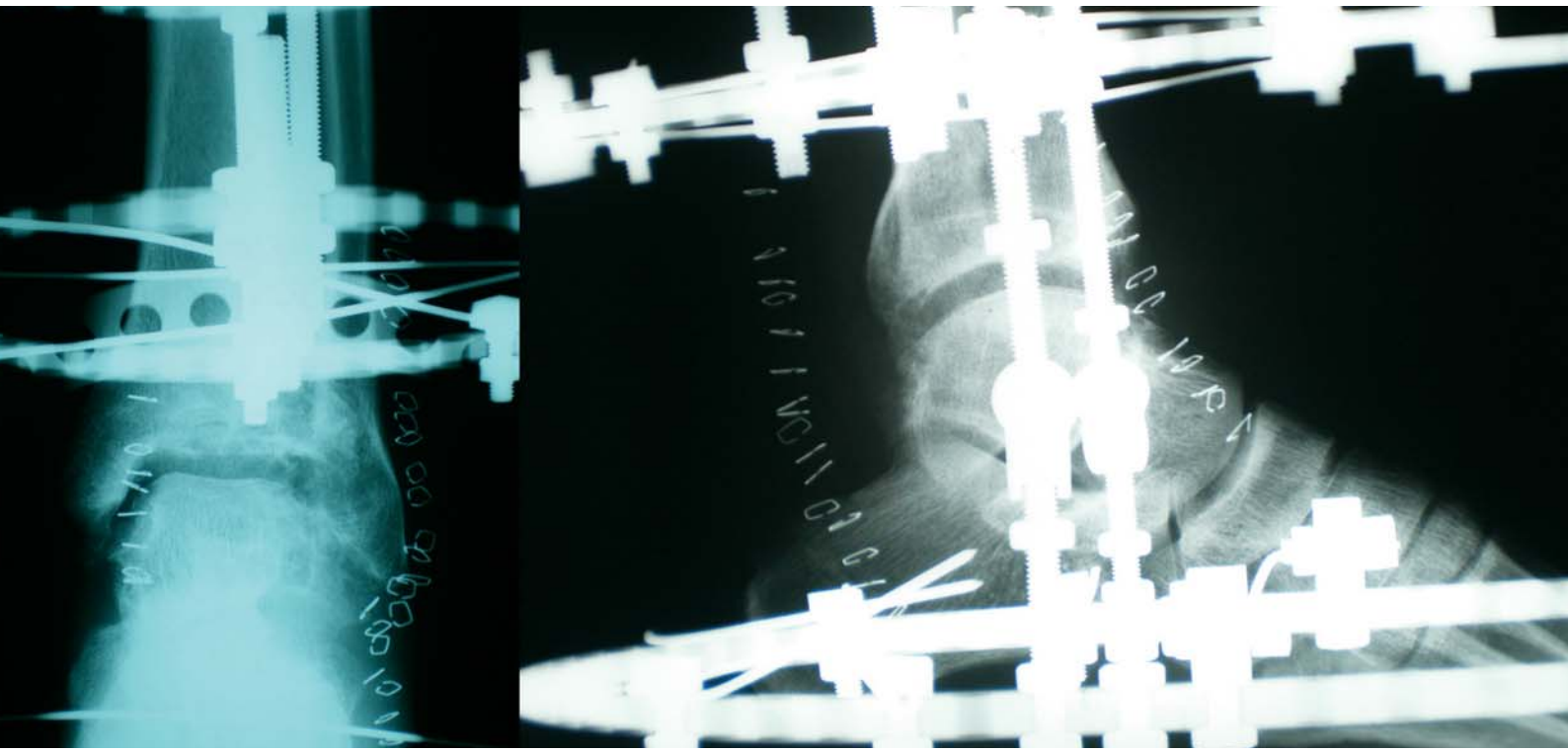


Retrospective Studies and Results in Foot and Ankle Reconstruction

ORTHOFIX®

Orthofix wishes to thank the following surgeons for their contribution to the development of the technique:

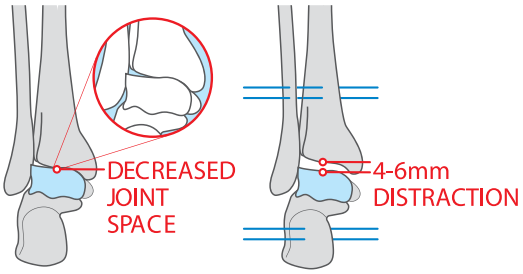
Edgardo R. Rodriguez, DPM
Clinical Instructor
Director: Chicago Foot & Ankle Deformity Correction Center

Other Key Contributors:
Paul Cannon, DPM
Jeffrey Hall, DPM
Clinton F. Holland, DPM
Travis S. Jensen, DPM
John P. Rachoy, DPM
Robert Sheffey, DPM
Raymond L. Smith, DPM
Tomasz Szmyd, DPM
George Vito, DPM

CASE STUDY 1
Ankle Distraction with Arthroplasty as an Alternative Treatment for Severe Ankle Arthritis

PURPOSE

A retrospective review was performed to determine the feasibility of utilizing ankle distraction with arthroplasty as an alternative to more aggressive traditional treatment modalities, such as fusion or total joint implant, for severe ankle arthritis. Outcomes for twenty-five patients who underwent ankle arthroplasty with distraction were reviewed and graded utilizing the Maryland foot score.



Before Ankle Distraction After Ankle Distraction

METHOD

1. A total of 25 patients, 12 men and 13 women, with a mean age of 44, ranging from 21 to 71 years of age were reviewed.
2. All 25 patients underwent open ankle arthroplasty with distraction.
3. 20 patients underwent ankle distraction utilizing a multiplanar external fixation system.
4. 5 patients underwent ankle distraction utilizing a monorail external fixator.
5. Each ankle was distracted 4-6 millimeters.
6. Distraction times ranged from 4-10 weeks, with an average distraction time of 8 weeks.
7. In all cases, patients were allowed to bear weight as tolerated one week post-operatively.

PROCEDURES

The procedure was performed with the patient in the supine position under general anesthesia. A thigh tourniquet was typically utilized for hemostasis. The ankle was exposed via a medial longitudinal incision. Care was taken to avoid the tendon of the tibialis anterior as well as the great saphenous vein. A longitudinal joint capsulotomy was performed and a capsular flat was created in order to adequately visualize the ankle mortise (Figure 3). Areas of hypertrophic bone and soft tissue were extensively debrided. The ankle was copiously irrigated with antibiotic impregnated saline and closed in an appropriate manner. Following closure the thigh tourniquet was released and the ankles were distracted utilizing external fixation.

Twenty patients underwent ankle distraction utilizing a multiplanar external fixation system. These systems consisted of two proximal rings, each attached to the tibia by two smooth percutaneous transosseous wires, and a distal foot plate or one-third ring, connected to the calcaneus with two smooth percutaneous transosseous wires and the midfoot with two smooth percutaneous transosseous wires (Figure 6); no talar wire was used. Five patients underwent ankle distraction utilizing a monorail external fixator attached to the proximal tibia with two half pins and both the talus and calcaneus with one half pin each (Figure 5). Each ankle was acutely distracted 4-6 millimeters (Figure 6). Care was taken to release any excess skin tension at pin sites in order to avoid local necrosis. Achilles tendon lengthening procedures were not performed. All patients were allowed to weight bear as tolerated one week postoperatively. Pin sites were cleansed with hydrogen peroxide or isopropyl alcohol from daily to weekly.

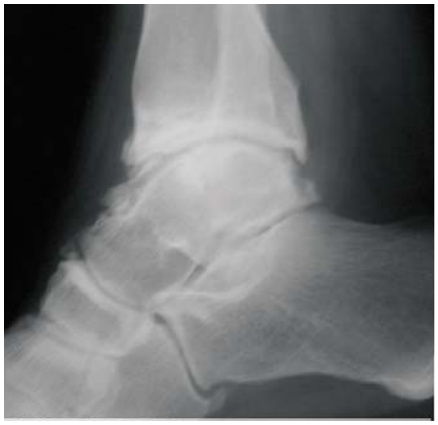


Figure 1: Predistraction

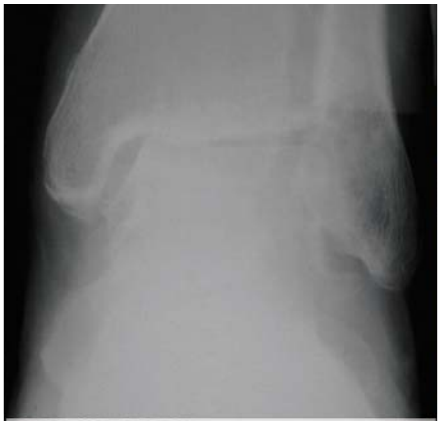


Figure 2: Predistraction

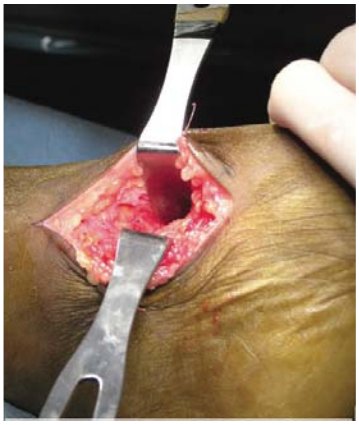


Figure 3: Anterior Ankle Surgical Approach

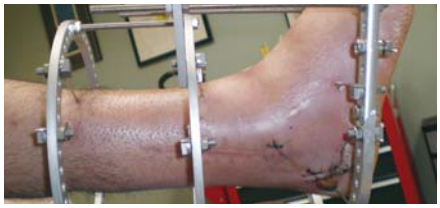


Figure 4: Ankle Distraction with Circular Ring Fixation

Figure 5: Ankle Distraction with Monorail

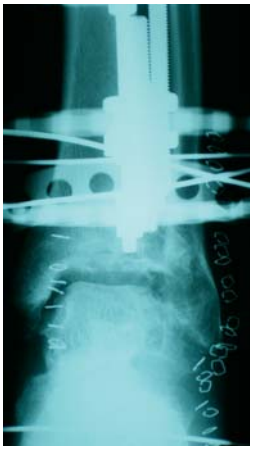


Figure 6: Ankle Distraction

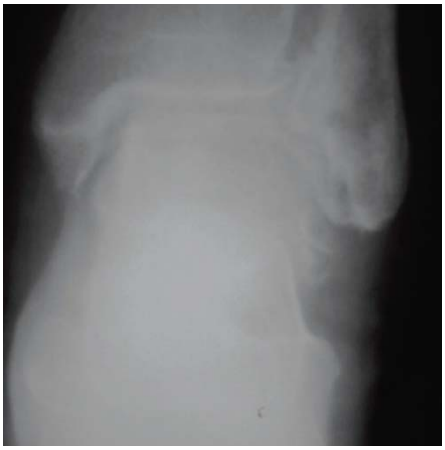


Figure 7: Post Distraction 24 Month Post-Op

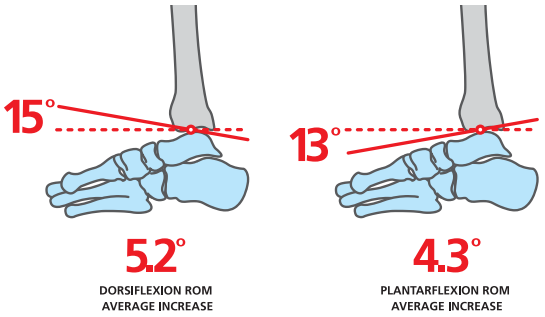
CASE STUDY 1 continued
Ankle Distraction with Arthroplasty as an Alternative Treatment for Severe Ankle Arthritis

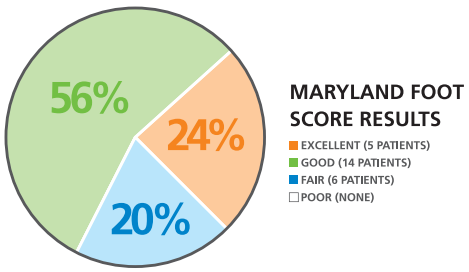
RESULTS

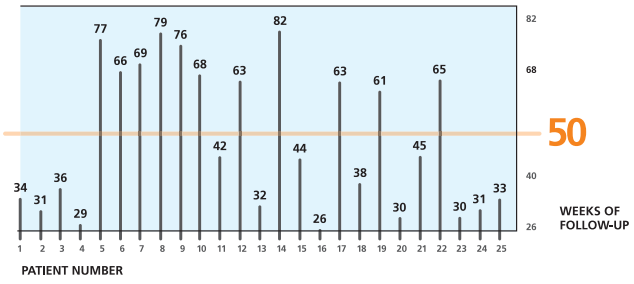
1. Increased dorsiflexion ROM: 1° to 15° Average increase of 5.2°.
2. Increased plantarflexion ROM: 0° to 13° Average increase of 4.3°.
3. Patients with minimal increase in ROM related a significant reduction in symptoms.
4. Patients were followed up for a mean of 50 weeks, with follow up time ranging from 29 to 82 weeks.

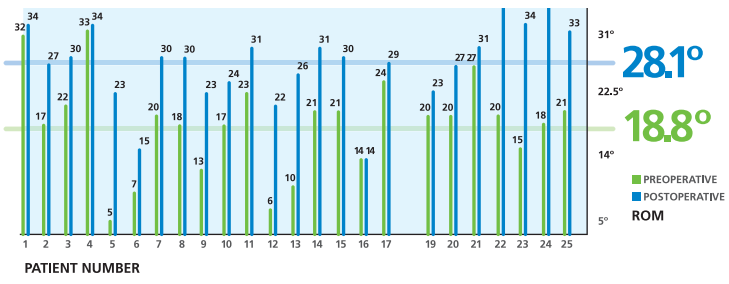
CONCLUSION

Although no single treatment is appropriate for every patient, the authors considered the use of ankle distraction with ankle arthroplasty a viable alternative to previously accepted treatments for severe ankle arthritis.







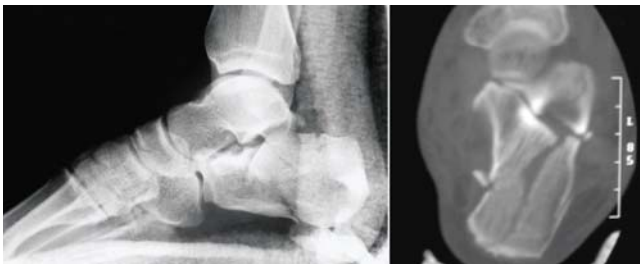


PATIENT KEY

Number	Age	Sex	Etiology	Distraction Modality	Weeks
1	32	F	Ankle Fracture	Multiplanar Rings	8
2	51	F	Rheumatoid	Multiplanar Rings	8
3	43	M	OCD	Multiplanar Rings	8
4	33	F	OCD	Multiplanar Rings	10
5	62	M	Ankle Contusion	Multiplanar Rings	8
6	75	F	Ankle Fracture	Multiplanar Rings	9
7	38	M	Ankle Fracture	Multiplanar Rings	9
8	41	F	Calcaneal Fracture	Multiplanar Rings	10
9	27	M	Calcaneal Fracture	Monorail	6
10	24	M	Ankle Fracture	Monorail	6
11	21	M	Ankle Fracture	Multiplanar Rings	10
12	35	M	Ankylosing Spondylisis	Monorail	6
13	58	F	Ankle Fracture	Multiplanar Rings	10
14	61	F	Osteoarthritis	Monorail	6
15	40	M	OCD	Multiplanar Rings	10
16	51	M	Ankle Contusion	Multiplanar Rings	10
17	67	M	Ankle Fracture	Multiplanar Rings	10
18	71	F	Osteoarthritis	Multiplanar Rings	10
19	45	F	OCD	Multiplanar Rings	10
20	24	F	Ankle Fracture	Monorail	6
21	55	F	OCD	Multiplanar Rings	10
22	44	F	Ankle Fracture	Multiplanar Rings	6
23	39	M	OCD	Multiplanar Rings	6
24	23	F	Ankle Fracture	Multiplanar Rings	7
25	37	M	Calcaneal Fracture	Multiplanar Rings	4
AVERAGE	44				8.12

CASE STUDY 2
Retrospective Comparative Analysis of Intra-Articular Calcaneal Fractures

PURPOSE

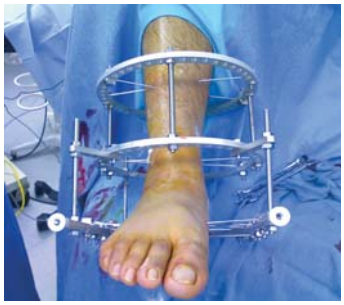


The purpose of this study was to compare outcomes following the treatment of intra-articular calcaneal fractures with circular frame fixation versus open reduction internal fixation (ORIF).

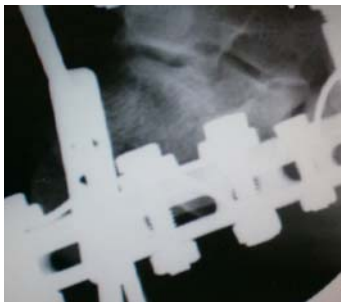
Ten patients with intra-articular calcaneal fractures were treated with a circular frame fixation device and retrospectively analyzed with the Maryland foot score. The average follow up was 48 months.

The results were compared to previously published data on intra-articular calcaneal fractures that were treated with circular frame fixation or ORIF and evaluated with the Maryland foot score.

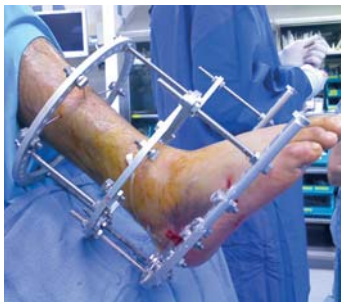
METHOD



Standard treatment consisted of placing a 3 ring multiplanar circular frame. A Steinman pin was introduced into the calcaneus from medial to lateral. It was essential that the direction of the pin match the orientation of the deformity. Traction of at least 30 pounds was applied to the Steinman pin.
The traction enables ligamentotaxis to reduce the deformity by restoring height and width.



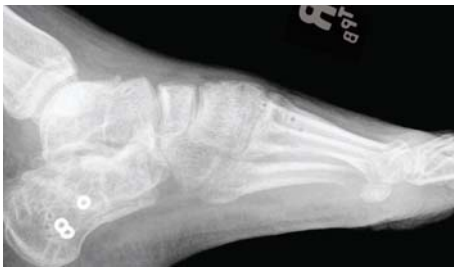
Once reduction of the deformity is achieved the frame can be secured to the extremity with the foot at a 90 degree angle to the leg. Smooth transosseous wires were used to secure the proximal 2 rings. Olive wires were utilized in the calcaneus in order to achieve side to side compression.
Standard lateral radiograph shows the subtalar joint is distracted once the frame is secured.



Traction can be removed once the frame is secured to the lower extremity. The entire procedure is to be performed under fluoroscopy to ensure proper anatomical placement of pins/wires.
Standard circular ring fixation device for comminuted intra-articular calcaneal fracture.

ADVERSE EVENTS

Complications were limited to superficial skin infections at the level of the wires, transient sural neuritis and transient peroneal tendonitis. One patient experienced a collapse of the posterior facet 2 weeks after the frame removal.



PROCEDURES

Following medical as well as anesthesia clearance, the surgeon should assess severity of fracture via evaluation of plain and CT films. Since external fixation does not involve extensive tissue dissection, the condition of the soft tissue does not prevent delay of the procedure. General indications for surgical management include a greater than 2 mm displacement of the posterior facet with disruption of the width, length, and height of the calcaneus. Fibulo-calcaneal impingement may result if the width of the calcaneus is not addressed.

The extremity is prepped and draped to the knee. A pre-assembled, circular Orthofix Sheffield Ring Fixator consisting of two leg rings and a foot plate are placed about the extremity. The authors have recently begun utilizing a low profile external fixator consisting of two leg rings and a half ring instead of a foot plate. This gives the patient a more cosmetically pleasing device about the extremity as well as allows greater ease of ambulation. Following application of the frame to the extremity a half pin is introduced into the posterior-plantar aspect of the calcaneus from a lateral to medial orientation. Care should be taken to avoid the critical neuro-vascular bundle on the medial aspect, as well as to allow placement of the trans-osseous wires. The Steiman pin is used for application of skeletal traction. The device consists of 30 lbs of weight which is placed and secured to the Steiman pin transecting the calcaneus. The force of the fracture reduction should be directed according to the mechanism of the break. The goal of traction is to utilize the principles of ligamentous taxity to reestablish, anatomically and functionally, the length and height of the calcaneus. The width of the calcaneus is restored via manual side to side compression while the traction device is in place. Next utilizing intra-operative fluoroscopy, the angles of Gissiane and Bohlers are addressed. A Brodens view is obtained to assess the posterior facet. If necessary, a small incision is made inferior to the lateral malleolus into which a thin osteotome is utilized under fluoroscopic guidance to raise the posterior facet, thus facilitating a more anatomically correct position of the calcaneus.

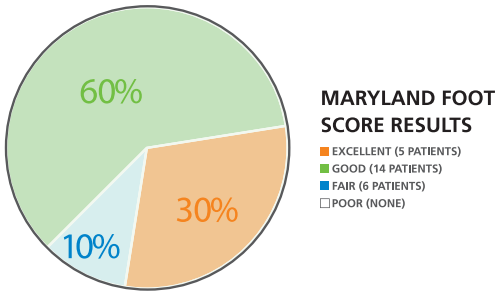
The Sheffield Ring Fixator is then attached to the extremity in the following manner. A frontal plane smooth wire is placed into the tibia at the level of the proximal ring. With the frame eccentrically positioned on the leg and foot, such that the frame is approximately two finger widths from the leg anteriorly, the wire is properly fixated to the ring and tensioned to 130kg. Another smooth wire is placed transversely into the calcaneus, properly fixated to the footplate and tensioned to 60kg. Three additional smooth tibial wires are added, as above, to secure the ring construct to the leg. The purpose of these transosseous wires is to maintain the foot in a 90 degree position to the leg. As needed, additional wires (including olive wires) are placed from opposing directions to further aid in reduction and maintenance of calcaneal width. Distraction of the subtalar joint is then accomplished by increasing the distance between the footplate and the distal tibial ring. This is achieved by loosening the frame hardware on the dorsal side of the ring and tightening the frame hardware on the plantar side. Fluoroscopic evaluation of the final fracture reduction is then made. If satisfactory reduction is appreciated, skeletal traction is then removed from the extremity.

CASE STUDY 2 continued
Retrospective Comparative Analysis of Intra-Articular Calcaneal Fractures

CONCLUSION

The results of the treatment of displaced intra-articular calcaneal fractures tend to be good-excellent regardless of whether ORIF or circular ring fixation is utilized except in Sanders Type IV. However, there is a distinct advantage to utilizing a circular frame in the treatment of Sanders Type IV due to the fact that the height and width are restored. By addressing the height and width with the initial procedure it allows a subsequent fusion to be performed more efficiently.

10-12 weeks post-operative result of reduction and stabilization of displaced intra-articular calcaneal fracture via 3-ring circular frame.



TREATMENT EVALUATION OF INTRAARTICULAR CALCANEAL FRACTURES UTILIZING CIRCULAR FRAME FIXATION

Number	Sanders Classification	Bohler's Angle Pre-Op	Bohler's Angle Post-Op	Post-Op Subtalar ROM Inversion	Post-Op Subtalar ROM Eversion	Maryland Foot Score	Circular Device
1	III	<0°	30°	18°	5°	83	Ilizarov
2	III	18°	21°	15°	8°	86	Sheffield
3	II	10°	22°	10°	4°	75	Sheffield
4	IV	15°	20°	12°	6°	68	Sheffield
5	III	<0°	30°	20°	10°	91	Sheffield
6	III	<0°	35°	15°	3°	85	Spatial-Taylor
7	II	18°	35°	20°	10°	66	Sheffield
8	III	15°	25°	5°	3°	87	Sheffield
9	IV	<0°	40°	2°	0°	66	Sheffield
10	II	10°	32°	18°	3°	86	Sheffield

Bohler's Angle normal value 20-40° (decreases with calcaneal fracture.)

Subtalar Joint ROM normal values: inversion 5-10°; eversion 25-30°

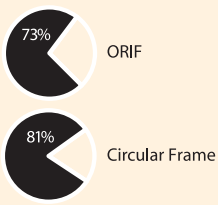
Maryland Foot Score: excellent 90-100, good 75-89, fair 50-74, poor <50.

Ilizarov, Sheffield and Spatial Taylor are respective trade names.

ORIF V. CIRCULAR FRAME FIXATION OF DISPLACED INTRAARTICULAR CALCANEAL FRACTURES

Study	Fixation	Fractures Treated	Good-Excellent Results Number	Good-Excellent Results Percentage
Asik, 2002	ORIF	19	13	68%
Asik, 2002	ORIF	26	20	67%
Yang, 2002	ORIF	38	31	81%
Tometta, 1996	ORIF	35	27	77%
Sanders, 1993	ORIF	120	80	66%
Talarico, 2004	Circular Frame	25	23	92%
Rodgriguez, 2005	Circular Frame	10	7	70%

Cumulative Good-Excellent Results

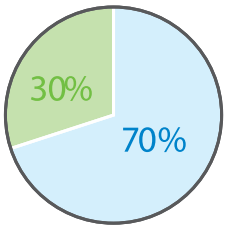


ORIF - Open Reduction and Internal Fixation

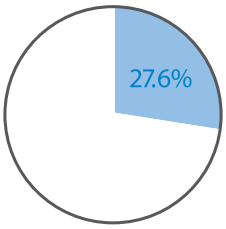
CASE STUDY 3
Charcot Foot Reconstruction Utilizing Multiplanar External Ring Fixation

PURPOSE

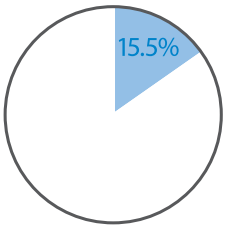
A retrospective case series of 58 patients with limb threatening Charcot deformity was performed. All patients were treated using multiplanar external ring fixation. There were 41 males and 17 females with a mean age of 55.7 years. 62% presented with Type 11 Diabetes and 38% with Type 1. The mean period of follow up was 6.1 years



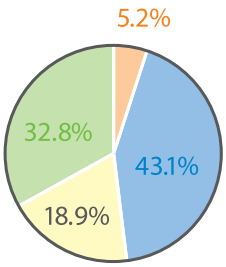
PATIENT GENDER
MALE (41)
FEMALE (17)



LOWER EXTREMITY OPEN ULCERATIONS (16)



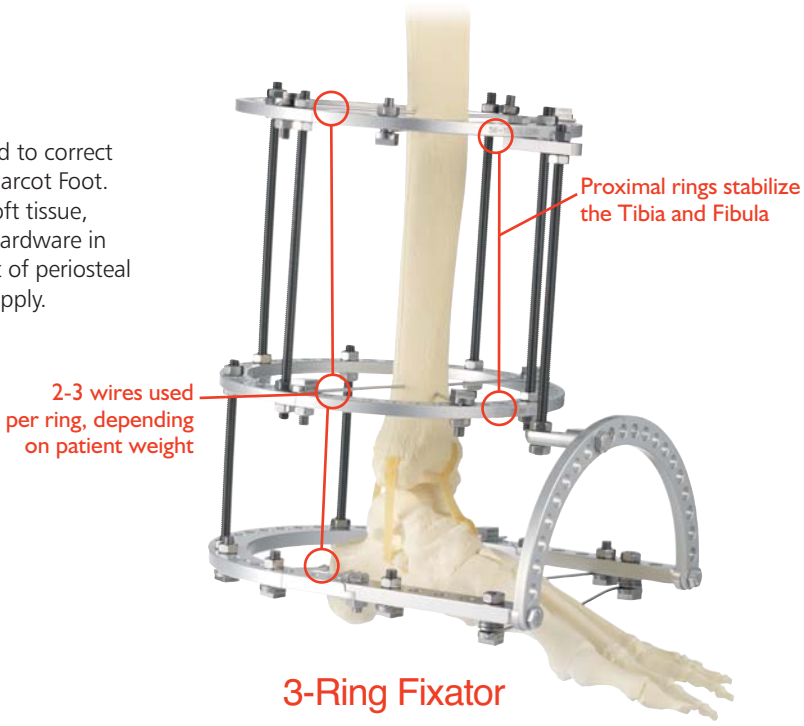
ACTIVE CIGARETTE SMOKERS (9)



LOCATION OF DEFORMITY
LISFRANC'S JOINT
MIDFOOT
REARFOOT
MULTIPLE OTHER SITES

METHOD

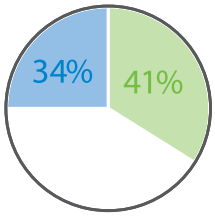
In this series, external ring fixation was used to correct multiplanar deformities in patients with Charcot Foot. Because of the poor quality of bone and soft tissue, external fixation was utilized to minimize hardware in the affected limbs, and reduce the amount of periosteal stripping in already compromised blood supply.



CASE STUDY 3 continued
Charcot Foot Reconstruction Utilizing Multiplanar External Ring Fixation

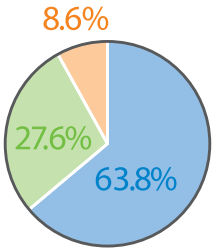
ADVERSE EVENTS

The complication rate is high owing to the combination of inherent complications that accompany external fixation and the complications associated with limb salvage procedures in Charcot patients who often have multiple comorbidities. The division into minor and major complications attempts to stratify the results into clinically manageable complications and those complications involving more extensive treatment.



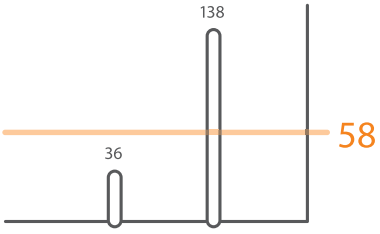
COMPLICATIONS (44)

- MINOR COMPLICATIONS: STAGE 1 OR 2 PIN INFECTIONS, WIRE BREAKAGE AND OSTEOLYSIS (20)
- MAJOR COMPLICATIONS: AMPUTATION, TIBIAL STRESS FRACTURE, REOCURRENCE AND INFECTION BEYOND STAGE 2 PIN TRACT INCLUDING OSTEOMYELITIS (24)

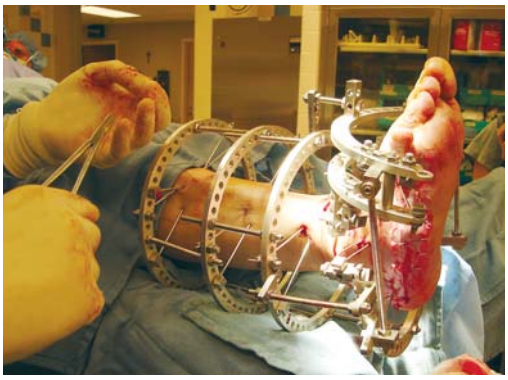


RESULTS (58)

- OSSEOUS UNION (37)
- STABLE FIBRO-OSSEOUS NON-UNION (16)
- BELOW KNEE AMPUTATION (5)



AVERAGE FOLLOW-UP (MONTHS)



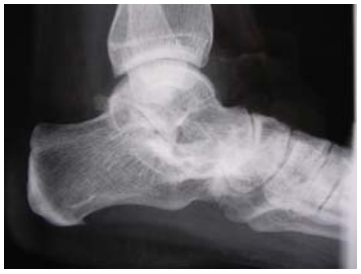
Patient with mid-foot Charcot deformity corrected and stabilized with TrueLok ring fixation system.

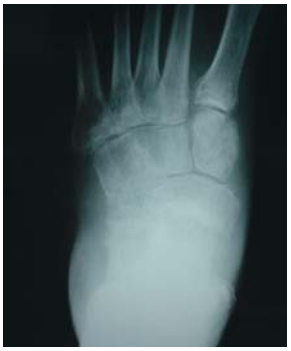
RESULTS

Limb salvage was successful in 53 of 58 patients (91%). Union was accomplished in 70% of those salvaged (37/53).

Outcomes were considered successful based on the achievement of a plantegrade foot that was braceable and/or shoeable, regardless of whether there was osseus union or not. This resulted in 48 of 58 patients (82.8%) achieving a "successful" result during the post-operative period, as described above.

Goal of correction is to achieve a plantegrade, shoeable, and/or braceable foot that allows patient to return to normal daily activities.





Post Triple Arthrodesis, 10 weeks post-op, fusion of all joints

TRIPLE ARTHRODESIS/CHARCOT SURGICAL NOTES

- The patient is placed in a supine position.
- If the patient has a posterior compartment contracture, a tendo-achilles lengthening is recommended to increase dorsiflexion of the foot.
- A medial incision over the talonavicular joint and another incision over the lateral aspect of the foot is performed to obtain access to the talocalcaneal and calcaneocuboid joints.
- Curettage and prep all three joints. Upon satisfactory apposition and alignment, temporary fixation is applied.
- Three .062 k-wires are utilized for temporary fixation: one for the subtalar joint, one for the talonavicular joint and one for the calcanealcuboid joint.
- The incisions are closed with the surgeons preferred method.
- The Sheffield Ring Fixator consists of two rings on the tibia and one ring around the posterior aspect of the calcaneus (foot-ring).
- Allow about an inch between the posterior aspect of the calcaneus and the foot-ring.
- The first fine 2.0 mm wire is inserted in the calcaneus parallel to the ankle joint. This wire is attached to the foot plate. The second wire is inserted on the most proximal ring parallel to the first wire. This will allow the surgeon proper foot manipulation prior to the insertion of the wires through the midfoot and hindfoot.
- From this point, the additional 2.0 wires are inserted in the tibia at the preferred order of the surgeon.

RECOMMENDATION USE OF THE K-WIRE CLAMP KITS (81541) FOR THE FOLLOWING WIRE ATTACHMENT.

- A 2.0 k-wire is introduced through the navicular and cuboid. This wire will be bent posterior on the foot ring to compress the midtarsal joint.
- A second 2.0 k-wire is introduced at the talar neck, avoiding penetration of the wire through the fibula or medial malleolus. This wire will be bent posterior and inferior to compress the subtalar joint.
- X-Rays are taken to ensure proper placement of wires and compression.
- A drain is applied for 24 hours post-op.
- Antibiotics are prescribed for a period of one week.
- If the patient has an underlying deformity at the level of the ankle, midfoot or hindfoot, this must be addressed prior to distraction.
- The patient must be encouraged to ambulate as tolerated to increase micro-motion and bone formation.
- Staples or sutures must not be removed until complete certainty of would healing has been obtained.
- Recommendation of suture removal is approximately 3 weeks.
- External fixator should only be removed when radiographic findings indicate complete bone healing.

CASE STUDY 4

Treatment of Osteochondral Lesions of the Talus with Cryopreserved Talar Allograft and Ankle Distraction with External Fixation

PURPOSE

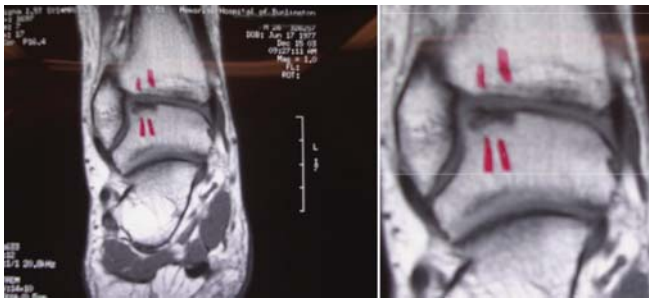
Osteochondral lesions of the talus are relatively frequent and are often associated with significant morbidity. These lesions represent a separated fragment of cartilage, with or without subchondral bone, typically arising secondary to trauma, with the incidence increased in patients with recurrent ankle injuries and significant ligamentous injuries. Treatment of osteochondral lesions depends on the extent, or classification of the lesion.

This case series presents the results of a retrospective review of 6 osteochondral lesions in 6 patients treated with transplantation of cryopreserved talar allograft and ankle joint distraction.

All patients complained of long standing ankle pain secondary to a traumatic episode confirmed through MRI (Figure 1). All surgeries were performed between 2002 and 2004. The average follow up time was 24 months.

METHOD AND PROCEDURES

- A retrospective review was performed of six patients treated for symptomatic osteochondral lesions.
- All patients underwent talar dome transplant with cryopreserved talar allograft as well as ankle joint distraction.
- The ankle was exposed via a medial longitudinal incision in patients with a medial gutter lesion and through a lateral longitudinal incision in patients with a lateral gutter lesion.
- In order to provide adequate exposure of the talar dome, a transverse osteotomy was performed through the medial malleolus at the level of the tibial plafond for medial gutter lesions and a transverse osteotomy was performed through the fibula above the level of the tibial plafond for lateral gutter lesions.
- The talar dome lesions were then visualized and resected utilizing an osteotome and mallet (Figure 1).
- The talus was fenestrated to enhance bony ingrowth into the allograft. An osteotome and mallet was utilized to obtain a graft from the cadaveric Talus of the same size, shape, configuration and anatomical locations the talar dome lesion of the patient (Figure 2).
- The talar graft was then implanted into the operative site and fixated into place utilizing the Magic Pin Fracture Fixation System. (Figure 3 and 4).



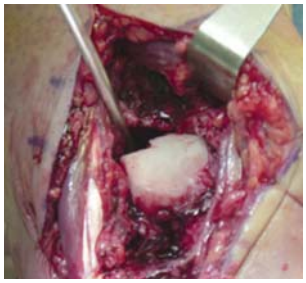


Figure 1

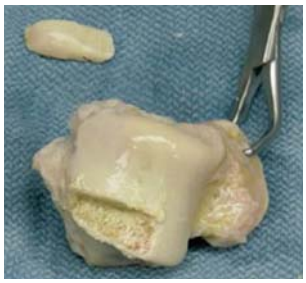


Figure 2

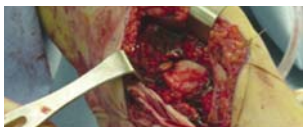


Figure 3

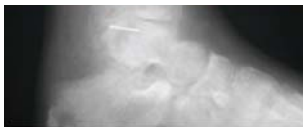


Figure 4

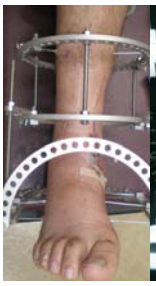


Figure 5

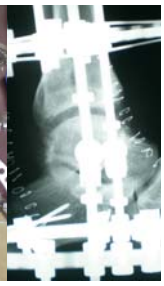
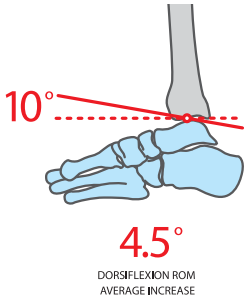
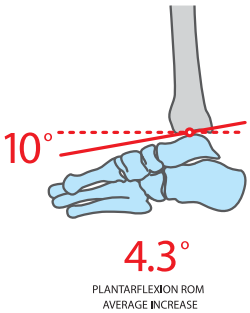


Figure 6

- The medial malleolar osteotomies were also fixated utilizing the Magic Pin Fracture Fixation System. One of the fibular osteotomies was fixated utilizing a five-hole plate and two of the fibular osteotomies were fixated with olive wires attached to the external fixator.
- Refer to Case Study #1 Operative Technique for ankle distraction.
- Each ankle was acutely distracted 4-6 millimeters. All patients were allowed to bear partial weight as tolerated one week postoperatively. All patients were removed from the external fixator at eight weeks and placed in a removable walker boot for another 8 weeks.





RESULTS

1. Serial Radiographs were taken throughout the postoperative course to assess appropriate healing and consolidation of the graft. Healing was gauged by trabeculation across the graft site as well as decreased pain and swelling at the affected ankle. All grafts showed complete consolidation within 16 weeks (figures 7 and 8).
2. All patients related subjective improvement in symptoms following distraction.
3. Postoperative dorsiflexion range of motion increased from 2º to 10º with an average increase of 4.5º while plantarflexion ranged from no increase to a 10º increase, with an average increase of 4.8º. Even patients with minimal increase or no increase in range of motion related a subjective decrease in symptoms as compared to preoperative examination.
4. Patient results were graded pre and postoperatively utilizing the Maryland Foot score. Preoperatively four patients (67%) were graded as fair and two patients (33%) were graded as poor. Postoperative scores ranged between 68 and 95 with a mean average of 83. Two patients (33%) were graded as excellent, three patients (50%) were graded as good, and one patient (17%) was graded as fair. No patients reported poor results. 83% of patients improved their score from fair/poor to good or excellent.

CASE STUDY 4 continued

Treatment of Osteochondral Lesiions of the Talus with Cryopreserved Talar Allograft and Ankle Distraction with External Fixation

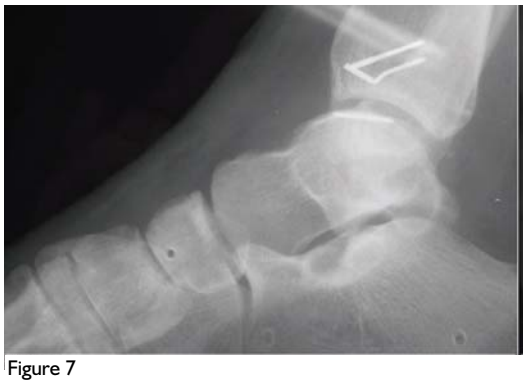


Figure 7

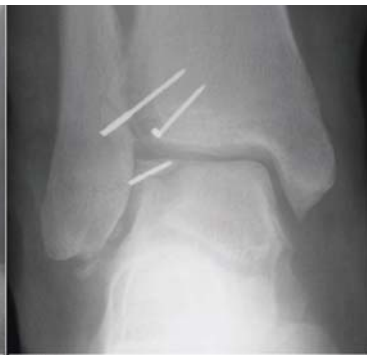
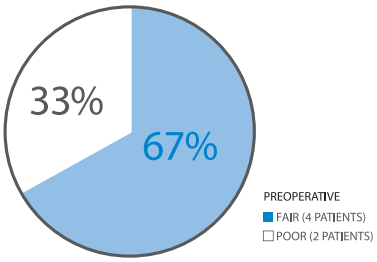
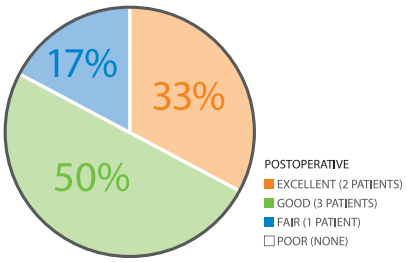


Figure 8





PATIENT KEY

Patient	Age	Sex	Side	Lesion size	Location	Etiology	Duration	Distraction time
1	33	F	R	2.5 x 2.0cm	Lat. Gutter	Ankle Fx	6y	8 weeks
2	26	M	R	1.5 x 1.5cm	Lat. Gutter	Ankle Fx	6y	8 weeks
3	40	M	L	3.2 x 1.8cm	Med. Gutter	Mult. Ankle Sprains	5m	8 weeks
4	39	M	L	2.3 x 1.5cm	Med. Gutter	Mult. Ankle Sprains	2y	8 weeks
5	51	M	L	2.4 x 1.8cm	Med. Gutter	Mult. Ankle Sprains	3y	8 weeks
6	39	M	R	0.8 x 0.8cm	Lat. Gutter	Mult. Ankle Sprains	2y	8 weeks

CONCLUSION

Talar dome lesions pose a difficult treatment dilemma to the foot and ankle specialist. The frequency of missed or incorrect diagnosis often creates a severe debilitating arthritic condition of the ankle joint. Talar allografts are particularly useful in large medial and lateral gutter lesions, allowing implantation with viable chondrocytes and intact hyaline cartilage. The author's distraction modality of choice is a three ring multiplanar external fixator. This configuration provides an extremely stable fixation device and allows for early weight bearing.

Distraction of the ankle allows neovascularization and consolidation of the talar dome into the body of the talus. Without distraction the talar dome could collapse under the weight of the ambulating patient. Distraction also produced a return to control levels of abnormal cartilage proteoglycan as well as a decrease in local inflammation of the ankle joint. Although technically challenging, talar dome transplantation with ankle distraction may allow patient to avoid other end stage procedures such as implant arthroplasty or ankle arthrodesis. We believe further investigation is warranted based on these initial findings.

Manufactured by: ORTHOFIX Srl
Via Delle Nazioni 9
37012 Bussolengo (Verona)
Italy

Telephone +39 045 6719000
Fax +39 045 6719380

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