

A Single-Center, Retrospective Study of Cryopreserved Umbilical Cord/Amniotic Membrane Tissue for Wound Repair in Patients Suffering from Diabetic Foot Ulcers

Demonstrating the effectiveness and safety of cryopreserved Umbilical Cord (cUC) used in patients diagnosed with Diabetes Mellitus and suffering from chronic diabetic foot ulcers.

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Introduction

Diabetic Foot Ulcers (DFUs) are a major complication of diabetes mellitus that develop in approximately 10-15% of patients throughout their lifetime.¹ DFU patients will spend more than double on medical expenses per year than the average person.² Unsuccessful treatment is responsible for roughly 80% of all diabetes-related lower-leg amputations.³

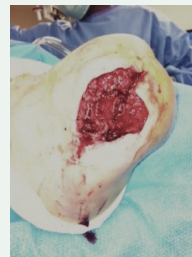
Wound healing is an innate physiological process that involves inflammation and tissue remodeling of the extracellular matrix.⁴ In pathological states, including underlying disease or local physiological insults, the wound repair process is altered and wounds become chronic. Diabetes mellitus is one such metabolic disorder that impedes the normal steps of the wound healing process. Many histopathological studies show a prolonged inflammatory phase in diabetic wounds, which causes a delay in the formation of mature granulation tissue and a parallel reduction in wound tensile strength.⁵

An emerging adjunct to post-surgical debridement of the DFU is the application of cryopreserved Umbilical Cord† (cUC) as an advanced therapy for chronic, non-healing wounds, due to its ability to modulate the local inflammatory environment.

Representative Case inside demonstrating cUC efficacy in this retrospective study

IN 13 WEEKS

FROM HERE...



TO HERE.



A 50-year old male patient with Type 2 diabetes and neuropathy in the lower extremities underwent transmetatarsal amputation and presented with recurrent ulceration to the lateral column of the remaining foot.

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 conducted of patients presenting with one or more DFUs that had undergone wound debridement and at least one application of cUC by the study surgeon (AR, DPM). Patient data including gender, co-morbidities, and prior treatments were collected (Table 1). In addition, weekly wound measurements monitoring wound progression were retrieved to document ulcer changes during the entire follow-up period.

Inclusion Criteria

- 18-90 years of age
- Confirmed diagnosis of DFU
- Confirmed application of cUC
- Post-product application outcome measurements of wound size by total surface area (cm², length x width) and/or photographic evidence
- Identification of number of applications of cUC applied to wound

Exclusion Criteria

- Less than 4 weeks of post-surgical outcome measurements

Table 1. Patient demographics and wound summary

Age (n=29)	Median	51 (range: 35-76)
	Mean	52.97 ± 1.83
Gender (n=29)	Male	24/29 (82.76%)
	Female	5/29 (17.24%)
Significant comorbidities (n=29)	Diabetes	29/29 (100%)
	Neuropathy	15/29 (51.7%)
	Hypertension	10/29 (34.4%)
	Osteomyelitis	10/29 (34.4%)
Prior treatments (n=32)	Debridement	21/32 (65.6%)
	Off-loading	14/32 (43.8%)
	Silvadene	3/32 (9.38%)
Wound location (n=32)	Forefoot	15/32 (46.9%)
	Midfoot	11/32 (34.4%)
	Hindfoot/ankle	6/32 (18.8%)
Initial wound area (n=32)	10.6 ± 2.15cm ²	
Wounds healed (n=32)	28 (87.5%)	
Time to wound closure (n=32)	13.8 ± 1.95 weeks (median: 9 weeks)	
Avg # applications of cUC (n=32)	1.68 ± 0.18	

Results

29 patients with a total of 32 wounds were identified and included with an average initial wound area of 10.6 ± 2.15 cm².

Of those, 28 wounds achieved complete wound closure, resulting in an overall healing rate of 87.5%.

For those that healed, the average wound closure time was 13.8 ± 1.95 weeks with a median of 9 weeks, and the average number of applications was 1.68 ± .18 (Table 1).

The time to wound closure was plotted for all wounds that healed (Figure 1).

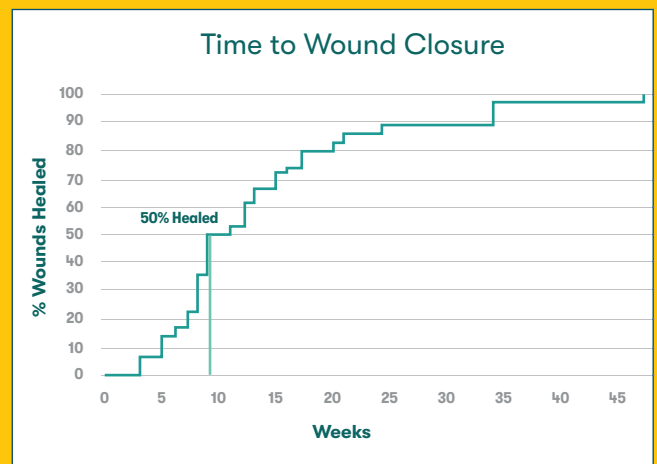


FIGURE 1. Time to Wound Closure

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

Cryopreserved umbilical cord may be effective as an advanced adjunct treatment modality to promote the healing of chronic diabetic foot ulcers.

Case Study

A Transmetatarsal Amputation with Recurrent Ulceration of the Lateral Column

A 50-year old male patient with Type 2 diabetes and neuropathy in the lower extremities underwent transmetatarsal amputation and presented with recurrent ulceration to the lateral column of the remaining foot.

Incision and drainage with partial metatarsectomy was performed on the presented wound (FIG. 1) with cUC (Neox 1K) application followed by negative pressure therapy (FIG. 2).

The wound began to shrink in size by week two post-operatively (FIG. 3) and at four weeks, the wound was approximately one-quarter of its original size. A second application of cUC (Neox 1K) was done at four-weeks after the initial application (FIG. 4).

The wound continued to reduce in area (FIG. 5 and FIG. 6) until complete epithelialization was reached at 13 weeks (FIG. 7).

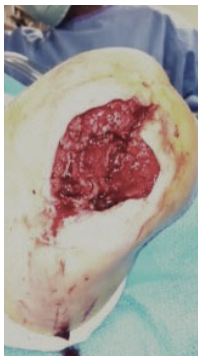


FIG. 1
Initial wound



FIG. 2
First Neox 1K
application



FIG. 3
Wound at 2 weeks



FIG. 4
Second Neox
application at
4 weeks



FIG. 5
Wound at 6 weeks



FIG. 6
Wound at 8 weeks



FIG. 7
Complete
epithelialization
at 13 weeks

Conclusion

Wound healing rates were higher than those published for the standard of care (87.5% vs. 24.2%)⁶ even with considerably larger average wound sizes (10.6 cm² vs. 2.80 cm²).⁷

Fewer applications of cUC were needed compared to a similar study assessing effectiveness of an amniotic membrane product for wound healing (1.68 vs. 6.00).⁸

The encouraging results of this retrospective study indicate that further investigation with prospective, randomized controlled trials to better evaluate the efficacy of cUC in treating chronic wounds is warranted.

With an average of only 1.68 applications of cUC necessary to achieve wound closure, these results also suggest that the use of cUC may reduce the overall cost burden associated with treatment of such wounds.

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