

# Effectiveness of Continuous Diffusion of Oxygen Adjunct Therapy to Improve Success Rate of Lower Extremity Surgically Closed Wound

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## OBJECTIVE

TO ASSESS THE USEFULNESS OF CONTINUOUS OXYGEN DIFFUSION TO BOOST HEALING PROCESS OF SURGICALLY CLOSED WOUNDS

## INTRODUCTION

- Significance & Impact:** Surgical wound complications such as tissue necrosis, infection, and dehiscence are highly prevalent in diabetic patients undergoing podiatric open interventions<sup>1,2</sup>.
- Tissue necrosis delay healing and prolong the inflammatory response, impeding re-epithelialization<sup>3</sup>.
- Gaps:** Currently there is no known therapy to reduce likelihood of tissue necrosis.
- Premise:** Level of transcutaneous oxygen could be a determinant factor in formation of tissue necrosis<sup>4</sup>. Thus a new method to improve surgical wound oxygenation may reduce likelihood of tissue necrosis.
- Our specific aim:** We proposed a proof of concept randomized control trial to examine effectiveness of a new dressing (TransCu O2®, O2 Concept, TX, Fig. 1) that supports continuous oxygen delivery (CDO) to the surgical site. We hypothesize that CDO is effective to accelerate wound healing process, reduce likelihood of tissue necrosis, and improve vascular factors in people with diabetes undergoing lower extremity minor amputations.

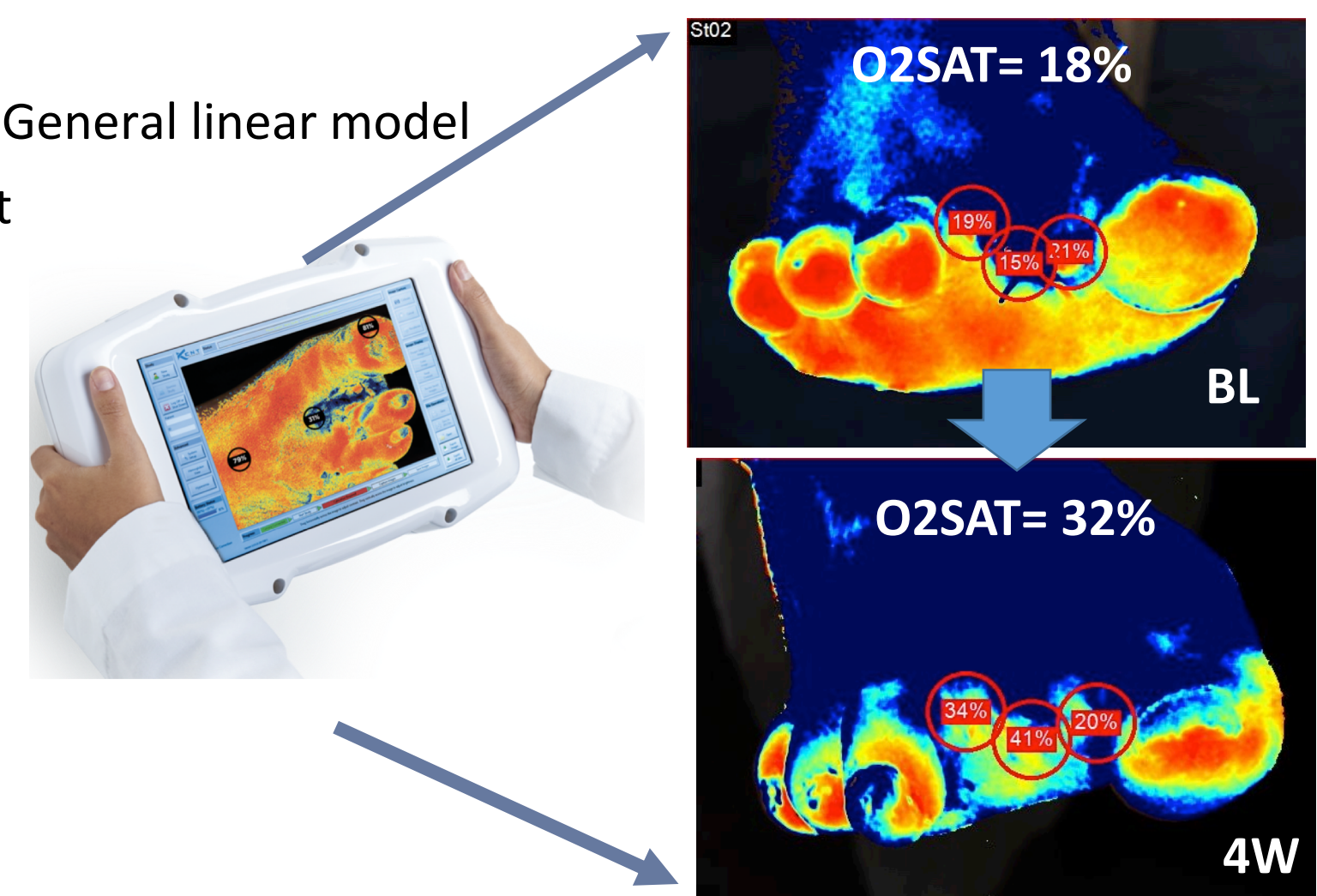
**Figure 1:** TransCu O<sub>2</sub>® Portable O<sub>2</sub> Delivery System (EO<sub>2</sub> Concepts, San Antonio, TX) for CDO



## MATERIALS & METHODS

- Study design:** RCT (N=19) of patients undergoing foot open surgery
- Control Group** (n = 7): standard of care
- Intervention Group** (n = 11): standard of care plus TransCu O<sub>2</sub>® device
- Duration: **4 weeks**
- Criteria**
- Inclusion:** 18-85 yrs diabetic patients, presence of a surgically closed wound due to minor lower extremity amputation.
- Exclusion:** Charcot arthropathy, major amputation, osteomyelitis, extreme gangrene, or excessive lymphedema
- Outcomes**
- Primary:** Necrosis, dehiscence, change in incision size.
- Secondary:** Tissue oxygen level quantified by SatO<sub>2</sub> (Fig. 2), % wound reduction at 4 wks.
- Statistical Analysis:** General linear model (repeated measures) test

**Figure 2:** Kent imaging. Utilizes short wavelength near infrared light to determine tissue oxygen saturation (SatO<sub>2</sub>) by detection of hemoglobin.

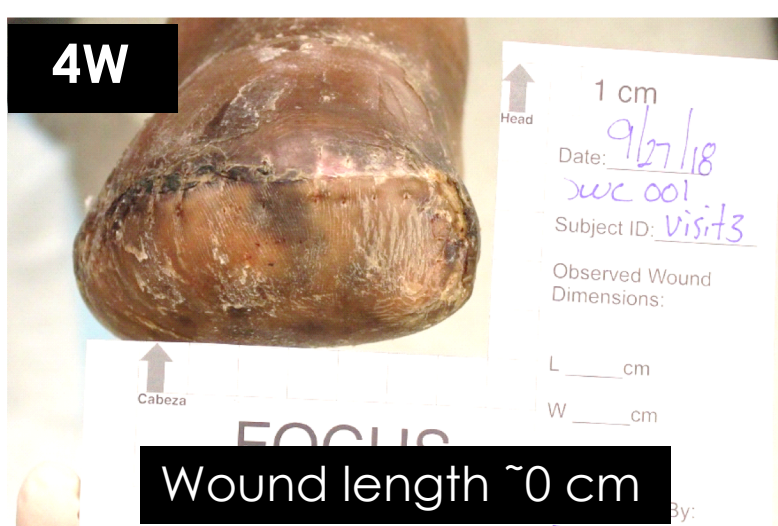


## RESULTS & FINDINGS

### Two typical intervention cases:

#### Cases

**Case 1:**  
-Procedure: TMA  
-Inpatient: 4d  
-Comorb: DM, HBP, CKD, HLP,  
-Daily meds: 5



#### Outcomes

Wound reduction: 100%  
AE: 0

**Case 2:**  
-Procedure: Hallux Amp  
-Inpatient: 9d  
-Comorb: DM  
-Daily meds: 7



Wound reduction: 100%  
AE: 0

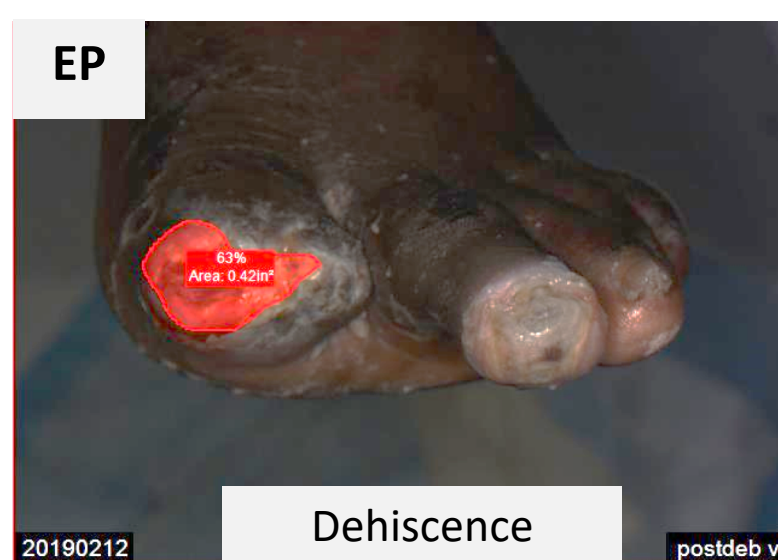
### Two typical control cases

**Case 3:**  
-Procedure: Toe(s) AMP  
-Inpatient: 13d  
-Comorb: HBP, CVD  
-Daily meds: 7

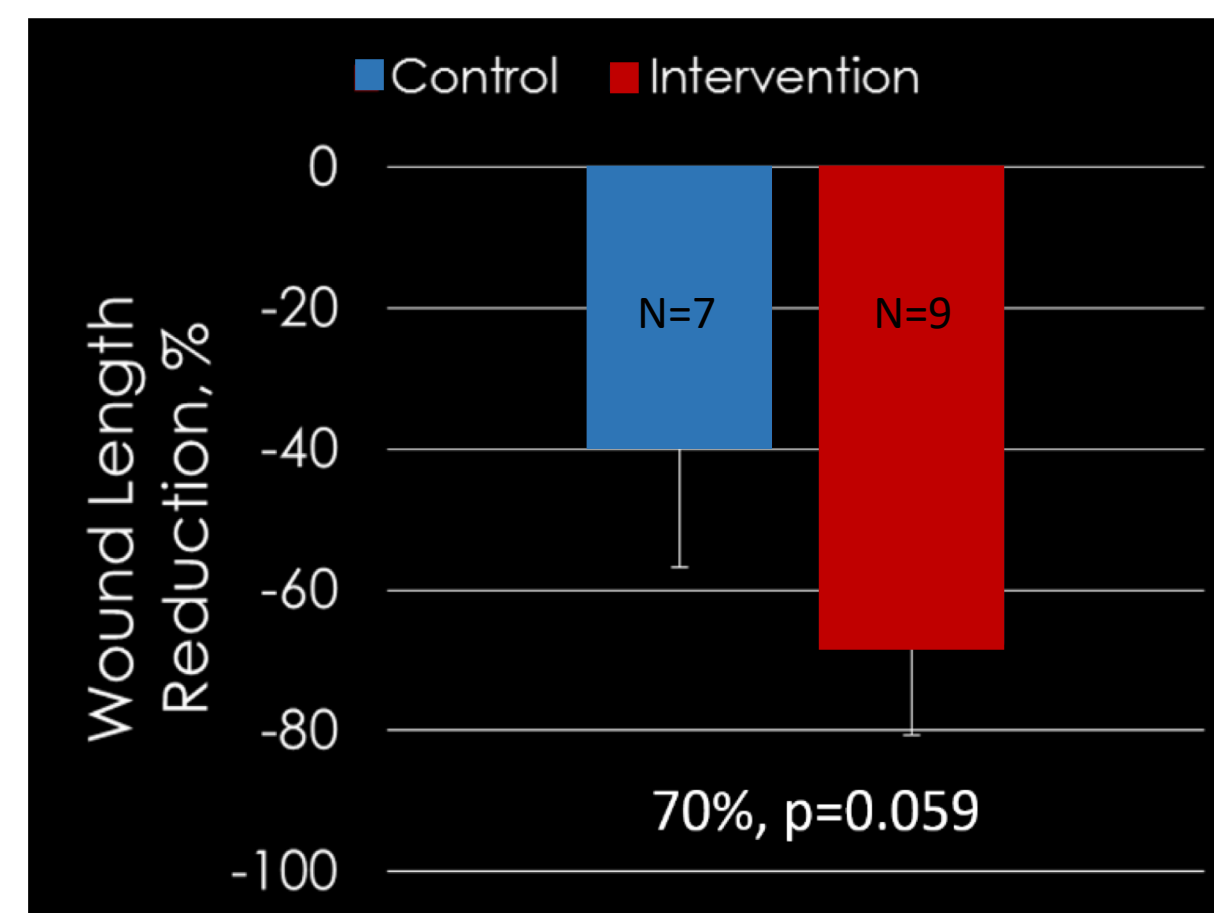
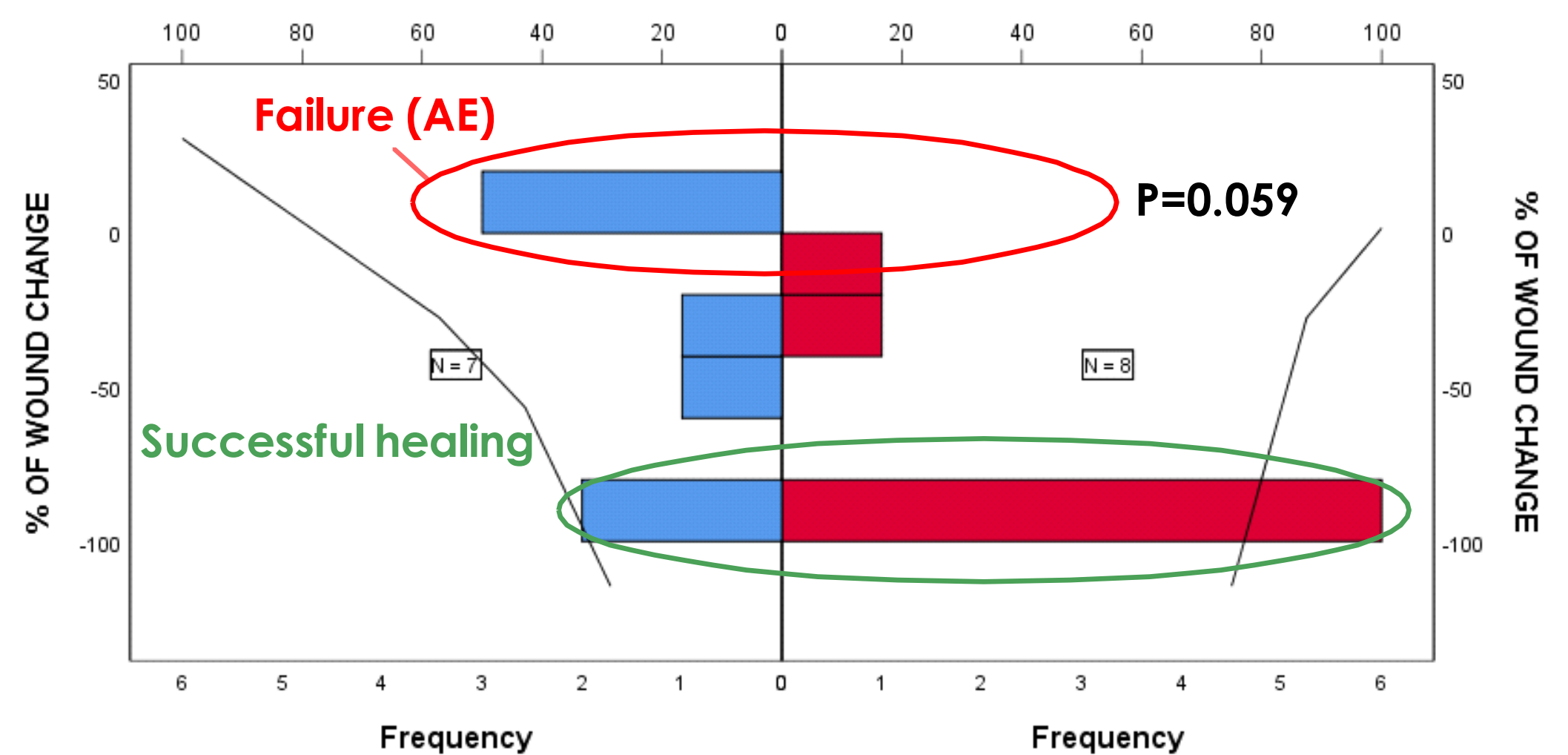


Wound reduction: 0%  
AE: Necrosis  
Dehiscence

**Case 4:**  
-Procedure: Toe(s) AMP  
-Inpatient: 12d  
-Comorb: DM, HBP, CVD,  
-Daily meds: 7



Wound reduction: 0%  
AE: Necrosis  
Dehiscence



At 4-week, incision length reduction was 70% higher in the IG

#### Summary

- Incident of tissue necrosis:** 43% (n=3) in CG v. 0 in IG
- Successful healing:** 75% in IG v. 29% in CG (p=0.059)
- Wound length reduction:** 70% higher in IG v. to CG (p=0.059)
- Others:** 2 IG cases (18%) reported saturated dressing which led to revision of protocol dressing.
- After revision, no adverse events were reported.

## DISCUSSION & CONCLUSION

- This is the first study reporting potential effectiveness of CDO in improving surgically closed wound outcomes for diabetic patients.
- The results support proof of concept feasibility, acceptability and noticeable trend in favor of CDO to accelerate healing in surgically closed wounds and reduce like hood of AEs.

## REFERENCES

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