



Clinical Use of NEOX® CORD 1K® as an Adjunct Therapy in Promoting Healing of Complex Wounds with Osteomyelitis

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The application of cryopreserved umbilical cord to complex chronic wounds that have exposed bone and tendon to help save digits and limbs from amputation.

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CORD 1K

INTRODUCTION

Treating lower extremity ulcers with exposed bone, tendon, muscle, and/or joint capsule with underlying osteomyelitis presents a considerable clinical challenge. These wounds often present with multiple complex comorbidities, and understanding which patients require hospitalization, antibiotic therapy, and operative intervention is critical to preventing major limb amputation.¹⁻³

Cryopreserved Umbilical Cord* (cUC) has emerged as a promising adjunct therapy option for complex wounds with underlying osteomyelitis. The present clinical study examines the results of cUC in treating chronic complex wounds complicated by osteomyelitis as a strategy for limb preservation.

METHODS

Clinical Data Retrieval

Following IRB approval, a retrospective chart review was performed of 31 patients presenting with 33 wounds with a confirmed diagnosis of osteomyelitis managed by the same surgeon (WC) between January 2013 and December 2014 (Table 1). Patient demographic information including significant co-morbidities, prior treatment modalities, and ulcer duration was collected. In addition, weekly measurements and photographs monitoring wound progression following cUC application were also retrieved to document the ulcer changes during the entire follow-up period (Table 2).

Wound Management

All ulcers underwent sharp surgical debridement and resection as needed. The exposed bone received an open cortex procedure⁴ to create ~3 equidistant holes through the cortical bone to access the underlying multipotent cells and the surgical wound was completely covered by cUC. All patients were discharged from the hospital if they were clinically stable, followed up weekly, and received additional application of cUC if necessary.

RESULTS

Of 33 wounds identified, 26 achieved complete healing, resulting in an overall wound healing rate of 78.8%. Five wounds were lost to follow-up, and one patient expired during the course of treatment. For the remaining 27 wounds that were not lost to follow-up, the healing rate was 96.3% (26/27). For wounds that healed, the mean time to wound closure was 16.02 ± 8.99 weeks (Figure 1 and 2) and the average number of applications of cUC was 1.24. In addition, following the initial patient evaluation, a total of 15 wounds in the study were recommended for amputation prior to treatment with cUC with only one wound going on to receive a BKA.

Gender	Male	26 (83.9%)
	Female	5 (16.1%)
Age	Median	57 (range: 35-90)
	Mean	58.3 ± 12.9
Ethnicity	Caucasian	12/31 (38.7%)
	African-American	10/31 (32.3%)
	Hispanic	6/31 (19.3%)
	Other	3/31 (9.7%)

Table 1: Patient Demographics

Initial wound area	$15.60 \pm 17.56 \text{ cm}^2$	
Wound duration	4 weeks – 1 year 7 months	
Wound exposure	Muscle, tendon, ligament, bone	27/33 (81.8%)
Osteomyelitis	33/33 (100%)	
Co-morbidities	Diabetes	26/31 (83.9%)
	Hypertension	23/31 (74.2%)
	Peripheral Vascular Disease	16/31 (51.6%)
	Renal Failure	12/31 (38.7%)
	Ischemia in affected limb	24/33 (72.7%)
	Gangrene	17/33 (51.5%)

Table 2: Wound Characteristics

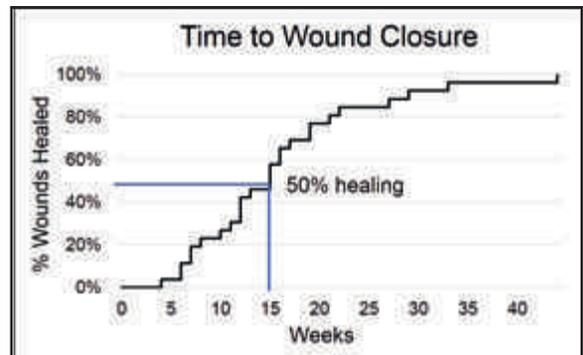


FIGURE 1. Time to Wound Closure

For wounds achieving complete closure, an analysis was performed on the total time to healing.

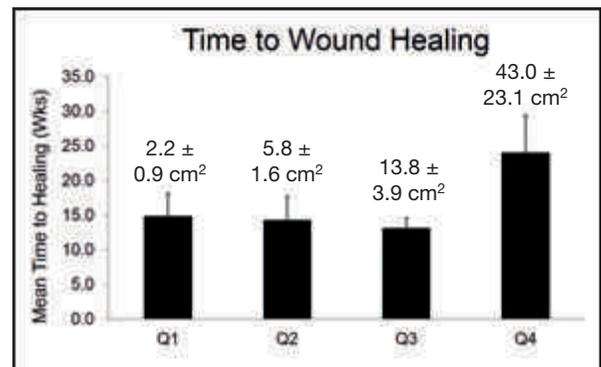


FIGURE 2. Initial Wound Area Effect on Wound Closure Time. Wounds were divided into quartiles based on initial wound area. Although there was a significant difference in initial wound size, there is no difference in the mean time to achieve wound closure, $p > 0.05$, when compared among the four quartiles.

The data suggest the application of Cryopreserved Umbilical Cord helps manage the wound closure of complex foot ulcers with exposed tendon, muscle, joint capsule, and/or bone with osteomyelitis.



CASE STUDY

A 63 year-old male with Type I diabetes and PVD presented with an open wound following right partial foot amputation. In addition to osteomyelitis, gangrene was present on the affected limb. The wound received sharp surgical debridement, open cortex procedure, and an application of cUC. Seven weeks post-cUC application, wound area was reduced by 44%. At 8 weeks, the wound received an additional application of cUC. The wound continued to show improvement, and achieved complete epithelialization and wound closure at 16 weeks from initial product application.

CONCLUSION

The data suggest Cryopreserved Umbilical Cord is effective in promoting wound healing of complex foot ulcers with exposed tendon, muscle, joint capsule, and/or bone with underlying osteomyelitis to avoid or to reduce the extent of limb amputation. These encouraging retrospective results warrant further investigation with prospective, randomized controlled trials to better understand the clinical and economic implications of this novel tissue therapy.

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