<td>68</td>
<td>N/A</td>
<td>16:12</td>
</tr>
<tr>
<td>2005</td>
<td>Kim et al</td>
<td>Korea</td>
<td>2.1</td>
<td>50 (50 bilateral, 1 S knee, other HF)</td>
<td>68</td>
<td>Low, not specific</td>
<td>48:2</td>
</tr>
</tbody>
</table>

Abbreviations: HF, high-flexion; S, standard; US, United States.
ence, the standard group having 2 cases and the high-flexion group having 9 cases (P = .055). Kim et al\textsuperscript{1} reported no radiolucent lines. The other studies did not mention radiolucent lines, but reported no loosening.\textsuperscript{1,3,4}

**DISCUSSION**

As with most of the other designs of the high-flexion TKA, the 3 designs reviewed showed no significant difference in postoperative flexion.\textsuperscript{1,5,7,8} Two different research groups had studied 2 of the devices, while the other device had been studied and published in only 1 article, so the number of studies is still relatively small.\textsuperscript{1,5} Nutton et al\textsuperscript{3} reported that their study had not enrolled a sufficient number of patients to detect a difference, but the researchers believed that even if the study had not been underpowered, there would still be no difference.

One prospective, randomized study by Weeden and Schmidt,\textsuperscript{9} omitted from our review due to lack of a sample size calculation in the study design, found a significant difference in flexion. In that study, the average flexion for the high-flexion device was 133°, compared to 120° for the standard device.\textsuperscript{9} The study differed from the others in 2 ways: it had a smaller sample size of 25 patients per group, and the average BMIs of 34.4 and 34.1 for the standard and high-flexion groups, respectively, were higher than the average BMIs in the other studies.\textsuperscript{1,5,9}

Dennis et al\textsuperscript{10} reported that various factors may influence postoperative flexion apart from implant design. Some of these factors include patient factors, surgical technique, knee kinematics, complications, and postoperative therapies. This would help explain why implant design alone has rarely shown a difference in postoperative knee flexion.\textsuperscript{1,5,7,8}

Patellar crepitus or clunk has been reported previously using the PFC knee system (DePuy, Warsaw, Indiana). Fuku-
naga et al\textsuperscript{11} reported their results showing a rate of patellar clunk syndrome in 13.3% of knees at a minimum follow-up of 2.3 years. In a multicenter study examining factors that contributed to developing patellar crepitus using this same cruciate substituting design, Dennis et al\textsuperscript{6} showed an incidence of patellar crepitus of 14%. Implicated factors that increased patellar crepitus included increased number of previous knee surgeries, decreased patellar component size, decreased composite patellar thickness, shorter pre- and postoperative patella tendon length, and increased posterior femoral condylar offset.\textsuperscript{6} Other associated factors were smaller femoral components, thicker tibial polyethylene inserts, and placement of the femoral component in a flexed position.\textsuperscript{5}

Hamilton et al\textsuperscript{2} found a statistically significant difference for patellar crepitus between the standard and high-flexion devices. The study was not designed to specifically evaluate for the presence of patellar crepitus, nor were the multitude of measurements done as in the study by Dennis et al.\textsuperscript{6} The authors hypothesize that this difference may be a false positive, where a true difference likely does not exist (type I or alpha error). A study by Choi et al\textsuperscript{1} supports this hypothesis. In a similar study design comparing the standard and high-flexion rotating platform knee (DePuy), they reported patellar clunk syndrome in 6 patients in the standard group and 3 in the high-flexion group. No statistical difference was found between these 2 groups.\textsuperscript{1}

Concern exists regarding early loosening of the femoral component in high-flexion designs. Han et al\textsuperscript{12} found loosening of the femoral component in 38% of knees with a posterior-stabilized, high-flexion design at 32 months. A greater percentage of patients whose radiographs showed radiolucent lines were able to squat, kneel, or sit cross-legged (85%) while only 49% of patients without radiolucencies were able to achieve those posi-

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**Table 2**

<table>
<thead>
<tr>
<th>Authors</th>
<th>Device</th>
<th>Manufacturer</th>
<th>Mean Flexion/ROM, deg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hamilton et al\textsuperscript{2}</td>
<td>PFC Sigma RP &amp; RP-F (posterior-stabilized, mobile-bearing)</td>
<td>DePuy Orthopaedics, Warsaw, Indiana</td>
<td>124±10.3 124.2±8.7   .949</td>
</tr>
<tr>
<td>Choi et al\textsuperscript{1}</td>
<td>PFC Sigma RP &amp; RP-F (posterior-stabilized, mobile-bearing)</td>
<td>DePuy Orthopaedics</td>
<td>130±10.7 128±11.5   .384</td>
</tr>
<tr>
<td>McCalden et al\textsuperscript{4}</td>
<td>Genesis II PS insert &amp; HF insert (posterior-stabilized, fixed-bearing)</td>
<td>Smith &amp; Nephew, Memphis, Tennessee</td>
<td>123±7 124±7    .811</td>
</tr>
<tr>
<td>Nutton et al\textsuperscript{3}</td>
<td>Nexgen LPS &amp; LPS-Flex (posterior-stabilized, fixed-bearing)</td>
<td>Zimmer, Warsaw, Indiana</td>
<td>106±17 110±17   N/A</td>
</tr>
<tr>
<td>Kim et al\textsuperscript{3}</td>
<td>Nexgen LPS &amp; LPS-Flex (posterior-stabilized, fixed-bearing)</td>
<td>Zimmer, Warsaw, Indiana</td>
<td>ROM: 135.8 ROM: 138.6    .41</td>
</tr>
</tbody>
</table>

*Abbreviations: deg, degrees; HF, high-flexion; ROM, range of motion; S, standard.*
It was suggested that the ability to achieve the high-flexion positions may compromise the long-term outcome of the implant since loosening of the femoral component is generally uncommon, occurring in <5% of knees. Dennis et al observed posterior femoral radiolucent lines in 42.9% in high-flexion knees at 4-year follow-up, and in our study comparing the standard and high-flexion designs, we noticed a trend toward a higher rate of femoral lucencies. The incidence of femoral lucencies in the standard and high-flexion groups was 3.1% and 13.4%, respectively. Further follow-up will be required to determine if the incidence of femoral loosening is higher using the high-flexion rotating platform design.

Based on the available literature, there appears to be little improvement in overall flexion using a high-flexion cruciate-substituting design. Furthermore, potential downsides to using the device include increased cost and the concern for a higher rate of complications such as femoral loosening. Some designs also require a thicker posterior condylar resection, which could compromise bone stock for future surgeries. At our institution, all of these factors have led to a discontinuation of the high-flexion rotating platform design. Further follow-up of this cohort will be important to document rates of femoral loosening, and with better congruity in higher degrees of flexion, the high-flexion designs may demonstrate better polyethylene wear over the long term.

**REFERENCES**


