


Is The Size of the Currently Available Implants for Total Hip Arthroplasty Adequate for Our Population?*

O tamanho dos implantes atualmente disponíveis para a artroplastia total do quadril está adequado à nossa população?

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Abstract

Objective To determine if the dimensions of selected national and imported implants used in total hip arthroplasty surgeries are adequate regarding the anthropometric profile of the Brazilian population.

Methods A retrospective study of patients submitted to primary total hip arthroplasty. Patients with femoral or acetabular morphological deformities that could influence the choice of implant size, including dysplasia and previous fractures, were excluded from the study. Two national implants and six imported implants were included in the study. Every patient was treated by the same group, with one of the four senior authors or under their strict supervision, following the same surgical technique. The data were analyzed regarding gender, age, fixation type and implant model.

Results The analysis of 682 hips submitted to total hip arthroplasty demonstrated that 2 models of cemented femoral stems and 1 of non-cemented stem did not seem to be perfectly adequate for the femoral morphology of the studied population, since these 3 implants were mostly used in the smallest size available, resulting in a non-Gaussian curve. The mean diameter of the native acetabulum was 54 mm in men and 52 mm in women.

Conclusion Out of the eight models studied, five were deemed adequate for the studied population. The other three models available in our market (two national models and one imported model) apparently require more appropriate sizing. We emphasize that anthropometric studies of the Brazilian hip are necessary to give scientific subsidies to the ideal implant design for our market.


Keywords

- ▶ arthroplasty, replacement, hip
- ▶ hip fractures
- ▶ hip prosthesis
- ▶ prosthesis design

Resumo

Objetivo Definir se as dimensões de alguns implantes de fabricação nacional e estrangeira utilizados nas cirurgias de artroplastia do quadril estão adequadas ao perfil antropométrico da população brasileira.

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Palavras-chave

- ▶ artroplastia de quadril
- ▶ fraturas do quadril
- ▶ próteses de quadril
- ▶ desenho de prótese

Métodos Estudo retrospectivo de pacientes submetidos a cirurgia primária de substituição artroplástica total do quadril. Foram excluídos deste estudo pacientes com alterações morfológicas femorais ou acetabulares que pudessem influenciar na escolha do tamanho dos implantes, tais como sequelas de displasia, trauma, entre outras. Foram incluídos neste estudo dois implantes de fabricação nacional e seis modelos importados. Todos os pacientes foram operados pela mesma equipe, por um dos quatro autores seniores ou sob sua supervisão direta, seguindo a mesma técnica cirúrgica. Os dados foram estatisticamente analisados em relação a gênero, idade, tipo de fixação e modelo dos implantes.

Resultados A análise estatística de 682 quadris submetidos a artroplastia total demonstrou que 2 modelos de hastes femorais cimentadas e 1 de haste não cimentada não estão perfeitamente adequados à morfologia femoral da população estudada, pois, na maioria dos casos, nestes 3 implantes, foi utilizado o menor tamanho disponível, resultando em uma curva não gaussiana. O diâmetro médio do acetábulo nativo foi de 54 mm nos homens e de 52 mm nas mulheres.

Conclusão Dos oito modelos estudados, cinco se mostraram adequados à população estudada. Outros três modelos disponíveis em nosso mercado (dois nacionais e um importado) parecem necessitar de um escalonamento mais adequado. Destacamos que são necessários estudos antropométricos do quadril da população brasileira para dar subsídios científicos ao desenho ideal dos implantes para o nosso mercado.

Introduction

Total hip arthroplasty represents one of the most revolutionary and successful surgical procedures in modern medicine, providing symptom relief and improving quality of life.¹

The basic concept of the procedure is the replacement of the degenerated joint surface by prosthetic components with innumerable design variations, fixation types and tribological pairs. These replacements generally fall into three distinct groups according to the type of implant fixation: cemented, non-cemented and hybrid (in which only one of the components is fixed with bone cement).

The correct choice of implants is of paramount importance, and the preoperative planning must be individualized to each patient for perfect restoration of hip biomechanics and function. The present study was motivated by the practical perception that, in some situations, the implant models seemed very large for our patients, sometimes requiring an adaptation of the individual to the implant and not the opposite, which would be desirable.

After reviewing the literature, the authors did not find data describing the average size of implants used in hip arthroplasty surgeries in the Brazilian population, or specific anthropometric studies regarding the Brazilian hip. These data are important because they may result in a better adaptation of the available implants and even have a financial impact, involving inventory volumes and so on.

Materials and Methods

After approval by the Ethics in Research Committee of our institution, the medical records and documents from patients submitted to total primary hip replacement pro-

cedures by one of the four senior surgeons and authors of this study or under their direct supervision from January 2014 to January 2018 were retrospectively evaluated. Surgical descriptions and records of orthoses, prostheses and special materials (OPSM) were reviewed, and the implant sizes used in these surgeries were surveyed.

The following inclusion criterion was used in sample selection: patients submitted to total primary hip arthroplasty, with no previous deformities.

The exclusion criteria were secondary factors that could influence the selection of implant size, such as hip dysplasia sequelae, acetabular fracture sequelae, proximal femoral fracture sequelae (excluding neck and femoral head fractures), revision arthroplasties, pelvic or femoral osteotomies, and/or conversion or desarthrodesis surgery.

All of the patients included in the present study underwent a routine preoperative evaluation (laboratory tests, radiographs, institutional preoperative protocol, and preoperative planning using radiographic images and analogical templates). The preoperative planning, which is routine in our service, enables an anticipation regarding stem width, offset and acetabular diameter. The patients were placed in lateral decubitus aided by pelvic stabilizers; the hip was approached by a posterolateral access, and intraoperative anatomical landmarks were used for the proper positioning of the components. Surgical implants manufactured in Brazil or other countries were used. The patients were evaluated according to gender, age, type of fixation and component model.

It is important to note that the present study considered the diameter of the last acetabular mill used during bone bed preparation to calculate the mean acetabular diameter.

In the present study, with eight models of femoral stem, the implant type and brand were chosen according to availability, personal preference of the surgeon and Dorr index. Since each manufacturer has a different nomenclature for the size of their femoral stems, a correlation table was created in which the smallest available implant of each system is indicated by the letter “A”, followed by the letter “B” and so on, according to the sizes available listed in the materials from each company (► **Attachment 1**).

The different models and sizes of the femoral implants used were analyzed according to the alphabetical correlation system developed. Their distribution curves were plotted to determine their resemblance to a normal, Gaussian curve.

Results

A total of 842 primary arthroplasties were performed within the specified period, 682 of which met the inclusion criteria, 326 (48%) in male patients and 356 (52%) in female patients. The average age of the general sample was 53 years, and ranged from 17 to 89 years.

The size of the acetabulum in the male patients ranged from 46 mm to 62 mm, with a mean value of 54 mm. In contrast, in the female patients, the size of the acetabulum ranged from 44 mm to 58 mm, with a mean value of 52 mm.

A total of 482 (70.7%) cemented femoral stems and 200 (29.3%) non-cemented stems were implanted. In the femoral replacements, the following systems were used: CStem and Summit (DePuy Synthes, Raynham, MA, US); Exeter and Accolade (Stryker, Portage, MI, US); Trilliance and Bicontact (Aesculap, Center Valley, PA, US); and Alpha and Co-10 (Baumer). All of the cemented stems used were of the polished type and presented wedge geometry, with three with double wedge (Exeter, Trilliance and Alpha) and one

with triple wedge (Cstem). All of the non-cemented stems were used for metaphyseal fixation; three were of the fit-and-fill type (Summit, Bicontact and Co-10) and one was of the taper type (Accolade). In total, 258 imported stems were implanted, 95 in male patients and 163 in female patients.

► **Table 1** shows the description of the population sample for each system.

Comparing the size of the national and imported cemented stems, we observed a more homogeneous distribution regarding the latter, as shown in ► **Figure 1**. Regarding the national materials, the smaller available sizes were predominantly used.

Comparing the size of the national and imported non-cemented stems, we also observed a more homogeneous distribution regarding the latter, as shown in ► **Figure 2**. Once again, regarding the national materials, the smaller available sizes were predominantly employed.

To ascertain the adequacy of the size distribution of the stems for a given population, the distribution curve pattern must present a normal or Gaussian pattern. In it, the majority of the population is in the middle of the curve, that is, using midsize implants, and smaller portions of the population are at the ends, that is, using small or large implants.

The percentages of each size of the cemented implants used were tabulated and converted into curves, as shown in ► **Figure 3**. The curves for the Trilliance and Alfa implants did not present a normal or Gaussian distribution pattern. This possibly indicates that the available sizes of these two implants are too large for the study population, since the smallest sizes were mostly used. The distribution of the Exeter and Cstem stems was closer to the Gaussian pattern, representing a more adequate design for the studied population.

The percentages of each non-cemented implant used were also tabulated and converted into curves, as shown in ► **Figure 4**. The Co-10 implant curve was the only one that did not demonstrate a normal or Gaussian distribution pattern.

Attachment 1 Nomenclature standardization

	CEMENTED FEMORAL STEMS				NON-CEMENTED FEMORAL STEMS			
	CSTEM	EXETER	TRILLIANCE	ALFA	SUMMIT	ACCOLADE	BICONTACT	CO-10
A	CDH	30	8	0	1	0	9	9
B	1	33	10	0.5	2	1	10	11
C	2	35.5	12	1	3	2	11	13
D	3	0	14	2	4	3	12	15
E	4	1	16	3	5	4	13	17
F	5	2	N/A	N/A	6	5	14	19
G	6	3	N/A	N/A	7	6	15	N/A
H	7	4	N/A	N/A	8	7	16	N/A
I	8	5	N/A	N/A	9	8	17	N/A
J	N/A	6	N/A	N/A	10	9	18	N/A
K	N/A	N/A	N/A	N/A	N/A	10	19	N/A
L	N/A	N/A	N/A	N/A	N/A	11	21	N/A

Note: Alphabetical system for the correlation of the different nomenclatures with the available sizes. Abbreviations: CDH, Congenital Dislocation of the Hip; N/A, size not available.

Table 1 Populationsample

	CEMENTED STEMS				NON-CEMENTED STEMS			
	CSTEM	EXETER	TRILLIANCE	ALFA	SUMMIT	ACCOLADE	BICONTACT	CO-10
TOTAL N	55	73	130	224	44	19	69	68
MALE N (%)	21 (23.3)	17 (32.8)	57 (43.8)	99 (44.1)	40 (90.9)	18 (94.7)	30 (43.4)	61 (89.7)
FEMALE N (%)	34 (76.7)	56 (61.8)	73 (56.1)	125 (55.8)	4 (9.1)	1 (5.3)	39 (56.5)	7 (10.2)
MEAN AGE (MIN-MAX)	66 (22-89)	62 (42-89)	56 (27-82)	64 (30-87)	49 (23-73)	48 (32-59)	52 (17-87)	64 (30-87)

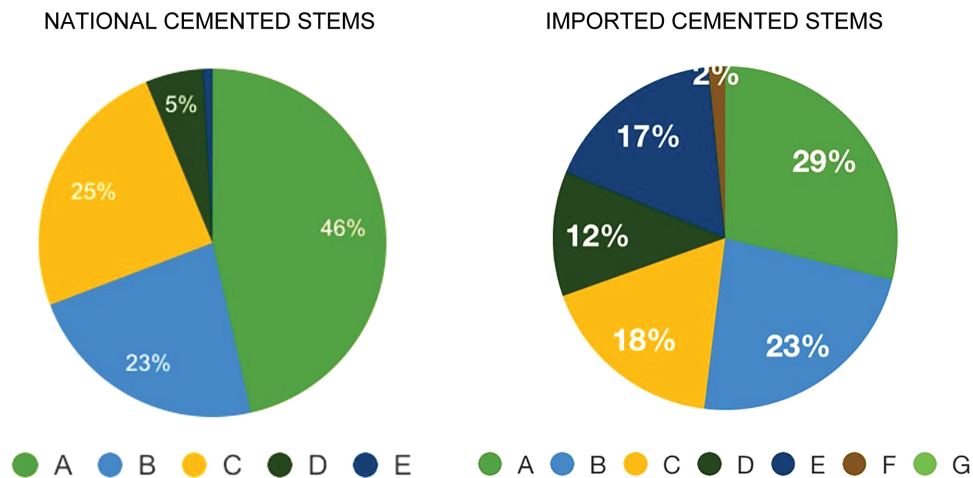


Fig. 1 Percentage distribution of the size of national and imported cemented stems.

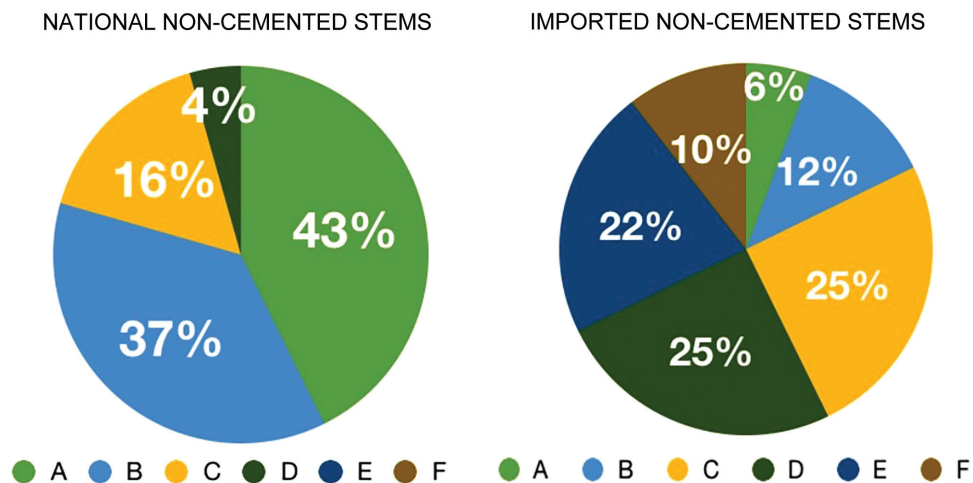


Fig. 2 Percentage distribution of the size of national and imported non-cemented stems.

This possibly demonstrates that the available sizes of this implant are too large for the study population. The curves for the Summit, Accolade and Bicontact stems were closer to Gaussian curves, representing a more adequate implant design.

Discussion

One of the primary objectives of hip replacement procedures is to restore joint anatomy and function.¹ As such, it is paramount to know how gender, age and basic joint conditions impact the

anatomical pattern of the joint.^{2,3} Anatomical studies have shown significant differences between genders, especially regarding femoral anatomy.⁴⁻⁸ Females tend to present a smaller neck-diaphysis angle, lower offset, shorter femoral neck, slender diaphysis and higher femoral anteversion.⁹ Wang et al,⁶ in a pelvic tomography study, found significant differences between genders regarding joint depth, acetabular version and acetabular diameter. According to their results, the female acetabulum tends to be deeper and in anteversion, but it has a smaller diameter compared to that of males.

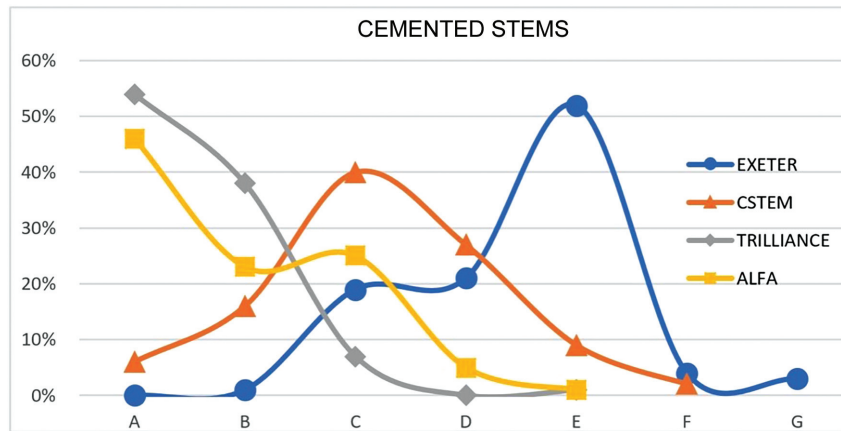


Fig. 3 Size distribution of national and imported cemented stems.

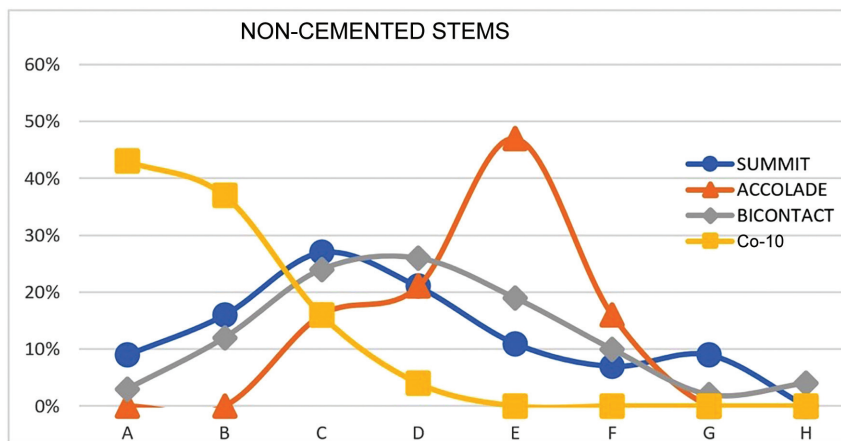


Fig. 4 Size distribution of national and imported non-cemented stems.

An anthropometric study by Noble et al⁵ demonstrated that most femoral anatomical parameters are close to the Gaussian distribution. As such, it would be expected that the size of the femoral implants should also be normally distributed for a better anatomical fit. The fact that the distribution curves of some implants in our study were non-Gaussian agrees with these findings, inferring that our population requires more adequate implant designs.

Since Brazil is a multiracial nation,¹⁰ it would be desirable to adapt implant sizes and models to the demographic characteristics of the population. Unfortunately, these types of studies are not yet available regarding our country.

The present study has some limitations inherent to its retrospective design, as well as to the selection bias of the implant type based on its availability and surgeon preference. In addition, it encompasses distinct realities of patients of the Brazilian Unified Health System or of those with private health insurances. As such, there was some discrepancy between subsamples regarding gender and implant type. There was no inter- or intra-observer critical analysis of implant quality or size.

On the other hand, the positive points of this study are the representative and diversified number of individuals and implants in the sample, reflecting the reality of a high-

demand service that is a reference in hip surgery and that serves the public and private sectors. In addition, since some curves presented non-Gaussian patterns, the initial hypothesis was corroborated by our findings. The data from this study can guide manufacturers and alert surgeons about implants requiring greater care, as well as encourage the research and development of anthropometric studies of the Brazilian hip to maximize the adequacy of the available implants.

Regarding femoral implants, there is a wide range of materials available in the Brazilian and international markets, and their sizes and numbering vary according to the manufacturer. However, despite some variations in implant size and numbering, there is a trend towards the use of smaller implants in ~ 70 to 80% of surgical procedures, regardless of fixation type, when national products are used. The opposite was observed with imported stems, which present better anatomical suitability, wider use and higher number of sizes from all but one manufacturer.

After analyzing the findings of this investigation, it seems clear that anthropometric studies in the Brazilian population are required to increase the adequacy of the national and imported implants available for hip arthroplasty.

Conclusion

Three out of the eight implants studied in our sample are not adequately sized for the study population.

Conflicts of Interest

The authors have no conflicts of interests to declare.

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