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Review and Case Report

Failure of the Compress® Prosthesis in an adolescent patient.

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Abstract: Introduction: Limb-sparing surgery after resection of a bone sarcoma 5 in the distal femur is a commonly performed procedure that, in young patients with the 6 classic systems, involved compromise of bone stock in subsequent revision surgeries. The search for new 7 systems with less aseptic loosening and less compromise of this stock has 8 led to the appearance of Compress® technology, ; (2) Material and Methods: we present the clinical case 9 of a 14-year-old male with osteosarcoma of the distal femur, in whom limb-preserving surgery was performed 10 with Compress® prosthesis; Results: 8 months after surgery , a peri-implant fracture 11 occurred as a complication, with replacement of the system without incident, without considerable 12 bone loss; Conclusions: osseointegrated compression systems are a valid option 13 for the surgical management of large bone defects. More long-term studies are necessary 14 to know its long-term survival and the factors involved in it.

Keywords: osseointegration, osteosarcoma, reconstruction, periprosthetic fracture, Compress, 16 prosthesis failure.

1. Introduction

Limb-sparing surgery after resection of a bone sarcoma in the 22 distal femur is a commonly performed procedure for the surgical management of 23 this pathology [1]. Classically, reconstruction has been carried out with long-stemmed tumor megaprostheses , both cemented and uncemented [2], the main cause of revision surgery being aseptic loosening [1,3] .

With an affected population that is generally young, and increasing survival rates 28 , the possibility of revision surgery is virtually assured 29 . So, if we assume a 50% implant survival at 15 years, 30 in an adolescent who survives a femoral bone sarcoma, at 50 years of age he may have undergone 31 two revision surgeries [4] .

In this context of the need for devices with greater survival, the 34 Compliant Pre-Stress (CPS) technology arose, where we found the so-called Compress® 35 prosthesis . The objective of this prosthesis is to achieve absolute stability through the 36 application of axial compression forces at the bone-implant interface, following the 37 principles of Wolff's Law. All of this, together with bone hypertrophy at the interface, a low 38 invasion of the medullary canal and the decrease in “stress shielding”, minimizes the 39 loss of bone stock [3]. Therefore, it has been considered that, in the long term, it could have 40 lower rates of aseptic loosening than traditional devices [5].

Without long-term clinical trials demonstrating the superiority of 43 CPS devices compared to traditional ones, the simplification of the management of periprosthetic 44 fractures that occur with the Compress® prosthesis is another point in favor of the use 45 of CPS technology [6].

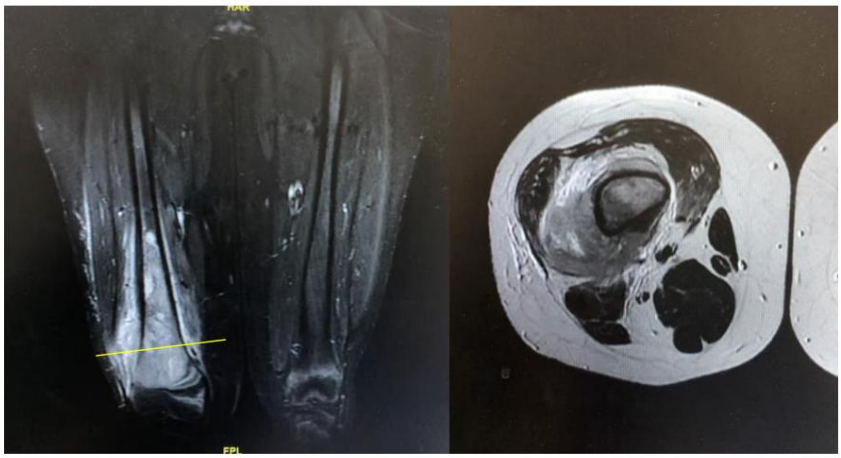
Below, we present the clinical case of a 14-year-old male patient, 48 wearer of a Compress® femoral prosthesis, who required revision surgery in the context of 49 a periprosthetic fracture of the femur.

2. Clinical case.

A 14-year-old male with no personal history of interest. He went to the 53 emergency department of his hospital for the first time , due to pain in the right thigh of two months' evolution. In the 54 emergency room, an examination was performed, palpating a mass at thigh level, after which an X-ray and 55 CT scan of the extremity was performed. He was referred to the Musculoskeletal Tumors 56 unit with suspicion of a malignant-looking bone tumor in the right femur.

An MRI of the right thigh was performed [Figure 1], extension study 59 and biopsy was taken, diagnosing high-grade conventional osteosarcoma, epithelioid lineage 60 , with no evidence of disease in other locations.

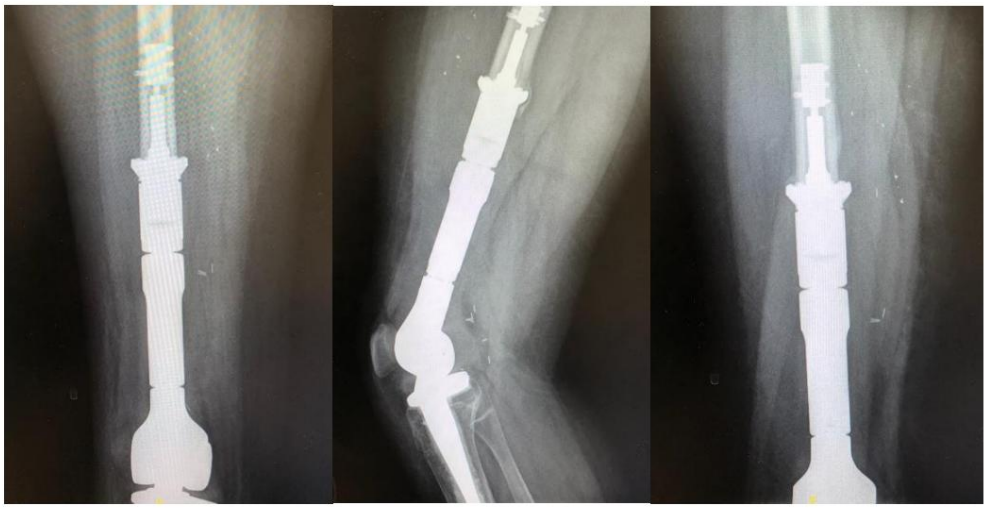
Treatment with the GEIS-33 protocol for localized osteosarcoma was started.



(to) **(b)**

Figure 1. Images obtained from the initial study with MRI of the right thigh **(a)** coronal section; **(b)** and axial section.

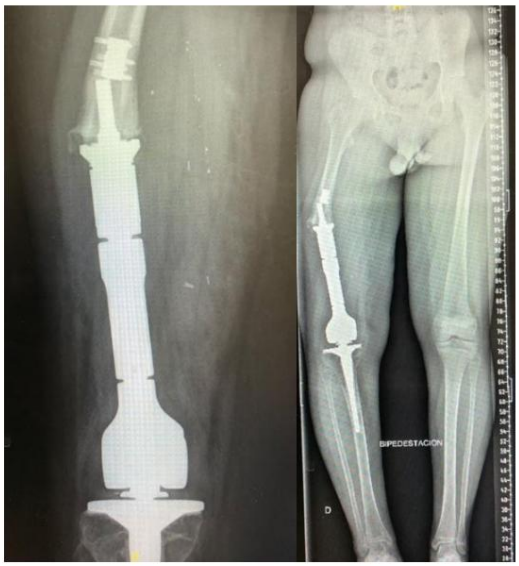
Two months after the start of neoadjuvant chemotherapy, tumor resection surgery is performed [Figure 2]. A medial parapatellar approach is made which is extended 71 along the medial aspect of the thigh. The femoral bundle was meticulously dissected and the tumor mass was resected en bloc 72 , resecting the distal 22 cm of the femur 73 along with part of the vastus medialis, laterals, and rectus femoris. After confirmation by Pathological Anatomy 74 of the presence of free margins, the Compress® 75 fixation system is placed . Only 4 pins can be put in and a compression of 800 76 pounds is applied. Subsequently, the prosthesis is placed in the femur and tibia, verifying correct 77 stability.



(to) (b) **(c)**

Figure 2. (a) Postoperative radiological control after the first intervention, where one of the pins is observed outside the anchorage cylinder. **(b)** Control 6 months after surgery where bone growth is seen in the posterior cortex and **(c)** in the medial and lateral cortices.

In the postoperative control X-ray, as findings, one of the 85 pins is observed outside the anchoring cylinder, thus the total number of effective pins being three. 86 After correct evolution on the ward, the patient was discharged without indication of support but 87 allowing active mobilization exercises. After two months of discharge, 88 began with progressive support until, 10 months after surgery, the patient attended 89 outpatient clinics reporting pain in the right thigh, with difficulty walking 90 and progressive deformity at that level that had been observed for 2 years. months. The radiographic 91 study carried out in consultations [Figure 3] shows a periprosthetic fracture of the right femur with 92 rupture of the implant. The study was completed with a CT of the right thigh.



(to) **(b)**

Figure 3. (a) Control X-ray in outpatient clinic showing the periprosthetic fracture and implant rupture together with **(b)** telemetry.

The patient is scheduled for a new intervention, preferably to replace the 99 femoral component of the prosthesis [Figure 4]. To do this, using a double 100 approach; medial and lateral parapatellar over the middle third of the femur; 101 complete extraction of the prosthesis was performed , without incident, after removing the locking pins. The 102 distal 3 cm of the femur are resected , obtaining healthy and bleeding bone on which a new 800-pound Compress® prosthesis is placed, 103 with 4 pins correctly positioned 104 in the postoperative control X-ray.

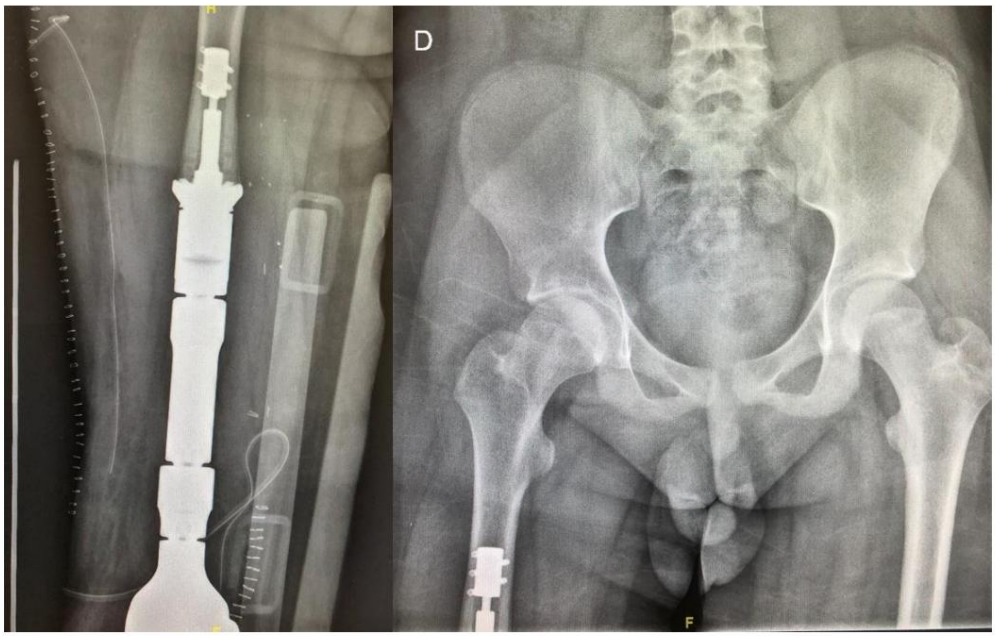


Figure 4. Radiographic control after revision surgery for peri-implant fracture.

3. Discussion

The Compress® prosthesis is based on the biomechanical principle of compressive 112 osseointegration , which seeks a greater coaptation between bone and implant, through a 113 porous titanium surface, through the application of continuous axial compression forces 114 between the two components [4].

This continuous compression is achieved involving a small amount of bone, since 117 only the presence of 8 cm of intramedullary canal is necessary to anchor the prosthesis [1, 5]. 118 Anchorage is performed through a titanium traction bar stabilized by bicortical pins 119 (usually 5) that connects with a cylinder that, at its contact end 120 with the bone, presents a concave porous titanium surface and, in the opposite end, 121 a compression bolt. When tightening said bolt, thanks to the action of the 122 Belleville washers that it houses inside, a compression force is produced between the bone 123 and the porous surface [4, 7][Figure 5]-

The applied compression force varies between 400-800 pounds [Table 1] and supposes 126 an immediate stable fixation of the implant, promotes bone hypertrophy at the end 127 in contact with the prosthesis, minimizes the appearance of stress-shielding and reduces the intramedullary 128 occupation of the bone and its exposure to particles that participate in 129 loosening. All of this aims, in theory, to reduce the rate of aseptic loosening 130

and thereby increase long-term implant survival, as well as preserve the patient's bone stock to the maximum for future surgeries [1, 2, 3, 4, 5, 7] .

These characteristics make it a very valid theoretical option for the reconstruction of large bone defects, although the authors contemplate a series of contraindications such as active or latent infection, mental conditions that prevent following strict guidelines for postoperative treatment or low quality bone or cortical thickness less than 2.5 mm that prevent stable fixation of the device [5].

Cortical thickness (mm)	Force (lbs)	Force (kg)
0.0 – 2.4	contraindicated	contraindicated
2.5 – 3.9	400	181
4.0 – 5.4	600	272
Greater than 5.5	800	363

Table 1. Depending on the thickness of the measured cortical bone, the use of a determined compression force is recommended. In the left column, its equivalence in kg. Applying insufficient force to the thickness of the patient's cortex can lead to failure due to loosening of the device , while excessive force can lead to periprosthetic fractures [5,8].

Although compressive osseointegration seems to be the definitive solution to the problems posed by reconstruction surgery for large bone defects, the literature published to date is scant, especially when it comes to long-term results. It seems that the survival of the prosthesis in terms of aseptic loosening is around 85% at 5 years [5] and 80% at 10 years [1] In medium-short-term studies, with follow-up between 2 and 5 years, shows aseptic loosening rates similar to those reported in cemented and uncemented implants, but with a difference in the time to onset of the complication [1, 5, 8, 9]. It seems that failures of the Compress® prosthesis tend to occur above all in the first two years after surgery, to later stabilize ; while in conventional implants, the trend over time is to increase. Knowing this trend, different authors defend that the long-term results in terms of loosening rate will show a superiority of the Compress® prosthesis with respect to conventional tumor prostheses [5, 8, 9].

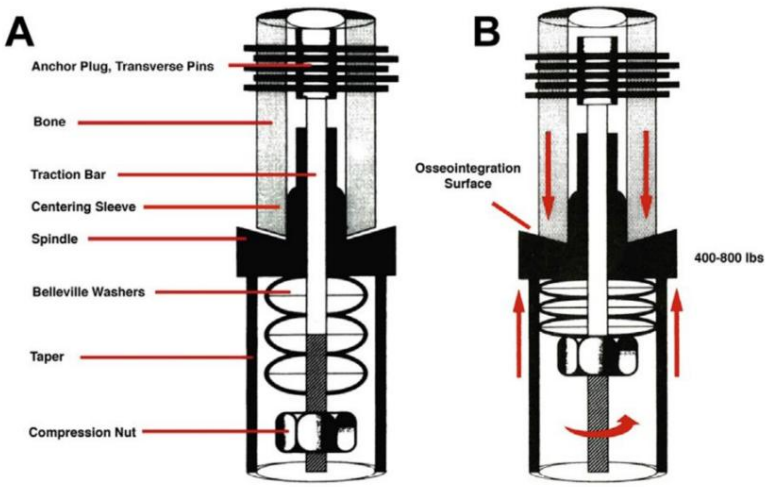


Figure 5. Diagram of components and operation of the implant. Once the anchorage cylinder is fixed, after tightening the compression bolt, compression forces are produced on the porous concave surface of titanium with the bone, which are around 400 to 800 lbs.

Likewise, the association of several factors in the appearance of aseptic loosening has been studied . No direct association has been found between factors specific to the patient such as sex, BMI, initial diagnosis, neoadjuvant, adjuvant or radiation, although in patients who have received preoperative chemotherapy there is a longer time until the appearance of radiological signs. of osseointegration. The amount of compression applied does not seem to be involved in the rate of loosening either, as long as the limits imposed by the thickness of the cortices are respected. In order to reduce mechanical failures due to torsional forces, biomechanical studies support the use of antirotational pins at the bone-implant interface. The surgical technique recommends the use of three anti-rotational pins, although several authors defend that the use of these pins could be associated with osteonecrosis due to interruption of vascular supply and fractures at this level. Without clear factors involved in the failure of the prosthesis, studies carried out on Compress® prostheses revised due to failure, show a different bone tissue than presented in those revised for another reason, with bone necrosis at the level of the osteoin- integration, which could be related to thermal necrosis or excessive periostization during bone preparation [4, 5, 7, 8].

Aseptic loosening should be suspected in patients with increased tenderness in the thigh and pain with hip rotations and flexion. The initial study must include radiographs of the affected limb. The parameters suggestive of failure of the prosthesis that can be found in radiography are: the progressive decrease in the distance between the anchorage and the centering ring, deformation of the implant that suggests it is bent or broken, and atrophy at the bony interface. [5] [Figure 6].

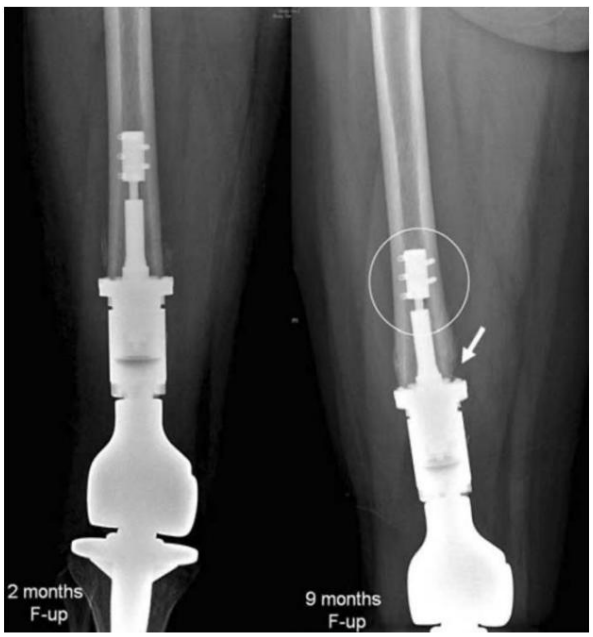


Figure 6. Control at 2 months and 9 months of the Compress® prosthesis, observing a failure of the system in the last control, with atrophy in the bony interface and shortening of the distance between the anchorage and the centering module [1].

In view of the management of failures of this prosthesis, a classification of 199 them has been made into three types depending on whether there is an isolated loosening, a fracture or 200 bone failure or both. In type I, there is only one failure in the fixation of the prosthesis, 201 with the indicated treatment being its replacement. In type IIA, there is bone failure 202 without signs of device loosening being observed, so treatment 203 must be aimed at controlling the fracture. In type IIB, both the fixation of the prosthesis 204 and the bone are affected, so a device replacement should be considered, 205 which can be either a new Compress® or a conventional device with a long stem 206 [8].

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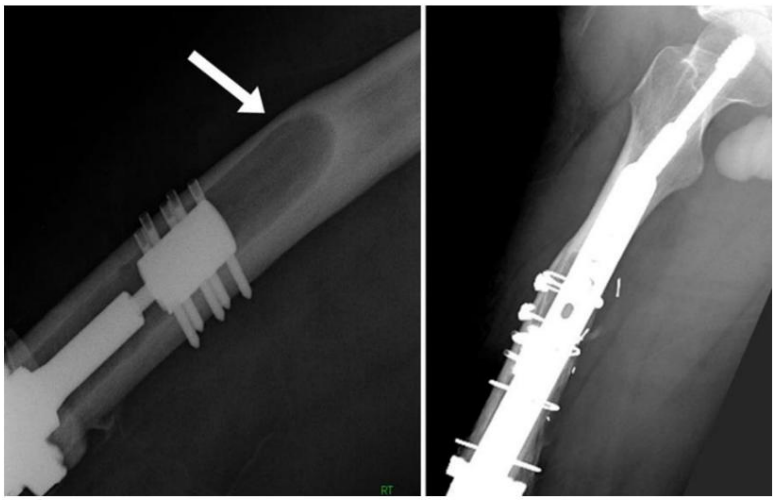

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Figure 6. Type IIA periprosthetic fracture managed with allograft and nail-sliding plate osteosynthesis [8].

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The replacement of the Compress® prosthesis is one of the main advantages that this device 214 offers us since, compared to conventional prosthesis replacements, 215 it means less surgical time and less loss of bone stock. Due to the short 216 intramedullary course, the absence of cement, and the ease of removal of the anchor with 217 pins, a resection of more than 3 mm is rarely required in aseptic loosening without 218 associated fracture. On some occasions, it is possible to replace only the 219 compression system, leaving the knee prosthesis intact. Several authors agree on the 220 advantage of the technical ease of replacement of this prosthesis and the opportunity for 221 replacement that it offers to young patients without requiring a total femur prosthesis or amputation 222 due to lack of bone stock [5, 8].

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4. Conclusions

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In our patient we consider the failure of the prosthesis, within the first two 227 years after surgery, could be due to the presence of only 3 effective stabilizing pins 228 , together with a situation of delayed osseointegration such as chemotherapy- 229 neoadjuvant pia. Osseointegrated compression systems are a valid option for 230 managing large bone defects in the distal extremity of the femur, although they are still a demanding 231 option from a surgical point of view.

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