A Novel Intervention Technique for Charcot Reconstruction

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STATEMENT OF PURPOSE

The purpose of this study was to present a novel intervention technique with injection of a calcium phosphate bone graft substitute in the early stages of charcot neuroarthropathy to maintain a stable plantigrade foot in an attempt to reduce progression of deformity, ulceration, amputation and limb loss.

METHODOLOGY & HYPOTHESIS

A prospective intervention technique performed on fifteen consecutive patients with early charcot neuroarthropathy (CN). Approval was obtained by our Institutional Review Board (Memorial Hospital protocol). Fifteen diabetic patient's with early stage charcot neuroarthropathy were accessed. One out of fifteen patients presented with CN of the ankle and was not included in the study. The remaining fourteen patients had CN of the midfoot and were included in our analysis. The inclusion criteria for this study were as follows; 1) Early charcot with minimal bone destruction, 2)Diabetic charcot neuroarthropathy of the midfoot, 3) Pre-operative and post-operative radiographs, 4) Advanced imaging for surgical planning, 5) Injection of a calcium phosphate bone graft substitute, 6) Minimum of two year follow-up.

Pre-operative and post-operative radiographs were measured to access midfoot collapse. Early CN staging was determined based on radiographic and physical examination findings. Radiographic measurements included: lateral talo-first metatarsal angle (Meary's), calcaneal inclination angle (CIA) and talar declination angle (TDA) (Figure 1). Normal measurement ranges were obtained from literature as follows: Meary's 0-15° (1), CIA 8.5-30° (1), and TDA 14-30° (2). These values were used to determine the hypothetical mean. Using a statistical calculator program one sample t-test was utilized for pre-operative and two year post-operative radiographic measurements for Meary's, CIA and TDA.

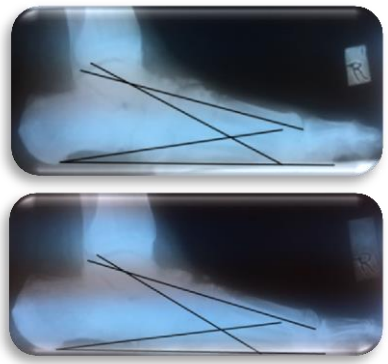

Figure 1.

METHODOLOGY & HYPOTHESIS CONT'D

Advanced imagining (MRI) was performed for all patients to identify bone marrow edema to determine injection placement of calcium phosphate injection (Figure 2). Thirteen patients had an external fixator device applied intra-operatively and one patient was placed into a previously casted custom CROW walker. Thirteen patient's with charcot of the midfoot also received IV infusion of Pamidronate Disodium.

Our hypothesis was that there would be minimal progression of longitudinal arch collapse between pre-operative and post-operative intervention as previously mentioned. The success of treatment was determined by pre-operative and post-operative radiographic measurements of Meary's, calcaneal inclination and talar declination angles. Technique was aimed to slow down the progression of osteoclastic activity with bisphosphonate, to buttress the bones at risk with calcium phosphate and applying an external fixation device or crow walker to off-loading , all while allowing time for ligamentous recovery.

PROCEDURES

Immediately upon initial diagnosis the patient was immobilized and then scheduled for IV infusion of a one time Pamidronate Disodium 60-90mg over 3hr duration. Within one week of IV infusion the following surgical intervention was performed.

Operative technique consisted of closed reduction and manipulation of fractures and/or dislocations. MRI imaging results were available intra-operatively to review areas planned for injection of calcium phosphate bone graft substitute based on bone marrow edema (Figure 2). Utilizing intra-operative fluoroscopy, with a minimum of two planes, placement of an end port injection trocar and cannula was performed in previously identified areas of medullary bone. The calcium phosphate bone graft substitute was injected under direct visualization utilizing dynamic fluoroscopy at all previously identified sites (Figure 3). A minimum of 10 minutes was allowed to pass before removal of trocar and cannula (Figure 4). Following removal of instruments, further manipulation as needed was performed to maintain a plantigrade position of the foot while application of Ilizarov-type multiplane external ring fixator or CROW walker was applied (Figure 5). No internal fixation was utilized to maintain position following surgical intervention.

Post-operative protocol consisted of; strict non-weightbearing for 3-5 days until pin sites were healed, at which point, patients were allowed to use the affected extremity only for transfers. Radiographs were obtained bi-weekly for 6weeks, monthly up to 6 months, then every 6 months. External fixation was removed at 5-6 weeks, at which time the patient was placed into a total contact cast and allowed to ambulate, while a custom molded total contact foot orthosis was made. Full weightbearing in custom foot orthosis was initiated at approximately 8 weeks. Patients were able to return to ambulatory job at 8-12 weeks.

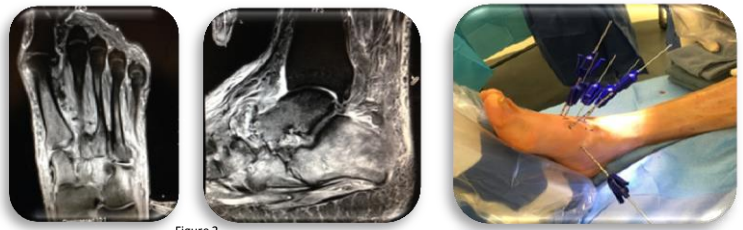

Figure 2.

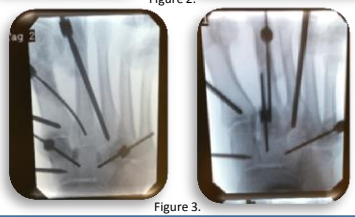

Figure 3.

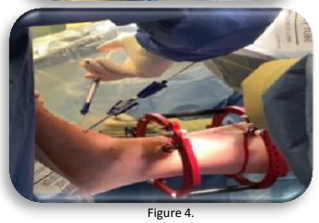

Figure 4.

Figure 5.

LITERATURE REVIEW

Charcot neuroarthropathy is a devastating disease that affects the joints of the foot and ankle. Complications associated with biomechanical deformity can lead to ulceration and limb loss. Charcot occurs in patients with peripheral neuropathy, which most commonly is associated with Diabetes Mellitus in developed countries. Other causes of peripheral neuropathy leading to increased risk of charcot neuroarthropathy in the foot and ankle include but not limited to: alcoholism, leprosy, tabes dorsalis, myelomeningocele, and congenital insensitivity to pain. (3) Although no definite cause has been identified, multiple theories exist trying to explain the disease process. (4-9) Most agree peripheral neuropathy in association with trauma leads to an inflammatory process causing uncontrolled osteolysis leading to progressive fractures and dislocations. (8) The most common site of deformity is within the midfoot at the tarsometatarsal joints.(10) A hallmark sign of deformity is the rocker bottom foot, but the condition can arise in other foot and ankle joints within the lower extremity.

Debate exists in the literature regarding conservative and surgical intervention. (11-13) It is well known that once a patient develops charcot, preventing joint collapse is very difficult. Charcot is a commonly missed diagnosis among medical specialists including primary care and emergency care physicians. This often time leads to delay in treatment and poor outcomes. (12) Most authors suggest waiting for later stages of the disease process before surgically intervening due to poor bone quality and difficulty with fixation.(14-15) Increased use of external fixation, has allowed surgeons have been able to be more aggressive in treating in the acute phases of charcot. Bisphosphonates have also been shown to interfere with the osteoclastic activity which can potentially prevent further destruction of the affected bones and joints. (16-18) They are considered a useful adjunct to both conservative and surgical intervention of the charcot foot. Bone marrow lesions have been treated successfully with the use of bone substitute materials. There are several advantages to using a calcium phosphate material including; the chemical structure mimics bone, can be delivered into bone in a minimally invasive fashion, osteoconductive properties, remodels and is replaced by new bone growth.

RESULTS

Illustrated in Table 1. are the normal angle measurements per established literature.

The ranges for Meary's, CIA and TDA had no significant changes, P-values were 0.0007, 0.0001, and 0.0013 respectively (Table 2).

Table 1. Normal Angle Measurements

	Ranges	Mean	Standard Deviation
Meary's	0 to 15	5.5	3.9
CIA	8.5 to 30	17.9	5.3
TDA	14 to 30	21.4	4.1

Table 2. Statistical Analysis

	N	P value	Hypothetical Mean	Actual Mean
Meary's	14	0.0007	16	8.07
CIA	14	0.0001	22	3.79
TDA	14	0.0013	17	9.21

ANALYSIS & DISCUSSION

The treatment of charcot neuroarthropathy remains controversial. The disease process is not well understood leading to a lack of consensus on preventative measures and treatment options. Patients often have multiple medical comorbidities leading to further difficulty in having a successful outcome. Often times this leads to a patient's inability to be compliant to offloading recommendations. There is also debate on what is considered a successful outcome. Most authors agree after a patient develops CN of the foot or ankle, limb salvage becomes the goal. We do know CN can lead to significant deformities in the foot and ankle leading to debilitating complications.

In this study we used a novel intervention technique to prevent joint collapse in the early stages of CN. A bisphosphonate was utilized on all but 1 patient to inhibit osteoclastic activity and prevent further bone resorption. The one patient who did not receive the bisphosphonate therapy had increased bone breakdown when compared to those who received this treatment. Intra-operatively a calcium phosphate bone graft substitute was injected into the bones previously identified by MRI as being in the active phase of the disease. An external fixator was then applied in all but one patient. This patient was recently casted for a custom CROW walker and was immediately placed in this device following intervention. This technique aided in maintaining a plantigrade foot and prevented need for major reconstructive procedures to restore function after 2 years of initial onset. All patients are currently ambulating as tolerated in custom foot orthoses.

The gold standard in the literature for treating the early phases of charcot includes a total contact cast with minimal weight bearing for up to 20 weeks. Often times this lasts up to 2 years before returning to normal shoe gear. If patients foot collapses during this time period they are at increased risk of ulceration, infection, and amputation. With this new technique for treatment of early CN patients recovery time is decreased dramatically.

We understand the there are limitations to this pilot study including a relatively short term follow-up of 2 years and a small patient sample size (N=14). Further trials will be necessary to establish this technique as a standard of care in the early stages of CN. This technique may give an option to reduce progression of deformity, ulceration, amputation, and limb loss in early stages of charcot neuroarthropathy.

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