Comparison of Regenerative Limb Salvage to Flap-based Reconstruction of Complex Extremity Wounds: A Randomized Control Trial

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Introduction

Traumatic and chronic wounds of the extremities require amputation unless reconstructive surgery can achieve soft tissue coverage of exposed critical structures: bone, tendon, nerve.

Free flap limb salvage (fLS) is the standard of care but is demanding:

- Trained microsurgeon
- Long surgeries with multiple revisions needed
- Extensive post operative monitoring
- Expensive: $170,000 per patient
- fails in 13-18% of attempts
- 75% of failures ultimately result in amputation.

An alternative technique is regenerative limb salvage (rLS) using dehydrated human amnion/chorion membrane (dHCAM)

Specific Aims:

The goal of this study was to compare rLS to fLS in a multi-centered, prospective, randomized controlled trial (RCT) with a crossover option upon reconstructive failure

Methods

Between 2016 and 2018, 48 subjects with complex wounds of the extremities were enrolled

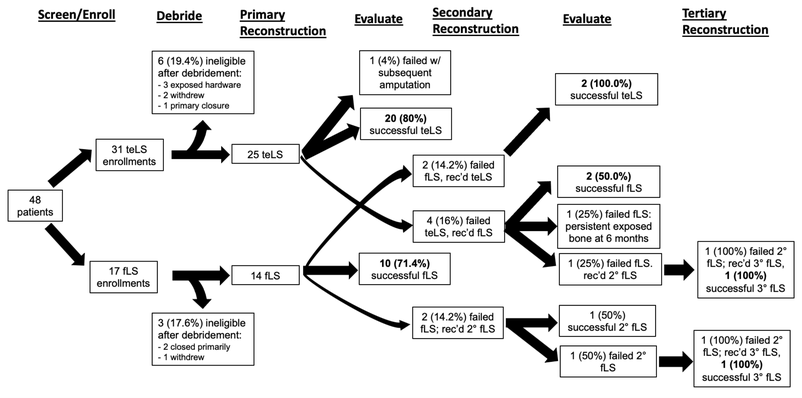
Exclusion criteria: malignancy, exposed hardware, non-flap candidates (ischemic limb, PVD)

Patients were randomized to fLS or rLS in a 1:2 ratio

Primary outcomes included

- comparing successful reconstruction
- time to definitive closure
- time to weight bearing

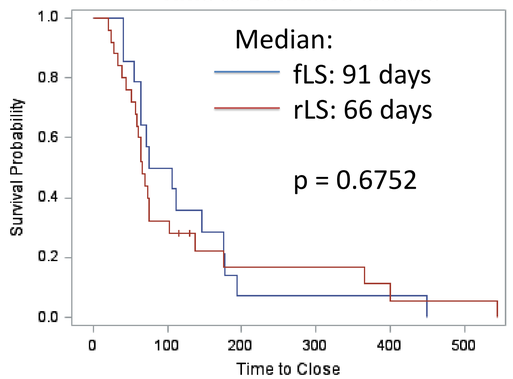
Methods



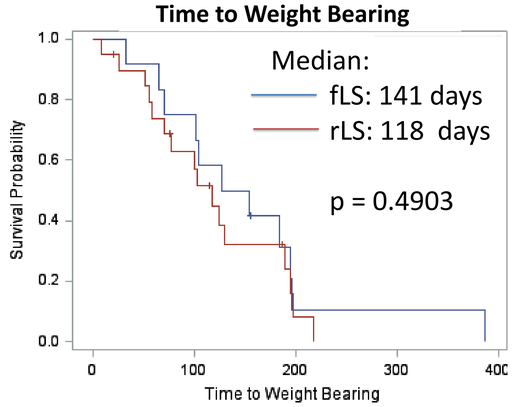
Results

	fLS (n=14)	teLS (n=25)	p-value
Success Rate, n (%)	12 (85.71)	20 (80)	1.0000
Persistent Exposed Structures, n (%)	0 (0)	1 (4)	1.0000

Time to Definitive Closure

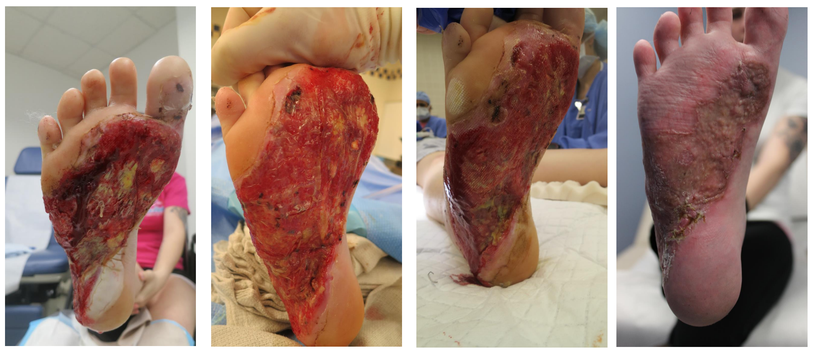


Time to Weight Bearing



Results

rLS: wound of the dorsal aspect of the foot with exposed tendon treated with dHCAM + skin grafting



rLS: wound of the plantar aspect of the foot with exposed tendon treated with dHCAM + skin grafting.

A) At time of presentation
B) Post-debridement and dHCAM application
C) Wound bed 5 days post treatment
D) Wound bed after skin grafting

Conclusions

- rLS success rate equivalent to conventional fLS
- Comparable time to definitive closure
- Less bulky than fLS, useful for some anatomic locations
- Several extra advantages:
  - No fLS options are lost
  - dHACM treatments can be performed in an outpatient setting, freeing up operating room and inpatient resources
  - Can be performed without microsurgical expertise thus increasing patient access to LS

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