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CLINICAL RESEARCH

Complex Ankle Arthrodesis Using the Ilizarov Method Yields High Rate of Fusion

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Abstract

Background Ankle arthrodesis may be achieved using the Ilizarov method. Comorbidities, such as diabetes, Charcot neuroarthropathy, osteomyelitis, leg length discrepancy, and smoking, can make an ankle fusion complex and may be associated with lower rates of healing.

Questions/Purposes We asked if (1) smoking and other comorbidities led to lower fusion rates, (2) time wearing the frame affected outcome, and (3) simultaneous tibial lengthening improved fusion rates.

Methods We retrospectively studied 101 patients who underwent complex ankle fusion using the Ilizarov technique. The median time wearing the frame was 25 weeks (range, 10–65 weeks). Twenty-four patients had simultaneous tibial lengthening. The minimum followup for 91 of the 101 patients was 27 months (median, 65 months; range, 27–134 months).

Results Fusion was achieved in 76 of 91 patients. Smoking was associated with a 54% rate of nonunion. Fifteen of 19 patients with Charcot neuroarthropathy achieved union but had a high rate of subsequent subtalar joint failure. Time wearing the frame did not affect union rates. Tibial lengthening did not improve ankle fusion rates.

Conclusion Smokers should be warned of the high risk of nonunion and we recommend they quit smoking. We also recommend surgeons recognize the higher nonunion rate in patients with Charcot neuroarthropathy. We believe tibial lengthening should not be performed to enhance healing at the fusion site.

Level of Evidence Level IV, prognostic study. See the Guidelines for Authors for a complete description of levels of evidence.

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Each author certifies that his or her institution approved the human protocol for this investigation, that all investigations were conducted in conformity with ethical principles of research, and that informed consent for participation in the study was obtained.

The work was performed at The Hospital for Special Surgery, New York, NY, USA.

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Introduction

Ankle arthrodesis has been established as a reasonable salvage procedure for many patients with advanced ankle

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degeneration and medical comorbidities [1, 3, 6, 8, 10, 11, 14, 16, 20–23, 25, 28–31]. Patients with diabetes, Charcot neuroarthropathy, osteomyelitis, bone defects, deformity, rheumatism, peripheral vascular disease, and who smoke reportedly have compromised bone healing [2], and traditionally have been treated nonoperatively or with amputation. Although not shown in the literature, performing a tibial osteotomy in the setting of an ankle fusion has been thought to enhance healing at the arthrodesis site [19]. The Ilizarov method [19] has been used in these complex cases [3, 5, 6, 8, 10, 11, 14, 16, 17, 20, 21, 23, 25, 28–31]. An improved understanding of the contributions of each complex variable (smoking, diabetes, Charcot neuroarthropathy, osteomyelitis, time wearing the external fixator, limb length discrepancy [LLD], and tibial lengthening) to the healing of ankle fusions would be valuable to provide information for patients' and surgeons'. A better understanding of outcome would likely influence the decision regarding whether to do limb salvage or opt for an amputation reconstruction. For example, it may be unwise to embark on a prolonged and painful reconstruction effort in someone who has comorbidities associated with a high risk for failure.

We therefore asked if: (1) smoking and other comorbidities increase the risk of nonunion, (2) the time wearing the frame affected healing, and (3) simultaneous tibial lengthening for LLD improved fusion rates.

Patients and Methods

We retrospectively studied all 110 patients who underwent Ilizarov ankle fusion at our institution from 1999 to 2008. All patients were referred for ankle fusion by fellowship-trained foot and ankle surgeons because the patients' ankle problems had been deemed too complex to be treated by arthrodesis using standard internal fixation techniques. Patients who underwent tibiocalcaneal or tibiotalocalcaneal fusion and those who had inadequate followup were excluded, leaving a cohort of 91 patients. The complexities and comorbidities were numerous (Table 1). The indications for use of this approach were: (1) ankle destruction with comorbidities (Type B host) [4], (2) infection about the ankle with arthrosis, (3) limb shortening with ankle arthrosis, (4) deformity about the ankle precluding internal fixation, (5) osteopenia precluding internal fixation, and (6) poor skin condition where wound breakdown was likely precluding internal fixation. A Type B host is a patient with malnutrition, immune deficiency, chronic hypoxia, malignancy, diabetes mellitus, renal/liver failure, tobacco use, chronic lymphedema, major vessel disease, or extensive scarring. A Type A host has none of these comorbidities [4]. Patients were candidates for lengthening if they had a LLD greater than 2.5 cm and were younger than 70 years. The relative contraindication for this technique was severe infection unresponsive to staged débridements. Exclusion criteria for the study included (1) the use of BMP during ankle fusion surgery, (2) patients who underwent tibiocalcaneal or tibiotalocalcaneal fusion surgery, and (3) patients who did not return for followup after surgery. No patients were excluded between the time of ankle fusion surgery and the time of frame removal. All patients with Charcot neuroarthropathy had Eichenholtz Stage 3 disease [9]. The minimum followup was 27 months with a mean followup of 70 months (range, 27–134 months). No patients were recalled specifically for this study; all data were obtained from medical records and radiographs. The hospital's institutional review board approved this study.

Table 1. Patient demographics

Demographics	Number of patients (n = 91)
Mean age (years) (range)	54 (10–85)
Mean BMI (kg/m^2) (range)	28 (17–50)
Deformity greater than 10°	47
Type A hosts	31
Type B hosts	60
Traumatic	53
Osteomyelitis	48
Bone loss greater than 2 cm	35
Tibial lengthening	24
Diabetes mellitus	19
Charcot	15
Smoking	13
Rheumatoid arthritis	7
Peripheral vascular disease	3

Type A host = a healthy person, Type B host = a person with malnutrition, immune deficiency, chronic hypoxia, malignancy, diabetes mellitus, renal/liver failure, tobacco use, chronic lymphedema, major vessel disease, or extensive scarring [4].

We asked that all patients complete the postoperative American Orthopaedic Foot and Ankle Society (AOFAS) questionnaire [16] during the normal course of their care because they were all part of a prospective database for patients treated with the Ilizarov method.

The senior author (SRR) operated on all patients using a previously described operative technique [28]. The majority of patients received spinal anesthesia with intravenous sedation. Medial and lateral approaches were used. The distal fibula and medial malleolus were resected. Flat cuts were made across the distal tibia and the proximal talus. An Ilizarov/Taylor Spatial Frame™ (TSF) (Smith & Nephew, Memphis, TN, USA) external fixator then was applied to the ankle, with two rings applied to the distal tibia. No tourniquet was used for the frame application. Each ring had a tensioned wire and a half pin fixated to the bone. The wire was a 1.8-mm K-wire tensioned to 130 kg. Hydroxyapatite-coated 6-mm tapered pins were used. The foot ring was closed anteriorly and fastened to the tibial ring block with rods, then four or five wires were inserted in multiple planes through the foot and tensioned to 130 kg. When the subtalar joint was not arthritic, the surgeon attempted to protect it from compression. He inserted a talus wire through the talar body, then arched it proximally and tensioned it, distracting the subtalar joint (Fig. 1A). For this construct, TSF rings were used and connected with simple threaded rods and compressed (Fig. 1B). Some patients had a bone defect greater than 3 cm. Acute shortening of 2 to 3 cm typically was accomplished without difficulty. Loss of a palpable pulse and inability to close the wounds owing to soft tissue rigidity were usually factors that limited acute shortening. In those cases, gradual shortening of 2 mm per day was performed with the TSF computer-navigated system (Fig. 2). This required the use of TSF struts to connect the rings in place of the threaded rods [18]. In patients for whom limb shortening was greater than 2.5 cm, we considered tibial lengthening [12]. In most cases, the lengthening was staged several weeks after the index fusion procedure. There were several reasons for this: (1) An active infection or history of infection at the fusion site could contaminate the proximal tibial osteotomy site. (2) Often we were not sure of the amount of shortening a patient had achieved until after the ankle fusion, when they could stand for the 51-inch radiograph (Fig. 3). (3) Simultaneous tibial osteotomy with ankle fusion exposed the patient to increased swelling, blood loss, and may have increased the risk of thromboembolism and compartment syndrome. We performed lengthening by adding a proximal tibial ring and connecting it to the existing distal tibial ring (Fig. 4). The osteotomy was performed just below the level of the tibial tubercle. Multiple drill holes were created, and an osteotome was used to crack the bone. A 7- to 10-day latency was followed by frame distraction at 1 mm per day. We obtained mounting parameters intraoperatively [13] to use the computer navigation feature of the TSF.

We allowed patients weightbearing for ambulation as tolerated. Patients with neuropathy were not permitted full weightbearing throughout treatment for fear of breaking the external fixator. Pin care began on the second postoperative day and was performed once daily after that. The patients' stay in the hospital ranged from 3 to 5 days.

Patients were followed up monthly in the office to assess bone healing. A physical examination, and AP, mortise, and lateral 17-inch ankle radiographs were performed at each visit. We closely followed patients undergoing lengthening, every 10 to 14 days, to assess complications and review the quality of the regenerate (Fig. 5). These patients performed frame adjustments on their own once educated in the proper technique [26]. We considered the

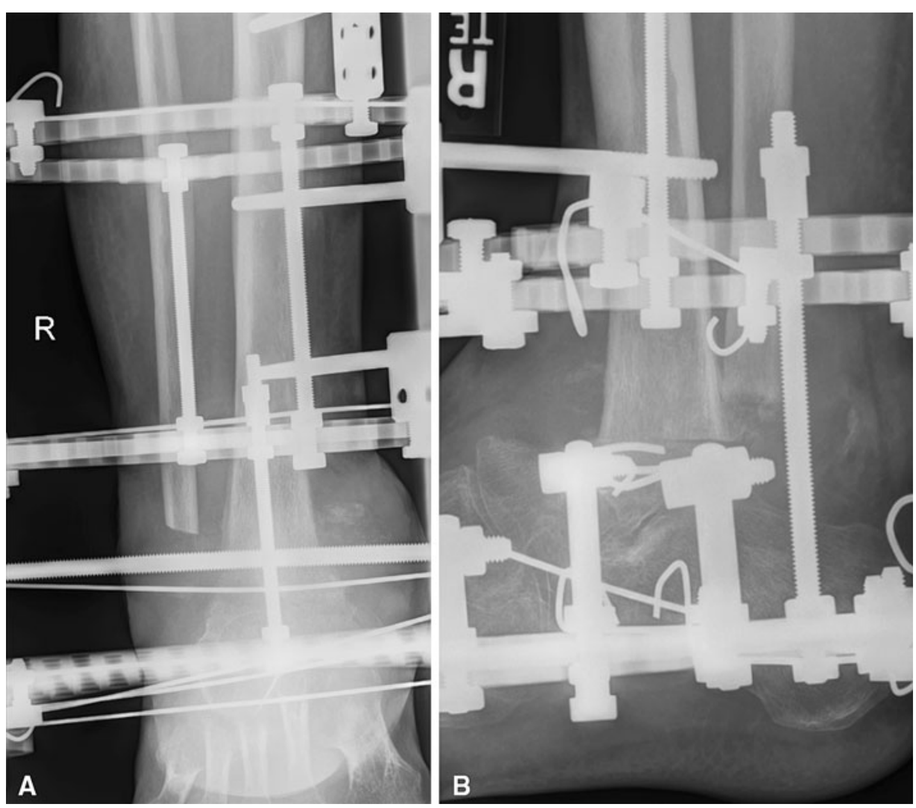
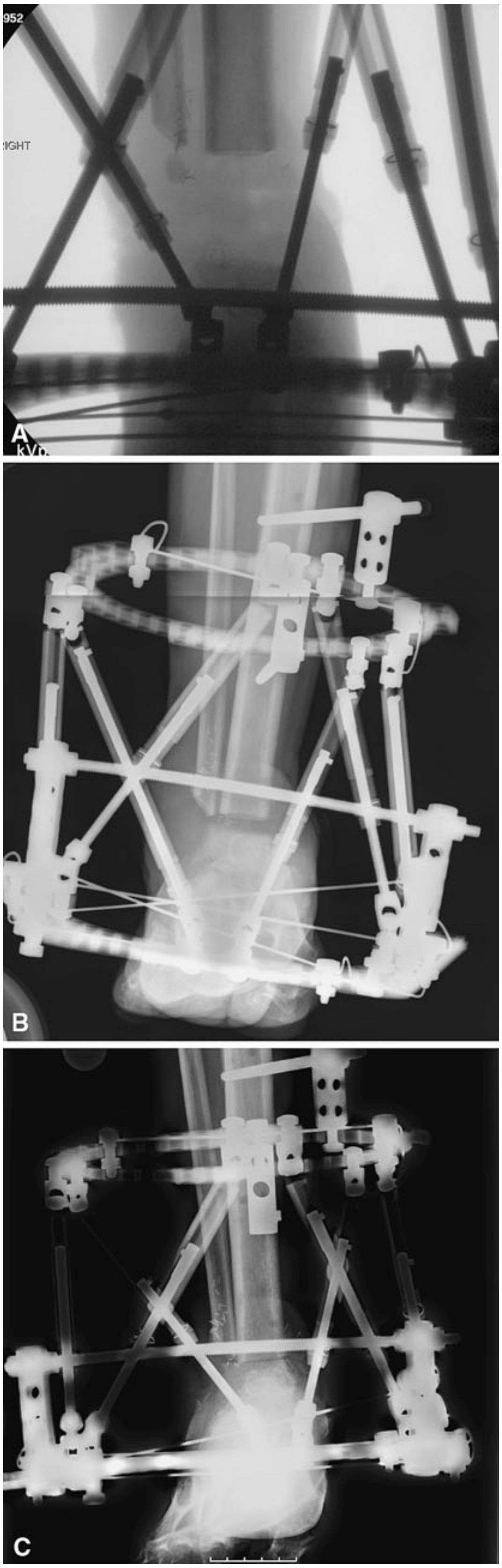


Fig. 1A–B The (**A**) AP and (**B**) lateral radiographs show a typical ankle fusion frame with a compressed tibiotalar fusion site. The talar wire is distracting the subtalar joint. The rings are connected with simple threaded rods.



◀ **Fig. 2A–C** (**A**) A large tibial bone resection was treated with acute shortening of 2 cm, but the remaining defect was 5 cm. The Taylor Spatial Frame (TSF) was used to gradually (**B**) shorten the defect (at a rate of 2 mm per day) and (**C**) dock the bone ends with a desirable alignment. TSF struts were used along with the computer program to guide the alignment at the docking site.

Fig. 3 This 51-inch, standing, hip-to-ankle radiograph shows a LLD in a patient treated for an infected ankle fusion. He was standing on a 5.5-cm block.

lengthening regenerate had healed when three of four cortices had healed as observed on the AP and lateral radiographs. The external fixator was removed with the patient under sedation. The median time wearing the external fixator was 25 weeks (range, 10–65 weeks).

After frame removal, patients wore a cast for 6 weeks for partial weightbearing. Patients then transitioned to a walker boot for a minimum of 6 weeks.

The primary outcome was bony union at the fusion site determined using plain film radiography with AP, lateral,

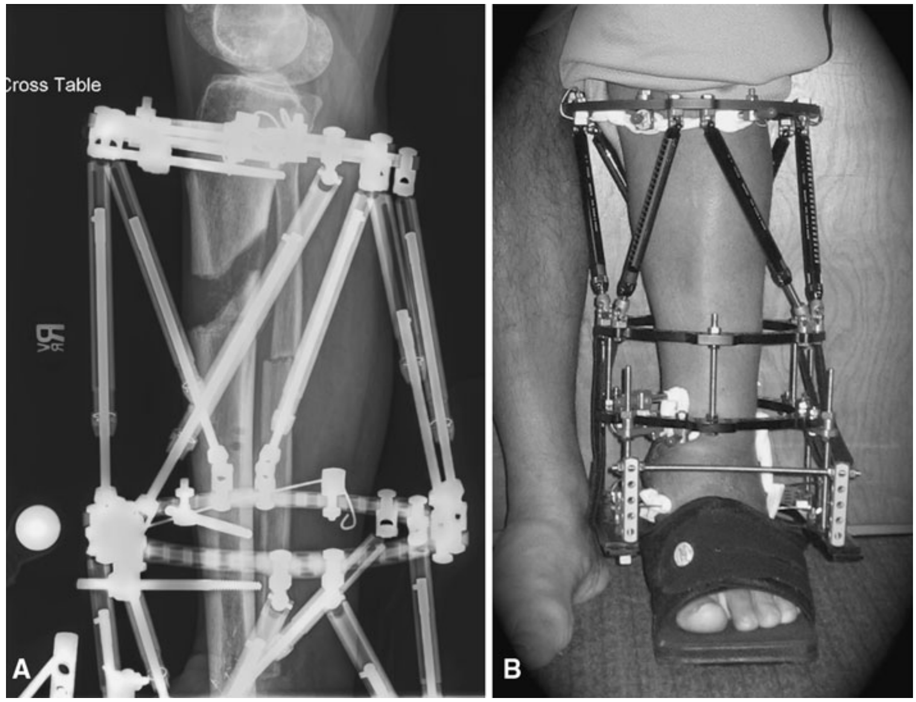


Fig. 4A–B (**A**) The proximal tibial ring was attached to the distal tibial ring which was being used for the ankle fusion. (**B**) The entire construct for classic ankle fusion and lengthening is shown with a closed foot ring, two distal tibial rings, and a proximal tibial lengthening ring that used TSF struts.

Fig. 5 This lateral radiograph of the proximal tibia shows typical regenerate bone formation at the lengthening site.

and mortise views. Secondary outcomes included the AOFAS hindfoot score. Scores were obtained at 6 months, 12 months, and then yearly after external fixator removal. The AOFAS scores were available for 49 of the 91 patients. Data were missing for 42 patients which represented failure to record a postoperative AOFAS score during followups. The mean AOFAS score at last followup was 71 points (range, 17–86 points). Complications were recorded from the charts and graded according to the classification system of Dindo et al. [7]. With regard to radiographs, patient demographics, charts, operative notes, and followup notes, there were no missing data for the variables we analyzed.

The senior author (SRR) examined the serial radiographs to assess healing. Healing was judged by cortical bridging at the fusion site and loss of lucency between fusion surfaces [3, 20–23]. Determination of healing was not straightforward and cortical bridging was not often seen. None of these fusions healed with callus, providing less evidence for healing. Radiographic assessments were unreliable for determining bone healing in most cases. Six months was used as the time wearing the frame to determine when a fusion should be healed. Most frames were removed at 6 months regardless of the radiographic appearance of the fusion. Nonunion was judged to have occurred after frame removal when there was a large lucency at the tibiotalar interface observed on the radiograph and there was motion at the fusion site on examination.

We computed means, medians, SD, ranges for continuous variables (BMI, degrees of deformity, and LLD) and frequencies and percentages for categorical variables (sex, laterality, Charcot neuroarthropathy, rheumatoid arthritis, diabetes mellitus, peripheral vascular disease, smoking, presence of infection, tibiotalar arthrodesis, deformity greater than 20°, and number of previous surgeries). Inferential analyses consisted of chi-square or Fisher's exact tests for discrete risk factors and independent sample t-tests for continuous outcome variables. To assess possible risk factors for nonunion we performed logistic regression for sex, Type B host, and LLD adjusted for smoking status to determine the effect of these variables on ankle fusion rates. A full model could not be calculated owing to the limited number of nonunions. All analyses were performed using SPSS® for Windows version 19.0 (SPSS®, Chicago, IL, USA).

Results

The total number of successful fusions was 76 of 91 (84%), and variables were identified that affected the union rate including smoking and Charcot neuroarthropathy. Nonunion was more common ($p < 0.001$) in patients who smoked: seven of 13 patients (54%) who smoked did not achieve healing of their fusion versus eight of 78 patients (10%) who did not smoke (Table 2). Smoking was so powerful a variable that the other variables were reanalyzed in nonsmokers. The fusion rate for patients with Charcot neuroarthropathy was 15 of 19 (73%), less than ($p = 0.04$) the rate for patients who did not have Charcot neuroarthropathy. This was analyzed in nonsmokers. Patients who were nonsmokers and did not have Charcot neuroarthropathy had a fusion rate of 93%. Patients with Charcot neuroarthropathy also had numerous complications, including tibial stress fractures in four patients, subtalar joint collapse after frame removal in three, total collapse of the calcaneal body in one, below knee amputation in one, and return to the operating room for frame revision in two (Table 3). Type A hosts had a fusion rate of 29 of 31 (94%), similar to ($p = 0.06$) the rate for patients who were Type B hosts. It is possible that with greater

Table 3. Complications of complex ankle arthrodesis

Complication*	Number	Treatment
Major		
Nonunion	15	See Figure 6
Tibial stress fracture	6	Casting (4), external fixation (2)
Malunion: deformity greater than 10°	4	Osteotomy with external fixation (3)
Broken fixation	3	Frame modification in the operating room
Tibial nerve neurapraxia	2	Tarsal tunnel release
Arterial embolus	1	Amputation of 1st and 2nd toes
Severe deep infection	1	Urgent below knee amputation
Minor (Grades I–II)		
Cellulitis	3	Intravenous antibiotics
Knee flexion contracture	1	Dynasplint® and physical therapy
Collapse of calcaneus	1	Bracing

* Based on classification by Dindo et al. [7]; Dynasplint®, Dynasplint® Systems Inc, Severna Park, MD, USA.

Table 2. Effect of each variable on bony union with and without smokers

Variable	All patients			Nonsmokers		
	Number	Union rate (%)	p value	Number	Union rate (%)	p value
Entire cohort	91	84		78	90	
Male sex	50	78	0.12	40	88	0.71
Deformity greater than 10°	47	85	0.67	42	90	1
Traumatic	53	81	0.50	40	93	0.47
Type A hosts	31	94	0.06	31	94	0.47
Type B hosts	60	78	0.06	47	87	0.47
Osteomyelitis	48	77	0.08	39	85	0.26
Tibial lengthening	24	79	0.53	18	94	0.67
Nonlengthening	67	85	0.53	60	88	0.67
Diabetes mellitus	19	84	1.0	16	88	0.66
Charcot neuroarthropathy	15	73	0.26	15	73	0.04
Smoking	13	46	0.0008	0		
Rheumatoid arthritis	7	86	1	6	83	0.49
Peripheral vascular disease	3	67	0.42	3	67	0.28
Time wearing the frame greater than 6 months	48	85	0.61	42	90	1
Time wearing the frame less than 6 months	43	81	0.61	36	89	1

Smoking impacted fusion rate profoundly and warranted reanalysis of the variables in nonsmokers to see if any other variables affected bone healing.

Table 4. Continuous variables union versus nonunion

Variable	Patients												p value
	All				Unions				Nonunions				
	Median	Quartile 1	Quartile 3	IQR	Median	Quartile 1	Quartile 3	IQR	Median	Quartile 1	Quartile 3	IQR	
Age (years)	55	46	66	20	57	46	67	21	54	41	62	21	0.37
BMI (kg/m^2)	27	25	32	8	27	25	33	8	26	25	28	4	0.16
AOFAS score	78	56	85	29	78	56	85	29	75	55	81	26	0.48
Time wearing frame (weeks)	25	20	29	9	25	20	29	9	22	18	27	8	0.24
LLD (cm)	2.0	1.3	3.0	1.7	2.0	1.0	2.5	1.5	3.0	2.0	3.4	1.4	0.04

IQR = interquartile range; BMI = body mass index; AOFAS = American Orthopaedic Foot and Ankle Society; LLD = limb length discrepancy.

numbers of patients there would be a difference between Types A and B hosts. However, when we excluded smokers from the Type B hosts there was no difference (p = 0.47) between host type.

Seventy-six of 91 patients (83%) who wore the frame for a mean of 29 weeks achieved healing, similar to (p = 0.06) the rate for patients who did not wear the frame for 29 weeks.

In patients with tibial lengthening, the average external fixation index (EFI) was 68 days/cm (range, 18–224 days/cm). The average bone healing index (BHI) was 49 days/cm (range, 16–86 days/cm). The average length achieved was 4.3 cm (range, 1–12 cm). Final LLD in this subgroup was 1.8 cm. The union rate for patients who had lengthening was 20 of 24 (83%), similar to the rate for patients who did not undergo lengthening. Although tibial lengthening did not affect ankle fusion healing, a greater preoperative LLD was associated with a higher risk (p = 0.04) of ankle nonunion (Table 4).

Thirty of the 91 patients had one or more major complication, however, none was life threatening (Grades IV–V), and all were able to be treated (Grades I–III). Complications and treatments were graded and recorded (Table 3). Nonunions occurred in 15 of 91 (16%) patients (Fig. 6).

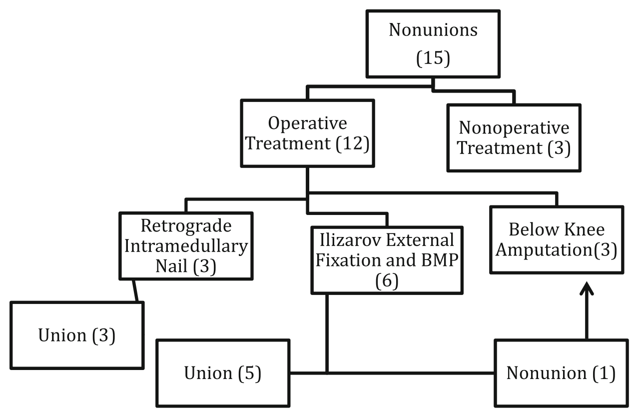


Fig. 6 The management of patients with nonunions after the Ilizarov ankle fusion is illustrated. Three patients had asymptomatic, stiff nonunions and elected nonoperative treatment. Three patients were disenchanted with limb salvage and elected amputation reconstruction to expedite their recovery. A fourth patient elected amputation after a second attempted fusion failed. Revision ankle fusion was successful with the Ilizarov method (five of six) and intramedullary nailing (three of three).

Discussion

Patients with ankle arthritis who are smokers, are Type B hosts, have Charcot neuroarthropathy, or LLD present a reconstructive challenge to the orthopaedic foot and ankle surgeon. Ankle fusion using circular fixation has been regarded as a last resort, limb-salvage procedure [3, 5, 6, 8, 10, 11, 14, 16, 17, 20, 21, 23, 25, 28–31] (Table 5). We asked whether (1) smoking and other comorbidities (Charcot neuroarthropathy, Type B hosts), (2) time wearing the frame, or (3) tibial lengthening affected union rate after ankle arthrodesis surgery?

This study had several limitations. It is a retrospective study. We were unable to quantify how many cigarettes per day were being smoked and were only able to identify active smokers. The number of risk factors that we could analyze was limited to information available in the patients' medical records. We had an insufficient number of patients and nonunions to ask whether factors such as time wearing the frame, diabetes, dependence on hemodialysis, and peripheral vascular disease were associated with increased rates of nonunion.

Of all comorbidities we found smoking to be the factor that affected fusion rate most profoundly: seven of 13 patients who smoked had a nonunion, but eight of 78 who did not smoke had a nonunion. Smoking reportedly has increased the nonunion rate in subtalar arthrodesis by 3.8 times [2]. One study noted that ankle and subtalar fusion were compromised by smoking [24], but another study showed smoking had little effect on fusion [15].

Table 5. Literature comparison for complex ankle arthrodesis treated with external fixation

Study	Complexity	Number of ankle fusions	Time wearing frame (months)	Fusion rate (%)	AOFAS score (of 86 points)
Zarutsky et al. [31]	Varied	43	3	81	
Bibbo et al. [1]	Varied/BMP-2	32	2.5	100	
Fabrin et al. [11]	Charcot neuroarthropathy	12	1.5	50	
Karapinar et al. [20]	Charcot neuroarthropathy	11	4	90	
Dalla Paola et al. [6]	Charcot neuroarthropathy	45	6.5	86	
Cierny et al. [3]	Infection	36		100 (Type A hosts) 83 (Type B hosts)	
Hawkins et al. [16]	Infection	16	6.5	75	
Kollig et al. [22]	Infection	15	4	93	
Saltzman [29]	Infection	8	3.5	87	
Salem et al. [28]	Infection	18	7	78	
Rochman et al. [25]	Infection	11	7.3	81	65
Kovoor et al. [23]	Infection	20	11	95	
Gessmann et al. [14]	Infection	37	3.9	87	68
Eylon et al. [10]	Minimal	17	3.8	100	65
Cracchiolo et al. [5]	Rheumatoid arthritis	11	4.8	79	
Katsenis et al. [21]	Revision	21	7.8	100	
Easley et al. [8]	Revision	22		86	66
Current study	Varied	91	6.5	84	65

Charcot neuroarthropathy is a risk factor for nonunion. Shorter external fixation times have been associated with poor results, particularly in patients with Charcot neuroarthropathy [11]. Ankle fusion has been challenging in patients with Charcot neuroarthropathy, often requiring external fixation [6, 20]. In our study, there were three subtalar complications in the patients with Charcot neuroarthropathy who otherwise had successful tibiotalar arthrodesis. We now consider tibiotalocalcaneal fusion for all patients with advanced neuropathy and ankle arthritis. Herscovici et al. [17] supported this recommendation by prescribing pantalar arthrodesis. We found Type A hosts had a 93% fusion rate and Type B hosts had a 78% fusion rate. This trended toward significance until the smokers were removed and the data were reanalyzed. Type B hosts not including smokers were at no increased risk for nonunion. Cierny et al. [3, 4] reported success rates of 100% in Type A hosts and 83% in Type B hosts. Our findings were similar to those reported by Cierny et al. [3]. It seems that smoking is one of the strongest predictors of failure among the factors that define a Type B host.

In our study, the median time wearing the external fixator was 25 weeks (range, 10–65 weeks). Salem et al. [28] reported on a group of 22 patients treated with the Ilizarov technique for posttraumatic ankle arthritis complicated by infection. External fixation time averaged 28 weeks, and the fusion rate was 14 of 18 (78%). The extended time required for fusion and the fusion rate in their series were similar to those in our complex fusion cohort. In another study, a cohort of patients with posttraumatic bone loss and infection was treated with the Ilizarov method with good results [23]. In that series, 19 of 20 (95%) patients achieved successful fusion after an average of 11 months wearing the external fixator. The high fusion rate may have been the result of the prolonged time wearing the external fixator. Our earlier patients wore the frame for 4 months, but two patients had nonunions of the fusion site. We attributed these early failures to insufficient time wearing the external fixator, therefore the time was increased to 6 months to improve fusion rates. We were unable to prove that 6 months wearing the frame was a predictor of fusion. However, patients who had union of their ankle fusion wore the frame an average of 29 weeks, and those who had nonunions wore the frame an average of 23 weeks, supporting our position that longer times wearing the frame were associated with higher union rates. Based on these data, 7 months wearing the frame may be more likely to yield a union than 6 months.

We found no evidence that osteotomy increased the fusion rate. Patients with lengthening had a lower fusion rate. When we considered how preoperative LLD influenced union, we noted that a greater LLD was associated with a higher risk of nonunion. The Ilizarov method has been used by numerous surgeons to equalize LLD through

Table 6. Literature comparison for tibial lengthening with ankle arthrodesis

Study	Number of patients	Lengthening (cm)*	External fixation index (days/cm)	Ankle fusion rate (%)	Lengthening complications
Rochman et al. [25]	8	4	54	87	Regenerate collapse angular deformity (1), delayed union of regenerate (1)
Tellisi et al. [30]	12	5.5	54	84	None
Katsenis et al. [21]	11	4	76	100	Pin site infection requiring exchange (4), premature consolidation (4)
Sakurakichi et al. [27]	6	4.1	35–144	100	None
Current study	24	4.3	68	83	Regenerate collapse valgus (1), knee flexion contracture (1)

* Number of days wearing the frame per centimeter of lengthening.

tibial lengthening and achieve ankle arthrodesis [21, 25, 27, 30]. Performing a tibial osteotomy in the setting of an ankle fusion has been thought to enhance healing at the arthrodesis site [4]. The theory was that the proximal tibial osteotomy brought increased blood flow to the extremity, improving the healing at the fusion site. However, the reported studies (Table 6) contain no data to support or refute this contention. We attributed this compromised healing to the increased complexity of patients with LLD who might require lengthening surgery.

Future research will focus on decreasing time wearing the external fixator and improving the fusion rate for patients with complex ankle arthrodesis. Recombinant BMP reportedly hastens bone healing in ankle fusions performed with internal or external fixation [1]. The extra expense of BMP may be offset by avoiding the need for further surgery and reducing frame-associated complications.

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