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Patient-Related Predictors of Treatment Failure After Primary Total Knee Arthroplasty for Osteoarthritis

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ABSTRACT

The aim was to identify patient-related predictors of treatment failure after primary total knee arthroplasty for osteoarthritis. Treatment failure included surgical revision or clinical failure, which was defined by less than 70 in any score of the Knee Society. Prospective follow-up was performed in 412 consecutive patients with a minimum of 5 years. Multivariate logistic regression analysis revealed that higher Charlson index, worse preoperative Knee Society function, and Western Ontario McMaster University pain component were significantly associated with treatment failure. This study identified clinically important patient-related predictors of treatment failure after TKA, which may be useful preoperatively in identifying patients with risk of failure.

Primary total knee arthroplasty (TKA) has been shown to provide significant improvements in knee function and quality of life to the majority of patients with knee osteoarthritis, but not all patients gain the same degree of improvement [1]. In addition, it has been observed that an important minority of patients have no improvement or their symptoms get worse [2]. Patient satisfaction is a potentially important determinant of your subsequent rating of outcome [3], and not all patients are satisfied with the outcomes of their TKA, with estimates up to 18% of dissatisfaction [4,5].

Most of the previous studies that reported outcomes and implant failure rates after TKR were series case, and they did not perform multivariate-adjusted statistical analyses [6]. It is important to identify factors that may influence outcomes following TKA so that surgeons are able to identify those patients who may be more at risk of poorer recovery following TKA [2]. Today, there is no consensus about the predictive factors that help in selecting candidates for TKA. Previous studies suggest considerable variability in risk factors for outcomes or revision rates [7,8]. Some studies have assessed the influence of patient-related predictors in the outcomes after primary TKA but they have focused on specific aspects, such as age and gender [9], overall outcomes [10,11], residual pain [12–14], patient satisfaction [3,5], motion [6,15], ambulation [16,17], returning to work [18], or risk of periprosthetic fracture [19]. Regarding implant failure, some authors have studied the risk of infection [20,21] or revision [22,23]. However, all previous studies have expressed the arthroplasty failure in term of implant survival; that is, the revision or the need to revision. The main objectives of the TKA are to provide improvements in pain and function. Consequently, we believe that poor clinical outcome would also have to be considered as treatment failure after TKA. To the best of our knowledge, this study is the first to analyze the poor clinical outcome as a failure of the treatment with TKA.

The aim of this study was to identify patient-related predictors of treatment failure, including both revision surgery and clinical failure following primary TKA at a minimum postoperative follow-up of 5 years.

Material and Methods

Approval to perform this study from our institutional review board was obtained, and informed consent was required. A minimum postoperative follow-up of 5 years was required to assess outcomes. Consecutive patients awaiting surgery for primary TKA at our center were eligible for the study. The inclusion criterion was index diagnosis of idiopathic osteoarthritis. Exclusion criteria were inflammatory arthropathies, or presence of tumor or metastasis at the time of surgery. Between January 2007 and December 2008, 383 consecutive patients (416 knees) who underwent primary TKA for idiopathic osteoarthritis were included in study. Of them, 4 patients were excluded because they died within 5 postoperative years for causes unrelated to the arthroplasty. There were no other losses to follow-up. Demographic and preoperative data of the remaining 379 patients

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(412 knees) are shown in Table 1. There were 33 (8.7%) bilateral procedures, but no simultaneous bilateral TKA was performed. In these bilateral cases each knee was considered individually. Failures were divided into two types: failure due to revision surgery (revision) and failure due to poor functional outcome (clinical failure).

Operative Protocol

All patients were treated in a standardized way under epidural anesthesia. An anterior midline skin incision and medial parapatellar arthrotomy were used. The surgical technique and instrumentation were similar in all cases. All patients received a standard knee replacement, Trekking (Samo Biomedica, Bologna, Italy) [24]. This knee system was a modern fixed-bearing modular prosthesis. The femoral component was cementless in CoCrMo alloy with porous titanium coating, and had 2 pegs for press-fit fixation. The tibial component was cemented modular metal-backed design with cruciform baseplate in CoCrMo alloy. The cement (vacuum-mixed Palacos with Gentamicin) was applied to the undersurface of the tibial implant and around the proximal 2 cm of the stem. Cross-linked polyethylene tibial insert was used. The patella was resurfaced in all patients. All patellae were all-polyethylene dome-shaped cemented design with three pegs. Depending on the ligament balance at the time of surgery, a cruciate-retaining (CR, 349 knees) or posterior stabilizing (PS, 63 knees) design was used.

Standard antibiotic and antithrombotic prophylaxis were given. Postoperatively, in all patients continuous passive motion machine was started on the first day. Active range of motion exercise also was performed under the supervision of the therapist. On the second postoperative day, patients began standing or walking with crutches or a walker.

Evaluations

Clinical and radiological evaluations were performed pre-operatively and post-operatively at 3, 6, and 12 months, and then yearly until at least 5 years unless death occurred before. All clinical evaluation forms were completed at each visit by two independent experienced observers (SGP, VGG). The Knee Society scores (KSS) [25] were used for clinical evaluations. Reduced Western Ontario MacMasters University (WOMAC) [26] and Short-Form Health Survey 12-items (SF-12) [27] questionnaires, both validated for our country, were also completed by the patients with the help of a physiotherapist at each annual evaluation. The WOMAC was transformed to a 0–100 scale, so a higher value implies a better outcome. SF-12 components were calculated on a 0–100 worst to best scale.

All postoperative radiographs were analyzed by two independent experienced surgeons (FMM, FLP) who did not know the clinical evaluations of the patients. Radiological evaluation was performed using standing anteroposterior, lateral and standard skyline views. The latest radiographs were assessed for alignment of the knee, position of the components, and presence and location of radiolucent lines on the basis of Knee Society zones [28]. Radiological coronal alignment of the knee was evaluated using the anatomical axes. Definitive loosening was defined as a complete radiolucent line wider than 1 mm in all zones, progressive radiolucent lines wider than 2 mm, subsidence greater than 2 mm, or a change in implant position. Polyethylene wear was considered when there was gross asymmetry or change in thickness.

Table 1
Baseline Data and Failure Rates.

	Patients	Revision	Clinical Failure	Total Failure	P^a
Gender					0.006
Female	314 (76.2%)	15 (4.8%)	36 (11.4%)	51 (16.2%)	
Male	98 (23.8%)	2 (2.0%)	4 (4.1%)	6 (6.1%)	
Age (mean, sd)	69.1 (5.6)	68.5 (5.4)	69.9 (5.4)	69.4 (5.4)	0.632
Age groups					0.357
<60	16 (3.9%)	1 (6.2%)	1 (6.2%)	2 (12.4%)	
60–69	199 (48.3%)	11 (5.5%)	20 (10.0%)	31 (15.5%)	
70–79	183 (44.4%)	4 (2.1%)	16 (8.7%)	20 (10.8%)	
80 +	14 (3.4%)	1 (7.1%)	3 (21.4%)	4 (28.5%)	
BMI (mean, sd)	31.6 (4.6)	32.4 (4.9)	31.5 (4.4)	31.9 (4.6)	0.630
BMI					0.233
Nonobesity	159 (38.6%)	4 (2.5%)	15 (9.4%)	19 (11.9%)	
Obesity	253 (61.4%)	13 (5.1%)	25 (9.8%)	38 (14.9%)	
Charlson index					0.001
Low	7 (1.7%)	0	1 (14.2%)	1 (14.2%)	
Medium	247 (59.9%)	12 (4.8%)	5 (2.0%)	17 (6.8%)	
High	158 (38.4%)	5 (3.1%)	34 (21.5%)	39 (24.6%)	
ASA					0.522
I-II	193 (46.9%)	10 (5.2%)	17 (8.8%)	27 (14.0%)	
III–IV	219 (53.1%)	7 (3.2%)	23 (10.5%)	30 (13.7%)	
Charnley class					0.018
A	148 (35.9%)	8 (5.4%)	20 (13.5%)	28 (18.9%)	
B	240 (58.3%)	10 (4.1%)	19 (7.9%)	29 (12.0%)	
C	24 (5.8%)	0	1 (4.2%)	1 (4.2%)	

sd: standard deviation.
[a] *P* value for total failure.

Variables of Interest

The primary outcome was failure of the treatment, which was defined as revision for any cause or clinical failure. Revision was defined as an additional surgery involving partial or complete removal or exchange of a component. Conditions for soft tissue treatment, such as irrigation and debridement with or without polyethylene exchange by infection were not included as failures. Clinical failure was defined as less than 70 points in postoperative KSS scores [25].

We considered several independent patient-related risk factors for revision or clinical failure. The demographic variables included age at surgery, gender, and body mass index (BMI). Age was also categorized into 4 groups (<60, 60–69, 70–89, and ≥80 years). BMI was categorized into 2 groups using the World Health Organization [29] classification system: nonobese (<30 kg/m^2, class 0, normal or overweight), and obese (≥30 kg/m^2). Preoperative clinical variables were American Society of Anesthesiologists score [30] (ASA, categorized as I–II, or III–IV), Charlson comorbidity index [31], Charnley class [32] (A, B, and C), and preoperative range of motion, KSS scores (knee and function) [25], WOMAC (pain and function scores) [26], and SF-12 (physical and mental components) [27]. Charlson index was categorized into 3 groups: low index (patients with no associated comorbidity), medium index (with one or two comorbidities), and high index (with more than two comorbidities). Because preoperative mobility level was an important functional predictor, both walking distance and use of walking aids were also analyzed separately from preoperative KSS. Preoperative walking distance was categorized into 2 groups: outdoors (able to walk outdoors), and indoors (unable to walk, or indoors only). Preoperative use of walking aids was categorized as group-1 (no aids or one cane), group-2 (two canes or walker), and group-3 (unable to walk).

Statistical Analysis

Statistical analysis was performed using SPSS software v. 10.0 (SPSS Inc., Chicago, USA). Preliminary univariate analysis to determine potential predictors included nonparametric and parametric two-tailed tests. Normality was assessed by Smirnov–Kolmogorov test. Categorical data were evaluated using chi-square test or Fisher's exact tests, and continuous variable were compared by Student t-test or Mann–Whitney U-test. Preoperative and postoperative continuous data were compared using paired Student t-test or Wilcoxon signed-rank test. Where appropriate, correlation between continuous data was evaluated by Pearson or Spearman coefficients. Subsequently, stepwise multiple logistic regression analysis was then used to test for the effect of each factor adjusted for the others. All variables were included

Table 2
Functional Outcomes.

	Preoperative	Postoperative	P
KSS knee	30.0 (8.5)	87.1 (9.2)	0.001
KSS function	38.5 (14.0)	86.9 (18.8)	0.001
Walking distance[a]	20.9 (7.3)	46.6 (8.1)	0.001
Walking aids[a]	−4.2 (4.4)	−1.6 (2.8)	0.001
Range of motion	89.7 (15.9)	98.1 (15.6)	0.001
WOMAC pain	37.8 (5.2)	88.9 (7.3)	0.001
WOMAC function	47.9 (9.5)	83.5 (10.9)	0.001
SF12 physical	19.0 (5.5)	79.7 (16.1)	0.001
SF12 mental	44.4 (11.6)	82.5 (14.6)	0.001

Mean (standard deviation).
[a] Subitems from Knee Society Score (KSS) function.

in the logistic regression analysis so as not to miss any possible interactions that may show a relationship unseen in univariate analysis. The continuous variables were also included as categorized. Odds ratios and the 95% confidence intervals were presented. Potential predictors of failure were calculated for the whole cohort and for subgroups. The results of subgroups were reported when they provide information that differs from the results of the main analyses. Separate logistic regression analyses were performed for the following dependent variables: revision, clinical failure (excluding revisions), and arthroplasty failure (both revision and clinical failure). In all analysis, statistical significance was considered for P values less than 0.05.

A power analysis of the study and effect size were performed in relation to the postoperative differences of KSS scores between patients with clinical failure and those with no clinical failure. An effect size of $d = 1.80$ and power of 0.81 for alpha 5% were obtained, which was considered adequate.

Results

Mean postoperative follow-up was 5.8 (range 5–6). Preoperative characteristics are shown in Table 1. There was a significant improvement ($P = 0.001$) in all mean postoperative outcome scores from the preoperative scores (Table 2). Mean range of motion improved significantly from 89.7° preoperatively to 98.1° postoperatively ($P = 0.001$). Flexion contracture greater than 10° was in 66 (16.1%) patients preoperatively, and in 12 (8.4%) patients postoperatively ($P = 0.001$). Preoperatively, there were 378 varus knees (mean 5.2°, range 1°–18°) and 33 valgus knee (mean 3.7°, range 2°–14°), and postoperatively all knees were in valgus (mean 4.6°, range 0°–10°). The mean alignment of the knee significantly improved at last follow-up ($P = 0.028$). Between TKA designs (CR or PS), there were no significant differences in all mean postoperative outcome scores ($P = 0.417$), range of motion ($P = 0.341$) or knee alignment ($P = 0.118$).

There were 17 (4.1%) failures because of surgical revision, and 40 (9.6%) other with clinical failure (Table 1). The causes for revision were wound deep infection in 3 patients who were treated with 2-stage revision and they had pain and poor results at last follow-up. Aseptic tibial loosening occurred in 7 patients with a time revision ranged from 4 to 5 years. Of these, one patient had an age of 56 years, in 3 other (age 62–67 years) the tibial component was malaligned in varus, and the 3 other had an age of 71–76 years. All the 7 patients were considered treatment failures. Four patients sustained a polyethylene insert wear with a time revision ranged from 4 to 5 years. In 2 of these (age 66–68 years) the inserts were of little thickness (7 mm) which were treated with only insert exchanges. The 2 other (age 70–76 years) had the tibial components malaligned in varus and they were treated with tibial revision. All the 4 patients were considered treatment failures. Periprosthetic femoral fracture occurred in 3 patients (age 68–81 years) related to a fall at 2–4 postoperative years, which were treated with open reduction and internal fixation. These 3 patients had pain and poor final results. Four other patients developed superficial infections which were treated with debridement and irrigation without insert exchange in 2 of them and with insert exchange in the 2 other. These 4 patients were not considered arthroplasty failures and the functional results were successful at last follow-up.

Regarding the aseptic revisions, there were 11 (3.1%) failures in patients undergoing CR design, and 3 (4.7%) in those with PS design, and this difference was not significant ($P = 0.364$). Univariate and multivariate analyses failed to show any significant association between patient-related variables and surgical revision as dependent variable, such as gender ($P = 0.450$), age ($P = 0.656$), BMI ($P = 0.303$), Charnley class ($P = 0.499$), ASA ($P = 0.374$), Charlson index ($P = 0.284$), preoperative KSS knee ($P = 0.752$) and function ($P = 0.116$) scores, preoperative range of motion ($P = 0.178$), preoperative walking distance ($P = 0.293$) and walking aids ($P = 0.248$), preoperative WOMAC pain ($P = 0.787$) and function (0.116) components, and preoperative SF-12 physical ($P = 0.785$) and mental ($P = 0.133$) components.

Regarding the clinical failures, there were 32 (9.1%) failures in patients undergoing CR design, and 8 (12.6%) in those with PS design, and this difference was not significant ($P = 0.253$). Predictors for clinical failure are shown in Table 3. In univariate analyses, age ($P = 0.452$), BMI ($P = 0.852$), Charnley class ($P = 0.119$), ASA ($P = 0.325$), preoperative walking aids ($P = 0.825$), preoperative WOMAC function ($P = 0.208$), and preoperative SF-12 physical ($P = 0.738$) and mental ($P = 0.179$) components were no potential predictors. In contrast, female gender ($P = 0.037$), high Charlson index ($P = 0.001$), preoperative KSS knee and function scores ($P = 0.001$), walking indoors only ($P = 0.001$), lower range of motion ($P = 0.043$), and preoperative WOMAC pain ($P = 0.001$) were potential predictors in univariate

Table 3
Patient-Related Predictors of Clinical Failure.

	Patients (n = 414)	Failure (n = 40)	Univariate P Value	Adjusted OR (95% CI)	Adjusted P Value
Gender					
Male	316	36		1 (ref)	
Female	98	4	0.026	1.50 (0.21–11.06)	0.653
Charlson index					
Low	7	7		1 (ref)	
Medium	249	5		1.03 (0.82–1.34)	0.458
High	158	28	0.001	2.11 (1.94–2.35)	0.027
KSS knee[a]	30.0 (8.5)	22.8 (8.0)	0.001	0.92 (0.79–1.08)	0.325
Range of motion[a]	89.5 (15.9)	84.8 (19.9)	0.043	1.01 (0.95–1.08)	0.590
KSS function[a]	38.5 (14.0)	21.8 (12.6)	0.001	0.76 (0.63–0.92)	0.006
Walking distance[a]	20.9 (7.3)	17.0 (7.9)	0.001	0.87 (0.66–1.14)	0.324
WOMAC pain[a]	37.8 (5.2)	33.1 (3.6)	0.001	0.30 (0.11–0.78)	0.015

ref: reference value. Univariate P value: between patients with clinical failure and patients with no clinical failure. OR: odds ratio. KSS: Knee Society score. WOMAC: Western Ontario MacMasters University.
[a] Continuous variable (mean, standard deviation).

analyses. However, multivariate regression analysis revealed that significant independent predictors of clinical failure were only high Charlson index (OR = 2.1, 95% CI 1.9–2.3, $P = 0.027$), lower preoperative KSS function score (OR = 0.7, 95% CI 0.6–0.9, $P = 0.006$), and worse preoperative WOMAC pain (OR = 0.3, 95% CI 0.1–0.7, $P = 0.015$).

Discussion

The majority of studies on outcomes after TKA report on complication or revision rates and its causes [22,23], but they do not focus on the poor functional results [2,7,10]. Several authors have investigated patient-related predictor for outcomes after primary TKA, but the reported risk estimates for failure are inconsistent in the literature [6]. These studies [5,10,12] have found the influence of different factors such as that age, gender, preoperative pain, poor function, low mental health, or multiple comorbid conditions are predictors of poorer outcomes. However, the most are retrospective studies and few are truly prospective or have reported results based on validated patient-centered outcome measures [5,15]. This study identified a number of clinically important predictions of clinical failures. Charlson comorbidity index, preoperative functional KSS, and preoperative pain were predictors of clinical failure after treatment with TKA.

The effect of age on TKA outcome has been variably reported in the literature. In our cohort, age was not predictor of outcome, as reported by others [2,11]. In contrast, other authors reported that age greater than 70 years was associated with poorer functional outcome [6,10]. In some studies, young age was identified as a risk factor for mechanical failure of TKA with a decreasing risk for every 10 year increments [22,23], or it was a risk factor for residual pain [12].

Influence of gender on outcome is also controversial. In this study, gender was no predictor of functional outcome but our cohort had an unbalanced high rate of women. Some authors observed worse outcomes in females than in males [10,12,16], while others found no difference between the genders [2,8,22]. Singh et al [6] reported that female gender was significantly associated with more knee pain, increased risk of functional limitation, and walking-aid dependence at 5 years after primary TKA.

The literature highlights that having a greater number of preoperative comorbidities was associated with worse outcomes [6,8,33,34], although this was not reported in all studies [2,11]. In the present study, higher comorbidity has been shown to be a negative prognostic factor for functional outcome, but did not affect the survival of the implant, which was also observed in other studies [35]. In contrast, Namba et al [22] found that the presence of comorbidities was associated with increased aseptic revision. Singh et al [6] found that higher comorbidity was associated with poorer function outcomes and walking aid dependency. In our study, BMI was not found to influence the results or revision rate. This finding confirms previous studies in patients with primary TKA [36], but was in contrast to other studies [37].

The WOMAC questionnaire was used to assess pain in this study. Preoperative pain was found to be a strong predictor of postoperative pain, which has also been found for other authors [12,13]. In addition, although the majority of patients benefited from TKA in terms of pain reduction, patients with higher preoperative pain tended to have poorer functional outcome. However, other authors found that patients with higher preoperative pain experienced a greater improvement in pain and functional scores than patients with lower preoperative pain [8]. Psychosocial variables can influence the pain response, but the SF-12 (mental component) was not correlated with the follow-up outcome in our study. Other authors found that preoperative WOMAC pain score was the strongest predictor for postoperative patient dissatisfaction after TKA [5]. Some studies have also suggested the preoperative mental health score of the SF-36 independently predicted the postoperative changes in all the domains of the SF-36 and WOMAC [8,10].

In this study, poorer preoperative functional status predicts worse clinical outcome, as reported by others [11,16]. It is well known that those with worse pain and function scores get the greatest improvement due to the potential for more improvement [2], but is difficult return to the same level of function as those with the least preoperative functional limitation [10,14]. In our study, KSS function score was identified as predictor of clinical outcome, while KSS knee score was not a predictor. Other studies have found associations between capability variables (walking distance, stair ascent or descent) [6,17].

This study has some limitations. The study evaluated only patients with 5-year follow up, which only provides short term outcome for patients undergoing TKA. Although our sample size was relatively small, the study was adequately powered to detect clinically relevant differences. Characteristics of the study population should be noted, because there was a dominance of female gender (314/98), and patients were relatively young with a mean age of 69 years. This should be considered before extrapolating our findings to other populations. The strengths of this study include the use of a reliable, valid and responsive instrument for assessing outcomes of TKA, and data collected prospectively with a good rate of follow-up

Conclusions

This study identified clinically important patient-related predictors of treatment failure after TKA. These findings may be useful preoperatively in identifying patients with a high risk of failure, especially those with multiple predictors of failure, in order to inform the patient of these potential risks.

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