

Clinical and Radiographic Analysis of the CEMENTFREE® Uncemented Hip Stem of National Manufacture. Short-Term Results

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ABSTRACT

Introduction: The stability of the femoral component and its resistance to subsidence are critical factors to achieve correct osseointegration and subsequent clinical success in cementless total hip arthroplasty. Few studies have evaluated the results of nationally manufactured stems, even in the short and medium term. Our objective is to clinically and radiologically analyze patients undergoing a total hip replacement with a nationally manufactured femoral component (Cementfree® stem). **Materials and Methods:** We carried out a retrospective study on patients who had undergone a total hip replacement with the Cementfree® stem between January 2015 and August 2020 by the same surgeon and at the same institution. **Results:** 46 uncemented stems were implanted in 42 patients with an age range between 60 and 81 years. The average follow-up was 3 years, with a minimum of 1 year and a maximum of 5 years. There was an evident improvement in the *Harris Hip Score* (an average of 47 preoperatively vs. 93 after surgery). The revision of the stem for aseptic loosening, in the Kaplan Meier analysis, demonstrated a 100% survival rate at 5 years. **Conclusion:** According to the results obtained in this research, hip arthroplasty with the nationally manufactured Cementfree® stem has proven to be an option comparable to other imported stems in terms of short-term clinical and radiographic outcomes. An evaluation of the outcomes in the medium and long term is pending.

Keywords: Arthroplasty; cementless prosthesis; metaphyseal fixation; osseointegration.

Level of Evidence: IV

Análisis clínico y radiográfico del vástago de cadera no cementado "CEMENTFREE"® de fabricación nacional. Resultados a corto plazo

RESUMEN

Introducción: La estabilidad del componente femoral y su resistencia al hundimiento son factores críticos para lograr una correcta osteointegración y el éxito clínico de la artroplastia total de cadera no cementada. Hay pocos estudios que evalúen los resultados con vástagos de fabricación nacional, aun los de corto y mediano plazo. El objetivo de este estudio fue realizar un análisis clínico y radiográfico de pacientes sometidos a un reemplazo total de cadera con implante de un componente femoral de fabricación nacional (CEMENTFREE®). **Materiales y Métodos:** Se llevó a cabo un estudio retrospectivo con pacientes sometidos a un reemplazo total de cadera con vástago CEMENTFREE®, entre enero de 2015 y agosto de 2020, a cargo del mismo cirujano y en la misma institución. **Resultados:** Se implantaron 46 vástagos sin cementación en 42 pacientes (rango etario: 60-81 años). El seguimiento promedio fue de 3 años (mín. 1 año, máx. 5 años). Aplicando el *Harris Hip Score* se observó una franca mejoría (promedio 47 en el preoperatorio y 93 después de la cirugía). La tasa de supervivencia fue del 100% a los 5 años. **Conclusión:** La artroplastia de cadera con el vástago CEMENTFREE® de fabricación nacional ha demostrado ser una opción comparable con otros vástagos importados, en cuanto a los resultados clínicos y radiográficos a corto plazo. Resta evaluar los resultados a mediano y largo plazo.

Palabras clave: Artroplastia; prótesis no cementada; fijación metafisaria; osteointegración.

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INTRODUCTION

Total hip replacement is one of the most successful procedures in Orthopedics and Traumatology, with long-term prosthesis survival rates of 95% at 15 years.¹ In recent decades, numerous uncemented stems have been developed and used in clinical practice. Clinical success depends on several factors: surgical technique, implant design, characteristics of the prosthesis surface, prosthesis material, type of fixation and, of course, the patient.² In 2010, the National Administration of Drugs, Food and Medical Technology (ANMAT) approved the CEMENTFREE® stem, manufactured by the company IMECO S.A., and it began distribution in Argentina and South America that same year. In 2015, we began using the CEMENTFREE® stem at our institution. The objective of this study was to perform a clinical-radiographic analysis of patients undergoing total hip replacement with the CEMENTFREE® stem of national manufacture, evaluating functional and radiographic outcomes, implant survival, and possible postoperative complications.

Materials and methods

We retrospectively evaluated total hip replacements performed between January 2015 and August 2020. All patients were implanted with the IMECO S.A. CEMENTFREE® femoral stem (Figure 1).



Figure 1. IMECO S.A. CEMENTFREE® stem.

The inclusion criteria were: patients with a diagnosis of disabling hip osteoarthritis of any etiology, who received a CEMENTFREE® stem implant with Dorr A and B femur geometry,³ regardless of age and sex.

Patients with a Dorr C index, patients with incomplete data recording that prevented adequate clinical and radiographic follow-up, and those with fractures were excluded.

In this series, all patients were evaluated by radiographs taken before surgery and in the immediate postoperative period, at 3, 6, and 12 months, and annually thereafter. Regarding the radiographic analysis, the “metaphyseal area” was considered to be Gruen zones 1, 2, 6 and 7, rough coating zones (Figure 2).⁴

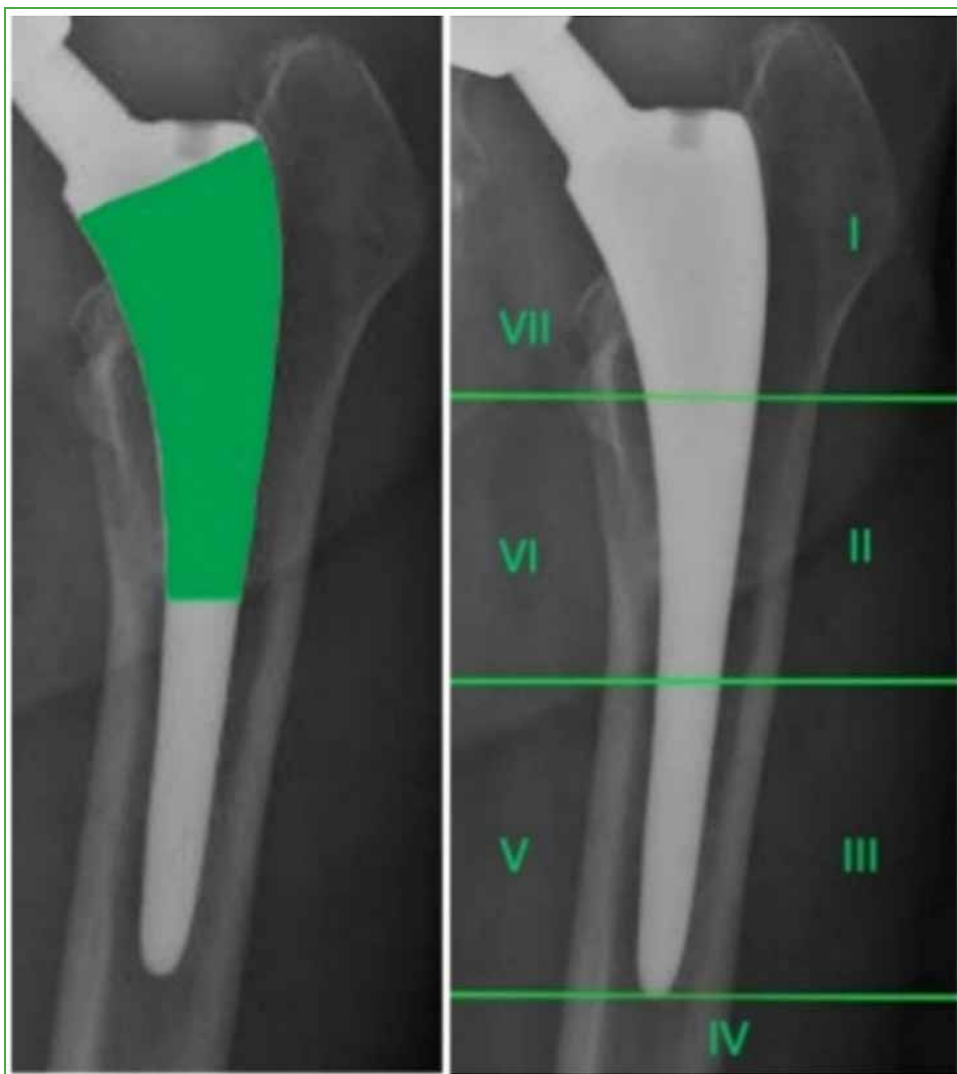


Figure 2. Rough coating areas

The variables that were considered in the analysis of the anteroposterior radiographs, according to Engh's criteria⁵ were: 1) sinking of the femoral stem >2 mm. There are several ways to measure subsidence. Radiostereometric analysis is the most reliable, with a precision of 0.2 mm, but it requires prospective planning, the implantation of tantalum markers, and stereoradiographs,⁶ so it is not appropriate for this series. We used the analog method with standard radiographs to determine subsidence; 2) appearance of radiolucent lines >1 mm in the areas where the rough surface of the implant is located (Gruen zones 1, 2, 6 and 7); 3) diaphyseal cortical hypertrophy: arbitrarily defined as cortical increase at the level of the femoral stem; 4) pedestal sign at the tip of the implant; 5) position of the stem: it was considered valgus if there was a lateral deviation >3°; varus, if there was >3° of medial deviation, or neutral.

All the patients were summoned within the aforementioned periods to record their evolution in the clinical records, from where data were collected, such as identity document, age, sex, address, telephone number, history, diagnosis, pre- and postoperative radiological status, date of surgery, implants used, and complications. All these data were processed in Excel spreadsheets for subsequent statistical analysis.

Two scales were used to assess the clinical outcome: the Harris Hip Score (HHS) and the WOMAC (Western Ontario and McMaster Universities Osteoarthritis Index).^{7,8}

Characteristics of the CEMENTFREE® stem

Implant description

It is a GR5 titanium alloy stem (Ti-6Al-4V) whose conical shape both in the anteroposterior and lateromedial directions determines the primary fixation in the metaphysis. At this same level, the stem has a rough titanium coating that ensures secondary fixation by osseointegration (on-growth).^{9,10} The pore of the plasma spray cover has a diameter of between 200 and 400 µm, which allows correct osseointegration of the implant.¹¹⁻¹⁴ In addition to being distally straight and conical, it is rectangular in its proximal portion. According to the classification proposed by Stulberg¹⁵, the stem studied has a metaphyseal fixation. The design offers a radius of medial curvature in an attempt to provide congruence with the morphology of the proximal femur that adjusts to its anatomy, making it particularly more applicable in the femoral calcar area. The distal end is cylindrical, with a smooth and polished surface, to prevent contact and bone growth between the implant and the femoral canal. Therefore, radiolucency and reactive lines around the smooth distal portion do not indicate an absence of osseointegration. This stem offers two offset options: a) the standard 133° and b) the extended 128°, the taper is 12/14. It is available in seven sizes. The mechanical deformation and fatigue tests were carried out at the School of Engineering of *Universidad Nacional de La Plata*, according to IRAM 9422/4 regulations. The analysis of roughness and adherence of the rough coating was carried out at the *Instituto Nacional de Tecnología Industrial (INTI)*.

Surgical technique

Pre-surgical planning was performed to determine the dimension of the components and the geometry of the proximal femur. All surgeries were performed by the same surgical team from the hip pathology unit, Orthopedics and Traumatology Service, *Hospital Central de San Isidro "Dr. Melchior A. Posse", Buenos Aires, Argentina*. The surgeries were performed under spinal anesthesia, with a posterolateral mini-approach. Antibiotic prophylaxis was always indicated with cefazolin 1 g, intravenously, 30 min before the skin incision, in addition to tranexamic acid 1 g, intravenously, at the time of anesthetic induction, according to the protocol of our institution.

Oral dabigatran was prescribed for preventive anticoagulation for 30 days after surgery. 24 hours after the intervention, sitting and standing were indicated.

RESULTS

Seventy-eight patients underwent surgery with the CEMENTFREE® stem, and 42 of them met the inclusion criteria. An uncemented cup was implanted in 31 patients and a cemented cup in the remaining 11. In all cases, a highly cross-linked polyethylene friction couple and a cobalt-chrome head were used, with a head diameter of 28 and 32 mm, determined by the diameter of the cups, which were made of grade 5 titanium with porous plasma-sprayed coating, optionally with three screws. When cementation was necessary, intermediate viscosity cement was used.

The series consisted of 25 women and 17 men, with an average age of 72 years (range: 60-81). Four underwent bilateral two-stage replacement. The morphotype of the femoral canal was classified according to Dorr: 89% type A (37 patients) and 11% type B (5 patients) (Figure 3). The mean postoperative follow-up was three years (range: 1-5).

Clinical evaluation

The functional outcomes were evaluated using the HHS and WOMAC, taking into account the preoperative period and the last control (Table 1). According to the HHS, the results were: excellent in one patient (2.5%), good in 40 (95%), fair in one (2.5%), and none were dissatisfied. The HHS changed, on average, from 47 (range: 28-74) before surgery to 93 (range: 71-97) after surgery. Regarding the WOMAC, the preoperative values indicated that 82% reported poor quality of life, but this value was modified and reached a satisfaction average of 99% after surgery.

Table 1. Functional scale

	WOMAC	HHS	Preoperative period		Last follow-up visit	
			WOMAC	HHS	WOMAC	HHS
Excellent	≤15	70-80	0%	0%	99%	95%
Good	≤30	60-69	0%	0%	1%	2.5%
Fair	≤50	50-59	18%	14%	0%	2.5%
Poor	≤90	≤50	82%	86%	0%	0%

HHS = Harris Hip Score, WOMAC = Western Ontario and McMaster Universities Osteoarthritis Index.

Radiographic analysis

The radiographic evaluation was carried out by an independent observer. The radiographs were compared and the analysis arose from the evaluation of the immediate postoperative radiograph and the last one recorded in an outpatient radiographic control available to the patient. Circumstantially, radiolucencies and calcar atrophy were recorded (zones 1 and 7, respectively). Since the radiolucencies found in zone 1 compromised <50%, they were not predictive of lack of osseointegration, according to Engh. Calcar atrophy was recorded in two patients, the development of which took place during the first two years. Implant subsidence of 3 mm was recorded in three patients. Despite this subsidence, the stem stabilized and osseointegrated correctly within the first three months. There was no implant fatigue, nor were there any cases of misalignment in the coronal plane (Table 2).

Table 2. Radiographic signs

Radiographic signs	Number of cases	Time of appearance
Radiolucency		
Zone 1	3	0
Zone 2	0	0
Zone 3	0	0
Zone 4	0	0
Zone 5	0	0
Zone 6	0	0
Zone 7	0	0
Sinking >2mm	3	1 year
Implant fatigue	0	0
Calcar atrophy	2	2 years
Component Orientation		
Varus	0	0
Valgus	0	0

Survival

All implants remained with stable bone fixation. One stem was removed due to a late infection of the prosthesis. It should be noted that it was fully osseointegrated and bone growth could be observed macroscopically in the porous coating area. Stem revision for aseptic loosening as an endpoint had a 100% survival rate at 5 years in the Kaplan-Meier analysis (Figure 3).

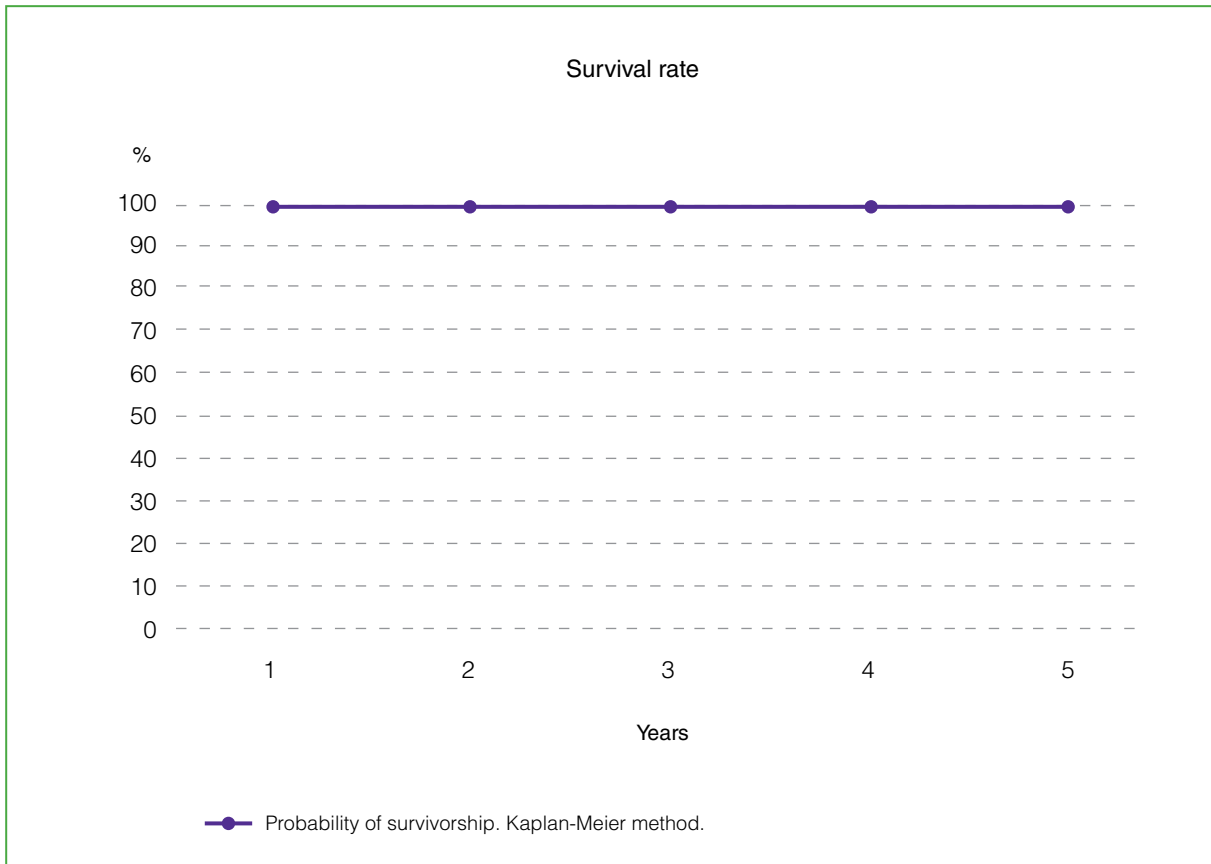


Figure 3. Kaplan-Meier analysis.

Complications

Three complications related to the surgical technique were recorded, accounting for 6.52% of the patients. *Surgical site infection*: an infected patient who underwent two-stage revision surgery.

Prosthesis dislocation: one patient suffered an episode of dislocation five days after surgery due to excessive hip flexion; a closed reduction was achieved under radiographic guidance. After reduction, radiography and computed tomography images were evaluated, showing the orientation of the well-anteverted components within the Lewinnek safety zone.

Neuropraxia: one patient evolved with symptoms of sciatic nerve injury, possibly due to unintentional indirect compression with the instruments, which manifested with compromised knee flexion, as well as compromised extension, flexion, inversion, and eversion of the foot. Knee extension remained normal. The neuropraxia completely reversed at seven months.

DISCUSSION

Femoral stem failures may be due to various factors, among which the following stand out: design, mineral composition, manufacturing technique, modularity, and technique.^{16,17} The clinical outcomes of our series are excellent and all stems were considered stable in the last radiographic control, despite the percentage of radiolucency in Gruen zone 1 that we found in our series, which could be due to the conical characteristic of the implant that causes it to be fixed distally in the metaphyseal zone, where the spot welds are observed in all cases. No stem suffered significant vertical subsidence that compromised its stability, or misalignment in the coronal plane (variation-valgization) after its implantation; the change in the initial position of the stem during the first two years after its implantation is associated with a higher rate of aseptic loosening, due to imperfect initial fixation.¹⁸ It should be noted that, during revision for infection in one patient, we observed macroscopic evidence of a direct, structural and functional connection between the bone and the surface of the weight-bearing implant. Despite the infection, complete osseointegration was achieved. It was the only stem we had to remove. When we analyzed the implant's adaptation and canal filling according to femoral morphology,¹⁹ we observed that there was complete contact between the entire surface of the implant and the bone in Dorr A femurs, and only metaphyseal contact in Dorr B femurs, which could be explained because the CEMENTFREE® stem is conical at the metaphyseal level and cylindrical at the distal portion and, in Dorr B cases, bicortical contact at the distal level is not always achieved. This did not represent a disadvantage given that the initial metaphyseal contact stabilized the implant and successfully achieved osseointegration. We adhere to the concept of Bochaty and Lopreite that every new implant entails a learning curve inherent in the adaptation process for its placement by the surgeon.²⁰ This series indicates an excellent success rate in the short term, since there were no intraoperative complications, such as calcar fracture. We attribute this advantage to the curvature of the implant on its medial side, which allows a more anatomical and convenient fit with the calcar femorale.²¹ There are few published clinical studies on the short-term survival of nationally manufactured implants. In international literature, the situation is similar. Steens et al. reported the clinical outcomes of an uncemented prosthesis with a 98% survival rate at six years of follow-up.²² In the article by Santori et al. on the use of an uncemented prosthesis with a metaphyseal fixation stem, a survival rate of 96% was reported at eight years of follow-up.²³ Kim et al. reported survival rates of 100% in 144 patients, with a follow-up of 4.5 years. It is important to note that this follow-up is relatively short.²⁴ Few publications have studied and determined the survival of this or another domestically manufactured stem in Argentina. Therefore, it seems important to us to continue studying and analyzing the results obtained to date in the medium and long term, given that the rate of complications to date seems to be very similar to that of traditional stems, as can be seen from the study by Cornel.²⁵ As the short-term results of the CEMENTFREE® stem have been excellent, we consider it important to study the evolution of the series every five years, intending to evaluate the medium- and long-term results.

This study has two limitations: it is retrospective, which could produce an information bias. The number of patients is low and prevents an adequate statistical evaluation, there is no control group and the follow-up is short. These aspects, together with the need for a longer follow-up in order to evaluate long-term complications, could have given greater generality to the inferences obtained, as well as reliability to the estimation of the probability of duration of the implant in the face of complications or other relevant events. As for strengths, we can mention that all patients were operated on by the same surgical team, which guaranteed a correct evaluation in terms of surgical technique and results. It is also an original and unpublished work, since it is based on the study of an uncemented stem of national manufacture. To date, all publications are about imported stems.

CONCLUSION

Hip arthroplasty with the CEMENTFREE® stem is an excellent short-term option for femoral hip replacement.

Conflict of interest: Dr. Carlos Vega: IMECO SA Consultant. The rest of the authors declare that they have no conflicts of interest.

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