

Preliminary Report on Phenom[®] Femoral Component in Total Hip Replacement: The Correlation between Outcome Scores in a Cross-Seccional Study

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Abstract

Background: The main purpose of the present study was to assess the short term performance of a cementless femoral stem in total hip replacement. **Me-thods:** Cross-sectional observational study of a 48-patient cohort with Phenom[®] femoral stems implanted between June 1, 2014 and September 1, 2018, to determine clinical performance, stability, and radiographic osseointegration. Patients were followed-up from 13 to 76 months (mean: 44.5 months) and assessed using the Harris Hip Score-HHS, the Hip Disability and Osteoarthritis Outcome Score-HOOS and radiographs. **Results:** All stems were radiologically stable. Mean Harris Hip Score was 89.8 and the HOOS was 80.4. No statistical differences were observed among patients with different diagnoses. **Conclusions:** The short-term results revealed satisfactory clinical outcomes and radiological signs of implant stability in all cases. Using two functional scores was useful in detecting biases and a low to moderate agreement was found between the scores.

Keywords

Osseointegration, Total Hip Replacement, Hip Prosthesis, Patient-Reported Outcome Scales, Functional Scores

1. Introduction

Total hip arthroplasty (THA) has become a frequent surgery due to its excellent

cost-effectiveness ratio [1]. In the 2019 annual report of the Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR), there are 82 possibilities for combining cementless implants [2] where the biological concept is applied and in which the rough surface favors bone growth in the pores of the implant, creating a rigid interface [3]. Various porous surfaces and metallic materials have been used to obtain fixation through bone growth in THA, such as coating or blasting the surface components with titanium plasma spray [4].

AOANJRR data from 2019 indicate that 65.4% of femoral implants used in the past five years are cementless, as well as 97.0% of acetabular components [2].

There are numerous types of femoral components made by different companies and many have been introduced into the world market within the last 10 years and hence data is not available on a large proportion of them.

Scarce publications on THA performance with Brazilian manufactured material report results similar to that of products manufactured in other countries [5] [6]. The early failures of previous models, from the 1980s and 1990s, are the reason for questions about the safety in the use of Brazilian-made implants [7]. The primary objective of the study was to verify the clinical-radiological shortterm performance of the Phenom[®] femoral stem and, secondarily, to compare scales of a self-reported outcome instrument and another physician-dependent one for greater accuracy in determining the results.

The Phenom[®] stem is manufactured in titanium alloy (Ti-6Al-4V) coated with titanium plasma spray over ³/₄ of the body in accordance with ASTM and *Anvisa* standards. The titanium plasma spray coating has a mean thickness of 150 μ m and the mean pore size is 224 μ m. It has a conical shape intended for axial stability and uniform transmission of mechanical forces. The implant is coupled by impaction for subsequent biological fixation and requires diaphyseal and metaphyseal broaching.

2. Method

Cross-sectional observational clinical study of 48 individuals with hip osteoarthritis who underwent primary THA between June 1, 2014 and September 1, 2018, in a tertiary-level university hospital (University Hospital of Federal University of Juiz de Fora, MG-Brazil), using Phenom[®] cementless femoral components (Víncula, Rio Claro, SP, Brazil) which were evaluated regarding the short term (mean follow-up 44.5 months) performance of the implant. Included in the study were individuals with degrees III or IV coxarthrosis according to the Kellgren & Lawrence classification for osteoarthrosis [8], with indication of primary THA by any diagnosis, in patients classified as ASA 1 and 2 [9] with BMI category 4, at most [10].

The study was approved by the institution's Research Ethics Committee (CAAE 19640419.4.0000.5133/Opinion No. 3.614.398) and the selected individuals agreed to participate through a Free and Informed Consent Form.

In all of them, the modified Hardinge lateral approach to the hip [11] in later-

al decubitus was used. The femoral stem under study was combined with MD-4 acetabular components (Víncula, Rio Claro-SP-Brazil) in 45 cases (93.8%) and from another source in 3 cases. All received two adjuvant titanium screws in the acetabulum and interchangeable 28 mm in diameter cobalt-chrome metal heads.

Second generation cephalosporin was used, with 2 gr. in the immediate preoperative period and 1 gr. every 8 h for 24 h. For thromboembolism prophylaxis, the stratified multimodal approach was adopted [12], with the use of compression stockings, early mobilization, and aspirin (200 mg/day for 30 days) (75.5%), reserving enoxaparin (20 IU/day for 21 days) for cases with high risk for thromboembolism (24.5%). Partial loading with crutches was allowed until the 45th day and afterwards full loading.

The clinical and radiological assessments were conducted by the senior author and the radiographs were also reviewed by a second independent trained observer, a hip surgeon not involved in the provision of care of the individuals under analysis. The clinical and functional variables were assessed using two specific instruments for the hip, the Hip Disability and Osteoarthritis Outcome Score-HOOS [13] [14] [15] questionnaire and the Harris Hip Score-HHS [16].

The hip abductor mechanism was assessed by means of active abduction with stabilization of the pelvis, in lateral decubitus, and the strength was classified as weak (grades 0, 1, and 2), intermediate (grade 3), and normal (grades 4 and 5) [17].

The analysis of the results between the scores differentiated them according to the minimal clinically important difference (MCID) value of 15 points for the HHS [18] [19] and HOOS [20]. A questionnaire on satisfaction with the procedure was also applied, with four-levels (very satisfied, satisfied, fairly satisfied, and dissatisfied).

Digital anteroposterior and lateral radiographs of the proximal femur and the hip joint, with a magnification factor of +10% were obtained in the preoperative, immediate postoperative, and the final consultation timeframes. On the femoral side, migration and/or subsidence, angulation of the implant in relation to the anatomical axis of the diaphysis, radiolucency lines and/or osteolysis, cortical hypertrophy and bone remodeling, proximal bone atrophy, and pedestal formation were analyzed according to Engh *et al.* [21].

The stems were classified as osseointegrated, fibrous stable, or unstable. To consider the presence of bone growth, we sought evidence of trabeculae between the cortex and the lower edge of the metaphyseal coating (spot welds) and the absence of axial or angular migration. Stable fibrous growth was defined as an implant lacked definite in growth but without progressive radiolucency lines or change in position. Loose stems are those that show evidence of progressive subsidence within the canal (axial or angular migration) and clear signs of loosening in AP radiographs using the Gruen zones as a reference [22].

On the acetabular side, indications of failure of fixation and osseo-integration of the implant are progressive or complete radiolucency lines, failures in the bone-implant interface and unfilled bone cysts associated or not with component migration which is considered consistent evidence of instability and loosening [23] [24] [25]. The location of the radiological findings was based on the classification by DeLee and Charnley [26] for the acetabulum. Heterotopic ossification was classified according to Brooker [27].

Quantitative variables were described by mean and standard deviation, minimum and maximum. Qualitative variables were described by absolute frequency and percentages. To test differences between groups in relation to the quantitative variables, the Student's t-test was used for independent samples. The effect size was evaluated by Cohen's d, using the following classification for interpretation: 0.20 - 0.49 = small; 0.50 - 0.79 = moderate; $\ge 0.80 =$ large [28]. To test differences between proportions, Fisher's exact test was used. In this case, the effect size was evaluated using Cramer's V, with the following classification for interpretation: 0.10 - 0.29 = small; 0.30 - 0.49 = moderate; $\ge 0.50 = \text{large}$ [28]. Secondly, the association between implant stability and the variables for etiology, age, positioning and size of the component, BMI, comorbidities, and contralateral involvement were evaluated. The correlation and agreement analysis between the HHS and HOOS scores was done using the Pearson correlation test and the intraclass correlation coefficient (ICC), respectively. The agreement between the HHS and HOOS classifications was measured by the Gamma correlation coefficient (G). All analyses were done using IBM SPSS V24 statistical software (IBM Corp., Armonk, NY). The value of p < 0.05 was adopted for statistical significance.

3. Results

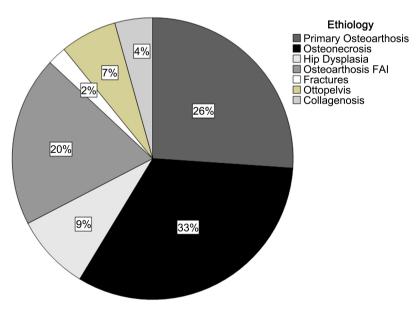


Table 1 shows the demographic characteristics of the sample and Figure 1shows the etiological distribution. Figure 2 shows the sizes of stems used.

Figure 1. Graph of the etiological distribution of the sample (n = 48).

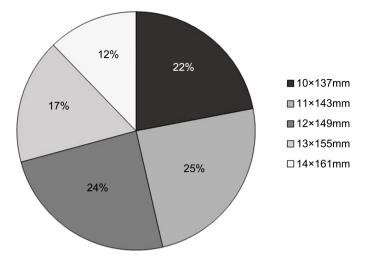


Figure 2. Chart of the dimensions of the most used stems.

| Variables | Mean ± SD (min max.) n (%) |
|---------------------------|-------------------------------|
| Age (years) | 61.5 ± 11.1 (39 - 80) |
| Men, n (%) | 30 (63.8%) |
| BMI (kg/m ²) | 27.9 ± 4.4 (17 - 43) |
| Overweight, n (%) | 35 (72.9%) |
| Education | |
| Elementary School | 26 (55.3%) |
| High school | 16 (34.0%) |
| University education | 5 (10.7%) |
| Retired, n (%) | 28 (59.6%) |
| Receives SS, n (%) | 12 (26.1%) |
| Presence of Comorbidities | |
| 0 | 8 (16.7%) |
| 1 to 2 | 36 (75.0%) |
| ≥ 3 | 4 (8.3%) |
| Follow-up time (months) | 33.5 ± 22.0 (13 - 135) |
| Complications | 4 (8.5%) |
| Readmission | 1 (2.1%) |

| Table 1. Demographic characteristics of | the sample $(n = 48)$. |
|---|-------------------------|
| | ine sumpre (in 10). |

A total of 48 patients participated in the study, most of them male, over 60 years old, and 83.3% with comorbidities. There was one case of femoral nerve neuropraxia in a dysplasia case with full recovery after four weeks, one superficial infection with favorable resolution after superficial debridement and antibiotics, and one case of deep vein thrombosis (DVT). One reoperation for hematoma drainage and debridement was necessary in an individual who received

enoxaparin, with no confirmed infection. Heterotopic ossification occurred in three cases (degree I = two and degree II = one).

One case among the three acetabular components withasource different from the MD-4's presented aseptic loosening with dome migration and indication for revision. The scores of this individual (case 31) were excluded from the statistical analysis, despite having a well-positioned and stable femoral component.

All stems were considered osseo integrated except forone case with diaphyseal cortical hypertrophy and pedestal formation which was classified as fibrous stability (Figure 3 and Figure 4). In 3 cases (6.2%) there was varus of the stem between 2° and 4° attributed to imperfect broaching. One case with a non-progressive subsidence of 2 mm was considered having bone growth.



Figure 3. Case 33—M.J.P.S.: AP radiography showing pedestal formation and cortical hypertrophy—Fibrous stability.



Figure 4. Case 13—M.A.S.: AP radiography showing formation of trabeculae between the cortex and metaphyseal coating of the implant (spot weld—osseointegration).

Satisfactory stability verified intraoperatively in all individuals was obtained. The mean abduction angle of the acetabular component was 46.3° (min. 38° - max. 55°). There was no measurable wear of the polyethylene insert.

Table 2 shows the summary description of the cases and **Table 3** shows the functional results and relevant data. Most patients (87.2%) had a satisfactory functional result for the HHS, normal muscle competence (85.1%), and declared they were very satisfied with the procedure (87.2%), highlighting pain cessation as the main reason. The variables sex, age group, retirement, education, BMI, comorbidities, and follow-up time were not associated with functionality assessed by the HHS (p > 0.05). There was no statistically significant association between HHS scores and degree of patient satisfaction ($\chi^2 = 2.613$; p = 0.11).

The patients evaluated as satisfactory HHS were those with the highest HOOS scores regarding stiffness, daily living, sports/recreation, and total HOOS (**Table 4**). The differences observed were of high significance (d > 0.80). Significance was found in the analysis of correlation between the HHS and HOOS scores, except for the pain subscale, with a statistically significant positive correlation of moderate magnitude, with correlation coefficients ranging between 0.23 and 0.60, and coefficients of determination between 5% to 36% (**Table 5**).

Table 2. Summary description of cases.

| N | Age | Sex | Side | Follow-up (months) | Diagnosis | HSS | HOOS | Relevant data |
|----|-----|--------|-------|-----------------------|---------------------------|-------|------|--------------------------|
| 1 | 77 | Male | Right | 25 | Collagenosis | 77.8 | 81.9 | |
| 2 | 52 | Male | Right | 29 | ONFH | 81.0 | 65.0 | |
| 3 | 57 | Female | Right | 41 | Primary coxarthrosis | 84.0 | 31.4 | |
| 4 | 69 | Male | Left | 72 | Primary coxarthrosis | 85.7 | 78.8 | |
| 5 | 67 | Female | Right | 26 | Otto Pelvis | 100.0 | 95.6 | |
| 6 | 71 | Male | Right | 24 | ONFH | 72.0 | 58.8 | |
| 7 | 61 | Male | Right | 31 | ONFH | 82.8 | 83.1 | Radiolucency 3 mm—1 zone |
| 8 | 55 | Male | Right | 32 | Femoral-acetabular impact | 93.0 | 69.4 | |
| 9 | 67 | Male | Left | 22 | Femoral-acetabular impact | 89.0 | 93.1 | |
| 10 | 59 | Male | Right | 31 | Primary coxarthrosis | 93.8 | 81.3 | |
| 11 | 67 | Male | Right | 76 | ONFH | 92.0 | 85.0 | DVT |
| 12 | 72 | Female | Left | 39 | ONFH | 92.0 | 93.8 | |
| 13 | 69 | Male | Left | 15 | ONFH | 97.0 | 93.8 | Subsidence 2 mm. |
| 14 | 39 | Male | Left | 14 | Dysplasia | 94.0 | 57.5 | Stem position—varus 3° |
| 15 | 79 | Female | Right | 19 | Dysplasia | 74.7 | 41.4 | Brooker Ossif. 2 |
| 16 | 54 | Male | Left | 31 | Trauma sequela | 92.0 | 55.9 | |

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|--------|-----|--------|-------|----|---------------------------|-------|-------|--|
| 17 | 58 | Male | Right | 15 | Otto Pelvis | 93.0 | 82.5 | |
| 18 | 70 | Female | Left | 24 | Femoral-acetabular impact | 93.0 | 86.9 | |
| 19 | 58 | Male | Right | 34 | Dysplasia | 95.8 | 76.3 | Femoral nerve neuropraxia |
| 20 | 57 | Male | Left | 18 | Femoral-acetabular impact | 94.0 | 68.8 | Stem position—varus 4° |
| 21 | 57 | Female | Left | 32 | Otto Pelvis | 92.9 | 65.6 | |
| 22 | 54 | Male | Left | 21 | ONFH | 80.7 | 92.5 | Brooker Ossif. 1 |
| 23 | 70 | Male | Left | 18 | Primary coxarthrosis | 99.3 | 96.6 | Acetabulum position = 55° |
| 24 | 69 | Female | Left | 15 | Femoral-acetabular impact | 86.9 | 68.1 | |
| 25 | 51 | Male | Left | 18 | ONFH | 77.0 | 52.5 | |
| 26 | 70 | Female | Right | 19 | Primary coxarthrosis | 88.0 | 93.1 | |
| 27 | 75 | Female | Left | 14 | ONFH | 97.0 | 95.0 | |
| 28 | 56 | Male | Left | 18 | Femoral-acetabular impact | 85.0 | 91.3 | |
| 29 | 54 | Male | Right | 13 | ONFH | 92.0 | 93.1 | |
| 30 | 47 | Male | Left | 30 | Femoral-acetabular impact | 96.0 | 55.6 | Brooker Ossif. 1 |
| 31 | 67 | Male | Right | 18 | Coxarthrosis | | | Acetabular loosening: Revision pending |
| 32 | 47 | Female | Right | 16 | Collagenosis | 100.0 | 98.1 | |
| 33 | 46 | Male | Left | 22 | Femoral-acetabular impact | 99.9 | 94.4 | Diaphyseal cortical hypertrophy and pedestal |
| 34 | 80 | Male | Left | 56 | Primary coxarthrosis | 86.0 | 87.5 | |
| 35 | 40 | Female | Right | 57 | ONFH | 63.0 | 59.4 | |
| 36 | 72 | Male | Right | 41 | Primary coxarthrosis | 90.0 | 96.9 | |
| 37 | 57 | Female | Left | 24 | ONFH | 100.0 | 98.1 | |
| 38 | 70 | Female | Right | 32 | Primary coxarthrosis | 87.9 | 36.3 | |
| 39 | 61 | Male | Right | 21 | Primary coxarthrosis | 100.0 | 95.6 | |
| 40 | 68 | Male | Left | 16 | ONFH | 80.0 | 78.8 | |
| 41 | 73 | Female | Left | 27 | Primary coxarthrosis | 94.0 | 93.1 | |
| 42 | 78 | Female | Right | 60 | Primary coxarthrosis | 85.2 | 82.5 | Superficial infection |
| 43 | 46 | Male | Left | 43 | Femoral-acetabular impact | 97.0 | 100.0 | |
| 44 | 49 | Male | Right | 48 | ONFH | 100.0 | 95.6 | |
| 45 | 78 | Female | Right | 63 | Primary coxarthrosis | 96.0 | 96.9 | |
| 46 | 65 | Male | Left | 43 | ONFH | 92.0 | 94.4 | Readmission: hematoma |
| 47 | 42 | Female | Right | 62 | Dysplasia | 100.0 | 98.1 | |
| 48 | 57 | Male | Right | 66 | Femoral-acetabular impact | 78.8 | 88.8 | |

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| Variables | Mean ± SD (min max.) n (%) |
|---------------------------------|-------------------------------|
| Functional parameters | |
| HHS | 89.8 ± 8.5 (63 - 100) |
| Excellent | 28 (59.6%) |
| Good | 13 (27.7%) |
| Fair | 5 (10.6%) |
| Poor | 1 (2.1%) |
| HOOS | 80.4 ± 18.1 (31.4 - 100) |
| Stiffness | 87.4 ± 18.2 (25.0 - 100) |
| Pain | 88.8 ± 18.5 (35.0 - 100) |
| Daily living | 83.1 ± 19.6 (32.4 - 100) |
| Sports/Recreation | 54.2 ± 29.3 (0.0 - 100) |
| Quality of life | $65.0 \pm 27.1 \ (0.0 - 100)$ |
| Degree of satisfaction | |
| Satisfied | 6 (12.8%) |
| Very satisfied | 41 (87.2%) |
| Contralateral involvement | 37 (78.7%) |
| Muscle competence | |
| 3 | 1 (2.1%) |
| 4 | 6 (12.8%) |
| 5 | 40 (85.1%) |
| Limb discrepancy | 3 (6.4%) |
| Relevant radiological data | |
| Heterotopic ossification | 3 (6.4%) |
| Diaphyseal cortical hypertrophy | 1 (2.1%) |
| Pedestal | 1 (2.1%) |
| Radiolucency and/or osteolysis | 1 (2.1%) |
| Stem subsidence | 1 (2.1%) |
| Varus of the stem | 2 (4.3%) |
| Verticalized acetabulum (>50°) | 2 (4.3%) |

Table 3. Functional characteristics and radiological data (n = 48).

Table 4. Variables associated with functionality after hip surgery.

| Variables | Satisfactory HHS (n = 41) | Unsatisfactory HHS (n = 6) | <i>p</i> -value | Effect size |
|-------------------|------------------------------|-------------------------------|-----------------|-------------|
| HOOS | | | | |
| Stiffness | 90.4 ± 15.1 | 66.9 ± 25.4 | 0.002* | 1.56 |
| Pain | 90.2 ± 17.3 | 78.7 ± 24.5 | 0.16 | 0.66 |
| Daily living | 85.8 ± 17.4 | 64.4 ± 24.9 | 0.01* | 1.23 |
| Sports/recreation | 59.4 ± 27.5 | 18.7 ± 11.2 | < 0.001* | 1.48 |
| Quality of life | 66.3 ± 26.6 | 56.2 ± 31.6 | 0.40 | 0.38 |
| HOOS Total | 82.8 ± 17.0 | 63.8 ± 18.0 | 0.01* | 1.12 |
| | 101 10 1100 | | | |

Mean \pm standard deviation; *Significant difference, p < 0.05; Effect size a: Cramer's V; b: Cohen's d.

Low to moderate agreement was found between the quantitative scores of the HHS and HOOS (ICC = 0.56; 95% CI: 0.21 - 0.75), suggesting that the functional assessment made by the physician has low to moderate agreement with the perception of functionality by the patient (**Figure 5**). The agreement between the scores is greater when an association is made between the classifications in the HHS and the HOOS based on the cut-off point of 85. In this case, there was a moderate agreement (Gamma = 0.78; p = 0.005), with 66% absolute agreement between the classifications (**Figure 6**).

Patients with contralateral involvement presented lower scores on the HHS and on the HOOS daily living and sports/recreation subscales (Table 6). The effect size observed in this case suggests that the differences between groups for the HHS are high magnitude, while for the HOOS daily living and sports/recreation they are moderate in magnitude.

| Variables | HHS | <i>p-</i> value | r (%) |
|-------------------|------|-----------------|-------|
| Stiffness | 0.43 | 0.002* | 18 |
| Pain | 0.23 | 0.11 | 5 |
| Daily living | 0.50 | <0.001* | 25 |
| Sports/recreation | 0.60 | <0.001* | 36 |
| Quality of life | 0.39 | 0.007* | 15 |
| HOOS | 0.50 | <0.001* | 25 |
| | | | |

Table 5. Pearson's correlation coefficients between the HHS and HOOS (n = 48).

*p < 0.05; R: Coefficient of determination (r²).

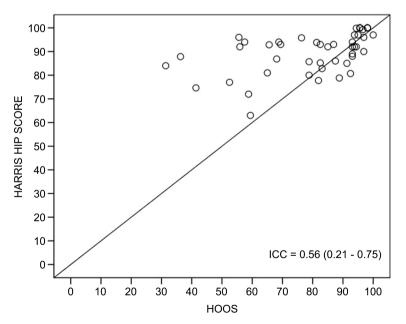


Figure 5. Scatterplot between the HHS and HOOS scores for analysis of agreement between the instruments. Notes: ICC: intraclass correlation coefficient (95% CI); p < 0.05.

Individuals with a supposed social security compensation bias had lower mean scores in the HHS and HOOS, with statistically significant differences being observed in the HOOS subscales of daily living, sports/recreation, quality of life, and total HOOS (**Table 7**). The size of the observed effect for the HHS and for the HOOS stiffness and pain subscales indicates that the differences between the groups are moderate in magnitude, while for the HOOS subscales of daily living, sports-recreation, quality of life, and total HOOS, the differences are high magnitude.

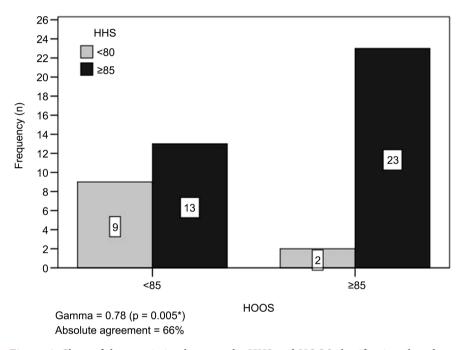


Figure 6. Chart of the association between the HHS and HOOS classifications based on the cut-off point of 85.

| Variables | With contralateral involvement (n = 37) | No contralateral involvement (n = 10) | <i>p</i> -value | Effect size |
|-------------------|---|---|-----------------|-------------|
| HHS | 88.2 ± 8.6 | 95.8 ± 4.9 | 0.01* | 0.88 |
| HOOS | | | | |
| Stiffness | 86.0 ± 19.1 | 92.5 ± 14.0 | 0.32 | 0.34 |
| Pain | 87.2 ± 19.2 | 94.5 ± 14.8 | 0.27 | 0.38 |
| Daily living | 80.3 ± 20.5 | 93.1 ± 11.4 | 0.01* | 0.62 |
| Sports/recreation | 49.9 ± 28.1 | 70.0 ± 29.7 | 0.05* | 0.71 |
| Quality of life | 61.9 ± 27.9 | 76.3 ± 21.6 | 0.14 | 0.52 |
| HOOS total | 78.0 ± 18.5 | 89.3 ± 14.0 | 0.08 | 0.61 |

 Table 6. Variables associated with the presence of contralateral involvement.

Mean \pm standard deviation; *Significant difference, p < 0.05; Effect size assessed by Cohen's d.

| | Receives SS | Does not receive SS | | |
|-------------------|-----------------|---------------------|-----------------|-------------|
| Variables | (n = 12) | (n = 34) | <i>p</i> -value | Effect size |
| HHS | 86.5 ± 8.6 | 90.9 ± 8.4 | 0.13 | 0.52 |
| HOOS | | | | |
| Stiffness | 80.0 ± 17.0 | 89.7 ± 18.4 | 0.12 | 0.55 |
| Pain | 81.2 ± 20.3 | 91.1 ± 17.5 | 0.12 | 0.52 |
| Daily living | 70.8 ± 17.0 | 87.0 ± 19.0 | 0.01* | 0.90 |
| Sports/recreation | 32.8 ± 26.7 | 60.9 ± 27.0 | 0.003* | 1.05 |
| Quality of life | 37.5 ± 26.0 | 74.4 ± 20.8 | <0.001* | 1.58 |
| HOOS total | 67.6 ± 14.8 | 84.4 ± 17.4 | 0.005* | 1.04 |

Table 7. Variables associated with possible social security compensation bias.

Mean \pm standard deviation; *Significant difference, p < 0.05; Effect size assessed by Cohen's d.

4. Discussion

The cohort studied has a high number of individuals diagnosed with osteonecrosis of the femoral head (ONFH) due to the service's macro regional referrals, implying a high percentage of bilateralism with repercussions on functional results.

Cementless femoral implants have good clinical results and long-term survival [29]. The present study is the first to highlight the clinical and radiological performance of the Phenom[®] femoral stem [30].

Short term results of the MD-4^{*} acetabular component used in 93.75% of cases were reported by Loures *et al.* [6].

Absence of progressive subsidence or early change in the positioning of a femoral stem is interpreted as a predictor of fixation stability and durability [31] [32] [33].

The HHS has been used to assess patients after THA since 1969. It consists of 4 subscales: pain, function, absence of deformity, and range of motion. It is a simple and quick scale. Unlike self-reports that have the inconvenience of ambiguity in answers and incomplete forms, the HHS is subject to the so-called "ceiling effect", which occurs when the highest score on the scale does not accurately assess the patient's level of ability. An observer's bias and marginalization of the patient's own perception are inherent to this instrument [34]. The HOOS is a scale that presented test-retest reliability with a high degree of consistency for its 5 subscales. The HOOS consists of 40 questions and its scale ranges from 0 to 100, representing the best function [13] [14] [15].

The applicability of the HOOS to the population in the low-education segment is poorly understood. Filling out the form proved to be difficult. Most respondents (89%) needed help from a monitor to fully answer the questionnaire. The issues related to quality of life (Q1 to Q4) were not well understood by 45% of respondents, which may be reflected as information bias. Halawi *et al.* [35] found a slight to moderate correlation between patient satisfaction and self-reported scales, and this correlation is slightly higher when using specific scales for certain diseases compared to generic health scales such as the SF-36. On the specific scales, the domain most consistently related to satisfaction is pain. These authors concluded that generic self-reported scales alone are not the best way to assess patient satisfaction in total arthroplasty, and recommend direct satisfaction questionnaires and disease-specific self-report scales to assess pain perception and satisfaction with the procedure [35].

Client satisfaction does not always coincide with the surgeon's view (HHS and radiological parameters) or with the data from the HOOS questionnaire, and inferences can be made about the existence of a combination of factors such as the situation regarding social security. The secondary gain arising from the operation is influenced by socio-cultural aspects, difficult to measure. In the sample studied, what was called "social security compensation bias" was observed in 5 individuals (10.4%) with high HHS and normal radiological parameters, who declared they were satisfied, but pointed to unexplained pain and/or levels of incapacity inconsistent with the objective data. The "social security compensation bias" is characterized by an apparent search for compensation and/or maintenance of an unreal situation of incapacity for work, even with adequate rehabilitation and satisfactory clinical and radiological parameters. This financially motivated variable would influence the measurement of results, thus being an information bias to be considered [36].

Noting the limitations of the study in view of the limited number of patients, the sample followed a pattern of homogeneity with respect to a number of variables and rigor in the application of the outcome scales. The evidence of implant radiological osseointegration, together with a satisfactory functional level in most cases, gains relevance in the context of the scarcity of publications that analyze Brazilian-made prostheses.

5. Conclusion

The short-term clinical and radiological results demonstrated implant stability and, in 98% of the cases, signs of osseointegration of the femoral componentevaluated, equivalent to the performance of similar products described in the literature, which can represent a predictive factor regarding the medium and long term survival of the implant. Continuity in the follow-up and a higher number of individuals are essential for definitive conclusions. The combined use of two outcome instruments proved to be useful in the identification of biases, in the measurement of the real functional and satisfaction levels, providing greater reliability in the interpretation of the data. The discrepancy between the physician's and the patient's perception regarding the functional status was statistically significant and low to moderate agreement between the scores was found. Individuals with lower functional scores were associated with contralateral hip involvement.

Consent Statement

Written informed consent was obtained from the patients for publication of this study.

Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

References

- Daigle, M.E., Weinstein, A.M., Katz, J.N. and Losina, E. (2012) The Cost-Effectiveness of Total Joint Arthroplasty: A Systematic Review of Published Literature. *Best Practice & Research Clinical Rheumatology*, 26, 649-658. https://doi.org/10.1016/j.berh.2012.07.013
- [2] Australian Orthopaedic Association National Joint Replacement Registry (2019) Australian Orthopaedic Association National Joint Replacement Registry Annual Report 2019. Australian Orthopaedic Association National Joint Replacement Registry, Melville.
- [3] Garino, J. and Beredjiklian, P. (2007) Adult Reconstruction and Arthroplasty. Mosby, Philadelphia.
- [4] D'Angelo, F., Murena, L., Campagnolo, M., Zatti, G. and Cherubino, P. (2008) Analysis of Bone Ingrowth on a Tantalum Cup. *Indian Journal of Orthopaedics*, 42, 275-278.
- [5] Diesel, C.V., Ribeiro, T.A., Macedo, C.A.S. and Galia, C.R. (2019) Resultados de sobrevida no médio prazo da haste femoral não cimentada Logical. *Revista Brasileira de Ortopedia*, 54, 453-458.
- [6] Loures, E.A., Simoni, L.F., Leite, I.C.G.L., Loures, D.N. and Loures, C.N. (2015) Preliminary Analysis on the MD-4[®] Plasma-Sprayed Titanium Acetabular Component. *Revista Brasileira de Ortopedia*, **50**, 206-213. https://doi.org/10.1016/j.rbo.2014.02.014
- [7] Picado, C.H.F., Martins, L.G.G.M., Garcia, F.L. and Kanabushi, C. (2004) Avaliação radiográfica do acetábulo rosqueado tipo CO-10. *Revista Brasileira de Ortopedia*, 39, 189-195.
- [8] Kellgren, J.H. and Lawrence, J.S. (1957) Radiological Assessment of Osteo-Arthrosis. *Annals of the Rheumatic Diseases*, 16, 494-502. <u>http://dx.doi.org/10.1136/ard.16.4.494</u>
- [9] American Society of Anesthesiologists (2020) ASA Physical Status Classification System.
 <u>https://www.asahq.org/standards-and-guidelines/asa-physical-status-classification-system</u>
- [10] World Health Organization (2020) Body Mass Index—BMI. <u>https://www.euro.who.int/en/health-topics/disease-prevention/nutrition/a-healthy-l</u> ifestyle/body-mass-index-bmi
- [11] Hardinge, K. (1982) The Direct Lateral Approach to the Hip. *The Journal of Bone and Joint Surgery, British Volume*, **64**, 17-19.
- [12] Loures, E.A., Rocha, G.M., Loures, D.N., Leite, I.C.G.L. and Loures, C.N. (2018) Multimodal Stratified Approach for Prevention of Thromboembolism in Patients Undergoing Total Hip Arthroplasty. *Open Journal of Orthopedics*, 8, 429-442.

https://doi.org/10.4236/ojo.2018.812045

- [13] Nilsdotter, A.K., Lohmander, L.S., Klässbo, M. and Roos, E.M. (2003) Hip Disability and Osteoarthritis Outcome Score (HOOS)—Validity and Responsiveness in Total Hip Replacement. *BMC Musculoskeletal Disorders*, 4, Article No. 10. https://doi.org/10.1186/1471-2474-4-10
- [14] Physiopedia (2020) Hip Disability and Osteoarthritis Outcome Score. Physiopedia. https://www.physio-pedia.com/Hip_Disability_and_Osteoarthritis_Outcome_Score
- [15] Machado, R.K., Casagrande, A.A., Pereira, G.R., Vissoci, J.R.N., Pietrobon, R., Ferreira, A.P.B., *et al.* (2019) Hip Disability and Osteoarthritis Outcome Score (HOOS): Um estudo de validação intercultural da versão na língua portuguesa. *Revista Brasileira de Ortopedia*, **54**, 282-287. https://doi.org/10.1055/s-0039-1691764
- [16] Guimarães, R.P., Alves, D.P.L., Azuaga, T.L., Ono, N.K., Honda, E., Polesello, G.C., et al. (2010) Tradução e adaptação transcultural do "Harris Hip Score modificado por Byrd". Acta Ortopédica Bras, 18, 339-342. https://doi.org/10.1590/S1413-78522010000600007
- [17] Kendall, F.P., McCreary, E.K., Provance, P.G., Rodgers, M.M. and Romani, W.A. (2007) Músculos-Provas e funções. Ed. Manole, Brazil.
- [18] Singh, J.A., Schleck, C., Harmsen, S. and Lewallen, D. (2016) Clinically Important Improvement Thresholds for Harris Hip Score and Its Ability to Predict Revision Risk after Primary Total Hip Arthroplasty. *BMC Musculoskeletal Disorders*, 17, Article No. 256. https://doi.org/10.1186/s12891-016-1106-8
- [19] van der Wees, P.J., Wammes, J.J.G., Akkermans, R.P., Koetsenruijter, J., Westert, G.P., van Kampen, A., *et al.* (2017) Patient-Reported Health Outcomes after Total Hip and Knee Surgery in a Dutch University Hospital Setting: Results of Twenty Years Clinical Registry. *BMC Musculoskeletal Disorders*, **18**, Article No. 97. https://doi.org/10.1186/s12891-017-1455-y
- [20] Lyman, S., Lee, Y.-Y., McLawhorn, A.S., Islam, W. and MacLean, C.H. (2018) What Are the Minimal and Substantial Improvements in the HOOS and KOOS and JR Versions after Total Joint Replacement? *Clinical Orthopaedics and Related Research*, **476**, 2432-2441. <u>https://doi.org/10.1097/CORR.00000000000456</u>
- [21] Engh, C.A., Massin, P. and Suthers, K.E. (1990) Roentgenographic Assessment of the Biologic Fixation of Porous-Surfaced Femoral Components. *Clinical Orthopaedics and Related Research*, 257, 107-128. https://doi.org/10.1097/00003086-199008000-00022
- [22] Gruen, T.A., McNeice, G.M. and Amstutz, H.C. (1979) "Modes of Failure" of Cemented Stem-Type Femoral Components: A Radiographic Analysis of Loosening. *Clin Orthop*, 141, 17-27. <u>https://doi.org/10.1097/00003086-197906000-00002</u>
- [23] Nunn, D., Freeman, M.A., Hill, P.F. and Evans, S.J. (1989) The Measurement of Migration of the Acetabular Component of Hip Prostheses. *The Journal of Bone and Joint Surgery. British Volume*, **71**, 629-631. https://doi.org/10.1302/0301-620X.71B4.2768311
- [24] Lakemeier, S., Aurand, G., Timmesfeld, N., Heyse, T.J., Fuchs-Wikelmann, S. and Schofer, M.D. (2010) Results of the Cementless Plasmacup in Revision Total Hip Arthroplasty: A Retrospective Study of 72 Cases with an Average Follow-Up of Eight Years. *BMC Musculoskeletal Disorders*, **11**, Article No. 101. <u>https://doi.org/10.1186/1471-2474-11-101</u>
- [25] Latimer, H.A. and Lachiewicz, P.F. (1996) Porous-Coated Acetabular Components with Screw Fixation. Five to Ten-Year Results. *The Journal of Bone & Joint Surgery*,

78, 975-981. https://doi.org/10.2106/00004623-199607000-00001

- [26] DeLee, J.G. and Charnley, J. (1976) Radiological Demarcation of Cemented Sockets in Total Hip Replacement. *Clinical Orthopaedics and Related Research*, **121**, 20-32. <u>https://doi.org/10.1097/00003086-197611000-00003</u>
- [27] Brooker, A.F., Bowerman, J.W., Robinson, R.A. and Riley, L.H. (1973) Ectopic Ossification Following Total Hip Replacement. Incidence and a Method of Classification. *Journal of Bone & Joint Surgery*, 55, 1629-1632. https://doi.org/10.2106/00004623-197355080-00006
- [28] Cohen, J. (1992) A Power Primer. *Psychological Bulletin*, **112**, 155-159. https://doi.org/10.1037/0033-2909.112.1.155
- [29] Jahnke, A., Engl, S., Altmeyer, C., Jakubowitz, E., Seeger, J.B., Rickert, M., et al. (2014) Changes of Periprosthetic Bone Density after a Cementless Short Hip Stem: A Clinical and Radiological Analysis. *International Orthopaedics*, 38, 2045-2050. https://doi.org/10.1007/s00264-014-2370-6
- [30] Víncula (2020) Phenom[®] PS. <u>http://vincula.com.br/produto/phenom-ps/</u>
- [31] Engh, C.A., Bobyn, J.D. and Glassman, A.H. (1987) Porous-Coated Hip Replacement. The Factors Governing Bone Ingrowth, Stress Shielding, and Clinical Results. *Journal of Bone and Joint Surgery, British Volume*, 69, 45-55. https://doi.org/10.1302/0301-620X.69B1.3818732
- [32] Cuckler, J.M., Moore, K.D., Lombardi, A.V., McPherson, E. and Emerson, R. (2004) Large versus Small Femoral Heads in Metal-on-Metal Total Hip Arthroplasty. *Journal of Arthroplasty*, **19**, 41-44. <u>https://doi.org/10.1016/j.arth.2004.09.006</u>
- [33] Röhrl, S.M., Nivbrant, B., Snorrason, F., Kärrholm, J. and Nilsson, K.G. (2006) Porous-Coated Cups Fixed with Screws: A 12-Year Clinical and Radiostereometric Follow-up Study of 50 Hips. *Acta Orthopaedica*, **77**, 393-401. https://doi.org/10.1080/17453670610046316
- [34] Nilsdotter, A. and Bremander, A. (2011) Measures of Hip Function and Symptoms: Harris Hip Score (HHS), Hip Disability and Osteoarthritis Outcome Score (HOOS), Oxford Hip Score (OHS), Lequesne Index of Severity for Osteoarthritis of the Hip (LISOH), and American Academy of Orthopedic Surgeons (AAOS) Hip and Knee Questionnaire. *Arthritis Care & Research*, 63, S200-S207. https://doi.org/10.1002/acr.20549
- [35] Halawi, M.J., Jongbloed, W., Baron, S., Savoy, L., Cote, M.P. and Lieberman, J.R. (2020) Patient-Reported Outcome Measures Are Not a Valid Proxy for Patient Satisfaction in Total Joint Arthroplasty. *Journal of Arthroplasty*, **35**, 335-339. https://doi.org/10.1016/j.arth.2019.09.033
- [36] Loures, E.A. and Leite, I.C.G. (2012) Análise da qualidade de vida de pacientes osteoartrósicos submetidos à artroplastia total do quadril. *Revista Brasileira de Ortopedia*, 47, 498-504. <u>https://doi.org/10.1590/S0102-36162012000400017</u>