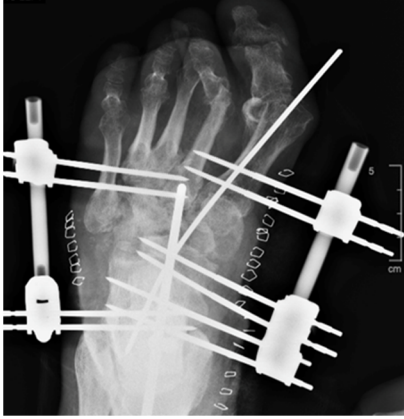


MULTIPLANAR MIDFOOT CHARCOT RECONSTRUCTION UTILIZING A MINI-RAIL EXTERNAL FIXATION DEVICE

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INTRODUCTION

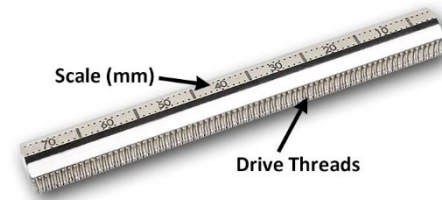
Charcot is a condition that affects 1% of all patients with neuropathy and 2% of patients with diabetic neuropathy. It is most common in the 4th and 5th decade of life. Patients who develop charcot neuroarthropathy are considered at high risk for limb loss. Limb loss in patients with diabetes and other co-morbidities leads to a 40% survivorship at 5 years. The goal of surgical reconstruction is to obtain and maintain a stable weight bearing surface for patients to ambulate as effectively as possible.

Effective healing depends on the minimization of the fracture gap and stability at the fracture site.¹ External fixation has been shown clinically to provide the characteristics for effective bone healing.

The AMDT Mini-Rail Fixator [AMDT Holdings, Inc., Collierville, TN USA], cleared for use in February 2017, is a unilateral external fixator capable of addressing a wide range of applications: simple or complex trauma, deformity correction, and lengthening procedures. The modularity of the components allows the surgeon to build a frame designed for the specific needs of the patient while taking into consideration complexity and affordability.

The components of the AMDT Mini-Rail Fixator consist of a Fixation Rail, three (3) different designs of Fixation Clamp that can transport along the Fixation Bar, and three (3) different designs of End Clamp. Fixation elements of a variety of lengths and diameters from 1.6mm to 3.0mm are provided to effectively stabilize bone segments of different sizes and shapes.

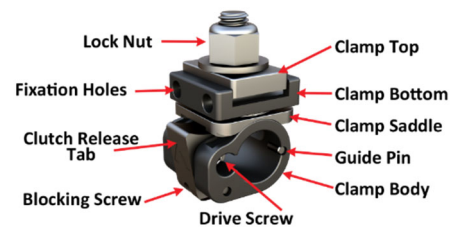
The Rail provides the stability for the Fixation Clamps. The rail is made of aluminum with a diameter of 9.0mm and comes in lengths of 50mm, 75mm, 100mm and 150mm. Drive threads along the Fixation Rail provide the capability for the Fixation Clamps to traverse the rail to exert a compressing or distracting force.



M709 Rail, 75mm

The Traveling Clamp is a component securing the Fixation Elements that engage the cortical bone and is capable of movement along the Rail.

The Traveling Clamps are designed to allow several clamps to move independently along the rail to provide the versatility of applying several points of compression and/or distraction along the same rail.

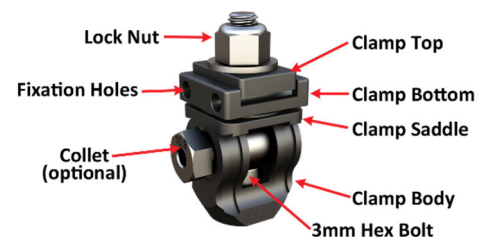


Traveling Clamp, Universal Clutched (M702)

Moving the Clutch Release Tab toward the rail engages the clutch, placing the drive screw in contact with the drive threads to secure the Fixation Clamp in place. Rotating the drive screw allows for subsequent adjustments.

A single Traveling Clamp or multiple Traveling Clamps can be moved using a clamp driver tool. The clamp driver tool has a hex shape (either shaft or tip) which engages the drive screw through which it passes. When the hex-shaped shaft within a drive screw turns, the clamp moves along the drive threads exerting either a compressing or distracting force.

The Traveling Clamp is capable of exerting variable levels of force that depend on how much torque is applied by the clamp driver tool.



End Clamp, Universal (M705)

The Universal End Clamp allows 3 degrees of freedom and is designed to be used in instances when placement of the fixation screws requires a great deal of precision. A rail attached to the Universal End Clamp has freedom to be placed in a 360° conical arc off the clamp. Rail trajectory becomes independent of fixation element placement. Precise and ideal alignment of the rail is simplified. This capability is particularly beneficial when utilizing the rail for callous distraction. The Universal End Clamp accepts bone screws with diameters from 2.0mm to 3.0mm and 1.0mm to 2.0mm Threaded Wires.

CASE STUDY

The patient is a 40-year male with diabetes treated at an outside facility for 2 years. He presented with a plantar lateral foot ulcer that failed conventional treatment and surgical management. Evaluation revealed substantial midfoot arthritis subluxation of the medial cuneiform dorsally, dislocation of the lateral midfoot plantarly, and a tight posterior calf muscle group. The patient was diagnosed with a midfoot Charcot deformity.



The patient underwent left foot Charcot realignment with multilevel joint fusion for salvage. In a step-wise fashion the rear foot was aligned anatomically under the leg to correct his equinus deformity. This was performed via the traditional Strayer calf lengthening procedure. The Strayer procedure was performed through the superficial

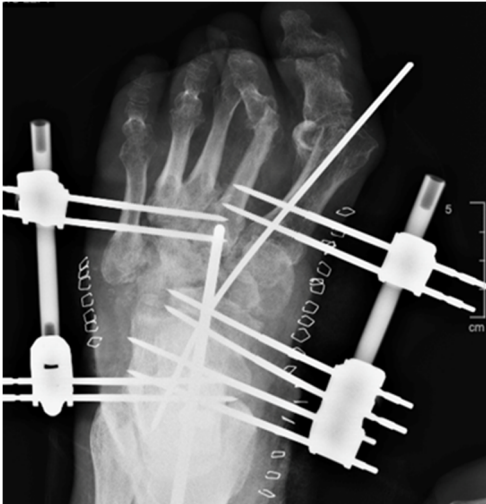
aponeurosis at the distal third of the lower leg. This allowed for some realignment of the foot under the leg. Utilizing a standard medial approach from the mid-shaft of the 1st metatarsal to behind the medial malleolus, access to the medial midfoot was obtained. Sub-periosteal dissection was utilized to gain access to the underlying bony deformities at this level.

The posterior tibial tendon was identified and transected. The anterior tibial tendon was identified, tagged and transected from the medial cuneiform. This was reflected to gain complete access to the midfoot. Each joint was individually debrided and denuded of all cartilage and Charcot debris. This was done across the 1st, 2nd and 3rd tarsometatarsal joints, and then followed by the naviculo-cuneiform joints. Access was obtained to the talonavicular joint and the subtalar joint complexes. These joints were also denuded of cartilage. The joints were then fenestrated with a drill bit. In order to gain further dorsiflexion of the foot upon the leg, the posterior aspect of the subtalar and ankle joint was accessed and a capsulotomy was performed. This allowed for optimal realignment of the foot under the leg. The subtalar joint was then fused with an 7.3mm compression screw 80mm in length. The ankle joint was then locked in neutral with a 4.8mm Steinman pin.

Under fluoroscopy, percutaneously, a long 2mm pin was traversed from the head of the 1st metatarsal, through the medial cuneiform, navicular and talus. This was now utilized to align the medial column for definitive fixation.

The lateral foot was opened through a small incision. The peroneus brevis tendon was then identified and transected from its insertion site. The 4th and 5th tarsometatarsal joint were identified and denuded of cartilage. This was also fenestrated. The foot was then evaluated under fluoroscopy. Optimal alignment was noted on multiple views. Deep, superficial and skin closure was then performed.





A 100mm AMDT rail with a universal end clamp and two (2) premounted universal traveling clamps was prebuilt on the back table for the medial column fusion. The proximal end clamp section was then placed over the head of the talus and secured in place. Under fluoroscopy, the rail was aligned with the medial column in plantar flexion and abduction. A provisional fixation point was secured with 3mm pin on the 1st metatarsal shaft. Images were obtained and confirmed optimal alignment of the talar segment and 1st metatarsal segment. The central section traveling clamp were then aligned with the medial cuneiform and navicular bone. The distal pin was placed into the medial cuneiform and the proximal pin was placed into the navicular. The remainder of the 3mm pins were then introduced in the talus and metatarsal to complete the external fixation. The metatarsal pins were angled from dorso medial to plantar lateral to allow for capture of the 1st, 2nd and 3rd metatarsals.

In a similar fashion, another 100mm AMDT rail with a universal end clamp and one (1) premounted universal traveling clamp was prebuilt on the back table. The end clamp was placed over the lateral calcaneus and the distal traveling clamp was placed in the general vicinity of the 5th met shaft. Two (2) pins were then introduced from plantar lateral to dorsomedial to capture the 4th and the 5th metatarsals.

Under fluoroscopy the medial traveling clamps were compressed to gain stable arthrodesis across the medial column and additional compression was able to be obtained across the talonavicular joint utilizing individual clamp compression. In a similar fashion the lateral rail was compressed to obtain solid fusion.

SURGEON COMMENTS

The advantage of the AMDT Mini-Rail is that it allows for multiplanar correction on a uniplanar device without the additional need for proximal stabilization of the limb in a circular fixator. This thereby appears to be a more reasonable option in those instances in which the surgeon may not want to utilize circular fixation devices yet obtain at least equivalent results. Furthermore, the AMDT Mini-Rail has the ability to produce additional individual level compression or distraction at each segment that has a clamp. The design features of the AMDT Mini-Rail include a cannulated drive screw incorporated in the clamp component that engages the drive threads in the rail. This unique characteristic enables multiple clamps to traverse the rail independently of one another. One or more clamps may be compressing while one or more clamps may be distracting, all occupying a single rail.

Existing designs of mini-rail fixators providing clamp movement do so with a concept similar to a nut on a bolt. Movement is initiated by either a turning a threaded shaft passing through a stationary threaded device like a bolt. Or it could be a threaded device like a bolt that turns on a stationary threaded shaft.

REFERENCES

1. Rüedi, T. P., & Murphy, W. M. (2007). AO principles of fracture management. Stuttgart: Thieme.



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