

Intramedullary nailing with an absorbable antibiotic bone graft substitute in fracture-related infections and osteomyelitis: a case series

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Abstract

Objectives: Fracture-related infections (FRI), infected nonunions, and osteomyelitis with bony instability require aggressive treatment involving systemic antibiotics and surgical debridement. Adjuvant local antibiotic therapy delivers higher and sustained concentrations directly to the site of infection while minimizing systemic toxicity. Antibiotic-loaded poly-methyl methacrylate remains a standard option but presents significant limitations, including nonbiodegradability, reduced antibiotic elution over time, and the need for subsequent removal. Cerament G is a bioabsorbable bone void filler composed of calcium sulfate, hydroxyapatite, and gentamicin sulfate. It provides sustained high-dose antibiotic release, promotes osteoconduction, and remodels into bone within 6 to 12 months, eliminating the need for removal. This makes Cerament G a compelling option for the treatment of FRI and osteomyelitis.

Methods: We describe a technique and case series using the Reamer-Irrigator-Aspirator (RIA) system, Cerament G injection via the 2Can device, and, when necessary, intramedullary nailing for the treatment of FRI and osteomyelitis. The technique was applied to 7 patients at a single Level-1 Trauma Center from 2022 to 2024 with FRI or osteomyelitis. Intramedullary nailing was performed in cases of nonunion or bony instability.

Results: The mean age of patients was 35 years, with a mean body mass index of 29.2. Three patients required adjuvant intramedullary nailing for stabilization. All patients were weight bearing as tolerated after surgery. At a mean follow-up of 14.4 months (6–21 months), there were no recurrence of infection, major complications, or amputations.

Conclusion: The combination of Cerament G and the RIA system represents a viable solution for FRI and osteomyelitis providing effective infection control and sustained antibiotic elution. This technique presents a promising alternative to traditional methods, although larger and longer-term studies are needed to confirm its efficacy.

Keywords: intramedullary nailing, absorbable antibiotic eluting bone graft substitute, bone graft substitute, osteomyelitis, fracture-related infections

1. Introduction

The initial treatment for fracture-related infections (FRI) and osteomyelitis (OM) is targeted systemic antibiotic therapy. When this is insufficient, debridement of necrotic bone to remove the infection nidus with local antibiotic therapy delivering high concentrations of antibiotics at the infection site is required. In cases where bony debridement compromises structural stability or in cases of infected nonunions, surgical intervention must address both the infection and bony instability simultaneously. First described in 2002 and now widely utilized, antibiotic coated

nails (ACN) are an effective way to stabilize the bone while providing high concentrations of local antibiotics with low systemic toxicity.^{1,2} Although prefabricated ACNs are available, most surgeons will create their own ACN using poly-methyl methacrylate (PMMA) mixed with antibiotics based on culture sensitivities coated around intramedullary nails, Ilizarov rods, guide rods, or threaded wires.

Although effective, using PMMA for ACN fabrication has several disadvantages. It is nonbiodegradable and necessitates reoperation for removal. In addition, PMMA and antibiotics can

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

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

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have deleterious effects on each other when mixed. PMMA's exothermic polymerization process can deactivate heat-sensitive antibiotics, and certain antibiotics may disrupt PMMA polymerization, compromising the cement's stability.^{3,4} Pharmacokinetic studies have shown that only a fraction of incorporated antibiotic is eluted from PMMA, with a high initial burst of antibiotic release followed by a rapid decline with minimal elution after the first week.^{5,6} This prolonged elution below minimum inhibitory concentration (MIC) from antibiotic-loaded PMMA has been shown to lead to the development of gentamicin and multidrug-resistant organisms.⁷

Absorbable antibiotic bone graft substitutes have been developed to mitigate these shortcomings. Cerament G (Bone-support, Lund, Sweden) is an injectable calcium-sulfate and hydroxyapatite-based ceramic bone void filler, which has been shown to have high, sustained local gentamicin elution far above the MIC of gentamicin-sensitive bacteria.^{8,9} In contrast to PMMA, it is bioabsorbable with osteoconductive properties to expedite remodeling of bone defects.^{10,11} Furthermore, mid- to long-term study results show a 94% infection eradication rate when Cerament G is utilized in a single-stage procedure for patients with FRI and chronic osteomyelitis.¹² We describe a surgical technique for the treatment of FRI and osteomyelitis, combining the use of the Reamer-Irrigator-Aspirator (RIA) system (Synthes, Inc., West Chester, Philadelphia) with Cerament G injected into the intramedullary canal with the 2Can (Flow-FX, Mokena, IL) and in the presence of instability due to nonunion intramedullary nailing of the long bone. The proposed benefits include thorough debridement of infected bone using the RIA system, followed by coating of the freshly debrided bone and dead space with calcium-sulfate/hydroxyapatite-based ceramic that elutes gentamicin. This approach leverages the ceramics bioabsorbability, osteoconductivity, and sustained antibiotic elution as compared to PMMA in the treatment for FRI, osteomyelitis, and infected nonunions.

2. Surgical technique

Imaging is essential for the assessment of bony necrosis, sequestra, and soft tissue abscesses. Plain radiographs may reveal sequestrum, cortical irregularities, and osteolysis in cases of FRI and osteomyelitis. For a more detailed evaluation of bony architecture and implant loosening, computed tomography (CT) was invaluable. Magnetic resonance imaging (MRI) is the gold standard for assessing soft tissue involvement, presence of abscesses, and intramedullary infection, although both modalities can be limited by metal artifact in the presence of hardware, hindering assessment of FRI and/or nonunion. However, modern protocols including dual-energy CT and metal-subtraction sequences on MRI can reduce artifact and improve visualization. Special attention was paid to identifying possible infection foci requiring open debridement and/or additional Cerament G. When soft tissue coverage was required, Plastic Surgery team was involved early to ensure coordinated, multidisciplinary care.

When present, sinus tracts were excised while preserving healthy tissue margins. The incision was centered over open wounds, sinus tracts, or areas of necrotic bone and soft tissue abscess as assessed on preoperative imaging. Before irrigation and debridement (I&D), >3 deep tissue and bone samples were obtained for culture with clean instruments avoiding contamination with superficial tissues as described by Metsemakers et al.¹³ Debridement was the critical step in our management of FRI and osteomyelitis, with the primary goal being the removal of all

necrotic tissue serving as a nidus for infection and reduction of bacterial load. After the initial debridement of the bone and soft tissue, we irrigated the area of concern with 3 L of normal saline followed by additional debridement as needed. After a thorough debridement, we irrigated with an additional 3 L of normal saline mixed with 30cc of Hibaclens (Mölnlycke Health Care, Peachtree Corners, GA) followed again by 3 L of normal saline.

The RIA system was utilized in cases of medullary osteomyelitis.¹⁴ Preoperative CT scan was used to measure the diameter of the isthmus of the canal to determine the required starting reamer size. A ball-tipped guide rod was placed through the opening hole in the proximal or distal femur or proximal tibia and seated in the appropriate position within the shaft under fluoroscopic guidance. Then, the canal was sequentially reamed the appropriately sized reamer needed, ensuring irrigation is flowing during the entirety of the reaming process to irrigate and aspirate the infected bone and minimize thermal necrosis. In cases requiring reconstruction with intramedullary nail, the canal was reamed to 2 mm larger than the intended intramedullary nail diameter. In cases without reconstruction, reaming was continued until chatter was achieved at the area of concern. The final reamer was repeatedly advanced up and down the canal until 3 L of saline was exhausted. Upon completion, all instrumentation was removed and the absence of iatrogenic fracture was confirmed with fluoroscopy.

After thorough debridement, Cerament G was mixed based on manufacture recommendations. For osteomyelitis, we used 20 cc of Cerament G, with 10 cc concentrated around the area of most concern identified intraoperatively or with imaging (Fig. 1). After mixing, we waited 4 minutes before application and, if possible, insufflated a tourniquet to enhance interdigitation within the bone. With or without the guide rod using the 2Can, the entire canal was injected with Cerament G under fluoroscopy to confirm intended placement and distribution throughout the canal. The 2Can was used to express the ceramic into the canal at the desired location (Fig. 1). For osteomyelitis cases with no fixation, we injected 10 cc at the location of the bone that was most concerning and an additional 10 cc evenly distributed along the remainder of the canal to completely fill the medullary canal (Table 1). For nonunions with FRI that required reconstruction, we injected 10 ccs of Cerament G into the canal before intramedullary nail placement with the 2Can to allow for controlled placement along the canal. Given the space occupied by the intramedullary nail, we found 10 cc of Cerament G was sufficient to completely fill the canal. Small volumes of Cerament G may extrude out of intramedullary nail interlocking holes. We thoroughly irrigated these percutaneous incisions before closure with normal saline to remove as much Cerament G from the soft tissue as possible. To date, we have not



Figure 1. Preoperative images: anteroposterior and lateral X-rays demonstrating intramedullary fixation with healed tibial shaft fracture in presence of clinically diagnosed FRI.

Table 1
Cerament G volumes and distribution.

Clinical scenario	Volume	Cerament G distribution
FRI or osteomyelitis w/o reconstruction	20 cc	10 cc at location of most concern; 10 cc distributed throughout canal
FRI w/reconstruction	10 cc	10 cc before intramedullary nail placement
Proximal 1/3 tibia		2 cc proximally/8 cc distally
Midshaft tibia		5 cc proximally/5 cc distally
Distal 1/3 tibia		8 cc proximally/2 cc distally

Volumes of CERAMENT G and distribution.

experienced adverse events from Cerament G extrusion from interlocking holes with no signs of heterotopic ossification. If bony stabilization was required, the final intramedullary nail was inserted over the ball-tipped guide rod before the Cerament G set. It takes approximately 15 minutes after application for the Cerament G to set and safely be drilled through after which interlocking screws were placed proximally and distally.

Cerament G was also used for management of cortical defects or dead space created by bony debridement. When possible, a tourniquet was insufflated to control blood flow, and the defect was packed with tape, dry swabs, or suction sponges to minimize moisture. When applying Cerament G, we ensured direct contact with cancellous bone, avoiding areas of sclerotic bone or proximity to the skin to prevent seroma formation. To fill cavities effectively, filling was started from deep to superficial, ensuring that all endosteal surfaces of the defect were covered with Cerament G before filling the middle. A dry swab was gently pressed on top to help interdigitate the Cerament G into the bone. Finally, any excess material was scraped off using a freer elevator or dental pick for a clean finish.

A reported adverse event with the use of Cerament G is persistent drainage of white serous fluid. Although this milky-white drainage can mimic pus, it is sterile and typically self-limiting. In our series, we monitored these patients closely postoperatively and found the serous drainage resolved spontaneously in ~1 week postoperatively in all cases with daily dressing changes.

Finally, after the application of Cerament G, the soft tissue and skin was closed in layers. In select cases, a “pants over vest” closure technique was utilized, directing subdermal dissection tangentially toward the fascia to improve tissue excursion. We used nonabsorbable monofilament (i.e., Prolene, Nylon) for skin closure as braided or absorbable sutures can harbor microorganisms and provoke inflammatory responses, respectively. Postoperatively, culture-guided intravenous (IV) antibiotics were administered for 6 weeks under the supervision of the Infectious Disease team.

We retrospectively reviewed all patients >18 years old with a diagnosis of FRI or osteomyelitis treated with this technique with or without adjuvant intramedullary nailing at our center between 2022 and 2024. Patients with less than 6 months of clinical and radiographic follow-up were excluded. Collected data included, age, sex, body mass index (BMI), comorbidities, diagnosis, operative details, length of stay, postoperative complications, culture results, date of latest follow-up, radiographic union, and infection persistence or recurrence. Infection persistence or recurrence was determined clinically based on patient history, physical exam, and radiographic findings. Radiographic union was defined as bridging callus on 3 or 4 cortices on AP and lateral radiographs.

3. Initial clinical experience

Seven patients at a Level 1 Trauma center were treated for FRI or osteomyelitis with this technique by a single fellowship trained

orthopaedic traumatologist (Table 2). Mean age at surgery was 35 years (21–46) with mean BMI of 29.2 kg/m² (23.3–38.7). Three of 7 patients had infected nonunions and required bony stabilization with an intramedullary nail. Five of 7 patients (71.4%) underwent open debridement in addition to intramedullary debridement with RIA. A mature local medial gastrocnemius flap was raised and closed by Plastic Surgery in one case to access the tibia for debridement. The flap and all primary closures healed, although in one case (1/7; 14.3%) there was prolonged milky-white serous drainage from the open debridement site treated with local wound care and daily dressing changes that resolved without reoperation. All patients were treated with culture-guided IV antibiotics for 6 weeks under the guidance of the Infectious Disease team based on culture results (Table 2). Average length of stay of the cohort was 5.14 days. To date, with a mean follow-up of 14.4 months (6–21 months), there have not been any recurrences of infection with all patients achieving radiographic union at latest follow-up. No patients required reoperation or amputation and there were no mortalities. Our sample size is small, and FRI and osteomyelitis can recur years after treatment; however, these findings represent promising preliminary results for this surgical technique.

3.1. Case 1

3.1.1. Patient information. A 31-year-old woman with a medical history of hyperlipidemia suffered an open Gustilo-Anderson II tibial and fibular shaft fractures after a motor vehicle collision. She underwent open I&D, intramedullary I&D with RIA, intramedullary nailing of the tibia, and primary closure of her open wound at an outside hospital. Approximately 1 year postoperatively, she presented to our hospital with continued pain, a draining wound from her distal tibia, and CT scan confirmed FRI with retained hardware and a healed fracture (Fig. 2).

She underwent removal of the tibia nail, I&D of the open tibial wound and intramedullary canal with RIA, excision of the sinus tract, open biopsy of the right tibia and lower extremity, and intramedullary placement of Cerament G, as described in the above surgical technique (Fig. 1). This was done in a single-stage manner.

3.1.2. Postoperative course. The patient was discharged to her home on postoperative day 4 with a 6-week course of IV antibiotics as directed by Infectious Disease. Surgical pathology revealed bone with reactive granulation tissue, evidence of acute and chronic inflammation. No organisms grew on culture. At 6-month follow-up, she remains pain-free without drainage and capable of full weight bearing (Fig. 3).

3.2. Case 2

3.2.1. Patient information. A 46-year-old man sustained open Gustilo-Anderson IIIB tibial and fibular shaft fractures in a

Table 2

Patient outcomes.

	Age	Sex	BMI	Comorbidities	Bone	Diagnosis	Open debridement	Stabilization	Closure	Culture results	Infection recurrence	Complication	LoS (d)	F/u (mo)
#1	31	F	38.7	HLD	Tibia	OM	Yes	None	Primary	NGTD	No	None	4	6
#2	46	M	26.4	HTN	Tibia	FRI w/ nonunion	Yes	IMN (13 mm)	Medial gastroc flap	<i>Proteus mirabilis</i>	No	None	2	14
#3	21	M	23.5	None	Tibia	FRI w/ nonunion	Yes	IMN (13 mm)	Primary	MRSA	No	Prolonged serous drainage*	10	19
#4	35	M	29.7	None	Femur	OM	No	None	Primary	<i>Enterobacter cloacae</i>	No	None	3	16
#5	37	M	23.3	IVDU, alcohol abuse	Femur	OM	No	None	Primary	MSSA	No	None	7	13
#6	43	M	33.4	None	Femur	FRI w/ nonunion	Yes	IMN (13 mm)	Primary	MSSA	No	None	4	12
#7	32	M	29.5	None	Femur	OM	Yes	None	Primary	MRSA	No	None	6	21

* Prolonged serous drainage was treated with local wound care and daily dressing changes and resolved spontaneously without return to the OR. NGTD = No growth to date, HLD = Hyperlipidemia, HTN = Hypertension, IMN = Intramedullary nail, IVDU = Intravenous Drug Use, MSSA = Methicillin sensitive Staph aureus, MRSA = Methicillin resistant Staph aureus.

motorcycle accident in June 2023. Initial management at an outside hospital included open I&D, intramedullary nailing of the tibia, and primary closure of his medial tibial shaft open wound. His

postoperative course was complicated by soft tissue coverage issues, tibial nonunion with FRI with multiple returns to the operating room for I&D, and skin grafting of his medial midshaft tibia wound.

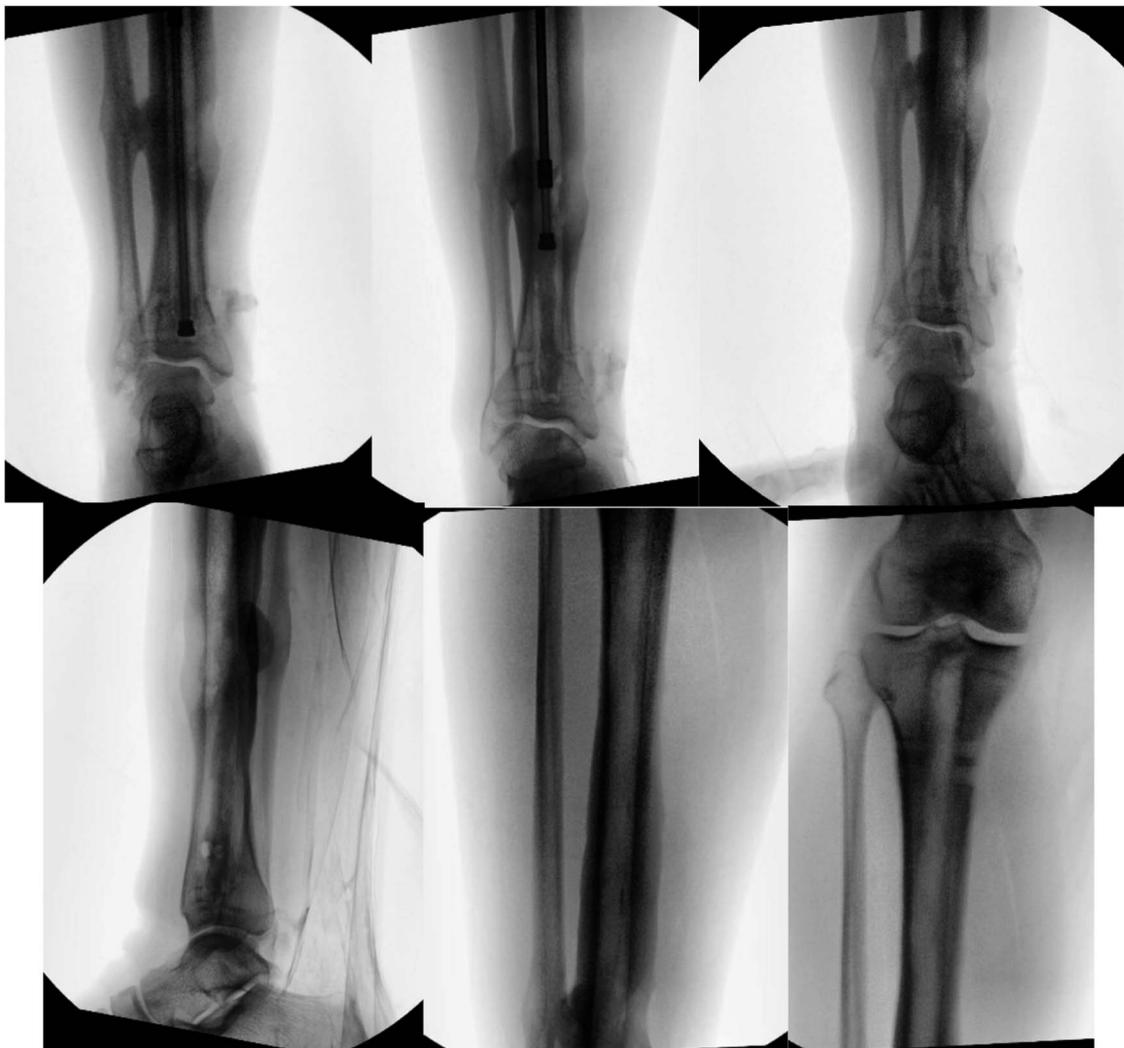


Figure 2. Intraoperative images: injecting CERAMENT G into the tibial canal with the 2-CAN.

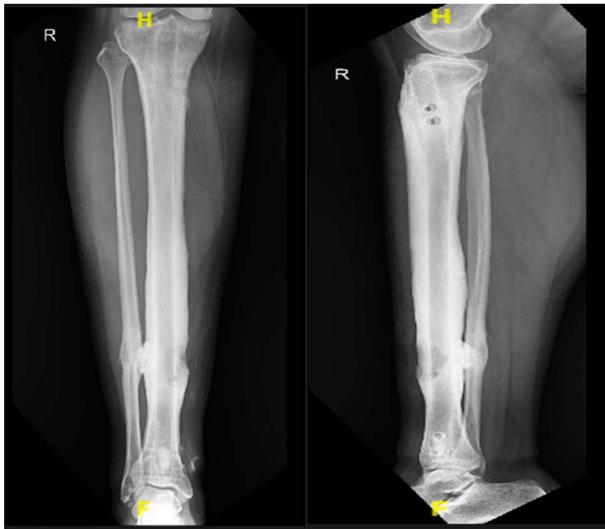


Figure 3. Six-week postoperative X-rays: the patient remains pain-free without drainage and is capable of full weight bearing.

The patient presented to our hospital 5 months after his injury and initial surgery with persistent pain and drainage from the lower extremity open wound (Fig. 4). CT scan demonstrated tibial shaft nonunion and findings concerning for tibial osteomyelitis with sequestrum. Tibia hardware removal and tibia open I&D were performed with subsequent repeat open and intramedullary I&D and tibia intramedullary nailing with a PMMA antibiotic-coated nail the following day (Fig. 5). He subsequently underwent gastrocnemius flap coverage and skin grafting by the Plastic Surgery team. Eight weeks later, after flap maturation, completion of a 6-week IV antibiotic course with a 2-week IV



Figure 4. Preoperative AP and lateral X-rays: the patient presented with persistent pain and drainage from the lower extremity open wound.

antibiotic holiday, he underwent flap elevation by the Plastic Surgery team followed by open biopsy of the tibia and soft tissue, which came back negative for infection. He then underwent removal of antibiotic-coated nail, intramedullary I&D with RIA, wound I&D, intramedullary placement of Cerament G, and insertion of a 13-mm intramedullary nail for his persistent tibial shaft nonunion (Fig. 6).

3.2.2. Postoperative course. The patient was discharged to his home on postoperative day 2. At 14-month follow-up, he remains pain-free without drainage and capable of full weight bearing with radiographic union of his tibia and has returned to work (Fig. 7).

4. Discussion

The surgical management of FRI and osteomyelitis, particularly when bony instability is present, requires a multifaceted approach. Part of this treatment approach includes culture-specific IV antibiotics for 6 weeks. However, there is promising data from the OVIVA and POvIV trials regarding the use of culture-specific oral antibiotics with equally effective eradication of infection as with IV antibiotics.^{15,16} PMMA antibiotic-coated nails have been widely used with good success, however, with notable limitations including poorly sustained antibiotic elution, nail-cement debonding, and need for removal.^{5,7,17,18} In response, bioabsorbable antibiotic bone graft substitutes like Cerament G have been developed, providing a reproducible and resorbable treatment option with controlled high-dose release of antibiotics.

Cerament G is a bioabsorbable synthetic bone void filler composed of 60% calcium sulfate, 40% hydroxyapatite, and gentamicin sulfate. Compared with PMMA, Cerament G achieves 4 times the initial local antibiotic concentration using $\frac{1}{4}$ of the antibiotic powder,⁹ with its antibiotic elution primarily driven by the natural resorption of calcium sulfate. In contrast, PMMA's prolonged low-level antibiotic release can persist for up to 5 years postimplantation, often failing to sustain concentrations above the MIC, potentially fostering antibiotic resistance and biofilm formation.⁷ In contrast, Cerament G exhibits transient supra-MIC antibiotic elution followed by complete resorption of the carrier within 6 to 12 months avoiding the prolonged, sub-MIC antibiotic release observed with retained PMMA, which is believed to promote bacterial resistance.^{10,11}

A reported adverse event with the use of Cerament G is persistent drainage of white serous fluid. Although this milky-white drainage can mimic pus, it is sterile and typically self-limiting. In our series, this occurred in one out of the 7 patients (14.2%). Postoperatively, this patient was monitored closely postoperatively and the serous drainage resolved in 1 week postoperatively with local wound care and daily dressing changes, without need for reoperation. Monitoring the drainage closely ensures that it remains within expected parameters as excessive or altered drainage may indicate complications that require further evaluation.

Another limitation of PMMA-coated intramedullary nails and rods lies in the need for an optimal cement mantle thickness of 1.5 to 2.5 mm to prevent shearing of the cement during insertion.¹⁹ Achieving this requires the use of smaller diameter nails or rods, which can compromise the overall mechanical stability of the construct, particularly in weight-bearing bones. In addition, the cement coating is prone to debonding under cyclic loading,

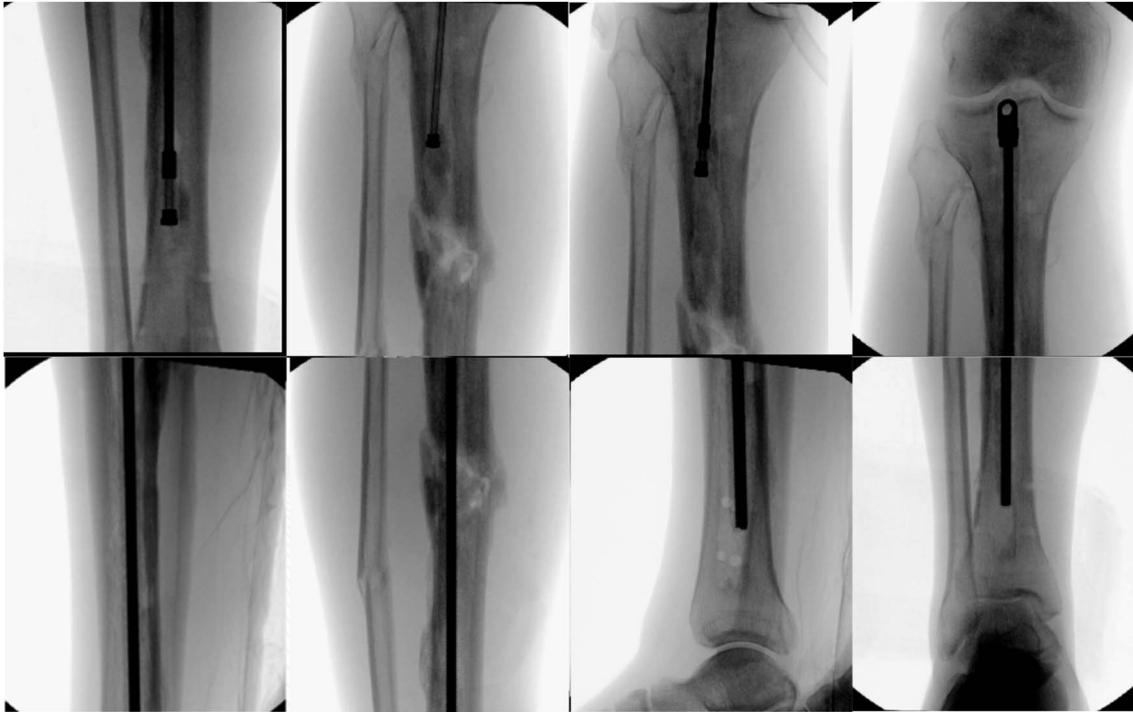


Figure 5. Intraoperative fluoroscopy of second I&D with antibiotic PMMA nail.

further reducing stability and increasing the risk of hardware failure.¹⁷ This trade-off between antibiotic delivery and mechanical support highlights a critical drawback of PMMA-coated implants, particularly in cases of significant bone loss where robust structural support is needed. Our technique using

Cerament G obviates this issue allowing surgeons to use appropriately sized intramedullary nails for optimal mechanical stability without compromising antibiotic efficacy or risking cement debonding. All patients in our case series were weight bearing as tolerated after surgery.

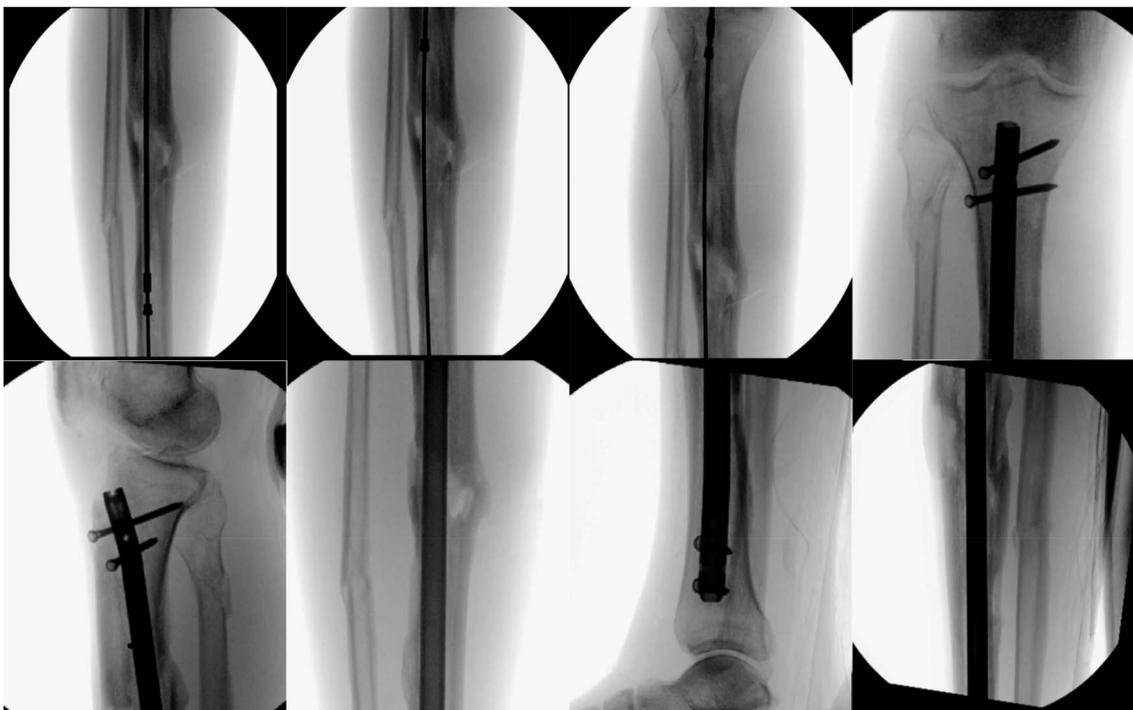


Figure 6. Intraoperative fluoroscopy of nonunion reconstruction with the intramedullary placement of CERAMENT G with intramedullary nailing for a persistent tibial shaft nonunion.

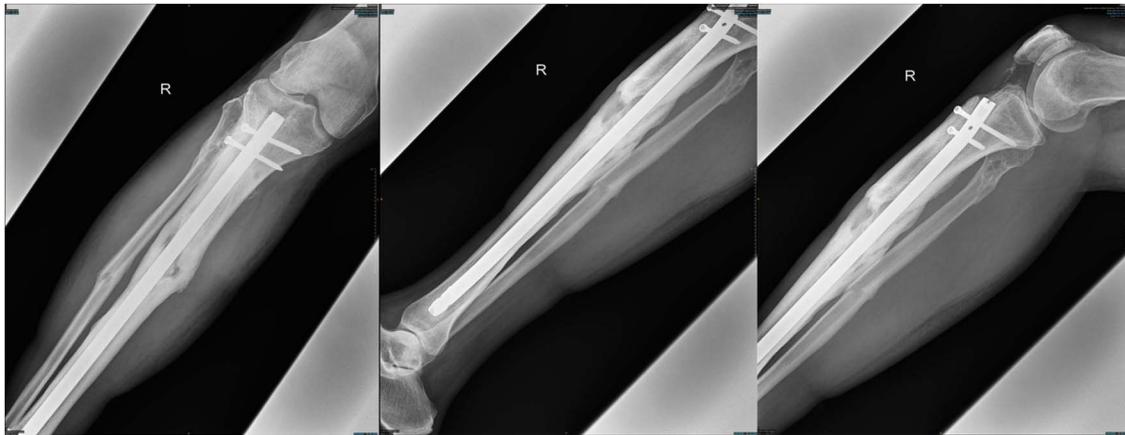


Figure 7. One-year follow-up: the patient remains pain-free without drainage and capable of full weight bearing with radiographic union of his tibia and has returned to work.

Emerging evidence highlights that single-stage surgical interventions may provide comparable infection control to traditional 2-stage approaches while reducing length of stay, OR time, and cost.^{11,13} Cerament G's bioabsorbable properties eliminate the need for subsequent staged removal and dead-space management. The material's hydroxyapatite component offers structural support and osteoconductivity for bony remodeling to match the resorption of the calcium sulfate. Although a multicenter, randomized controlled trial found Cerament bone void filler to be noninferior to gold-standard autologous iliac bone grafting for the treatment of proximal tibia bone defects,²⁰ it should be noted that Cerament G may be most suitable for small to moderate sized defects and may not adequately address critical size defects. Cerament G's bioabsorbability and ability to support natural bony remodeling may limit bacterial colonization and biofilm formation on the bone void filler—a risk associated with PMMA.²¹ In a systematic review of 505 patients with chronic osteomyelitis treated with various single-stage techniques including alternative absorbable antibiotic carriers, debridement plus Cerament G was found to have a nonrecurrence rate of 97.40%.²²

There are several limitations to our study primarily related to it being a case series. The small sample size of 7 patients limits statistical power making it difficult to draw definitive conclusions. Second, the lack of comparison groups treated with traditional methods, such as PMMA-coated nails or two-stage procedures, prevents assessment of the relative effectiveness of this technique. Third, infection may recur years after treatment and our follow-up range of 6 to 21 months may be insufficient to detect these late recurrences. In addition, although infection eradication was achieved in all patients, patient-reported outcome measures were not assessed. This limits our understanding of the technique's impact on functional restoration, which in addition to infection eradication is a key goal of treatment. Finally, as a single-center, single-surgeon 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 studies with standardized functional outcomes and longer follow-up.

5. Conclusion

The combination of Cerament G with delivery using the 2Can and the RIA system offers a promising solution for FRI and

osteomyelitis. Cerament G's bioabsorbability, superior antibiotic elution profile, and facilitation of bone remodeling represents a compelling alternative to traditional PMMA-based methods. Further research is needed to confirm its long-term efficacy and infection recurrence rates.

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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