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RECONSTRUCTION OF SEGMENTAL BONE DEFECTS DUE TO CHRONIC OSTEOMYELITIS WITH USE OF AN EXTERNAL FIXATOR AND AN INTRAMEDULLARY NAIL

[SCIENTIFIC ARTICLE]

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Abstract

Background: Callus distraction over an intramedullary nail is a rarely used technique for the reconstruction of intercalary defects of the femur and tibia after radical débridement of chronic osteomyelitic foci. The aim of

this study was to summarize our experience with distraction osteogenesis performed with an external fixator combined with an intramedullary nail for the treatment of bone defects and limb-shortening resulting from radical débridement of chronic osteomyelitis.

Methods: Thirteen patients who ranged in age from eighteen to sixty-three years underwent radical débridement to treat a nonunion associated with chronic osteomyelitis of the tibia (seven patients) and femur (six patients). The lesions were classified, according to the Cierny-Mader classification system, as type IVA (nine) and type IVB (four). The resulting segmental defects and any limb-length discrepancy were then reconstructed with use of distraction osteogenesis over an intramedullary nail. Two patients required a local gastrocnemius flap. Free nonvascularized fibular grafts were added to the distraction site for augmentation of a femoral defect at the time of external fixator removal and locking of the nail in two patients. At the time of the latest follow-up, functional and radiographic results were evaluated with use of the criteria of Paley et al.

Results: The mean size of the defect was 10 cm (range, 6 to 13 cm) in the femur and 7 cm (range, 5 to 10 cm) in the tibia. The mean external fixator index was 13.5 days per centimeter, the consolidation index was 31.7 days/cm, and the mean time to union at the docking site was nine months (range, five to sixteen months). At a mean follow-up of 47.3 months, eleven of the thirteen patients had an excellent result in terms of both bone and functional assessment. There were two recurrences of infection necessitating nail removal. These patients underwent revision with an Ilizarov fixator. Subsequently, the infection was controlled and the nonunions healed.

Conclusions: This combined method may prove to be an improvement on the classic techniques for the treatment of a nonunion of a long bone associated with chronic osteomyelitis, in terms of external fixation period and consolidation index. The earlier removal of the external fixator is associated with increased patient comfort, a decreased complication rate, and a convenient and rapid rehabilitation.

Level of Evidence: Therapeutic <u>Level IV.</u> See Instructions to Authors for a complete description of levels of evidence.

Musculoskeletal infections remain a common problem. Because of better staging systems, developed surgical techniques, antibiotics, and adjuvant treatment modalities such as hyperbaric oxygen, the treatment strategy for chronic osteomyelitis has changed to a great extent over the past twenty years 1.

Chronic osteomyelitis leads to necrosis of bone and soft tissues to a variable extent. The dead bone forms a nidus for hosting pathogens. Moreover, the host defense mechanisms are often not in an optimal condition to deal with microorganisms, and antibiotic delivery to the infection site may be impaired because of poor circulation 2.

Cierny et al. classified chronic osteomyelitis into four anatomical types, a system that is known as the Cierny-Mader classification, and further staged the pathology according to the extent of the local and systemic compromise in the patient 3. They developed guidelines for management according to the system.

Appropriate radical débridement requires excision of all necrotic bone and soft tissue, often resulting in limb instability. The unstable situation requires some type of fixation and reconstruction of the resultant bone and soft-tissue defects. Since the introduction of distraction osteogenesis by Ilizarov, the technique has been employed successfully to achieve union, correct deformity, reestablish limb-length equality, and reconstruct segmental defects 4.

The time spent in an external fixator (the external fixation index) depends on the length of distraction required and is not free of complications. When the distraction phase is over, the consolidation phase, which is more than double the distraction time, becomes difficult for the patient to tolerate. Removal of the external fixator before satisfactory consolidation has occurred is associated with fracture, deformity, and shortening occurring through the distracted callus 5.

To decrease the time that the patient must remain in the frame, distraction over an intramedullary nail has been investigated in both animal and clinical studies 6,7. The main purpose of this combined technique is reduction of the external fixation period to increase the comfort and activity level of the patient. In this technique, as soon as distraction is finished, the nail is statically locked and the external fixator is removed. The consolidation phase is then allowed to proceed, with stabilization provided by the intramedullary nail. Thus, complications associated with premature removal of the fixator can be avoided.

This retrospective cohort study summarizes our experience with distraction osteogenesis with use of an external fixator combined with an intramedullary nail for the treatment of segmental defects and limb-shortening resulting from radical débridement of a focus of chronic osteomyelitis.

Materials and Methods

The cases of a consecutive series of thirteen patients with Cierny-Mader type-IVA and type-IVB osteomyelitis were reviewed retrospectively (Table I). All laboratory parameters to measure active infection such as C-reactive protein levels, the erythrocyte sedimentation rate, and the white blood-cell count and differential obtained at the time of nail insertion were normal. Demographic data were collected after reviewing the medical record and the registry maintained in our department of the patients undergoing distraction osteogenesis.

Case	Gender, Age (Yr)	Bone	No. of Previous Operations	Cierry-Mader Stage	Operation to Repair Defects*
1	M, 18	Tibia	20	IVA	Ilizarov, intramedullary nail
2	M, 63	Femur	2	IVB (local)	Orthofix, intramedullary nail
3	F, 52	Tibia	3	IVA	Ilizarov, intramedullary nail
4	M, 49	Tibia	3	IVA	Ilizarov, intramedullary nail
5	M, 31	Tibia	1	IVB (local)	Ilizarov, intramedullary nail
6	F. 28	Femur	4	IVB (local)	Orthofix, intramedullary nai
7	M, 33	Tibia	1	IVB (local)	Ilizarov, intramedullary nail
8	F, 46	Femur	6	IVA	Orthofix, intramedullary nail
9	F, 36	Tibia	5	IVA	Ilizarov, intramedullary nail
10	M, 21	Femur	3	IVA	Orthofix, intramedullary nai
11	F. 38	Femur	5	IVA	Orthofix, intramedullary nai
12	M, 26	Femur	2	IVA	Orthofix, intramedullary nai
13	M, 28	Tibia	4	IVA	Ilizarov, intramedullary nail

TABLE I Demographic Data on the Patients

Bone Loss (cm)	External Fixation Time (mo)	Bone-Healing Time (mo)	Bone Status at Latest Follow-up	Functional Status at Latest Follow-up
5	2.0	6	Union, excellent	Excellent
13	6.0	10	Union, excellent	Good
6	2.7	5	Union, excellent	Excellent
7	3.2	7	Union, excellent	Excellent
6	2.7	6	Union (infection), good	Excellent
9	4.0	6	Union, excellent	Excellent
9	4.0	12	Union, excellent	Good
9	4.0	16	Union, excellent	Excellent
6	2.5	5	Union, excellent	Excellent
12	5.5	12	Union, excellent	Excellent
11	5.0	13	Union, excellent	Excellent
6	2.5	5	Union (infection), good	Excellent
10	5.0	13	Union, excellent	Excellent

TABLE I (continued)

The patients had had an average of 4.5 surgical procedures (range, one to twenty procedures) before presenting to our clinic. All patients were assessed for local skin condition, shortening, deformity, distal

neurovascular status, joint function, and nutritional index. Angiography was performed to identify any vascular injury from previous interventions. Magnetic resonance imaging was used to examine the entire long bone and identify any distant or skipped infection and any foci of dead bone. The pathology was classified according to the Cierny-Mader system 3.

There were seven tibiae and six femora. In the tibial group, two patients had only a segmental defect, two patients had deformity associated with a segmental defect, one patient had an infection around a total knee prosthesis after tumor excision, and two patients had a combination of a segmental defect and shortening. In the femoral group, only one patient had shortening and one had a segmental defect but no shortening. The remaining four patients had a segmental defect combined with deformity.

Operative Technique

Step I

Hardware removal and radical resection of dead bone with débridement of the infected scarred soft tissue was performed, and representative tissue cultures, including the sinus tract for all dead bone, were obtained. Cortical bleeding, described as the so-called paprika sign, was accepted as an indication of vital tissue 8. The dead space was filled with custom-made antibiotic-impregnated polymethylmethacrylate beads (a combination of 2.4 g of teicoplanin and 40 g of polymethylmethacrylate powder). Patients who had an intramedullary implant were managed with implant removal and insertion of an antibiotic-impregnated polymethylmethacrylate cement rod in place of the nail and then with immobilization of the limb in a custom-made brace 9. In the remaining patients, stabilization was achieved with a temporary external fixator. Small soft-tissue defects, resulting from débridement of infected soft tissues and fistulae, ranging from 2 to 3 cm in size, were closed during acute shortening in three patients (Cases 2, 10, and 11)10. Antibiotics that were appropriate according to the findings on culture and sensitivity were given for a minimum of six weeks or until the erythrocyte sedimentation rate and Creactive protein level returned to normal limits (Table II).

	Prior to Step I			Prior to Step II		
Case	C-Reactive Protein* (mg/L)	Erythrocyte Sedimentation Rate† (mm/h)	Findings on Culture†	C-Reactive Protein (mg/L)	Erythrocyte Sedimentation Rate (mm/h)	Findings on Culture
1	45	52	MSSA	0.8	12	Sterile
2	57	66	MRSA	1.0	10	Sterile
3	98	72	MRSA and Pseudo- monas aeroginosa	2.4	12	Sterile
4	86	70	MRSA	1.0	14	Sterile
5	48	67	MRSA	3.0	11	Sterile
6	72	70	MRSA	2.2	10	Sterile
7	54	50	MSSA	2.0	8	Sterile
8	110	88	MRSA and Pseudo- monas aeroginosa	4.0	14	Sterile
9	42	50	MRSA	3.2	10	Sterile
10	60	58	MSSA	3.0	12	Sterile
11	46	52	MSSA	1.0	7	Sterile
12	82	91	MRSA	0.4	9	Sterile
13	78	90	MRSA	1.0	11	Sterile

*Normal values are 0.00 to 5.00 mg/L. †Normal values are 0 to 20 mm/h. †MSSA = methicillin-sensitive Staphylococcus aureus, and MRSA = methicillin-resistant Staphylococcus aureus.

TABLE II Laboratory and Microbiologic Data

Step II (Intramedullary Nail Insertion, Application of External Fixator, and Osteotomy)

After a period of six weeks, or when the C-reactive protein level and erythrocyte sedimentation rate had returned to normal values, the patient underwent removal of the antibiotic beads or cement rod. A biopsy specimen obtained from the bone gap was sent for Gram-staining and frozen-section analysis. The absence of microorganisms on Gram-staining and <5 polymorphonuclear leucocytes per high-power field were taken as an indication of the resolution of infection. Antegrade nailing was used only for patients with a segmental defect but without a limb-length discrepancy. Retrograde nailing was used for the treatment of shortening combined with a segmental defect. With retrograde nailing, the nails were locked distally and the excess length of the nail was left in the soft tissues proximally. With distraction, the nail glided distally until the correct length was achieved and the nail was locked at the completion of lengthening. For the patients undergoing segmental transport to treat a bone defect without a length discrepancy, antegrade nailing was performed. Additional holes were predrilled at the planned site of locking of the segment at the completion of bone transport to prevent recoil of the segment.

Treatment of Femoral Defects: The patient was placed supine on a radiolucent table with the limbs in a scissors position with a bolster below the pelvis on the involved side. By means of a standard approach (through the piriformis fossa for antegrade nailing and through a parapatellar incision for retrograde nailing), the medullary canal was reamed over a guidewire to a diameter 1.5 mm larger than that of the intramedullary nail

to be used. With lengthening procedures, the goal was to provide sufficient nail length on both sides of the regenerated bone at the end of distraction. This necessitated the use of an intramedullary nail that was longer than the length of the femur, and retrograde nailing allowed the excess nail length to protrude into the buttock until distraction was completed, by which time the nail would have glided gradually to its correct position. The proximal part of the femur was overreamed because the proximal part of the nail was larger. An appropriately placed corticotomy was then done percutaneously with an osteotome. Finally, an intramedullary nail (TriGen; Smith and Nephew, Memphis, Tennessee) of appropriate size was inserted and locked proximally, distally, or on both sides according to the planned distraction.

Two to three Schanz screws were inserted proximal to the level of the osteotomy site, and two to three Schanz screws were then inserted distal to it without contacting an intramedullary nail 11. At least 1 mm of free space should exist between the Schanz screws and the intramedullary nail to prevent medullary infection triggered by a pin-site infection 12. This can be achieved with use of the cannulated drill-bit technique described by Paley et al.13.

Treatment of Tibial Defects: After the medullary canal was reamed 1.5 mm larger than the planned size of nail, the nail was inserted and a three-ring circular external fixator was applied. A corticotomy was done at the appropriate level. For the patient with shortening and a segmental defect, an intramedullary nail of the eventual desired length of the tibia was inserted and left proud proximally so that it could slide distally during treatment.

Postoperative Care

Distraction was started on the seventh postoperative day 4. The rate of the distraction was 1 mm per day, divided into four equal increments. An epidural catheter was placed for postoperative pain management, and range-of-motion exercises of the hip and knee were initiated as soon as the patient's comfort allowed. In patients with a longer tibial intramedullary nail, knee exercises were postponed until the nail came to lie inside the bone during lengthening. Full weight-bearing with two crutches was started as soon as possible.

Step III (Removal of the External Fixator and Static Locking of the Nail)

After the distraction was completed, the nails were statically locked and the external fixators removed. Autogenous cancellous bone graft was added at the docking site. In two patients 8,14, a nonvascularized fibular graft was inserted into the posteromedial distraction site to provide additional support and decrease the amount of forces transmitted through

the nail until total consolidation. In both patients, the distraction site was in the proximal third of the femur.

A functional assessment was done with use of the criteria of Paley et al.15. The functional results were based on five criteria: substantial limp, equinus rigidity of the ankle, soft-tissue dystrophy (skin hypersensitivity, insensitivity of the sole, or decubitus), pain, and inactivity (unemployment because of the leg injury or an inability to return to daily activities because of the leg injury). The result was considered excellent when the patient was active and had none of the other four criteria, good when the patient was active and had one or two of the other four criteria, and fair when the patient was active and had three or four of the other criteria or had had an amputation.

The bone was assessed for union, infection, deformity, limb-length discrepancy, and mechanical insufficiencies at the docking site. The result was considered excellent when the following criteria were met: union, no infection, a deformity of $<7^{\circ}$, and a length discrepancy of <2.5 cm in the tibia and femur. The result was considered good when there was union and any two of the other criteria, fair when there was union and one of the other criteria, and poor when there was nonunion or refracture or none of the other criteria.

In the outpatient clinic, patients were screened for local signs and symptoms of infection and sinus formation or drainage, and the erythrocyte sedimentation rate and C-reactive protein levels were monitorized serially. Conventional radiographs were made every two weeks during the distraction phase and once every month during the consolidation phase.

The external fixation index was calculated as the duration of external fixation in days divided by the total amount of bone transported and/or the amount of lengthening in centimeters. The radiographic consolidation index was calculated as the time to the appearance of consolidation of at least three cortices on the anteroposterior and lateral radiographs in days divided by the total amount of bone transported and/or the amount of lengthening in centimeters.

Results

Thirteen patients treated with the combined technique were followed for a mean of 47.3 months (range, thirty-six to fifty-nine months). The laboratory studies are reported in Table II. The mean hospital stay was nine days (range, five to fourteen days). The mean total duration of treatment was nine months (range, five to sixteen months). The average external fixation index was 13.5 days/cm (range, 12.0 to 15.0 days/cm). The mean radiographic consolidation index was 31.7 days/cm (range, 20.0 to 53.0 days/cm).

There were two failures defined by recurrent drainage and elevated erythrocyte sedimentation rates and C-reactive protein levels. Eleven patients were apparently disease-free and able to walk without support at the time of the final follow-up.

All thirteen patients were evaluated with respect to the functional and bone results. With use of the criteria described above, the results in terms of bone-healing and those for function were excellent for eleven patients and good for two patients. Complete union was achieved in all patients. Refracture or malalignment was not observed after removal of the frame. The demographic data on our patients are shown in Table I (Figs. 1-A through 1-F).



Figs. 1-A through 1-F Case 9. A thirty-six-year-old woman with Cierny-Mader type-IVA chronic osteomyelitis of the tibia. **Fig. 1-A** Preoperative clinical photograph. **Fig. 1-B** Preoperative anteroposterior radiograph.

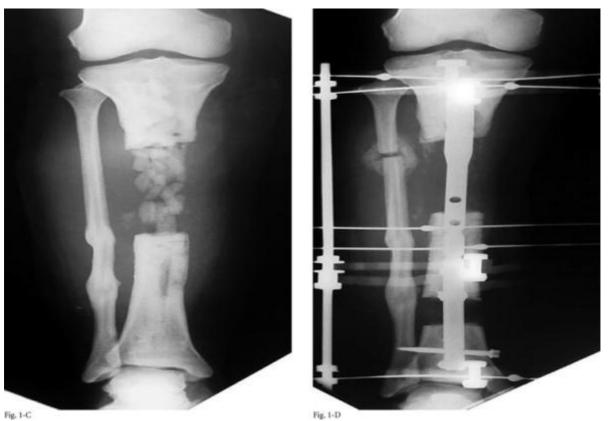


Fig. 1-C A radiograph made after radical resection of the infected bone segment with débridement and placement of antibiotic beads. **Fig. 1-D** Bone segment distraction with a circular external fixator over an intramedullary nail.



Fig. 1-E Postoperative anteroposterior radiograph following frame removal. **Fig. 1-F** Postoperative lateral radiograph following frame removal.

Complications

With use of the classification system of Paley 5, minor complications were the problems that did not require additional surgery and major complications were identified as either obstacles that resolved with additional surgery or true complications or sequelae that remained unresolved at the end of the treatment period (Table III).

Complications*	No. of Complications	No. of Patients	Complication Rate (%)
Problems (minor complication)		CO. CO.	
Grade-1 and 2 soft-tissue inflammation and infection	6	6	50
Delayed maturation of regenerate site	1	1	8
Transient knee flexion contracture	1	1	8
Total	8		66
Obstacles (major complication and solution)			
Reinfection (irrigation and débridement)	2	2	17
Total	2		17
Sequelae (true complication)			
Knee contracture of >5°	2	2	17
Total	2		17
All complications	12		100

TABLE III Complications Encountered in the Study Group

Pain was the most common complaint during the distraction period, observed particularly in patients requiring lengthening in excess of 4 cm. It was relieved consistently by oral analgesics. The most frequent complication in this study was pin-track infection, which was seen in six patients. Six grade-1 infections, according to the system of Paley 5, were treated by local care with use of Betadine (povidone-iodine) solution and oral antibiotics (750 mg of ciprofloxacin twice daily), with resolution at all pin sites. We did not perform any additional surgery for delayed maturation at the distraction site or to treat the two transient knee flexion contractures. The contractures resolved with intensive physiotherapy.

Two patients had failures in the form of recurrent drainage, and both involved the tibia. Both patients underwent repeat débridement, removal of the intramedullary nail, and application of an Ilizarov fixator and administration of antibiotics for six weeks, with parenteral administration during the initial three weeks and oral administration during the last three weeks. Soft-tissue defects resulting from repeat débridement were reconstructed with local gastrocnemius muscle flaps and split-thickness skin grafts. Subsequently, in both patients, the infection was eradicated and the nonunion healed, resulting in good function and a good radiographic outcome. These two patients were fully able to walk without support at the time of the most recent follow-up.

Discussion

Infected nonunion of a long bone remains a therapeutic challenge. Such patients usually have had numerous previous surgical interventions, resulting in bone defects and soft-tissue compromise. Beginning with the study by Papineau et al., many treatment modalities have been described 14–24. All such studies have described a common problem of delayed bone-healing. Several factors have been blamed for this delay, with the

most important being unsuccessful eradication of infection 17,18,23,24, and infection has been reported to be the main cause of delayed union or nonunion 15,17,18,20,23,25–28. Thus, complete cure of the infection is the mainstay of treatment in infected nonunions.

Today, as a result of changing concepts and advanced reconstruction techniques, chronic osteomyelitis can be cured. The concept of burning an infection in the fire of an Ilizarov device, as described by Ilizarov 29, has changed to the current philosophy that the only cure for osteomyelitis is radical debridement until live and bleeding bone is reached, as described by Cierny et al.1,3,30. All patients in the current series were managed according to the principles of Cierny et al.

The extent of débridement necessary to obtain live and uninfected bone usually results in a bone defect, which requires complex reconstruction. This challenge can often be addressed by distraction osteogenesis.

The disadvantage of this treatment modality, however, is the long-lasting consolidation period, which takes about two times as long as the treatment period, causing great patient discomfort. Our combined treatment with an intramedullary nail and an external fixator shortens the time needed for external fixation. Bone-segment transfer over an intramedullary nail with use of an external fixator is a well-established technique 6,7; the use of the method in the treatment of segmental defects resulting from débridement of osteomyelitis is a new concept. The main purpose of the combined technique is to reduce the external fixation period, thus increasing the comfort and activity level of the patient.

This established technique is seldom used in the treatment of osteomyelitis because of the risk of the infection extending along the length of the involved bone. We believe that this danger is overcome with the use of the radical débridement technique and removal of all dead and infected tissue as described by Cierny et al.1,3,30. Placement of antibiotic-loaded, custom-made bone cement beads and/or rods provides sustained local antibiotic delivery and fills the dead space. Intraoperative tissue cultures identify the appropriate antibiotic therapy to be continued until the second stage is undertaken. Currently, we mix teicoplanin powder with the bone cement. Teicoplanin is effective against methicillin-resistant *Staphylococcus aureus* both locally and systemically 31. It can also be administered as a single-dose intramuscular injection after the patient has been discharged.

Total resolution of the infection is demonstrated by a return of the C-reactive protein level and erythrocyte sedimentation rate to values to within normal limits, usually within six weeks. In the current series, all patients but two demonstrated a normal C-reactive protein level and erythrocyte sedimentation rate by six weeks after the radical débridement. Eradication of infection was also demonstrated by frozen

sections and cultures of tissue obtained from the bone ends during the reconstructive procedure. This same infection treatment protocol and similarly successful results have been reported for the treatment of infections around total knee replacements 25–28,32–34.

Beside addressing the chronic infection, the radical débridement should disturb the bone circulation as little as possible so that successful results can be obtained with the secondary reconstruction. Periosteal circulation should be maximally protected during débridement. Reaming and intramedullary nail placement compromise medullary blood flow and, following the second stage, bone-healing initially relies on periosteal newbone formation 6,35–37.

A review of the medical literature yielded a small number of studies describing the combined technique for the treatment of chronic osteomyelitis. Raschke et al. reported on the results of the treatment in four patients with open tibial fractures 6. They used an intramedullary nail and the monorail external fixator and had a mean external fixation index of 17.9 days/cm and a mean consolidation index of 41.2 days/cm. Hoffmann et al. reported on the results of treatment in thirty patients with infected tibial nonunions 37. Fifteen patients had reconstruction with the combination of an intramedullary nail and a special wire system, and the remaining patients were managed with an intramedullary nail and an external fixator. The mean external fixation index was 12.2 days/cm for the former group and 13.7 days/cm for the latter group. That study did not report any data regarding consolidation indices.

The current retrospective study consisting of thirteen patients yielded a mean external fixation index of 13.5 days/cm and a mean consolidation index of 31.7 days/cm. The indices were similar in the femur and the tibia. These results are comparable with those in the previous studies mentioned above. In addition, the excellent results in terms of the bone and function scores for eleven of our thirteen patients demonstrate the success of the combined method.

The main purpose of the current study was to investigate a method to obtain eradication of infection and to demonstrate that this method can shorten the external fixation index and decrease the complication rate. Studies on the classic segment transport with the Ilizarov device in the treatment of infected nonunions have described a mean external fixation index of 54.9 days/cm, which is much longer than the mean external fixation index in the present study of 13.5 days/cm 17–20,24. The same studies noted a mean of two complications per patient, which is twice the complication rate in our study. We believe that the lower complication rate in our study resulted from both the shorter external fixation index and our meticulous application technique, in which careful attention was paid to radical débridement of all dead tissue and to the insertion of Schanz

screws with a clear space left between the screws and the intramedullary nail.

Another valuable reconstruction method for the treatment of an infected nonunion in a long bone is the use of vascularized bone grafts 38,39. One study has noted a mean time to bone-healing of approximately seven months in the femur and six months in the tibia 38. The total number of major complications, such as recurrence of infection and graft failure, exceeded the number of complications reported in the present study. Besides, our combined technique provides two very important, superior features compared with vascularized bone grafts. First, there is no donor-site morbidity, and the vascularized fibula can be kept as a last alternative. Second, with the combined technique, bone segment transfer and lengthening can be achieved with the same procedure, but the vascularized bone graft can only bridge the defect and cannot overcome a length discrepancy.

The weaknesses of our study are the absence of a control group and our small number of patients. Nevertheless, we describe a new and successful alternative technique for the treatment of the challenging problem of chronic osteomyelitis.

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