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RESEARCH

Distal femur replacement for infected bone defects due to end-stage periprosthetic joint infection or trauma: a staged strategy protocol using the stemless Compress® device protected with a fast resorbable antibiotic-loaded hydrogel

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Abstract

Background Distal femur replacement (DFR) with a stemmed megaprosthesis represents a challenge due to high rates of loosening and limited reconstructive options if the implant fails. Such an unfavourable scenario is even more complex where there are also infected bone defects. The Compress® device was developed to provide an alternative to traditional intramedullary stems. We report on the outcomes of a staged protocol using the Compress® DFR, protected with a vancomycin–gentamicin-loaded hydrogel, in infected non-oncological scenarios.

Methods Retrospective longitudinal cohort study including patients with infected defects of the distal femur following orthopaedic trauma or periprosthetic joint infection (PJI) and managed with the protocol described. Protocol features, microbiological data, radiological results, complications, infection control, and implant survivorship were assessed. Minimum follow-up was 18 months or until implant removal.

Results 21 cases of Compress® DFR were included. On average, patients had 4.9 prior surgeries and 14.5 cm distal femur bone defects after pseudo-oncological resection. After median follow-up of 42 months (18–83 months), no infection recurrence occurred; limb salvage was achieved in all cases. Five patients experienced aseptic loosening, all within the first 7 post-operative months. Beyond this time threshold, no further implant failures were observed, resulting in a cumulative implant survival rate of 75% at 1 and 5 years, and of 75% at final follow-up.

Conclusion Staged Compress® DFR with antibiotic-loaded hydrogel protection is a reliable option for selected patients with distal femoral bone defects, offering high infection control, durable implant survivorship, and simplified revision. Aseptic failures occurred primarily within the early post-operative months, highlighting the need for close monitoring during this critical period. This approach provides a promising solution for complex non-oncological cases involving infected distal femoral bone defects.

Keywords Distal femur replacement · Compress® device · Periprosthetic joint infection · Infected bone defect · Limb salvage · DAC® hydrogel

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Introduction

Infected bone defect is one of the most difficult conditions to treat following orthopaedic trauma or periprosthetic joint infection (PJI). In cases of an infected distal femur with juxta-articular involvement, the challenges are even more formidable, due to limited limb salvage options [1]. In recent years there has been increasing interest in distal femur replacement (DFR) in non-oncological scenarios [2].

Stemmed DFR represents a particularly unfavourable biomechanical scenario, with a high complication rate. DFR

after a failed total knee arthroplasty also shows significant failure rates, with a 47% aseptic loosening rate after 8 years. Revision-free survival is estimated at 62.5% at 3 years and 41% at 10 years [3, 4]. Even more concerning are the limited reconstructive options if the implant fails, due to poor remaining bone stock. The increased risk of infection with such massive implants is widely recognised, with failed infection control rates ranging from 3% to more than 30% [5].

The Compress® compliant Pre-Stress (CPS) device (Zimmer-Biomet®, Warsaw, Indiana, USA) is a fixation system with a very short intramedullary segment (stemless), designed to avoid some of the limitations of stemmed implants. Its primary stability is based on initial compression, with long-term stability achieved through implant osseointegration. Suggested advantages are greater bone stock preservation and longer implant survivorship, with series showing a survivorship rate of 80% at 10 years [6].

Since 2015, a comprehensive two-stage limb salvage strategy protocol has become the standard of care [7] in our specialty-dedicated unit, for managing end-stage knee PJI cases with massive distal femur bone loss or infected distal femur juxta-articular bone defects due to trauma: (1) pseudo-oncological bone resection and temporary handmade static spacer; (2) stemless DFR using the Compress® device; (3) mega-implant surface protection strategy using an antibiotic-loaded antibacterial hydrogel (Defensive Antibacterial Coating—DAC®; Novagenit, Mexxolombardo, Italy) [8].

Considering all the aforementioned, we aimed to evaluate the outcomes of this limb salvage strategy by focussing on: (1) infection control, (2) midterm survivorship of the Compress® device, (3) protocol-related complications, and (4) limb salvage rate. Given the current lack of scientific evidence on the use of Compress® DFR in infected non-tumoral settings, this study seeks to fill that gap by offering valuable insights into infection control and implant durability.

Methods

Following IRB approval, this study was conducted as a longitudinal cohort study. The institutional database was retrospectively reviewed to identify all patients with infected distal femur bone defects treated under this novel protocol between January 2015 and January 2022.

Inclusion criteria: (1) use of Compress® DFR for managing infected bone defects (either PJI or trauma-related infections) with a minimum post-operative follow-up of 18 months, (2) implementation of a two-stage surgical approach, and (3) application of DAC® as implant coating. To ensure the robustness and reliability of the findings, patients were excluded if they lacked complete follow-up data, failed to adhere to the full protocol, presented with oncological conditions, or did not fulfil the inclusion criteria.

Outcome variable

Primary endpoints were infection control rate and medium-term Compress® implant survival rate. The following data were recorded from our institutional database: (a) demographics; (b) comorbidities; (c) previous surgeries; (d) first-stage intraoperative data; (e) second-stage intraoperative data; (e) post-operative data: Compress®-related complications, unexpected reinterventions, radiological findings.

Definitions

1. Infection definition: post-traumatic cases with an established diagnosis of deep infection, according to international-consensus criteria [9]. PJI cases with an established diagnosis of chronic PJI, according the 2021 EBJIS criteria definition [10].
2. Compress® radiological evaluation: 1 point for narrowed interface contour, 2 points for unaltered contour, and 3 points for widened contour [11, 12].
3. Infection eradication, based on Delphi-method consensus criteria [13]: (a) healed wound without fistula or drainage and no infection recurrence caused by the same organism strain; (b) no subsequent surgical intervention for infection after reimplantation surgery; (c) no PJI-related mortality. Necessity for suppressive antibiotic treatment or onset of another PJI caused by a different microorganism was also deemed as treatment failures.

Operative technique description

Limb salvage was carried out following a two-stage surgical strategy with all surgeries performed by the senior author (P.C.). During the first stage, a medial parapatellar approach is used, and extended through a tibial tubercle osteotomy when needed [14]. Implant removal and radical bone debridement is performed following a pseudo-oncological approach, involving segmental resection of the distal femur. Bone viability is assessed after releasing the tourniquet by identifying punctate bone bleeding, commonly known as the "Paprika sign." The residual intramedullary canal is routinely reamed and irrigated with saline solution without additives. A temporary static spacer is used (Fig. 1a/b) to fill dead space and stabilise the extremity [15]. Antibiotic treatment is selected according to the susceptibility profile of the isolated bacteria.

During the second stage, the spacer is removed and a second aggressive debridement is performed, with sample collection. Indications for Compress® implantation include > 2.5 mm cortical thickness of viable remaining

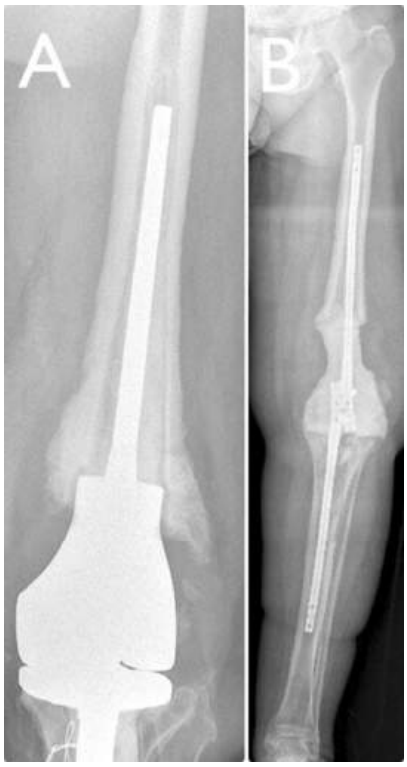

Fig. 1 **a** Radiograph showing implant loosening as a consequence of a lack of osseointegration between implant and host bone; **b** radiograph showing a temporary static spacer used to obliterate the dead space and stabilise the extremity during the first stage

proximal femur, without areas of cortical defect, and > 4 cm of residual subtrochanteric femur to accommodate the smaller anchor plug. The Compress® implant is used in accordance with the manufacturer's recommended technique, which can be found elsewhere [16], and attached to an OSS® (*Orthopaedic Salvage System*—Zimmer-Biomet®, Warsaw, Indiana, USA) rotating hinge platform (Fig. 2). The system offers two anchor plug/spindle options: short Compress® requires 45 mm of medullary placement, whereas standard Compress® needs 80 mm.

Coating protocol

DAC® hydrogel is prepared intraoperatively according to the following protocol, developed by our unit. A vancomycin–gentamicin solution is prepared by diluting 1 g of vancomycin powder in 20 cc distilled water. Then 5 cc of this solution is combined with 3 ampoules of 80 mg liquid gentamicin. Next, 5 cc of this solution is mixed with 5 cc of DAC® powder and allowed to sit for 10 min before 20 cc of the resulting vancomycin–gentamicin-DAC® mixture is taken. The solution remains stable for up to 5 h. It is applied directly to the tibial stem and the extramedullary surfaces of the femoral component (Fig. 3). The rationale for selecting

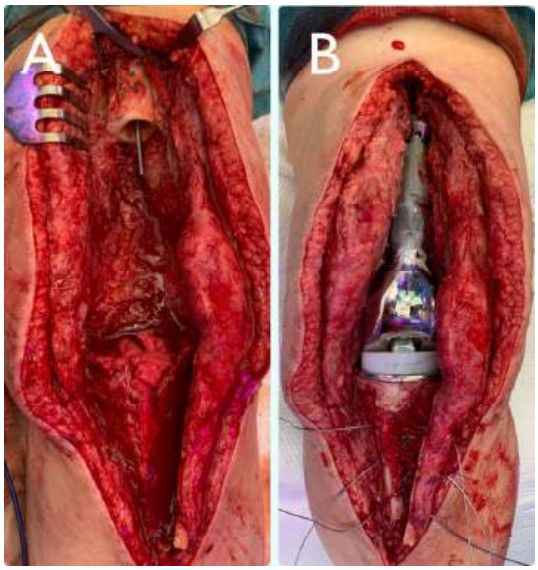

Fig. 2 **a** Aggressive debridement is performed again; **b** Compress® system is implanted and attached to a rotating hinge prosthesis (Orthopaedic Salvage System, OSS®)

this antibiotic combination is supported by extensive data on local pathogen profiles and antibiotic resistance patterns, gathered through our experience as a national reference centre for infections. Specifically, our previously published studies on periprosthetic joint infection [17, 18] and chronic osteomyelitis [19] have demonstrated that combining vancomycin and gentamicin provides effective coverage for more than 90% of the pathogens typically encountered in these clinical settings.

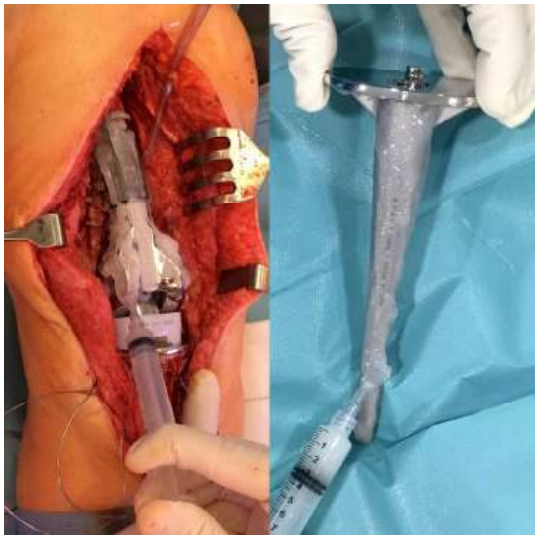

Fig. 3 The Defensive Antibacterial Coating (DAC®) hydrogel coating is spread by direct application onto the extramedullary surface of the femoral implant and tibial stem during the second stage

Follow-up and rehabilitation protocol

After discharge, patients were seen at 3 weeks, 6 weeks, 3 months, 6 months, and annually thereafter. Patients received a strict rehabilitation programme, though the program was not begun until correct evolution of the surgical wound was confirmed. For the first 6 weeks, the program focussed on passive knee motion, with no weight-bearing allowed. A maximum of 50% weight-bearing was then allowed for the subsequent 6 weeks, after which the patient progressed to full weight-bearing as tolerated.

Data analysis

Descriptive statistics and Kaplan–Meier analysis were employed to summarise patient outcomes and evaluate medium-term implant survivorship, considering the clinical variability of the cohort. Descriptive statistics were used to report patient demographics and surgical complications. Categorical variables were expressed as absolute values and percentages, while continuous variables were summarised using measures of central tendency (mean or median) and range. Kaplan–Meier survival curves were constructed to illustrate the medium-term survivorship of the Compress® device. All statistical analyses were performed using Stata v.14.9 software.

Results

In our database review, there were identified 31 cases of DFR using the Compress® device. After excluding ineligible cases, 21 cases with distal femur infected bone defects who had undergone the two-stage reconstruction protocol were finally included. Of these, 76.1% were males with an average age of 58 years (range: 19–80); median follow-up in this series was 42 months (range: 18–83).

Reason for distal femur replacement: 16 cases due to distal femur infected fractures; 5 cases due to end-stage PJI. The complexity of these cases is reflected in the number of previous procedures, prior to our index surgery. There was an average of 5.12 in our post-traumatic group, and 4.8 in PJI group. Patient demographics and specific comorbidities are shown in Table 1.

Characteristics of the first and second surgical steps are summarised in Table 2. Regarding microbiological results,

Table 1 Summary of patient demographics and specific comorbidities

Case	Age	Sex	Risk factor	ASA	Fracture type/G-A	Number of previous procedures
1	52	M	None	I	Open/IIIA	8
2	41	M	Smoker	II	Open/IIIA	2
3	61	F	BMI > 30	II	Open/IIIA	3
4*	61	F	BMI > 30	II	Aseptic loosening	4
5	75	M	None	II	Closed	1
6	78	F	DM	II	Closed	8
7	51	M	None	I	Open/IIIB	4
8	56	M	BMI > 30	II	Open/II	6
9	67	M	Smoker, BMI > 30	II	Open/IIIA	2
10	53	M	Smoker	II	Open/IIIA	2
11	48	M	Smoker	II	Open/IIIA	8
12*	48	M	Smoker	II	Aseptic loosening	8
13	67	M	DM, BMI > 30	III	PJI	3
14	80	F	DM	II	PJI	2
15	39	M	None	II	Open/IIIA	14
16	19	M	Smoker	II	Open/IIIA	5
17	69	M	None	II	Open/IIIA	6
18	68	M	None	II	PJI	3
19	60	M	None	II	Closed	7
20	75	F	None	II	PJI	5
21	50	M	Smoker, BMI > 30	III	Open/IIIA	4

Age = reported in years, F = female, M = male, BMI = body mass index (values over 30 indicate obesity), ASA = American Society of Anesthesiologists Physical Status Classification System (I = healthy, II = Mild systemic disease, III = Severe systemic disease), Fracture type/G-A: based on Gustilo-Anderson classification for open fractures

*Revision Compress cases after Compress failure

Table 2 Summary of case operative characteristics

Case	Bone defect (cm)	Isolated microorganism	Cement spacer	TTO	CPS-Plug	Compression (lbs)	OSS length (cm)	Local ATB
1	23.5 cm	Polimicrobiane	Dynamic	Yes (2 T)	Standard	400 lbs	23	DAC®
2	15 cm	Negative	Dynamic	Yes (1,2 T)	Short	800 lbs	13	DAC®
3	13 cm	*MRSA*	Static	Yes (1,2 T)	Short	400 lbs	13	DAC®
4*	16 cm	Negative	None	Yes (2 T)	Short	400 lbs	17	DAC®
5	14.5 cm	*CNS*	Dynamic	Yes (1,2 T)	Short	400 lbs	16	DAC®
6	18 cm	*Pseudomonas* spp.	Static	No	Short	400 lbs	18	DAC®
7	15 cm	*MRSA*	Static	No	Short	600 lbs	13	DAC®
8	8 cm	*CNS*	Static	Yes (2 T)	Short	400 lbs	8	DAC®
9	13 cm	Negative	Static	Yes (2 T)	Short	800 lbs	18	DAC®
10	12 cm	*CNS*	Static	No	Short	400 lbs	13	DAC®
11	9 cm	*Pseudomonas* spp.	Static	Yes (2 T)	Short	400 lbs	8	DAC®
12*	14 cm	Negative	None	Yes (2 T)	Short	600 lbs	15	DAC®
13	12 cm	*CNS*	Static	Yes (2t)	Short	400 lbs	19	DAC®
14	21 cm	Negative	Static	No	Short	400 lbs	24	DAC®
15	20 cm	Negative	Static	Yes (2 T)	Short	400 lbs	22	DAC®
16	6 cm	Negative	Static	Yes (2 T)	Short	600 lbs	8	DAC®
17	5 cm	Negative	Static	No	Short	800 lbs	6	DAC®
18	11.5 cm	*CNS*	Static	Yes (2 T)	Short	800 lbs	17	DAC®
19	20.5 cm	*CNS*	Static	No	Short	400 lbs	20	DAC®
20	22 cm	*MRSA*	Static	No	Short	600 lbs	24	DAC®
21	17 cm	*CNS*	Static	Yes (2 T)	Short	800 lbs	18	DAC®

Bone defect: measured in cm, ranging in this dataset, 5–23.5 cm. CNS = coagulase-negative *Staphylococcus*, MRSA = Methicillin-resistant *Staphylococcus aureus*; TTO = tibial tubercle osteotomy (yes/no, and when it was performed, first stage 1 T or/and second stage 2 T). DAC = Defensive Antibacterial Coating (DAC®) hydrogel. The cells highlighted in * are from two cases of re-Compress®

coagulase-negative Staphylococcus strains were the most frequent pathogens found in our series, isolated in 33.3% of our cases. Eight cases presented negative cultures, despite unequivocal signs of infection. Further information on infection-causing microorganisms can be found in Table 2.

In this series, the mean distal femoral bone resection was 14.57 cm (range 8–23.5 cm). A static cement spacer was used in all cases without reported spacer-related complications. After the first stage, one patient experienced skin necrosis, which was resolved with a microsurgical ALT free flap. During the second stage, all microbiological cultures were negative; mean Compress®-OSS® reconstruction length was 15.85 cm. Detailed characteristics of Compress® implant in Table 2. Antibiotic-loaded hydrogel was used in all cases according to the described protocol, with no recorded intraoperative complication.

As to the principal endpoint of our study, after a mean follow-up of 42 months we did not observe any infection relapse in this series of patients, with an overall infection control rate of 100% following our stringent infection control criteria. All cases achieved limb salvage.

Regarding Compress® device-related complications, during early follow-up, five cases experienced Compress® fixation failure due to aseptic loosening, requiring isolated replacement of the femoral component (all cultures negative). Interestingly, all failures occurred in the first 7 months (range: 3–7); during the full weight-bearing step of the post-operative rehabilitation protocol (Table 3). Beyond this time threshold, no further implant failures were observed, resulting in a cumulative implant survival rate of 75% at 1 and 5 years, and of 75% at final follow-up (Fig. 4).

Regarding radiological evaluation, 71.4% showed bone hypertrophy on X-ray; all cases with bone hypertrophy scored 3 points (Fig. 5). All six cases without bone hypertrophy (scoring 1 or 2 points) experienced aseptic failures, except for one patient. This suggests a lack of bone osseointegration as the fundamental reason for failure. All failures required isolated revision of the femoral component: two new Compress® devices, two cemented stemmed MPs, and one total femur arthroplasty.

Table 3 Summary of compress failure case characteristics

Case	Age	Sex	Risk factors	Pedestal	Rx. score	Cause	FU (years)	Cultures IOP	Revision implant	Histology
1	61	F	BMI > 30	No	1point	Aseptic loosening	7	Negative	Compress	Chronic Inflammation changes
2	53	M	Smoker, BMI > 30	No	1point	Aseptic loosening	4	Negative	Cemented OSS®	Chronic Inflammation changes
3	48	M	Smoker	No	2 points	Implant Breakage	5	Negative	Compress	Foci of medullary necrosis
4	80	F	DM	No	2 points	Implant Breakage	3	Negative	Cemented OSS®	Chronic Inflammation changes
5	75	F	Non	No	1point	Implant Breakage	7	Negative	TFA OSS®	Chronic Inflammation changes

Age = reported in yeas; F = female, M = male; BMI = body mass index (values over 30 indicate obesity); DM = diabetes mellitus; Pedestal = presence of pedestal formation noted (Yes/No); Rx Score = Groundland score (3 points system assessing radiographic features); FU = follow-up duration in years of post-surgical follow-up; IOP = intraoperative, TFA = total femur arthroplasty

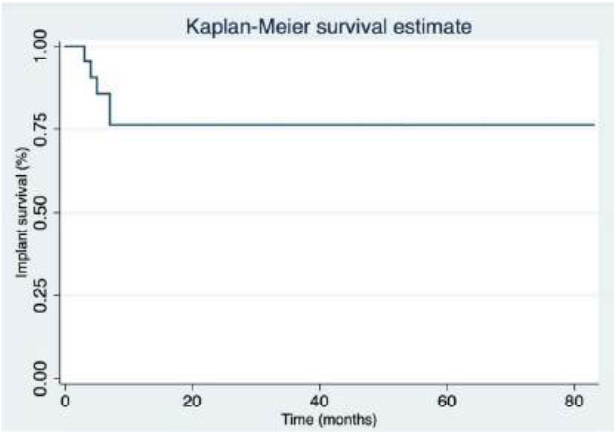

Fig. 4 Graph of Kaplan–Meier survival curve for our series of compress implants after infected bone defect resection of the distal femur, after a midterm follow-up of 5 years

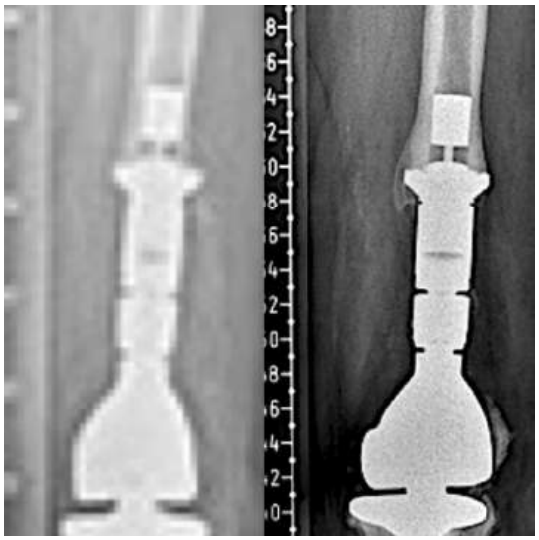

Fig. 5 An AP radiograph (case #13) reveals bone hypertrophy in the interface host bone–implant which indicates a scoring of 3 points according to the Groundland radiographic scale

Discussion

In this cohort of 21 patients with infected distal femur bone defects managed using the Compress® distal femoral replacement (DFR), a limb salvage rate of 100% was achieved. By employing a two-stage surgical strategy combined with an antibiotic-loaded resorbable hydrogel coating, no cases of infection recurrence were observed after a median follow-up period of 42 months. The 5-year implant survivorship for the Compress® distal femur replacement was 75%, with no mechanical failures occurring beyond 7 months post-operatively. To our knowledge,

this represents the largest series of its sort reported in a non-oncological context.

The recurrence of infection in previously infected cases managed with megaprostheses constitutes a significant clinical challenge. The principle that "the larger the implant surface, the greater the risk of bacterial adhesion" is particularly relevant in this setting. Notably, the literature addressing such scenarios remains scarce, with reported infection rates ranging from 3 to 30% [5]. Distal femoral replacements (DFRs) present an even greater concern, with a relative risk of revision due to reinfection of 3.33 ($p = 0.056$) [20].

In the current series, we observed no infection relapse after a median follow-up of 42 months, following a very stringent infection control criterion. The included cases had undergone multiple prior surgical procedures, a well-established risk factor for treatment failure due to the potential presence of deep osteomyelitis and compromised soft tissue integrity. The high success rate in infection control can be attributed to three key factors: (a) extensive bone resection to eradicate potential osteomyelitis foci, (b) the use of a staged approach particularly suited to complex cases, and (c) the application of surface-coating technology to mitigate bacterial colonisation of implant surfaces.

While single-stage procedures may be applicable in select infected cases, we advocate for a staged approach in more complex scenarios. This strategy facilitates precise microbiological diagnosis, allows for rigorous infection control monitoring, and simplifies the management of complications. Crucially, it provides an opportunity for patient and soft tissue optimisation prior to reimplantation of a new megaprosthesis under improved physiological conditions, thereby reducing the risk of bacterial recolonisation.

The risk of recolonisation remains a pivotal concern in these cases, prompting the development of various surface modification and coating technologies aimed at reducing bacterial adherence. Available coating options are limited, and their clinical efficacy remains controversial. Defensive Antibacterial Coating (DAC®) is a hydrogel composed of covalently linked hyaluronan and poly-D,L-lactide. Although originally designed as a stand-alone product to reduce perioperative bacterial adhesion (passive antifolding effect), the gel can be loaded with different antibiotic (active antibacterial effect) concentrations [20]. When mixed with antibiotics, the compound can quickly deliver local antibiotics in amounts hundreds or thousands of times higher than the minimum inhibitory concentration for up to 72 h, inhibiting biofilm formation on different substrates and planktonic bacterial growth in vitro [21]. DAC® is reabsorbed in 72 h, with no observed deleterious effect on bone healing or implant osseointegration in animal models. Hydrogel effectiveness and safety have been proved in two single-blind randomised controlled multi-centre trials in the field of trauma and orthopaedic [8, 20]. For instance, in a multi-centre randomised prospective study [20] involving 380 total joint arthroplasties, patients were randomly assigned to receive either a standard implant or an implant coated with antibiotic-loaded DAC®. After a mean follow-up of 145 months, 11 early surgical site infections were documented in the control group compared to only one in the treatment group (6% vs. 0.6%; $p = 0.003$), suggesting that hydrogel coating may significantly reduce the incidence of acute periprosthetic joint infections. The absence of hydrogel-related complications and our favourable infection control outcomes warrant further investigation into the potential role of this coating strategy.

Distal femur replacement (DFR) presents a particularly challenging biomechanical environment, characterised by high rates of early aseptic loosening. Published series have reported aseptic failure rates as high as 18% at 5 years and 47% at 8 years [3]. The long stem length inherent to these implants results in elevated bending stresses and rotational instability, predisposing them to early mechanical failure. Moreover, revisions involving long-stemmed implants often result in substantial bone stock loss, which may preclude further revision surgery [21].

The Compress® implant was developed as an alternative to traditional stemmed megaprostheses, specifically designed to address their limitations. Primarily utilised in oncological reconstructions, evidence regarding its efficacy in infected cases remains scarce. By leveraging Wolff's law, the Compress® system promotes hypertrophy at the bone–implant interface through axial compression, thereby facilitating stable, high-pressure fixation with shorter working lengths and reduced bone resection requirements [12]. Potential advantages of the Compress® implant include improved bone stock preservation, reduced stress shielding, and enhanced biomechanical stability. Nonetheless, it is not devoid of complications, with mechanical failure being a notable concern.

Our Compress® distal femur replacement survivorship rate was 75% at 5 years, with all failures occurring in the first 7 months in this very complex scenario. Although long-term data are limited, previous studies—predominantly in oncological cohorts—have reported comparable outcomes. Healey et al. [22] retrospectively analysed 82 distal femur reconstructions using the stemless Compress® implant in oncological patients, reporting survivorship rates of 85% at 5 years and 80% at 10 years. The slightly lower survivorship observed in our series may be attributed to the increased complexity of septic, multi-operated cases compared to oncological cases, where factors such as advanced age, irradiated bone, and metabolic disorders (e.g. diabetes, osteoporosis) often contraindicate the use of Compress® implants [12, 22]. These differences underscore the distinct nature of our cohort.

Comparative studies assessing implant survivorship between Compress® and stemmed megaprostheses have yielded mixed results. In a retrospective analysis by Pedtke et al. [11], 26 oncological patients undergoing distal femoral reconstruction with Compress® implants were compared with 26 matched patients treated with cemented intramedullary stems. Kaplan–Meier analysis demonstrated a significantly longer 5-year implant survival rate ($p = 0.0001$) in the Compress® group (83.5% vs. 66.6%) using revision or amputation as the endpoint. Aseptic failure patterns also differ between the two implant types: Compress® implants typically fail due to insufficient osseointegration at the bone–implant interface, whereas stemmed implants fail progressively over time. This highlights the importance of bone biology in implant fixation, as mechanical failure becomes inevitable if osseointegration is not achieved [21]. The reported aseptic failure rates for Compress® implants range from 4 to 25% [12]. Importantly, once osseointegration is achieved, the long-term risk of aseptic failure is minimal. Our findings corroborate this, as all mechanical failures occurred within the first 7 months post-operatively, with no subsequent failures observed. Groundland et al. [12] reported similar outcomes in a cohort of 25 oncological patients with proximal or distal femoral replacements using Compress® implants. In their series, patients over the age of 50 were excluded, whereas the mean age in our cohort was 58 years (range: 19–80). Among the 20 patients who were followed for over 10 years, only three required revision due to aseptic failure, all occurring within 29 months of surgery, with a median of 16 months. Interestingly, all revisions were successfully managed with a new Compress® implant without further complications.

Traditional radiographic parameters used to assess megaprosthesis fixation are inadequate for predicting aseptic failure in Compress® device [23]. Groundland [12] proposed a simplified three-point scale based on host bone response. In our series, 15 patients demonstrated a radiological pedestal, each scoring 3 points. Notably, none of the five patients who experienced mechanical failure scored 3; instead, 69% scored only 1. These findings suggest that this radiological grading system is effective for evaluating osseointegration status and predicting mechanical failure risk. Based on our observations, we recommend close follow-up during the first post-operative year, including periodic radiological assessment of osseointegration at the bone–implant interface.

Several limitations of this study warrant consideration. Its retrospective design, dependent on medical records, carries an inherent risk of incomplete data and potential bias. The absence of a control group employing alternative distal femur stemmed megaprostheses in comparable clinical contexts precludes direct comparative analysis. Furthermore, the lack of a comparator group utilising Compress® implants without hydrogel coating hinders an isolated assessment of the coating's impact. Although the sample size is relatively small, it aligns with similar investigations and likely constitutes the largest reported series in septic, non-oncological settings. Additionally, all cases were managed within a single high-volume, specialised centre, potentially limiting the generalisability of the findings to less-experienced institutions. Despite being developed in a specialised setting, this protocol could be adapted for broader clinical application with appropriate training and resource allocation. Given the inherent complexity of these cases, referral to high-volume centres with substantial expertise in managing complex infections remains advisable. Prospective studies with larger sample sizes, multi-centre collaboration, and extended follow-up periods are imperative to corroborate these findings and refine the clinical use of stemless megaprostheses in infected scenarios. Such research would offer a more robust understanding of the long-term safety and efficacy of this innovative approach.

Conclusion

Distal femur replacement (DFR) using the Compress® device with hydrogel coating is a viable option for managing extensive infected bone defects, achieving 100% infection control and a midterm survivorship rate of 75%. All aseptic failures occurred during the early post-operative period, with no further loosening beyond the 7-month threshold. Although developed in a specialised centre, this protocol could be adapted to other clinical settings with proper training and resource allocation. This approach provides a promising solution for complex non-oncological cases involving infected distal femoral bone defects.

Author contribution PSC and MHV wrote the main manuscript text; RF prepared the DAC protocol; CA and MV contributed in preparing figures and tables. All authors reviewed the manuscript.

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Data availability No datasets were generated or analysed during the current study.

Declarations

Conflict of interest The authors declare no competing interests.

Ethical statement All authors have participated in this paper, and we affirm that it has not been sent to any other journal. The Ethics Committee of our centre approved this study (Institutional Review Board—IRB approval).

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