THE RESULTS OF A COMPARISON OF A BRAZILIAN AND AN IMPORTED KNEE PROSTHESIS - 5 YEARS OF FOLLOW-UP

OS RESULTADOS DE UMA COMPARAÇÃO DE UMA PRÓTESE DE JOELHO BRASILEIRA E UMA IMPORTADA - CINCO ANOS DE ACOMPANHAMENTO

JOAO HENRIQUE COSTA CALEGARI1, THIAGO CAVALCANTE COELHO MARQUEZE1, OMAR SHARID TEIXEIRA EL KADRI1, EIKE JEFFERSON GALDINO PEREIRA2, ALEXANDRE OLIVEIRA QUEIROZ3, PAULO ROBERTO BIGNARDI2, MARCUS VINCENCIUS DANIELI1,2,3, JOAO PAULO FERNANDES GUERREIRO1,2,3

1. Hospital Evangélico de Londrina, PR, Brazil.
2. Pontifícia Universidade Católica do Paraná (PUCPR), Faculdade de Medicina, Campus Londrina, PR, Brazil.
3. Hospital de Ortopedia UNIORT.E, Londrina, PR, Brazil.

ABSTRACT

Introduction: To compare the functional results, satisfaction rates, and revisions of total knee arthroplasties performed by the same surgical team using either Brazilian or imported implants, with a minimum follow-up of 5 years after surgery. Materials and Methods: A retrospective cohort study analyzing the medical records and interviews of patients who underwent total knee arthroplasty with Brazilian or imported implants with a minimum of 5 years after surgery. Results: One hundred and fifty patients were evaluated (164 knees). In the functional questionnaire, 71% of patients had favorable answers in the group of patients who underwent surgery using the Brazilian prosthesis and 74.8% in the group with imported implants (p=0.634). There was no statistical difference in satisfaction between the groups, with 78.4% of patients satisfied or very satisfied in the Brazilian implant group and 90.7% in the imported implant group (p=0.053). Loosening of the implants was reported in 5.3% versus 4.7% (p>0.999). Conclusion: The total knee arthroplasties performed by the same surgical team with a minimum follow-up period of 5 years showed similar levels of satisfaction, function, and complications with both the Brazilian and imported implants.

Keywords: Arthroplasty. Replacement. Knee. Knee prosthesis.

INTRODUCTION

Degenerative osteoarthritis affects 4% of the Brazilian population1. The best solution found to treat advanced knee osteoarthritis is total arthroplasty and, in developed countries, the increase in arthroplasties already produces relevant social and economic impacts1. A large proportion of total knee arthroplasties in our country is performed with imported implants which, thanks to the exchange rate discrepancy, transportation, taxes and import costs, can cost twice the price of the material manufactured in Brazil2. Imported implants are widely used abroad, many cases are monitored and have durability rates that reach up to 82% in 25 years3. Some Brazilian implants have shown good durability in biomechanical

All authors declare no potential conflict of interest related to this article.
tests, but we do not have large clinical studies with a long follow-up period proving the same durability and results. Some national case series have already demonstrated good results and low revision rate with some Brazilian implants in a medium-term follow-up.

The choice of implant impacts health care costs and generates a lot of conflicts between surgeons and health managers. Our objective was to evaluate whether there are differences in functional results, satisfaction rates and revisions between Brazilian and imported implants used by the same surgical team and with a minimum follow-up of 5 years after surgery.

Our hypothesis was that there is no difference in satisfaction, function, and revision rates between imported and Brazilian implants used by the same surgical team with a minimum follow-up time of 5 years.

MATERIALS AND METHODS

A retrospective cohort study was carried out with analysis of medical records of 377 patients who underwent total knee arthroplasty using Brazilian and imported implants. All patients were operated on by the same team, which included three knee surgeons, between 2010 and 2015. The data collection took place between August 2020 and June 2021 after approval by the Research Ethics Committee.

The preoperative inclusion criteria were patients with primary osteoarthritis, Ahlbäck classification of arthrosis type 3, 4 and 5. The postoperative inclusion criteria were a minimum follow-up of 5 years and complete medical records. The preoperative exclusion criteria were valgus deformity, osteoarthritis secondary to inflammatory diseases and fracture sequelae. The postoperative exclusion criteria were patellar replacement, use of an implant with preservation of the posterior cruciate ligament, the impossibility of phone contact for interview and patients who did not agree to participate in the phone interview after reading the informed consent form.

The selected cases were subdivided into two groups: "national" when undergoing surgery with the Brazilian implant (MB®, Meta Bio Ltd., Rio Claro, São Paulo, Brazil) and "imported" when undergoing with the imported implant (NexGen®, Zimmer, Warsaw, IN, USA). The two models of prosthesis used have a similar design (Figure 1) and compatible surgical instruments. The choice of the type of implant for each patient was based on the option of the surgeon, the patient, and the health plan at the time of surgery.

In medical records, we searched for the following information: name, gender, date of birth, date of surgery, type of implant used and whether the patient underwent a new surgery (arthrofibrosis release, cleaning without exchange material, osteosynthesis due to peri-prosthesis fracture or revision surgery), if the patient underwent revision surgery, what was the cause (stiffness, infection, aseptic loosening, peri-prosthetic fracture or anterior pain requiring patellar replacement). In the interview with the patient, we searched for new information about treatments or the need for new surgeries not reported in the medical record and asked about the degree of satisfaction with the procedure (very dissatisfied, a little dissatisfied, a little satisfied, satisfied or very satisfied), if he would undergo the surgery again (if yes or no), and if there were symptoms at that moment related to the operated knee (yes or no), what symptoms were present: any difficulty to walk (yes or no), if he could support his body weight on the operated leg (yes or no), if he had any difficulty using stairs (yes or no), any difficulty to squat (yes or no), the presence of knee swelling (yes or no), if he could bend the knee to 90 degrees of flexion (yes or no), if he felt any disturb such as crackles or "noise" when moving the knee (yes or no).

For the analysis of qualitative variables, the Chi-square test or Fisher’s Exact test was used. For quantitative variables, the Shapiro-Wilk test was first applied to verify normality, then the Mann-Whitney test was used for non-normal data and t test for variables with Gaussian distribution. The results were analyzed using the Statistical Package for Social Sciences program (SPSS Inc., Chicago, IL, USA) – 18.0, with a confidence level of 5% being established for all applied tests.

RESULTS

We selected 125 patients (143 knees) that met the inclusion and exclusion criteria. There were 57 patients in national group and 68 in the imported group. The two groups matched in age, sex, and follow up (Table 1).

Regarding the answers to the functional questionnaire that we created, we found 71% of patients with favorable responses in the group of patients submitted to the Brazilian prosthesis and 74.8% in the group with imported implants, with no statistical difference between the groups (Figure 2). Regarding satisfaction, there was also no statistical difference between the groups with 78.4% of satisfied or very satisfied patients in the group with Brazilian implants and 90.7% in the group of patients with imported prosthesis (Figure 3).

Evaluating new surgeries, aseptic loosening and other causes, we found similar rates between the implants (Table 2).

Table 1. Demographic data.

|                | National | Imported | P Value |
|----------------|----------|----------|---------|
| Age (years)    | 76.1 ± 6.5| 74.8 ± 7.7| 0.294   |
| Gender (F/M)   | 43/14    | 67/21    | 0.698   |
| Follow-up (years) | 6.85 (5.2 - 9.64)* | 6.56 (5.18 - 9.96)* | 0.292   |

*Average (IQR).

![Figure 1. A and B: Brazilian Implant; C and D: Imported Implant.](image)

![Figure 2. Function Questionnaire (p=0.634).](image)
Healy WL, Iorio R. Implant selection and cost for total joint arthroplasty: conflict

Pécora JR, Romero V. Evaluation of Polyethylene Wear in a Brazilian Ultra-

Bittencourt C. HC de São Paulo cria prótese de joelho mais barata

Acta Ortop Bras. 2022;30(1):e253870 Page 2 of 3

REFERENCES

In a literature review, Labek et al.13 found a 12% rate of revisions in

Aseptic loosening rate in this study was 4.8% in the evaluated patients.

This study shows that, in a medium-term follow up, the results

Total knee arthroplasty performed by the same surgical team in

We know that the implant is just one of the factors that lead to a

This study has several limitations. First, the mean follow-up time was 6.6

Our study showed, as well as the few previous case series using Brazilian implants12-13 that the Brazilian implant has

There are several other factors that hinder the analysis of the results of arthroplasties in our country, such as:

This study shows that, in a retrospective cohort, similar results of improvement in function

satisfaction rate, functional results and complications.

Our results of satisfaction and functional questionnaire were compa-

lishing; the lack of documentation of results; the low adherence of

patients to long-term follow-ups (especially in cases with good results);

cultural, structural, and socioeconomic issues that limits the access
to medical services1,14. Our study showed, as well as the few previous case series using Brazilian implants12-13 that the Brazilian implant has results comparable to the imported. A better investment in registries and in follow-up of patients using these implants can lead to an increase in the reliability of the Brazilian implant. This can contribute to cost

reduction and economic improvement for our healthcare system.

CONCLUSION

Total knee arthroplasty performed by the same surgical team in a minimum follow-up period of 5 years showed similar levels of satisfaction, function, and complications between the Brazilian and imported implants used.

Table 2. Complications

|                  | National | Imported | P Value |
|------------------|----------|----------|---------|
| New surgery      | 11/57 (19.3%) | 12/86 (14.0%) | 0.725   |
| Infection        | 3/57 (5.3%) | 4/86 (4.7%)   | >0.999  |
| Aseptic loosening| 3/57 (5.3%) | 4/86 (4.7%)   | >0.999  |
| Arthrofibrosis   | 2/57 (3.5%) | 2/86 (2.3%)   | >0.999  |
| Fracture         | 0/57 (0%)  | 1/86 (1.2%)   | >0.999  |
| Haematoma        | 3/57 (5.3%) | 1/86 (1.2%)   | 0.301   |

DISCUSSION

This study shows that, in a medium-term follow up, the results of surgeries with Brazilian and imported implants performed by the same medical team had statistically similar results regarding satisfaction rate, functional results and complications.

Each author contributed individually and significantly to the development of this article. JHCC: drafted the article, sought volunteers and analyzed the data; TCCM: drafted the article, sought volunteers and analyzed the data; OSTEK: drafted the article, sought volunteers and analyzed the data, EJGP: drafted the article, sought volunteers and analyzed the data, AQO: reviewed the article and contributed to the intellectual concept of the study; PRB: performed statistical analysis and reviewed the article; MVD: reviewed the article and contributed to the intellectual concept of the study; JPPF: drafted and reviewed the article, performed statistical analysis and contributed to the intellectual concept of the study and the entire research project.

AUTHORS’ CONTRIBUTION:

1. Ferreira MC, Oliveira JCP, Zidan FF, Franciozi CEDS, Luzo MVM, Abdalla RJ. Total knee and hip arthroplasty: the reality of assistance in Brazilian public health care. Rev Bras Ortop. 2018. 8:53(4):432-440.

2. Bittencourt C. HC de São Paulo cria prótese de joelho mais barata que as importadas. Folha de São Paulo. [Internet]. Set 2014. [acesso em junho 2021]. Disponível em: https://www.unasus.gov.br/noticia/hc-de-sao-paulo-cria-protese-de-joelho-mais-barata-que-importadas

3. Evans JT, Walker RW, Evans JP, Born AW, Sayers A, Whitehouse MR. How long does a knee replacement last? A systematic review and meta-analysis of case series and national registry reports with more than 15 years of follow-up. Lancet. 2019. 16:393(10172):655-63.

4. Pécora JR, Romero V. Evaluation of Polyethylene Wear in a Brazilian Ultra-congruent Knee Prosthesis with a Rotating Platform. Rev Bras Ortop (São Paulo). 2021.56(1):42-46.

5. Barretto JM, Malta M, E Albuquerque RP, de Assis DP, Campos AS. Medium-term assessment of total knee arthroplasty with implant made in brazil. Rev Bras Ortop 2015. 6:46(5):540-5.

6. Vasconcelos JW, Leite LMDS, Sousa JCA, Sousa JOM, Santos E Santos MF. Medium-term evaluation of total knee arthroplasty without patellar replacement. Rev Bras Ortop. 2013. 13(48)(3):251-56.

7. Healy WL, Iorio R. Implant selection and cost for total joint arthroplasty: conflict between surgeons and hospitals. Clin Orthop Relat Res. 2007.457:57-63.

8. Kahlenberg CA, Lyman S, Joseph AD, Chiu YF, Padgett DE. Comparison of patient-reported outcomes based on implant brand in total knee arthroplasty: a prospective cohort study. Bone Joint J. 2019. 101-B(7_Supple_C):48-54.

9. Ahlbäck S. Osteoarthrosis of the knee. A radiographic investigation. Acta Radiol Diagn (Stockh). 1968:Suppl 277:7-72. PMID: 5706059.

10. Vasconcelos JW, Leite LMDS, Sousa JCA, Sousa JOM, Santos E Santos MF. Medium-term evaluation of total knee arthroplasty without patellar replacement. Rev Bras Ortop. 2013. 13:48(3):251-56.

11. Villardi A, Veiga LT, Mandarino M, Schott M. Artroplastia total do joelho: revisão sistemática. Rev Bras Ortop. 2015.30;50(3):290-4.

12. Kahlenberg CA, Lyman S, Joseph AD, Chiu YF, Padgett DE. Comparison of patient-reported outcomes based on implant brand in total knee arthroplasty: a prospective cohort study. Bone Joint J. 2019.101-B(7_Supple_C):48-54.

13. Labek G, Thaler M, Janda W, Agreiter M, Stöckl B. Revision rates after total joint replacement: cumulative results from worldwide joint register datasets. J Bone Joint Surg Br. 2011. 93(3):293-7. Erratum in: J Bone Joint Surg Br. 2011 Jul;93(7):998. PMID: 21357948.

14. Guglielmetti LG, da Costa PP, de Paula Leite Cury R, de Oliveira VM, Severino NR, de Camargo OP. Total knee arthroplasty with mobile tibial weight-bearing: clinical evaluation after a minimum of five years of postoperative follow-up. Rev Bras Ortop. 2013. 30;56(3):290-4.