Patient-reported outcome measures and patient satisfaction after total knee replacement for osteoarthritis in Egyptian patients: An observational Study

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ABSTRACT

Introduction: Together with the clinical and radiological evaluation, patient-reported outcome measures (PROMs) provide a valuable tool to measure the success of TKA. This prospective study looked at the clinical outcome and patients' satisfaction following TKA using different PROM and scores at one-year post-operative.

Materials and Methods: A prospective cohort study was performed at an elective arthroplasty unit in Menoufia University Hospitals, Egypt, on 132 patients who received primary TKA from 1 May 2021 to 1 May 2022 with a minimum one-year follow-up. All Patients received fixed bearing posterior stabilized knee TKA because knee arthritis, either primary or secondary to autoimmune disorder were included. Demographic data were collected: age, sex, weight, height, body mass index (kg/m2), comorbidities, socioeconomic status, and occupation. Three scores were used for prospective evaluation. Oxford Knee Score (OKS), Western Ontario and McMaster Universities Osteoarthritis Index score (WOMAC), and VAS (Visual Analogue Scale). During the follow-up visits, the participants were then asked to conduct their PROM (6 months and one year), and radiological and functional outcomes were recorded.

Results : 132 patients with mean age 58.5±8.1 (range 35 to 80), a higher proportion of the patient's population were females 105 (79.5%), the body mass index was 28.8±1.37.

Comparing the results received on 6 months and 12-month follow-up visits to that recorded preoperative. significant improvement of OKS, WOMAC score, and VAS, this was seen when comparing the measures at 6 months postoperative to the preoperative,12 months postoperative to the preoperative, and 6 months postoperative to 12 months postoperatively, with significant improvement between each of the pairs (P= <0.001).

Correlation between both OKS and WOMAC score at 12 months postoperative and age, and BMI.

At the 12-month follow-up visit, patients who gave responses on a 4-point Likert scale, with overall patient satisfaction was 72.7% (96 patients); with a dissatisfaction rate of 27.3% (36 patients).

Conclusion: Despite being highly successful in relieving pain, TKA does not meet the expectations of all patients, especially those with demanding levels of knee activities. PROMs that measure functional outcomes should consider patients of different cultures and lifestyles.

INTRODUCTION

Total knee arthroplasty (TKA) has been one of the most successful surgical procedures over the last 50 years that reduce pain and improve the patient's quality of life. There have been reports of varying patient satisfaction levels, ranging from 80% to 90%. However, this level of satisfaction may drop to only 65% when specific types of activities performed with the knee in mid-flexion were evaluated.[1-4] Hence, implant design, limb alignment, and surgical techniques are in continuous development.

Patient-reported outcome measures (PROMs) offer a useful tool to assess the effectiveness of TKA in addition to the clinical and radiological evaluation.[5] Oxford Knee Score (OKS)[6], WOMAC (Western Ontario and McMaster Universities Osteoarthritis Index)[7], and Knee Injury and Osteoarthritis Outcome Score for joint replacement (KOOS, JR)[8] are now widely used for predicting the outcome after TKA with preoperative pain and functional status, as measured by PROMs, and are used to predict pain and functional ability after TKA.

Interestingly, though patients with higher levels of preoperative pain and disability show the greatest improvements in PROM scores, they do not achieve as good postoperative scores comparable to patients with less preoperative pain and better baseline functions.[9,10]

Indeed, a variety of factors, even those unrelated to the surgery itself, influence patient satisfaction, making it a multifaceted problem. (type of surgery, type of anesthesia, operative time, complications, implant type, component alignment, soft tissue balance, and deformity correction), postoperative factors (postoperative care, improved range of motion, pain improvement, hospital experience, etc.) as well as patients' non-modifiable parameters.[11,12]

PROM is a valuable tool for the assessment of patients' satisfaction in relation to their daily activities. It is important

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to note that these activities vary in different societies and cultures. So, what may be suitable for a patient in a Western culture might not necessarily be satisfactory for the Asian and Middle Eastern populations. Female sex and related co-morbidities were the main preoperative variables that had a negative impact on patient satisfaction.[1,13]

PROMS reporting in the North African population was deficient[13,14] with a big differences between such population and Western patients regarding activity of daily living and their culture.

This prospective study looked at the clinical outcome and patient satisfaction following TKA in a North African society using different PROM and scores at one year post-operative.

MATERIALS AND METHODS

Study design

This is a prospective cohort study performed at an elective arthroplasty unit in Menoufia University Hospitals-EGYPT on 132 patients who received primary TKA from 1 May 2021 to 1 May 2022 with a minimum one-year follow-up. Written informed consent was obtained from each patient, and the Menoufia University Research Ethics Committee granted ethical approval. All methods were performed in accordance with the relevant guidelines and regulations.

All Patients received fixed bearing posterior stabilized knee TKA (PS Nex Gen Zimmer-Biomet) due to knee arthritis either primary or secondary to autoimmune disorder were included. All patients received cemented implants without patellar resurfacing aiming for neutral mechanical alignment. Having a stem to the tibial tray was not an exclusion criterion while using a constrained implant, metal augments, bone graft, or revision surgery were excluded. Patients with cognitive disorders, who missed follow-up or did not respond to their questionnaire were excluded from the study. 165 patients were operated on during the study inclusion period. Twenty-six patients were lost to follow-up, most of whom were from distant districts. Seven patients completed the follow-up period but did not respond to the PROMs questionnaire. A total of 132 patients were included in the final analysis.

Data collection

The following demographic data were collected: Age, sex, weight, height, body mass index (kg/m2), comorbidities, socioeconomic status, and occupation.

All patients received standard preoperative evaluation including medical assessment and informed consent (giving full details about the procedure and, a video demonstration that was prepared for the patients published on social media). Standard radiological evaluation of standing weight-bearing anteroposterior (AP), Lateral, and Patellofemoral (skyline) radiographs in addition to long leg standing radiographs from pelvis to ankle to assess limb alignment and degree of deformity.

Three scores were used for prospective evaluation. The Oxford Knee Score (OKS), The Western Ontario and McMaster Universities Osteoarthritis Index score (WOMAC), and the VAS (Visual Analogue Scale). During the follow-up visits, the participants were then asked to conduct their PROM (6 months and one year), and radiological and functional outcomes were recorded.

At 12-month patients were asked to report their overall satisfaction with their operation on a 4-point Likert scale with response categories consisting of very satisfied, somewhat satisfied, somewhat dissatisfied, and very dissatisfied.[15] Patients were specifically asked if they would recommend total knee replacement for one of their relatives if needed.

Surgical technique

All procedures were performed at a university hospital that provides free health services under the care of arthroplasty surgeons. The surgical interventions were performed by supervised trainees, consultants, and senior consultants.

Spinal anesthesia was used in all cases. Surgical interventions were performed with the use of pneumatic tourniquets through the medial parapatellar approach. Double skin preparation and draping using alcohol-based Povidine iodine 10% was applied.

Posterior stabilized Nex-Gen (Zimmer Biomet ®) implants were used in all patients aiming for neutral mechanical alignment. Pain control protocol using periarticular cocktail injection, NSAIDs was used. The postoperative protocol included early mobilization, chemical prophylaxis for venous thromboembolism (VTE) and antibiotic prophylaxis for 48 hours post-operative. After discharge, patients were scheduled for outpatient follow-up visits at 6 and 12 weeks, followed by assessments at 6 months and 1 year postoperatively.

Statistical analysis

IBM SPSS version 26 was used to gather, tabulate, and statistically analyze the data. Quantitative data were expressed as mean ($\bar{x}$) and standard deviation (SD), whilst qualitative data were expressed as number (No.) and percentage (%). Quantitative variables between two groups of regularly distributed data are compared using the Student's t-test (t), a test of significance; quantitative variables between two groups of non-normally distributed data are compared using the Mann-Whitney's test (U). The Wilcoxon test was used to compare different readings of non-normally distributed data in the same group. The Friedman test was used for the comparison of quantitative variables between more than two consecutive measures in the same group of not-normally distributed data with the LSD test as a post hoc test. Chi-square test ($\chi 2$) was used to study the association between qualitative variables. Pearson correlation was used to show the correlation between two continuous normally distributed variables. Significant variables in bivariate analysis were entered into the regression model. We adjusted for age, sex, BMI, and preoperative and postoperative VAS pain scores by adding these variables to the model. Statistical significance was set at a $p\text{-value} < 0.05$.

RESULTS

132 patients were included in this study with mean age 58.5±8.1(range 35 to 80), a higher proportion of the patient's population were females 105(79.5%) while males were 27 (20.5%). body mass index was 28.8±1.37(range 26-34). The surgical intervention was conducted by trainees in 66 patients, consultants in 40 patients, and senior consultants in 26 patients. A tourniquet was applied in all cases with a mean tourniquet time of 70 +/- 12 (average +/- SD). (Table I) During the 6-month and 12-month visits, a significant improvement in OKS, WOMAC score, and VAS showed significant improvement compared to the preoperative measures, the best records were reached at 12-month follow-up visits. (Table II)

Comparing the results obtained at 6-month and 12-month follow-up visits to that recorded preoperative. significant improvement of OKS, WOMAC score, and VAS, this was seen when comparing the measures at 6 months postoperative to the preoperative,[12] months postoperative to the preoperative, and 6 months postoperative to 12 months postoperative, with significant improvement between each of the pairs (p=<0.001). (Table III)

Significant Correlation between WOMAC score at 12 months postoperative and comorbidities such as DM and combined DM and HTN, while no association with gender and other comorbidities such as HTN and RA. Significant Association between OKS score at 12 months postoperative and comorbidities, while no association with gender. (Table IV, V) low BMI, controlled blood pressure, and low VAS at 6 and 12 months postoperative were significant predictors of higher Oxford knee score. High VAS for pain at 6 and 12 months postoperative were significant predictors of higher WOMAC scores.

Correlation between both OKS and WOMAC score at 12 months postoperative and age, and BMI.

At the 12-month follow-up visit, patients who gave a response on a 4-point Likert scale as very satisfied, or somewhat satisfied, were considered satisfied with overall patient satisfaction of 72.7% (96 patients); while patients who gave responses as somewhat dissatisfied or very dissatisfied were considered as dissatisfied with dissatisfaction rate 27.3% (36 patients).

Radiological evaluation of the operated knees showed satisfactory postoperative alignment within 3 degrees from the neutral mechanical axis with no outliers.

DISCUSSION

This study on Egyptian patients who received TKA for OA revealed an overall dissatisfaction rate of (27.3%). The detailed analysis of the data confirmed a significant improvement in their knee scores OKS from 8.09±3.23 to 31.6±5.86 (-9.979, P value <0.001) and WOMAC score from 80.11±6.05 to 32.98±12.2 (-9.973 p-value <0.001) (preoperative to postoperative at 12 months, respectively). However, 27.3% of the patients were dissatisfied to some extent.

Dissatisfaction is multifactorial.[12,16–19] Patient satisfaction is one of the most important outcome measurements after TKA.[1,20] Patient selection, preoperative preparation, surgical procedure, and postoperative rehabilitation protocols are key factors for successful knee arthroplasty and hence patient satisfaction. Pain relief and correcting deformity do not always guarantee patients' satisfaction.

A negative correlation has been drawn between the postoperative OKS and old age or high BMI. Hasegawa et al. analyzed 109 patients (130 osteoarthritic knees) who underwent primary TKA with navigation and reported that patient satisfaction after TKA correlated negatively with old age 20. However, Lange et al. found a higher satisfaction rate with TKA in older patients (91%) compared to the younger (86%).[21]

Matsuda et al. reported that older age and postoperative varus alignment were negatively correlated with patient satisfaction. Postoperative stiffness or limited ROM was also suggested as an important factor in postoperative patient dissatisfaction.[22]

Most of the patients experienced pain relief, better mobility, good alignment, and improved activities of daily living. At one-year postoperative follow-up, 27.3% of patients were not satisfied after their TKA, The Lower satisfaction rate compared to what was reported in the literature may be attributed to cultural issues as many of the daily activities in the eastern societies (squatting, kneeling, social life, religious activities and sitting on the ground) needs wide ROM and axial loading in flexion. Hence, patients can achieve significant improvement in the WOMAC score yet can still be dissatisfied with the overall outcome. This observation raises the point that scores that measured functional demand in Western culture may not be suitable to measure outcomes in Asian or Middle Eastern cultures.

The large variation in satisfaction rates (65–90%) could be a result of variations in the cultural setting and the way PROMs are implemented. Although PROMs have been translated and validated in Egypt, a recent assessment found limitations in measurement error reporting and response that could compromise dependability.[23] Saudi Arabia, on the other hand, has incorporated PROMs into its Vision 2030 plan in order to support patient-centered, standardized treatment.[24] Despite the scattered implementation of PROMs in various Asian nations, these efforts demonstrate regional development. Therefore, the results for Egyptian patients probably show both methodological shortcomings and regional strengths, highlighting the necessity of harmonizing PROMs in non-Western contexts.[25,26]

Scott et al. in their study have focused on the inability of TKA to meet patient high knee flexion activities such as kneeling and squatting, considering both the least fulfilled patient expectations together with the ability to return to paid work and sexual activity.[15,16] Also, some patients experienced a variable degree of pain at 12 months follow-up (3.39±1.27). Unfulfilled pain relief was the most crucial factor for patients who did not report being satisfied with their surgery at six weeks and one year.[17,18] Postoperative pain improves over time, and satisfaction also improves.[4,17,18]

Table I: Demographic data

Variable		Studied cases No.=132
Age (years):	Mean ±SD	58.5±8.1
	Range	35-80
Gender		
No. (%)	Female	105 (79.5%)
	Male	27 (20.5%)
BMI	(Mean ± SD)	28.79±1.37
	Range	26-34
Socioeconomic status	Low	17 (12.9)
	Middle	115 (87.1)
Surgeon	Less than 5 years post doctorate	66(50)
	5 years to 10 years	40(30.3)
	More than 10 years	26(19.7)
Diagnosis	OA	122(92.4%)
	RA	10(7.6%)
Comorbidities	DM	13(9.8)
	HTN	17(12.9)
	DM&HTN	11(8.3)
	COPD	2(1.5)

Table II: Repeated measures of preoperative, 6- and 12-months postoperative scores of WOMAC score, OKS, VAS

Variable		Preoperative	6 months postoperative	12 months postoperative	Test of sign#	p-value
WOMAC score	Mean ± SD.	80.11±6.05	47.9±10.44	32.98±12.2	262.015	<0.001**
	Range	70-92	30 – 72	15 – 62		
	Median (IQR)	79(75.3 -86)	47(40 – 54)	30(23 – 42)		
OKS	Mean ± SD.	8.09±3.23	24±5.11	31.6±5.86	262.015	<0.001**
	Range	2 – 17	12- 33	17 – 40		
	Median (IQR)	9(5 – 11)	24(21 – 28)	33(27 – 36)		
VAS	Mean ± SD.	8.36±0.7	5±1.13	3.39±1.27	259.107	<0.001**
	Range	7-10	3-8	2-7		
	Median (IQR)	5(8 – 9)	5(4-6)	3(2-4)		

#=Friedman Test
IQR=Interquartile range
**P value statistically highly significant

Table III: Paired differences in OKS and WOMAC score between preoperative, 6 months postoperative and 12 months postoperative

Variable		6 months postoperative-preoperative	12 months postoperative-preoperative	6 months postoperative-12 months postoperative
WOMAC score	Z	-9.972	-9.973	-9.912
	P value	<0.001**	<0.001**	<0.001**
OKS	Z	-9.976	-9.979	-9.909
	P value	<0.001**	<0.001**	<0.001**
VAS	Z	-10.052	-10.078	-9.924
	P value	<0.001**	<0.001**	<0.001**

**P value statistically highly significant

Table IV: Association between WOMAC score at 12 months postoperative and sex, and comorbidities

Variable		WOMAC score 12 m postoperative Median (IQR)	Test of sign. @	p-value
Gender	Female	30(18 - 43)	0.068	0.946
	Male	30(18 – 41)		
DM	Yes	42(27 -55)	2.297	0.017*
	NO	30(23 – 38)		
HTN	Yes	33(30 – 45)	1.717	0.086
	NO	30(23 – 42)		
Both DM&HTN	Yes	44(35 -57)	2.732	0.006*
	NO	30(23 – 38.5)		
RA	Yes	42(28.5 – 56)	1.933	0.053
	NO	30(23 – 40.25)		

@=Mann-Whitney Test
IQR=Interquartile range
*P value statistically significant

Table V: Association between OKS at 12 months postoperative and sex, and comorbidities

Variable		OKS—12 m postoperative Mean ± SD.	Test of sign. ^	p-value
Gender	Female	31.63±5.9	0.036	0.971
	Male	31.59±5.7		
DM	Yes	27±7	3.092	0.002*
	NO	32.12±5.52		
HTN	Yes	29.94±4.7	1.273	0.025*
	NO	31.87±5.99		
Both DM&HTN	Yes	27±6.27	2.803	0.006*
	NO	32.05±5.6		
RA	Yes	27.3±7.33	2.473	0.015*
	NO	31.98±5.6		

^= Student t Test IQR=Interquartile range
*P value statistically significant

For many patients, pain relief and improved mobility are sufficient for satisfaction 27. However, Deakin et al suggest that a preoperative focus on the pain relief and mobility advantages of TKA is most likely to give an accurate idea of what expectations may be fulfilled by surgery.

Preoperative counseling of the patients includes activities that they may not be able to engage in such as squatting and kneeling. the author thought that Dissatisfaction did not seem to be only a result of unrealistic expectations such as squatting and kneeling.[4] Dissatisfaction may be related to other symptoms unrelated to the replaced knee.[19]

Deakin et al show that TKA did not fulfill patients' expectations of kneeling, squatting, ability to return to paid work, and sexual activity, and these expectations should be better managed in the preoperative education process4.

Practical advice is crucial for treating patients with high flexion needs, which are typical in many non-Western contexts, in addition to the requirement for culturally appropriate PROMs. Using visual aids and examples that are culturally appropriate, preoperative counseling should evaluate lifestyle and functional expectations. It takes customized surgical planning, the right implant choice, and the optimization of modifiable risk factors including obesity and restricted preoperative movement to achieve deep flexion after surgery. By using these tactics, patient satisfaction can be raised and expectations can be more realistically met.

The high correlation with pain and function and satisfaction emphasizes the need to relate these as appropriate preoperative expectations.[16]

In this study, the presence of preoperative comorbidities like Diabetes, HTN, and RA negatively affected the postoperative PROMs (OKS, WOMAC) results.

Clement et al compared the PROMs preoperatively to those at 2 years post-surgery, the overall satisfaction was influenced by DM, depression, and back pain.[28]

A retrospective cohort of 2521 patients undergoing primary unilateral TKA was identified from an established regional arthroplasty database. Walker et al encountered those patients with lung disease, DM, gastric ulcer, kidney disease, liver disease, depression, and back pain, and those with poorer preoperative functional scores (WOMAC and SF12) to have significantly lower levels of satisfaction.[7]

Simon et al concluded that Finding the factors that affect survey completion can assist remove selection biases in PROMs, which are being utilized more and more as a quality measurement.[25]

Felix et al analyzed a prospective cohort study, 61% of the patients reported satisfactory outcomes; patients were satisfied with the results if postoperative WOMAC was ≥82.49. Patients with high absolute preoperative PROM scores were more likely to remain dissatisfied.[29] According to Jain et al (prospective multicenter study), greater patient expectations anticipate greater PROMs, but not satisfaction, in TKA patients.[16]

First, the study was limited by a small sample size and a relatively short follow-up period. Additionally, the narrow inclusion criteria and broad exclusion of patient samples may limit generalizability. Participation in the PROMs was also potentially influenced by external factors such as literacy, language barriers, and the fact that some patients had traveled from distant regions for their surgery 30. On the other hand, the study's strengths include its prospective design, the use of three different assessment scores, and a study population representative of an Eastern cultural background. One year follow-up is the standard point of best functional outcome and a common point of outcome reporting, so in terms of satisfaction, one year is an appropriate point 31.we believe that longer follow up period and a bigger sample size will makes the interpretation of data more confident , we will try to avoid these confounding issues in the future studies , considering multi centric studies with long term follow up period. Also, a more qualitative based PROMs will be considered in future research for better understanding and interpretation of the outcome.

CONCLUSION

Despite being highly successful in relieving pain, TKA does not meet the expectations of all patients, especially those

with demanding levels of knee activities. PROMs that measure functional outcomes should consider patients of different cultures and lifestyles. The older group of patients, those with high BMI and different comorbidities, should be counseled carefully in regard to the postoperative outcome. Recent philosophies in phenotypic knee joint inclination as well as development in prosthetic designs could improve patients' satisfaction but this remains to be seen.

Ethics approval

The study was conducted after the approval of the institutional review board of Menoufia university-faculty of medicine

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