

# Clinical Evaluation of Tendon Repair with the Application of Lyophilized Full Thickness Human Amniotic Membrane



Anthony Colonna<sup>1\*</sup> DPM, Meghan Richline<sup>1</sup> DPM PGY-3, Hyun Ju Lim<sup>2</sup> Ph.D.

<sup>1</sup>LECOM College of Podiatric Medicine, Erie, PA 16509, <sup>2</sup>LifeLink® Foundation Research & Development, Tampa, FL 33619

#### INTRODUCTION

Adhesion formation between repaired tendons and surrounding tissues is one of the main complications after tendon repair resulting in a poor clinical outcome. Human amniotic membrane is an established modality in epithelial defects that acts as an anti-inflammatory, nonimmunogenic, and mechanical barrier to promote epithelialization and inhibit fibrosis and scar formation. This case study presents the clinical outcome of two patients who received a lyophilized full thickness human amniotic membrane (FT-AC) after tendon repair surgery as an adhesion barrier.

#### **METHODS**

The first patient is a 53-year-old male who was having pain in his right lower extremity for the last 1.5 years with no improvement. He rated the pain as 6/10, tight and pulling in nature. Intraoperative diagnosis included an acute Achilles rupture, peroneal tendinitis, and a severe split tear. During surgery, debridement of non-viable tissues occurred with repair of the Achilles tendon and Peroneus brevis. FT-AC was wrapped around both tendons and secured by sutures.

The second patient is a 49-year-old female who complained of right posterior heel and calf pain for one year. She rated the pain as 7/10, achy and shooting in nature. Intraoperative diagnosis included a peroneal tendon tear and Achilles tendinosis with thickening. During surgery, 40% of the Achilles tendon was debrided, peroneus brevis and longus tenosynovectomies were performed, and a peroneus brevis excision of a low-lying muscle belly was completed. After re-tubularization and repair of peroneal tendons, FT-AC was applied to both tendons and secured by sutures.

### RESULTS

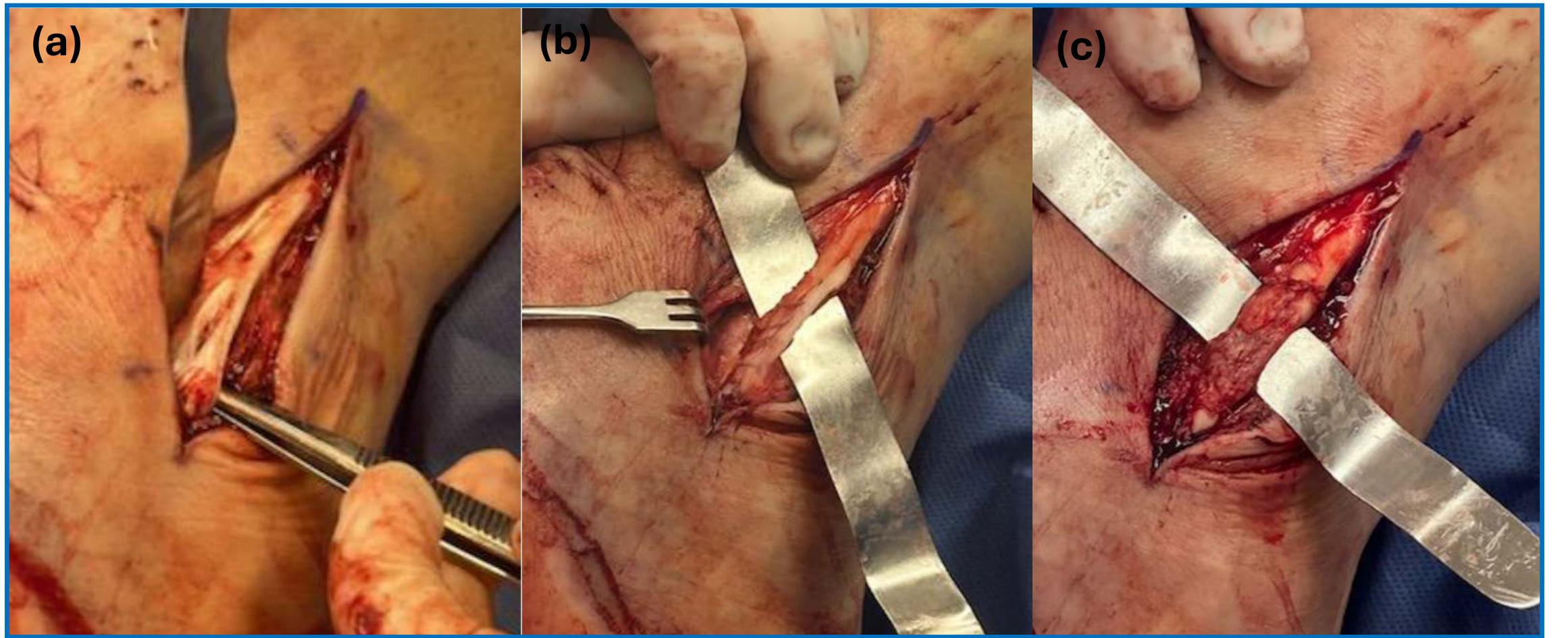
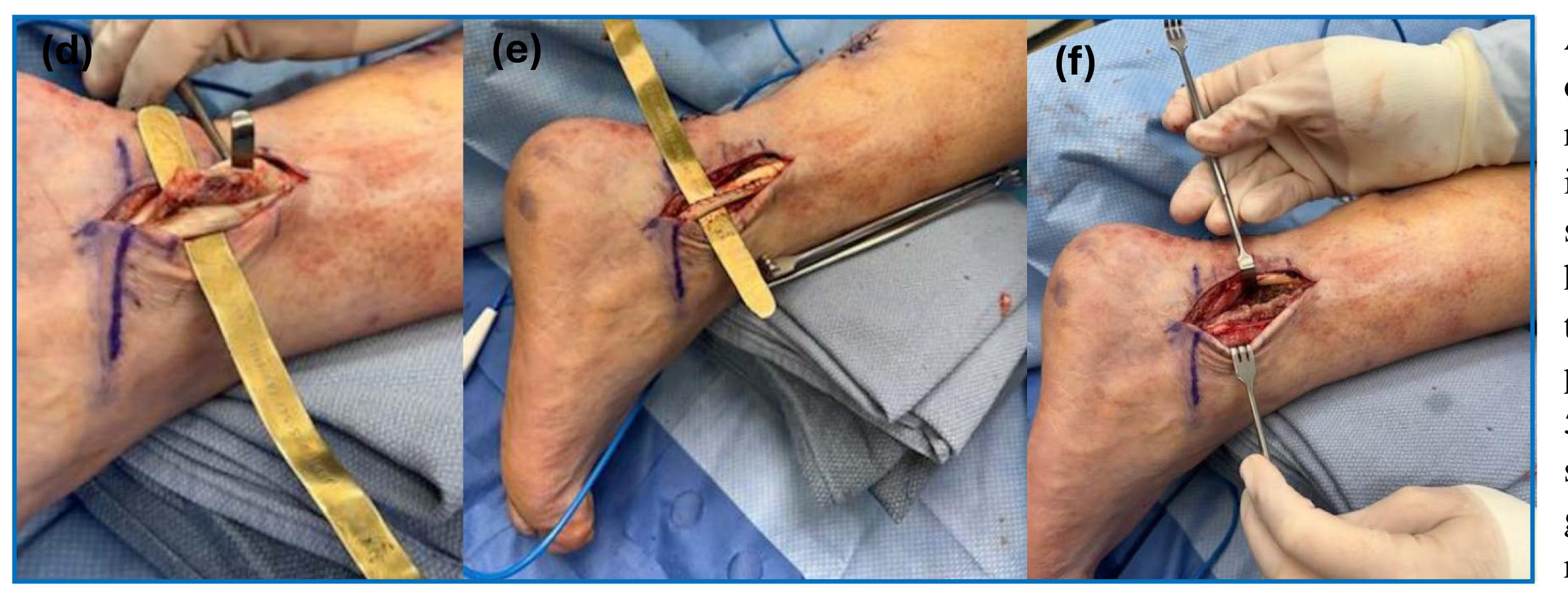


Figure 1. Procedure pictures. (a) – (c) are the first patient intraoperative views, and (d) - (e)are the second patient intraoperative views. (a) view of tearing to peroneal tendon, (b) view of peroneal tendon following repair and debridement, (c) view of peroneal tendon following repair and graft application. (d) view of the damaged peroneal tendon, (e) view of repaired tendon with reperoneal tubularization, and (f) view of the peroneal tendon following graft application.



At 3 months postoperation, the first patient
rated pain as 1/10, and the
incision site appeared
stable and healed with no
hypertrophic scarring. The
tendon also still has good
plantar flexion strength. At
5 months, the patient
started to use normal shoegear, and the final pain
rating was 2/10.

The second patient had mild pain to the posterior mid-substance of the Achilles tendon and showed good plantarflexory strength. Regular shoe-gear use was started at 4 months post-operation, and the pain rate was 3 out of 10. The functionality post-operation was improved overall. There are no reported adverse events related to the FT-AC post-surgery.

## DISCUSSION

FT-AC is a tissue allograft, processed using a proprietary method (RegeneCleanse®). The graft maintained the mechanical and biological properties of native tissues. FT-AC will be a valuable tool to prevent adhesion during tendon repair procedures and tendon reinforcement.