

Brief communication

Preliminary outcomes of proximal femur megaspacers

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ABSTRACT

There are very few therapeutic alternatives for patients with proximal femoral epiphyseal bone deficit combined with a fracture at another level and signs of infection. This combination can be successfully managed with a proximal femur megaspacer. This article is intended to review our variation of this technique and to show the initial results obtained from 11 cases. Of these 11 cases, there were 6 women and 5 men. The mean age was 66 years. The average number of previous surgeries was 3. Definitive prosthetic reconstructive treatment was achieved in 7 of these 11 subjects. The average time to reimplantation was 11.7 months. Fractures or nonunion healed uneventfully. Bone union and infection control were achieved in 10 of the 11 patients.

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Introduction

Local antibiotic therapy with polymethylmethacrylate (PMMA) and antibiotic-coated spacers (commercially available or manufactured ad hoc) is a recognized technique usually used by surgeons for prosthetic hip [1–12] and femur shaft infections [13–16]. However, this strategy has some limitations when treating a proximal femur infection and an infected nonunion of diaphyseal fracture (Table 1) (Fig. 1a and b). In this scenario, the implantation of traditional spacers is not feasible. We have used a variation of this surgical technique that combines the benefits of 2 other well-known surgical procedures.

One of them is the implantation of the antibiotic cement-coated intramedullary nails used for the treatment of osteomyelitis associated with fractures or infected nonunions of long bones [13,14,17]. This technique allows intramedullary debridement (through reaming, intramedullary irrigation, and debris removal), provides both fracture stability and high local concentration of antibiotics, and restores limb function by maintaining joint mobility and allowing weight-bearing ambulation.

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The other surgical procedure involves articulated antibiotic-loaded cement hip spacers [1,2,7,12,18]. They are considered the gold standard for the 2-stage treatment of periprosthetic infections [5] with eradication rates higher than 90% in some published series [1,7]. In addition to the local antibiotic release, this procedure has the advantage of maintaining limb length and joint mobility and is characterized by reduced fibrosis and soft tissue contracture, thus favoring second-time reimplantation procedures [3]. By allowing load transmission, demineralization due to disuse is reduced, and bone mechanical resistance is maintained. These spacers achieve excellent acetabular dead space control; however, neither mechanical shaft stability nor optimal intramedullary dead space management are achieved [19,20].

The notion of proximal femur megaspacer arises from a combination of these 2 strategies (Fig. 1c). This technique aims at achieving fracture union and infection control and at favoring a further definitive reconstruction by preserving bone stock (Fig. 1d).

The purpose of this article was to describe the surgical technique and show the initial results of our case series.

Material and methods

We conducted a retrospective analysis of patients treated with this technique between May 2013 and February 2017. We evaluated the medical history, the number of previous surgeries, and the final

Table 1

Variable combinations of femur injuries associated with bone infection.

Proximal femur	Femoral shaft
Infected total hip replacement	Periprosthetic fracture
Infected hip hemiarthroplasty	Infected pseudarthrosis
Avascular necrosis	Femoral shaft fractures (as part of an ipsilateral femoral shaft/femoral neck fractures)
Septic arthritis sequelae	
Proximal femur fractures (as part of a segmental femoral shaft/femoral neck fracture)	

diagnoses that led to the placement of a megaspacer. To assess the infection, deep bone samples were obtained before the surgical intervention.

This technique is intended to achieve consolidation of femoral shaft fractures or nonunion and to control the infection before a definitive prosthetic reconstruction is performed. During the follow-up, we performed anteroposterior and lateral radiographs to evaluate complications and/or signs of union at day 15 and day 45, month 3 and month 6, and then on a quarterly basis. For infection surveillance purposes, laboratory tests (white blood cell count, erythrocyte sedimentation, and quantitative C-reactive protein) were performed monthly.

Immediate and late complications, both intraoperative and postoperative, including subsequent surgeries, were recorded.

Surgical technique

Materials

The surgical table shall include:

- Two surgical cement units to cover the intramedullary nail and 2 units for the cephalic module;
- Antibiotics based on infectious cultures and antibiogram;



Figure 2. Materials used in the proximal femur megaspacer assembly. From left to right: 60-ml syringe, Bonneau syringe, Bonneau syringe with the 60-ml syringe plunger, surgical cement with lyophilized antibiotics, polymerizing solution, rubber bulb of the Bonneau syringe, and cephalomedullary device (LFN DePuy Synthes).

- Cephalomedullary nail (PFN® DePuy Synthes—LFN® DePuy Synthes);
- 60 ml syringe;
- Bonneau/washing syringe;
- Plastic tubes of various diameters: 12, 14, or 16 mm (BT-63, BT-95).
- 24F Foley catheter (Fig. 2).

Preparation and implant assembly

The surgical steps are similar to those described by Sancineto and Barla [13] in 2008. The antibiotic-loaded cement is prepared by adding the lyophilized antibiotic to the cement powder in pre-established quantities (Table 2). Both components were mixed, and the resulting mixture is then mixed with the polymerizing solution.

After reaming the canal, we selected a tube with a diameter 2 mm smaller than the diameter of the femoral canal and an



Figure 1. Anteroposterior radiographs of the left femur of a 68-year-old female at different stages of treatment. (a) First visit, cemented total left hip prosthesis with septic loosening after 2 surgical revisions in another center and a medial cortical perforation; (b) postoperative radiograph after the implant removal. Megaspacer implant had to be suspended because of intraoperative complications (vascular injury associated with intraoperative fracture); (c) immediate postoperative radiograph after proximal femur megaspacer implantation; (d) 6-month postoperative radiograph after reimplantation of distal fixation total hip prosthesis having consolidated the fracture, with normalization of laboratory parameters of infection.

Table 2

Amount of antibiotics per dose of cement.

Antibiotic	Dose
Tobramycin	1 g
Vancomycin	4 g
Imipenem	2 g
Colistin	1 g

intramedullary nail with a diameter 4 mm smaller. For example, if we ream up to 16 mm, the diameter of the tube should be 14 mm, and the diameter of the nail should be 10 mm, so that we can achieve a circumferential cement layer of 2 mm around the implant. The tube was cut to the same length as the nail. The Bonneau syringe and the plunger of the 60 mm syringe were used to fill the tube with antibiotic-impregnated PMMA (Fig. 3a). Then, the nail attached to its extraction devise was inserted into the tube (Fig. 3b). This procedure allows nail manipulation and prevents the

cement from occluding the thread at the time of placing the nail insertion handle. We wait for the setting of cement and try to achieve a uniform layer throughout the nail. Cement leakage into nail cannulation cannot be avoided because no guidewire will be used to insert the nail. The same technique as for solid nails will be followed.

The tube was removed through a longitudinal cut, and the cemented nail end was rasped to achieve a smooth sliding surface (Fig. 3c). Nail locking holes were drilled in the cement under fluoroscopic guidance (Fig. 3d).

To prepare the cephalic module, we used 2 doses of antibiotic-impregnated cement (Table 2) to fill-up the bulb of the Bonneau's syringe. The cephalic anchor holes of the nail should be drilled before cement setting. We placed two 6-mm Schanz screws (Fig. 4a) at the same position as that of the cephalic screws (Fig. 4b and c). Then, the modules were assembled by placing the cephalic screws into the cephalic module using the guidewire handle (Fig. 4d).

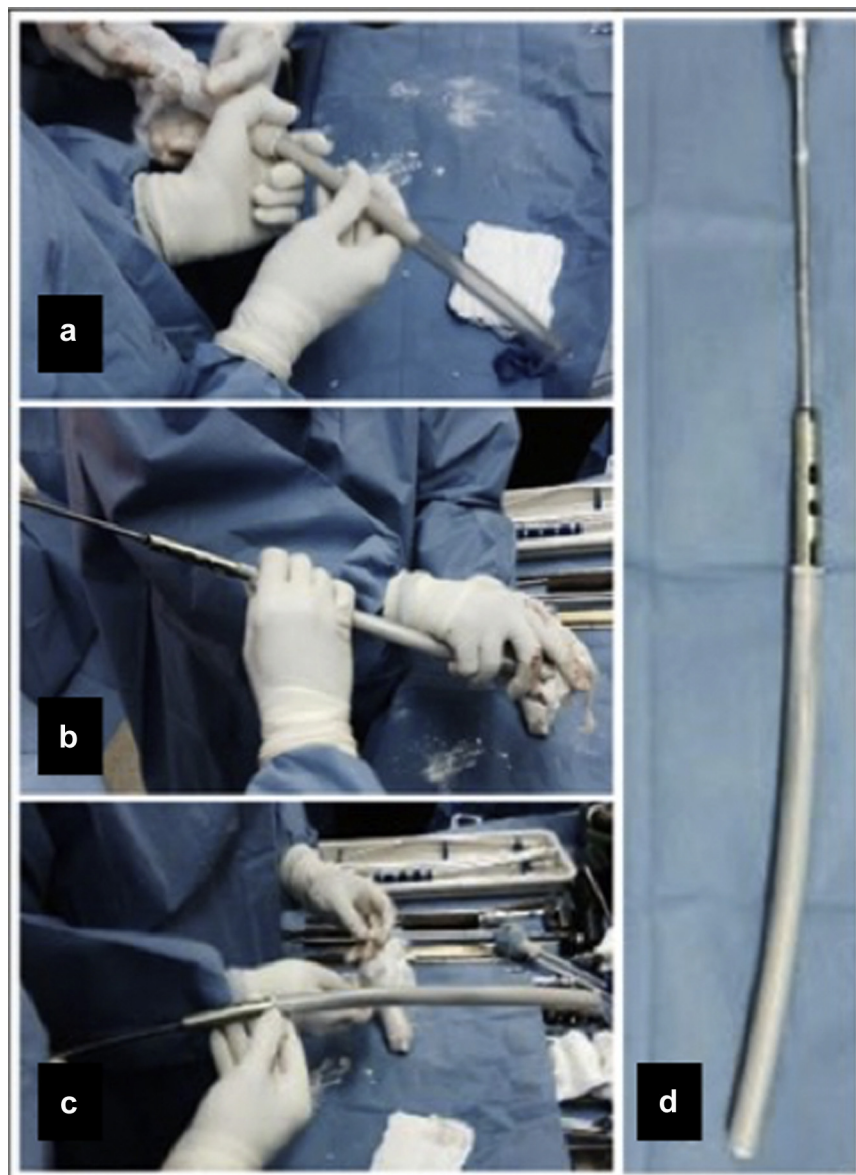


Figure 3. (a, b, c and d) Surgical steps for intramedullary nail cementation (see text for further explanation).



Figure 4. Cephalic preparation and assembly. (a) Rubber pear of the Bonneau syringe filled with surgical cement with an antibiotic; note the placement of 2 Schanz screws of 6 mm occupying the space destined to the cephalic screws of the cephalomedullary device. (b and c) Axial and sagittal view of the cephalic module, respectively, once the Schanz screws and the rubber bulb have been removed. (d) View of the intramedullary device assembled outside the patient with the cement-coated components and antibiotics and with the cephalic module threaded.

Intramedullary reaming and implant placement

We used a posterolateral approach with the patient placed in a lateral position. The intramedullary canal was reamed under fluoroscopic control (Fig. 5a–d).

We made a bony window in the lateral distal femur to be able to perform an intramedullary washout with an antegrade flow of saline solution injected under pressure into the canal through the proximal femur approach.

Thereafter, a Foley catheter was introduced with the help of the reaming guidewire down to the distal femur (Fig. 6a). The guidewire was removed, and the catheter balloon was inflated with 10 mL of saline solution (Fig. 6b). At this point, the catheter was removed by pulling it backwards (Fig. 6c) resembling the Fogarty technique used for deep vein thrombosis. The intramedullary reaming process consists in carrying out this maneuver repeatedly to remove the reaming debris through retrograde mechanical dragging (Fig. 6d).

The megaspacer was made by setting the cement head into the acetabulum, and then the nail was inserted into the femur shaft as a solid nail. Both components (a shaft and head) were finally assembled by joining them with cephalic screws through the greater trochanter (Fig. 5e–g). Finally, the distal interlocking screws were placed freehand (Fig. 5h and i).

It should be noted that these procedures were performed simultaneously rather than sequentially as interdependent processes were involved. Namely, the maximum diameter of the reaming canal should be known for the preparation of a custom-made megaspacer. This also reduces the surgical time.

Results

Twelve proximal femur megaspacers were custom made from May 2013 to February 2017. One patient was lost to follow-up.

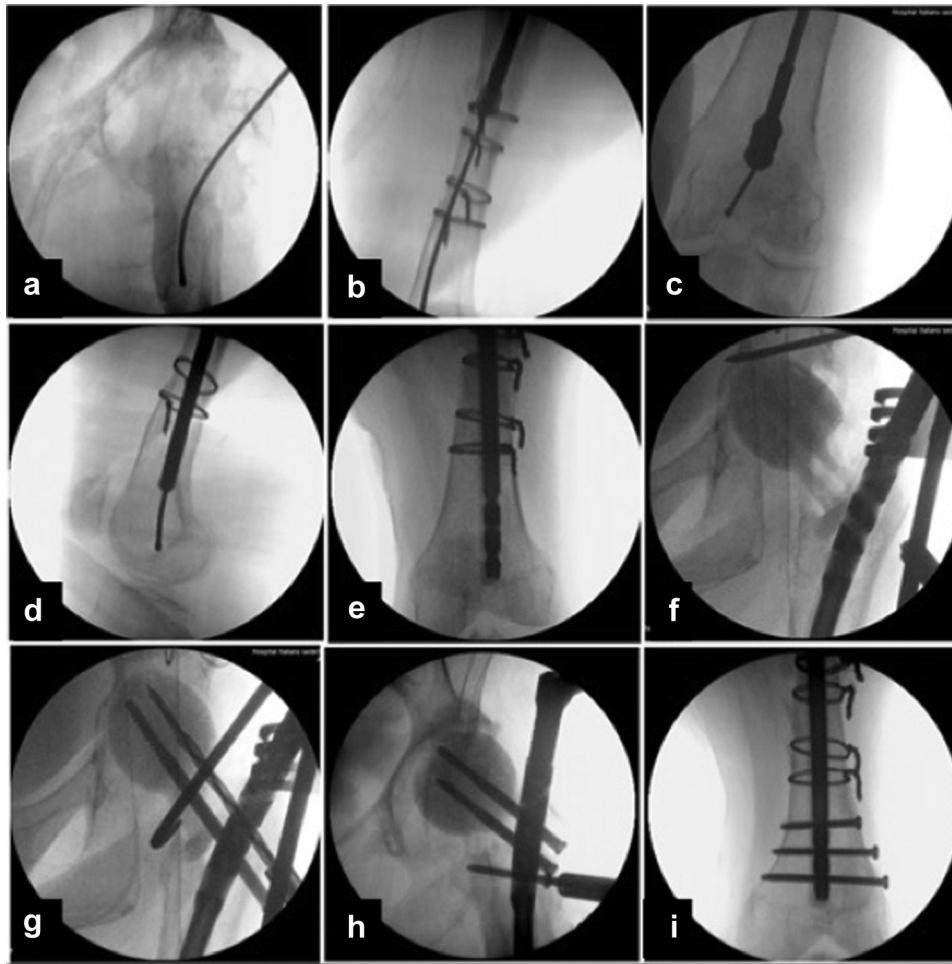


Figure 5. Proximal femur megaspacer implantation. (a) Advancement of the reaming guide into the intramedullary canal; (b, c, and d) progressive reaming of the femoral intramedullary canal; (e) placement of the intramedullary nail coated with a cement mantle and antibiotics; (f) cephalic cement module with antibiotic housed in the acetabulum cavity; (g) cephalic module is threaded with 2 screws with the help of a hook; (h) proximal nail blockage; and (i) distal nail blockage.

Eleven cases were finally included in our series. Six patients were women and 5 were men. The mean age at the time of surgery was 66 years (range 48–84). [Table 3](#) summarizes the demographic data and surgical details of each patient.

Seven of the 11 patients had a medical history of total hip replacement: 2 due to hip osteoarthritis and 5 due to femoral neck fracture. The remaining 4 patients had a medical history of reduction and osteosynthesis: 3 patients presented segmental femur

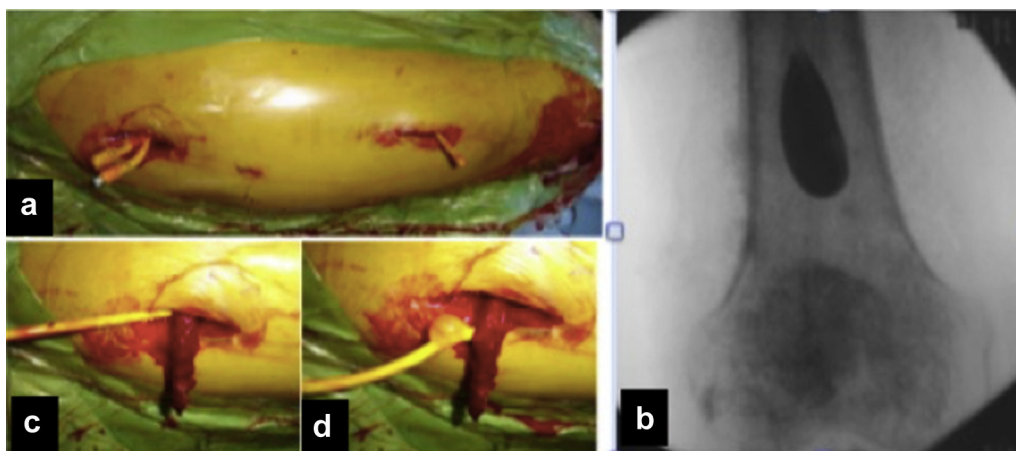


Figure 6. Intramedullary debridement technique. (a) Foley catheter passage from the proximal to the distal aspect of the femur. (b) Contrast fluid infused into the catheter balloon and then into the medullary canal (just in this case to demonstrate balloon insufflation). (c and d) Retrograde extraction of the catheter with residual debridement material from the medullary canal.

Table 3
Demographic and surgical data.

n	Age/sex	Initial diagnosis	Diagnosis prior to megaspacer	Number of previous surgeries	Cultures	Megaspacer follow-up (months)	Reimplantation
1	48/M	Ipsilateral femoral shaft/femoral neck fractures	Septic loosening of THR + infected femur pseudarthrosis	3	MRSA + <i>Pseudomonas aeruginosa</i>	17	Distal fixation THR + osteosynthesis
2	67/F	Femoral neck fracture	Septic loosening of THR + femoral shaft fracture	3	Negative	10	Distal fixation THR
3	82/F	Femoral neck fracture	Septic loosening of THR + femur shaft fracture	2	MRSA + <i>Enterobacter cloacae</i> + <i>Enterococcus faecalis</i>		no
4	84/F	Femoral neck fracture	Infected periprosthetic hip fracture	3	<i>E faecalis</i>	16	Distal fixation THR
5	78/M	Hip osteoarthritis	Aseptic loosening of THR + femur shaft fracture	5	<i>Proteus</i> + <i>Klebsiella</i>		No
6	66/F	Pertrochanteric fracture	Infected femur pseudarthrosis + avascular necrosis	1	Negative	7	Distal fixation THR
7	51/M	Pertrochanteric fracture	Infected femur pseudarthrosis + avascular necrosis	1	<i>E faecalis</i> + <i>E cloacae</i> + <i>Staphylococcus epidermidis</i>	14	Distal fixation THR
8	50/M	Ipsilateral femoral shaft/femoral neck fractures	Infected femur pseudarthrosis + avascular necrosis	1	<i>P aeruginosa</i> + <i>S. epidermidis</i>	11	Distal fixation THR
9	66/F	Hip osteoarthritis	Infected Periprosthetic hip fracture	3	<i>S. epidermidis</i>	7	Distal fixation THR
10	65/M	Ipsilateral femoral shaft/femoral neck fractures	Septic loosening of THR + infected femur pseudarthrosis	7	Negative		No
11	70/F	Femoral neck fracture	Septic loosening of THR + infected distal femur pseudarthrosis	3	Lactobacillus sp.		No

MRSA, methicillin-resistant staphylococcus aureus; THR, total hip replacement.

fracture and 2 patients presented subtrochanteric fracture. The final diagnoses that led to the need for a megaspacer placement was 4 septic loosening of total hip prosthesis associated to an infected femur nonunion, 2 septic loosening of total hip replacement revision and a femur shaft fracture, 3 infected femur nonunions with avascular necrosis of the femoral head, and 2 infected periprosthetic fractures. The average number of previous surgeries was 3 (range 1–7).

In 7 of the 11 patients, we achieved a definitive prosthetic reconstructive treatment. The average time elapsed from the megaspacer placement to reimplantation was 11.7 months (range 7 to 17). All 7 cases were reconstructed with a distal fixation total hip prosthesis. In 1 case (patient number 1), a 4.5 locking compression plate was also used on the lateral aspect of the femur to protect the area of the previous fracture. All 7 patients achieved normalized laboratory parameters of infection and showed radiographic signs of consolidation.

Three of the 4 remaining patients are in the prosthetic reimplantation process with negative laboratory parameters of infection. The other patient presents an active osteomyelitis with a sinus tract drainage for whom a new megaspacer replacement is planned. This procedure has been delayed due to insurance problems.

Six postoperative complications were recorded: 3 spacer subluxations, 1 locking screws loosening, 1 case of cut-through of a cephalic screw that eroded the cement head, and an infectious reactivation (already mentioned). There were no intraoperative complications. Three patients required reoperation: 1 underwent the repositioning of loose distal locking screw and the other 2 needed an antibiotic-cemented acetabular roof to avoid further subluxation episodes.

Discussion

Antibiotic-coated hip spacer for periprosthetic infection treatment are described in detail in the literature [2,4,5,7,8,10,12,20,21], as well as the use of antibiotic-coated intramedullary nails for

infected long bones fractures or infected nonunions [13,14,16,17,22,23]. However, there are few reports describing therapeutic options applied to cases in which a deficit of proximal bone stock of the femur coexist with a femur shaft defect (fracture or nonunion) in the context of an infection; most of them were case reports about a single and unique salvage technique.

We present a small and heterogeneous series. They are extreme cases. Our patients developed the same clinical status after different complications, but all of them share the diagnostic triad of lack of proximal femur bone stock, an ipsilateral shaft defect, and osteomyelitis.

Younger et al. [24] published the results of a retrospective analysis of 30 infected hip prostheses with metaphyseal bone stock deficit. They proposed a 2-stage revision surgery. In the first surgery, they used a commercial antibiotic-coated cement spacer to replace the proximal deficit, and in the second surgery, a stent and structural bone graft were used for the prosthetic reconstruction. They obtained a high rate of infection control (96%). Similarly, in 2008, Sherman et al. [25] reported a case of a patient with a septic hip loosening associated with a periprosthetic fracture and a large bone defect. They also performed a 2-stage treatment. First, they implanted a spacer consisting of a hemiprosthesis coated with cement and antibiotics, together with a cement spacer block to cover the distal defect. In the second stage, they performed the reimplantation with a total femoral prosthesis. The authors used large approaches with soft tissue injury, important debridement, and removal of bone stock.

These custom-made spacers are not mechanically stable, weight-bearing ambulation is not allowed, and in some cases, a hip abduction splint is necessary to avoid dislocations. Conversely, megaspacers have the advantage of allowing weight-bearing ambulation (Fig. 7), and they are biologically favorable as they preserve viable bone stock generating less soft tissue lesion for implantation.

Ben-Lulu et al. [26] analyzed patients with a large bone femur deficit after extraction of an infected total hip replacement. They



Figure 7. Patient with implanted megaspacer ambulates without assistance. (a and b) One foot standing. Clinical images without assistance; (c) posterolateral hip approach. (d) Panoramic long-cassette radiograph of lower limbs showing the presence of the proximal femur megaspacer and a 3-cm limb-length discrepancy.

used prefabricated spacers coupled with intramedullary nails and, depending on the type of bone defect, they incorporated plates, boxes, and acetabular rings coated with cement and antibiotics. They obtained an infection control rate of 90% (10 of 11 patients) and reported no complications. These spacers, as the ones we have used, generate adequate antibiotic release throughout the infected segment associated with correct management of dead space. However, they do not allow the patient to bear weight on the affected limb, limiting functional rehabilitation. On the other hand, the large amount of synthetic and prosthetic material used increases costs and could become a source of persistent infection.

Recently, Canham et al. [27] and Saez-Ruiz et al. [28] have reported 2 different techniques for the fabrication of total femur megaspacers in patients with total femur bone stock loss. These 2 surgical strategies have the same objective: to control infection to

make a prosthetic reconstruction possible. However, they have several differences compared with the ones we are discussing in this article. The main difference is that these are biarticular spacers where both the hip and knee are affected, and the entire femur is resected, including proximal tibial debridement as well. Our intention was to preserve as much bone stock as possible. With our own technique, we perform an aggressive debridement of the remaining femur, and we try at the same time not to involve the distal joint. We believe that the invasion of the proximal tibia could pose a risk of infection dissemination in a sterile bone. The distal femur resection described by Canham [27] and Saez-Ruiz [28] brings about new knee instability, thus making it necessary for patients to use a knee orthosis for light toe-touch weight-bearing ambulation. Our spacer design intends to allow full weight-bearing ambulation after 3 weeks (the time required for soft tissue healing). The authors [27,28] describe a posterolateral approach because of extensile properties. While they perform large approaches that will potentially damage the soft tissue envelope, we intend to preserve it because we believe that it is of capital importance for fracture healing and effective antibiotic delivery.

In 2017, Shields et al. [29] described a surgical technique in 3 patients who had a proximal femur bone stock deficit after oncological resections. This surgical technique is very similar to the one we are discussing in this article as both of them keep the distal femur bone stock. The difference is that they perform a total resection of the proximal area of the femur and maintain only a trochanteric slice of bone for muscle attachment. This implies greater soft tissue damage. The other difference is that not all the nail is coated with PMMA and antibiotics. We believe that, with an implant completely coated with antibiotic, we will achieve a higher concentration of antibiotics in all the femoral canals, a better control of the dead space and, in the long term, a more stable construction.

Our series is small and heterogeneous. However, after different complications, they all arrive at the same pathological triad: proximal epiphyseal femur bone stock deficit, ipsilateral shaft defect, such as an acute fracture, or nonunion associated with osteomyelitis. As described previously, our surgical technique has not been published before. The aging population and an exponential exposure to hip replacements may increase the frequency of this complex scenario.

Conclusions

There are a few therapeutic alternatives for patients with proximal femoral epiphysis combined with a fracture at another level and signs of infection. The proximal femur megaspacer is a novel surgical technique for the management of this combination. This procedure is aggressive in terms of debridement, protects the soft tissue envelope, releases high concentration of local antibiotics, promotes fracture union through adequate stability, maintains bone stock, and favors secondary reimplantation. Both mobility and ability to ambulate are maintained. In our experience, all patients achieved bone union, and laboratory parameters of infection were normalized in 10 of 11 subjects.

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