A Retrospective Comparison of Hindfoot and Ankle Tendon Repairs with and without Acellular Amniotic Scaffolds

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STATEMENT OF PURPOSE

The purpose of the present report was to compare outcomes between patients who received acellular human amniotic scaffold grafts following tendon repair of the hindfoot and ankle with a similar group of surgical patients who did not receive the graft.

LITERATURE REVIEW

The use of amnionic membrane in surgery has been documented for over 100 years and has been shown to be especially useful in decreasing inflammation and scar tissue formation (1-4), as well as inhibiting bacterial infection (1,2) and promoting angiogenesis (1,2,5).

There are a number of animal studies that have investigated the effects of an amniotic membrane on tendon healing (REF), and there is growing evidence that amniotic membranes possess the intrinsic ability to promote tendon healing by increasing the number of proliferating tenocytes (2,7,8), decreasing adhesion formation (3,4,6), and increasing tendon strength by increasing the number of collagen crosslinks (6). Despite these findings, there is a lack of human studies that examine the clinical findings of patients who have undergone tendon repair with the addition of amniotic membrane.

HYPOTHESIS

We hypothesized that patients who received a decellularized, dehydrated, human amniotic membrane graft would show greater improvements in postoperative pain, return to activity, and wound dehiscence, compared with patient who did not receive a decellularized, dehydrated, human amniotic membrane graft.

METHODOLOGY

Level of Evidence: IV

Study Design: Chart Review
- A chart review was performed to identify consecutive patients that underwent primary tendon repair with (treatment group) and without (control group) application of a decellularized, dehydrated, human amniotic membrane.

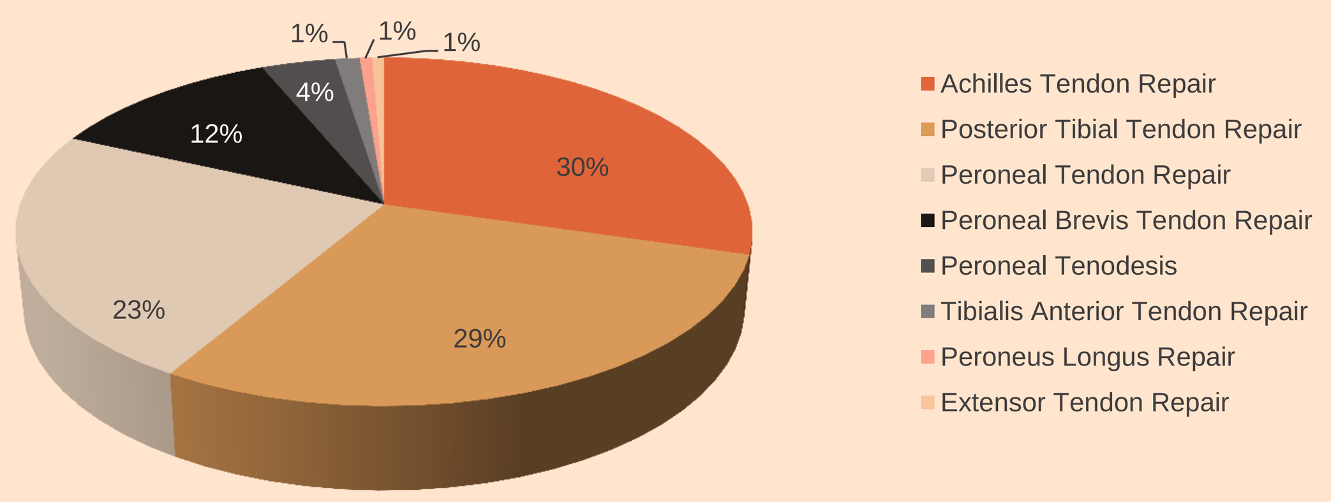
Inclusion Criteria
- ≥18 years of age
- Underwent primary tendon repair
- Procedure performed by one surgeon (S.A.B.)

Exclusion Criteria
- Previous repair of the involved tendon
- Acute traumatic injury, involving laceration or severance of the repaired tendon
- Fusion of the subtalar joint performed concomitantly with posterior tibial tendon repair

Outcomes
- Postoperative pain
- Return to activity
- Wound dehiscence

Statistical Analyses
- Outcomes were compared between the two groups using an independent samples t-test.
- Nominal variables were compared using Fisher's exact test.
- Statistical significance was set at the 5% level ($p \leq 0.05$).
- Data presented as mean ± standard deviation or count (%).

Figure 1. Tendon Repair Procedures



RESULTS

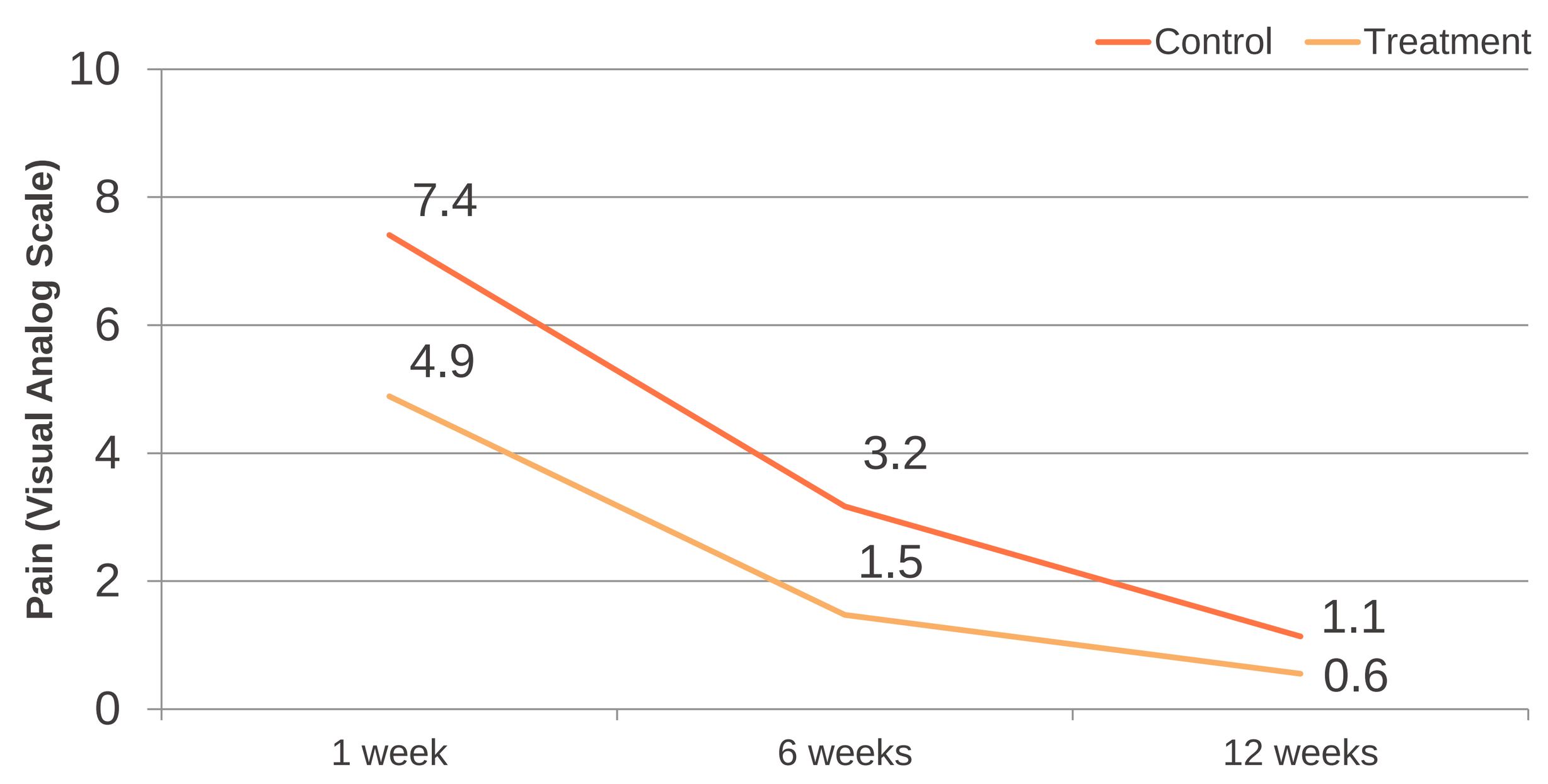
Table 1: Patient Demographics and Concomitant Procedures

Demographic	All Patients	Treatment Group	Control Group	P-Value
Patients	159 (100.0)	100 (62.9)	59 (37.1)	
Age (years)	50.3 ± 14.5	50.1 ± 15.1	50.5 ± 13.6	0.889
Gender				0.386
Men	54 (34.0)	31 (31.0)	23 (39.0)	
Women	105 (66.0)	69 (69.0)	36 (61.0)	
Additional Bony Procedures				0.622
Yes	72 (45.3)	47 (47.0)	25 (42.4)	
No	87 (54.7)	53 (53.0)	34 (57.6)	

Table 2: Outcomes

Outcome	Treatment	Control	P-Value
Postoperative Pain	2.3 ± 2.2	3.5 ± 2.7	<0.001
# Physical Therapy Sessions	9.1 ± 2.7	11.6 ± 2.9	<0.001
Time to Walk 4 Blocks (days)	68.9 ± 20.7	88.5 ± 19.3	<0.001
Wound Dehiscence	3 (3.0)	6 (10.2)	0.078

Figure 2. Postoperative Pain



There was a statistically significant reduction in pain across time ($P < 0.001$). The treatment group reported significantly lower pain (2.3 ± 2.2 VAS), compared with the control group (3.5 ± 2.7 VAS; $P < 0.001$).

Figure 3A. Return to Activity

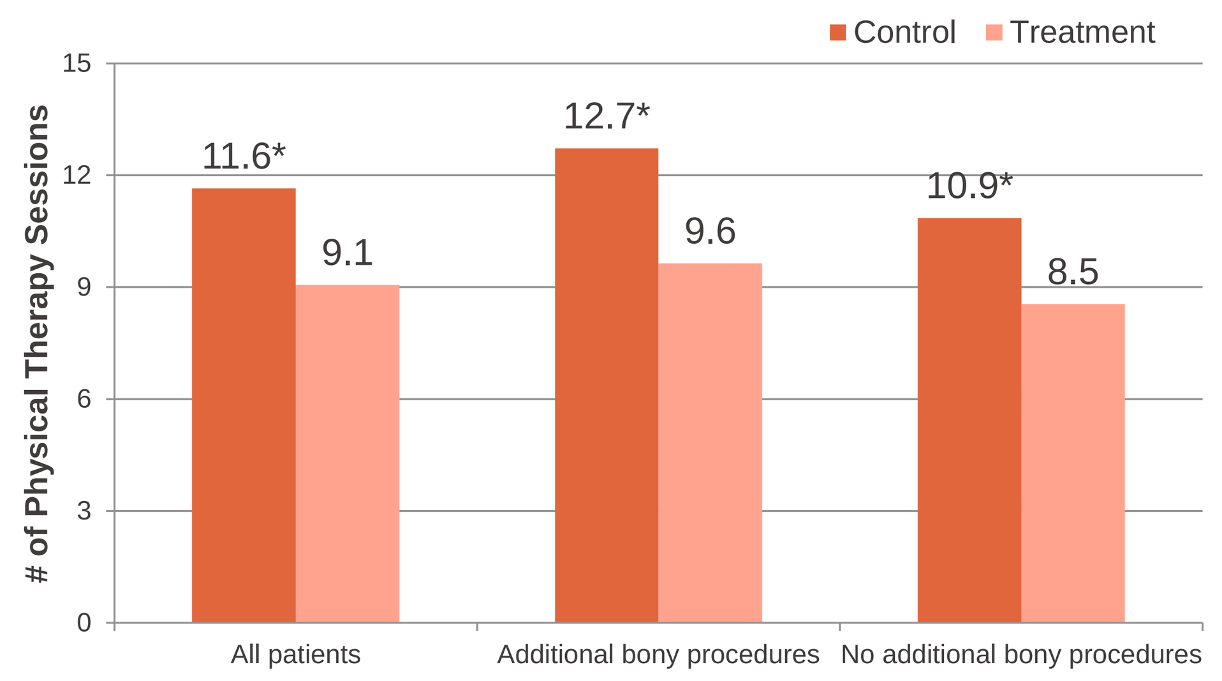


Figure 3B. Return to Activity

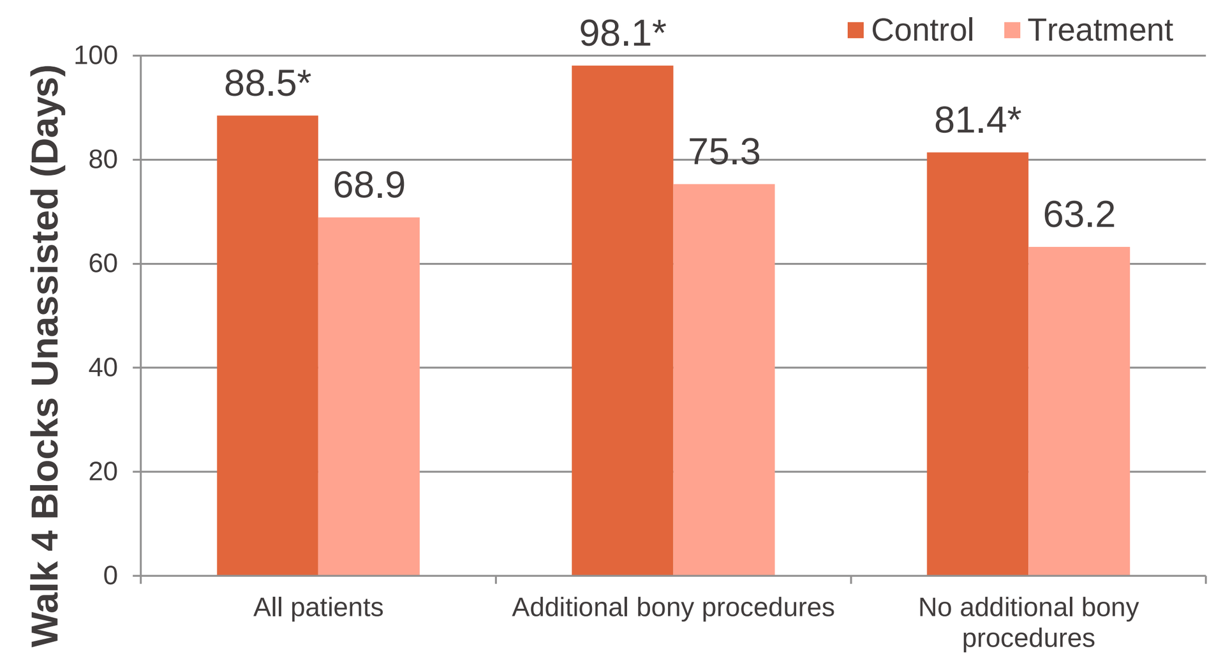
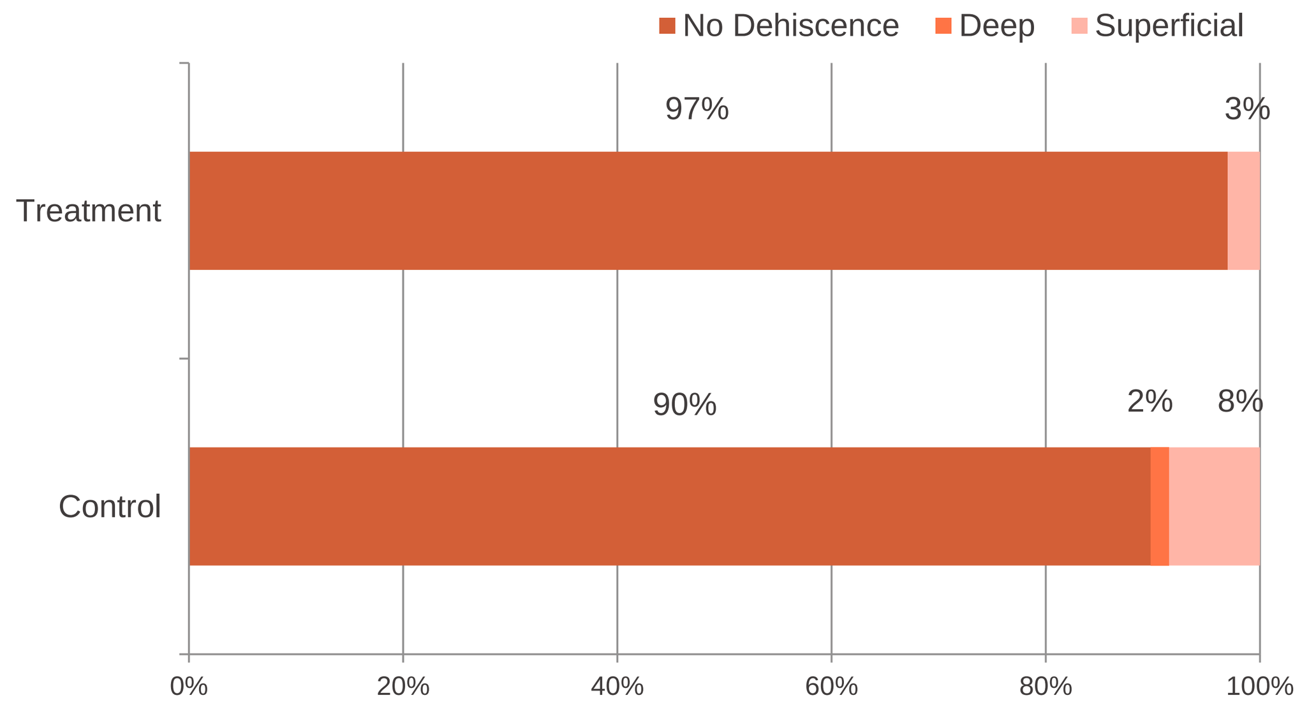


Figure 4. Wound Dehiscence



DISCUSSION

The healing process following repair of a tendon often results in excessive fibrous collagen deposition, which can lead to decreased function of the tendon and increased discomfort for the patient. Intraoperative prophylactic treatment strategies have consisted of bovine collagen wraps, sheets of hyaluronic acid and hydropscopic polymer based barriers (REF). However, none of these has been consistently shown to decrease pain in published studies. The present investigation sought to investigate patient outcomes with application of dehydrated, acellular human amniotic membranes.

We hypothesized that patients treated with a three-dimensional, dehydrated, acellular amniotic membrane scaffold would have a faster return to activity with less pain and fewer cases of wound dehiscence. Our results adhered to expectation for two of the three study endpoints. Application of an amniotic membrane was found to significantly improve pain ($P < 0.001$), reduce the number of physical therapy visits, ($P < 0.001$), and decrease the number of days required to walk four blocks unassisted ($P < 0.001$). The rate of dehiscence was similar between the two groups ($P = 0.08$).

There are a number of limitations, which could potentially threaten the validity of our conclusions. Given the retrospective nature of the study, there is an inherent potential for bias. Additionally, our data is limited to the information contained in the patient's medical records. For this reason, the number of physical therapy visits and time to walk 4 block unassisted were used as an indicator of return to activity. With a prospective study, return to activity could be better defined and more closely monitored. Given these limitations, a prospective study is warranted to fully evaluate the effect of dehydrated, acellular human amniotic membranes in terms of the parameters we used to evaluate outcomes.

The findings of the present study demonstrate the benefits of acellular human amniotic membranes in tendon healing, lending support to the existing evidence throughout the literature. Aprospectively designed study is warranted to evaluate the use of this biologic scaffold for tendon repair in the foot and ankle.

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