Clinical/Basic Science Research Article

OPEN

Intramedullary nailing with absorbable antibiotic-eluting ceramic for fracture-related infection prophylaxis in high-risk open fractures: a case series and technique

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Abstract

Objectives: Fracture-related infection (FRI) is a devastating complication of open fractures and remains common even with ideal open fracture care including prompt systemic antibiotics and thorough surgical debridement. There is growing interest in the use of adjuvant local antibiotics; however, traditional carriers like polymethylmethacrylate (PMMA) are limited by subtherapeutic elution, biofilm formation, and the need for secondary removal. We describe a technique of in vivo augmentation of intramedullary nailing with Cerament G, a resorbable gentamicin-eluting calcium sulfate/hydroxyapatite ceramic, delivered through the 2-CAN device for targeted antibiotic prophylaxis.

Methods: Nine patients (mean age 44 years; 22% female) with Gustilo–Anderson Type II (n = 3), IIIA (n = 4), IIIB (n = 1), and IIIC (n = 1) open fractures of the tibia, femur, or humerus underwent this technique at a Level 1 trauma center by a single fellowship-trained orthopaedic traumatologist. Postoperative outcomes included FRI incidence, fracture union, complications, and functional recovery.

Results: At a mean follow-up of 9.1 months (2.6–17.1 months), all fractures achieved union with no cases of FRI. Two GA IIIB/C cases required flap coverage, including one flap failure successfully revised. Self-limiting serous drainage (n = 3) resolved within 1 week. No secondary procedures for infection, implant removal, or amputations occurred.

Conclusion: Intramedullary nailing and intraoperative augmentation with Cerament G using the 2-CAN device offer a technically simple, time-efficient strategy for FRI prophylaxis in high-risk open fractures. The technique provides sustained local antibiotic delivery, avoids PMMA-related complications, and maximizes biomechanical stability by eliminating nail downsizing. Early results demonstrate promising infection prophylaxis, warranting further prospective trials to validate long-term efficacy and cost-effectiveness.

Keywords: intramedullary nailing, absorbable antibiotic-eluting bone graft substitute, absorbable antibiotic-eluting ceramic, open fracture

1. Introduction

Open fractures represent a significant challenge in orthopaedic trauma care, with fracture-related infections (FRIs) posing a major complication that adversely affects patient outcomes, prolongs length of stay, and significantly increases costs.[1] Despite adherence to established management practices—including prompt systemic intravenous (IV) antibiotic administration and surgical debridement—FRI rates remain unacceptably high.[2,3] These persistent infection risks underscore the limitations of systemic therapies, particularly in cases of compromised local vasculature, such as tibia fractures or mangled extremities, where inadequate tissue penetration or vascular compromise may diminish delivery of systemic IV antibiotics.

The limitations of systemic therapy have driven interest in local antibiotic delivery, with particular interest in antibiotic-loaded carriers for prolonged elution. Polymethylmethacrylate (PMMA) antibiotic beads and coated implants offer sustained antibiotic release; however, studies have found the elution to be characterized by a high initial burst, followed by prolonged subtherapeutic antibiotic levels below minimum inhibitory concentration

S. M. Sandilands: Consultant and research support from BONESUPPORT AB Inc. Consultant for Skeletal Dynamics. Consultant for Smith and Nephew. A. V. Daji has no conflict of interest to disclose.

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The study was deemed exempt from Institutional Review Board and Animal use Committee Review.

OTAI (2026) e478

Received: 20 May 2025 / Accepted: 16 January 2026
Published online 5 March 2026

http://dx.doi.org/10.1097/OI9.0000000000000478

(MIC).[4–6] This may promote the development of antibiotic resistance, with retrieval studies demonstrating colonization of PMMA beads and the presence of biofilm.[5,6] In addition, the exothermic polymerization reaction can denature heat-sensitive antibiotics, and PMMA is a nonresorbable foreign material that necessitates secondary removal. This can be fraught with complications as the PMMA mantle can debond from the IMN during both insertion and removal.[7] Intramedullary nailing with an absorbable antibiotic ceramic has emerged as an alternative option, given these disadvantages.[8] In vivo application of flowable antibiotic ceramic-based carrier leads to pressurization and interdigitation of the ceramic into cancellous bone during nail insertion and uniform coating of the IMN.[9] This allows for the use of adequately sized IMNs without the need for downsizing of the nail diameter and compromising fracture stability.

We present a surgical technique and a case series of Gustilo–Anderson (GA) Type II/III long bone fractures treated with gentamicin-augmented antibiotic nails using the 2-CAN intramedullary delivery device (Flow-FX, Mokena, IL). Cerament G (Bonesupport AB, Lund, Sweden) is an injectable calcium sulfate/hydroxyapatite ceramic impregnated with gentamicin. The formulation achieves high local antibiotic concentrations while exhibiting osteoconductive and bioabsorbable properties. The 2-CAN's double-channeled cannula keeps the guidewire clean for ease of insertion of the intramedullary nail and allows for precise delivery of Cerament G at the desired location. Unlike intramedullary nails coated with PMMA, Cerament G–augmented IMNs do not need to be removed, prevents prolonged subtherapeutic antibiotic elution, and does not necessitate the need for nail downsizing to accommodate a cement mantle. This surgical technique guide outlines a standardized surgical protocol for the in vivo application of Cerament G through a double-channeled cannula in the management of open fractures treated with intramedullary nailing.

2. Surgical technique

We use this technique for open Gustilo–Anderson Type II/III long bone fractures treated with intramedullary nails. For fractures with mild contamination and a wound amenable to primary closure, we proceed with irrigation and debridement (I&D) followed by Cerament G application, intramedullary nailing, and wound closure. For moderately or grossly contaminated fractures, the fracture is initially stabilized with an external fixator and serial I&Ds are performed until a clean wound bed can be achieved and soft tissue permits definitive fixation. All open fractures are administered IV antibiotics within 1 hour of presentation to the ED in accordance with the hospital's open fracture protocol.

Thorough debridement of contamination and devitalized tissue is critical in the prevention of fracture-related infection when addressing open fractures. In standard fashion, the nail start point, opening reaming, and passing of the ball-tip guidewire across the fracture site are performed. Sequential reaming is performed until chatter is achieved at the isthmus of the long bone. We do not downsize nail diameter or excessively over-ream to accommodate the Cerament G; instead, we use the same nail diameter we would have selected for a closed fracture and over-ream by the standard 2 mm. For example, if isthmic chatter was achieved with a 12-mm reamer, then a 10-mm intramedullary nail would be used. While reaming, begin mixing Cerament G on the back table according to manufacturer recommendations. We recommend using 10 cc of Cerament G spread through the intramedullary canal with a concentration at the fracture site. After mixing, it is advisable to wait 3 to 4 minutes before application and, if possible, insufflate a tourniquet to enhance interdigitation within the bone. In our series, tourniquets were placed before draping for tibial nails and were insufflated to 250 mm Hg during the application of Cerament G into the medullary canal. Using the 2-CAN device over the ball-tipped guidewire, inject the entire canal with Cerament G using fluoroscopy to confirm intended placement and distribution throughout the canal. Backfill the canal starting from the end of the ball-tip guidewire pulling toward the nail insertion site. The 2-CAN device allows for controlled expression of the ceramic into the desired area (Fig. 1). Following application of the Cerament G, the tourniquet is deflated with an average tourniquet time of approximately 3 minutes.

For midshaft long bone fractures, we recommend 5 cc in the proximal aspect of the bone and 5cc across the distal aspect, with a concentration at the fracture site and location of the open traumatic wound. For proximal or distal 1/3 fractures, inject 2 cc in the short fragment and 8 cc in the long fragment, again, with a concentration at the fracture site (Table 1). Using the 2-CAN

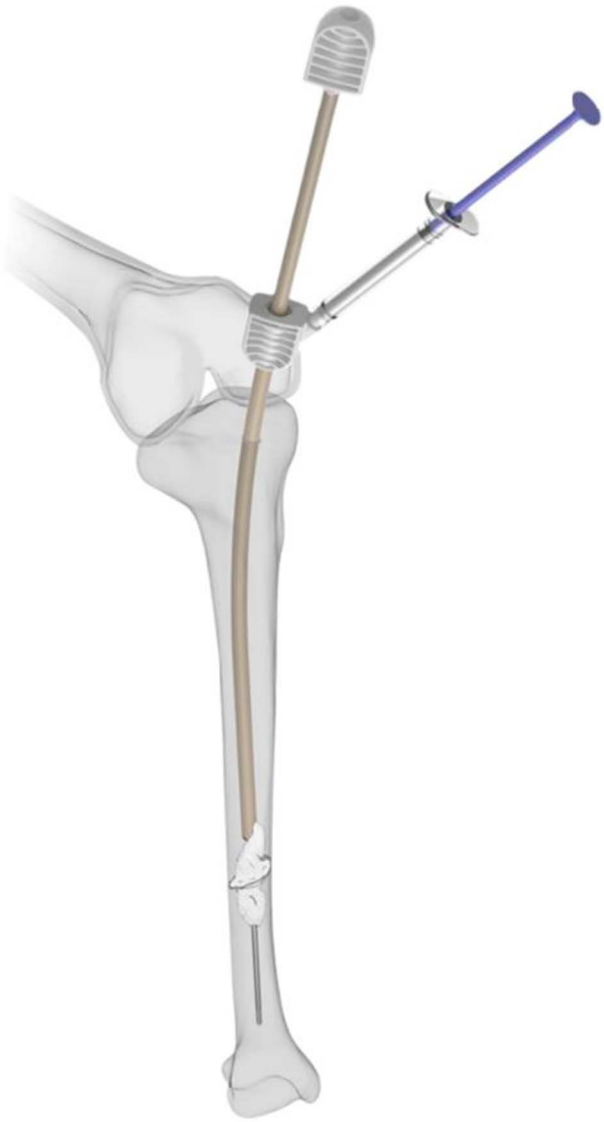

Figure 1. 2-CAN delivery device.

device, express 2 cc at the proximal and distal ends of the fracture site, serving as an osteoconductive scaffold ensuring high antibiotic elution at the area of greatest risk. Small volumes of Cerament G may extrude out of the fracture site; however, we have not experienced adverse events from Cerament G in the soft tissues with no signs of heterotopic ossification to date. Following application of the Cerament G, remove the 2-CAN device and insert the intramedullary nail over the ball-tipped guidewire in standard fashion. Approximately 10 minutes following application of the Cerament G, it can be safely drilled through for proximal and distal interlocking screws.

One documented complication associated with Cerament G is persistent drainage of a serous, milky-white fluid. While this discharge may mimic purulent exudate, it is sterile and self-limiting. Close monitoring of the drainage is essential to confirm it remains within expected postoperative parameters, as deviations in volume, color, or consistency may indicate FRI that requires further assessment. In our series, we found that the serous drainage resolved spontaneously in approximately 1 week post-operatively in all cases with daily dressing changes.

Finally, attention should be turned to closure. For open wounds that are amenable to primary closure, we recommend layered closure with nonabsorbable monofilament, followed by skin closure with a nonbraided monofilament suture (i.e., Nylon and Prolene). For wounds not amenable to tension-free primary closure, we use wound vacs and involve plastic surgery for early soft-tissue coverage, ideally within 5 to 7 days. All open fractures are administered IV antibiotics until 48 hours after soft-tissue coverage in accordance with the hospital's open fracture protocol.

3. Initial clinical experience

Nine patients at a Level 1 trauma center were treated for open tibia, femur, and humerus fractures by a single fellowship-trained orthopaedic traumatologist (Table 2). Two of 9 (22%) were female, with a mean age of 44 years (21–76) and a mean BMI of 28.3 kg/m^2 (18.8–36.1). Three (33%) of the patients had GA Type II, 4 (44%) had GA Type IIIA, one (11%) had GA Type IIIB, and one (11%) had GA Type IIIC open fractures, all treated with intramedullary nails. Plastic surgery was consulted on the day of presentation from the Trauma Bay for GA Type IIIB/C fractures for multidisciplinary management of soft-tissue coverage needs, with a goal of soft-tissue coverage within 5 to 7 days. Similarly, vascular surgery was consulted from the Trauma Bay for all GA IIIC fractures. All patients in the series received intravenous antibiotics within 1 hour of presentation in accordance with the hospital's open fracture protocol. The mean length of stay (LoS) for the cohort was 13.7 days. To date, with a mean follow-up of 9.1 months (2.9–17.1 months), all patients in the case series have achieved healing of their fracture without evidence of FRI. The modified radiographic union score for tibial fractures (mRUST) was used to grade healing of the fractures in the cohort[10] (Table 2). Three patients experienced prolonged serous drainage from the open fracture site likely attributable to Cerament G, all of which resolved within 1 week with local wound care and daily dressing changes. One patient had necrosis of his lateral split-thickness skin graft, requiring re-grafting. Another patient experienced failure of his anterolateral thigh free flap, requiring a return to OR for a free latissimus dorsi flap. No patients required amputation, and there have been no mortalities. Although our case series is limited in size and follow-up, these findings represent promising preliminary results for this surgical technique as prophylaxis for FRIs.

Table 1

Cerament G volumes and distribution.

Long bone	Volume	Cerament G distribution
Proximal 1/3	10 cc	2 cc proximally/8 cc distally
Midshaft	10 cc	5 cc proximally/5 cc distally
Distal 1/3	10 cc	8 cc proximally/2 cc distally

4. Case 1

4.1. Patient information

A 36-year-old man with no significant medical history presented with a GA II distal 1/3 tibia/fibula fracture and an open, contaminated 3 × 1 cm anteromedial wound after falling off a horse and subsequently being stepped on by the horse (Fig. 2). On presentation to the ED, the fracture was irrigated, reduced, and splinted. IV antibiotics were administered in accordance with the hospital's open fracture protocol. The next day, HD2, he was taken to the OR for I&D, external fixation, and primary closure of the anteromedial wound. On HD4, he was taken back to the OR for repeat I&D, external fixator removal, tibial intramedullary nailing with Cerament G, and closure of the anteromedial wound (Fig. 3). He was made weight bearing as tolerated to the operative extremity. He was discharged home on HD6.

4.2. Postoperative course

At the 3-month follow-up, x-rays confirmed fracture healing with a mRUST score of 11 and no clinical or radiographic signs of FRI (Fig. 4). The patient ambulates without pain and has resumed normal activities.

5. Case 2

5.1. Patient information

A 75-year-old woman had a GA IIIA midshaft tibia and fibular shaft fracture with an open 8 × 2 cm medial wound after a pedestrian versus car accident (Fig. 5). In the ED, the fractures were irrigated, reduced, and splinted. IV antibiotics were administered in the Trauma Bay in accordance with the hospital's open fracture protocol. On the day of presentation, the patient was taken emergently to the OR for I&D, tibial intramedullary nailing with Cerament G, and primary closure of the open medial wound (Fig. 6). Postoperatively, she was made weight bearing as tolerated. She experienced prolonged serous drainage from the primarily closed open medial wound likely attributable to Cerament G. This was treated with local wound care and daily dressing changes and resolved on postoperative day 6. She was discharged to a skilled nursing facility on HD7.

5.2. Postoperative course

At 6-month follow-up, x-rays demonstrated union of the tibia and fibula fractures with a mRUST score of 16 without clinical or radiographic evidence of FRI (Fig. 7). The patient can ambulate without pain and has resumed activities of daily living without issue.

6. Discussion

FRI results in prolonged hospitalization, multiple reoperations, extended systemic antibiotic use, and, in severe cases, limb amputation, with affected patients often experiencing long-term

Table 2

Patient outcomes.

	Age	Sex	BMI	Comorbidities	MOI	Bone	GA grade	Wound	Contamination	Stabilization	Closure	Osteointegration	FRI	Complication	LoS (d)	Outcome/mRUST score	F/u (mo)
#1	42	M	31.4	Hx of ipsilateral femur OM	Scooter vs MVC	Midshaft tibia/fib	IIIA	AL tibia 6 × 4 cm	Mild	10 mm tibia IMN	Primary	Yes	None	None	4	Ambulates with mild knee pain; returned to work. mRUST score 16	12.3
#2	47	M	31.6	R knee d/L, tib plateau fx, left fem neck/shaft	Ped vs MVC	Distal 1/3 tibia/fib	IIIA	PM distal tibia 7 × 2 cm	Mild s/p ex-fix and I&D	11.5 mm tibia IMN	Primary	Yes	None	Prolonged serous drainage*	13	Ambulating without pain and no assistive devices. mRUST score 12	12.7
#3	58	M	36.1	Obesity	Crush between cars	Midshaft tibia/fib	IIIB	Lateral tibia 15 × 6 cm	Mild s/p ex-fix and I&D	10 mm tibia IMN	Wound vac > STSG	Yes	None	Necrosis of lateral wound STSG requiring regrafting	24	Ambulating without pain and no assistive devices; mRUST score 14	5.9
#4	21	M	20.6	None	Ped vs motorcycle	Distal 1/3 tibia/fib	IIIC	Anterior tibia 23 × 8 cm w/ anterior tibial artery injury	Mild s/p ex-fix and I&D	10 mm tibia IMN	Free latissimus dorsi flap	Yes	None	Free ALT flap failure	41	Ambulating without pain and no assistive devices; returned to work. mRUST score 12	17.1
#5	76	F	28.1	Anemia	MVC	Pilon w/ nonreconstructable joint	II	Posterolateral ankle 3 × 1 cm	Mild s/p ex-fix and I&D	10 mm TTC IMN	Primary	Yes	None	None	3	Ambulating without pain and no assistive devices	8.3
#6	36	M	34.1	None	Fall from horse	Distal 1/3 tibia/fib	II	Anteromedial distal tibia 3 × 1 cm	Mild s/p ex-fix and I&D	10 mm tibia IMN	Primary	Yes	None	None	6	Ambulates without pain and has returned to work. mRUST score 11	2.9
#7	75	F	29.8	None	Ped vs MVC	Midshaft-distal tibia/fib	IIIA	Medial distal tibia 8 × 2 cm	Mild	10 mm tibia IMN	Primary	Yes	None	Prolonged serous drainage*	7	Ambulates without pain and has returned to ADLs. mRUST score 16	5.9
#8	22	M	18.8	None	Motorcycle accident	Humeral shaft	II	Lateral humerus 2 × 2 cm	Mild	8/7 mm humerus IMN	Primary	Yes	None	None	20	Returned to work with mild pain. mRUST score 13	11.9
#9	23	M	23.8	None	Motorcycle accident	Distal femur shaft	IIIA	Anterior distal femur 13 × 5 cm	Mild s/p ex-fix and I&D	10 mm retrograde femur IMN	Primary	Yes	None	Prolonged serous drainage*	5	Ambulating without pain and no assistive devices; returned to work. mRUST score 11	5.0

* Prolonged serous drainage was treated with local wound care and daily dressing changes and resolved spontaneously without return to the OR.
ADLs, activities of daily living; STSG, split-thickness skin graft.

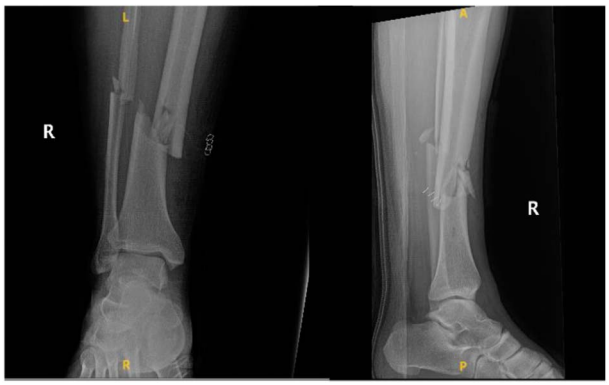

Figure 2. Preoperative AP and lateral x-rays demonstrating an open tibial shaft fracture.

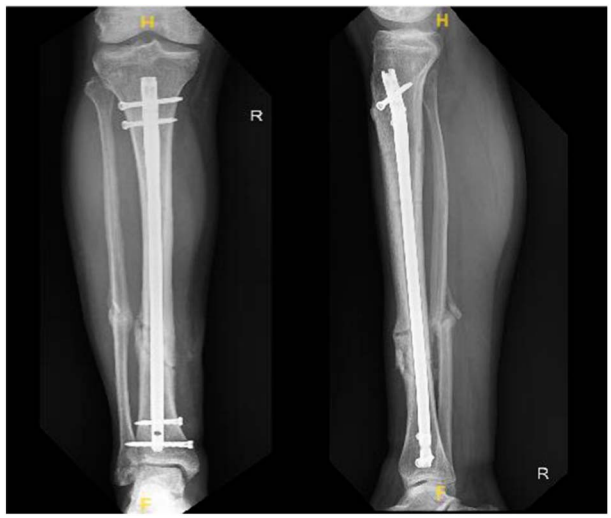

Figure 4. Three-month postoperative x-rays demonstrating a healed fracture.

disability, chronic pain, and reduced work capacity and quality of life.[1,11,12] The economic impact is equally profound, as total costs for FRI are reported to be 6.5 to 8 times higher than for non-FRI long bone fractures, and the global burden of FRI now exceeds that of periprosthetic joint infection.[1,11,12] These sobering outcomes underscore the urgent need for more effective prophylactic strategies in high-risk fractures, particularly GA Type II/III open fractures, which remain a complex clinical challenge with persistently high infection rates despite adherence to gold-standard systemic antibiotics and surgical debridement.[1,13] This substantial patient and financial burden has driven increasing interest in adjunctive local antibiotic therapies to complement systemic IV antibiotics.[14,15] Several retrospective studies have demonstrated promising reductions in infection rates,[3,16] leading to the VANCO randomized controlled trial, which supported topical vancomycin for reducing Gram-positive infections in high-risk tibial plateau and pilon fractures, although its efficacy against Gram-negative organisms was limited.[17] Additional retrospective data from 168 open fractures support the use of aqueous aminoglycoside injection in reducing FRI.[18] However, naked antibiotics—whether powdered or aqueous—have short therapeutic windows and fail to address dead space or cortical defects. By contrast, Cerament G is osteoconductive and provides sustained local antibiotic elution above the MIC for 28 days, with an initial burst release 250 times the MIC.[19] In addition, complete resorption of the carrier within 6 to 12 months avoids the prolonged, sub-MIC antibiotic release, which has been associated with antibiotic resistance.[20,21]

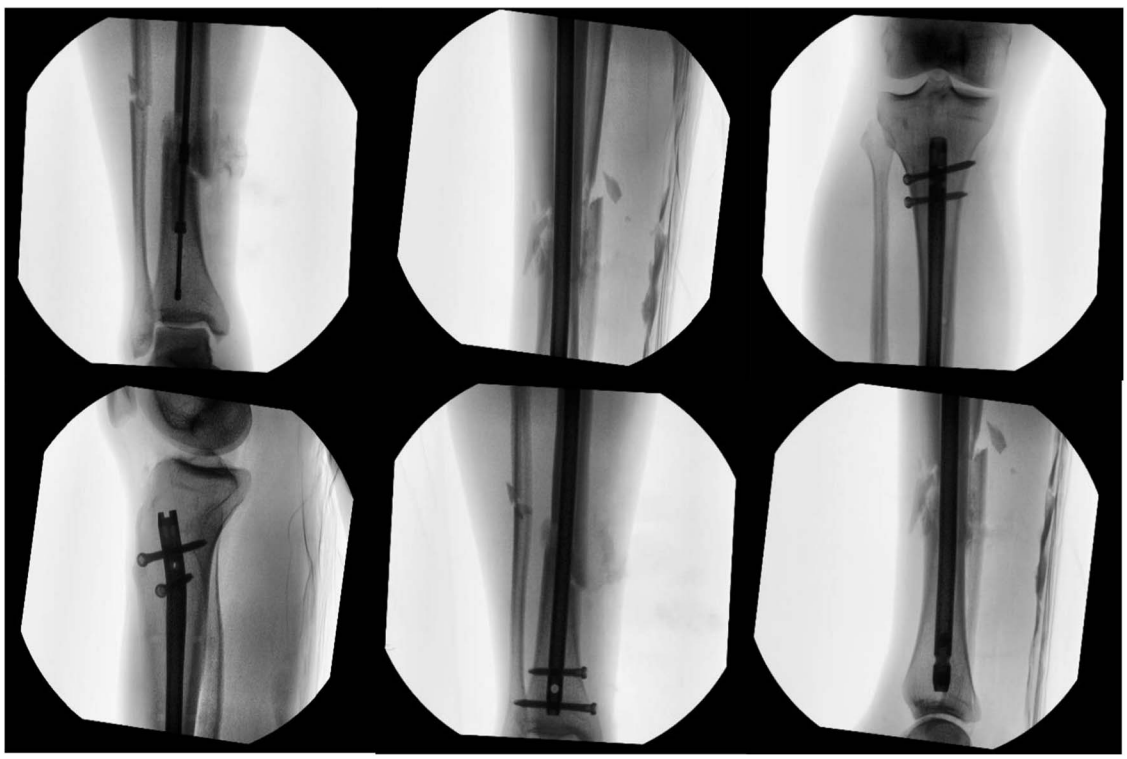

Figure 3. Intraoperative images showing injection of Cerament G into the tibial canal using the 2-CAN device, followed by intramedullary fixation.

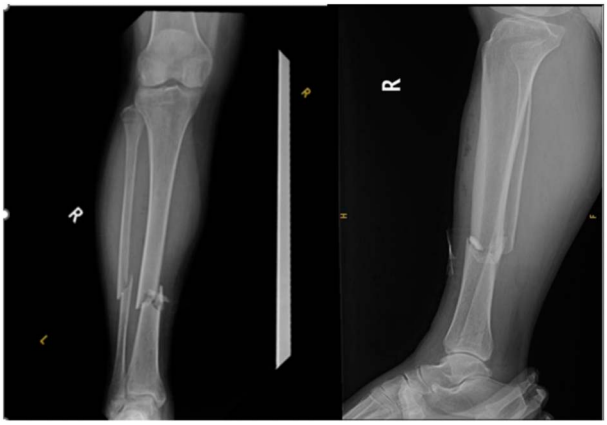

Figure 5. Preoperative AP and lateral x-rays demonstrating an open tibial shaft fracture.

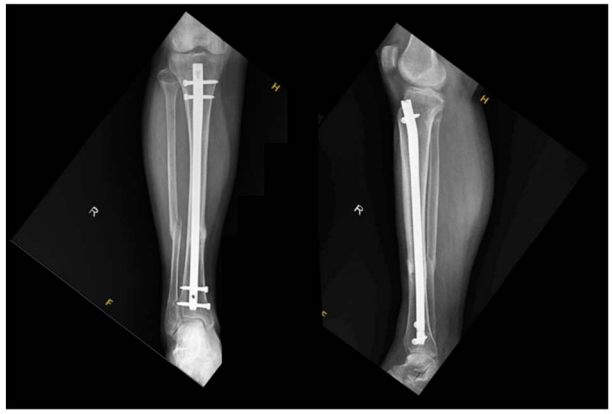

Figure 7. Six-month postoperative x-rays demonstrating a healed fracture.

Loading an antibiotic into a carrier helps overcome these challenges with sustained local antibiotic elution while augmenting fracture stability. PMMA coating of guidewires, rods, and IMNs has become standard of care for staged treatment of FRIs and infected nonunions.[13,22] However, PMMA coating of intramedullary nails is a time-consuming and technically challenging method of prophylaxis against FRI in high-risk open fractures. By contrast, INaac with Cerament G requires a few minutes of back-table preparation while the surgeon is reaming and can be ready for injection into the intramedullary canal immediately following the final reamer. Additional fluoroscopic shots are helpful for ensuring that the Cerament G is being delivered evenly in the medullary canal with the 2-CAN; however, in our experience, this only negligibly increases the total fluoroscopic time and radiation exposure of the case.

Cerament G's flowable calcium sulfate/hydroxyapatite mix offers several advantages over PMMA: sustained supra-MIC elution of gentamicin over 3 to 4 weeks,[23] osteoconductive and bioabsorbable properties eliminating the need for removal,[20,24] and technical simplicity with in vivo augmentation of the nail due to its flowable nature. This enables interdigitation of the Cerament G into the medullary bone during nail insertion—avoiding the need to downsize the nail diameter or over-ream the canal to accommodate a cement mantle.[9] By contrast, PMMA-coated IMNs require a nail diameter 3.0 to 3.5 mm smaller than the final reamer size to allow space for a 1.5 to 2 mm cement coating.[25] This introduces risk of iatrogenic fracture during reaming or compromised stability if a small diameter nail is used.

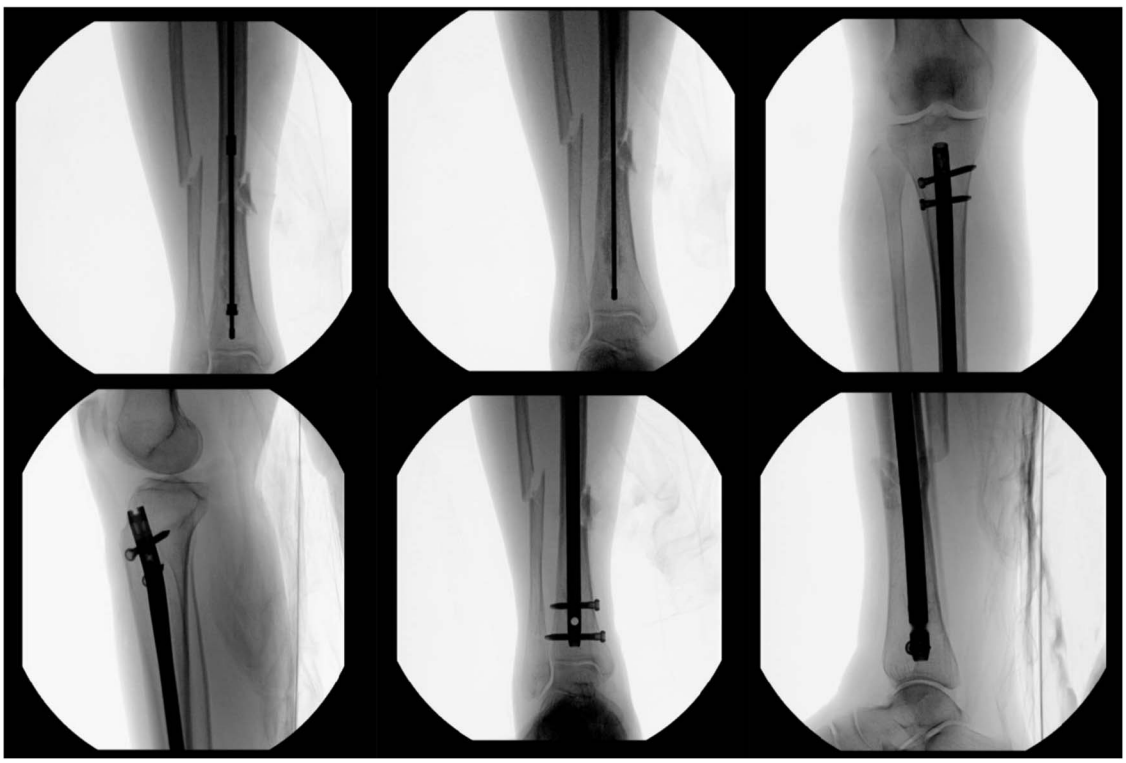

Figure 6. Intraoperative images showing injection of Cerament G into the tibial canal using the 2-CAN device, followed by intramedullary fixation.

In addition, achieving uniform PMMA coating on IMNs ex vivo is technically demanding and time-consuming.[26] Great care must be taken during insertion to avoid cement-nail debonding, which can leave areas of the implant exposed for colonization. Removal of the nail and reaming to a larger size is advisable if any resistance is encountered on insertion to prevent debonding. Similarly, nail retrieval can be fraught with complications. Debonding is common and retained cement left behind can serve as a nidus for infection and harbor biofilm.[27]

FRI is a common and devastating complication of open fractures, with reported rates ranging from 8% to 12% in GA Type II fractures and from 17% to 40% for GA Type III injuries despite modern protocols.[17,28–30]

This technique reflects an evolving paradigm shift in the treatment of open fractures, with recent high-level evidence supporting the use of local antibiotic delivery for prophylaxis of Gram-positive FRI in high-risk open fractures.[17] We describe a technique of INaac with Cerament G and the 2-CAN using standard-sized implants for local antibiotic coverage in high-risk open fractures. Future studies should focus on long-term outcomes, cost-effectiveness, and optimal antibiotic formulations to further optimize FRI prevention.

There are several limitations to consider when interpreting the initial clinical results of this case series. The small sample size of 9 patients and limited mean follow-up period of 5.9 months (2.6–12.7 months) may be insufficient to capture late presentations of FRI. In addition, the lack of a control or comparison group prevents assessing the relative effectiveness of this technique. While FRI has been avoided to date in all patients in the series, patient-reported outcome measures were not assessed, limiting our understanding of the technique's impact on functional restoration and patient satisfaction. Finally, as a single-surgeon, single-center study, selection and procedural bias limits the generalizability of these findings. Our findings with this technique represent promising preliminary results; however, these limitations highlight the need for larger, comparative, prospective studies with longer-term follow-up.

7. Conclusion

We present a surgical technique for the use of intramedullary nailing with an absorbable antibiotic ceramic with Cerament G for prophylaxis against FRI in high-risk open fractures. By addressing the limitations of powdered or PMMA-based delivery, this approach may represent a technically simple, time-efficient, prophylaxis against FRI. Short- to mid-term results of this technique in our case series are promising; however, controlled prospective trials and cost-effectiveness studies are needed.

We attest that all authors have complied with the journal's ethical standards and requirements.

Data availability statement

The datasets generated during and/or analyzed during the current study are not publicly available, but are available from the corresponding author on reasonable request.

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