

EPIFLO® (TCOT) STUDY OVERVIEW

A Prospective, Randomized, Blinded, Controlled Trial Comparing Transdermal Continuous Oxygen Therapy (TCOT) to Moist Wound Therapy for the Treatment of Diabetic Foot Ulcers

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THE ROLE OF OXYGEN IN WOUND HEALING

The role of oxygen in regard to wound healing is well known. While mild hypoxia may stimulate angiogenesis and wound repair, hypoxia, commonly encountered in chronic wounds, impairs wound healing. Case series and randomized controlled clinical trials regarding healing of wounds with topical oxygen therapy suggest improved wound healing and/or reduction in bacterial burden.

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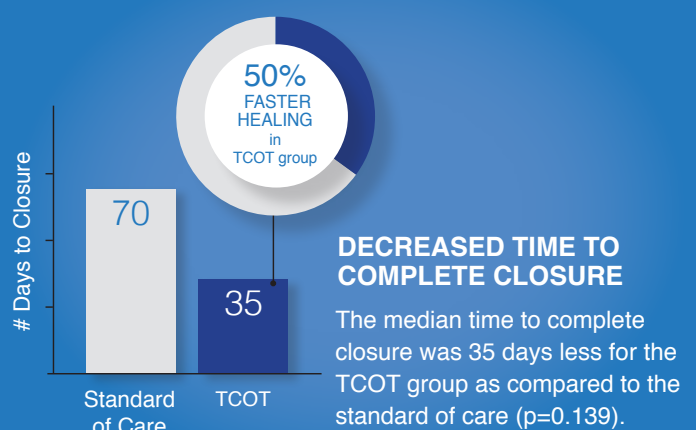
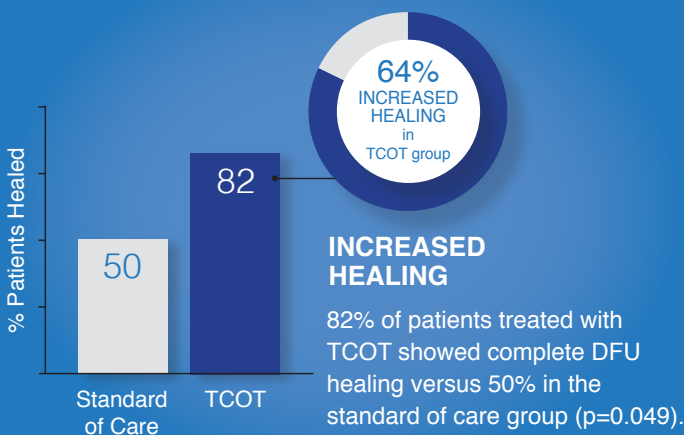
Transdermal continuous oxygen therapy (TCOT) is the continuous delivery of a very low dose (3 mL/hour) of 98%+ pure oxygen directly to the wound site allowing uninterrupted treatment. Because of the very low flow rate, the wound does not dry out and a moist wound healing environment is maintained.

STUDY RESULTS

This was a prospective, randomized, blinded, multicenter, parallel study comparing TCOT with moist wound therapy (MWT) to MWT alone (standard of care) in the treatment of chronic diabetic foot ulcers (DFUs). Of the 130 study participants enrolled into the study safety population, 128 were classified as the intent-to-treat population: 65 in the TCOT group and 63 in the standard of care group, with 61 from each group in the per protocol (PP) population. Wound evaluations, debridement, and treatment occurred once weekly until the wound healed or up to 12 weeks. In the PP population, 34 out of 61 TCOT-treated subjects (56%) had completely healed wounds compared to 31 out of 61 (51%) in the standard of care group. The TCOT group also showed an increase in the healing rate starting at week 3 which continued to outpace the healing rates of the standard of care group until week 10 of the 12-week study.

SUBSET DATA FOR PATIENTS: 65 YEARS OF AGE OR OLDER

The stratification of patients into subgroups allowed for study results to be observed in patients 65 years of age or older. In this group, increased healing and a decreased time to closure were both observed.



CONCLUSION

Within the sub-population of Medicare beneficiaries over 65, 25.8% suffer from diabetes with the incidence of DFUs averaging 8%. The costs associated with diabetes complications—such as treating and managing chronic wounds—are staggering.^{1,2}

TCOT provides a cost-effective and portable option for oxygen therapy for chronic wound treatment. This study suggests that TCOT can increase healing and reduce time to complete closure in older patients suffering from DFUs.

REFERENCES

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- Margolis D, Malay DS, Hoffstad OJ, et al. Prevalence of diabetes, diabetic foot ulcer, and lower extremity amputation among Medicare beneficiaries, 2006-2008. Data Points #1. Rockville, MD: Agency for Healthcare Research and Quality (AHRQ); 2011. *Data Points Publication Series* [Internet]. AHRQ Publication No. 10(11)-EHC009-EF.