ORIGINAL RESEARCH

Preliminary Outcomes of a Staged Percutaneous Retrograde Prefabricated Gentamicin-coated Intramedullary Nail to Manage Complications after Ankle Fusion through Tibial Bone Transport

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Received on: 11 September 2022; *Accepted on:* 04 December 2023; *Published on:* 17 January 2024

Abstract

Aim: Distal tibial injuries combining bone loss, articular destruction and infection can be treated through distraction osteogenesis combined with ankle fusion. Bone transport is not without complications. This study investigates our preliminary results using a retrograde prefabricated gentamicin-coated nail (ETN PROtect®) to treat complications after infected bone defects of the distal tibial were managed by ankle arthrodesis and distraction osteogenesis.

Materials and methods: This is a retrospective case series study. All consecutive patients with bone transport complications after ankle arthrodesis and distraction osteogenesis who were subsequently operated on using a retrograde ETN PROtect® nail were analysed. The cases occurred between 2017 and 2020. The primary objective was to report on the resolution of the clinical problem and the risk of deep infection after nail implantation.

Results: Five patients have included: two docking site non-unions, two regenerated bone fractures and one hypotrophic regenerated bone. These complications were resolved in all patients (5/5, 100%). A painless, stable and plantigrade ankle arthrodesis was achieved in all cases. No patient developed a local infection or required nail removal (mean follow-up: 35.2 months). The mean LEFS score was 46.8 ± 13.8 and the mean knee ROM was 112 ± 12.7°. All patients tolerated full weight-bearing. All patients were very satisfied with the procedure (mean SAPS score was 93.8 points).

Conclusion: The staged retrograde nailing technique using the ETN PROtect® nail may represent an effective and safe treatment for bone transport complications in high-infection-risk patients. Furthermore, the technique allows simultaneous achievement of ankle arthrodesis. The patients had good functional outcomes and were satisfied with the procedure.

Clinical significance: This strategy of using retrograde gentamicin-coated tibial nails offers a solution to resolve bone transport complications while simultaneously achieving functional ankle arthrodesis.

Keywords: Ankle fusion, Antibiotic coating, Bone defect, Bone infection, Bone transport, Cohort study, ETN PROtect, Infection prophylaxis, Tibial nail.

Strategies in Trauma and Limb Reconstruction (2023): 10.5005/jp-journals-10080-1595

Introduction

Distal tibial injuries combining bone loss, articular involvement and infection are some of the most difficult conditions to treat in musculoskeletal trauma and remain a challenge for both patients and surgeons. Ankle fusion after trauma or septic joint destruction is intended as a limb-sparing procedure and is to obtain a stable, painless and plantigrade foot.[1,2] In cases of extensive bone loss, bone reconstruction techniques are needed to achieve a solid ankle-bony fusion and preserve a functional limb length. The currently available biological techniques for the reconstruction of such massive bone defects can be divided into bone-replacement techniques (namely, the induced membrane technique and microsurgical transfer of bone) and bone-regeneration techniques based on distraction osteogenesis.[3] Distraction osteogenesis techniques using external fixation devices are commonly indicated for segmental bone defects in the adult lower limb.[4] Furthermore, tibial bone transport or shortening-lengthening procedures can be used to achieve tibiotalar or tibiocalcaneal arthrodesis in such difficult-to-treat

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How to cite this article: Pujol O, Vicente M, Castellanos S, *et al.* Preliminary Outcomes of a Staged Percutaneous Retrograde

cases.[5] However, bone transport is not without its complications; the complication rate can be as high as 44%.[4,6] Such complications are associated with reconstruction delay, suboptimal functional outcomes, unplanned further surgeries, and a limb-threatening risk. Psychological burden, pain and a decrease in quality of life are also linked with these events.[7]

Little attention has been given to the use of intramedullary nails in the treatment of bone transport complications.[6,8,9] Its indications are limited but it may be useful for providing increased stability in treating non-union at the docking site, lack of ossification of the regenerate column, or callus fracture. However, the use of an intramedullary nail after prolonged external fixation is controversial due to the potential risk of infection – reportedly to be as high as 7.4–33.3%.[8,9] In recent years, antibiotic-coated nails have been developed to reduce infection risk. Specifically, the Expert Tibia Nail (ETN) PROtect® (DePuy Synthes, Oberdorf, Switzerland) features a gentamicin coating which aims to reduce bacterial colonization and prevent local infection through its broad-spectrum and bactericidal effects.[10] Although the currently available PROtect® nail was designed to be used in an anterograde fashion, in this case, series study retrograde nailing was used as the cases were of complications around reconstruction and ankle fusion using distraction osteogenesis techniques.

The present study sought to report the preliminary results of using a prefabricated gentamicin-coated intramedullary nail to treat complications in cases where infected bone defects of the distal tibia were managed originally with ankle arthrodesis and distraction osteogenesis techniques. The main objective was to report on the resolution rate and the risk of deep infection after nail implantation.

Materials and Methods

Study Design

This is a retrospective case series study. After institutional review board (IRB) approval, a retrospective search of the institutional database of a Level 1 hospital which houses a national-referral musculoskeletal infection unit was conducted. We reviewed all consecutive cases between January 2017 and December 2020 of infected distal bone defects managed initially by ankle fusion combined with distraction osteogenesis and in which a retrograde ETN PROtect® nail was used to treat a bone transport complication. Patients received information about the study and signed an informed consent form.

The inclusion criteria were: a) an adult patient, b) external fixation bone transport to treat distal tibial segmental bone defects due to infection, c) ankle fusion procedure (tibiotalar or tibiocalcaneal fusion), d) a retrograde ETN PROtect® nail used to treat bone transport complications and e) a minimum follow-up of one year after nail implantation. Patients who did not meet inclusion criteria were excluded from the study.

Outcome Variables

The primary objective of this study was to report on the resolution rate and the risk of deep infection after retrograde nailing using this strategy.

The following data were recorded: a) demographics, b) surgery data, c) microorganism causing infection, d) reason for bone transport, e) bone defect length after surgical debridement, f) regenerated bone length, g) time on external fixator, h) bone transport complication requiring intramedullary nailing, i) nail complications, and j) time of follow-up.

Definitions

- Infection was diagnosed according to the international consensus criteria.[11] At least one definitive criterion had to be met: a) presence of a sinus track, b) bone or osteosynthesis material exposure, c) positive histology test, d) pus or intraoperative abscess, e) ≥2 positive cultures of the same pathogen.
- Eradication of infection was declared according to the internationally accepted criteria: a) healed wound, b) no recurrence caused by the same organism at one-year follow-up, c) no subsequent surgical intervention due to infection after reimplantation surgery, d) no infection-related mortality and e) absence of a requirement for suppressive antibiotic treatment.[12]
- Patient satisfaction was assessed using the self-administered patient satisfaction scale (SAPS): a short, reliable and valid four-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). Items are scored on a four-point Likert scale using the options "very satisfied" (100 points), "somewhat satisfied" (75 points), "somewhat dissatisfied" (50 points), and "very dissatisfied" (25 points).
- Patient functional outcome was based on the lower-extremity functional scale (LEFS): A twenty-item scale assessing patient ability to perform everyday tasks. Its maximum possible score is 80.
- The following definitions were used for the bone transport complications that were subsequently treated with the antibiotic-coated intramedullary nail:
  - Docking-site non-union: "Docking site" is defined as the terminus of travel of two segments of bone that are gradually brought into approximation during bone transport. Docking-site non-union is one of the main difficulties in bone transport procedures.[13]
  - Hypotrophic regenerate bone: Slow regenerate bone formation and maturation. Radiologic images may show an irregular and heterogeneous appearance, with lower bone density and multiple cysts.[14]
  - Regenerate bone fracture: Fracture occurring around the regenerate bone after lengthening. Such fractures can be classified according to their sites and patterns: i) within the regenerate, ii) junctional, iii) through a screw or half-pin track, and iv) distant site.[15]

Operative Technique Description

The procedure was carried out in two stages to minimize the risk of infection. All surgeries were performed by the senior surgeon (PC) following the same surgical protocol, as described below.

During the first stage of the procedure, the external fixator device is removed and pin tracks are debrided. In cases of pin or

Prefabricated Gentamicin-coated Intramedullary Nail to Manage Complications after Ankle Fusion through Tibial Bone Transport. Strategies Trauma Limb Reconstr 2023;18(3):155–162.

Source of support: Nil

Conflict of interest: None

Patient consent statement: The author(s) have obtained written informed consent from the patient for publication of the case report details and related images.

wire track infection, multiple samples are sent to the microbiology laboratory and a broad-spectrum antibiotic treatment is started under the guidance of an infectious disease expert who is part of our multidisciplinary team. Once the culture results are available, the antibiotic treatment is switched to pathogen-specific oral antibiotic treatment (if available). The limb is placed in a cast, rest is encouraged and pin tracks are assessed for healing.

After a minimum latency period of 10–14 days, the second stage is performed under targeted prophylactic antibiotics.[8] The patient is positioned supine on a radiolucent table. The procedure is done percutaneously. In cases of regenerated bone fractures, the closed reduction under an image intensifier is achieved before nail insertion. In the case of docking-site non-union, a "closed docking-site strategy" is preferred, in the hope that intramedullary reaming is sufficient to remove interposed soft tissue and autograft the zone, avoiding the risk of skin problems in these compromised areas.

Through a trans-calcaneal approach, the optimal entry point is identified. Under fluoroscopic control, a guide wire is retrogradely inserted, crossing the subtalar and tibiotalar articulations until the distal tibia is in line with the tibial axis. The medullary canal is opened using a drill. Progressive reaming is performed for all cases until a diameter 1.5 mm larger than the selected nail's diameter is reached. Cultures are taken from the reamed bone. The nail is inserted retrogradely. The nail should be turned laterally (Herzog curve pointed laterally) during insertion to avoid ankle varus. The intramedullary tibial nail used in all cases was the Expert Tibia Nail (ETN) PROtect® (DePuy Synthes, Oberdorf, Switzerland). This is a Titanium-6Aluminium-7Niob (Ti-6Al-7Nb, TAN) alloy nail, with a fully resorbable coating consisting of a polymatrix (D, L-lactide; PDLLA) which contains gentamicin. The total amount of antibiotics on a single implant ranges from 15.3 to 60 mg, depending on the nail size. In cases of tibio-talo-calcaneal fusion, the subtalar joint is not routinely approached or prepared. In revisional tibio-calcaneal arthrodesis cases, no further specific procedures are ordinarily required. In cases of docking-site non-union with a normotrophic regenerated bone segment, the nail should bypass the new bone segment proximally in order to minimize the risk of regenerated bone fracture or plastic deformity. The nail position is checked fluoroscopically for both proximal and distal extents. Finally, the proximal and distal locking options are chosen according to the stability required. Normally a minimum of two proximal locking screws are used. In cases of tibio-talo-calcaneal fusion, distal locking screws are inserted in both the talus and the calcaneus.

Follow-up Protocol

Patients are discharged once soft tissue healing is deemed favourable. Partial weight-bearing is allowed for the subsequent 2–3 weeks after which the patient progresses to full weightbearing as tolerated. Patients are scheduled for follow-up appointments every 2–3 weeks. During these visits, they are evaluated clinically and radiologically. Regular clinical and radiographic follow-up continues until the solid union is confirmed, the regenerate column matures completely, and infection relapse is ruled out. Whenever feasible, a final outpatient appointment is scheduled during which the patient is examined by a member of the dedicated team to perform the lower-extremity functional scale test (LEFS) and record the patient's satisfaction with the procedure (SAPS).

Statistical Analysis

Descriptive statistics were used to present the cohort's characteristics. Categorical variables were described by their absolute values and percentages. Continuous variables were presented by their measures of central tendency (mean) and range. Statistical analysis was conducted using IBM SPSS v. 20.0 (IBM Corp., Armonk, NY, USA).

Results

After a review of the database, there were five patients identified in whom a retrograde ETN PROtect® nail was used as a definitive treatment after complications from ankle fusion and distraction osteogenesis. There were four males (80.0%) and one woman (20%); the average age was 49.4 ± 11.3 years (range 32–65 years). The mean follow-up after nail insertion was 35.2 months (patient details are shown in Table 1).

All patients had undergone surgery including bone transport to achieve a solid ankle fusion for septic distal tibial bone defects with articular involvement. In three patients, the aetiology was a fracture-related infection (two open fractures and one closed fracture infected after ORIF). Two patients had ankle arthrodesis that became infected after surgery. Infection was diagnosed in three patients based on positive cultures (two *S. Aureus* and one *S. Epidermidis*). Two patients had negative cultures despite unequivocal signs of infection (pus presence and positive histology).

In this cohort, the mean bone defect length was 38.8 ± 15.0 mm (range 15–60 mm). All bone transports were performed with the use of external fixators: four patients were treated with an Ilizarov-type circular external fixator (Truelok® Hex; Orthofix, Verona, Italy) and one with a monolateral external fixator (LRS®; Orthofix, Verona, Italy). The period with external fixation was 13.4 ± 5.2 months (range 8–23 months) and the regenerated bone length was 39.4 ± 18.3 mm (range 15–70 mm). The bone healing index was 3.9 months/cm. A tibiocalcaneal arthrodesis was performed in three patients, with tibiotalar arthrodesis used in the other two. Two patients (2/5, 40%) required soft-tissue reconstruction, one with a microsurgical free flap and the other with a local rotational flap.

The complications were non-union at the docking site in two patients, traumatic regenerated bone fracture in two patients and hypotrophic regenerated bone in one patient. In all cases, retrograde intramedullary tibial nailing using the ETN PROtect® was carried out. These complications were resolved with the use of a retrograde nail in all patients (5/5, 100%) without any additional procedure. Furthermore, a painless and stable ankle arthrodesis in the plantigrade position was achieved in all patients. No signs of local infection appeared in any patient (5/5, 100%) at the end of the follow-up. No patient suffered any complications after nail insertion, and none have required nail removal.

The mean LEFS test score (ranges between 0 and 80 points) at the end of the follow-up was 46.8 ± 13.8 (range 30–67). All patients tolerated full weight-bearing. Knee ROM was 112 ± 12.7° (range 90–120°). All patients were very satisfied with the procedure (mean SAPS score was 93.8 points). The patients' post-operative clinical outcomes are shown in Table 2.

Discussion

In this preliminary series of five patients who had complications from treatment by ankle arthrodesis and bone transport, we report a resolution of the complications in all cases through a strategy of two-stage revision ankle fusion and retrograde nailing with a gentamicin-coated ETN PROtect® nail. Employing such a

Table 1: Details of five patients treated with retrograde prefabricated gentamicin-coated intramedullary nails due to bone transport complications in cases of distal tibial infected bone defects managed with ankle arthrodesis through distraction osteogenesis techniques

Case	*Gender*[1]	*Age (years)*	*Etiology of bone defect*	*Infection-causing microorganism*	*Soft tissue reconstruction*	*Bone defect length (mm)*	*External fixation system*	*External fixation time (months)*	*Regenerated bone length (mm)*	*Bone healing index (months/cm)*	*Bone transport complication*
1	M	65	Infected ankle arthrodesis attempt	*S. aureus*	No	40	Ilizarov circular external fixator	23	42	5.48	Hypotrophic regenerate bone
2	M	46	Infected open pilon fracture	Negative (but pus presence and positive histology)	Yes (Free flap)	60	Monolateral external fixator	13	70	1.86	Non-union at the docking site
3	M	32	Infected open pilon fracture	*S. aureus*	No	15	Ilizarov circular external fixator	8	15	5.33	Non-union at the docking site
4	M	46	Closed ankle fracture infected after ORIF	*S. epidermidis*	No	47	Ilizarov circular external fixator	10	42	2.38	Regenerate bone fracture
5	F	58	Infected ankle arthrodesis attempt	Negative (but pus presence and positive histology)	Yes (Local flap)	32	Ilizarov circular external fixator	13	28	4.64	Regenerate bone fracture

[1]Gender: F, female; M, male

Table 2: Patients' post-operative clinical outcomes

Case	*Nail insertion*	*Resolution of bone transport complication*	*Painless and stable AA*	*Local infection*	*LEFS*[1]	*Full weight-bearing*	*Knee ROM*[2]	*Ankle ROM*[2]	*Satisfaction*	*Complication or nail removal*
1	Retrograde (AA[3])	Yes	Yes	No	46	Yes	0–120°	0° (AA)	Very satisfied	No
2	Retrograde (AA)	Yes	Yes	No	67	Yes	0–120°	0° (AA)	Very satisfied	No
3	Retrograde (AA)	Yes	Yes	No	57	Yes	0–120°	0° (AA)	Very satisfied	No
4	Retrograde (AA)	Yes	Yes	No	34	Yes	0–90°	0° (AA)	Very satisfied	No
5	Retrograde (AA)	Yes	Yes	No	30	Yes	0–110°	0° (AA)	Very satisfied	No

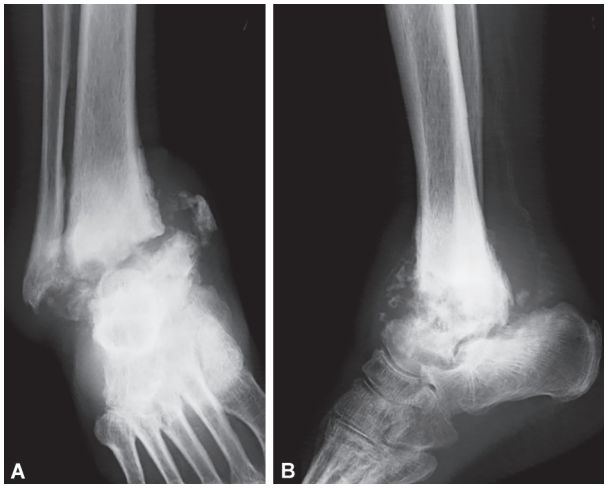
[1]LEFS, lower extremity functional scale; [2] ROM, range of motion; [3]AA, ankle arthrodesis

staged strategy and a prophylactic antibiotic-coated nail, we found no infection complications following the second stage after a mean follow-up of 35.2 months. Functional and patient satisfaction outcomes were encouraging, showing that this limb-salvage protocol may be a viable option in such difficult-to-treat cases. To the best of our knowledge, this is the first report on the use of this type of nail to resolve bone transport complications.

Bone transport techniques using external fixation devices are useful in managing infected segmental bone defects of the distal tibia. There are unique advantages for use in sepsis: these are temporary implants positioned far from the infected area; there is minimal invasiveness to the soft tissue in its application; reconstruction of massive bone defects can be achieved regardless of length; ankle arthrodesis is possible simultaneously in cases of articular destruction; and the device allows for early weight-bearing.[4] However, bone transport for infected bone defects is a complex and lengthy procedure. Its complication rate can be as high as 44%, including failure of distraction osteogenesis, premature consolidation, hypotrophic regenerate bone, regenerate fracture, non-union at the docking site, pin track infection, relapse of infection, joint stiffness and nerve palsy.[6,16] In our series of five patients with bone transport complications, two were operated upon due to non-union at the docking site, two due to traumatic regenerated bone fracture and one due to hypotrophic regenerated bone. These complications are associated with delays in progress in treatment and often create the need for further surgeries. This may explain the long external fixation time observed in our study, with an average bone healing index of 3.4 months/cm. Furthermore, suboptimal functional outcomes, psychological burden, pain and decreased quality of life are also linked with these events.[7]

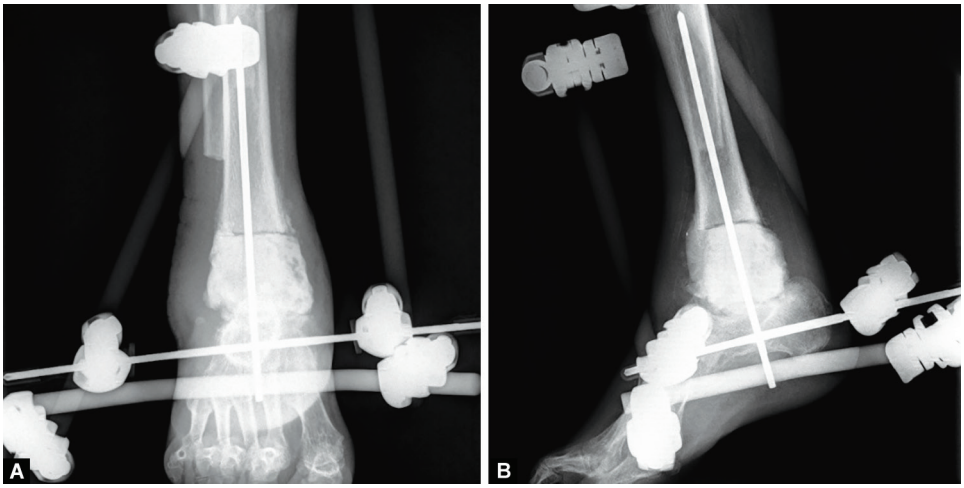
One option for treating mechanical complications of bone transport is the use of an intramedullary nail. In our series, all bone transport complications were successfully treated with a retrograde nailing technique in a percutaneous fashion. In the case of hypotrophic regenerated bone, the internal device was implanted prophylactically to avoid high fracture risk with the removal of the fixator, and to achieve some degree of autografting subsequent to the sequential reaming. In the case of the regenerate fracture, closed or percutaneous reduction and internal fixation were achieved with the nailing. Finally, non-union of the docking site was solved with a "closed docking site" strategy; here reaming was used as a "preparation of docking site" tool and the bone debris as a source of autologous graft before nail stabilization. In a series similar to our group, Lai et al.[8] reported a series of 27 bone transport complications treated with antegrade nailing (nine with non-union at the docking site, nine with callus fracture, seven with poor tolerance and two with hypotrophic regenerated bone), solving the problem in all cases. Biz and Iacobellis[9] reported a similar series with nine patients, reporting nailing as a good solution for regenerated bone and docking site problems. Nevertheless, these studies also highlighted the high risk of potential septic failure in such a scenario. The rate of deep infection associated with nailing after external fixation bone transport is reported to be 7.4–33%.[8,9] Treatment with intramedullary nails has other limitations as well; its use may not be possible in the case of deformed bones, narrow intramedullary canals or fractures with very short distal fragments. For these difficult but rare cases, the repeated use of external fixation is an option to consider.

The use of internal implants in cases with a high risk of infection such as after bone transport due to septic tibial defects, is controversial.[15] Therefore, the use of antibacterial or antibiotic-coated tibial nails may be an attractive option in such patients. Local antibiotic therapy is considered a useful and safe adjuvant to prevent deep infection; it provides high local concentrations of antibiotic without systemic effects.[17,18] For instance, in the high-infection-risk scenario of open tibia fractures treated with nailing, a systematic review found that the deep infection rate was lower when locally delivered antibiotics were administrated as an adjunctive prophylactic therapy.[19] Specifically, the ETN PROtect® nail has proved its efficacy in preventing deep infection in tibial fractures with a high risk of infection. Schmidmaier et al.[20] performed a multicentre prospective study evaluating the outcomes of 99 patients with high-infection-risk tibial fractures (including open fractures and revision surgeries) treated with ETN PROtect®. The study showed a relatively low rate of deep infection (5%) without any local or systemic toxic effects related to gentamicin. They stated that the use of an antibiotic-coated implant might reduce bacterial adhesion and could therefore reduce the rate of implant-related infection or osteomyelitis. Similarly, Fuchs et al.[10] studied 21 patients treated with the ETN PROtect® nail, reporting no deep infection after 6 months of follow-up. They concluded that their preliminary outcomes support the use of this gentamicin-coated implant as a new potential treatment option for the prevention of infection. However, the use of an antibiotic-coated nail in the high-infection-risk scenario of the cases illustrated here has not previously been studied. In our small series, none of the five patients presented with deep infection after a mean follow-up of 35.2 months after nail insertion.

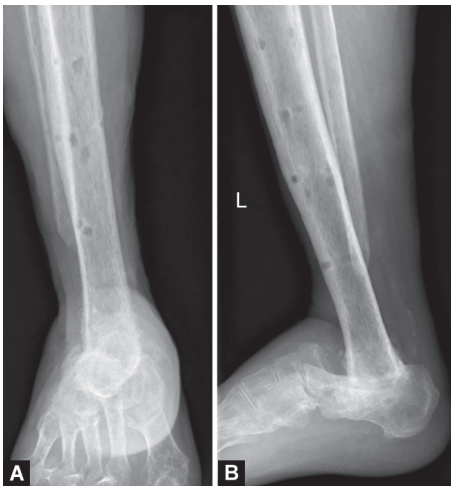


Figs 1A and B: This figure shows a 46-year-old male patient (case 4) with a distal tibia injury combining bone loss, articular destruction and infection after a closed ankle fracture originally treated with ORIF. (A) Anteroposterior X-ray image; (B) Lateral X-ray image

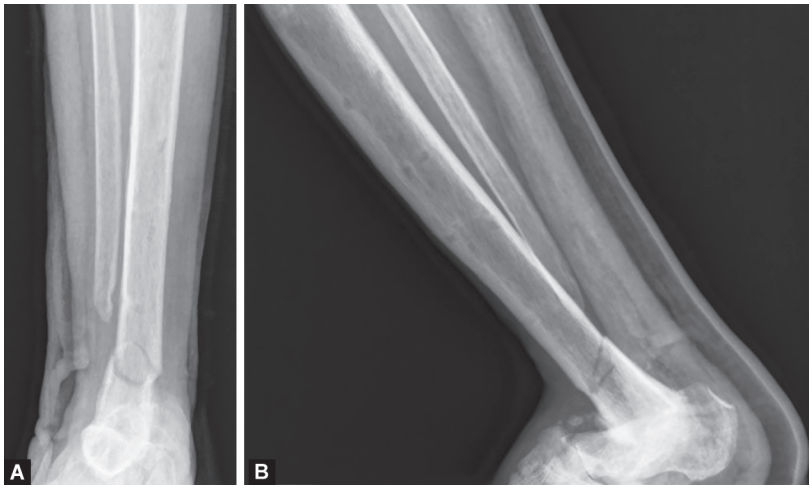
Multiple surgical techniques have been described for the salvage of failed ankle arthrodesis after traumatic or septic joint destruction or both, intended as limb-sparing procedures to obtain a stable, painless and plantigrade foot. Among them, circular external fixation offers multiple advantages in high-infection-risk cases.[5] In our case series, an antibiotic-coated nail and trans calcaneal retrograde technique have been used to treat complications after bone transport while simultaneously achieving definitive ankle arthrodesis (Figs 1 to 5). Brauns and Lammens[1] published a series of ten infected distal tibial defects



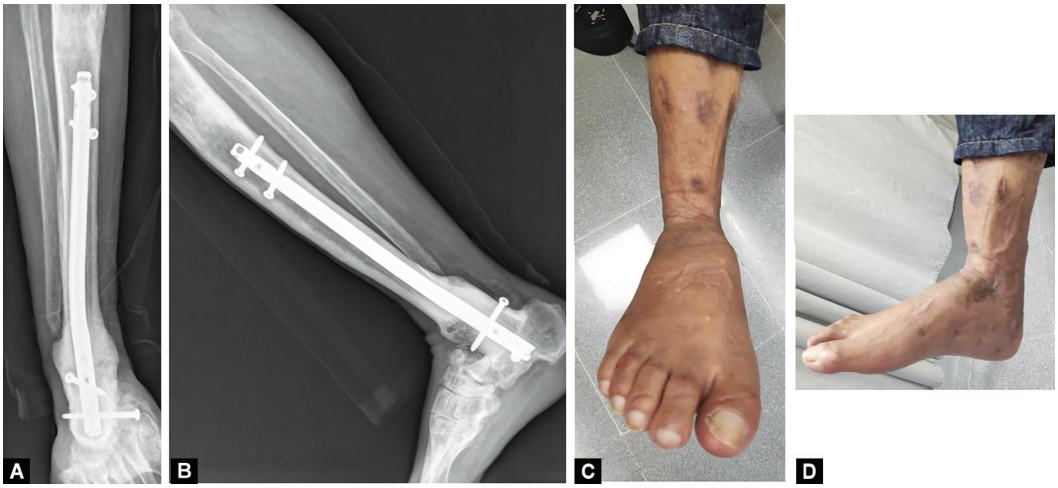
Figs 2A and B: Radical surgical debridement was performed, removing all devitalized bone and soft tissue. Cultures registered positive for *S. epidermidis*; targeted antibiotic treatment was indicated. An antibiotic-loaded cement spacer was implanted in the bone defect and a monolateral external fixator was applied to stabilize the segment. (A) Anteroposterior X-ray image; (B) Lateral X-ray image



Figs 3A and B: Bone transport through a circular external fixator was used for bone reconstruction purposes and to achieve a tibiocalcaneal ankle arthrodesis. Regenerate bone length was 42 mm; external fixation time was 10 months. (A) Anteroposterior X-ray image; (B) Lateral X-ray image



Figs 4A and B: Five months after external fixator removal the patient suffered a bone transport complication consisting of a regenerate bone fracture due to low-energy trauma. (A) Anteroposterior X-ray image; (B) Lateral X-ray image



Figs 5A to D: Revisional ankle fusion using a retrograde prefabricated gentamicin-coated intramedullary nail (ETN PROtect®) to treat the regenerate bone fracture. (A and B) Anteroposterior and lateral X-ray images showing that the bone transport complication was solved without any additional procedure; (C and D) Clinical photographs of patients, showing that painless and stable ankle arthrodesis in a plantigrade position was achieved. No signs of local infection appeared at the end of follow-up

treated with radical resection, external-fixation bone transport and ankle arthrodesis. They reported that five of these patients presented with non-union, which was successfully resolved using a retrograde nailing technique. Ninety percent of their patients tolerated full weight-bearing and were able to perform activities of daily living. Similarly, Chen et al.[2] presented a staged protocol for septic ankle joint destruction, consisting of radical debridement and external fixation bone transport followed by non-antibiotic-coated nailing for arthrodesis. Their twelve patients were ultimately able to walk on a plantigrade foot with full weight-bearing and with the mean AOFAS ankle and hindfoot score raised from 21.5 to 65.5 points. However, four patients (33.3%) required nail removal due to infection relapse. In our series, patients presented relatively good functional outcomes (all tolerated full weight-bearing, knee ROM was 112 $\pm$ 12.7° and LEFS test score was 46.8 $\pm$ 13.8), taking into account that they had sustained very severe injuries and had multiple previous surgeries. It should be noted that all our patients were very satisfied with the procedure (mean SAPS score was 93.8 points) and none suffered any complication after nail insertion or required nail removal.

There are some limitations to this preliminary study, including those inherent in any retrospective study without a randomized control group. The small sample size also represents a potential bias, as it limits the study's statistical power and the generalizability of results. In our national referral musculoskeletal infection unit, we have only been able to include five patients between 2017 and 2020, reflecting the rarity of this scenario.

Conclusion

The staged retrograde nailing technique using the ETN PROtect® shows potential as an effective and safe treatment for bone transport complications in high-infection-risk patients. Furthermore, it achieves ankle arthrodesis from the same surgical procedure. Patients present good functional outcomes and are very satisfied with the procedure.

Clinical Significance

This reported strategy is novel in using retrograde gentamicin-coated tibial nails and aims to resolve bone transport complications while simultaneously achieving functional ankle arthrodesis.

Ethical Approval

The study was approved by our centre's Ethics Committee (CEIC). The study was performed in accordance with the ethical standards laid down in the 1964 Declaration of Helsinki.

Acknowledgements

The authors wish to thank Russell Williams of RoundlyWorded.com for his editorial recommendations. We further wish to thank our entire multidisciplinary team; without their help, it would be far more difficult to treat patients of this type.

This work was conducted within the framework of the doctorate in Surgery of the Universitat Autònoma de Barcelona.

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