

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

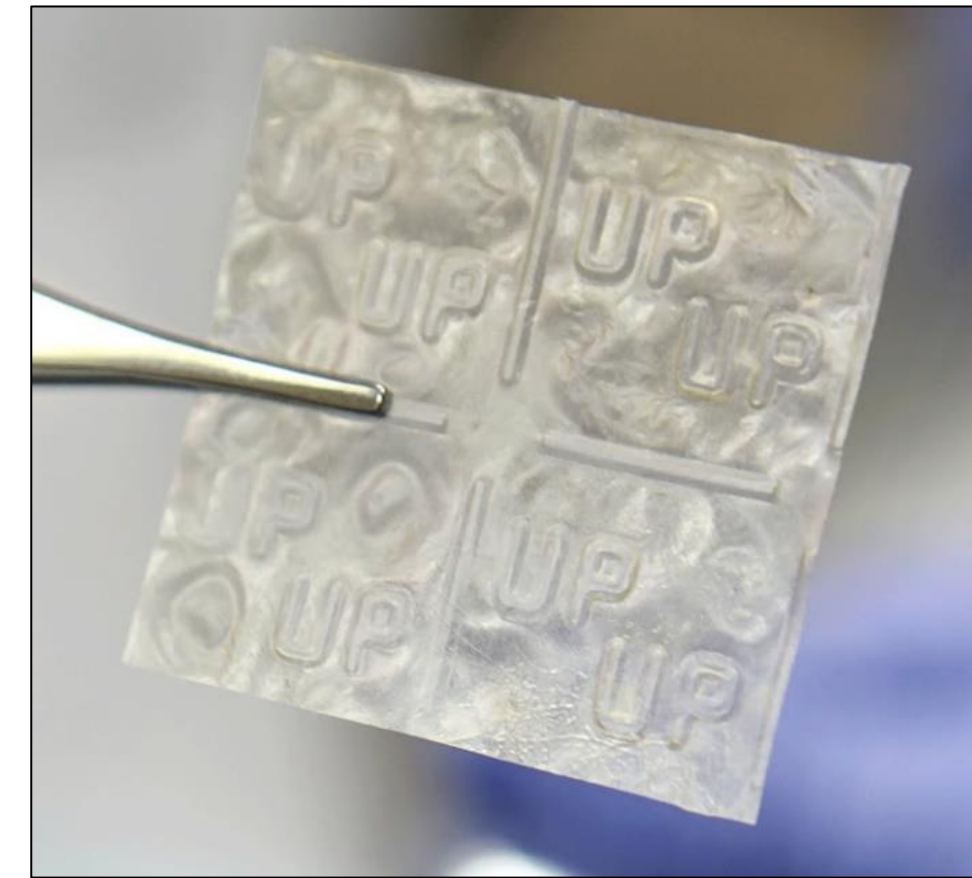
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Introduction

Extremity wounds with exposed critical structures (e.g. including periosteum-stripped bone, paratenon-stripped tendon) may lead to amputation unless durable soft tissue coverage is achieved.

Flap-based limb salvage (fLS) is the standard of care but requires:

- Trained reconstructive surgeon/microsurgeon
- Long operative times
- Extensive post operative monitoring
- High associated cost
- Significant failure rate
- Failure necessitates another flap or amputation



An alternative technique is regenerative limb salvage (rLS) using dehydrated human amnion/chorion membrane (dHACM) + skin grafting

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

IRB approved multicenter prospective RCT enrolling patients from 2016 and 2018

48 subjects with complex extremity wounds (> 1 exposed critical structure)

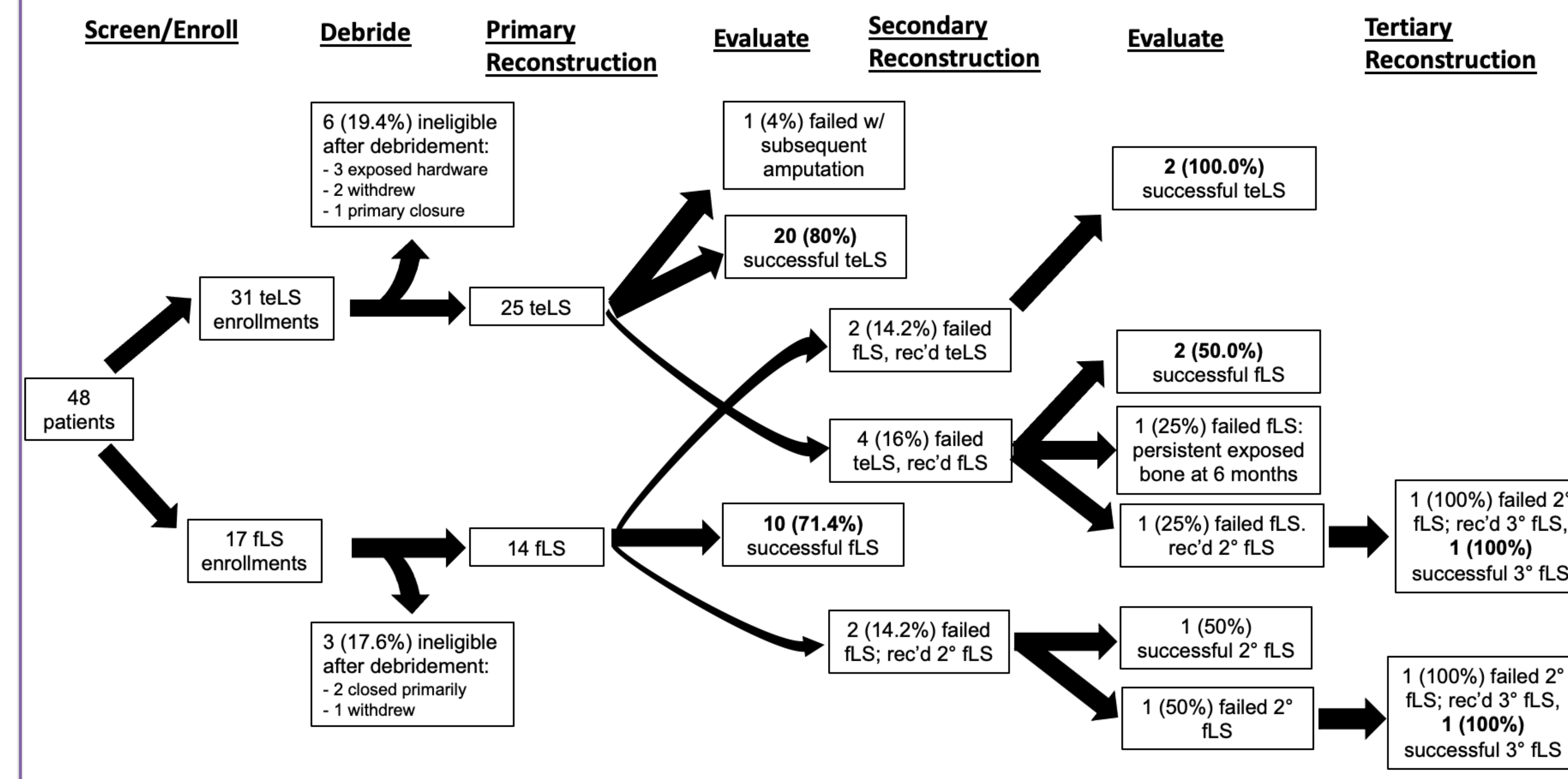
Exclusion criteria: malignancy, exposed hardware, poor lap candidates (ischemic limb, PVD)

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

Primary outcomes included:

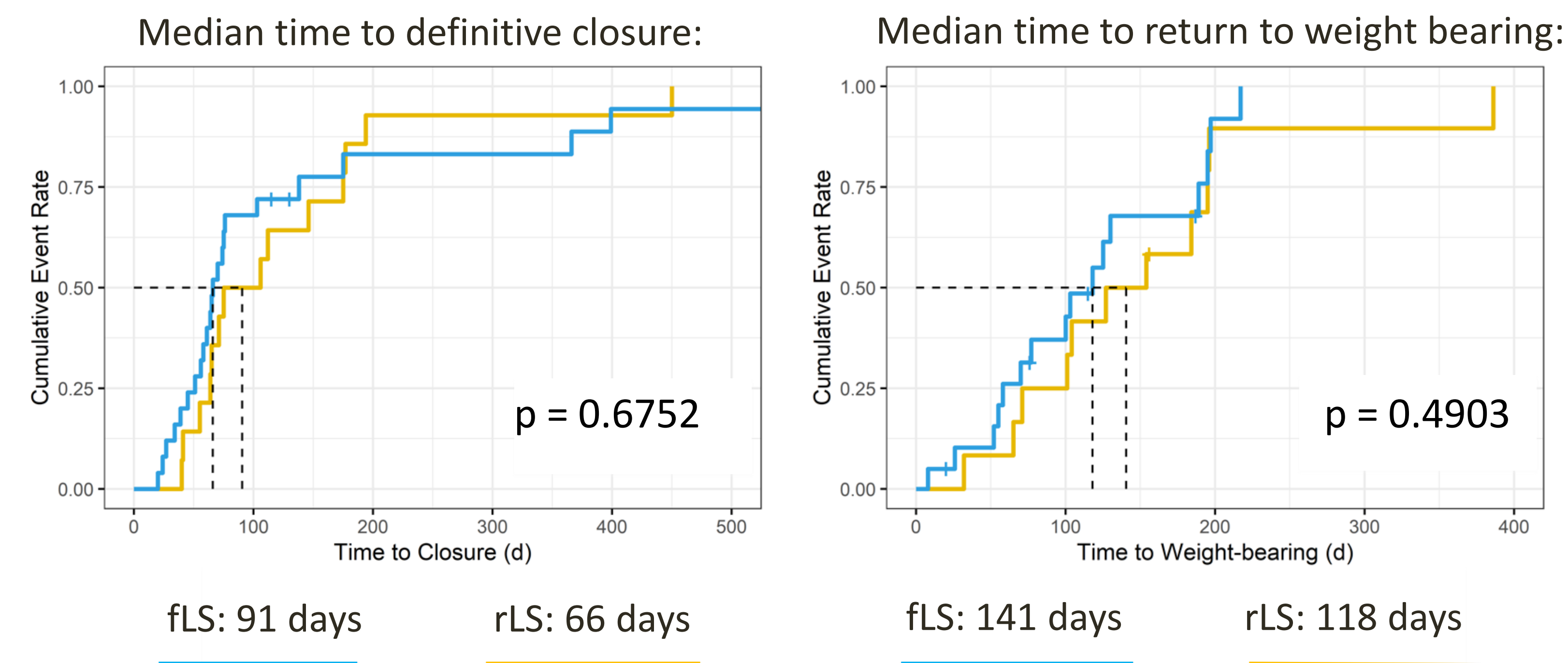
- Success rate of reconstruction
- Persistence of exposed structures at 6mo
- Time to return to weight bearing
- Time to definitive closure

Methods



Results

	fLS (n=14)	teLS (n=25)	p-value
Success Rate, n (%)	10 (71.4)	20 (80.0)	1.000
Persistent Exposed Structures 6mo, n (%)	0 (0)	1 (4)	1.000



Results



Wound of the plantar aspect of the foot with exposed tendon treated with dHACM + skin grafting A) At time of presentation B) Post-debridement and dHACM application C) Wound bed 5 days post treatment D) Wound bed after skin grafting E) 1.5 years post injury

Conclusions

- Success rate of rLS equivalent to conventional fLS
- Comparable time to definitive closure and return to weight bearing
- 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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