



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



Alejandro Lizaur-Utrilla, PhD, MD^a, Santiago Gonzalez-Parreño, MD^a, Francisco A. Miralles-Muñoz, MD^a, Fernando A. Lopez-Prats, PhD, MD^b, Vicente Gil-Guillen, PhD, MD^c

^a Department of Orthopaedic Surgery, Elda University Hospital, Elda, Alicante, Spain

^b Department of Orthopaedic Surgery, Faculty of Medicine, Miguel Hernandez, University, Elche, Alicante, Spain

^c Unit of Clinical Investigation, Elda University Hospital, Elda, Alicante, Spain

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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.

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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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Reprint requests: A. Lizaur-Utrilla, PhD, MD, Department Orthopaedic Surgery, Elda University Hospital, Ctra Elda-Sax s/n, 03600 Elda, Alicante, Spain.

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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 Mac-

Masters 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.

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/m², class 0, normal or overweight), and obese (≥30 kg/m²). 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, step-wise multiple logistic regression analysis was then used to test for the effect of each factor adjusted for the others. All variables were included

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.

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