New Total Knee Arthroplasty Designs: Do Young Patients Notice?

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Abstract

Background Although the volume of total knee arthroplasties (TKAs) performed in the United States continues to increase, recent reports have shown the percentage of patients who remain “unsatisfied” is as high as 15% to 30%. Recently, several newer implant designs have been developed to potentially improve patient outcomes.

Questions/purposes The purpose of this study was to determine the impact of high-flex, gender-specific, and

rotating-platform TKA designs on patient satisfaction and functional outcomes.

Methods A four-center study was designed to quantify the degree of residual symptoms and functional deficits in patients undergoing TKA with newer implant designs compared with a 10-year-old, cruciate-retaining (CR) TKA system introduced in 2003. Each contributing surgeon was fellowship-trained and specialized in joint replacement surgery. Only patients younger than 60 years old were included. Data were collected by an independent, third-party survey center blinded to the implant type, who

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Each author certifies that his or her institution approved the human protocol for this investigation, that all investigations were conducted in conformity with ethical principles of research, and that informed consent for participation in the study was obtained.

This work was performed at Washington University School of Medicine, St Louis, MO, USA, in cooperation with the University of Wisconsin Survey Center, Madison, WI, USA; Joint Implant Surgeons, Inc, New Albany, OH, USA; Colorado Joint Replacement Center, Denver, CO, USA; and Rush University Medical Center, Chicago, IL, USA.

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administered questionnaires about patient satisfaction, residual symptoms, function, and pre- and postoperative activity levels using previously published survey instruments. Two hundred thirty-seven CR, 137 rotating-platform, 88 gender-specific, and 65 high-flex TKAs were included in the analysis. Differences in baseline demographic variables were accounted for using multiple logistic regression statistical analyses.

Results Patients who received certain newer designs reported more residual symptoms (grinding, popping, and clicking) in the 30 days before survey administration than the group receiving a 10-year-old CR design (CR, 24% [57 of 237 patients] versus gender-specific, 36% [32 of 88 patients]; odds ratio [OR], 2.1; 95% confidence interval [CI], 1.1–3.8; $p = 0.03$; and rotating-platform, 43% [59 of 137 patients]; OR, 2.2; 95% CI, 1.3–3.7; $p < 0.001$). They also reported more functional problems, including getting in and out of a chair (CR, 19% [46 of 237 patients] versus gender-specific, 37% [32 of 88 patients]; OR, 1.0; 95% CI, 1.1–3.5; $p = 0.001$). Patients with newer TKA designs did not demonstrate any improvements in function or patient satisfaction versus those who received the 10-year-old CR design.

Conclusions When interviewed by an independent, blinded third party, the use of newer implant designs did not improve patient satisfaction and the presence of residual symptoms when compared with patients who received the 10-year-old CR design. Future studies should prospectively determine whether the purported benefits of newer implant designs improve patient-perceived outcomes.

Level of Evidence Level III, therapeutic study. See Guidelines for Authors for a complete description of levels of evidence.

Introduction

The number of TKAs performed in the United States has increased dramatically, particularly in patients younger than 60 years old [21]. However, TKA in younger individuals is associated with higher rates of revision and with decreased patient satisfaction [22, 33, 41]. Although TKA demonstrates survivorship above 90% at 10 years and beyond [25, 27, 42], recent studies focusing on patient

satisfaction as the primary outcome measure have been less encouraging with Noble et al. [33] reporting that only 75% are satisfied or very satisfied [8, 30]. Several manufacturers have implemented specific design modifications in an attempt to improve patient outcomes, including the introduction of the gender-specific, high-flex, and rotating-platform (RP) TKA designs.

Surgeons have traditionally emphasized knee flexion as a hallmark of clinical success [28]. As a result, manufacturers have introduced novel designs with specific features targeting high flexion. Others have pointed to higher levels of dissatisfaction among women receiving traditional designs and developed implants believed to address the differences in bony anatomy between the typical man and the typical woman [12, 15, 17, 20]. Finally, although RP TKAs provide theoretical advantages in terms of improved kinematics and reduced bearing surface wear, these implants (as well as gender-specific and high-flex designs) have failed to demonstrate superior results over prior cruciate-retaining (CR) implant designs [6, 7, 15, 27, 29, 42]. Therefore, concerns remain regarding both the necessity and clinical use of these design modifications and whether patients perceive improved outcomes with their use [15, 19, 29].

We therefore sought to determine the impact of RP, gender-specific, and high-flex TKA designs on patient satisfaction and functional outcomes versus a 10-year-old CR design using an independent, blinded, third-party survey instrument. We specifically sought to evaluate these variables in young patients.

Patients and Methods

Four total joint centers (Washington University School of Medicine, St Louis, MO, USA; Joint Implant Surgeons, New Albany, OH, USA; Colorado Joint Replacement Center, Denver, CO, USA; Rush University Medical Center, Chicago, IL, USA) and an independent third-party survey center (University of Wisconsin Survey Center [UWSC], Madison, WI, USA) participated. Each center had an active joint replacement registry, all surgeons were fellowship-trained performing more than 200 TKAs per year, and each contributed patients meeting the inclusion criteria. Before initiation of the study, institutional review board approval was obtained at the Washington University School of Medicine to serve as the coordinating center, and each participating center obtained approval from its institutional review board.

Inclusion criteria for this study were (1) men and women between 18 and 60 years old; (2) patients requiring primary knee surgery as a result of noninflammatory arthritis (degenerative joint disease) such as osteoarthritis, traumatic

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arthritis, or avascular necrosis; and (3) use of a gender-specific, high-flex, RP or 10-year-old CR design (Vanguard; Biomet Inc, Warsaw, IN, USA). Only patients younger than 60 years old were included, because newer TKA implants are more frequently used in a younger population. The CR TKA design chosen was introduced in 2003 and was considered the standard because it has had 10 years of clinical use and had no unique design features claimed to improve motion, kinematics, or symptoms [4, 32]. We excluded (1) subjects with a history of infection or sepsis in the knee, fracture, dislocation, or revision to the operated knee; and (2) patients with extensive medical comorbidities including hypertension, renal failure, coronary artery disease, liver disease, sickle cell disease, respiratory disease, cancer, etc, that would limit their activity level. Investigators queried their total joint registries and compiled a list of patients meeting the inclusion criteria, who had undergone a primary TKA within 1 to 4 years of the start of the study and had a minimum of 1 year of clinical followup.

A total of three surgeons from two centers contributed patients to the CR cohort. These surgeons used the 10-year-old CR design in all patients regardless of age and activity level, and those surgeons did not use any of the “newer” implant designs described. One surgeon at a single center contributed all patients to the RP cohort and zero patients to the remaining cohorts. This surgeon uses the RP design in all patients younger than 60 years without any specific inclusion or exclusion criteria. One surgeon at a single institution contributed patients to both the gender-specific and high-flex cohorts. This surgeon used the gender-specific implant in all females regardless of age and the high-flex design in all males regardless of age. A second surgeon at the same institution uses the gender-specific implant in all patients regardless of age or sex if intraoperatively a standard component appeared to have overhang of the native femur. For that surgeon, if a patient did not receive a gender-specific implant, they received a high-flex implant.

Of the 1017 patients who were eligible for inclusion, 527 (51.8%) were successfully interviewed, including 237 CR, 137 RP, 88 gender-specific, and 65 high-flex TKAs. All gender-specific and high-flex implants were CR designs, whereas 56 of the RP implants were CR and 81

were posterior-stabilized designs. The mean age of the patients was 55 ± 5 years old with 63 of patients being women. The mean length of followup from the time of their TKA arthroplasty was 2.6 ± 0.9 years (range, 1.0–4.7 years). The groups were generally similar at baseline in terms of their age. However, patients in the gender-specific group had a decreased length of followup, whereas patients in the RP cohort had higher presymptomatic and postoperative UCLA scores (Table 1). Furthermore, chi square tests revealed differences between the cohorts for gender, minority status, education level, and household income (Table 2). These variations were accounted for during statistical analyses.

We used a previously described survey [4, 24, 31] reporting specific data regarding satisfaction, function, residual symptoms, and ability to return to most preferred preoperative activity 1 to 4 years after TKA. Although this tool has been used in those prior reports, it has not been validated in terms of repeatability, responsiveness to changes in patients' clinical status, ceiling effects, and other important parameters. The questionnaire was administered by an independent, third-party survey center blinded to the treatment arm. Each center mailed advance notification letters to its patients approximately 1 week before its respective batch entered the field. Interviewers read a telephone script to obtain verbal consent before administering the survey. A screening section ensured participants met the inclusion criteria, and the full questionnaire was administered to those patients who both provided verbal consent and were determined to be eligible and capable to participate. All interviews were conducted in English. The telephone survey protocol included 25 telephone call attempts per patient. In general, cases involving refusals to participate were called back in an attempt to convert the refusal into a completed interview. If a second refusal occurred, no further attempts were made. The final data were sent from the UWSC through a secure web site in SPSS format (Version 16.0; SPSS Inc, Chicago, IL, USA) [34].

The UCLA score was determined to assess each patient's preoperative and postoperative activity level [30, 45]. The satisfaction section was constructed from a

Table 1. A comparison of baseline continuous variables between the cohorts*

Variable	CR	RP	High-flex	Gender-specific	p value
Age (years)	55.94 (6.38)	56.69 (6.43)	55.08 (6.61)	55.95 (5.77)	0.2264
Length of followup (years)	2.64 (1.40)	2.66 (1.29)	2.46 (1.31)	2.25 (1.31)	0.0271
Presymptomatic UCLA score	7.00 (3.00)	8.00 (3.00)	7.00 (3.00)	6.00 (3.00)	< 0.0001
Postoperative UCLA score	6.00 (2.00)	7.00 (3.00)	6.00 (2.00)	6.00 (1.00)	< 0.0001

* Kruskal-Wallis tests were used to assess any differences between groups for continuous variables. Median with interquartile range in parentheses is presented; CR = cruciate-retaining; RP = rotating-platform.

Table 2. A comparison of baseline categorical variables between the cohorts*

Variable	CR	RP	High-flex	Gender-specific	p value
Gender					
Male	78 (33%)	73 (53%)	40 (62%)	5 (6%)	< 0.0001
Female	159 (67%)	64 (47%)	25 (38%)	83 (94%)	
Minority status					
Minority	15 (6%)	12 (9%)	20 (30%)	28 (32%)	< 0.0001
Not minority	222 (94%)	123 (91%)	25 (70%)	59 (68%)	
Education level					
Less than high school	8 (3%)	0 (0%)	4 (6%)	1 (1%)	0.0181
More than high school	229 (97%)	137 (100%)	61 (94%)	87 (99%)	
Household income					
< USD 25,000/year	44 (19%)	22 (16%)	14 (22%)	13 (15%)	0.0308
> USD 25,000/year	193 (81%)	115 (84%)	51 (78%)	75 (85%)	

* Chi-square tests were used to compare the cohorts. Data are presented as the absolute number and percentage of each cohort in parentheses; CR = cruciate-retaining; RP = rotating-platform.

review of recent investigations detailing patient satisfaction and function after TKA [5, 9, 33]. Questions were based on previous studies determining which factors are most important to patients and/or most highly correlated with patient satisfaction [9, 10, 33, 36]. Responses were grouped into two broad categories of either “never/rare” or “sometimes/often/frequent,” similar to the methodology described by Bourne et al. [9]. Furthermore, patients were asked if their knee felt “normal” to them. The patient-specific functional scale [11, 18, 39] was incorporated to determine whether there was one or more recreational activities critical to the patient, of which they had to limit their preoperative participation because of knee symptoms. The percentage of patients who were able to return to this critical activity within the last 30 days of being surveyed was determined. Questions related to patient satisfaction consisted of asking the patient about the overall function of the knee, the ability to perform normal activities of daily living, and satisfaction with the degree of pain relief. The principle questions related to residual symptoms inquired about the presence of any pain or stiffness in the knee; audible noises from the knee including popping, clicking, or grinding; and experiencing any swelling or a sense of tightness in the knee. To assess function, the patient was asked about the ability to get in and out of a car, getting in and out of a chair, going up and down stairs, and the presence of any limp [5, 34].

A chi-square test or Fisher’s exact test was performed for categorical variables, whereas a nonparametric Kruskal-Wallis test was used for continuous variables. Significant variables were considered as covariates to be adjusted in the multivariable analysis. Univariate logistic regression was conducted first to explore the association between implant types and the outcomes of interest; then multiple logistic

regression was used to further confirm the association after adjusting for identified patient characteristics. Demographic and clinical variables such as age, gender, minority status (“minority” considered black, Hispanic, or other), education (less than high school versus high school graduate and above), income (less than USD 25,000 per year versus > USD 25,000), length of followup, and prearthritic UCLA scores were considered as potential confounders and adjusted in the models. All of the analyses were performed using SAS 9.2 (Cary, NC, USA). A p value < 0.05 was considered statistically significant.

Results

Satisfaction

With the numbers available, patients receiving newer implant designs were not more likely to be satisfied than patients receiving the 10-year-old CR design. Two hundred twenty-three of 237 patients (94%) in the CR cohort were satisfied with the overall functioning of their knee. In comparison, 124 of 137 patients (91%) in the RP cohort (odds ratio [OR], 1.1; 95% confidence interval [CI], 0.4–3.3; p = 0.4), 81 of 88 patients (92%) in the gender-specific cohort (OR, 1.0; 95% CI, 0.3–2.9; p = 0.5), and 62 of 65 patients (95%) in the high-flex cohort (OR, 0.2; 95% CI, 0.01–2.4; p = 0.3) were satisfied with the overall functioning of their knee. Two hundred twenty of 237 patients (93%) in the CR cohort were satisfied with their degree of pain relief. In comparison, 124 of 137 patients (91%) in the RP cohort (OR, 1.7; 95% CI, 0.7–4.3; p = 0.4), 81 of 88 patients (92%) in the gender-specific cohort (OR, 1.1; 95% CI, 0.4–3.1; p = 0.6), and 59 of 65 patients (91%) in the

high-flex cohort (OR, 1.4; 95% CI, 0.4–4.4; $p = 0.4$) were satisfied with their degree of pain relief.

Only 167 of 237 patients (71%) reported their knee to feel “normal” versus 89 of 137 patients (65%) in the RP cohort (OR, 1.7; 95% CI, 0.7–4.3; $p = 0.3$), 61 of 88 patients (69%) in the gender-specific cohort (OR, 1.1; 95% CI, 0.4–3.1; $p = 0.8$), and 47 of 65 patients (72%) in the high-flex cohort (OR, 1.4; 95% CI, 0.4–4.4; $p = 0.8$).

Function and Residual Symptoms

For many of the functional endpoints, there were no differences between the 10-year-old CR and newer implant designs; where differences were detected, they all favored the older CR design.

After controlling for confounding variables including gender and income, we found patients in the RP cohort to be more likely to report grinding/popping/clicking in their knee. Fifty-seven of 237 patients (24%) in the CR group reported grinding/popping/clicking in their knee versus 59 of 137 patients (43%) in the RP group (OR, 2.2; 95% CI, 1.3–3.7; $p < 0.001$).

After controlling for confounding variables including gender, minority status, and income, we found patients in the gender-specific TKA group had a higher risk of having difficulty getting in and out of a chair and were more likely to report grinding/popping/clicking in their knee. Forty-six of 237 patients (19%) in the CR group noted difficulty getting in and out of a chair versus 32 of 88 (36%) in the gender-specific group (OR, 1.9; 95% CI, 1.1–3.5; $p = 0.001$). Fifty-seven of 237 patients (24%) in the CR group reported grinding/popping/clicking in their knee versus 32 of 88 (36%) in the gender-specific group (OR, 2.1; 95% CI, 1.1–3.8; $p = 0.03$).

After controlling for confounding variables including gender, income, and minority status, no differences were found between the CR and high-flex cohorts for the presence of residual symptoms (OR range, 1.0–1.7; 95% CI, 0.8–3.6; p value range, 0.1–0.8).

Discussion

Although TKA continues to be effective in providing pain relief and improved function in the majority of patients with degenerative joint disease [26, 28, 44], recent studies have demonstrated a high percentage of patients undergoing TKA to experience residual symptoms and dissatisfaction [9, 33–35]. Furthermore, because the volume of TKAs is disproportionately increasing in younger patients, function and satisfaction in this group of patients becomes even more important [23, 43]. In a retrospective review of 60 patients with a mean age of 55.4 years by Price et al. [35], 25 (42%)

reported persistent pain, and implant survivorship was only 82% at 12 years. In response to findings like these, several newer implant designs have been introduced with the goal of improving patient satisfaction after TKA. The purpose of this study was to determine the impact of RP, gender-specific, and high-flex designs on patient satisfaction, the presence of residual symptoms, and functional outcomes. We found overall few differences among the implants, and where differences were detected (mainly in function, none in satisfaction), they favored the older CR design over the newer implants.

This study had several limitations that are important to recognize when interpreting our data.

First, because this study was retrospective, we can only determine the presence of an association of modern implant designs with residual symptoms and not necessarily causation. Second, use of a retrospective survey method has the potential for recall bias, but we tried to limit the degree of bias by only including patients who received a TKA within 1 to 4 years after the start of the study. In addition, although the survey instrument has been used in prior reports, it has not been validated in terms of repeatability, responsiveness to changes in patients' clinical status, ceiling effects, and other important parameters. Furthermore, this instrument may not be the correct tool for assessing the purported benefits of newer implant designs such as increased durability (RP), patellar tracking (gender-specific), and increased flexion (high-flex). However, we feel that the questions selected for this survey are meaningful because they were based on prior studies determining factors most important to patients and/or most highly correlated with patient satisfaction, which was our primary outcome measure [9, 33].

Third, the sizes of the cohorts in this study are relatively small. The number of patients successfully interviewed was limited, because we only included patients who received their arthroplasty within a specified time period and were younger than 60 years old. A study analyzing larger cohorts might have shown differences in outcome with the use of each respective implant design. Furthermore, because we only included patients who had not undergone revision (to assess the presence of residual symptoms), failure rates with each of these implant designs were not reported, which may affect our results. However, we purposely excluded revision patients because the goal of our study was to evaluate patient-perceived outcomes in young patients with functioning implants. Lastly, although the median age between cohorts was similar, differences were present in baseline demographic between cohorts, including an increased presymptomatic UCLA score in the RP cohort, and differences in the percentage of males in each cohort. Although this is clearly not ideal when making comparisons among cohorts, we felt that use of multiple logistic regression analyses accounting for these

discrepancies would still allow us to determine whether patient satisfaction was improved using a “new” implant design. Furthermore, although we controlled for certain potential confounders during a multiple logistic regression analysis, patient symptoms can arise from a number of factors not analyzed in this retrospective study. Potential confounders include, but are not limited to, surgical technique, implant malalignment, and the complexity of preoperative bony and soft tissue deformity.

Rotating-platform TKAs were developed to address concerns regarding polyethylene wear and osteolysis while potentially reproducing a more physiologic pattern of movement, reduced transfer of stress to the implant-bone interface versus fixed-bearing implants with the goal of improved functional results [2, 3, 13, 31]. However, clinical studies have failed to demonstrate significant improvements with the use of RP implants [3, 7, 31]. Bistolfi et al. [7] performed a retrospective review of 100 fixed-bearing versus 100 RP implants at a mean followup of 116 months. They noted no significant differences between the two cohorts with respect to clinical outcomes or cumulative implant survival. Furthermore, Kelly et al. [19] performed a retrieval analysis of 48 RP TKAs and demonstrated the degree and severity of polyethylene wear damage to be the same as seen in fixed-bearing implants, questioning the design’s ability to reduce future osteolysis and component loosening. Our study demonstrates patients in the RP cohort to experience more grinding/popping/clicking in the last 30 days than patients in the CR cohort, thus again raising questions regarding the patients’ perceived benefits with this design modification.

Gender-specific implant designs were introduced with the intent of accommodating the distal femoral morphologic differences seen in females versus males with the belief that component modifications would lead to improved results. Gender-specific implants typically have a thinner trochlear flange to decrease patellofemoral pressures, an increased trochlear angle, and a higher height-to-width aspect to accommodate the decreased width of the female distal femur [8]. Most studies assessing the outcome of gender-specific designs have failed to demonstrate any superiority versus conventional implants [20, 40, 42]. Song et al. [40], in a review of 50 patients with bilateral osteoarthritis who received a conventional implant in one knee and a gender-specific implant in the other, demonstrated no subjective preferences or superiority in clinical outcomes between the two TKAs. Our study showed patients in the gender-specific cohort had a higher prevalence of grinding/popping/clicking and difficulty getting in and out of a chair versus patients who received a 10-year-old CR design. Therefore, our data further question the necessity of gender-specific implants because they demonstrated no patient-perceived benefits.

A third, recent design modification has been the introduction of the high-flex TKA design. The degree of flexion obtained after a TKA has traditionally been considered a marker of clinical success [29]. Design features include a reduced posterior femoral condylar radius with thickened posterior femoral condyles and modifications in the tibial and femoral components to accommodate the extensor mechanism in deep flexion and to improve physiologic femoral rollback [3, 14, 16, 41]. Although daily activities such as ascending and descending stairs are known to require 90° to 120° of flexion, numerous studies have demonstrated knee flexion to rarely exceed 110° to 115° after a TKA [1, 37, 38], raising questions about the ability of modified implant designs to significantly increase these values. Although certain studies have demonstrated improved results regarding the degree of flexion achieved using high-flex implants, whether patients perceive this increase to be clinically significant remains controversial [21, 24, 42]. Thomsen et al. [42], in a double-blind, randomized controlled trial of 36 patients undergoing one-stage bilateral TKA with a CR TKA in one knee and a high-flex TKA in the contralateral knee, demonstrated the high-flex TKAs to achieve a mean of 7° greater knee flexion. However, there was no difference in satisfaction scores or the “feel” of the knee between the two implants, questioning the relevance of this degree of improved flexion. Furthermore, other studies have failed to demonstrate improved ROM, functional outcomes, or survival rates with the use of high-flex designs [21, 24]. Our study found no differences between the high-flex and 10-year-old CR with regard to patient satisfaction and residual symptoms.

Because novel implants cost more, the onus is on their advocates to demonstrate superior outcomes compared with older designs before their widespread use. Numerous studies have failed to demonstrate significant improvements in clinical outcomes or survivorship with RP, gender-specific, and high-flex designs. This study further questions the use of these designs, because patients interviewed by an independent, blinded third party reported increased residual symptoms and functional difficulties after receiving a more recent implant with purported design advances versus a 10-year-old CR design.

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