Preliminary results of a retrospective study utilizing a type 1 collagen xenograft in foot and ankle soft tissue reconstructive procedures

Purpose
Investigation and preliminary results/comlications seen with the use of a type 1 collagen biomplant utilized in soft tissue reconstructive procedures. A study by Derwin et al in 2006 showed that the elastic moduli of collagen matrix materials other than Pegasus was an order of magnitude lower than that of a tendon, suggesting a limited mechanical role in augmentation of tendon repair. Another previous study on collagen implants showed an increase in inflammatory cell formation around their implants in conjunction with delayed resorption in glutaraldehyde treated products. Pegasus Biologies offers new technology in a non-toxic, non-glutaraldehyde method of stabilizing bioplants. Other methods of stabilizing bioplants use chemicals or radiation, which have been suspected to cause tissue damage, thereby increasing the chance of inflammatory responses and implant failure. It is thought that many of the existing biological patches and grafts now offered in the marketplace may go through the digestion phase before sufficient remodeling has occurred by the host tissue leaving weak and inadequate scar tissue and possible loss of stabilization.

Materials and Methods
The present study is a retrospective review of observed complications and results in 34 patients who received the type 1 collagen xenograft since February of 2006.

Results
6 total inflammatory type reactions following implantation of the biomplant occurred out of the 34 total patients (17.6%). Of these 6 cases, 4 of the biomplants were removed with subsequent pathology reports indicating 2 cases of granulomatous giant cell reaction with augmentation of a posterior talon bone tendon repair and a delayed ATF repair; 1 case of a foreign body giant cell reaction in a delayed ATF repair (See Pics 5-6); and a reactive foreign body giant cell reaction with augmentation of a posterior talon bone tendon repair.

The remaining two complications were also unknown soft tissue mass reactions. Both lesions involved a mild inflammatory response following a delayed ATF repair. Due to lack of restrictions and other personal commitments the lesions have not been assessed since the time. Both inflammatory reactions resolved without consequence following a single course of oral steroids and now present as asymptomatic lesions of the lateral ankle. There was a correlation of these complications with certain methods of reconstruction. 4 of the complications involved folding over or overlap of the graft to increase tensile strength. Of these 4, 100% were used for total replacement of a complete ATF rather than augmentation or reinforcement. Further use of the graft has suggested that a better bone-to-graft interface via an interference or bicortical screw and increased tensile strength without having to fold or overlap the graft. Also, although never used, we also recommended not using absorbable suture due to the possibility of resorption prior to full incorporation of the graft and loss of stabilization. Despite the observed complications many positive results were observed with the use of the collagen implant. All tendon and ligament procedures resulted in excellent correction with no instances of re-capture or loss of stabilization. The joint resurfacing procedures all resulted in improved ROM with no observed complications. And the use of the biomplant for chronic wound coverage have all resulted in increased wound healing with no observed complications.

In the advent of new tissue stabilizing and sterilization technologies, the use of biomplants for macular/skeletal soft tissue reconstructions has increased. Physicians have to be aware with so many options when it comes to these new materials and implants available for augmentation and are often necessary to facilitate reconstructive procedures of the foot and ankle. It is our duty to present the explicit facts regarding our use of these products. We have reported preliminary results and observed complications involving mild inflammatory responses and soft tissue mass formation following insertion of a type 1 collagen xenograft.

Procedures
A total of 34 cases were performed over the last year including the following list of procedures: 19 Delayed Ankle Ligament Repairs; 7 Ankle Joint Resurfacing Procedures; 4 Posterior Tibial Tendon Repair Augmentations; 1 First MRI Resurfacing Procedure; 3 Ulceration Applications following intra-operative debridement. (See Figures 1-4)

Complications
- 4 Cases of granulomatous giant cell reaction
- 1 Case of a foreign body giant cell reaction
- 2 Cases: Foreign Body Giant Cell Reaction with augmentation of a posterior talon bone tendon repair and a delayed ATF repair
- 1 Case: Foreign Body Giant Cell Reaction in a delayed ATF repair

Significance of Findings
High levels of proms and collagenase are present in damaged tendons, ligaments, and their respective joint spaces and studies have shown that inhibition of the collagenase has been shown to increase tendon healing. Collagenase is now used to improve tendon healing by inhibiting collagenase. Collagenase has shown decreased susceptibility to this enzymatic degradation and theoretically will exhibit increased strength through the remodeling process of tissue healing. Despite the observed complications, we have seen increased reliability and strength of soft tissue reconstructive procedures utilizing the Pegasus type 1 collagen matrix biomplant which support this hypothesis. Further data will need to be collected to ascertain the overall immunogenicity of the biomplant.

References