Initial Case Studies on the Use of Amniotic Tissue in Tendon Surgery

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Materials and Methods: 5 Consecutive patients with tendon pathology were included in this review. Tendon pathology was confirmed via physical exam and MR imaging. Patients were educated regarding the technology and products and written consent was obtained. The patients were between the ages of 30 and 55. Inclusion criteria included isolated tendon injury or pathology, which had been resistant to conservative therapy for greater than 3 months. Exclusion was the presence of active infection. After surgical debridement had been carried out, direct repair was performed and the tendon was then reinforced with the "NuCel System" (Nutech Medical). The NuCel system was the NuShield dry membrane which had been saturated with NuCel amnion. This was done to provide the optimal conductive scaffold and the inductive growth factors to the amniotic stem cells. Throughout this review, the technique of saturation of the membrane with the cells will be referred to as "NuCel system". Debridement and repair of the tendons was performed in the operating room following standard technique. Once the tendon had been debrided of all pathologic tissue and/or injury was repaired, the system was secured to the tendon with 4-0 absorbable suture. Patients were followed up weekly up to 3 months in outpatient clinic. Initial follow up was at 5 days post operatively, then weekly until post-operative week 4m then biweekly for the remainder of the study. Parameters in the assessment included pain, swelling, range of motion at 6 weeks, strength at 6 weeks, and incidence of re-rupture.

Case Study 1

M.I. is a 47 yr. old female patient, otherwise healthy, who initially presented with a chief complaint of pain in the posterior part of her Right ankle. An MRI study revealed mucoid degeneration with concomitant fibrotic degeneration. The entire lesion measured 3cm in length and 1 slightly over 1cm in width. It was painful on palpation with notable induration. It was decided to sharply debride and excuse the lesion and apply the NuCel System around the tendon after the debridement prior to repair of the paratenon layer. At the first follow up, the surgical site revealed no edema, nor erythema, nor pain. The patient also admitted to not being compliant with postoperative instructions and that she had kept her leg in a dependent position during the weekend. At 4 weeks post operatively, the patient was transitioned into a CAM walker with weight bearing as tolerated into the CAM walker. Pain at the second follow up was minimal and she was no longer taking any medications to control her pain. Sutures were removed at two weeks and physical therapy initiated. At 5 weeks post operatively patient had absolutely no pain with unrestricted range of motion and full strength against resistance of her Achilles tendon. Passive dorsiflexion with STJ in neutral position was over ten degrees. Patient was progressed to weight bearing as tolerated into a normal shoe. She was followed up on a three week interval with

continued progression in strength and range of motion. To date the patient has not have any reoccurrences or ruptures of the Achilles tendon and ambulates without and restrictions.

Case Study 2

F.A. is a 47 year old female patient who presented to clinic with a chief complaint of painful left foot and ankle. She was otherwise healthy on physical exam there was generalized pain on the medial aspect of her ankle and navicular tuberosity, and sever pain along the peroneal tendons. An MRI study revealed a normal Achilles tendon but sinusitis of the PT tendon distal to the level of the malleoli, minimal thickening and inflammation of the plantar fascia. Plain film studies revealed no fractures. The planned procedure, was repair of the peroneal tendons, debridement of the posterior tibial tendon with Kidner procedure, Lapidus procedure and repair of Lisfranc's ligament by arthrodesis if the 2nd met to the intermediate and medial cuneiform with NuCel System. The tendon repairs would be done with NuCel membrane. At the first postoperative visit, the patient stated that she was having no pain, the incision sited were intact with no indication of infection. Patient was kept in clamshell splint until second postoperative visit. At two weeks, sutures were removed and physical therapy initiated. At 6.5 weeks it was noted radiographically that the 2nd met cuneiform arthrodesis site was healing much faster than the Lapidus arthrodesis site where no NuCel system had been applied. At this point the patient was transitioned to PWB with CAM walker. At 8 weeks all arthrodesis sited were healed and patient also had unrestricted range and strength of motion at the posterior tibial and peroneal tendons. At 3 months post op patient presents with no pain and unrestricted activity.

Case Study 3

C.R. is a 31 yr. old female patient, otherwise healthy, with continued waxing and waning pain in her left Achilles tendon area with no history of trauma. Physical exam revealed pain on palpation at the watershed and insertion point of the Achilles tendon at the calcaneus. An MRI study revealed mild insertional tendinosis of the Achilles tendon. Plain film study revealed mild degenerative exostoses of the calcaneus. The planned surgical procedure consisted of debridement of exostoses and detachment, debridement and reattachment of the Achilles tendon with application of NuCel System. At the first follow up, patient stated that she fell in the interim. However, she denied any pain and the surgical site showed no dehiscence, or signs of infection. Plain film study revealed no displacement or migration of the bone anchors. Sutures were removed at two weeks and physical therapy initiated. At 5 weeks, the patient had no pain and unrestricted range of motion with full strength of the Achilles tendon. At 7 weeks post op she was weight bearing as tolerated in normal shoe gear.

Case Study 4

M.P. is a 52 yr. old female patient, with a history of type II DM and Hypertension. She presented with pain in her right ankle and was diagnosed with an Achilles tendon tear with palpable gap and partially intact plantarflexory response, and plantar fasciitis, all findings confirmed by MRI. Surgery was performed on 2/3 and consisted of debridement and repair of Achilles tendon with NuCel System and open plantar fasciotomy. Sutures removed at two weeks and physical therapy initiated per protocol. At 4 weeks post-op, patient had no pain with full range of motion and full strength against resistance. She was progressed to WBAT in CAM walker and then to weight bearing as tolerated at 6 weeks. Patient sustained fractures of metatarsal 3 and 5 at 2 months postoperatively as the result of a fall. However, there was no rupture of the Achilles tendon.

Case Study 5

P.L. is a 49 yr. old female patient otherwise healthy who was diagnosed with a healed previous cuboid fracture and current peroneus brevis tear to the Left foot confirmed by MRI. Repair of peroneus brevis with application of NuCel System was scheduled. At the first follow up, 5 days s/p, patient denied any pain at the surgical site or elsewhere in foot. There was minimal edema but no clinical signs of infection. Sutures were removed at two weeks and physical therapy initiated. At 4 weeks patient has unrestricted range of motion with full strength of the peroneus brevis tendon and no pain. Patient was progressed to weight bearing as tolerated in the CAM walker and physical therapy continued for 8 weeks. To date, at two months s/p, she is weight bearing as tolerated with no restrictions.

A full write-up of these cases for presentation is currently in process