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Are Gender-Specific Implants Necessary for Total Knee Replacement?

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From the Kaiser Permanente National Total Joint Registry

INTRODUCTION

The concept of "gender-specific" knee arthroplasty has recently been promoted to address anatomical characteristics of the female knee, which theoretically could predispose to a poor result following total knee replacement (TKR). The idea has generated much interest, due in part to aggressive marketing and media campaigns. However, the clinical need for implants designed specifically for the female knee has not been established. Given the proven success of existing gender-neutral designs over long follow-up intervals and the premium cost of new implant designs, evidence of clinical need and implant effectiveness should be a prerequisite for widespread acceptance of gender-specific TKR.

Although anatomical and mechanical differences have been documented between male and female knees [1,2], there is little clinical evidence that outcomes of TKR in women are inferior to outcomes in men. If the rationale that women require a "gender-specific" knee arthroplasty is correct, then it should be possible to document a difference in current surgical knee arthroplasty outcomes based on gender. Studies comparing clinical outcomes between men and women have shown little if any difference between the two groups [3,4,5].

Since 2001, the Kaiser Permanente Total Joint Replacement Registry has been collecting prospective data on primary and revision total knee and hip procedures of Kaiser Foundation Health Plan members. Currently, the registry includes data on more than 27,000 knee replacements. The purpose of this study is to compare short-term (on average, less than 2 years) revision rates, outcomes of pain, satisfaction and range of motion (ROM) within this patient population. Our null hypothesis was that gender is not a factor in short-term revision rates, outcomes of pain, satisfaction and knee ROM following TKR.

MATERIALS & METHODS

We reviewed prospectively collected data to determine whether a difference existed between men and women following primary TKR with standard (gender-neutral) implants.

Data Sources

- Kaiser Permanente's National Total Joint Replacement (TJR) Registry. The database contains detailed information on patient demographics, diagnoses, and surgical technique, and limited outcomes data including revision, range of motion, pain and satisfaction. Pain and satisfaction are recorded at pre-operative and post-operative visits using a verbal analog 0-10 scale. At the time of this review, data were available on 21,579 primary TKRs.

Inclusion / Exclusion Criteria

- All primary TKRs registered between April 2001 and March 2006, with a valid gender (n = 20,718) were included
- All procedures not identified as a primary TKR were excluded (e.g., revision procedures, conversion procedures, ORIFs and unicompartmental knee arthroplasties)

Statistical Analyses

- Pearson Chi-Square was used to compare categorical variables (co-morbidities, reason for surgery, surgical exposure, cement, complications)
- Mann-Whitney was used to compare pre-operative and post-operative continuous variables (age, BMI, ASA score, pain, flexion, extension, satisfaction)
- Chi-Square was used to compare revision rate, Life Tables to compare survival, and Multivariate Logistic Regression to assess whether the risk for revision, overall infection and deep infection are higher while adjusting for gender, age, ASA category and primary diagnosis
- Statistical significance was set at $p<0.05$, and adequate power was defined as 0.8

RESULTS

Patient demographics of the 20,718 primary TKRs included in the study are displayed in Table 1. Mean age (68.01 years vs 68.08 years, p=0.911) and ASA Score (2.35 vs. 2.36, p=0.642) at the time of surgery were similar for males and females. Males had a lower mean BMI (30.76 vs. 32.07, p<0.001), a higher rate of diabetes (16.1% vs. 13.8%, p=0.001), a lower rate of rheumatoid arthritis (1.1% vs. 2.6%, p<0.001), and a higher rate of post-traumatic arthritis (2.0% vs. 1.0%, p<0.001).

Table 1: Patient Demographics

Item	Males	Females	P-Value
Gender	7,468	13,250	
Age	68.01	68.08	0.911
BMI	30.76	32.07	<0.001
Diabetes Co-Morbidity	16.1%	13.8%	0.001
Reason for Surgery			
Rheumatoid Arthritis	1.1%	2.6%	<0.001
Post-Traumatic Arthritis	2.0%	1.0%	<0.001
ASA Score	2.35	2.36	0.642

Table 2 shows a comparison of surgical technique. No differences in surgical exposure (parapatella, tubercle osteotomy, computer assisted surgery, midvastus, quadriceps release, mini incision, subvastus, trivector) were observed between males and females (p>0.05). Males had a lower rate of cemented components (87.6% vs. 91.0%, p<0.001), a higher rate of hybrid implants (9.0% vs. 6.9%, p<0.001), and a higher rate of uncemented components (3.4% vs. 2.2%, p<0.001).

Table 2: Surgical Technique

	Males	Females	P-Value
Surgical Exposure			>0.05
Cement			
Cemented	87.6%	91.0%	<0.001
Hybrid	9.0%	6.9%	<0.001
Uncemented	3.4%	2.2%	<0.001

Displayed in Table 3 is a comparison of surgical outcomes:

- Males had a higher rate of overall infections and deep infections than females (1.1% vs. 0.8%, p=0.006; 1.0% vs. 0.6%, p=0.001)
- No difference in revision rate was observed between genders (1.5% vs. 1.2%, p>0.05); with current sample sizes, there was adequate power to detect an absolute difference of 0.5%
- Males had a lower change or improvement in pain than females at >9 months post-op (5.05 vs. 5.41, p<0.001); with current sample sizes, there was adequate power to detect a difference of 0.36
- No difference in change of flexion was observed between genders at >9 months post-op (2.31 vs. 2.62, p>0.05); with current sample sizes, there was adequate power to detect a difference of 1.7
- Males had a higher change or improvement in extension than females at >9 months post-op (3.02 vs. 2.85, p=0.023); with current sample sizes, there was adequate power to detect a difference of 0.7
- No difference in satisfaction was observed between genders at >9 months post-op (9.16 vs. 9.16, p>0.05) ; with current sample sizes, there was adequate power to detect a difference of 0.2

Table 3: Outcomes*

Items	Males	Females	P-Value
Complications			
Overall Infections	1.1%	0.8%	0.006
Deep Infections	1.0%	0.6%	0.001
Revision Rate	1.5%	1.2%	0.110
Change from Pre-Op to >9 Months Post-Op	Change (SD)	Change (SD)	P-Value
Pain (scale = 0-10, no pain to worst possible pain)	5.05 (3.00)	5.41 (3.10)	<0.001
Flexion	2.31 (15.32)	2.62 (16.03)	0.580
Extension	3.02 (6.00)	2.85 (6.78)	0.023
>9 Months Post-Op	Value (SD)	Value (SD)	P-Value
Satisfaction (scale = 0-10, extremely dissatisfied to extremely satisfied)	9.16 (1.80)	9.16 (1.82)	0.473

*SD = Standard Deviation

Table 4 reports the findings of Multivariate Logistic Regression:

- Revision: <55 year old patients and patients with ASA Score 3&4 have a higher risk of revision [2.9 odds ratio (2.0,4.4 95% CI, p<0.001); 1.4 odds ratio (1.1,1.8 95% CI, p=0.004)
- Overall Infection: Males, <55 year old patients and patients with an ASA Score 3&4 have a higher risk of overall infection [1.5 odds ratio (1.1,2.1 95% CI, p=0.013); 2.5 odds ratio (1.5,4.2 95% CI, p<0.001); 1.6 odds ratio (1.2,2.1 95% CI, p=0.003)]
- Deep Infection: Males, <55 year old patients, patients with ASA Score 3&4 and patients with a primary diagnosis of osteoarthritis have a higher risk of deep infection [2.7 odds ratio (1.7,4.5 95% CI, p<0.001); 2.3 odds ratio (1.3,4.2 95% CI, p=0.007); 2.8 odds ratio (1.8,4.5 95% CI, p<0.001); 1.8 odds ratio (1.2,2.8 95% CI, p=0.008)]

Table 4: Outcomes – Multivariate Logistic Regression

Variable	Significance	Odds Ratio	95.0% CI	
Revision				
Gender (male / female)	0.137	1.235	0.935	1.632
Age Category (<55, >=55)	<0.001	2.942	1.969	4.397
ASA Category (1&2, 3&4)	0.004	1.440	1.124	1.846
Osteoarthritis (yes / no)	0.732	0.930	0.616	1.405
Overall Infection				
Gender (male / female)	0.013	1.499	1.089	2.064
Age Category (<55, >=55)	<0.001	2.517	1.518	4.174
ASA Category (1&2, 3&4)	0.003	1.566	1.169	2.097
Osteoarthritis (yes / no)	0.053	1.507	0.995	2.283
Deep Infection				
Gender (male / female)	<0.001	2.731	1.652	4.517
Age Category (<55, >=55)	0.007	2.314	1.263	4.241
ASA Category (1&2, 3&4)	<0.001	2.831	1.777	4.508
Osteoarthritis (yes / no)	0.008	1.816	1.171	2.815

DISCUSSION

If anatomical and mechanical differences between men and women result in a "poor fit" for women when gender-neutral TKR implants are used, then unfavorable effects of implant design deficiencies should be apparent soon after surgery. We would expect revision rate, pain, satisfaction or ROM differences to be apparent within the first year after the procedure

Average follow-up for all primary TKRs was 602 days for males and 604 days for females (overall follow-up = 603 days).

Similar revision rates were observed between men and women. Mean time to revision was 325 days for males and 355 days for females (overall time to revision = 343 days).

Women had statistically greater improvement in pain scores (greater decrease in pain) compared to men at greater than 9 months post-op, though the clinical significance is not clear.

No difference in change of flexion was observed between genders at >9 months post-op. Men had a statistically greater improvement in extension than women at greater than 9 months post-op. However, the extension ROM difference was small and its clinical significance is not clear.

Patient satisfaction between men and women was similar at greater than 9 months post-op.

Multivariate Logistic Regression analysis shows that women are not at risk with regard to the outcomes of revision, overall infection or deep infection.

This study has several limitations. First, despite the large sample size, registry data have only been collected since 2001, and follow-up of registered procedures is short. However, if poor outcomes can be expected due to poor fit of the implants, then we believe they should be apparent within the follow-up period employed in this study. Another important limitation is that follow-up information on pain, satisfaction and ROM was available only on patients who have returned for clinical evaluation.

CONCLUSION

When a new TKR implant is promoted for market, patient outcome data should justify the need for a new implant. Despite theoretical evidence based on anatomical differences between males and females, it is the responsibility of the orthopedic community to ensure that new implants being marketed are warranted based on demonstrated clinical need. Short-term data from our registry do not support a need for gender-specific implant designs for TKR at this time.

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