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Original Article

Reconstruction of infected post-traumatic bone defects of the distal femur with the Compress® implant. Preliminary results of a staged non-biological strategy

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ABSTRACT

Introduction: Infected post-traumatic distal femur defects remain a therapeutic challenge. Non-biological reconstruction offers an option for avoiding complex biological knee arthrodesis procedures. The Compress® implant is an alternative to the traditional distal femur stemmed megaprosthesis. The aim of this study is to analyse the first patients treated with a distal femur Compress® prosthesis to manage massive infected post-traumatic defects of the distal femur with joint involvement.

Methods: We retrospectively reviewed all patients with massive infected defects of the distal femur where this implant was used in a two-stage strategy, together with an antibacterial coating hydrogel (DAC®). The specific protocol, microbiological data, clinical and radiological results, complications, functional results and prosthesis survivorship were determined. Follow-up was for a minimum of 12 months, or until implant removal.

Results: Ten patients (11 Compress® implants) with a mean age of 52 years (range 35-73) were included. On average, patients had undergone 4.4 previous surgical procedures before index surgery. The mean bone defect was 14 cm (range 8-21). After a median follow-up of 27 months (range 12-50 months) no patient had presented with recurrence of the infection, and limb salvage was achieved in all cases. Two patients suffered aseptic loosening which required revision of the femoral component. The short-term survivorship of the implant in our series was 81.8% at 4 years, with all failures occurring in the first 7 months. After this 7-month time threshold, we encountered no further loosening. Regarding functional outcomes, patients had a mean knee ROM of -4/86, expressed high overall satisfaction with the procedure according to the SAPS scale, and had an average LEFS of 52.5% (40-72.5%).

Conclusion: Non-biological reconstruction of the distal femur with the Compress® implant is a valid option in selected patients with massive infected defects with joint involvement. Survivorship was high, with all loosening occurring in the first months after surgery—representing a failure in the osseointegration of the implant.

Introduction

Despite great therapeutic advances, infected bone defects represent one of the most difficult conditions to treat following orthopaedic trauma; they remain a challenge for both patients and surgeons [1]. In real-world practice, successful, simultaneous treatment of both infection and bone defects is far from a resolved topic. The current *biological* techniques for reconstruction of massive bone defects are limited; they can be divided into two main groups [1,2]: bone-replacement techniques (autologous cancellous bone grafting, induced membrane technique, or free vascularized bone grafting) and bone-regeneration techniques (techniques based on distraction osteogenesis). If such defects occur at the level of the distal femur (juxta-articular infected bone defects), the challenges are even more formidable, due to the lack of valid limb sal-

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vage options [3]. In such extreme cases, an above-knee amputation (AKA) may be the only valid option. In order to avoid AKA, bone reconstruction techniques are often combined with knee arthrodesis [3–6], based on the classical belief that arthrodesis is preferable to amputation [4],[7].

To avoid such complex procedures, as well as the poor functional result of a stiff knee, there has been a growing interest in the use of megaprostheses (MP) in this non-oncological scenario [8]. Such a non-biological solution is undoubtedly an attractive option for avoiding knee arthrodesis or amputation in juxta-articular infected bone defects.

Concerns about risk of infection [9–11] and mega-implant longevity [10],[12] exist in the orthopaedic community in such difficult-to-treat scenarios. Moreover, failures of stemmed MPs leave surgeons with very limited reconstructive options, due to the poor remaining femoral bone stock [13].

The Compress® compliant Pre-Stress (CPS) device (Zimmer Biomet, Warsaw, Indiana, USA) is a fixation system with a very short intramedullary segment (stemless implant). Its primary stability is based on initial compression; long-term stability is achieved through osseointegration of the implant (compressive osseointegration) [14]. According to recent publications focused on DF substitution, Compress® survivorship rate (80% at 10 years) is an improvement over that of stemmed implants [15,16]. Another advantage is preservation of bone stock if the implant fails, making revision much easier than in the case of stemmed prostheses [15].

In 2015, we initiated a protocol for non-biological reconstruction of infected critical-size bone defects of the distal femur with articular implication. In such limb-threatening injuries, a two-stage limb-salvage strategy was implemented: 1) First stage: pseudo-oncological bone resection + temporary hand-made knee spacer followed by 2) Second stage: Compress® distal femur reconstruction protected with an antibiotic-loaded antibacterial hydrogel (DAC®) coating [17,18].

The primary aim of this study was to investigate our preliminary outcomes and postoperative complications following the introduction of this new management protocol. Considering all the factors discussed above, we sought to study the outcomes of this strategy, focusing on: **1**) Limb-salvage rate, **2**) Compress® compliant Pre-Stress (CPS) device survivorship rate and complications, **3**) infection eradication rate, **4**) patient satisfaction and patient functioning after the procedure. Currently, there are few scientific reports that have evaluated the usefulness of the Compress® implant in non-tumoral infected distal femurs. To the best of our knowledge, the majority of these data are from cohorts of tumour patients.

Materials and methods

Study design

After institutional review board (IRB) approval, we performed a retrospective search of our prospective institutional database. Our centre is a 1000-bed tertiary university hospital which houses a national-reference musculoskeletal infection unit. All consecutive cases treated with a Compress® implant to manage a distal femur infected bone defect were identified and reviewed. The search included all patients operated upon by our dedicated Septic Unit during the period from January 2015 through March 2019.

Inclusion criteria

(1) Use of this type of modular mega-implant to manage DF post-traumatic infected bone defects, with a minimum follow-up of 12 months or until implant removal. (2) Two-stage strategy. (3) Patients with no post-surgery tracking data were excluded, (4) as were cases in which the Compress® system was used to treat end-stage periprosthetic joint infections.

Outcome Variable

The primary end points in this series were infection eradication rate and CPS® device survivorship rate. The following data were recorded from our prospective institutional database: **a**) *demographics,* **b**) *comorbidities*: smoking habit, high body mass index (BMI), American Society of Anaesthesiologists (ASA) Status Classification System **c**) *injury description*: date and characteristics of the injury, open fracture classification (Gustilo-Anderson classification) and number of previous procedures **d**) First-stage *intraoperative data*: date of surgery, length of final bone defect (cm), spacer technique, first-stage etiological microbiology e) Second-stage *intraoperative data:* date of surgery, type of CPS® anchor plug, magnitude of CPS® compression (400 lbs, 600 lbs, 800 lbs), size of OSS-Compress® implant, use of local antibiotic and intraoperative microbiological isolation e) *Postoperative data*: Compress®-related complications, need for unexpected reinterventions, radiological findings such as presence of CPS®-related bony hypertrophy or CPS® fixation failure.

Whenever feasible a final outpatient appointment was scheduled, where each patient was examined by a member of our dedicated team to assess the following (see *Definitions*): leg-length discrepancy (LLD), knee range of movement (ROM), VAS scale, the self-administered patient satisfaction scale (SAPS) and the Lower-Extremity Functional Scale (*LEFS*).

Definitions

1 *Infection definition:* all included patients having an established diagnosis of deep infection, according the following criteria (infection is diagnosed if $\geqslant$ 1 criterion is fulfilled): 1. Presence of a sinus tract; 2. Bone or osteosynthesis material exposure; 3. Positive histology; 4. Pus or intraoperative abscess; 5. $\geqslant$ 2 positive cultures to the same pathogen [19].
2 Compress® *aseptic failure* was defined as the presence of 1) periprosthetic femoral fracture with implant failure; 2) implant breakage; 3) transverse pin migration; 4) progressive, gross decrease in the distance between the anchor plug base and the top of the spindle sleeve; and/or 5) progressive radiolucency at the bone-prosthetic interface, when compared to initial postoperative radiographs [20].
3 *Infection* eradication was described according to internationally accepted criteria [21]: (**a**) infection eradication, characterized by a healed wound and no infection recurrence caused by the same organism at one-year follow-up; (**b**) no subsequent surgical intervention for infection after reimplantation surgery; (**c**) no occurrence of PJI-related mortality and (**d**) absence of suppressive antibiotic treatment.
4 *Limb-length discrepancy (LLD)* was measured using standing full-length AP computed radiography of both lower extremities, with the pelvis level.
5 *Residual pain* was measured using the Visual Analogue Scale (VAS), which is a validated, subjective measure for acute and chronic pain, with 0 representing no pain and 10 the maximum degree of pain imaginable [22].
6 *Patient satisfaction outcomes* were assessed using the Self-Administered Patient Satisfaction Scale (SAPS), a short, reliable and valid 4-item scale (overall satisfaction with the surgery, the extent of pain relief, the ability to perform home or yard work and the ability to perform recreational activities) for assessing patient satisfaction. Items are scored on a 4-point Likert scale,

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using the options “very satisfied”, “somewhat satisfied”, “somewhat dissatisfied”, and “very dissatisfied” [23].

7 *Patient functional outcome* was based on a twenty-item scale called the Lower-Extremity Functional Scale (LEFS) assessing patient ability to perform everyday tasks. Its maximum possible score is 80 [24].

Operative technique description

Limb salvage was carried out in a two-stage procedure. All surgeries were performed by the senior surgeon (P.C.) following the same surgical protocol, as described below:

The initial surgery begins with radical debridement of all devitalized bone and soft tissue. A sterile tourniquet is ordinarily used, and antibiotics are withheld until deep tissue samples are harvested for microbiological study. A minimum of 6 deep microbiological samples are taken. An extensive medial parapatellar approach is usually followed; in the event that it must be extended, a tibial tubercle osteotomy is performed. Any hardware present is removed, and definition of non-viable bone tissue is determined by the senior surgeon using the classic paprika sign. A pseudo-oncological approach is typically followed, through segmental bone resection of the distal femur. After debridement, the surgical field is thoroughly irrigated with a low-pressure lavage system, using saline solution without additives. To fill the dead space and stabilize the extremity, during the first stage we normally employ a temporary static hand-fabricated arthrodesis spacer, using two antibiotic-coated nails (Trigen® Meta-Nail®; Smith&Nephew; Memphis, USA). We coat the nails with vancomycin-gentamicin-loaded acrylic bone cement (*Vancogenx®* bone cement, Tecres SpA, Sommacampagna, Italy), with an additional 2g dose of powdered tobramycin and 2g of powdered vancomycin per 40g bag of cement. The prepared nails are introduced into the tibia in anterograde fashion, and in retrograde fashion into the femur. They are connected with cerclages, and the femorotibial space is filled with high-dose antibiotic cement (*Vancogenx®* bone cement with an additional 4g dose of powdered tobramycin and 4g of powdered vancomycin per 40g of cement) [25] (Fig. 1).

All patients followed a similar postoperative antibiotic protocol, under the guidance of an infectious disease expert who is part of our multidisciplinary team. Once correct wound evolution has been verified, the patient is discharged home. Follow-up is performed in our out-patient office; patients are assessed for presence of spacer-related complications and infection recurrence.

Upon completion of antibiotic treatment, an antibiotic holiday period is begun, minimum duration two weeks. Timing of reimplantation is based on laboratory values and clinical improvements.

The second stage is performed under targeted prophylactic guided antibiotics. The spacer is removed and a second aggressive debridement is performed, with sample collection. The indications for CPS® implantation include a minimum 2.5 mm cortical thickness of viable remaining proximal femur, without areas of cortical defect and with a minimum 4 cm of residual subtrochanteric femur to accommodate the smaller anchor plug. If during the procedure the bone appears atrophic, a new cut is made until bleeding, viable bone is observed. The Compress® osseointegration fixation implant is used in accordance with the manufacturer’s recommended technique (which can be found elsewhere [16]), and attached to an Orthopaedic Salvage System (OSS®, Zimmer Biomet, Warsaw, Indiana, USA) rotating hinged platform. Compressive force at the implant-bone interface is determined based on cortical thickness, per manufacturerś guidelines: <2.5 mm, use not indicated; 2.5–3.9 mm: 400 lbs; 4–5.4 mm: 600 lbs; 5.5 mm: 800 lbs. The system is available in two different anchor plug/spindle options—the short Compress® device requires 45 mm of medullary placement, while the standard Compress® device requires 80 mm.

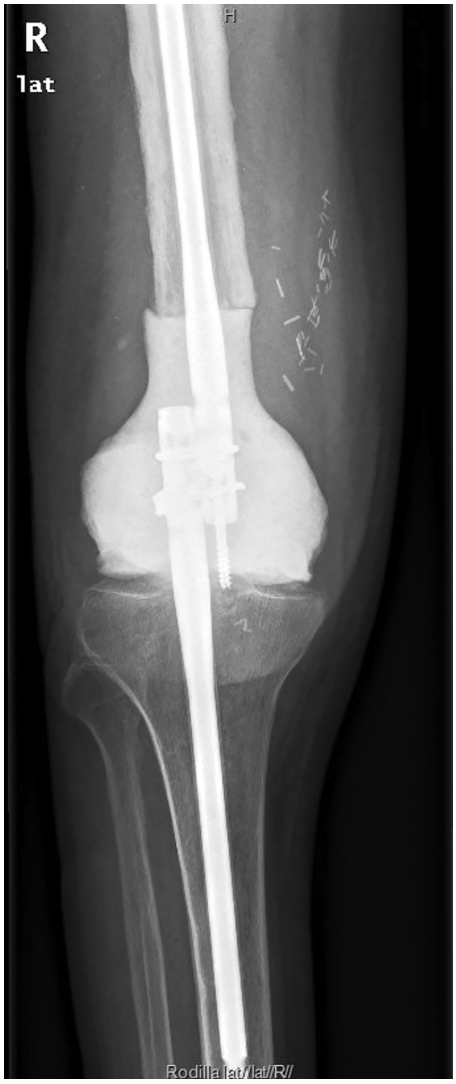

Fig. 1. Radiograph showing an example of a temporary knee arthrodesis type cement spacer (case #11) during the first stage. The spacer must simulate the shape of the prosthesis (in coronal and sagittal planes) to avoid space conflicts during the second stage.

In order to preserve as much bone stock as possible, the shortest anchor plug configuration is typically used. De-rotational pins are used in all patients. Finally, once the Compress® prosthesis is implanted, we assemble the OSS® DF-MP. The size of the final construct is chosen according to the size of the bone defect. In the tibial side, the non-modular long OSS® tibial tray is normally used. This in an uncemented tray with only metaphyseal cementation.

Coating protocol

DAC® hydrogel is prepared intra-operatively according manufacturerś indications; by protocol, we load the hydrogel with vancomycin and gentamicin. Ten minutes after mixing, the DAC® is applied to both femoral and tibial components, by directly spreading it on the extramedullary surfaces of the femoral implant and tibial stem *(Fig. 2)*.

After closure, prophylactic incisional negative pressure wound therapy—iNPWT (PICO®, Smith&Nephew; Memphis, USA)—is used in all cases, for a minimum of one week.

Following surgery, patients were maintained on systemic antibiotics against the first-stage-isolated microorganism until microbio-

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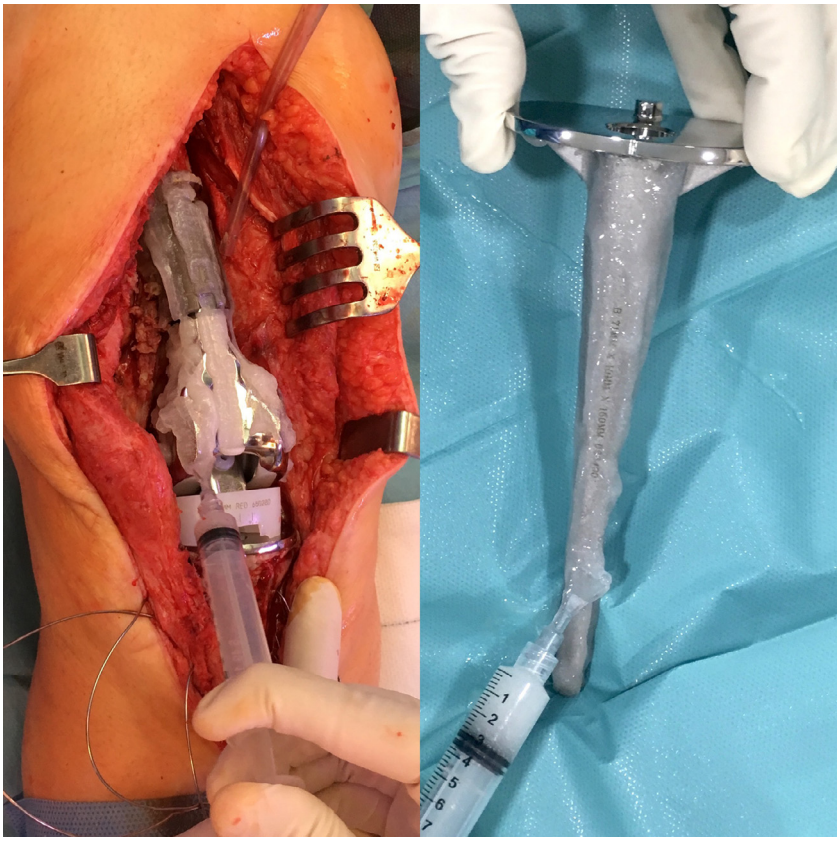

Fig. 2. The Defensive Antibacterial Coating (DAC®) hydrogel coating is spread onto the extramedular zone of the femoral implant and in the stem of the tibial component during the second stage.

logical results were available. If, after 7-10 days, the cultures were deemed negative, antibiotic treatment was withdrawn.

Follow-up protocol

After discharge, patients were seen in our offices at 3 weeks, 6 weeks, 3 months, 6 months, and annually thereafter. Patients received a standard rehabilitation program; this is delayed until the correct evolution of the surgical wound is confirmed. For the first 6 weeks, they worked on passive knee motion, with no weightbearing allowed. A maximum of 50% weightbearing was then allowed for the subsequent 6 weeks, after which they progressed to full weightbearing as tolerated. At each follow-up visit, the senior surgeon assessed the patient for infection relapse, mobility, knee ROM and pain. Radiographs were evaluated for evidence of CPS® fixation failure, periprosthetic fractures or CPS®-related bony hypertrophy. At the final out-patient appointment a functional evaluation was performed using the LEFS scale, and satisfaction was measured using the SAPS scale.

The survival of the Compress® DF megaprosthesis was estimated using the Kaplan-Meier method, beginning the day of the operation and ending on the date of removal or latest follow-up.

Statistical Analysis

Demographic factors and clinical characteristics were summarized as counts and percentages for categorical variables. Means were calculated for continuous variables. We performed survival analysis of the device using the Kaplan-Meir log-rank technique using the Stata® v.14.0 software (StataCorp. Lakeway Dr College Station, TX).

Results

After review of our database, we included 10 patients (11 Compress® cases) with infected massive distal femur bone loss and articular implication, and in whom a CSP® device had been implanted. Of these, 8 were males, with an average age of 52 years (range 35-73). Distribution of patient demographics and specific comorbidities can be found in Table 1.

All patients had initially presented with a fracture of the distal femur with joint implication; 8 of 10 were open fractures, of which 7 of 8 were classified as Gustilo Type III. On average, the selected patients had undergone 4.4 previous surgeries (range 1-8) before our index procedure.

Characteristics of the first and second surgical steps are summarized in Table 2. Regarding first-stage microbiological results, it is significant that 4 of 10 cultures were negative despite unequivocal signs of infection. Among positives cases, the most frequently isolated microorganism was Coagulase-negative *Staphylococcus* (CoNS) (3/10). The mean distal femoral bone defect after segmental bone resection was 14 cm (range=8-21cm) in this series. In all cases a hand-made antibiotic-loaded cement spacer was used to obliterate dead space and provide skeletal stability. Globally, in 7 of 10 cases a static spacer (temporary cement knee arthrodesis) was used. A dynamic spacer was used in the first three cases of the series. After one of these spacers dislocated, we switched to using static spacers and experienced no further complications of this sort. No other spacer-related complications were registered.

One patient with multiple previous surgeries and many surgical incisions of the knee and distal femoral skin area suffered a skin necrosis which required a microsurgical free flap (ALT free flap) to resolve the soft tissue defect.

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Table 1
Summary of case characteristics.

Case	Age	Sex	Risk factors	ASA	Fracture type/G-A	Previous procedures
1	45	M	None	I	Open / IIIA	8
2	35	M	Smoker	II	Open / IIIA	2
3	55	F	BMI>30	II	Open /IIIA	3
4*	56	F	BMI>30	II	Open /IIIA	4
5	70	M	None	II	Closed	1
6	73	F	DM	II	Closed	8
7	46	M	None	I	Open / IIIB	4
8	51	M	BMI>30	II	Open / II	6
9	52	M	Smoker BMI>30	II	Open / IIIA	2
10	48	M	Smoker BMI>30	II	Open / IIIA	2
11	45	M	Smoker	II	Open / IIIA	8

Legend: F=female, M=Male, BMI=body mass index, ASA= American anesthesia society scale, G-A: Gustilo-Anderson classification;
4*: Revisional Compress case after Compress failure.

Table 2
Summary of cases operative characteristics.

Case	1-ST			2-ST				
	Bone defect (cm)	Isolated microorganism	Cement spacer	TTA osteotomy	CPS®-Plug	Compression (lbs.)	OSS® length	Local ATB
1	21	*S. aureus, Klebsiella spp.*	Dynamic	Yes	Standard	400	20	Septocoll®
2	15	Negative culture	Dynamic	Yes	Short	800	13	Septocoll®
3	13	Negative culture	Static	Yes	Short	400	13	DAC-VG
4*	16	Negative culture	None	Yes	Short	400	17	DAC-VG
5	14,5	CNS	Dynamic	Yes	Short	400	16	DAC-VG
6	18	*Pseudomonas aeruginosa.*	Static	No	Short	400	18	DAC-VG
7	15	CNS	Static	No	Short	600	13	DAC-VG
8	8	CNS	Static	Yes	Short	400	8	DAC-VG
9	13	Negative culture	Static	Yes	Short	800	18	DAC-VG
10	12	CNS	Static	No	Short	400	13	DAC-VG
11	9	Negative culture	Static	yes	Short	400	8	DAC-VG

Legend: 1-ST= First stage surgery; 2-ST: Second-stage surgery; CNS=Coagulase-negative *Staphylococcus*, S. aureus= *Staphylococcus aureus*.
CPS®= Compress® compliant Pre-Stress device; OSS®= Orthopaedic Salvage System; ATB=antibiotic; DAC= *Disposable Antibacterial Coating; VG: vancomycin and gentamicin;* Lbs.: pounds; 4*: Revisional Compress case after Compress failure.

During the second stage, all microbiological cultures were deemed negative. Regarding compression and length of the implants used, 10 of our cases used a short CPS® plug, applying 400 lbs of compression in 8 of 11 cases. The final modular OSS® mean length was 14 cm (range 8-20cm). As for MP antibiotic coating, vancomycin-gentamicin DAC® was used in 9 of 11 cases. In the first two cases of this series a gentamicin-loaded collagen fleece (Septocoll-E®, Biomet Deutschland GmbH, Berlin, Germany) was used to wrap the extramedullary portion of the implant. At present, Septocoll-E® is not available in our country.

Compress®-related complications: Overall, we observed two CPS® fixation failures (aseptic loosening) in this series, both requiring isolated replacement of the femoral component. In the first case, loosening occurred after 7 months from the index procedure, when the patient was performing full weight bearing without any reported incident. In this case, we performed a femoral revision using another Compress® device; intraoperative cultures were negative. There were no further incidents in this case after 20 months of follow-up (*Fig. 3*). The loosening of the second case occurred at 4 months; in this case we performed a femoral replacement using a cemented OSS® femoral component; again, intraoperative cultures were negative. It is remarkable that both these patients had a BMI > 30. We found no cases of implant breakage, nor any periprosthetic fractures in the series. Taking these two cases into consideration, the short-medium survivorship rate (4.1 years) of the implant in our series was 81.8% (*Fig. 4*), with all failures occurring in the first 7 months. After this time threshold we had no further implant failure. In 10 of 11 cases we observed bone hypertrophy formation in the follow-up X-rays. In one patient we observed progressive radiolucency at the bone-prosthetic interface around the spindle. No periprosthetic fractures nor pin migrations were recorded during follow-up.

After a mean follow-up of 27 months (range 12-50 months) limb salvage was achieved in all patients in this series of limb-threatening infected femoral injuries. No patient (10/10) presented signs of recurrence of the infection at the end of the follow-up. Mean Limb-Length Discrepancy (LLD) was 1.8cm (range= 0.2-3.8cm).

In terms of functional outcomes (Table 3), among the 9 evaluable cases we analysed knee ROM, VAS, walking aid and LEFS scale. Patients had a mean knee ROM of -4/86 degrees (Minimum extension: -20° /Maximum flexion: 100°). The mean VAS score was 2.3 (range 0-6) with 3 patients expressing no pain. With regard to walking aid, 6 patients used assistance, from these 3 patients used a bipedal weight bearing aid and 3 patients used no walking aid. The mean LEFS score was 52.5% (52.5/80), indicating that most patients were able to walk more than 1 km or go up or down 10 stairs, but were unable to run on uneven ground. Regarding patient satisfaction with the procedure, 9 out of 9 patients stated they were "*very satisfied*". As to pain relief satisfaction, 3 patients were "*very satisfied*" and 2 patients were "*moderately satisfied*". With regard to satisfaction with improvement in home/yard work, 3 patients stated they were "very satisfied", while 5 patients were "*moderately satisfied*". In terms of outdoor recreational activities, 4 patients were "moderately dissatisfied". No patient expressed dissatisfaction in response to any survey question. Overall satisfaction scores on SAPS showed a mean of 86 points, demonstrating a high overall satisfaction with the procedure.

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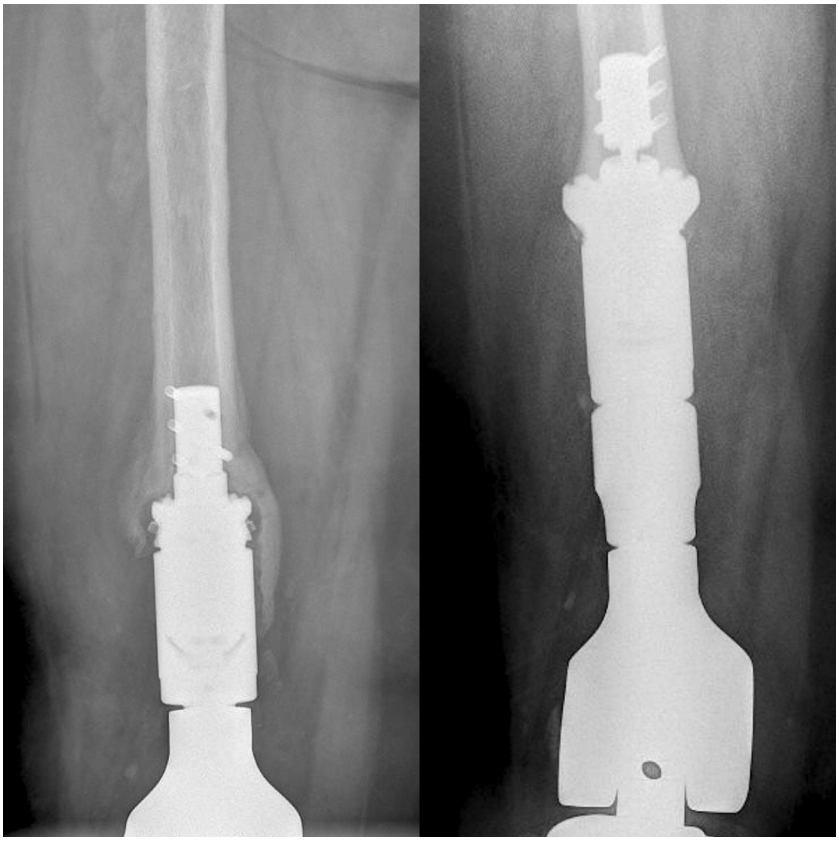

Fig. 3. **a**) An AP radiograph (case #3) reveals mechanical failure 7 months after placement of a Distal Femur CPS®-OSS® implant. **b**) AP radiograph (case #4) taken 20 months after her second revision CPS® implant shows radiographic evidence of bone hypertrophy (osseointegration) proximal to the spindle. Ease of revision is one of the main advantages of this strategy.

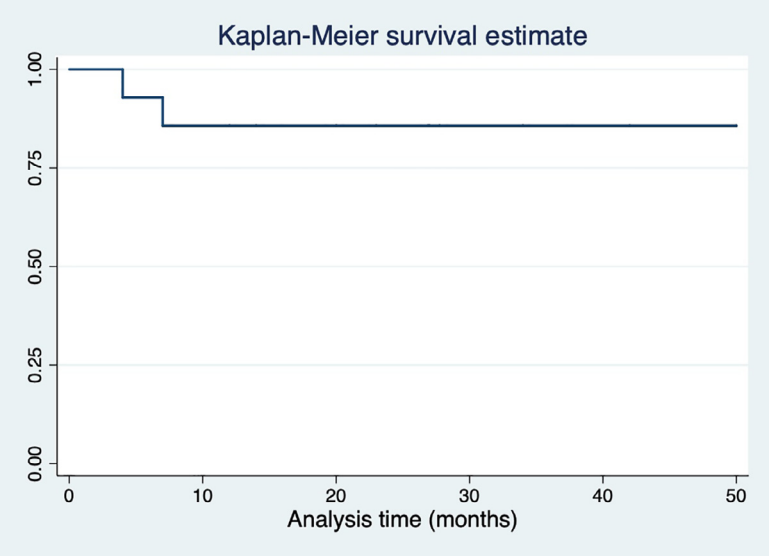

Fig. 4. Kaplan-Meier survivorship curve.

Discussion

In this preliminary series of 10 patients (11 cases) with infected distal femur bone defects managed with Compress® compliant Pre-Stress (CPS) devices, we demonstrate a limb-salvage rate of 100% after a median follow-up of 27 months. Employing a two-stage strategy and a rapidly resorbable antibacterial hydrogel coating, we found no infection relapse following the second stage. The short-midterm Compress® survivorship rate (4.5 years) was 81.8%. Functional and patient satisfaction outcomes were encouraging, showing that this limb-salvage protocol is a viable alternative to knee arthrodesis in post-traumatic distal femur infected cases (Fig. 5).

Infected bone defect represents one of the most difficult conditions to treat following orthopaedic trauma. In the case of juxta-articular infected bone defects of the distal femur, options are even

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Table 3
Summary of final Follow-up outcomes:

Case	FU (Months)	CPS®- Complications	Infection eradication	ROM knee (E/F)	LLD	Vas	LEFS
1	50	No	Yes	0/90	3.8	6	58.8
2	42	No	Yes	0/90	1.2	0	65
3	7	Aseptic loosening	Yes	-	-	-	-
4*	20	No	Yes	-20/100	3	4	40
5	34	No	Yes	0/70	2.4	5	63.7
6	23	No	Yes	0/90	0.2	2	48.8
7	20	No	Yes	-10/50	0.8	0	68.8
8	27	No	Yes	0/90	1	2	47.5
9	12	No	Yes	0/95	0.8	2	58.8
10	4	Aseptic loosening	Yes	-	-	-	-
11	14	No	Yes	-10/95	3	0	72.5

Legend: FU=follow-up, CPS®= Compress® compliant Pre-Stress device; ROM=Range of motion (extension/flexion); LLD= leg length discrepancy.
VAS= Visual Analogue Scale; LEFS= Lower-Extremity Functional Scale; 4*: Revisional Compress case after Compress failure.

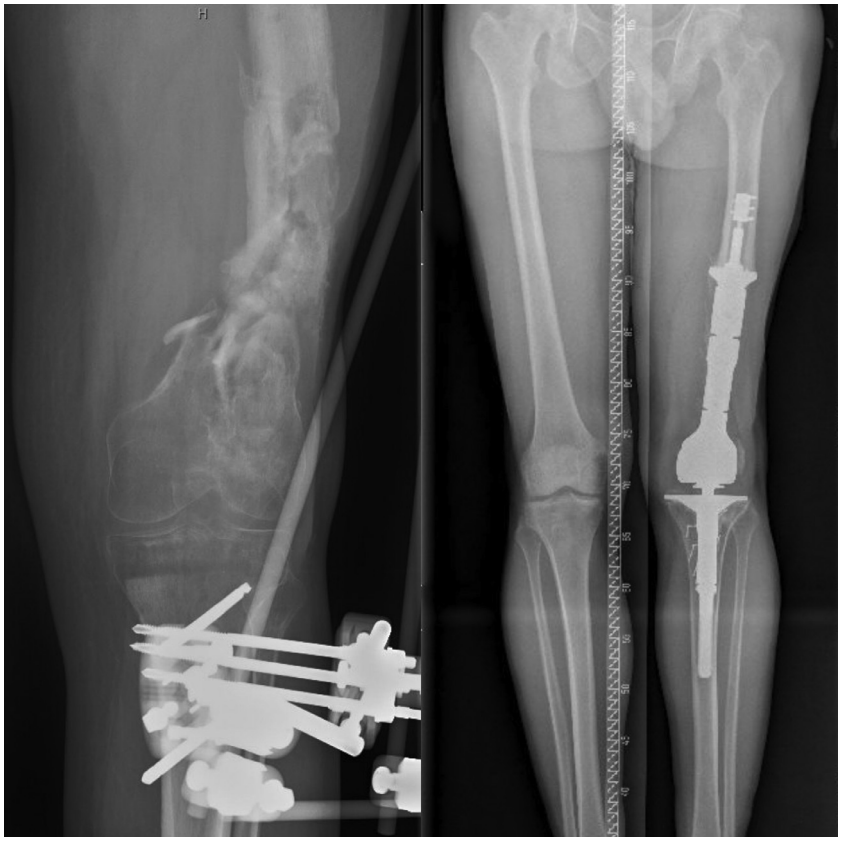

Fig. 5. a-b: (a) Preoperative and (b) postoperative radiographs of a 45-year-old man who sustained a Type IIIA open femoral fracture. (A) After 8 unsuccessful surgeries he was referred to us with massive distal femur osteomyelitis. B) this x-ray (case #1) demonstrates stable osseointegration at 4 years after implantation of a 21 cm distal femur CPS implant.

more limited since biological techniques alone allow us to reconstruct the bone defect itself, but not the compromised joint. In certain cases, knee arthrodesis may be the only valid option for avoiding amputation (AKA). Although the patient may consider arthrodesis as a failure, a fused limb is more efficient and functional that one with an AKA; thus, fusion is preferable to amputation in any population [7],[26]. In the trauma setting, bone defects are frequently larger than after primary or revision failed prosthesis; therefore knee arthrodesis should be done, using a combination of biological bone reconstruction techniques, to achieve solid bone fusion [3–6]. We implemented the described non-biological limb-salvage protocol in an attempt of achieve a better functional result and avoid the patient having to undergo long and complex reconstructive techniques.

The first concern regarding our proposal would be the risk of infection relapse using a tumour-style approach in a previously protracted infection scenario. Our patients had undergone an average of 4.4 previous unsuccessful surgeries; this is clearly a risk factor for failure, due to the potential presence of deep osteomyelitis in the remaining bone. Additionally, one could argue that, due to the large artificial surface of such tumour-style implants, the risk of bacterial adherence may be higher. The axiom, “the larger the implant surface, the higher the risk of bacterial adhesion” could apply in this arena [8]. Given the relative rarity of non-tumoral indications, current reported series of MP infections are few, with those few studies reporting infection rates ranging from 3% to greater than 30% [9],[11]. In a previous study by our own group, where modular MPs were used to treat end-stage periprosthetic joint in-

fections (PJIs), we found an overall infection eradication rate of 83% after median follow-up of 4 years [8]. In the present study we observed no infection recurrence after a maximum follow-up of 50 months. It seems likely that our achievement of such a high percentage of eradication was a result of these factors: (**a**) treatment was carried out using a two-stage strategy, with the undoubted advantages it affords in the most complex infected cases (**b**) the option to perform extensive bone resections—allowing much more aggressive debridement than in normal surgeries, thereby eliminating potential osteomyelitis foci that might otherwise have perpetuated the infection [27] and (**c**) the adjuvant effect of coating the MP with an antibiotic-loaded antibacterial hydrogel.

For us, a staged approach has inherent advantages in these difficult-to-treat cases [8]: it allows us to obtain an accurate etiological diagnosis; we can check the evolution of the infection and soft tissues; the patient is allowed to recover physiologically and thus face the second stage well optimized, and, finally, it is easier to resolve complications that may arise. The type of temporary cement spacer used is an important factor in such a staged approach. In the presence of extensive bone and soft-tissue defects, articulating spacers can lead to joint instability, with risk of complications such as dislocation, extensor mechanism erosion, progressive bone loss and soft-tissue problems. To avoid such complications and to allow soft-tissue resuscitation, we consider use of a static and very stable spacer offers an unbeatable advantage. After a dynamic spacer dislocation, we abandoned the use of mobile spacers in these patients. Similar temporary knee-fusion spacer techniques have recently been published in the PJI scenario, with good results [28].

There is a growing trend toward using MPs with surface modifications, to reduce risk of implant colonization. Most studies of such cases focus on use of silver-modified implants [29],[30]. Due to the increased risk of bacterial adhesion in tumour-style implants, in our dedicated Septic Unit we initiated a protocol of using silver-coated MPs in all previously infected end-stage cases (data not yet published). In the case of the Compress® OSS®, such silver coating is not available. To circumvent this drawback, we implemented a strategy of using a specially designed antibiotic-loaded fast-resorbable antibacterial hydrogel coating. The Defensive Antibacterial Coating (DAC®, Novagenit Srl, Mexxolombardo, Italy) is a hydrogel composed of covalently linked hyaluronan and *poly-D,L-lactide* which can be loaded with different antibiotic concentrations. The rationale behind this approach is that the hydrogel coating may offer efficacy against early bacterial colonization, providing protection of the implant for the time needed to win the "race to the surface" [31]. The compound can quickly deliver local antibiotics, thus inhibiting biofilm formation on different substrates, and planktonic bacterial growth in vitro [32]. In our series, we achieved 100% infection control, with no instance of relapse or reinfection. Further, no local or systemic side effects related to the DAC® hydrogel coating were observed in our patients. Based on our data, it appears that DAC® may be a useful adjunctive treatment in those MPs with no available silver coating. A direct comparison of both coatings would be necessary to be able to state this as fact.

The second concern regarding such a non-biological approach is the reported high mechanical failure rate in the MPs employed. Distal femur substitution presents a highly unfavourable biomechanical environment, with a higher failure rate when compared with conventional total knee revision systems [9], making revision surgery relatively common and challenging. Use of stemmed distal femoral MPs has become the most widely used reconstruction strategy [33]. The substantial length of such MPs creates high bending stresses at the prosthesis-host interface, which may contribute to loosening. In the case of cemented stemmed MPs, particle-induced osteolysis is among the principal failure modes [14],[33],[34]. Overall MP survivability in distal femoral reconstructions varies greatly in the literature; the published results show a survivorship between 75 and 90% at 5 years [34]. In an extensive study by Jeys et al.[35], including 228 distal femoral MPs, aseptic loosening accounted for 13.6% of all failures, with a median time to revision due to mechanical failure of 9.3 years. Moreover, Unwin et al. found, at 10 years postoperatively, 32.6% of patients who had distal femoral MPs had undergone revision for aseptic loosening [12]. Even more troubling is the fact that after fracture or loosening of a prior cemented or uncemented stem, the surgeon is faced with a very demanding revision procedure, where in some cases a total femur arthroplasty is the only acceptable option [36,37].

The Compress® compliant Pre-Stress (CPS) device was developed to provide an alternative, and to bypass the drawbacks of traditional cemented or uncemented intramedullary stems. Such a technology was developed in an attempt to capitalise on the healing response of bone to compressive force (*compressive osseointegration*). It is well known, in the field of orthopaedic traumatology, that healing of fractures can be hastened by the application of compressive force via plate osteosynthesis. The CPS® implant uses compression via a short traction bar to stimulate osseointegration at the bone-prosthetic interface (compressive osseointegration), to promote hypertrophy of the loaded bone, and to avoid stress-bypass of the host bone around a stiff intramedullary stem [14],[34],[38],[39]. The use of a medullary device of relatively low stiffness allows for direct stress transfer to the bone during normal cyclical loading, and this fact, together with ongoing compliant force delivered to the bone interface, results in bone hypertrophy according to Wolff's law [14]. This **stemless** design provides immediate, stable anchorage and theoretically should help avoid the long-term complications of aseptic loosening secondary to stress-shielding, and particle-induced osteolysis [14],[34]. In short-term comparison studies, the device has been shown to have equivalent or higher survival than cemented and press-fit stemmed implants for primary oncologic reconstruction [15].

The minimal residual femoral bone needed to accommodate the CPS® implant makes it a useful option for preserving bone stock in relatively young patients with long life expectancy. Due to its design, if a fracture or loosening does occur, Compress® offers a comparatively straightforward revision, given the ease of extraction of the intramedullary portion of the device, and the minimal amount of bone (as little as 2 to 4 cm) that must be resected before implantation of a new device [36].

For all the aforementioned reasons, we have selected this system to manage post-traumatic infected distal femur bone defects. The simpler revision and the preservation of bone stock, together with a survival rate at least as good as that of traditional implants, are the main reasons for our choice.

In terms of implant survival, we found in our series an early survivorship of 81.8% at 4.1 years of follow-up; thus, our results are consistent with other short-term outcomes (less than 5 years) published concerning DF-Compress®. In a retrospective study by Healey et al. [16], including 82 patients (tumour reconstruction in 80 patients) who had undergone Compress® knee arthroplasty, survivorship was 85% at 5 years and 80% at 10 years. Moreover, Zimel et al. retrospectively reviewed 27 patients who had experienced failure of a distal femoral oncologic megaprosthesis, and had then been revised to a CPS® implant. They reported a cumulative incidence of mechanical failure of 11% at both 5 and 10 years. These failures occurred early on, at a median of 5 months (range, 5–10 months). Aseptic CPS® failures described in existing literature [13] [40] [41] have typically been reported in the early months post-implantation, suggesting that once osseointegration of the implant has been achieved, long-term survival is almost guaranteed. We note that the two aseptic failures in our series took place in 7th and 4th postoperative months, respectively. In a retrospective study by Farfalli et al [42], comparing intramedullary un-

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cemented press-fit DF-MPs (n=50) against DF-Compress® (n=41), the authors found that the Compress® prosthesis has similar 5-year survival rate, as compared to uncemented prostheses (88% versus 85%), but that in the CPS® group, no failures were observed after 1-year follow-up. This data is consistent with our findings, and leads us to the preliminary conclusion that loosening occurring in the first months after surgery represents a failure of implant osseointegration.

The two patients who sustained early mechanical failure of their DF-CPS® implants were carefully scrutinized to identify factors contributing to the failures. We found that both patients were young and obese. According to the data we have, they strictly followed the postoperative protocol. We are not aware of patient weight having been described as a risk factor for CPS® fixation failure [38], but one may argue that in such patients there may be an excess of stress at the bone-prosthesis interface, which could lead to failure. In terms of revision, both procedures were found to be quite straightforward and easily completed. In the case revised with another CPS® device, we found massive osseointegration in the postoperative x-rays, with no further complications after 20 months of follow-up. We can affirm that one of the main advantages of these system is the facility of revision in case of failure, a fact of enormous importance in this arena [36].

In this infected scenario, our main goal is limb salvage with infection eradication, thus avoiding amputation or knee arthrodesis. Therefore, our functional goals are not as demanding as in primary or revision total-knee cases. We have used the LEFS scale in combination with the ROM and VAS scales to offer a general view of patient outcomes. After a review of the currently available literature regarding DF-Compress®, we found just one series of cases reporting an active 90° arc of motion of the affected knee maintained in 81% of the series' oncological patients [13]. The lower range of motion in our patients (mean knee ROM of -4/86 degrees) could easily be attributed to their different circumstances, including traumatic, multi-operational injuries and significant soft-tissue alterations. In any event, we believe the ROM our patients achieved to be quite satisfactory, undoubtedly an improvement over the results of a stiff knee. Patient satisfaction is recognized by health care providers and regulators as a measure of healthcare quality [43]. Our level of patient satisfaction was excellent, with 100% reporting they were very satisfied, overall, with the procedure. We also found acceptable satisfaction levels in relation to home/yard work and recreational activities. A prospective study of 463 patients treated for limb-threatening injuries (including open Type III Gustilo fractures) found that patient satisfaction after surgical treatment of lower-extremity injury is predicted more by function, pain, and the presence of depression at 2 years than by any underlying characteristic of the patient, injury or treatment [44]. We could add that in our series, the patients' reported satisfaction could be related to their previous conditions of disability and pain, and/or their histories of multiple unsuccessful surgeries. We speculate that a possible explanation may be that the majority of our patients felt their problems had finally been solved, after what may have been years of suffering.

Limitations: We recognize both the strengths and limitations of the present research. The first limitation lies in the study's retrospective nature. Retrospective studies rely on chart notes from which important data may be lacking, increasing bias incidence. A second major limitation is our lack of a comparison group; absence of a control group makes it impossible to compare results directly with those of fixation with conventional cemented or uncemented intramedullary stems. Our third limitation concerns sample size, and our limited follow-up period. Our series of 10 patients (11 cases) is small, but homogeneous with respect to anatomic location and prosthetic device used. The consistencies of our well-established protocol and strict follow-up add, in our opinion, to the homogeneity and validity of our study. Ours is an independent series of non-oncologic patients managed with a DF-Compress® device in a very specific arena. To the best of our knowledge, ours is also the first study reporting outcomes using such a staged, non-oncological strategy after post-traumatic infected distal femur bone loss. We must highlight the fact that the majority of reports focused on DF-Compress® survival concern series of oncologic patients. Nevertheless, studies employing prospective data retrieval, larger patient bases and more extensive follow-up are undoubtedly needed.

Conclusion

According to our preliminary data, a staged non-biological reconstruction procedure using a distal femur Compress® implant protected with an antibacterial hydrogel coating (DAC®) is a promising option in treating active patients with massive post-traumatic distal femur infected defects with joint involvement, in order to avoid knee arthrodesis or amputation. We achieved infection eradication in all cases. Short-term implant survivorship was high (82%), with all mechanical failures occurring within the first few months after surgery, making revision surgery simple. In addition, our patients reported high overall satisfaction with the procedure and demonstrated good functional results, reinforcing our intention to standardize the use of this procedure in selected patients.

Declaration of interests

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests:

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