



Original Article

Quality-of-life assessment among patients undergoing total knee arthroplasty in Manaus[☆]

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ABSTRACT

Objective: this study had the aim of assessing the quality of life among patients undergoing total knee arthroplasty (TKA). For this, the SF-36 and WOMAC questionnaires respectively were used to make comparisons with preoperative values.

Methods: a prospective observational cohort study was conducted, with blinded analysis on the results from 107 TKAs in 99 patients, between June 2010 and October 2011. The present study included 55 knees/patients, among whom 73% were female and 27% were male. The patients' mean age was 68 years. The SF-36 and WOMAC questionnaires (which have been validated for the Portuguese language) were applied immediately before and six months after the surgical procedure.

Results: the statistical and graphical analyses indicated that the variables presented normal distribution. From the data, it was seen that all the indices underwent positive changes after the surgery.

Conclusions: despite the initial morbidity, TKA is a very successful form of treatment for severe osteoarthritis of the knee (i.e. more than two joint compartments affected and/or Ahlback classification greater than 3), from a functional point of view, with improvement of the patients' quality of life, as confirmed in the present study. This study presented evidence level IV (description of case series), with analysis on the results, without a comparative study.

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Avaliação da qualidade de vida em pacientes submetidos à artroplastia total do joelho em Manaus

RESUMO

Objetivo: avaliar a qualidade de vida em pacientes submetidos à artroplastia total do joelho (ATJ) com o uso dos questionários SF-36 (Medical Outcomes Study 36 – Item Short Form Health Survey) e WOMAC (Western Ontario and McMaster Universities Osteoarthritis Index) e compará-los com os valores pré-operatórios.

Palavras-chave:

Joelho/cirurgia
Artroplastia
Qualidade de vida
Avaliação

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Métodos: foi feito um estudo prospectivo, observacional, coorte com análise cega dos resultados, com 107 ATJ em 99 pacientes, de junho de 2010 a outubro de 2011. Incluídos no estudo 55 joelhos/pacientes: 73% eram do sexo feminino e 27% do masculino. A média de idade foi de 68 anos. Foram aplicados os questionários SF-36 e WOMAC, validados para língua portuguesa, imediatamente antes e seis meses após o procedimento cirúrgico.

Resultados: a análise estatística e gráfica indica que as variáveis tiveram distribuição normal. Observando os dados, verifica-se que todos os índices sofreram alterações positivas depois da cirurgia.

Conclusões: a artroplastia total do joelho, apesar da morbidade inicial, é uma modalidade bem-sucedida de tratamento para osteoartrite grave (mais de dois compartimentos articulares acometidos e/ou classificação de Ahlback maior do que 3) do joelho do ponto de vista funcional, com melhoria da qualidade de vida dos pacientes, dados esses confirmados nesta pesquisa. Nível de evidência IV, descrição de série de casos, com análise de resultados, sem estudo comparativo.

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Introduction

According to the World Health Organization (WHO), quality of life (QoL) refers to individuals' perception of their position in life, within the cultural context and value system in which they live and in relation to their aims, expectations and social standards. QoL is a subjective construct that involves self-perception and is composed of multiple positive, negative and bidirectional dimensions, such as physical function and emotional and social wellbeing.¹

In developed countries, osteoarthritis (OA) is the most frequent cause of incapacity among musculoskeletal diseases, and the knee is most frequent site of involvement, with considerably decreased QoL among the individuals affected. It has been estimated that 4% of the Brazilian population suffer from OA. The knee is the joint that is second most affected by the disease, with 37% of the cases.²

One of the ways of evaluating the functional losses and treatments associated with knee OA consists of questionnaires in which individuals report their difficulties. Because of the specificity of the WOMAC questionnaire, it is widely recommended for this purpose. In 2002, the version for the Portuguese language was presented, with adaptation for Brazilian culture in order to ease comprehension among readers. The measurement, reproducibility and validity properties were well demonstrated and the original parameters were maintained. Hence, it became a useful instrument for evaluating the quality of life of individuals with OA.³

Total knee arthroplasty (TKA) has been recognized as one of the most successful orthopedic procedures, with one of the best cost/benefit ratios within the field of orthopedics. It provides significant QoL improvements and more than 95% implant survival after 15 years.⁴ TKA is a reliable procedure for reducing the pain and incapacity associated with many pathological conditions of the knee, particularly OA. In conjunction with improvement of pain, gains in knee flexion are an important factor in relation to the result and functional success after TKA, given that through achieving greater flexion, it seems that patients are even benefited in relation to going up and down stairs adequately. The overall results and findings relating to satisfaction and

improvement of QoL among patients undergoing TKA need to be considered.⁵

Patients undergoing TKA expect the best result possible. Their expectations and satisfaction vary greatly, as do the instruments to measure these factors. Unsurprisingly, the reports relating to patient satisfaction show large variations. The role of expectations relating to obtaining satisfactory surgery still requires clarification in the literature. Surgeons take the view that expectations regarding the results need to be worked on, even before the surgery.⁶

SF-36, an easily administered and understood generic instrument, can be used to assess QoL. This is a multidimensional questionnaire comprising 36 items within eight scales or components, and it is not specific for any given age, disease or treatment group. It therefore allows comparisons between different pathological conditions or different treatments.⁷

This study had the main aim of evaluating QoL and knee function among patients undergoing TKA, using the SF-36 and WOMAC questionnaires, applied before the operation and six months afterwards, and to compare the latter with the preoperative values.

Materials and methods

This was a prospective observational cohort study with blinded analysis on the results, in relation to 107 TKA procedures that were performed on 99 patients between June 2010 and October 2011, with a minimum follow-up of six months.

From the estimated overall population, the sample size was calculated by means of a formula for estimating proportions for a finite N.

The sample size was estimated in relation to the total number of patients hospitalized at the orthopedics clinic of our institution and was calculated using the mathematical expression shown in Fig. 1, in which:

$$n = \frac{Z^2 \cdot \hat{p} \cdot \hat{q} \cdot N}{d^2 (N-1) + Z^2 \cdot \hat{p} \cdot \hat{q} \cdot N}$$

Fig. 1 – Mathematical expression for calculating the sample size.

N : Estimated size of the population studied, i.e. the total number of patients hospitalized in the orthopedics clinic between June 2010 and October 2011 ($N = 1518$);

\hat{p} : Mean proportion of patients within the inclusion criteria ($\hat{p} = 0.10$);

\hat{q} : Non-incident cases ($\hat{q} = 0.9$);

d : Margin of error ($d = 0.05$);

Z : 95% confidence coefficient ($Z = 1.96$).

The precision level used was 5%, with a 95% confidence level. Thus, a sample size of 32 patients was obtained, considering that the approximate proportion of patients who were within the inclusion criteria reached 10%.

The inclusion criteria were as follows: varus deviation greater than 15°; valgus deviation greater than 10° (measured using the anatomical axes of the femur and tibia); femorotibial subluxation in the frontal plane; anteriorization of the tibia in relation to the femur on lateral radiographs; severe compromising of two of the three compartments of the knee; or arthrotic knees without any of the above alterations that were refractory to conservative treatment for at least six months. The Ahlbäck classification,⁸ as modified by Keyes et al.,⁹ was used for radiographic staging of the degenerative disease of the knee, in which 56.4% of the patients presented type IV. Regarding the angular deformity (deviation from the axis), 76% of the knees presented varus deformity (less than 5° valgus in relation to the femorotibial anatomical axis, with a mean of 2° and range from 5° valgus to 18° varus) and only 24% of the knees presented valgus deformity (more than 7° valgus in relation to the femorotibial anatomical axis, with a mean of 13° and range from 8° to 25°).

Among the patients who fulfilled the profile for undergoing the surgical procedure, 73% were female and 27% were male, with a minimum age of 49 years and maximum of 91 (mean: 68). The right side accounted for 60% of the cases.

Fifty-five patients were excluded from the study for the following reasons: undergoing bilateral TKA (16); arthrosis due to inflammatory causes (three); death (three); psychological abnormalities that impeded understanding of the protocol (four); refusal to sign the free and informed consent statement (seven); secondary arthrosis (two); infection (three); and loss of follow-up (17). Thus, 71 operated knees were excluded and 36 knees remained to be studied. All the patients signed an informed consent statement before they were included in the study, and this statement had been evaluated and approved by the hospital's ethics committee, under the protocol number 01259112.1.0000.0007.

In the evening before the surgical procedure, the patient received the WOMAC and SF-36 protocols to be answered and handed in on the morning of the surgery. All the procedures were carried out by the same knee specialist surgeon. The operations were performed using the same anesthetic technique and the same joint access route (medially through the vastus; personal preference). The surgical procedure followed was in conformity with the technical standards for TKA and total knee prostheses made by Baumer (AKS model) were used.

Six months after the operation, the patients were reassessed by another knee specialist surgeon who had not had previous outpatient contact and had not participated in the surgical procedure. New radiographs of the knee

were produced in anteroposterior and lateral views and new WOMAC and SF-36 protocols were handed in, in order to record and compare the results. Since the WOMAC scale is counted from 0 (best result) to 96 (worst result), and with the aim of facilitating comprehension and analysis of the results, we inverted the Likert scale (the psychometric response scale generally used in questionnaires and the one most used in opinion polls) of the original questionnaire. In answering a questionnaire based on this scale, the respondents specify their level of agreement through an affirmation. This scale is thus named because of a report published by Likert to explain its use¹⁰: "1" is the worst result and "5" is the best, within each response (in the original questionnaire, the best result was 0 and the worst was 4).

For the statistical analyses, the Minitab 14 software and the Statistical Package for the Social Sciences (SPSS), version 13.0, were used. The data were then subjected to descriptive statistical analysis. To assess normality, the Shapiro-Wilk test was used, and to evaluate associations between the categorical variables, Pearson's chi-square test was used, or Fisher's exact test when necessary.

Results

One indication of normal probability on graphs is that the cloud of points has to be around a straight line. It can be seen from Figs. 2-7 that these points are around the straight line, which gives an indication that the observations present normality.

Student's *t* test and the nonparametric Wilcoxon test were performed to compare the variables. The QoL index measured using the SF-36 and WOMAC questionnaires improved significantly after the surgery.

Figs. 8-10 show that the SF-36 indices improved in relation to the analysis done before the surgery, but that only two variables reached 50% of the maximum value, which were the mental domain of SF-36 (mean of 39 before the operation and 52 afterwards) and WOMAC (mean of 28 before the operation and 85 afterwards). The physical domain of the SF-36 did not reach a postoperative change of more than 50%. It started from a mean of 28 before the operation and reached a mean of 46 after the operation.

It should be emphasized that because WOMAC is a specific index for knee and hip OA, its postoperative changes were more pronounced.

Discussion

Traditionally, the concept of QoL was delegated to philosophers and poets. However, among doctors and researchers today, there is growing interest in transforming this into a quantitative measurement that could be used in clinical trials and from which the results thus obtained could be compared between different populations and even between different diseases.

Aging has been a reason for constant concern and questioning within socioeconomic and cultural contexts around the world. In Brazil, because of the flattening of the demographic pyramid caused by the decline in the mortality rate

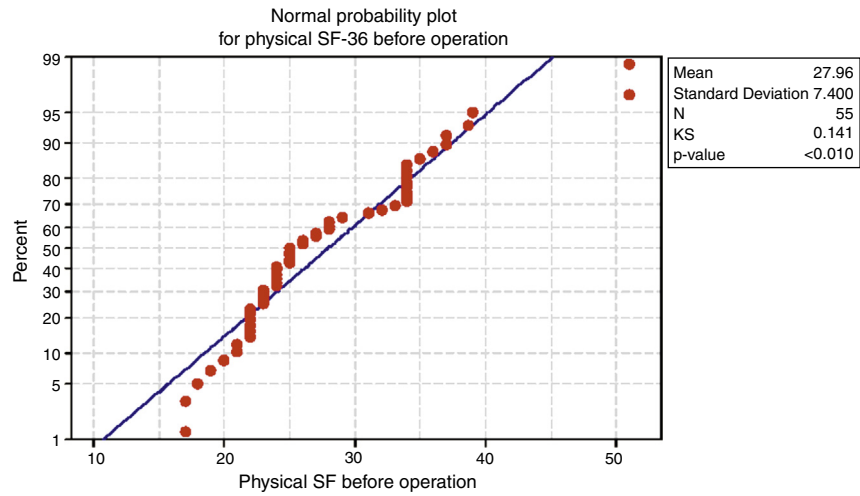


Fig. 2 – Normal probability of the physical variable of SF-36 before the operation.

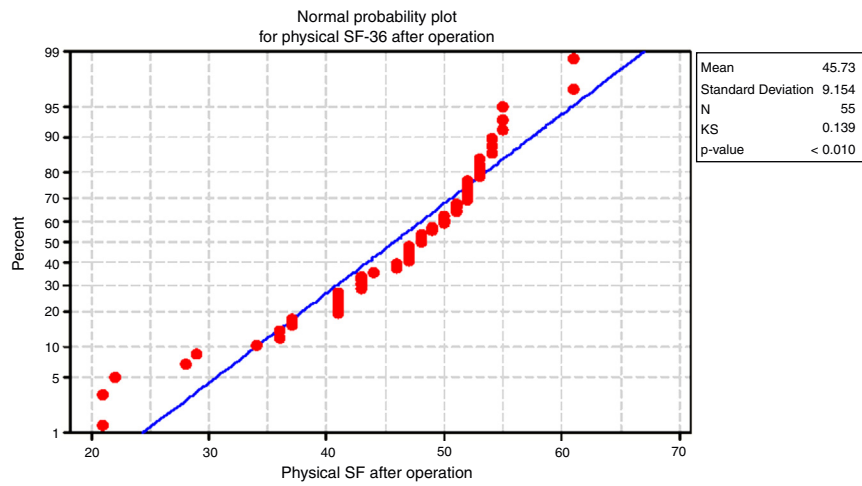


Fig. 3 – Normal probability of the physical variable of SF-36 after the operation.

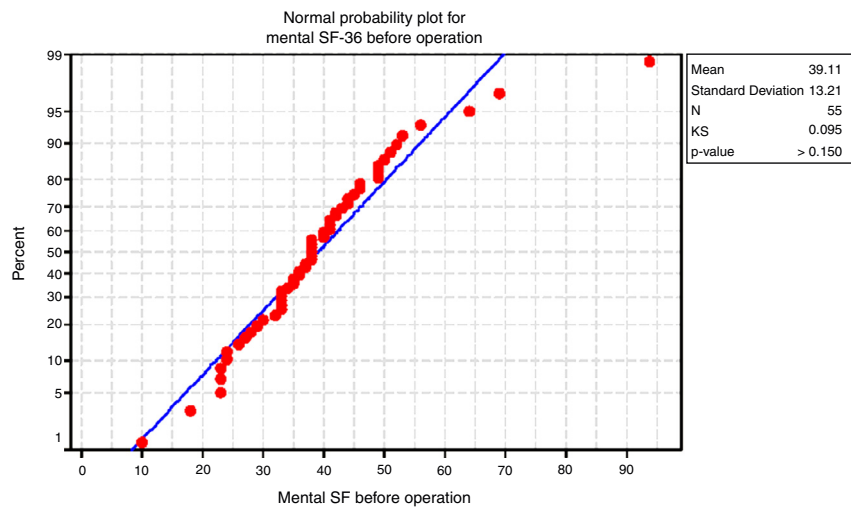


Fig. 4 – Normal probability of the mental variable of SF-36 before the operation.

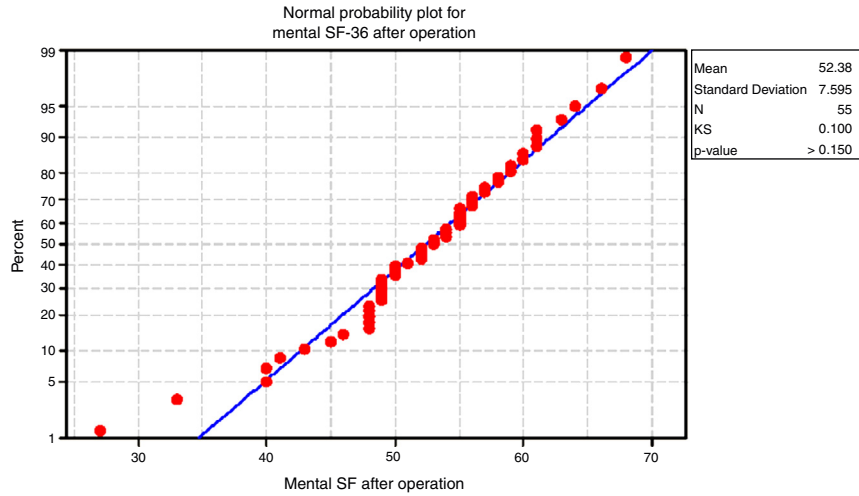


Fig. 5 - Normal probability of the mental variable of SF-36 after the operation.

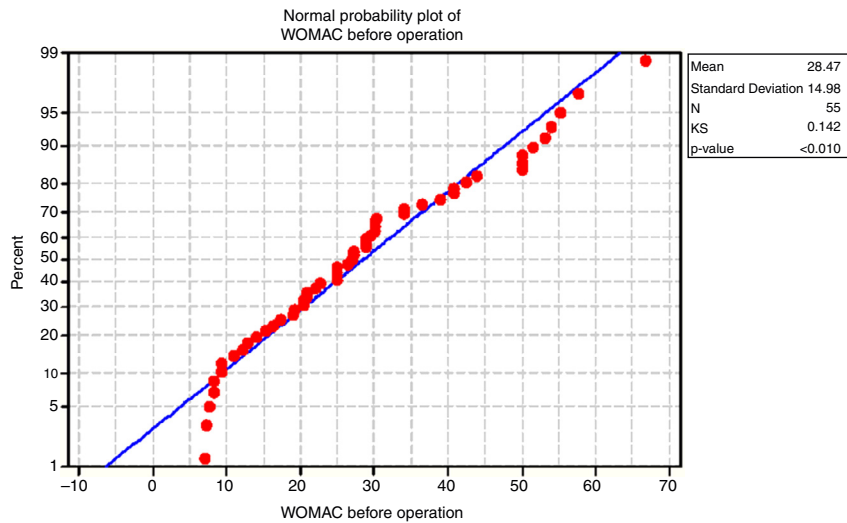


Fig. 6 - Normal probability of the WOMAC variable before the operation.

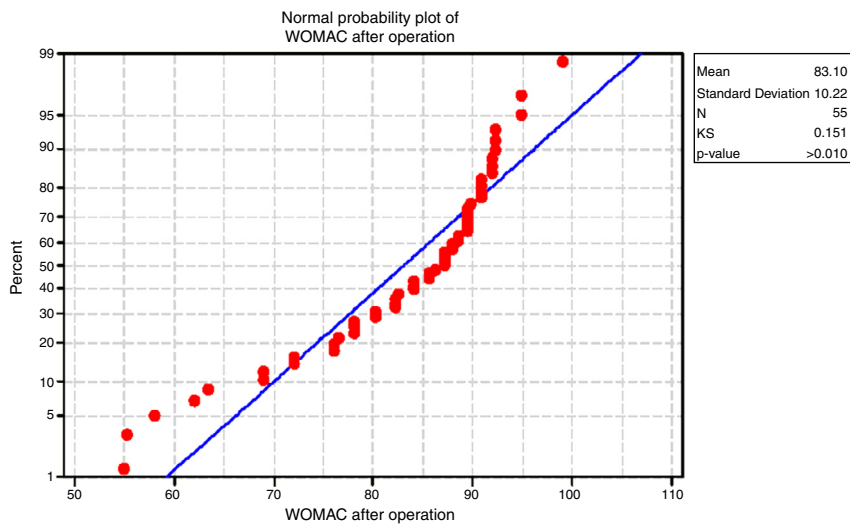


Fig. 7 - Normal probability of the WOMAC variable after the operation.

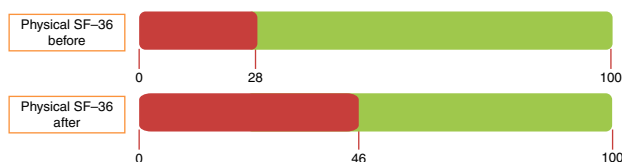


Fig. 8 – Mean scores for the physical variable of SF-36 before and after the operation.

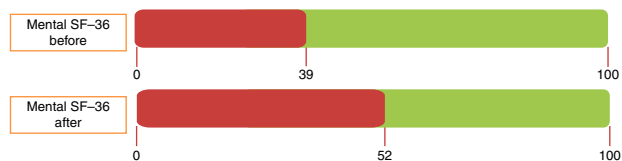


Fig. 9 – Mean scores for the mental variable of SF-36 before and after the operation.

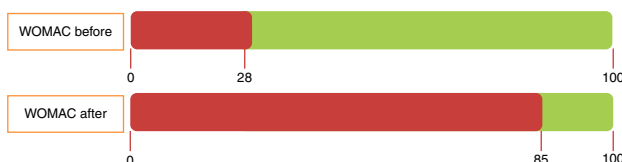


Fig. 10 – Mean scores for the WOMAC variables before and after the operation.

and also the decreased birth rate, healthcare policies have been led to focus full attention on elderly people's health. In environments with limitations on resources, results from questionnaires are of particular importance for comparing the cost/benefit ratios of medical interventions.¹¹

SF-36 is a generic instrument for assessing QoL that was created in 1976.¹² It is easy to administer and understand, but it is not as extensive as previous protocols. It is a multidimensional questionnaire formed by 36 items that are grouped into eight scales or components: functional capacity, physical aspects, pain, general state of health, vitality, social aspects, emotional aspects and mental health. These are grouped into two major domains (physical and mental) that can be analyzed independently. They present a final score from 0 to 100, in which 0 corresponds to the worst general state of health and 100 to the best state.¹³

OA is manifested mainly through joint pain. In the beginning, it is mild, intermittent and of low intensity. With the progression of the disease, it becomes continuous and diffuse, with basically mechanical characteristics. The evolution of the process leads to gradual loss of joint stability and consequently to pain of greater intensity, with functional limitation of the joint.¹⁴

WOMAC is an instrument developed in 1982⁵⁻¹⁶ for use among patients with knee or hip OA and it contains 24 questions that are grouped in three dimensions: five to assess pain, two for joint stiffness and 17 for physical capacity. WOMAC scores can range from 0 and 96 and can be divided into three different scores: pain (0-20), articular stiffness (0-8) and physical capacity (0-68). The higher the score is, the worse

the dimension evaluated is. It is widely used in clinical trials as a measurement of the evolution of treatment results, and also in population-based studies.¹⁷

TKA has the aims of relieving pain, correcting deformities, enabling functional range of motion and maintaining stability and function of the knee for day-to-day activities.^{18,19}

Surgery is indicated if conservative treatment fails. In planning this approach, the patient's age, physical demands, expectations regarding the treatment results, type of arthrosis, body weight and disease evolution need to be taken into consideration.²⁰

The indication for TKA is based on the deviation from the axis, compromising of the knee joint compartments and patient's age, along with the functional incapacity caused by pain that is refractory to conservative treatment and by diminished range of motion. Classically, the set of deformities determines the criteria for indicating TKA: varus deviation greater than 15°; valgus deviation greater than 10°; femorotibial subluxation in the frontal plane; anteriorization of the tibia in relation to the femur on lateral radiographs and severe compromising of two of the three knee joint compartments, going from obliteration of the joint space and major outgrowths of osteophytosis to femorotibial subluxation in the frontal plane.¹⁴

According to Bugała-Szpak et al.,²¹ age, sex, presence of other implants and preoperative knee contracture do not give rise to significant differences in the scores of knee questionnaires for evaluating QoL, and this was corroborated by Mahomed et al.²² However, the results from arthroplasty were better among patients whose preoperative range of motion was greater than 90° and this is important from a clinical point of view, since the functional result also depends on the patients' capacity to flex the operated knee. The positive effects from the surgery, functional rehabilitation and improvement of QoL could be seen as early as the fourth week of follow-up after TKA in the study by Bertsch et al.²³ and also as predictors of self-perceived health one year after surgery, according to Baumann et al.²⁴ This improvement of QoL occurred mainly in the domains of physical function and emotional status. Personal satisfaction is an important indicator of health that is rapidly available to doctors. In 2012, Lavernia et al.²⁵ stated that the biggest improvement of pain and physical function occurred within three to six months after the surgery, which corroborated the application of questionnaires six months after the surgical procedure. The improvement in health relating to QoL after surgery is also evident and includes domains such as social function, mental health and vigor.²⁵

According to Babazadeh et al.,²⁶ changes to the height of the joint line of the prosthesis were related to changes to the range of motion and significantly affected the functional results. The recent results from the study by Hofmann et al.²⁷ showed that there was a correlation between the postoperative radiographic evaluation and the various clinical scores. These authors suggested that the QoL score should be included in the TKA follow-up. In this study, the clinical results obtained were better when the joint line was reproduced anatomically.

TKA has presented excellent results with survival rates greater than 90% in follow-ups longer than 10 and 20 years.²⁸

The patient satisfaction rate after TKA is high (90%) and 93% of the patients would undergo this procedure again.²⁹ The QoL results demonstrated that TKA presents an excellent cost/benefit relationship and analysis on published studies shows that it is a highly effective procedure, with favorable results from surgical interventions.²¹⁻²⁵ The dimension scores from WOMAC, especially pain, improved significantly after seven years and were influenced negatively by obesity and complications after hospital discharge, according to a study by Núñez et al.³⁰

Although the advantages of TKA have already become established, some authors³¹⁻³⁷ demonstrated that only 81% of the patients expressed total satisfaction with primary TKA and, when asked about improvements in pain and function with regard to performing activities of daily living, the ranges were from 72% to 86% and from 70% to 84%, respectively. The main factors associated with this dissatisfaction were the patients' real expectations; low preoperative WOMAC score; low WOMAC score after one year of follow-up; and complications that led to readmission to hospital.

In the present study, there was a large and statistically significant improvement in postoperative WOMAC score, with data similar to the literature.³⁰⁻³⁵

Despite the short time interval between the surgical procedure and application of the questionnaires, there is backing in the literature for this²⁴ and the scores found in the present study were similar to those of previous studies cited above.

With the aim of diminishing the bias in applying the questionnaires, they were filled out by the patients themselves; the six-month assessment was conducted by another surgeon who had not participated in the surgery and the patients were not registered in this surgeon's outpatient clinic. The limitations of the present study that can be cited include the lack of division of the patients according to the type of implant (with or without preservation of the posterior cruciate ligament), use of patella resurfacing or not and the degree and type of deformity (varus or valgus). However, these were not objectives of the present study.

Conclusion

With the sample evaluated, the results were absolutely coherent in relation to the literature. They confirm TKA as an established procedure with substantial improvement of QoL.

Conflicts of interest

The authors declare no conflicts of interest.

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