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Medium-term Results Evaluation between Gender-Specific x Conventional Total Knee Arthroplasty Prostheses*

Avaliação de resultados a médio prazo entre artroscopia total de joelho com prótese gênero-específica x prótese convencional

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Abstract

Objective To compare the postoperative functional result of total knee arthroplasty (TKA) with gender-specific prosthesis versus TKA with conventional prosthesis in a 5-year period.

Methods Retrospective study with functional evaluation of 30 patients (15 patients from each group) using scores (Knee Injury and Osteoarthritis Outcome Score [KOOS], Western Ontario and McMaster Universities arthritis index [WOMAC], and The Knee Society Clinical Rating System [KSS]) and range of motion (ROM) as methods of assessment.

Results The differences found between the score values and ROM were not statistically significant.

Conclusion The gender-specific prosthesis presents functional results equal to those of conventional prosthesis after 5 years postoperatively.

Keywords
- knee arthroplasty
- female
- outcome assessment

Resumo

Objetivo Comparar o resultado funcional pós-operatório das artroplastias totais de joelho (ATJs) com próteses gênero-específicas x convencionais no prazo de 5 anos.

Métodos Estudo retrospectivo com avaliação funcional de 30 pacientes (15 pacientes de cada grupo) utilizando o preenchimento de escores (*Knee Injury and Osteoarthritis Outcome Score* [KOOS], *Western Ontario and McMaster Universities arthritis index* [WOMAC] e *The Knee Society Clinical Rating System* [KSS]) e amplitude de movimento (ADM).

Resultados A diferença encontrada entre os valores de escores e ADM foram estatisticamente não significantes.

Conclusão A prótese gênero-específica apresenta resultados funcionais iguais aos da prótese convencional no prazo de 5 anos de pós-operatorio.

Palavras-chave
- artroplastia do joelho
- feminino
- avaliação de resultados

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Introduction

Several factors may influence the result of total knee arthroplasties (TKAs), such as preoperative range of motion (ROM), the surgical technique adopted, implant design, and postoperative rehabilitation.

Historically, TKA has been proved successful in several short- and long-term studies about functional recovery and pain relief of patients. Currently, about 60% of patients undergoing TKA are women,[1–3] and many discussions have been held in recent decades regarding the influence of gender in the short- or long-term results.[4–7]

Many anatomical and anthropometric studies have shown morphological differences in the distal femur of women compared to men, with the female femur being more trapezoidal in shape, with smaller anteroposterior offset, and the condyle dimension narrower on the mid-lateral axis.[8–10]

In recent years, the model of gender-specific prosthesis has been introduced in the market in order to respect these anatomical differences between the knees of men and women. The difference between these implants and the conventional implants consists of a smaller mid-lateral femoral component to avoid the prominence and contact of the prosthesis with soft tissues, which could lead to pain. The anterior femoral flange thickness is also reduced to better accommodate female condyles, aiming to prevent overstuffing of the anterior compartment, and the angle of the trochlear groove is increased by 3 degrees, respecting the increased Q angle of women.[11]

However, the potential advantages of gender-specific prostheses have not been demonstrated in most studies, so there is no consensus in the literature about the need for gender-specific implant designs.[12–14]

Thus, the present study aims to perform a comparative medium-term (5 years) postoperative assessment of satisfaction and functional rehabilitation of female patients submitted to TKA with conventional implants versus those with gender-specific implants.

Methods

The present study was approved by the research ethics committee of the Faculdade de Medicina do ABC (CAAE 51201915.1.0000.5484). It was retrospectively performed from April 2017 to December 2017 with 30 female patients undergoing TKA for primary gonarthrosis in a public university hospital.

The patients were divided into 2 groups with the same number of individuals. Group A used the gender-specific implant, Gender Solutions Natural-Knee System (Zimmer Biomet, Warsaw, IN, USA) with a model developed for female patients, and Group B individuals underwent TKA with conventional implant from Exactech Optetrak Logic Primary System (Exactech, Gainesville, FL, USA).

All surgeries were performed between January and December 2012. The patients were evaluated 5 years postoperatively.

The surgeries were performed by different surgeons, and in all cases the same surgical technique was adopted. All prostheses were performed with posterior cruciate ligament (PCL) sacrifice, flexo-extension space balancing, patella preservation and fixed tibial base. All prostheses were fixed by cementation, using a tourniquet removed only after skin closure, and compression dressing application. An aspiration drain was used on all knees and removed on the second postoperative day. All patients received a physiotherapy treatment in which they were stimulated to move the knee and ankle on the first day, and, on the second day, they started walker-assisted gait training with full load. The patients were discharged on the third postoperative day if there was no medical impediment.

All 30 patients were evaluated using functional outcome assessment instruments, with the following scores: Knee Injury and Osteoarthritis Outcome Score (KOOS), The Knee Society Clinical Rating System (KSS) and Western Ontario and McMaster Universities arthritis index (WOMAC). Patients were also evaluated for ROM and were weighed and measured at the time of assessment.

Results

►**Table 1** contains data collected from patients undergoing arthroplasty with Exactech prosthesis. The following data were noted and tabulated: age, body mass index (BMI), KSS, WOMAC, and KOOS.

►**Table 2** contains data collected from patients submitted to gender-specific prosthesis arthroplasty (Gender [Zimmer Biomet]). The following data were noted and tabulated: age, BMI, KSS, WOMAC, KOOS.

►**Table 3** contains statistical description and comparison between both groups studied for the considered variables of interest.

These groups present statistically non-significant differences for all variables of interest, that is, both groups are statistically similar. (►**Figures 1–4**).

Discussion

There are well-documented anatomical differences between men and women regarding lower limb alignment and distal femoral anatomy. Women have a valgus and anteroposterior dimension of distal femur slightly enlarged, while the mediolateral diameter is narrower.[4,8] These findings have led some authors to conclude that there is a need to develop implants that can adapt better to these anatomical variations.[9] The fundamental premise of this approach assumes that the results of TKA performed in women are inferior, and some of the causes of these worse outcomes are related to these anatomical differences and the need for gender-specific implants.[15]

Implant models with gender-specific design were developed based on existing anatomical differences in the distal end of the femur, when comparing men and women.[5,16–21] Some studies have been conducted trying to establish the superiority of gender-specific implants over conventional

Table 1 Data of patients undergoing arthroplasty with Exactech Optetrak (Exactech) type prosthesis.

EXACTECH					
Ptts	**AGE**	**BMI**	**KSS**	**WOMAC**	**KOOS**
1	73	29.9	74	93.9	91.1
2	71	33.5	70	93.2	88.7
3	39	24.4	75	93.9	91.1
4	68	31.1	74	93.2	88.7
5	74	38	52	92.4	87.5
6	69	37.89	77	81.8	78.5
7	79	25.3	77	86.4	83.9
8	75	32.6	72	87.9	85.7
9	73	33.7	77	84.1	81.5
10	80	36.97	62	81.9	78.6
11	80	34.6	64	83.3	80.4
12	73	28.7	74	88.6	85.1
13	80	25	75	80.3	76.2
14	86	33.3	75	90.9	85.7
15	78	35	79	88.6	85.1
MEAN	73.2	31.997 33333	71.8	88.026 66667	84.52

Abbreviations: BMI, body mass index; KOOS, Knee Injury and Osteoarthritis Outcome Score; KSS, The Knee Society Clinical Rating System; Ptts, patients; WOMAC, Western Ontario and McMaster Universities arthritis index.

Table 2 Data from patients undergoing arthroplasty with the Gender Solutions (Zimmer Biomet) type prosthesis.

GENDER					
Ptts	**AGE**	**BMI**	**KSS**	**WOMAC**	**KOOS**
1	83	32.6	70	83.3	81.5
2	79	30.4	74	93.2	78.6
3	78	30	75	87.9	85.7
4	73	34.13	77	81.8	80.4
5	64	34.8	74	92.4	88.7
6	69	29	74	84.1	81.5
7	74	39.1	72	92.4	85.1
8	81	33.6	79	93.2	91.1
9	68	34	75	93.9	91.1
10	75	33.2	72	93.2	87.5
11	77	28.6	72	88.6	85.7
12	71	31.2	64	83.3	81.5
13	74	29.5	60	86.4	83.6
14	76	33.3	72	93.2	88.7
15	DEATH (in 04/04/2014) cause: cerebrovascular accident (CVA)				
MEAN	74.428 57143	32.387 85714	72.142 8571	89.064 28571	85.05

Abbreviations: CVA, cerebrovascular accident; BMI, body mass index; KOOS, Knee Injury and Osteoarthritis Outcome Score; KSS, The Knee Society Clinical Rating System; Ptts, patients, WOMAC, Western Ontario and McMaster Universities arthritis index.

unisex implants when used on women's knees,[22] but it remains unclear how much the anatomical differences between men and women can influence TKA results.[23,24]

In our study, we did not find a statistically significant difference in relation to postoperative ROM with the use of gender-specific implants.[12] Song et al[12] conducted a prospective study with 40 female patients undergoing simultaneous bilateral TKA in which a conventional implant was used on one knee, and a gender-specific implant was used in the other one, and, in the ROM evaluation after 24 to 36 months postoperative, similar and statistically nonsignificant results between the groups were found. These data conflict with the hypothesis that conventional implants cause overfilling in the patellofemoral compartment, since the anteroposterior dimension of the female condyle is smaller, and it may lead to a decrease in the postoperative ROM.[16,25] Despite the reduced flange height in the Gender Solutions natural-knee implant (Zimmer Biomet), postoperative ROM was similar when comparing the two groups.

Two Level I studies were conducted in Korea by Kim et al[20,26] with 223 female patients undergoing bilateral TKA, totaling 446 TKAs. The patients were randomized to determine which knee would receive a gender-specific implant or a unisex implant. The authors found no difference in any of the studies regarding ROM, satisfaction, or KSS and WOMAC scores. Johnson et al,[11] after a meta-analysis study involving 253 studies, claim that no postoperative difference was found between TKA and total hip arthroplasty using gender-specific implants in comparison to conventional implants.

Song et al,[12] in a prospective study in which 50 patients underwent simultaneous bilateral TKA, one knee with a conventional unisex implant and the other with a gender-specific implant, state that they did not observe significant differences when comparing ROM, hospital for special surgery (HSS), and WOMAC scores. Clarke and Hentz,[27] in a similar prospective study with 46 patients undergoing simultaneous bilateral TKA, also concluded that there is no functional difference by the HSS score between the two types of implants in the postoperative period after 2 years of follow-up.

However, we know that our study has a few limitations. The first is that we did not evaluate preoperative conditions, such as ROM and functional scores, which are known factors influencing the outcomes after TKA, but this was minimized by excluding patients with ROM below 90 ° and with severe deformities, or when bone grafting or revision implants were required. The second is related to the medium term follow-up, only 5 years, which makes it impossible for us to draw long-term conclusions about satisfaction; however, recent studies show that these rates reach a plateau after 1 year of surgery and do not change much after this period.[26,28]

In summary, we can say that there are few studies in the literature that refer to the analysis of postoperative efficacy of gender-specific implants and, in our retrospective study of 30 female patients, the apparent superiority of gender-

Table 3 Mann-Whitney test application in order to verify possible differences between both groups for the variables of interest

Variable	Group	n	Mean	Standard deviation	Min.	Max.	Percentile 25	Percentile 50 (median)	Percentile 75	*P*-value
AGE	Exactech	15	73.20	10.63	39.00	86.00	71.00	74.00	80.00	0.948
	Gender	14	74.43	5.21	64.00	83.00	70.50	74.50	78.25	
	Total	29	73.79	8.34	39.00	86.00	71.00	74.00	79.00	
BMI	Exactech	15	32.00	4.52	24.40	38.00	28.70	33.30	35.00	0.930
	Gender	14	32.39	2.84	28.60	39.10	29.88	32.90	34.03	
	Total	29	32.19	3.74	24.40	39.10	29.70	33.20	34.37	
KSS	Exactech	15	71.80	7.22	52.00	79.00	70.00	74.00	77.00	0.522
	Gender	14	72.14	4.93	60.00	79.00	71.50	73.00	75.00	
	Total	29	71.97	6.12	52.00	79.00	71.00	74.00	75.00	
WOMAC	Exactech	15	88.03	4.83	80.30	93.90	83.30	88.60	93.20	0.629
	Gender	14	89.06	4.53	81.80	93.90	83.90	90.50	93.20	
	Total	29	88.53	4.63	80.30	93.90	83.70	88.60	93.20	
KOOS	Exactech	15	84.52	4.64	76.20	91.10	80.40	85.10	88.70	0.759
	Gender	14	85.05	4.02	78.60	91.10	81.50	85.40	88.70	
	Total	29	84.78	4.28	76.20	91.10	81.50	85.10	88.70	
ROM (degrees)	Exactech	15	103.33	9.00	90.00	120.00	100.00	100.00	110.00	0.982
	Gender	14	103.57	8.42	90.00	120.00	100.00	100.00	110.00	
	Total	29	103.45	8.57	90.00	120.00	100.00	100.00	110.00	

Abbreviations: BMI, body mass index; KOOS, Knee Injury and Osteoarthritis Outcome Score; KSS, The Knee Society Clinical Rating System; Min., minimum; Max., maximum; ROM, range of motion; WOMAC, Western Ontario and McMaster Universities arthritis index.

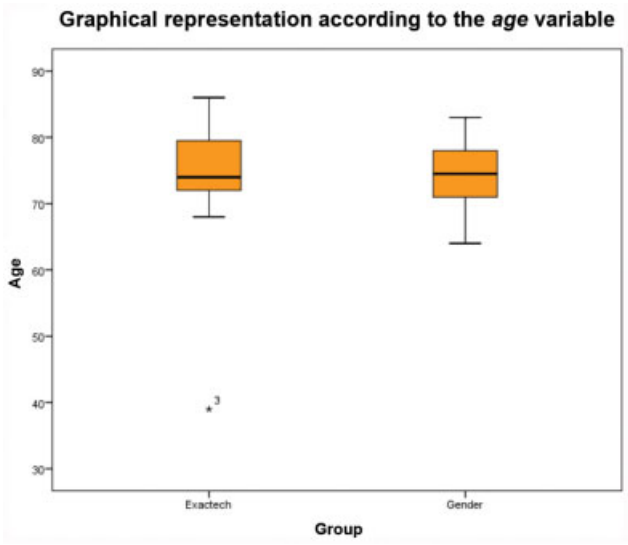

Fig. 1 Graphical representation according to the *age* variable.

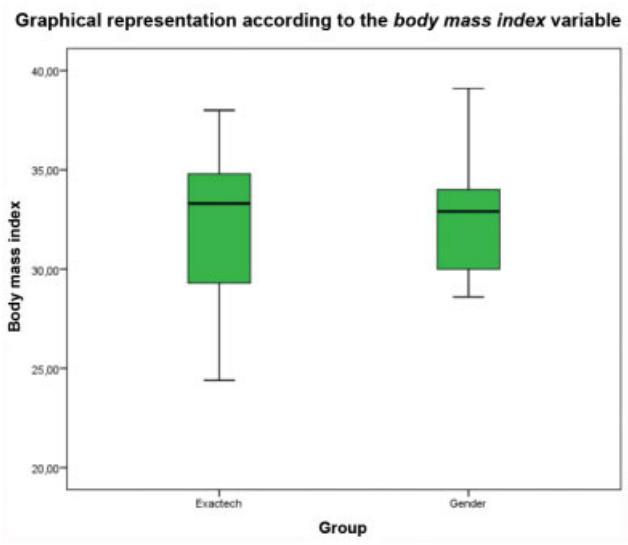

Fig. 2 Graphical representation according to the *body mass index* variable.

specific implant design for better adaptation to the anatomical differences of the female knee did not show superior clinical and functional results when compared to conventional implants.

Conclusion

The present study did not demonstrate clinical benefits of gender-specific prosthesis in female patients when

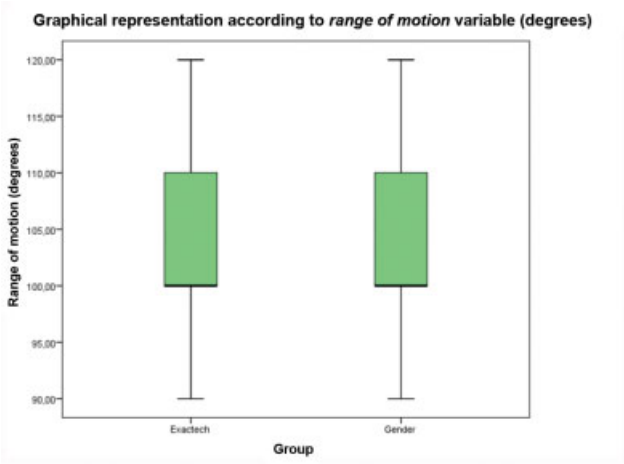

Fig. 3 Graphical representation according to *range of motion* variable (degrees).

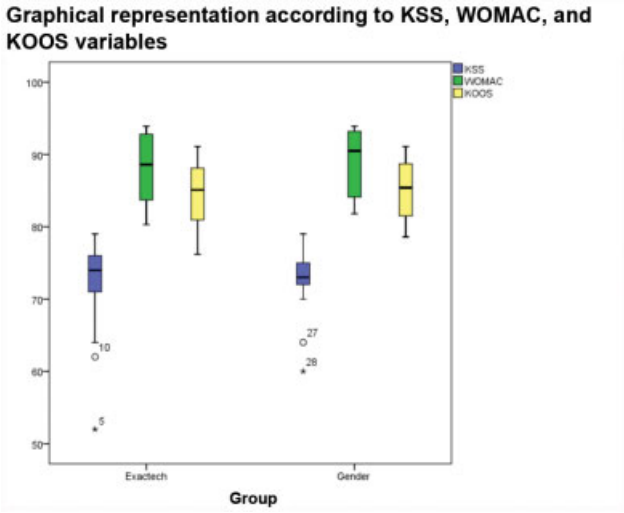

Fig. 4 Graphical representation according to KSS, WOMAC, and KOOS variables. Abbreviations: KOOS, Knee Injury and Osteoarthritis Outcome Score; KSS, The Knee Society Clinical Rating System; WOMAC, Western Ontario and McMaster Universities arthritis index.

compared to conventional implants without gender distinction during a medium-term follow-up.

Conflict of Interests

The authors have no conflict of interests to declare.

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