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Single-Stage Treatment Protocol for Presumed Aseptic Diaphyseal Nonunion

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Introduction

This article describes the general surgical technique for treating presumed diaphyseal nonunion with a one-stage procedure involving intraoperative removal of specimens for culture, revision open reduction and internal fixation (ORIF) with a plate or nail, and bone-grafting.

There is no standardized protocol for surgical treatment of diaphyseal nonunions[1]. Historically, the approach for infected (septic) nonunions has differed from that for nonunions that are not infected (aseptic)[2,3]. It is generally accepted that nonunions that are clearly infected (e.g., with draining sinuses, fistulas, or exposed or loose implants) should be treated in a two-stage manner, with removal of unstable or failed implants, debridement of the nonunion site, local and/or systemic antibiotics, and some form of external fixation or use of antibiotic-coated rods in the first stage and definitive fixation and autologous bone-grafting in the second stage, performed at a later time[4]. Nonunions that are clearly not infected are treated in a single-stage manner.

Occasionally, it is unclear whether or not a nonunion is infected. These *presumed aseptic nonunions* present a challenge to the treating surgeon. Can one assume that it is safe to remove implants and perform revision internal fixation with bone-grafting in a one-stage procedure, or is it more prudent to treat the nonunion as if it were infected and perform a two-stage procedure? While laboratory values such as the erythrocyte sedimentation rate (ESR), white blood-cell (WBC) count, and C-reactive protein (CRP) level may be of aid in treatment decisions, they are generally nonspecific and there is often borderline elevation in these marker levels[5,6]. In such scenarios, we have adopted a standardized treatment protocol that involves withholding preoperative antibiotics, removing intraoperative specimens for culture, and treating the nonunion definitively in one stage. We employ this protocol for all nonunions of diaphyseal fractures that were previously treated surgically in patients with no history or clinical signs of associated infection (Video 1 and Figs. 1-A through 2-E). The outcomes of this protocol have been reported previously[7].

Step 1: Preoperative Evaluation

Take a careful history, evaluate the extremity and wound, and note comorbidities and medications.

- Take a careful history to determine whether the patient had an open fracture, any wound infection including cellulitis, treatment with antibiotics beyond the standard perioperative protocol lasting twenty-four hours, any subsequent surgical procedures to address infection, or fevers and chills or other systemic symptoms associated with wound erythema or swelling.
- Evaluate the involved extremity, including the range of motion and any deformity, and examine the wound itself for signs of infection, sinuses, or nonhealing.
- Note any comorbidities (e.g., peripheral vascular disease and diabetes mellitus) and medications.

Step 2: Preoperative Planning

Preoperative planning is essential before revision nonunion surgery.

- Often prior implants are broken and need to be removed with specialized devices. Scrutinize previous operative reports for details on exposure and the type of implant used. When a nail was used, ascertain its size so that a larger nail can be employed if exchange nailing is performed.
- Any substantial deformity should be addressed at the time of the revision operation. If deformity correction is required, obtain preoperative imaging studies, including three-joint standing radiographs and/or computed tomography (CT) scans, to compare alignment, length, and rotation with those on the contralateral side.
- Order routine laboratory tests, including measurements of the ESR, CRP level, and WBC count. We generally do not obtain special studies such as positron-emission tomography (PET)-CT, indium-labeled white cell scan, etc.

Step 3: Debridement, Implant Removal, and Cultures

Debride the nonunion site, remove all failed and loose implants, and take specimens for culture; withhold antibiotics until all culture specimens have been obtained.

- Prepare and drape the involved extremity in a standard fashion. A tourniquet is generally not used, although one can be employed if necessary.
- Use prior surgical incisions whenever possible to avoid additional soft-tissue stripping and devitalization. Preserve nerves and vascular structures during standard surgical approaches.
- Approach and identify the nonunion site and thoroughly debride it with a combination of curets, rongeurs, and other standard debridement instruments. Excise all fibrous tissue down to bone in order to stimulate bone growth and remove impediments to bone-bridging.
- Remove all failed and loose implants.
- Take specimens, using a culture swab, from the nonunion site for five aerobic and five anaerobic cultures as well as for gram staining. Also obtain a pathologic tissue sample from the nonunion site. In addition, send one screw or plate for culture. We very rarely send local fluid for a cell count unless gross purulence or a large seroma is encountered.
- Once the culture specimens have been taken, administer antibiotics intravenously. In the absence of an allergy, use a first-generation cephalosporin.
- Using a sharp chisel or osteotome, roughen the cortical bone by making multiple nicks or partial cuts—i.e., perform “fish scaling” or “petaling”—to increase the surface of bleeding bone that will be covered with bone graft[8].
- Debride the nonunion site of all fibrous material and open the medullary canal on both sides of the nonunion with a small drill until bleeding bone marrow is encountered.
- Irrigate the wound copiously with at least 1 L of sterile normal saline solution.

Step 4: Open Reduction and Internal Fixation

Reduce the fracture and use interfragmentary fixation and/or compression, or a bridging plate.

- Reduce the fracture and hold it in position with clamps and/or wires.
- Depending on the amount of bone loss and the type of nonunion (transverse, oblique, or gap), use interfragmentary fixation and/or compression across the nonunion site or employ a bridging plate construct to maintain the reduction of the nonunion. Use the bridging construct when interfragmentary fixation cannot be obtained because of a lack of cortical bone or the presence of small fracture fragments that do not allow application of a lag screw or compression across the nonunion site. In many cases, a fracture that was previously fixed with a plate can be nailed and vice versa.
- Various bone grafts or commercially available bone-graft alternatives, including autologous bone graft (e.g., from the iliac crest or obtained with a Reamer/Irrigator/Aspirator [RIA]; Synthes, West Chester, Pennsylvania), allograft bone chips, and demineralized bone matrix, can be used to assist in bone-healing[9].
- Close the wounds in a standard fashion, almost always over a drain. The drain is typically removed on the first postoperative day if there was <30 mL of output over the prior shift.

Alternative: Exchange Nailing

When alignment is adequate and there is no substantial deformity, or the deformity is correctible with closed techniques, exchange nailing can be employed without actually opening the nonunion site.

- Remove the prior nail, ream the canal, and in most cases insert a larger-diameter nail.
- Remove canal-reaming material to send for culture and then administer antibiotics.
- An RIA can be used in conjunction with exchange nailing to debride and copiously irrigate the canal.

Step 5: Postoperative Care

If any of the five cultures are positive, consult an infectious disease specialist with experience in treating musculoskeletal infections.

- Administer antibiotics postoperatively for twenty-four hours. Check cultures daily until finalized. We allow five days of incubation at our institution.
- If any of the five cultures are positive, consult an infectious disease specialist with experience in treating musculoskeletal infections. Antibiotics are administered according to the number of positive cultures and the organism grown on culture, with the duration and route of antibiotic administration chosen in consultation with the infectious disease specialist. Often, if only one culture is positive, the organism is considered

- a contaminant and the patient is not treated for infection. Again, this decision is made in close consultation with the infectious disease specialist.
- Base weight-bearing recommendations on the nonunion pattern and characteristics and the extremity involved. Range-of-motion exercises are begun early in the postoperative period.

Results

We have used this protocol at our institution for patients with prior fracture surgery who subsequently developed a nonunion, with or without implant failure, that had no obvious infectious etiology. The protocol is simple and straightforward, allowing the surgeon to proceed with either revision ORIF or exchange nailing without the need for a two-stage technique. We have found that taking five culture specimens provides sufficient sensitivity to detect an infectious etiology for the nonunion while not interfering with our ability to perform the revision operation in one stage.

An important finding from our original study was that the patients who had positive cultures (29% [twenty-five] of the eighty-seven patients in the series) had growth of low-virulence organisms that, in most cases, were treated effectively (i.e., did not require additional surgery) with antibiotics under the direction of an experienced infectious diseases physician[7]. Of the twenty-five patients who had at least one positive intraoperative culture, seven (28%) eventually required at least one more operation to obtain healing of the nonunion and only one had persistence of deep infection. Four of the twenty-five patients had only one positive culture and, after consultation with an infectious disease specialist, the organism was considered a contaminant and the patient did not receive long-term antibiotic therapy. None of these four patients required additional surgery. No patient with presumed aseptic nonunion treated with this protocol went on to require an amputation because the infection did not heal. We suspect that this protocol is safe because infected nonunions caused by more virulent organisms are more likely to present with obvious signs of infection such as wound problems or signs of systemic sepsis.

What to Watch For

Indications

- Any nonunion of a diaphyseal fracture that had been treated with internal fixation (either a plate or nail) provided that there is no history or signs of infection.
- Prior open fracture itself is not a contraindication as many of the patients who were treated successfully with our protocol had had an open fracture[7].

Contraindications

- An active infection or history of wound infection.
- Nonunions involving a large bone defect without any cortical apposition are more likely to require a structural bone-grafting procedure such as the Masquelet technique[10], which is a two-stage operation.
- Nonunions requiring a structural bone-grafting procedure such as the Masquelet technique, distraction osteogenesis, or vascularized fibular autograft were not included in our series[7]. These tend to be more challenging cases in which multiple procedures are required to obtain osseous bridging and fracture-healing.

Pitfalls & Challenges

- Nonunion surgery is challenging.
- The operative report of the surgeon who performed the prior fracture surgery is useful as it provides information regarding prior instrumentation such as nails or plates and screws.
- Standard nail and broken-screw removal sets are available and should be used as necessary.
- The patient should be informed that, despite careful preoperative planning, findings during the surgery might necessitate a deviation from the original plan.
- If gross purulence is noted, an intraoperative decision needs to be made whether to proceed with revision fixation or convert to a staged procedure by debriding the wound and then using an external fixation device or an antibiotic-coated nail. If there is purulence or other obvious signs of infection we generally do not place bone graft but use antibiotic-coated beads instead. We remove the beads at six weeks and then add bone graft.
- If a substantial deformity is present, we typically remove the nail, open the fracture site, debride the nonunion site, correct the deformity, and then proceed either with a revision ORIF with a plate and screws or with revision nailing. Malreduction resulting from the initial nailing is often difficult, although not impossible, to correct with revision nailing. A new starting point and/or the aid of a universal distractor may be necessary. Nonunions of malreduced previously nailed diaphyseal fractures can be technically challenging to treat, and we often choose to apply a plate in these cases.
- A corollary to the previous scenario is nailing of a nonunion of a previously plated fracture. The

nail can be placed with relative ease across previously stripped nonunion sites with poor bone quality—essentially a bridging construct. In addition, bone graft can be applied to the nonunion site in this scenario.

- Methods of bone-grafting in the presence of nonunion vary. Iliac crest bone-grafting is still considered the standard of care, although some studies have shown the utility of using bone obtained from femoral reaming[9]. Although we used iliac crest bone-grafting in some of the patients in our study, we also used bone-graft substitutes such as demineralized bone matrix in many cases[7]. A discussion of the use and method of bone-grafting is beyond the scope of this article. However, no bone graft is used in certain situations, such as an exchange nailing involving placement of a larger nail. The greater size of the implant provides enough stability for the fracture nonunion to heal. These are typically hypertrophic nonunions where callus is present but, because of a lack of mechanical stability, the fracture did not heal. We do employ bone-grafting, or bone-grafting substitutes depending on the clinical situation, when the nonunion is atrophic, to provide stability in addition to that derived from the implants.

Clinical Comments

- Even though we usually relied on the history and physical examination alone to decide when to use this protocol, we recommend an inflammatory and metabolic work-up whenever it is suspected that an infection or metabolic bone disease is contributing to poor bone biology.

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Fig. 1-A

Fig. 1-B

Fig. 1-C

Figs. 1-A through 1-F An eighteen-year-old female pedestrian sustained a closed fracture of the proximal one-third of the tibia and an associated fibular fracture when she was struck by an automobile. She was treated with reamed tibial intramedullary nailing at another (not our) institution. **Fig. 1-A** Anteroposterior and lateral radiographs made at the time of presentation to our institution, nine months following the intramedullary nailing, demonstrate a tibial nonunion with varus and flexion deformities. The patient stated that she had persistent pain and was unable to progressively bear weight following the initial fracture surgery. **Fig. 1-B** Revision ORIF was performed with debridement of the nonunion site, removal of culture specimens intraoperatively, correction of the deformity with use of a proximal tibial locking plate, and compression across the nonunion site with placement of interfragmentary compression lag screws. *Staphylococcus epidermidis* grew on culture of the operative specimens, and the patient was treated with antibiotics intravenously for eight weeks. **Fig. 1-C** Anteroposterior and lateral radiographs made six months after the revision ORIF suggest a delayed union of the tibia and a healed fibular fracture.

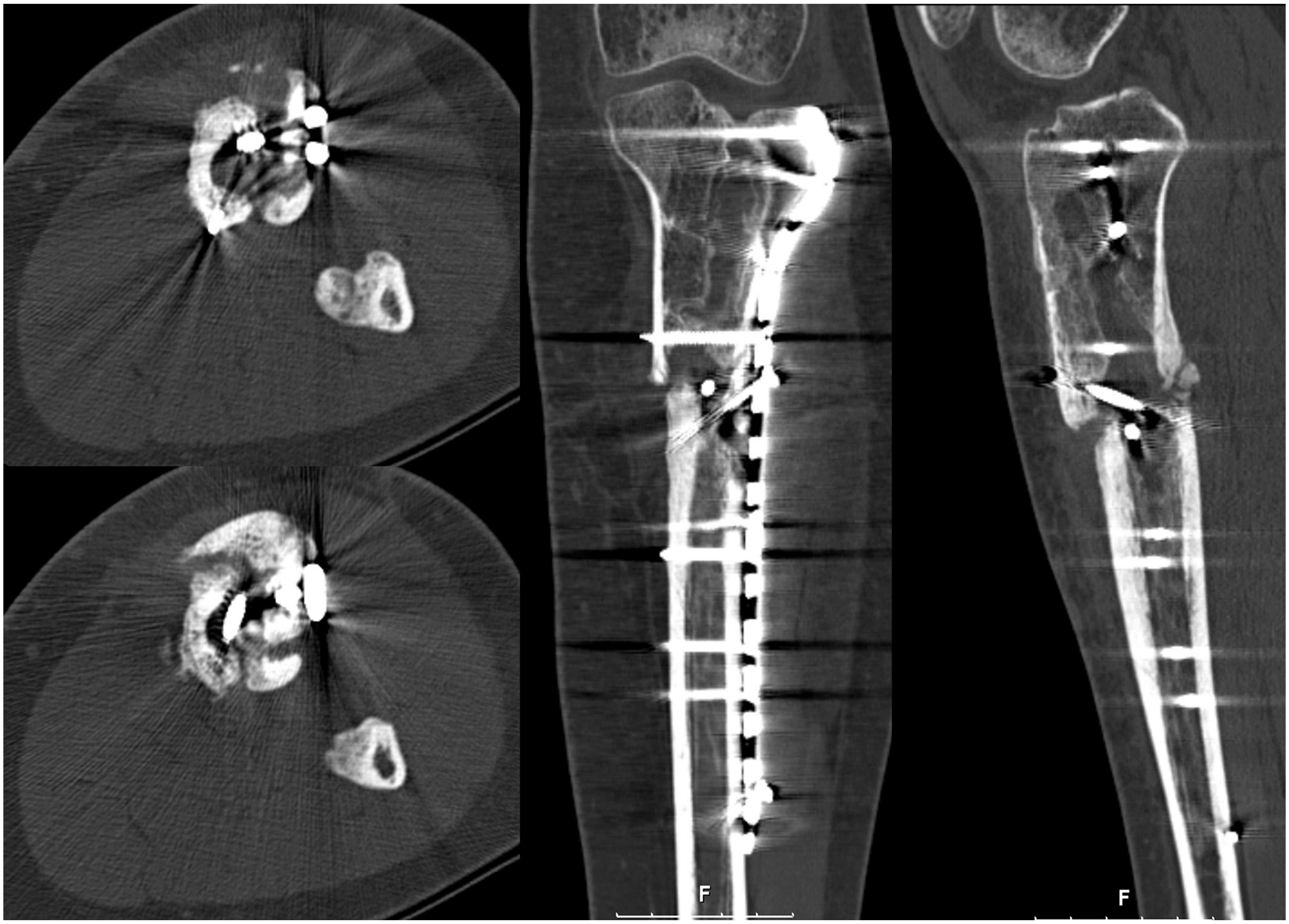

Fig. 1-D

CT scan confirming a lack of bridging callus and persistent nonunion.

Fig. 1-E

The patient underwent a second revision ORIF with debridement of the nonunion site and bone-grafting along with fixation with double plates. Cultures of specimens taken intraoperatively were negative.

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Fig. 1-F

Radiographs made at four months postoperatively show a healed proximal part of the tibia. The patient had no pain, had a full range of motion of the knee, and had returned to all of her preinjury activities.

Fig. 2-A

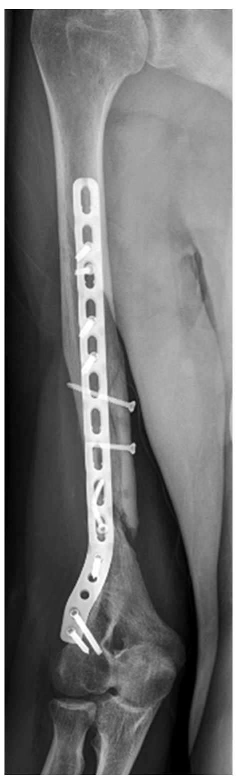

Fig. 2-B

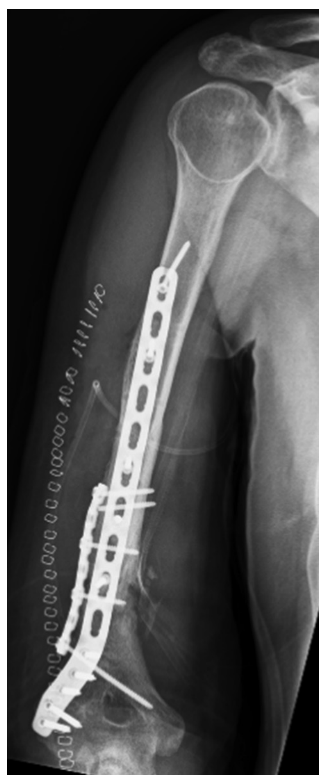

Fig. 2-C

Figs. 2-A through 2-E Case seen in Video 1. A forty-five-year-old man sustained an open fracture of the right humerus with radial nerve palsy when he fell onto his right arm while hang gliding outside his home country. He underwent irrigation, debridement, and external fixation. **Fig. 2-B** Two weeks after he returned to his home country, the patient underwent removal of the external fixation device and ORIF at another (not our) institution. At nine months postoperatively, there were no visible signs of healing and he continued to have pain as well as a persistent radial nerve palsy. **Fig. 2-C** At our institution, the patient underwent revision ORIF with debridement of the nonunion site, removal of specimens intraoperatively for culture, bone-grafting, and interfragmentary fixation.

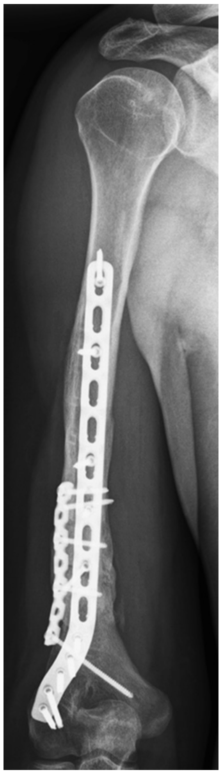

Fig. 2-D

Fig. 2-E

Figs. 2-D and 2-E At six months postoperatively, there was radiographic evidence of union, the patient had no pain, and radial nerve function had nearly fully returned.

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