Analysis of the outcome in male and female patients using a unisex total knee replacement system

D. F. Dalury,
J. B. Mason,
J. A. Murphy,
M. J. Adams

From St. Joseph Medical Center, Baltimore, USA

Gender-specific total knee replacement has generated much interest recently. We reviewed 1970 Sigma knees implanted in 920 women and 592 men with a mean age of 69.7 years.

At a mean follow-up of 7.3 years (minimum, five years), we found minimal differences in the outcome between genders. At the final follow-up, men had a higher overall Knee Society score and more osteolysis (3.8% vs 1.1%). However, there were no significant differences between men and women in terms of complications or improvements in knee function, pain score or range of movement. The estimated ten-year survivorship was 97% in women and 98% in men (p = 0.96).

We concluded that there was little difference in outcome between the genders treated by a modern unisex design of total knee replacement in this large multicentre study.

Recently, there has been increasing interest in the differences between male and female patients undergoing total knee replacement (TKR). Several manufacturers of implants have marketed these differences through advertisements in the media and on the Internet. A search on Google for the term ‘gender knee’ showed 545 000 hits in October 2007 and 1 910 000 hits in January 2008. Several publications have reported anatomical differences in the femur between males and females,1–5 pointing out that female femora tend to be narrower, have a higher ‘Q’ angle,6,7 and a lower anterior condylar profile. Despite these differences, few long-term follow-up studies of TKR have examined the outcome in relation to gender.

The aim of this retrospective multicentre study was to determine if there were significant differences in outcome between male and female patients undergoing TKR using a modern unisex knee replacement system.

Patients and Methods

Between June 1996 and December 1997, 1970 TKRs were performed at eight centres in 1512 patients, 1054 with unilateral and 458 with bilateral procedures.

All the patients had the same implant system (PFC Sigma; Depuy, Warsaw, Indiana). Of the 1316 knees, 1068 (81.2%) had a cruciate-retaining design and 248 (18.8%) had a cruciate-sacrificing design. All the implants were cemented.

All the patients were prospectively followed clinically and radiologically. Clinical status was recorded pre- and post-operatively using the Knee Society scoring system for pain (maximum 50 points), function (maximum 100 points), and the overall knee scores (maximum 100 points).8 An independent radiographer (TAG) measured osteolysis, stress shielding, radiological loosening and zones of lucency.9–11 Because radiolucent lines are often observed immediately after surgery with no change in later evaluations, the zone of lucency was


J Bone Joint Surg [Br]
2009;91-B:357-60.
Received 11 September 2008; Accepted 19 November 2008
assessed in two different ways. First, it was noted if the radioluency was considered to be progressive, which was defined as an increase in width from an early observation to the last review, or when the width remained the same but the lucency expanded to a neighbouring zone. Secondly, circumferential radioluency was defined as a radiolucent line ≥ 1 mm wide noted in all zones surrounding a component from any radiological view.

Statistical analysis. Survivorship was analysed using the Kaplan-Meier and the Cox proportional hazards methods. Failure was defined as revision for any reason. As is customary with survivorship analysis, all 1970 knees were included in the analysis. The Kaplan-Meier method was used to produce an unadjusted survivorship graph (Fig. 1) whereas the Cox proportional hazards method was used to determine if there were any survivorship differences between genders while controlling for potentially confounding covariates. Because the Knee Society scores and measurements of movement were not distributed normally, the non-parametric Mann-Whitney U test was used to compare continuous data. Fisher’s exact test was used for categorical comparisons. A p-value ≤ 0.05 was used as the threshold for significance.

Results

The men and women had comparable mean pre-operative knee scores (men, 51.48; women, 53.93; Mann-Whitney rank sum test, p = 0.056), but the latter had significantly lower mean pre-operative pain (7.27 vs 8.66, respectively) and pre-operative function scores (43.68 vs 51.59, respectively; Mann-Whitney rank sum test, p < 0.001).

At the final follow-up, there was no significant difference between the groups in terms of improvement in the knee function score, the pain score and flexion and extension (Table I). However, men had more improvement in the mean overall knee score (35.95 vs 31.06, respectively, Mann-Whitney rank sum test, p = 0.003) than women.

Radiological review showed no significant differences between men and women in terms of stress shielding (5.68% and 3.97%, respectively) or radiological loosening (0.28% and 0.38%, respectively). However, there was a significant difference in the rate of osteolysis in men and women (3.84% and 1.14%, respectively, Fisher’s exact test, p < 0.001) and progressive radiolucencies (4.69% and 1.99%, respectively, Pearson chi-squared test, p = 0.001).

There was no significant difference between men and women in terms of overall complications (any complication; 2.68% and 2.02%, respectively).

A total of 40 knees were revised for any reason. Kaplan-Meier survivorship analysis provided a ten-year estimate of 97.8%12 (95% confidence interval (CI) 96.2 to 99.5) at 9.2 years for men and 96.9% for women (95% CI 94.1 to 99.7) at 9.5 years (log rank test, p = 0.964; Fig. 1).

Two Cox proportional hazards models were constructed, both containing six potentially confounding covariates including age, centre, bilateral status, BMI, state of the posterior cruciate ligament, and the interaction between age and BMI. The first model had the 40 revisions coded as failures, whereas the second also included the 293 knees which had been lost to follow-up as failures. This latter worst-case method was carried out to show that knees without recent follow-up did not change the survivorship comparison between genders. No statistically significant differences were found between genders in either model. In the first and second (worst case) models, gender was removed as not being significant (p = 0.161 and p = 0.886, respectively). Therefore there were no statistical differences in survivorship between genders when accounting for potentially confounding variables. The result was the same when the 293 knees lost to follow-up were considered as failures.

Discussion

Various authors have reported differences between male and female knees. Women have a higher Q angle (2.7° to 5.8° higher), presumably because of their wider hips and generally shorter femora. Patellofemoral contact areas are higher in men at flexion arcs > 30°,1 but women have higher pressures in the patellofemoral joints.1 Femora tend to be narrower in women than in men even if their lengths are similar,2,13 and the distal femur in women tends to be trapezoidal in shape, whereas in men it is more rectangular. The nature of these differences is not universally accepted. Some studies have shown no differences in the Q angle between men and women.14

The impact of anatomical variations on the outcome of TKR between the genders is unclear. Early designs of TKR were based on means of anteroposterior/mediolateral ratios, most of which fell into an approximate ratio of 0.8.2,13 In narrow femora, there is a potential for overhang of the implant, which may lead to soft-tissue impingement and pain. The thinner anterior condyles seen in some female femora could lead to a relative overstuffing of the
Table I. The clinical outcomes in terms of knee function, flexion, and extension and pain scores between the genders

<table>
<thead>
<tr>
<th></th>
<th>Women</th>
<th>Men</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age in years</strong></td>
<td>68.44</td>
<td>68.79</td>
<td>0.571</td>
</tr>
<tr>
<td><strong>Changes</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Overall knee scores</td>
<td>31.06</td>
<td>27.25</td>
<td>0.003</td>
</tr>
<tr>
<td>Function</td>
<td>23.26</td>
<td>32.28</td>
<td>1.0</td>
</tr>
<tr>
<td>Flexion</td>
<td>-1.25</td>
<td>14.73</td>
<td>0.009</td>
</tr>
<tr>
<td>Extension</td>
<td>-3.43</td>
<td>78.2</td>
<td>0.006</td>
</tr>
<tr>
<td>Pain</td>
<td>33.82</td>
<td>18.46</td>
<td>0.968</td>
</tr>
<tr>
<td><strong>Pre-operative</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Overall knee score</td>
<td>53.93</td>
<td>23.44</td>
<td>0.056</td>
</tr>
<tr>
<td>Function</td>
<td>43.68</td>
<td>22.81</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Flexion</td>
<td>114.49</td>
<td>13.15</td>
<td>0.009</td>
</tr>
<tr>
<td>Extension</td>
<td>4.82</td>
<td>7.95</td>
<td>0.986</td>
</tr>
<tr>
<td>Pain</td>
<td>7.27</td>
<td>11.71</td>
<td>0.004</td>
</tr>
<tr>
<td><strong>Post-operative</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Overall knee score</td>
<td>86.5</td>
<td>17.99</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Function</td>
<td>67.22</td>
<td>29.89</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Flexion</td>
<td>113.78</td>
<td>11.65</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Extension</td>
<td>1.36</td>
<td>3.11</td>
<td>0.003</td>
</tr>
<tr>
<td>Pain</td>
<td>41.34</td>
<td>15.57</td>
<td>0.005</td>
</tr>
</tbody>
</table>

* Mann-Whitney U test

patellofemoral groove, which in turn could theoretically lead to pain and limitation of movement. Surgeons traditionally have recognised the need to match the implant carefully to the distal femur and have often made intra-operative adjustments, including downsizing, upsizing, lateralising and flexing of the femur to accommodate different femoral shapes.

There are few reports that specifically address male against female outcomes after TKR, the results of which have been mixed. For example, Vincent et al\textsuperscript{15} found that men had generally a better outcome than women, but, in a large retrospective cohort study, Rand et al\textsuperscript{4} and Rand and Ilstrup\textsuperscript{16} found that female TKR patients had better survivorship at ten years than male patients (93% vs 88%, respectively). Other authors\textsuperscript{17-19} found little or no differences between the two groups. Most other series made no comment on differences between men and women.

In our multicentre study using a single, unisex implant system, we found some differences between men and women. At the final follow-up, men had higher post-operative Knee Society scores and a greater degree of change in their pre-operative to post-operative score than women. However, we could identify no significant differences between men and women with regard to improvement in the pain score, function score and measurement of flexion or extension.

Our finding of statistically worse pre-operative scores in women than in men is not new. Petterson et al\textsuperscript{20} and Scuderi et al\textsuperscript{19} noted similar discrepancies in pre-operative knee scores in women and have suggested that this may have been based in part on delay in seeking care, because women are often primary caregivers, subjugating their own health to that of those for whom they care, and higher incidences of obesity. Ayers et al\textsuperscript{21} and Saleh et al\textsuperscript{22} pointed out that a higher incidence of poorer emotional health and depression before TKR in women could be detrimental to the outcome after TKR. In our study, women and men had comparable improvement in their scores, but the post-operative function score in women remained worse to that in men, perhaps because of the significant pre-operative differences.

Our rates of complications were comparable between the two groups and only an increase in osteolysis seen in men was significant. Estimates of implant survivorship for the two groups were similar.

The strengths of our study included the large number of knees reviewed and the robustness of the results, applicable to different surgeons and geographical locations, because of the multicentre nature of the study.

The weaknesses included the retrospective nature and the large proportion of knees (14.9%) lost to follow-up. However, there was no statistical difference in the proportions of knees lost to follow-up between genders (Fisher's exact test, p = 0.333). In addition, the primary analysis (Cox proportional hazards analysis) comparing time to failure for each gender adjusted for covariates was conducted on the assumption that all knees lost to follow-up were considered to be failures at the time of their last follow-up. This worst-case analysis was carried out in addition to the traditional analysis when failure equals revision for any reason. The conclusions were identical and gender did not predict failure. In addition, the Knee Society score has substantial limitations in its sensitivity in documenting differences between patient cohorts and designs and in measuring psychometrics.

Our large multi-centre study, like others, showed that women tended to present later for surgery, with lower function and pain scores. Using a single, modern unisex design of TKR, we did not find any significant difference between men and women in terms of improvement in function and pain or in estimated survivorship curves at ten years.

The authors would like to thank T. A. Gruen for his contribution to this paper. The author or one more of the authors have received or will receive benefits for personal or professional use from a commercial party related directly or indirectly to the subject of this article.

References


