A Study Evaluating Cryopreserved Umbilical Tissue versus Bilayer Meshed Wound Dressing for Surgical Limb Salvage

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INTRODUCTION

Complex wounds are a therapeutic challenge for wound care providers. Bilayered meshed wound dressing (BMWD) was adapted for surgical treatment of complex wounds and used to induce granulation followed by skin grafting[1,2]. This approach, however, requires at least two surgeries.

Recently, cryopreserved umbilical cord tissue allograft (vCUT) became commercially available. vCUT retains the extracellular matrix, growth factors, endogenous neonatal stem cells, fibroblasts and epithelial cells of the native tissue and is indicated for use in the management of acute and chronic wounds[3]. In 2018, McGinness et al. retrospectively analyzed 10 patients with complex wounds as a result of gas gangrene who received one intraoperative vCUT application. All 10 patients achieved complete wound closure, with fewer complications and in a shorter amount of time compared to traditional inpatient management of gas gangrene[4].

In this study, we hypothesized that vCUT can be used as an alternative for surgical limb salvage in a single-staged procedure.

STUDY OBJECTIVE

The objective of this retrospective study is to evaluate and compare vCUT and BMWD in the surgical treatment of complex wounds.

STUDY DESIGN

- **19 patients with complex wounds** who were qualified for surgical treatment randomly received either one application of vCUT or BMWD intraoperatively (9 vCUT- and 10 BMWD-treated patients).
- Post-application, wounds were evaluated weekly. Patients were followed until closure.
- **Primary outcome**: 100% granulation (or mean time to granulation).
- Additional outcomes: time to STSG for eligible patients, the proportion of patients who achieved complete wound closure, time to complete wound closure, and the number of wound-related adverse events (AEs).
- Written informed consent was obtained from all patients before any study procedures were performed.
- Statistical Analysis: For continuous variables, descriptive statistics included the mean, standard deviation, median, and subject counts. For categorical variables, statistics included frequencies and percentages. Fisher's exact test was used to determine whether differences between groups were significant ($p<0.05$).

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RESULTS

Patient demographics and wound characteristics were balanced between two treatment groups

Table 1. Patient Demographics and Wound Characteristics

	vCUT (n=9)	BMWD (n=10)	*p* values
Mean age (years)	56.7 ± 10.5	61.5 ± 18.6	0.505
Gender (male, n, %)	5 (55.6%)	3 (30.0%)	0.370
Race (n, %)			
White or Caucasian	2 (22.2%)	1 (10.0%)	0.582
Black or African American	7 (77.8%)	9 (90.0%)	
Mean BMI	34.8 ± 9.5	26.8+/-7.2	0.053
BMI ≥ 30 (n,%)	5 (55.6%)	3 (30.0%)	0.370
Mean Glycated Hemoglobin	7.5 ± 1.7	7.14 ± 2.4	0.714
Mean baseline wound size (cm^2)	24.9 ± 21.7	63.4 ± 63.0	0.100
Mean Baseline wound volume	9.9 ± 7.13	69.9 ± 110.5	0.123

Patient co-morbidities included: DM, HTN, HLD, CKD, CHF, ESRD
Wound etiologies included: DFUs, VLUs, PU, arterial, surgical and mixed. Wound locations included: dorsal, plantar, lateral, toe and heel, ankle, TMA site, 5th ray amputation site, leg.

Clinical and Safety Outcomes

No statistically significant differences were found between two treatment groups

- A mean time to 100% granulation was 68 days (n=8) and 43.1 days (n=9) in the vCUT and BMWD groups, respectively.
- Wound closure in patients without STSG was 67% (4/6) with mean of 100.5 days to closure versus 20% (1/5) with 232 days to closure in vCUT and BMWD, respectively.
- Two vCUT patients and 5 BMWD patients received a STSG.
- Time to discharge ranged from 48 to 232 days.
- There were 3 and 1 wound-related infections in the vCUT and BMWD groups, respectively.
- There were 2 and 1 wound-related amputations in the vCUT and BMWD groups, respectively.

ABBREVIATIONS

BMWD: bilayer meshed wound dressing; CHF: congestive heart failure; CKD: chronic kidney disease; DFU: diabetic foot ulcer; DM: Diabetes Mellitus; ESRD: end-stage renal disease; HLD: hyperlipidemia; HTN: hypertension PU: pressure ulcer; TMA: transmetatarsal amputation; vCUT: viable cryopreserved umbilical tissue; VLU: venous leg ulcer

REPRESENTATIVE CASES

vCUT CASE

Pre-vCUT application

vCUT patient healed at 64 days

49 year old male with a chronic 3.15 cm^2 DFU and medical history of DM, CKD, HTN, and HLD received intraoperative application of vCUT. **Granulation was achieved at 43 days. Closure was achieved at 64 days.**

BMWD CASE

Pre-BMWD application

BMWD patient healed at 89 days

43 year old female with a 13.95 cm^2 DFU at the 5th ray amputation site and a medical history of DM, HTN, and ESRD received intraoperative application of BMWD. **Granulation was achieved at 40 days. Closure was achieved at 89 days.**

CONCLUSION

In conclusion, vCUT is a good alternative to BMWD for limb salvage in lower extremity complex wounds. Single intraoperative application of vCUT may induce granulation over exposed deep structures without further surgical intervention or skin grafting.

REFERENCES

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