Impact of the Origin of Surgical Cement in Patients with Hip Fractures Treated with Arthroplasty. Comparative Study on 153 Patients

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ABSTRACT

Introduction: The objective of this study was to determine whether the use of national or imported cement has an impact on the clinical and radiological outcomes of a series of hip fracture patients treated with arthroplasty. **Materials and Methods:** We retrospectively analyzed 153 patients with hip fractures who were treated consecutively with arthroplasty (total or partial) between 2017 and 2019 at our center, with a minimum follow-up of 24 months. The patients were divided into two groups based on the origin of the cement, and we compared preoperative characteristics, functional outcomes (Parker index and Harris Hip Score - HHS), complications, mechanical loosening, and prosthetic survival. **Results:** In 99 cases (64.7%), national cement was used, and in 54 cases (35.3%), imported cement was used. There were 96 total hip arthroplasties (81 cemented and 15 hybrid) and 57 bipolar hemiarthroplasties. The mean follow-up was 47 ± 1.1 months. No significant differences were found between the groups in functional outcomes (Parker: 5.3 ± 0.4 vs. 5.5 ± 0.6; p = 0.88; HHS: 84.5 ± 6.6 vs. 85.9 ± 7.5; p = 0.28), complication rates (6% vs. 5.5%; p = 0.99), revisions (2.6% vs. 1.9%; p = 0.69), or prosthetic survival (96% vs. 94.5%; p = 0.69). **Conclusion:** The results of this study suggest that the origin of surgical cement does not significantly affect clinical or radiological outcomes in patients undergoing total or partial hip arthroplasty for hip fracture.

Keywords: Hip fracture; hip arthroplasty; bipolar hemiarthroplasty; surgical bone cement.
Level of Evidence: III

Impacto del origen del cemento quirúrgico en pacientes con fractura de cadera tratados con artroplastia. Estudio comparativo de 153 pacientes

RESUMEN

Objetivo: Determinar si el uso de cemento nacional o importado impacta en los resultados clínico-radiográficos de una serie de pacientes con fractura de cadera tratados con artroplastia. **Materiales y Métodos:** Se analizó, de manera retrospectiva, a 153 pacientes con fractura de cadera tratados consecutivamente con una artroplastia (total o parcial), entre 2017 y 2019, en nuestro hospital, y un seguimiento mínimo de 24 meses. Se dividió a la serie en dos grupos según el origen del cemento y se compararon las siguientes variables: características preoperatorias, resultados funcionales (índice de Parker y HHS), complicaciones, aflojamiento mecánico y supervivencia de la prótesis. **Resultados:** En 99 (64,7%) casos, se utilizó cemento de origen nacional y, en 54 (35,3%), importado. Noventa y seis eran artroplastias totales (81 cementadas y 15 hibridas) y 57, hemiartroplastias bipolares. La media de seguimiento fue de 47 ± 1.1 meses. No se hallaron diferencias significativas entre los grupos en cuanto a los resultados funcionales (Parker 5,3 ± 0,4 vs. 5,5 ± 0,6; p = 0,88; HHS 84,5 ± 6,6 vs. 85,9 ± 7,5; p = 0,28), la tasa de complicaciones (6% vs. 5,5%; p = 0,99), las revisiones (2,6% vs. 1,9%; p = 0,69), ni la supervivencia de la prótesis (96% vs. 94,5%; p = 0,69). **Conclusión:** Los resultados sugieren que el origen de fabricación del cemento no afecta significativamente los resultados clínico-radiográficos luego de una artroplastia total o parcial por fractura de cadera.

Palabras clave: Fractura de cadera; artroplastia de cadera; hemiartroplastia bipolar; cemento óseo quirúrgico.
Nivel de Evidencia: III

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INTRODUCTION

Hip fractures significantly impact patient morbidity and mortality, especially among older adults, and represent a global public health challenge.[1,2] In our country, the incidence of hip fractures is approximately 264 cases per 100.000 inhabitants, with a predominance in females (3:1).[3,4]

Arthroplasty (total or partial) is a common treatment option for hip fractures.[5-7] Surgeons can choose between three types of prosthesis fixation in arthroplasty: cemented, uncemented, or hybrid fixation (uncemented cup and cemented stem). This decision largely depends on the patient's characteristics and the surgeon's experience.[5-9] Although the use of cementless components has increased in recent decades, there is no definitive consensus on the best fixation method, as both hybrid and cemented fixation have shown excellent outcomes with 15- to 20-year follow-ups.[8-13]

In Argentina, surgical cements from both domestic and imported manufacturers are available, but to our knowledge, no studies have evaluated the outcomes of hip arthroplasty based on the origin of the cements. Therefore, the purpose of this study was to evaluate the clinical-functional and radiographic outcomes of hip fracture patients treated with arthroplasty, comparing the use of domestic and imported cements.

Our study hypothesizes that the origin of the cement does not significantly affect clinical outcomes.

MATERIALS AND METHODS

We conducted an observational, analytical cohort study. We retrospectively analyzed patients who underwent hip fracture surgery in our department between January 2017 and December 2019. The study was approved by our hospital's Institutional Review Board.

Inclusion criteria were patients with hip fractures treated with total or partial (bipolar) hip arthroplasty, where at least one component (cup or stem) was cemented, and who completed a minimum follow-up of 24 months. Patients with pathological fractures, previous hip surgeries, or those referred from another center with prior treatment were excluded.

Out of the initial 311 patients identified, 158 were excluded for having exclusively uncemented components; 25, due to pathological fractures; 20, because of previous surgeries on the affected hip; and five, for not meeting the minimum follow-up requirement. The final series included 153 patients. Table 1 provides a general description of the cohort.

For the analysis, the series was divided into two groups: one group used domestically produced cement (Subiton, Laboratorios SL, Argentina) and the other used imported cement (Cemex Genta, Tecres, Somm, Italy). Both cements are low-viscosity.

Surgical Technique

All surgeries were performed in a laminar airflow operating room under hypotensive spinal anesthesia. Antibiotic prophylaxis was administered with 1 g of intravenous cefazolin 30 minutes before the skin incision, along with a dose of tranexamic acid during anesthesia induction. All patients were placed in the supine position and operated on using an anterolateral approach (Bauer).[14] Cup cementing was performed using an ad hoc impactor to pressurize the cement and ensure regularity of the cement mantle.

For the femoral stems, either second- or third-generation cementing techniques were used, depending on availability, patient characteristics, and the surgeon's preference.

Antithrombotic prophylaxis was administered with 40 mg of subcutaneous low-molecular-weight heparin for 30 days.

Postoperative rehabilitation began with sitting on the first postoperative day, with isometric exercises. Walking with a walker was initiated on the second postoperative day. Patients were advised to use a walker or two forearm crutches for the first three weeks, followed by a single cane for the next three weeks. Postoperative follow-ups were scheduled at 3 and 6 weeks, 3, 6, and 12 months, and then annually.

Clinical Analysis

Clinical and functional assessments were performed using the Parker Mobility Score to compare pre- and postoperative function,[15] and the Harris Hip Score (HHS) at the end of the follow-up period.[16]

Table 1. Description of the patients included in the study

Variables	(n = 153)
Sex, n (%) Female Male	 120 (78.5) 33 (21.5)
Age, median (range)	82.85 (76.5-88.5)
Diagnosis, n (%) Lateral fracture Medial fracture	 72 (47.0) 81 (53.0)
CCI, n (%) ≤4 >5	 92 (60.0) 61 (40.0)
ASA, n (%) I-II III-IV	 87 (56.9) 66 (43.1)
Comorbidities, n (%) Diabetes Renal failure Obesity Rheumatoid arthritis Other	 19 (12.4) 10 (6.5) 9 (5.9) 10 (6.5) 105 (68.6)
Preoperative Parker score, median (range)	5.6 (1.0-9.0)
Total arthroplasties, n (%) Cemented Hybrid Bipolar hemiarthroplasty, n (%)	96 (62.7) 81 (52.9) 15 (9.8) 57 (37.2)

CCI = Charlson comorbidity index, ASA = *American Association of Anesthesiologists*.

Radiographic Analysis

Anteroposterior and lateral projections of both hips were used for radiographic evaluation. In the immediate postoperative images, the quality of stem cementation was assessed according to Barrack's classification. [17]

The presence of radiolucent lines around the implants and their location were classified based on the zones described by DeLee-Charnley and by Gruen.[18]

Loosening of the cemented acetabular component was evaluated using the DeLee-Charnley and Hodgkinson criteria.[18] Loosening was defined as the presence of radiolucent lines in all three zones or evidence of implant migration.[19,20] The Harris criteria were used to assess loosening of the femoral stems.[21]

At the end of the follow-up period, the rate of loosening and prosthesis survival were determined, with prosthesis revision for any cause as the cut-off point. Complication and mortality rates were also recorded at the end of the study.

Statistical Analysis

Qualitative variables are expressed as percentages and frequencies, while numerical variables are reported as means and standard deviations or medians and interquartile ranges, depending on their distribution. Continuous variables were compared using the Student's t-test, while categorical variables were analyzed using the chi-square test (or Fisher's exact test, if necessary) or ANOVA. Prosthesis survival was calculated using the Kaplan-Meier method. A p-value of <0.05 was considered statistically significant.

All data were recorded in an Excel spreadsheet (Redmond, WA, USA), and statistical calculations were performed using GraphPad Prism 9.0 (La Jolla, CA, USA).

RESULTS

Domestic cement was used in 99 patients (64.7%), while imported cement was used in 54 patients (35.3%). When comparing preoperative characteristics, a significantly higher percentage of patients in the domestic cement group had a Charlson comorbidity index >5 (p = 0.0002) (Table 2).

Table 2. Comparative analysis between groups of patients with domestic or imported cement.

Variable	Domestic cement (n = 99)	Imported cement (n = 54)	p
Sex, n (%)			
Female	76 (76.5)	44 (81.0)	0.45
Male	23 (23.5)	10 (19.0)	
Age (mean, SD)	83.7 ± 6.7	82.1 ± 5.9	0.85
Diagnosis, n (%)			
Lateral fracture	42 (42.5)	30 (55.0)	0.85
Medial fracture	57 (57.5)	24 (45.0)	
CCI, n (%)			
≤4	49 (49.5)	43 (79.0)	0.0002
>5	50 (50.5)	11 (21.0)	
ASA, n (%)			
I-II	53 (53.5)	34 (63.0)	0.26
III-IV	46 (46.5)	20 (37.0)	
Comorbidities, n (%)			
Diabetes	14 (14.5)	5 (9.0)	0.38
Renal failure	7 (7.5)	3 (5.0)	0.71
Obesity	7 (7.5)	2 (3.0)	0.39
Rheumatoid arthritis	5 (5.5)	5 (9.0)	0.31
Total arthroplasties, n (%)	60 (60.6)	36 (66.6)	
Hybrid	10 (10.1)	5 (9.2)	0.72
Total cementation	50 (50.5)	31 (57.4)	
Bipolar hemiarthroplasty, n (%)	38 (38.8)	19 (35.18)	
Follow-up, months (mean, SD)	48 ± 3.1	46 ± 2.6	0.54

SD = standard deviation; CCI = Charlson comorbidity index; ASA = *American Association of Anesthesiologists*.

Clinical-Functional Outcomes

There were no significant differences in preoperative (domestic 5.9 ± 0.7 vs. imported 5.7 ± 0.9; p = 0.78) or postoperative (domestic 5.3 ± 0.4 vs. imported 5.5 ± 0.6; p = 0.88) Parker scores between the two groups.

The mean Harris Hip Score (HHS) at the conclusion of the study was 88.9 ± 6.7, with no significant differences between the domestic (84.5 ± 6.6) and imported (85.9 ± 7.5) cement groups (p = 0.28).

Radiographic Outcomes

Thirty (37%) of the 81 cemented cups exhibited demarcation lines at the end of follow-up: 28 in zone 1 and two in zones 1-3, all of which measured less than 1 mm.

Regarding the stems, nine (5.9%) showed demarcation: six in zone 2 and three in zones 2 and 6, with no progression by the end of the study. No significant differences were found between the groups concerning the incidence of demarcation in either acetabular cups or stems (Table 3).

Table 3. Comparative radiographic outcomes.

Variable	Domestic cement (n = 99)	Imported cement (n = 54)	p
Dorr classification, n (%)			
A	4 (4.5)	3 (5.5)	
B	35 (35.5)	21 (38.0)	0.80
C	60 (60.0)	30 (55.5)	
Antibiotic-loaded cement, n (%)	95 (95.6)	50 (92.6)	0.37
Quality of cementation, n (%)			
Barrack A	59 (59.5)	31 (57.4)	0.79
Barrack B	40 (40.5)	23 (42.6)	
Demarcation, n (%)			
Cup	19 (38.0)	11 (35.5)	0.86
Stem	5 (5.0)	4 (7.4)	0.35

Complications, Revisions, and Mortality

There were nine (5.9%) complications: six (6%) in the domestic cement group and three (5.4%) in the imported cement group, with no significant difference between the two (p = 0.99) (Table 4). There were seven (4.6%) revisions: four (2.6%) in the domestic cement group and three (1.9%) in the imported cement group, with no significant difference (p = 0.69). Two (2%) patients in the domestic cement group and one (1.8%) in the imported cement group developed periprosthetic infections at 8, 11, and 16 months, respectively. All were treated with two-stage revision surgeries that successfully eradicated the infections. Three patients experienced periprosthetic fractures due to falls: two (2%) in the domestic cement group, requiring prosthesis replacement, while the remaining patient was treated with osteosynthesis.

In the imported cement group, there was one case (1.8%) of dislocation, which required revision surgery with the placement of a dual mobility cup; no recurrences were noted by the end of the study.

Table 4. Comparison of complication rates.

Complications n (%)	Domestic cement (n = 99)	Imported cement (n = 54)	p
Periprosthetic infection	2 (2.0)	1 (1.8)	0.99
Dislocation	0 (0.0)	1 (1.8)	0.12
Aseptic loosening	0 (0.0)	0 (0.0)	-
Periprosthetic fracture	2 (2.0)	1 (1.8)	0.99
Cement syndrome	0 (0.0)	0 (0.0)	-
Deep vein thrombosis	2 (2.0)	0 (0.0)	0.54

The overall mortality rate for the series was 4.6% (n = 7). Three patients (7%) in the domestic cement group and four (7.4%) in the imported cement group died (p = 0.25). The overall prosthesis survival rate was 95.4% (96% in the domestic cement group and 94.5% in the imported cement group) (p = 0.69). No significant differences in prosthesis survival were observed at 30 days (p = 0.66), at one year (p = 0.70), or at the end of the study (p = 0.69) (Figure).

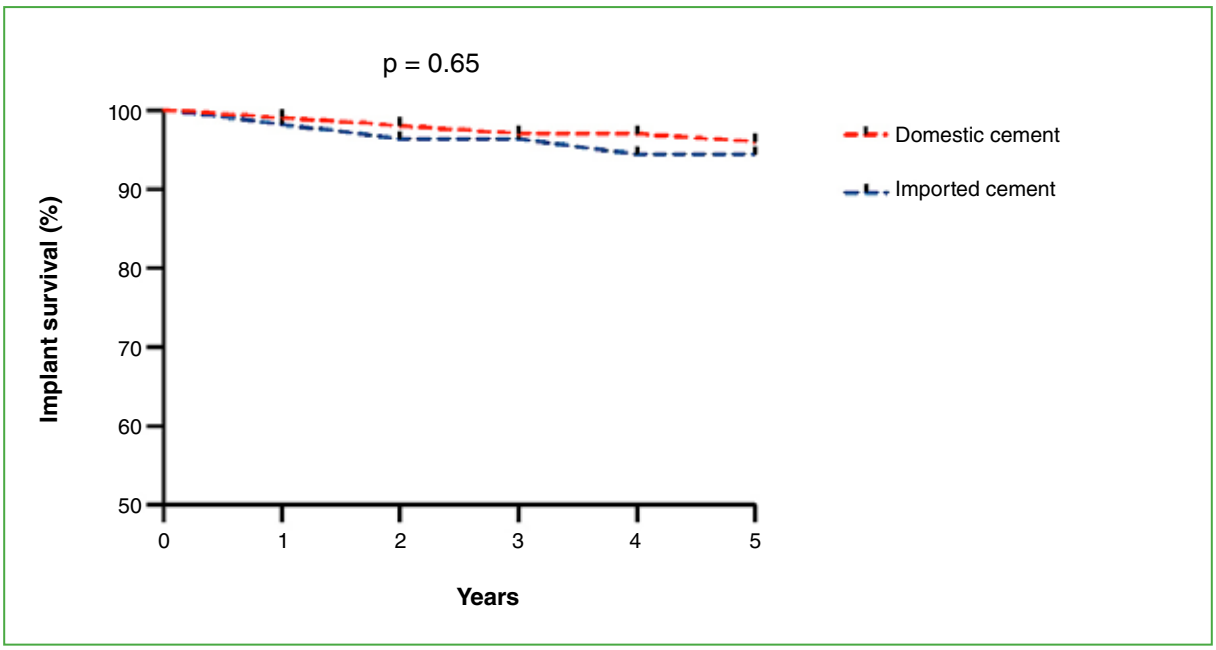

Figure. Survival analysis with the Kaplan-Meier method, without significant differences.

DISCUSSION

The most important finding of our study is that there was no significant difference in clinical-radiographic outcomes or prosthesis survival between domestic and imported cement used in hip fractures treated with arthroplasty. This supports our initial hypothesis.

Although the use of cementless components in hip arthroplasty has increased in recent decades,[22] several authors have reported excellent short-, medium-, and long-term outcomes with cemented replacements. Liu et al.[22] observed that the Harris Hip Score (HHS) was significantly higher in the cemented group compared to the cementless group (cementless 74.09 ± 6.23 vs. cemented 79.01 ± 10.21, p = 0.012) in 461 hip arthroplasties with a minimum follow-up of 5 years. Similarly, Mao et al.[23] reported on 268 patients treated with cemented vs. cementless hip arthroplasty with a minimum follow-up of 5 years, showing HHS scores of 79.39 ± 16.92 vs. 74.18 ± 17.55 (cemented vs. cementless, respectively, p = 0.011).

In our study, in line with the findings of these authors,[22,23] patients returned to their pre-fracture activity levels, one of the main goals of treatment, and achieved good functional outcomes at the end of follow-up. Furthermore, no significant differences were observed in these scores based on the origin of the cement, which we attribute primarily to proper surgical technique. At the end of the study, 37% of the acetabular cups showed signs of demarcation, but no progression was observed. Ritter et al.[24] reported that early signs of demarcation around cemented cups could increase the likelihood of early loosening by almost 28%. However, Takaoka et al.[25] conducted a radiographic analysis of 187 hip arthroplasties and found radiolucent lines around the cups in 21.2% of cases after 12 months or longer, with none progressing during an average follow-up of 13 years. These lines had no impact on functional outcomes or prosthesis survival.

One of the most common long-term complications of cemented stems is mechanical loosening.[26] Beckenbaugh et al.[27] described loosening rates of 20-24% after 5 years of follow-up, increasing to 40% after 10 years. In our study, no mechanical loosening was recorded, although the rate of demarcation around the stems was 5.9%. This may be related to the relatively short follow-up in our series. There were no significant differences in the incidence of demarcation between the acetabular components (domestic 38% vs. imported 35.5%; p = 0.86) or the femoral components (domestic 5% vs. imported 7.5%; p = 0.35).

The use of cemented components has been associated with complications such as "cement disease"[28] or "cement-bone implantation syndrome".[29] In this study, no cases of this syndrome were observed, which may be attributed to its low incidence (approximately 2-5%)[29] and the relatively small sample size. The overall complication rate in our study was 5.9% (n = 9), with no direct relationship to the origin of the cement. The domestic cement group showed a slightly higher complication rate (6% vs. 5.4%), but this difference was not statistically significant (p = 0.99). This could be related to the significantly higher percentage of patients with a Charlson comorbidity index >5 in the domestic cement group.[30,31] This contrasts with Espehaug et al.,[32] who analyzed 17,323 arthroplasties and found that the adjusted 10-year failure rate ranged from 5.9% for PALACOS®-fixed implants containing gentamicin to 17% for those fixed with CMW3®. The estimated overall prosthesis survival rate in our study was 95.4% after an average follow-up of almost 5 years, with similar rates in both the domestic cement group (96%) and the imported cement group (94.5%). These findings are consistent with Hailer et al.,[33] who analyzed 170,413 arthroplasties from the Swedish registry and found a 94% survival rate after 10 years. Likewise, Kam et al.[34] reported a survival rate of 88% in a study of 168 patients with cemented arthroplasties followed for 18 years. We believe that the high prosthesis survival rate observed in our study is related to the appropriate surgical technique, as all patients, regardless of the cement's origin, had good cementation quality (Barrack A or B).

To our knowledge, this is the first study to perform a sub analysis of the results of cemented arthroplasty according to the origin of cement manufacture.

To our knowledge, this is the first study to conduct a sub analysis of cemented arthroplasty outcomes based on the origin of cement manufacture.

Our study has some limitations, including its retrospective design and the relatively small sample size. It is important to note that these are preliminary short-term results. Additionally, the findings may be influenced by the fact that the study was conducted in a high-volume arthroplasty center with surgeons experienced in this type of procedure. However, we believe this study provides a foundation for future research that can establish more definitive conclusions with a higher level of evidence.

CONCLUSIONS

The use of cemented components remains a viable strategy for hip fracture arthroplasty, with excellent short- and medium-term outcomes and survival rates. The findings of this study suggest that the manufacturing origin of the cement (domestic or imported) does not significantly impact outcomes. We will continue to analyze this series to establish long-term results.

Conflict of interest: The authors declare no conflicts of interest.

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