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

Results

<table>
<thead>
<tr>
<th></th>
<th>fLS (n=14)</th>
<th>rLS (n=25)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Success Rate, n (%)</td>
<td>12 (85.71)</td>
<td>20 (80)</td>
<td>1.0000</td>
</tr>
<tr>
<td>Persistent Exposed Structures, n (%)</td>
<td>0 (0)</td>
<td>1 (4)</td>
<td>1.0000</td>
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</tbody>
</table>

Time to Definitive Closure

Median:
- fLS: 91 days
- rLS: 66 days

p = 0.3752

Time to Weight Bearing

Median:
- fLS: 141 days
- rLS: 118 days

p = 0.4903

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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