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The John Insall Award

Gender-specific Total Knee Replacement

Prospectively Collected Clinical Outcomes

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Abstract Gender-specific total knee replacement design is a recent and debated topic. We determined the survivorship and clinical outcomes of a large primary total knee arthroplasty cohort, specifically assessing any differences between gender groups. A consecutive cohort of 3817 patients with 5279 primary total knee replacements (3100 female, 2179 male) with a minimum of 2 years followup were evaluated. Preoperative, latest, and change in clinical outcome scores (WOMAC, SF-12, KSCRS) were compared. While men had higher raw scores preoperatively, women had greater improvement in all WOMAC domains including pain (29.87 versus 27.3), joint stiffness (26.78 versus 24.26), function (27.21 versus 23.09), and total scores (28.35 versus 25.09). There were no gender differences in improvements of the SF-12 physical scores. Men had greater improvement in Knee Society function (22.1 versus 18.63) and total scores (70.01 versus 65.42), but not the Knee Society knee score (47.83 versus 46.64). Revision rates were 10.2% for men and 8% for women. Women demonstrated greater implant survivorship, greater improvement in WOMAC scores, equal improvements in SF-12 scores, and less improvement in only the Knee Society function and total scores. The data refute the hypothesis of inferior clinical outcome for women following total knee arthroplasty when using standard components.
Level of Evidence: Level II, prognostic study. See the Guidelines for Authors for a complete description of levels of evidence.

Each author certifies that he or she has no commercial associations (eg, consultancies, stock ownership, equity interest, patent/licensing arrangements, etc) that might pose a conflict of interest in connection with the submitted article.
Each author certifies that his or her institution has approved the human protocol for this investigation and that all investigations were conducted in conformity with ethical principles of research, and that informed consent for participation in the study was obtained.

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Introduction

Recently much debate and discussion has focused on the effect of gender and the results of total knee arthroplasty (TKA) [3–5, 8]. The release of a new knee system (Gender Solutions™, Zimmer Inc., Warsaw, IN) marketed specifically to women catalyzed this debate. The challenge has been the lack of evidence that any implant changes or modifications could result in a clinical improvement to patient outcomes and more specifically the lack of support that women have inferior outcomes following TKA using conventional knee replacement systems using available devices.

There are specific gender differences seen with respect to access to care and anatomic variability. Several reports demonstrate that, in general, women tend to delay surgery for their arthritic knees and may wait until their symptoms are more severe than men [12, 13]. There may also be a gender bias with physicians more likely to recommend total knee arthroplasty to a male patient than a female patient [6]. Several authors have demonstrated distal femoral morphological differences, with the female knee tending to be slightly narrower than the male knee for any given anteroposterior dimension [7, 10]. However, there is substantial variability in these patterns [7, 10], and there are more differences between races than between genders [11, 14, 17–20].

One of the outstanding questions is whether women derive less benefit, or perhaps less predictable benefit, from

total knee replacement than do their male counterparts with conventional devices. While there is no ideal patient-specific or disease-specific clinical outcome tool, there are several validated scoring systems in current use for the evaluation of the arthritic patient.

We therefore reviewed prospectively collected clinical outcome scores (WOMAC, SF-12, KSCRS) used in our institution in a consecutive series of patients undergoing TKA to determine whether gender influenced preoperative, postoperative, and change scores.

Materials and Methods

We identified from our database a consecutive series of 3817 patients with 5279 primary total knee replacements between 1988 and 2004. Criteria for inclusion into the study consisted of a primary diagnosis of degenerative arthritis and a minimum followup of 2 years. There were 3100 women and 2179 men. Beginning in 1973 patients undergoing total joint arthroplasty surgery have had demographic data collected prospectively, which was then entered into an institutional clinical database. Beginning in 1988 this included surgical information, and preoperative and postoperative WOMAC, SF-12 (version 1), and Knee Society clinical ratings (KSCRS) scores. All surgeries were performed at a single institution by one of five surgeons (SJM, RBB, RWM, DDN, and CHR). Ethics approval was granted by the institution's internal review board.

Multiple orthopaedic manufacturers and implant designs were used over this period of time including: 2419 Genesis® I and II (Smith and Nephew Inc., Memphis, TN), 1279 AMK® (DePuy Orthopaedics Inc., Johnson and Johnson, Warsaw, IN), 552 Miller-Galante I and II (Zimmer Inc., Warsaw, IN), 314 SAL® (Sulzer Orthopaedics Ltd, Switzerland), 170 Sigma® (DePuy Orthopaedics Inc., Johnson and Johnson, Warsaw, IN), 115 Natural-Knee® (Zimmer Inc., Warsaw, IN), and 430 were performed with a variety of other primary knee replacement systems.

Preoperative and latest clinical outcome scores were analyzed as well as the change in score between preoperative and latest score. Categorical variables (eg, gender, BMI group, survival status) were analyzed using crosstabs with chi-square test. Student's t-test with Levene's test for equality of variance was used to analyze continuous variables (eg, height, weight, outcome score totals). We used SPSS v.15 (SPSS Inc., Chicago, IL) for all analyses.

Results

The average ages of the women (69 ± 9 years) and the men (68.5 ± 8.8 years) at surgery were similar ($p = 0.051$) (Table 1). The average implantation time was greater ($p = 0.013$) for women than men (10.5 ± 6 years versus 10.1 ± 6 years, respectively). Men were taller (mean, 173.9 cm versus 159.5 cm) and heavier (mean, 92 kg versus 82.4 kg) than the women ($p < 0.0001$), but the female patients had a higher ($p < 0.0001$) BMI (mean, 32.4 versus 30.4). More ($p < 0.0001$) women were morbidly obese (BMI > 40) than men (13.4% versus 4%). Compared to the female patients, a higher ($p < 0.0001$) percentage of males had a preoperative varus alignment (64.5% versus 55.2%). More ($p < 0.0001$) women had a preoperative valgus alignment than men (18.6% versus 8.2%).

Table 1. Patient demographics by gender

Variable	Gender		p Value
	Female	Male	
N (number of cases)	3100	2179	na
Followup (mean, years)	10.5 ± 6	10.1 ± 6	0.013
Age (mean)	69.02 ± 9.11	68.53 ± 8.84	0.050
Height, cm (mean)	159.53 ± 7.36	173.93 ± 8.06	< 0.0001
Weight, kg (mean)	82.43 ± 17.52	91.99 ± 16.68	< 0.0001
BMI (mean)	32.43 ± 6.78	30.39 ± 5	< 0.0001
Morbidly obese (%)	13.4%	4%	< 0.0001
Previous operation (%)	60.2%	68.8%	< 0.0001
Varus alignment	55.2%	64.5%	< 0.0001
Valgus alignment	18.6%	8.2%	< 0.0001

All preoperative outcome measure scores (WOMAC, SF-12, KSCRS) were different between the genders with men having higher ($p < 0.0001$) scores in all cases. All latest outcome measure scores also demonstrated male patients had higher ($p < 0.013$) scores. The change scores (preoperatively to latest postoperative) demonstrated gender-specific differences. The change in WOMAC scores for all domains (pain, joint stiffness, function, and total) demonstrated a greater change ($p < 0.019$) in women (Table 2). The change in SF-12 mental score was statistically significant ($p < 0.001$) between genders in favor of the female (females 0.6459 versus males −0.9614) (Table 3). The change in SF-12 pain score was similar between genders (females 8 versus males 7.92; $p = 0.866$). Men had greater ($p < 0.0001$) improvement in KSCRS total from preoperative to latest scores than females (70.01 versus 65.42, respectively) (Table 4). Preoperative, latest, and change in outcomes scores and significances were recorded (Tables 2–4).

The revision rate was higher ($p = 0.006$) for men than for women (223 revisions or 10.2% versus 249 revisions or 8%). Men had more revisions for polyethylene wear than women (37.2% of male revisions, 26.5% of female revisions; $p = 0.012$) and more infections (two-stage procedure) (17% of male revisions, 8.8% of female

Table 2. Preoperative, latest, and change in WOMAC scores, number of cases, mean values, standard deviations, and significance grouped by gender

WOMAC	Gender	N	Mean ± SD	p Value
Preoperative				
Pain	Female	1537	44.08 ± 17.73	< 0.0001
	Male	1074	48.34 ± 17.51	
Joint stiffness	Female	1543	38.75 ± 19.16	< 0.0001
	Male	1076	43.91 ± 20.21	
Function	Female	1533	42.51 ± 17.32	< 0.0001
	Male	1073	47.71 ± 17.19	
Total	Female	1532	42.38 ± 15.86	< 0.0001
	Male	1072	47.2 ± 16	
Latest				
Pain	Female	2211	73.06 ± 23.56	0.008
	Male	1535	75.08 ± 22.65	
Joint stiffness	Female	2245	65.03 ± 23.79	0.001
	Male	1541	67.71 ± 23.47	
Function	Female	2193	67.9 ± 22.5	0.001
	Male	1525	70.35 ± 22.26	
Total	Female	2187	69.57 ± 21.51	0.001
	Male	1522	71.85 ± 21.04	
Change				
Pain	Female	1500	29.87 ± 24.69	0.008
	Male	1064	27.3 ± 23.56	
Joint stiffness	Female	1522	26.78 ± 26.79	0.019
	Male	1069	24.26 ± 27.1	
Function	Female	1488	27.21 ± 22.96	< 0.0001
	Male	1057	23.09 ± 22.66	
Total	Female	1485	28.35 ± 22.26	< 0.0001
	Male	1055	25.09 ± 21.8	

revisions; $p = 0.008$) (Table 5). All other revision relationships were similar between the genders.

Discussion

There are well-documented anatomic variations between the male and female lower extremity in terms of alignment and distal femoral anatomy. Women tend towards more valgus alignment and for any given anteroposterior dimension tend towards a narrower medial-lateral dimension [7, 10]. These findings have led some authors to conclude there is a need to develop specific knee implants designed to better fit these anatomic variations [4]. The fundamental premise of this approach assumes that outcomes for women are inferior following total knee replacements and at least some of these inferior outcomes must be due to the inherent differences in anatomy and thus need for gender specific designs.

Table 3. Preoperative, latest, and change in SF-12 scores, number of cases, mean values, standard deviations, and significance grouped by gender

SF-12	Gender	N	Mean ± SD	p Value
Preoperative				
MCS	Female	1507	51.53 ± 11.15	< **0.0001**
	Male	1040	54.38 ± 10.36	
PCS	Female	1507	29.1 ± 7.31	< **0.0001**
	Male	1040	31.64 ± 8.13	
Latest				
MCS	Female	2246	51.79 ± 10.73	< **0.0001**
	Male	1522	53.09 ± 9.97	
PCS	Female	2246	36.48 ± 10.65	< **0.0001**
	Male	1522	39.1 ± 11.13	
Change				
MCS	Female	1491	0.65 ± 11.62	< **0.0001**
	Male	1027	−0.96 ± 10.24	
PCS	Female	1491	8 ± 11.04	0.866
	Male	1027	7.92 ± 11.79	

Table 4. Preoperative, latest, and change in KSCRS scores, number of cases, mean values, standard deviations, and significance grouped by gender

KSCRS	Gender	N	Mean ± SD	p Value
Preoperative				
Function	Female	2527	41.33 ± 16.25	< **0.0001**
	Male	1781	48.67 ± 14.01	
Knee	Female	2407	40.17 ± 15.29	0.419
	Male	1694	40.55 ± 14.49	
Total	Female	2407	81.58 ± 24.97	< **0.0001**
	Male	1694	89.41 ± 22.29	
Latest				
Function	Female	2954	59.98 ± 26.16	< **0.0001**
	Male	2073	70.76 ± 23.78	
Knee	Female	2871	86.66 ± 16.73	**0.013**
	Male	2004	87.85 ± 16.36	
Total	Female	2871	147.06 ± 35.7	< **0.0001**
	Male	2004	158.84 ± 33.58	
Change				
Function	Female	2483	18.63 ± 24.81	< **0.0001**
	Male	1747	22.1 ± 23.46	
Knee	Female	2307	46.64 ± 21.85	0.084
	Male	1615	47.83 ± 20.84	
Total	Female	2307	65.42 ± 37.7	< **0.0001**
	Male	1615	70.01 ± 36.07	

This series reflects the results of various surgeons utilizing multiple implants and is much less likely to be biased by the results of one implant or design or technique.

Table 5. Revision rates and reason for revisions grouped by gender

Reason	Revision rate		p Value
	Female	Male	
Aseptic loosening	18.9%	17%	0.604
Polyethylene wear	26.5%	37.2%	**0.012**
Osteolysis	9.2%	7.6%	0.53
Instability	17.3%	16.1%	0.744
Implant fracture	1.2%	1.3%	0.892
Bone fracture	3.2%	2.2%	0.52
Patellar maltracking	0%	0%	na
Failed patellar component	8%	9.9%	0.485
Infection	10.4%	18.4%	**0.014**
Total	8%	10.2%	**0.006**

At the same time, subtleties in implant sizing between implant designs and their relative effects cannot be determined. It remains to be demonstrated if specific total knee designs do demonstrate gender differences in outcomes. It is possible the outcome measures that have been historically collected fail to capture the nuances of postoperative outcomes, such as anterior knee pain.

However, it has never been demonstrated in the literature that women indeed have poorer outcomes following total knee replacement surgery. In one of the few reports looking at patient satisfaction following total knee replacement, Robertsson et al. [16] reported on 27,372 patients having had a total knee replacement and reported 18% of women were unsatisfied or uncertain, compared with 16% of men. There were no preoperative evaluations in that series and it is critical that one considers the baseline differences in the population to begin with, as Paradowski et al. [15] demonstrated that in a general population survey women had more knee-related complaints than men.

In the current study a significant difference was seen in implant survivorship between genders with men having a higher revision rate than women (10.2% and 8% respectively). Other authors have demonstrated similar findings [2]. Perhaps the largest series demonstrating this trend is seen in the Australian Joint Registry [1], reporting on 134,799 primary total knee replacements. A statistically significant difference is seen in the cumulative 5 year revision rate of 4% for men and 3.3% for women. However, a report discussing the revision rates of 35,857 unicompartmental and total knee arthroplasties in the Swedish Arthroplasty Registry did not demonstrate any differences between genders in revision rates [9].

Historically authors have focused on preoperative and postoperative scores; however, it is the change scores that represent the effect of the intervention under investigation. Absolute preoperative and postoperative scores are affected by many factors including disease state, comorbidities, and test bias. Men, in general, demonstrate a greater functional capacity on these scoring systems, but this must be taken into account when reporting the results of total knee replacements and the effect that the surgery has on the improvement in patients' outcomes. Without taking into account the change in scores from preoperative to postoperative, conclusions may be drawn that more accurately represent the bias in the test itself, rather than the effect of the surgery.

In this large series of patients we could not demonstrate a definitive gender bias in outcome scores. Women demonstrated the greatest improvement in all domains of the WOMAC scores including pain, joint stiffness, function, and total scores and each of these was statistically significant. While the raw postoperative scores for men were indeed better than for women, it was even more so preoperatively, and quite clearly the female patients derived equal if not greater benefit from receiving a total knee replacement than their male counterparts. The same findings are demonstrated in the SF-12 scoring system. Women begin and end with lower absolute physical scores than men, however, the change in scores, representing the effect of the total knee replacement, are not different between the groups. Additionally women demonstrated a statistically significantly greater improvement in the SF-12 mental scores than the men. It was only in the Knee Society clinical rating scores that men had greater improvement than the women.

Our data suggest no negative female gender bias in outcomes, but instead demonstrate women in general had overall the greatest improvements in outcomes scores with a lower revision rate than men.

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