Prospective Clinical and Surgical Evaluation of the Safety and Efficacy of Acellular Human-Dermis in the Repair of Tendons and Ligaments of the Foot and Ankle

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Presenter

My disclosure is in the Final AOFAS Program Book
I have a potential conflict with this presentation due to
This clinical study was funded by Zimmer-Biomet
I am the Primary Investigator PERI has received research funds to complete this trial

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Tendon augmentation grafts have been shown to be successful in achieving enhanced stability in the repair of soft tissue structures of the foot and ankle.

Biomechanical testing has shown allogenic grafts to be among the strongest soft tissue repair matrices, providing as much as a three-fold increase in load to failure compared to suture alone.

The purpose of this trial This is a prospective, single-center WIRB-approved (protocol #20121835) clinical trial evaluating a sterile acellular human-dermis (AHD) to supplement the repair of the Achilles tendon, Posterior-Tibial tendon and lateral-ankle ligaments.
This is a prospective, single-center WIRB-approved trial evaluating a sterile acellular human-dermis (AHD) to supplement the repair of the Achilles tendon, Posterior-Tibial tendon and Lateral-ankle ligaments. AHD was placed directly over the repaired soft-tissue structure during the surgical procedure and sewed into place with 2-0 fiber-reinforced suture in lateral trap fashion by a single surgeon.

- Twenty Three consecutive patients were enrolled
  - Achilles repairs n=11
  - Lateral Ankle Stabilization n=7
  - Posterior Tibial Repair n=5
Methods

- **Primary Objective**
  
  To establish that Acellular human dermis is efficacious in the repair of soft tissue structures of the foot and ankle.

- **Secondary Objectives**
  
  - Demonstrate the safety and lack of soft-tissue reaction
  - VAS pain-scales evaluated at intervals up to 12 months
  - AOFAS-hindfoot scores evaluated at intervals up to 12 months
  - SF-36 scores were evaluated at intervals up to 12 months.
  - An ultrasound was performed of the soft tissue repaired at the final visit to establish integrity and lack of fluid or inflammation around the soft tissue repair patch.

  A modified intent-to-treat analysis was performed and general linear-modeling with repeated measures was used to analyze the data.

Patients were followed up at time of surgery, 2 weeks, 6 weeks, 12 weeks, 6 months and one year (time points 1-6), with the Ultrasound performed at the last visit.
Methods
Repair Technique

- Achilles
  - The achilles was repaired with #2 fiber-reinforced suture using a modified Krakow, and a size specific piece of ADM was sewed over the repair with 2-0 fiber reinforced suture using a lateral trap technique.
Lateral Ankle

The lateral ankle ligament was repaired with a knotless suture, closure was achieved with standard Gould modification, and lateral ankle was reinforced with ADM sewn in with 2-0 fiber reinforced suture in a lateral trap fashion.
**Posterior Tibial Tendons**

- The posterior tibial tendons were repaired with 2-0 fiber reinforced suture, the FDL transferred through the navicular, the two tendons sewed together with a 2-0 fiber reinforced suture, and the ADM applied and sewn into place with 2-0 fiber reinforced suture.
The overall change in SF-36 physical component score was statistically significant with a partial- $\eta^2$ of 0.87, a power of 100($p=1.3 \times 10^{-30}$), indicating very-significant changes in all three scores over-time.
AOFAS hindfoot scale-scores were statistically significant with a partial-\(\eta^2\) of 0.88, a power of 100\%(p=1.9 \times 10^{-26})
Visual to Analog Scale: The overall effect was statistically significant with a partial $\eta^2$ of 0.8, a power of 100% ($p=1.2 \times 10^{-14}$), indicating very significant changes in pain over time.

Ultrasound was performed on all subjects and all patients studied showed intact Tendons / Ligaments without a fluid signal noted within the soft tissue structure examined.
Conclusions

- Addition of an allogenic repair patch (Dermaspan ACD) with a running locking suture technique in 3 common applications shows:
  - A statistically significant increase in AOFAS Hindfoot Scale Scores
  - A statistically significant increase in SF-36 physical function scores
  - A statistically significant decrease in VAS scores
  - Ultrasound at one-year showed a lack of fluid signal, with all tendons and ligaments intact.

Comparisons between groups was not possible due to small study “n”

The overall statistical improvement in all scores studied suggests the allogenic repair patches may be a helpful adjunct for Foot and Ankle Surgeons for tendon and ligament repair.

References