Cellular & Tissue-Based Products & the Diabetic Foot

Is there an association between application of cellular & tissue-based products and healing in diabetic foot ulcers?

Introduction & background

Cellular and tissue-based products (CTBP) have been demonstrated to improve the healing of chronic ulcers (Yonezawa et al. 2007) and specifically diabetic foot ulcers (Kirsner et al. 2013). The purpose of this analysis is to examine the association between healing and application of CTBP in a large sample of diabetic foot ulcers treated in Healogics Wound Care Centers®.

Sample & methods

The sample for this analysis includes all discharged wounds treated at Healogics Wound Care Centers in 2019. The analysis excludes consultations, wounds that were seen only once and those with missing data on key study elements. The study is limited to diabetic ulcers located on the foot or toe (DFU). The sample is also limited to single wound patient admissions in order to accurately associate the CTBP treatment with the correct treated wound and wound outcome. Further, we limited the analysis to wounds in treatment for at least 30 days, resulting in a final sample size of 12,046 wounds.

The outcome of interest was whether the wound healed. To measure the treatment, we created a dichotomous measure of receipt of at least one application of a CTBP.

Healogics®
The power to heal

Results

Of the wounds in the analytic sample, 8.5 percent had at least one CTBP application during the treatment period. Figure 1 displays the percentage of wounds that were in treatment for 30 days or more that healed by application of a CTBP. Wounds that had at least one application of a CTBP had a significantly higher healing rate ($p<0.05$).

Figure 1. Percent Healed by CTBP Utilization

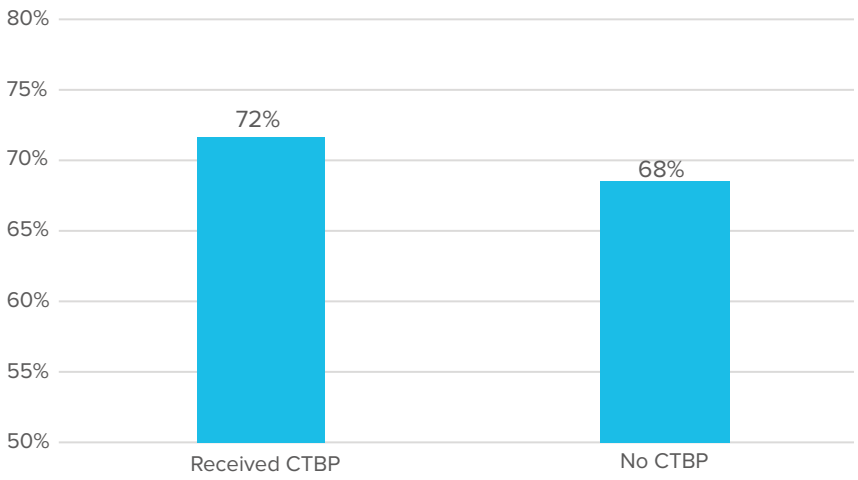

Table 1 displays the odds ratios from a binary logistic regression predicting healing. Across all DFU grades, the application of a CTBP is associated with a 16% higher odds of healing compared to wounds that did not receive a CTBP application, which is significant at $p<.05$ overall. When examining this effect across diabetic ulcer Wagner grades, it's only significant for wounds of Wagner grades 3 and 4. Wounds of Wagner grade 3 were 1.42x more likely to heal and wounds of Wagner grade 4 were 5.2x more likely to heal when given one or more CTBP applications.

Table 1. Odds of Healing when the patient received a CTBP versus no CTBP by grade of Diabetic foot ulcer.

DFU Grade	Odds Ratio	95% CI	
		Lower	Upper
Overall	1.16	1.01	1.34
Grade 1	1.08	0.83	1.43
Grade 2	0.99	0.80	1.25
Grade 3	1.42	1.01	2.03
Grade 4	5.20	1.94	18.16

Conclusion

The purpose of this analysis was to measure the association between healing and CTBP application in a large sample of diabetic foot ulcers. As in previous studies, the results of the analysis suggest that application of a CTBP increased the probability of DFU healing, particularly in wounds of Wagner grades 3 and 4. However, CTBP application was only measured as a binary outcome, and additional analysis is needed to understand the impact on healing by the timing of CTBP application, product type and the total number of applications.

References:

Kirsner, Robert S., Michael L. Sabolinski, Nathan B. Parsons, et al. 2015. Comparative effectiveness of bioengineered living cellular construct vs. a dehydrated human amniotic membrane allograft for the treatment of diabetic foot ulcers in a real world setting. Wound Repair and Regeneration 23: 737-744.

Yonezawa, Masao, Hideaki Tanizaki, Naoko Inoguchi, et al. 2007. Clinical study with allogenic cultured dermal substitutes for chronic leg ulcers. International Journal of Dermatology 46: 36-42.