Comparison of Copper Oxide Dressings (COD) to Negative Pressure Wound Therapy (NPWT)

Preliminary results of wound healing parameters in a randomized controlled trial

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Introduction

Negative Pressure Wound Therapy (NPWT) is the standard of care for treating large and deep wounds, with randomized control trials (RCT) favoring its use to fill the deep cavities and enhance wound closure. Copper Oxide Dressings (COD) have been recently introduced into clinical practice due to their antimicrobial properties. Basic science research and clinical experience showed their positive effect also in inducing wound healing, including stimulation of autolytic debridement, granulation tissue formation and epithelization.

Method

We initiated a randomized controlled trial with 60 diabetic patients comparing the reduction of wound size during 3 months of treatment between COD management to NPWT, as the primary end point, by using an artificial intelligence program (Tissue Analytics, TA).

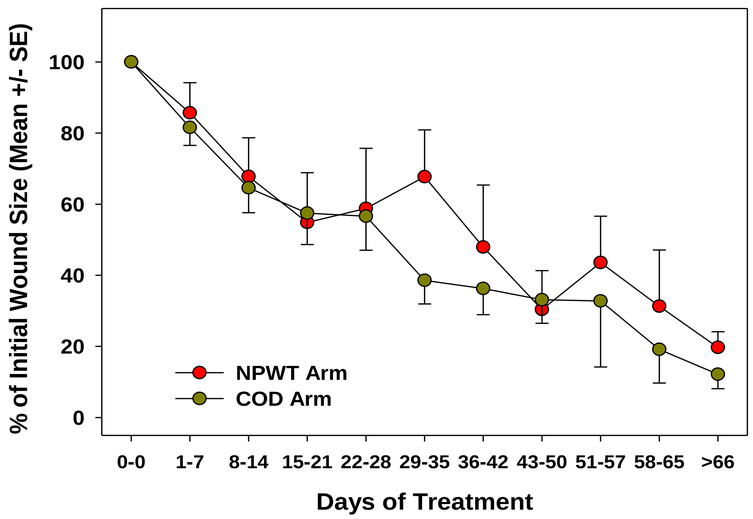
Results

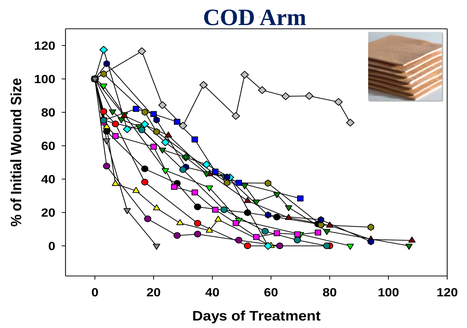
29 patients have finished the study. Of the 14 patients in the NPWT arm, 5 dropped from the study, 4 due to worsening foot condition and 1 due to his general health condition. All 15 patients in the COD arm completed the study. Average wound area was 21.02±23.36 cm^2 in the COD arm and 14.84±13.17 cm^2 in the NPWT arm (p=0.41). Reduction of wound size assessed by TA was 61.5% and 41% (p=0.04) after 1 month, 80.9% and 69% (p=0.28) after 2 months, and 88% and 84% (p=0.17) after 3 months, in the COD and NPWT arms, respectively. 7 wounds (46.7%) were closed in the COD arm and 4 wounds (28.6%) were closed in the NPWT arm. The average time to closure the wounds was 60.14 and 77.75 days in the COD and NPWT Arms, respectively (p=0.18). COD therapy was statistically significantly more convenient (Visual Analog Score [VAS] was 8.44 vs. 5.33; p=0.002) and less painful (VAS was 1.15 vs. 2.19; p=0.67) to the patients in the COD arm than in the NPWT arm. The medical personnel scored COD application as more convenient than the NPWT application (8.29 vs. 6; p=0.007). The mean application time was shorter for the COD compared to the NPWT (8.5 vs. 13.25 minutes; p<0.001). Cost is estimated to be ~15% in the COD Arm compared to NPWT Arm.

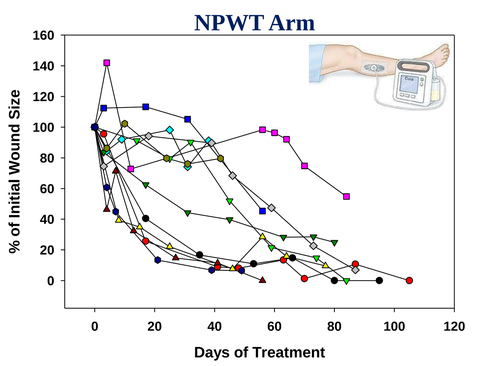
Conclusions

The preliminary results of this RCT study indicate statistically significant non-inferiority of COD dressing therapy compared to NPWT in terms of wound healing rate and superior results in terms of convenience, reduced application time and cost. The findings suggest that COD may be considered as first line of treatment for wounds in diabetic patients when NPWT deemed necessary.

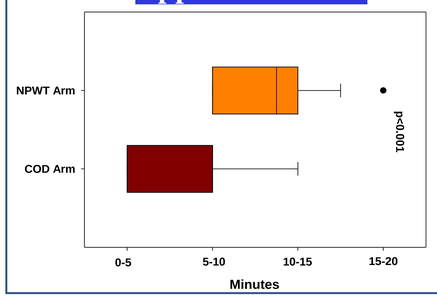
Wound Size



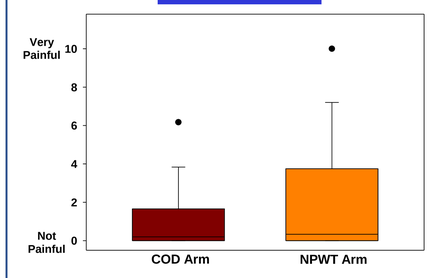




Application Time

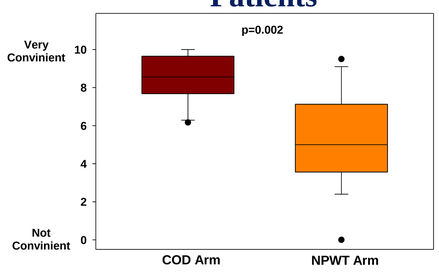


Patient Pain

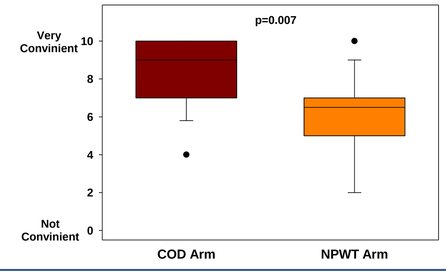


Convenience

Patients



Nurses/Care Givers



Patient No. 24. - COD Arm

Disclosure: Dr. Eyal Melamed and Dr. Michael Pinzur are members of the advisory board of MedCu, the COD manufacturing company.