

# Application of Acellular Amniotic Scaffold Following Total Ankle Replacement: A Retrospective Comparison

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## STATEMENT OF PURPOSE

The purpose of this study was to compare the incidence of surgical wound dehiscence in patients who underwent total ankle replacement with placement of an acellular dehydrated human amniotic membrane with patients who did not receive an acellular dehydrated human amniotic membrane.

## ITERATURE REVIEW

Breakdown of an operative incision resulting in a wound is one of the most devastating complications following total ankle replacement (TAR). The ankle joint is particularly prone to incisional complications following TAR, given the avascular nature of the anterior envelop and motion restrictions after surgery. It is important to initiate return to activity early in the postoperative period to prevent soft tissue contracture and loss of range of motion. The ankle incision must be epithelialized to safely begin weight bearing and initiate range of motion exercise to reduce the risk of dehiscence.

The use of human amniotic membranes are becoming more popular due to the increasing evidence, demonstrating their ability to promote epithelialization, decrease postoperative inflammation and scarring, and improve pain; while potentially preventing infection and aiding in the revascularization of tissues [2-15].

There are no studies to date that have applied amniotic membrane following total ankle replacement (TAR) as a proactive means of reducing surgical incisional healing complications.

## **HYPOTHESIS**

We hypothesized that patients who received a decellularized, dehydrated, human amniotic membrane graft would have less wound dehiscence, quicker time to healing, and sooner initiation of physical therapy as compared with patient who did not receive a decellularized, dehydrated, human amniotic membrane graft.

## METHODOLOGY

### Level of Evidence: III

Study Design: Chart Review

• A retrospective chart review was performed to identify consecutive patients that underwent TAR with (treatment group) and without (control group) application of acellular dehydrated, human amniotic membrane.

#### Inclusion Criteria

- ≥18 years of age
- Underwent Total Ankle Arthroplasty
- Procedure performed by one surgeon (S.A.B.)

### **Exclusion Criteria**

- postoperative acute traumatic injury that could potentially interfere with wound healing
- Revisional Total Ankle Arthroplasty

### Surgical Technique

- Classic anterior approach excluding the 2 Zimmer implants
- 4 cm by 4 cm Biovance amniotic scaffold (Figure 1) was placed at the flexion point of the ankle joint and the extensor retinaculum was closed with 2-0 monocryl

### Outcomes

- Evaluate Postoperative wound dehiscence
- Time to wound healing
- Time to initiate physical therapy
- Duration of physical therapy

### Statistical Analyses

- Outcomes were compared between the two groups using an independent samples t-test.
- Nominal variables were compared using Chi-Square test.
- Statistical significance was set at the 5% level ( $p \le 0.05$ ).
- Data presented as mean ± standard deviation or count (%).



Figure 2A: Amniotic membrane application.

## RESULTS

Implant	Manufacturer	All Patients	Treatment	Control
Cadence™ Total Ankle System	Integra LifeSciences, Plainsboro, NJ	22 (23.4)	21 (44.7)	1 (2.1)
INBONE <sup>™</sup> Total Ankle System	Wright Medical, Memphis, TN	3 (3.2)	-	3 (6.4)
INFINITY™ Total Ankle System	Wright Medical, Memphis, TN	6 (6.4)	-	6 (12.8)
INFINITY™ Tibia & INBONE™ Talus	Wright Medical, Memphis, TN	10 (10.6)	-	10 (21.3
Integra® XT	Integra LifeSciences, Plainsboro, NJ	1 (1.1)	-	1 (2.1)
Salto Talaris® Ankle	Integra LifeSciences, Plainsboro, NJ	7 (7.4)	3 (6.4)	4 (8.5)
STAR <sup>™</sup> Ankle	Stryker, Mahwah, NJ	43 (45.7)	23 (48.9)	20 (42.6
Trabecular Metal™ Total Ankle	Zimmer Biomet, Warsaw, IN	2 (2.1)		2 (4.3)
Total		94 (100.0)	47 (100.0)	47 (100.0)

Table 1: Total ankle replacement implant. Data presented as count (%).

Patient Demographics	All Patients	Treatment	Control	P-Value		
Patients	94 (100.0)	47 (50.0)	47 (50.0)			
Age (years)	60.9 ± 10.9	63.5 ± 10.1	58.3 ± 11.1	0.020		
BMI (kg/m <sup>2</sup> )	31.8 ± 5.6	31.6 ± 4.9	31.9 ± 6.2	0.821		
Gender				0.200		
Men	55 (58.5)	31 (66.0)	24 (51.1)			
Women	39 (41.5)	16 (34.0)	23 (48.9)			
Operative Side				0.832		
Left	43 (45.7)	22 (46.8)	21 (44.7)			
Right	51 (54.3)	25 (53.2)	26 (55.3)			
Smoking Status				0.307		
Former Smoker	13 (14.0)	9 (19.6)	4 (8.5)			
Non-Smoker	65 (69.9)	30 (65.2)	35 (74.5)			
Smoker	15 (16.1)	7 (15.2)	8 (17.0)			
Co-morbidities						
Diabetes Mellitus	10 (10.6)	6 (12.8)	4 (8.5)	0.740		
Neuropathy	1 (1.1)		1 (2.1)	1.00		
"Smoking status was not available for one patient in the treatment group.						

Table 2: Patient demographics. Data presented as mean ± SD and count (%).

Outcomes	All Patients	Treatment	Control
Wound Dehiscence	12 (12.8)	3 (6.4)	9 (19.1)
Superficial Wound	7 (7.4)	2 (4.3)	5 (10.6)
Deep Wound	5 (5.3)	1 (2.1)	4 (8.5)
No Wound Dehiscence	82 (87.2)	44 (96.3)	38 (80.9)
Total	94 (100.0)	47 (100.0)	47 (100.0)

Table 3: Wound dehiscence. Data presented count (%).



Figure 3: Wound dehiscence. Wound dehiscence is stratified into no wound dehiscence, deep wound dehiscence, and superficial wound dehiscence. The count and percentage are plotted for the treatment and control groups. Data presented as count (%).



Figure 5: Time to physical therapy initiation. Time to physical therapy initiation in days is plotted for both the treatment and the control group. Data presented as mean ± standard deviation.

Abbreviations: PT: Physical Therapy.

While there is inherently some incidence of dehiscence related to surgical technique, we feel this is minimized within our study due to surgeon's experience and the understanding of the importance of preservation of soft tissue envelope. Previous studies reported by the author demonstrated a wound complication rate of 14% with focus on preservation of tissue alone [16]. This complication rate is much improved from earlier published studies by Myerson which reported upwards of 32% wound complication rate before techniques improved [17]. Our data demonstrate a dehiscence rate decrease from 19.1% to 6.4% with the use of an amniotic scaffold. It is important to note that our data included all patients classified as having a delay in wound closure, and we are aggressive in our treatment. A few of the superficial dehiscence patients could have been classified as delayed skin healing as we did not distinguish these patients separately.

While not statistically significant, this study also showed that patients treated with a dehydrated, acellular human amniotic membrane began physical therapy approximately 10 days earlier than their control counterparts. This is significant due to the importance of early range of motion with physical therapy for a successful outcome and reduction of stiffness following TAR. Early mobilization is further supported throughout literature with a notably faster attainment of short term mobility milestones, increase in functional outcomes, and decrease in costs with total joint replacements [11].

Human amniotic membranes have many desirable properties that have the potential to positively impact the healing environment following TAR and prevent incision dehiscence. This retrospective comparative study found a statistically significant decrease in the cases of incisional dehiscence with the use of a dehydrated, acellular human amniotic membrane. These findings adhered to expectation and suggest that the dehydrated, acellular human amniotic membrane may help prevent cases of surgical wound dehiscence following total ankle replacement.

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## DISCUSSION

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