Comparative Clinical-Radiological Analysis of First-Generation vs. Second-Generation Flat Cementless Femoral Stems

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ABSTRACT

Introduction: The design of the femoral implant is essential for its adaptation to the different types of femoral canals. The objective of this study is to describe the adaptability of the implant and the type of fixation (fill and fit) of second-generation flat femoral stems compared to first-generation femoral stems. **Materials and Methods:** We described the radiological characteristics of patients who had undergone bilateral total hip replacement between 2007 and 2020 in our institution with both a first-generation Accolade TMZF (Stryker Orthopedics) and a second-generation Accolade II (Stryker Orthopedics) flat cementless femoral implant. Demographic variables, adaptation, and canal filling were studied. The modified Harris Hip Score and the WOMAC index were analyzed. **Results:** Forty-two patients (84 cases) were included in the sample. In group 1 (Accolade TMZF) we obtained an average canal fill of 81% and in group 2 (Accolade II), we obtained an average of 84%. In group 1, the type of fixation (fit) was type 1 (60%), type 2 (16%) and type 3 (24%). In group 2, it was type 1 (88%), type 2 (7%) and type 3 (5%). The modified Harris Hip Score for group 1 was 88 and, for group 2, 87.5. The WOMAC score for group 1 was 2.5 and for group 2 it was 3. **Conclusion:** The adaptability of the implant is essential for primary stability and its osseointegration/biological fixation. This adaptability is more precise with second-generation flat femoral stems.

Keywords: second-generation flat femoral stems; femoral adaptability; femoral fixation; mediolateral.
Level of Evidence: IV

Análisis clínico-radiológico comparativo de tallos femorales no cementados planos de primera vs. segunda generación

RESUMEN

Introducción: El diseño del implante femoral es imprescindible para su adaptación a los distintos tipos de canales. El objetivo del estudio fue comparar la adaptabilidad del implante y el tipo de contacto de los tallos femorales planos de segunda generación. **Materiales y Métodos:** Se analizó a los pacientes sometidos a un reemplazo total de cadera bilateral en nuestra institución, entre 2007 y 2020, a quienes se les colocó un tallo de primera generación (Accolade TMZF) en una cadera y de segunda generación (Accolade II) en la contralateral. Se estudiaron las variables demográficas, la adaptación y el llenado del canal. Se analizó el *Harris Hip Score* modificado y el índice WOMAC. **Resultados:** Se incluyó a 42 pacientes (84 casos). En el grupo 1 (Accolade TMZF), la ocupación de canal fue del 81% y, en el grupo 2 (Accolade II), del 84%. En el grupo 1, el contacto fue tipo 1 (60%), tipo 2 (16%) y tipo 3 (24%). En el grupo 2, fue tipo 1 (88%), tipo 2 (7%) y tipo 3 (5%). El *Harris Hip Score* modificado para el grupo 1 fue 88 y, para el grupo 2, 87,5. El puntaje WOMAC para el grupo 1 fue 2,5 y, para el grupo 2, de 3. **Conclusión:** La adaptabilidad del implante es fundamental para la estabilidad primaria y su osteointegración/fijación biológica. En nuestra muestra, es más precisa con tallos de segunda generación debido a las modificaciones del diseño.

Palabras clave: Tallos femorales planos; segunda generación; adaptabilidad femoral; fijación proximal, mediolateral.
Nivel de Evidencia: IV

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INTRODUCTION

The use of cementless stems in hip joint replacement has increased in the last 20 years due to the great demand from increasingly younger and more demanding patients. The constant evolution of the different implants caused their geometric design, materials, and type of surface to change over time. The geometric design is essential to achieve an acceptable adaptation to the different types of femoral canals,[1] in order to facilitate their osseointegration/biological fixation and thus achieve maximum durability of the system.

Second-generation Accolade II implants (Stryker Orthopedics, Mahwah, New Jersey, USA) have a morphometric wedge design with a variable medial curve to facilitate adaptation to the different geometries of the proximal femur, shorter than the first generation and with medial lateral metaphyseal anchorage. They were designed with a special program (SOMA - Stryker, Orthopedics), evaluating 3D models with a database of different femoral canal morphologies. This database compiles variants of bone size, shape, and density, as well as age, sex, and demographic variations[2,3] (Figure 1).

Figure 1. 3D models for the development of the second-generation Accolade II implant.

The objective of the study was to compare the adaptability and the type of contact (adaptation and canal filling) between the second-generation flat femoral stems and the first-generation femoral stems with respect to the morphology of the proximal femur. The working hypothesis was to demonstrate the versatility of second-generation femoral stems and its correlation with clinical evolution based on Dorr[4] A and C morphology.

MATERIALS AND METHODS

A descriptive, observational, retrospective, and longitudinal study was carried out. Data from patients who had undergone bilateral total hip replacement between 2007 and 2020 were collected.

In our institution, 3342 hip joint replacements were performed between 2007 and 2020, 89% were cementless; 9.2%, hybrids, and 1.8%, cemented. The Accolade II stem was used in 98.2% of the cementless joint replacements. From this sample, patients with primary hip joint replacement with an Accolade TMZF cementless femoral stem (Stryker Orthopedics, Mahwah, New Jersey, USA) and then, in another instance, with an Accolade II femoral stem (Stryker Orthopedics, Mahwah, New Jersey, USA) in the contralateral hip were included. Patients with significant metaphyseal-diaphyseal deformities were excluded (an implant with other fixation characteristics was chosen for them).

All were operated on by the same surgical team, at the same institution, under the same protocol.

The patients were divided into two groups: group 1 (Accolade TMZF) and, after surgery of the contralateral hip, group 2 (Accolade II). The follow-up and the postoperative protocol were the same for both groups.

Radiological controls were performed in the immediate postoperative period, at months 1, 3, 6, and 12, and then annually.

The following variables were recorded:

1. Age at the time of surgery.
2. Sex.
3. Morphology of the femoral canal according to Dorr's classification.[4] It was analyzed by radiographs and computed tomography of both hips.
4. Type of contact, adaptation, and percentage of femoral canal fill in the coronal plane. These measurements were made on the anteroposterior radiograph of both hips at the third month after surgery, taking the immediate postoperative radiograph as a reference, and were carried out by two of the authors. The inter- and intra-observer reliability of the canal filling ratio and adaptation measurements were evaluated by randomly selecting 15 radiographs as in the study by Issa et al.[3] A Pearson correlation coefficient of 0.87 and 0.89 was obtained for the inter- and intra-observer reliability in the adaptation measurements and of 0.81 and 0.83 for the inter- and intra-observer reliability in the canal filling ratio measurements.

The adaptation of the femoral stem was evaluated in two areas: the proximal region (hydroxyapatite coating area) and the distal region (from where the hydroxyapatite coating ends to 10 mm proximal to the tip of the femoral stem). The medial gap was measured in the proximal region between the femoral stem and the medial cortex, thus obtaining the minimum (*Pmin*; minimum distance from the medial cortex to the implant) and maximum distance (*Pmax*; maximum distance from the medial cortex to the implant). In the distal region, the medial and lateral gap between the femoral stem and the cortex was recorded, and the minimum (*Dmin M;* minimum distance from the medial cortex to the implant), maximum (*Dmax M*; maximum distance from medial cortex to implant), medial, and lateral (*Dmin L*; minimum distance from the lateral cortex to the implant and *Dmax L*; maximum distance from the lateral cortex to the implant) distances were obtained. (Figure 2).

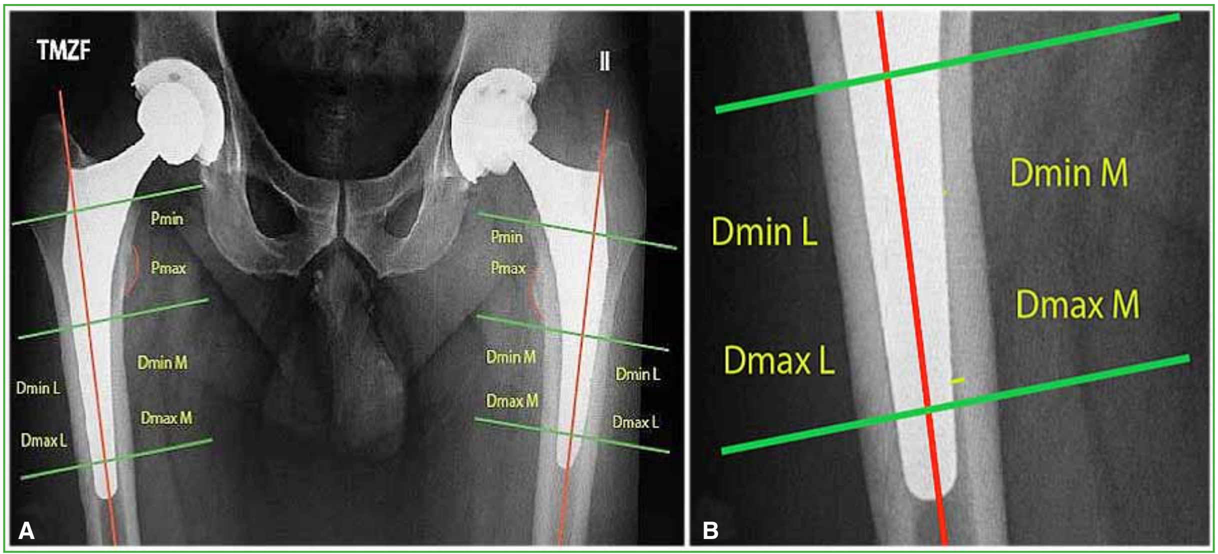

Figure 2. Adaptation of the femoral stem. **A.** Measurements **B.** Detail.

With these measurements, the contact was classified as type 1 (global) when there is a proximal and distal fixation (the difference between the proximal and distal gap is 2 mm or less), type 2 (proximal) when the fixation is only proximal, and type 3 (distal) when the contact is only distal (Figure 3).[3]

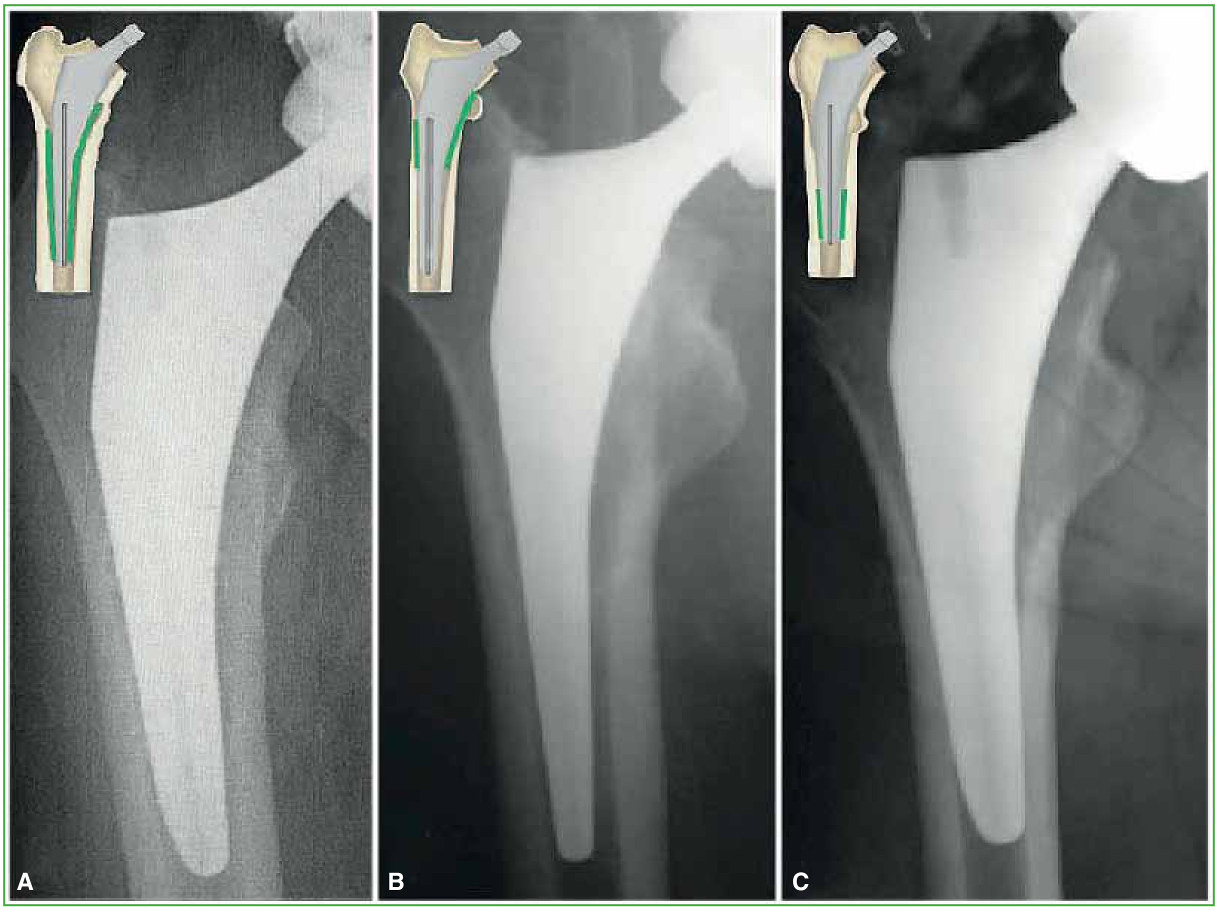

Figure 3. Types of contact. **A.** Type 1 (global). **B.** Type 2 (proximal). **C.** Type 3. (distal).

The femoral canal filling ratio by the implant in the coronal plane was evaluated in three areas (measurement of the implant width divided by the width of the femoral canal): from proximal to 10 mm above the lesser trochanter (FP), from medial to 60 mm below the lesser trochanter (F60) and from distal to 2.5 mm proximal to the tip of the femoral stem (F2.5) (Figure 4).

5. Valgus, varus, and normal orientation of the implant, analyzing the axis of the femoral stem with respect to the axis of the femoral canal in the coronal plane.
6. Presence of radiolucencies (radiolucency around the femoral stem).
7. Subsidence (progressive caudal migration of the implant >1.5 mm).[5]
8. Loosening (symptoms correlating with radiological images).
9. Post-surgical infection.
10. Periprosthetic fracture, intraoperatively or in the immediate postoperative period.
11. Dislocation.
12. Modified *Harris Hip Score* (mHHS).
13. *Western Ontario and McMaster* (WOMAC).

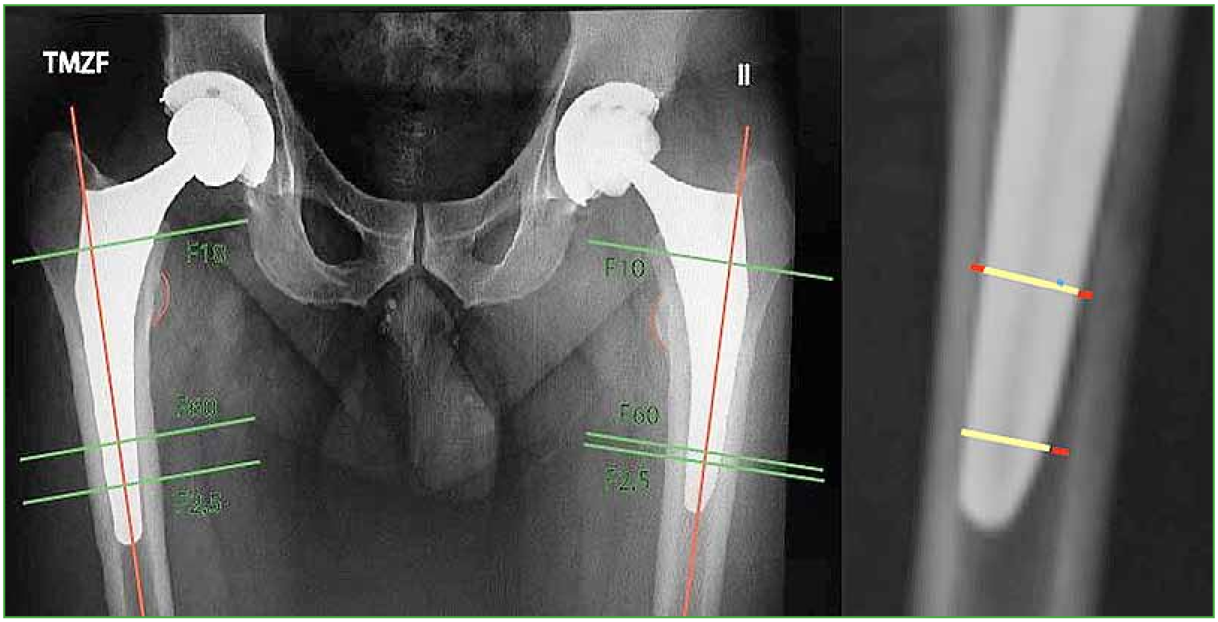

Figure 4. Femoral canal filling.

Statistical analysis

Categorical variables are presented with absolute number and percentage; continuous variables of normal distribution, with average and standard deviation (SD); those with asymmetric distribution, with median, interquartile range (Q1-Q3), minimum and maximum. The distribution of the variables was evaluated using the Shapiro-Wilk test. The appropriate statistic was used for paired samples according to whether the variable was continuous or categorical, the data distribution and the sample size. The level of statistical significance was $p < 0.05$. The data were entered into an Excel spreadsheet and the statistical program used was RStudio.

FINDINGS

Forty-three patients met the inclusion criteria. One was excluded due to loss to follow-up; therefore, the final sample consisted of 42 patients (84 cases). Twenty-two (52.4%) were men. The average age was 59.3 years (SD 10 years) in group 1 and 65.1 years (SD 10 years) in group 2, with a statistically significant difference ($p < 0.05$). Group 1 patients had undergone surgery between 2007 and 2017, with a follow-up of 89.6 months (range 29-171); those in group 2, between 2017 and 2020, with a follow-up of 27.7 months (range 8-41), with a statistically significant difference ($p < 0.05$). The average interval between both surgeries was 61.3 months (range 9-144). In both groups, the acetabular implant used was the Trident Acetabular Cup (Stryker Orthopedics, Mahwah, New Jersey, USA). The friction torque of choice in both cases was adapted to the age and demand from the patient (Metal-Polyethylene X3; Ceramic-Polyethylene X3). The main radiological characteristics are shown in Table 1.

When comparing canal adaptation and filling according to femoral morphology, in Dorr A canals the average filling ratio was 81% in group 1 (Accolade TMZF) and 86% in group 2 (Accolade II). These figures were 79% and 86%, respectively, for Dorr B, and 79% and 77%, respectively, for Dorr C. Regarding adaptation in group 1, in Dorr A canals, contact type 1 (50%) and type 3 (50%) predominated and there was no contact type 2 in the four Dorr A cases. In Dorr B canals, type 1 contact (64%) predominated, followed by type 3 (19%) and type 2 (17%). In Dorr C canals, contact type 2 (50%) and type 3 (50%) predominated and there was no contact type 1 in the two Dorr C cases. Regarding adaptation in group 2, in Dorr A canals, type 1 contact predominated (100%). In Dorr B canals, type 1 contact predominated (89%), and type 2 and 3 were both 5.5%. In Dorr C canals, contact type 1 (50%) and type 2 (50%) predominated and there was no contact type 3 in the two Dorr C cases (Table 2).

Table 1. Radiological characteristics of group 1 Accolade TMZF and group 2 Accolade II.

	Group 1 Accolade TMZF	Group 2 Accolade II	p
Dorr n (%) A B C	 4 (9) 36 (86) 2 (5)	 4 (9) 36 (86) 2 (5)	 0.9
Adaptation * (mm) M (Q1-Q2) [min-max] Proximal gap Medial distal gap Lateral distal gap	 2.5 (2-3.5) [0.5-7] 1.5 (0.5-2.37) [0-7] 1.5 (0.5-2) [0-4]	 2.1 (1.5-2.5) [0.5-4] 1.4 (0.5-2) [0-6] 1.4 (0.5-2) [0-4.5]	 0.0008 0.339 0.798
Adaptation n (%) Type 1 Type 2 Type 3	 25 (60) 7 (16) 10 (24)	 37 (88) 3 (7) 2 (5)	 0.009
Canal filling ** M (Q1-Q2) [min-max] F10 F60 F2.5	 74 (70,25-75,75) [58-85] 87 (83-91.5) [57-100] 85.5 (81.25-92) [58-100]	 75 (72,25-80) [63-87] 90 (85-94.75) [63-100] 90 (85-94.75) [55-100]	 0.001 0.013 0.028
Total canal filling *** M (Q1-Q2) [min-max]	81 (79-85.75) [64-93]	84 (82-89) [65-92]	0.002
mHHS M (Q1-Q2) [min-max]	88 (84-91) [69-91]	87.5 (84-91) [59-91]	0.4
WOMAC M (Q1-Q2) [min-max]	2.5 (0-6.5) [0-26]	3 (0-6) [0-38]	0.8

mHHS = *Modified Harris Hip Score*, WOMAC = *Western Ontario and McMaster,* n = absolute value, M = median, Q1 = first quartile, Q3 = third quartile, min = minimum, max = maximum. * Distance in millimeters, ** Femoral canal filling percentage, *** Total femoral canal filling percentage.

Table 2. Average percentage according to the type of contact (adaptation) of the femoral stem and average femoral canal filling percentage by the implant according to the morphology of the medullary canal (Dorr).

	Group 1 Accolade TMZF	Group 2 Accolade II
Type 1/2/3 adaptation (%) Dorr A Dorr B Dorr C	 50/0/50 64/17/19 0/50/50	 100/0/0 89/5.5/5.5 50/50/0
Canal filling (%) Dorr A Dorr B Dorr C	 81 79 79	 86 86 77

Table 1 shows the mHHS and WOMAC scores for both hips in the distant postoperative period (7.4 years on average in Accolade TMZF and 2.3 years in Accolade II).

All patients presented the same Dorr type in both femoral canals.

The orientation of the femoral stems was varus in three cases (7.14%) from group 1 and one (2.4%) from group 2. Orientation was valgus in two (4.8%) stems from group 1 and one (2.4%) from group 2. The remaining 77 (91.7%) femoral stems had a normal orientation.

No radiolucencies, implant subsidence, or loosening were observed in any of the 84 (100%) hip replacements throughout the evaluation. One patient (group 2) suffered an infectious process that was resolved with surgical debridement and replacement of mobile components. One patient from group 1 had a major trochanter fracture three years after surgery due to a fall from standing height and received non-invasive treatment.

Two dislocation episodes were recorded in the same patient, within three months after surgery: anterior dislocation after the first surgery (Accolade TMZF) and posterior dislocation after the second surgery (Accolade II), both treated with closed reduction, without another episode to date.

DISCUSSION

Different aspects must be considered when choosing the ideal implant: the manufacturing material, the surface, the fixation mode, and its geometry. The evolution of the different designs of femoral components aims to improve results and patient satisfaction.

The design of the first-generation Accolade TMZF originates from Muller ME self-locking flat trapezoidal stem, which was modified while preserving, in part, these characteristics so that it can be adapted to the current needs of hip reconstruction surgery.

The titanium, molybdenum, zirconium, and iron alloy in its current design increases its modulus of elasticity to make it closer to that of bone and significantly improves load transfers compared to other materials. The Accolade surface treated with "Pure Fix HA" (hydroxyapatite) accelerates the biological fixation process, this associated with its design produces an excellent combination to achieve initial stability and integration, which improves the durability of the system.

However, some drawbacks were found related to its adaptability to the different geometric types of the proximal femur, especially Dorr A and C.[5]

The new Accolade II design made from the same materials and the same surface has modifications to its geometric design that solve the adaptability issues of the TMZF design.

Issa et al. analyzed the adaptation parameters of the Accolade TMZF and Accolade II femoral stems in 100 total hip replacements and found a high percentage of better canal filling in the second-generation stem (Accolade II), 90.6% vs. 85.3% at the medial level and 88.1% vs. 76.6% at the distal level, with respect to the first-generation stem (Accolade TMZF),[3] probably because the medial curve in the Accolade TMZF is fixed and, in the Accolade II, it is variable, one of its main modifications.

Articles have been published on the adaptation of the femoral stem and its complications, such as the absence of osseointegration, subsidence, intraoperative or immediate postoperative periprosthetic fractures, residual thigh pain, etc.[5-8] The geometry of the implant, its material, the host's age and bone quality, the placement technique, and the relationship between the implant design-femur are factors indicated in these reports.[1,9,10] In order to decrease micromotion and facilitate osseointegration, intimate contact between the cortical bone and the implant is necessary.[11] In our study, we observed a predominance in the type of global contact (type 1) in group 2 of 88% compared to 60% in group 1.

Regarding the adaptation of the implant to the different types of femoral canals, we believe that the variability of the medial curve allows a better adaptation to the femurs of types A and B (according to Dorr) and thus a greater medial contact to facilitate the load transmission of the implant to the medial femoral cortex and an adequate metaphyseal-diaphyseal contact allowing the correct functioning of the porous integration surface.

There were no significant differences in the clinical-functional evaluation of both groups in the mHHS and WOMAC scores (p 0.4 and 0.8), respectively. 95.2% (40 patients) of group 1 and 92.8% of group 2 (3 patients) exceeded 74 points in the mHHS, which is considered an acceptable improvement[12], that is, a good general functional outcome in both groups.

As limitations of the study, we can mention the number of patients (n = 42), mainly when analyzing the adaptability of the implant in the less frequent morphological types of femur (Dorr A and C) which are generally associated with inconveniences in implantation. Group 2 follow-up is too short (8 to 41 months, average 27.7 months) to assess the long-term radiological criteria of the implant or implant-related complications. The clinical evaluation of both groups was with a different evolution (average 7.4 vs. 2.3 years), without a preoperative clinical record, in addition to an average age difference of both groups of 5.8 years (average age of Accolade TMZF, 59.3 years and Accolade II, 65.1 years). The radiological measurements were made in the coronal plane (as it is a mediolateral fixation implant), no measurements were made in the sagittal plane; therefore, the canal filling ratio is relative (generally a deficit filling in the lateral radiograph, since it is not the way of fixation of flat femoral stems).

CONCLUSIONS

The adaptability of the implant in the femoral canal is essential to facilitate its osseointegration/biological fixation and, in our sample, it is more precise with second-generation flat femoral stems. We believe that their use is recommendable in Dorr A and B canals, and it has very good adaptability in Dorr C. As mentioned above, it is necessary to have a larger sample, mainly to analyze their adaptability in the Dorr A and C canals. A longer follow-up is also essential in group 2 because the local and global outcomes with the Accolade TMZF are excellent in relation to implant fixation, integration, and duration.

Conflict of interests: The authors declare they do not have any conflict of interests.

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