

Clinical Use of Neox[®] 1K as an Adjunct Therapy in Promoting Healing of Complex Wounds with Osteomyelitis*

Demonstrating 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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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. This clinical study examines the results of cUC in treating chronic complex wounds complicated by osteomyelitis as a strategy for limb preservation.

Representative Case demonstrating cUC efficacy in this retrospective study

IN 15 WEEKS

FROM HERE...



TO HERE.



A 63 year-old male with Type I Diabetes and PVD presented with an open wound in the midfoot following right partial foot amputation. In addition to osteomyelitis, gangrene was present on the affected limb.

This Retrospective Study Examined the Effectiveness of cUC Application in Aiding the Healing of Chronic DFUs

Methods

Clinical Review Data

Following IRB approval, a retrospective chart review was performed on 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 comorbidities, prior treatment modalities, and ulcer duration was collected. In addition, weekly measurements and photographs monitoring wound progression following cUC (Neox 1K) application were also retrieved to document the ulcer changes during the entire follow-up period (Table 1).

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 (Neox 1K). All patients were clinically stable. Patients were then followed-up with weekly, and received additional application of cUC (Neox 1K) if necessary.

Table 1. Patient demographics and wound summary

Gender	Male	26 (83.9%)
	Female	5 (16.1%)
Age	Median	57 (range: 35-90)
	Mean	58.3 ± 12.9
Race	Caucasian	12/31 (38.7%)
	African-American	10/31 (32.3%)
	Hispanic	6/31 (19.3%)
	Other	3/31 (9.7%)
Significant comorbidities	Diabetes	26/31 (83.9%)
	Hypertension	23/31 (74.2%)
	Peripheral vascular disease	16/31 (51.6%)
	Renal failure	12/31 (38.7%)
	Coronary artery disease	9/31 (29%)
	Ischemia in affected limb (wounds)	24/33 (72.7%)
	Gangrene (wounds)	17/33 (51.5%)
Initial wound area	15.6 ± 17.7 cm ²	
Wound duration	3 weeks-1 year 7 months	
Wound exposure	Muscle, tendon, ligament, bone	27/33 (81.8%)
Osteomyelitis	33/33 (100%)	
Concomitant treatments	Hyperbaric oxygen	6/33 (18.2%)
	rhPDGF gel	1/33 (3%)
Wounds healed	26/33 (78.8%)	
Avg time to healing	16.02 ± 9.25 weeks (range: 4-44 weeks)	
Avg # applications of cUC	1.24 ± 0.44	

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 the average number of applications of cUC (Neox 1K) 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 (Neox 1K) with only one wound going on to receive a BKA.

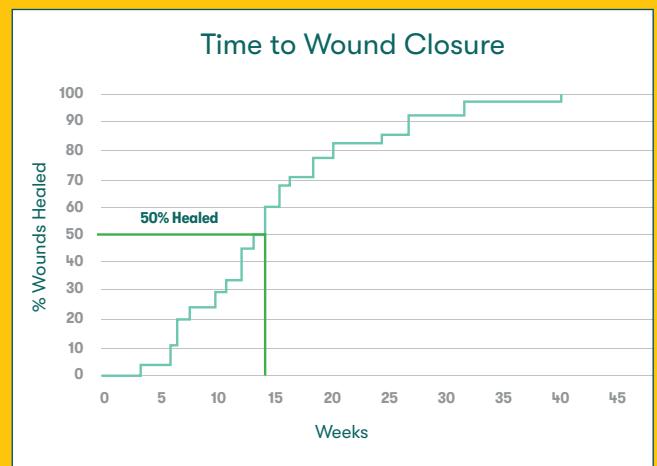


FIGURE 1. Time to Wound Closure
For wounds achieving complete closure, an analysis was performed on the total time to healing.

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

First Ray Amputation

A 63 year-old male with Type I diabetes and PVD presented with an open wound in the midfoot following right partial foot amputation. In addition to osteomyelitis, gangrene was present on the affected limb (FIG. 1). Following sharp surgical debridement and open cortex procedure (FIG. 2), cUC (Neox 1K) was applied directly over the wound bed (FIG. 3).

At 7 weeks, the wound showed a 44% reduction in the surface area (FIG. 4). At 9 weeks, a second cUC (Neox 1K) was applied after sharp debridement and open cortex procedure (FIG. 5).

The wound showed continuous healing at 11 weeks (FIG. 6) and went on to complete healing at 15 weeks (FIG. 7). The wound remained healed with no recurrence at 28 weeks after the initial cUC (Neox 1K) application (FIG. 8).



FIG. 1
Initial wound

FIG. 2
After debridement

FIG. 3
First Neox 1K
application

FIG. 4
Wound at 7 weeks

FIG. 5
Second Neox 1K
application

FIG. 6
Wound at 11 weeks

FIG. 7
Complete healing
at 15 weeks

FIG. 8
No recurrence
at 28 weeks

Conclusion

The results suggest that cUC used as an adjunct tissue therapy in conjunction with surgical debridement, resection of infected bone, open cortex, and antibiotic treatment may be an effective overall treatment strategy to promote wound healing of complex foot ulcers associated with osteomyelitis.

A total of 26 wounds achieved complete wound closure as evidenced by complete epithelialization, resulting in an overall healing rate of 78.8%. Following initial treatment and application of cUC, five patients were lost to follow-up and one patient expired due to causes not believed to be related to the study product.

For the 27 wounds not lost to follow-up, the overall healing rate was 96.3% (26/27). For the 26 wounds that completely healed, the average time to wound closure was 16.0 ± 9.3 weeks (range: 4–44 weeks). Twenty-one of the 26 wounds which healed received a single application of cUC, and two applications of cUC were needed to achieve healing of the remaining five wounds, with the second application occurring between four and 10 weeks after the initial application.

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