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

Introduction

Complex extremity wounds present unique challenges to the reconstructive surgeon. Flap-based limb salvage (fLS) is the standard of care for achieving durable coverage of exposed bone and tendon, but this approach is resource intensive. An alternative technique is regenerative limb salvage (rLS) using dehydrated human amnion/chorion membrane (dHCCAM). We previously reported successful rLS case series in adults and children. 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. Patients were randomized to fLS or rLS in a 1:2 ratio. Primary outcomes included a composite endpoint comprising successful reconstruction, time to definitive closure, and time to weight bearing.

Results

Following debridement, 39 subjects met inclusion criteria and were randomized to fLS (n=14) or rLS (n=25). Demographics and critical wound area were similar between groups: fLS median (IQR) 10 cm² (2.5-74.5) vs. rLS 9 cm² (2.5-20; p=0.59). Success of primary reconstruction (p=1.000), time to definitive closure (p=0.6752), time to weight bearing (p=0.4903) and complication rates (p=1.000) were similar between groups. The primary reconstructive method was successful for 85.7% of fLS patients and 80% of rLS patients (p=1.000).

Conclusion

This prospective RCT suggests that rLS is a viable alternative to traditional fLS . Since rLS requires fewer hospital resources and preserves flap options, it may be considered for limb salvage patients.