Wound healing parameters in a randomized controlled trial (RCT) demonstrate non-inferiority of Copper Dressings (COD) management to Negative Pressure Wound Therapy (NPWT) of diabetic foot wounds



Eyal A. Melamed, MD¹; Tohar Roth, MSc²; Gadi Borkow, PhD²

¹Department of Orthopaedics, Rambam Health Care Campus, Haifa, Israel; ²MedCu Technologies Ltd., Herzliya, Israel



AIM

Compare the wound healing efficacy, cost, convenience and complications between Negative Pressure Wound Therapy (NPWT) and Copper Oxide Dressings (COD) in the management of diabetic foot wounds.

Method

A Randomized controlled trial (RCT) with 40 DFW, in whom NPWT was indicated. 21 patients were enrolled in the COD arm and 19 in the control arm NPWT followed by Aquacell dressings up to 3 months. Primary end point was wound size reduction, assessed by artificial intelligence program. Secondary endpoints were convenience, application time, pain, and cost.

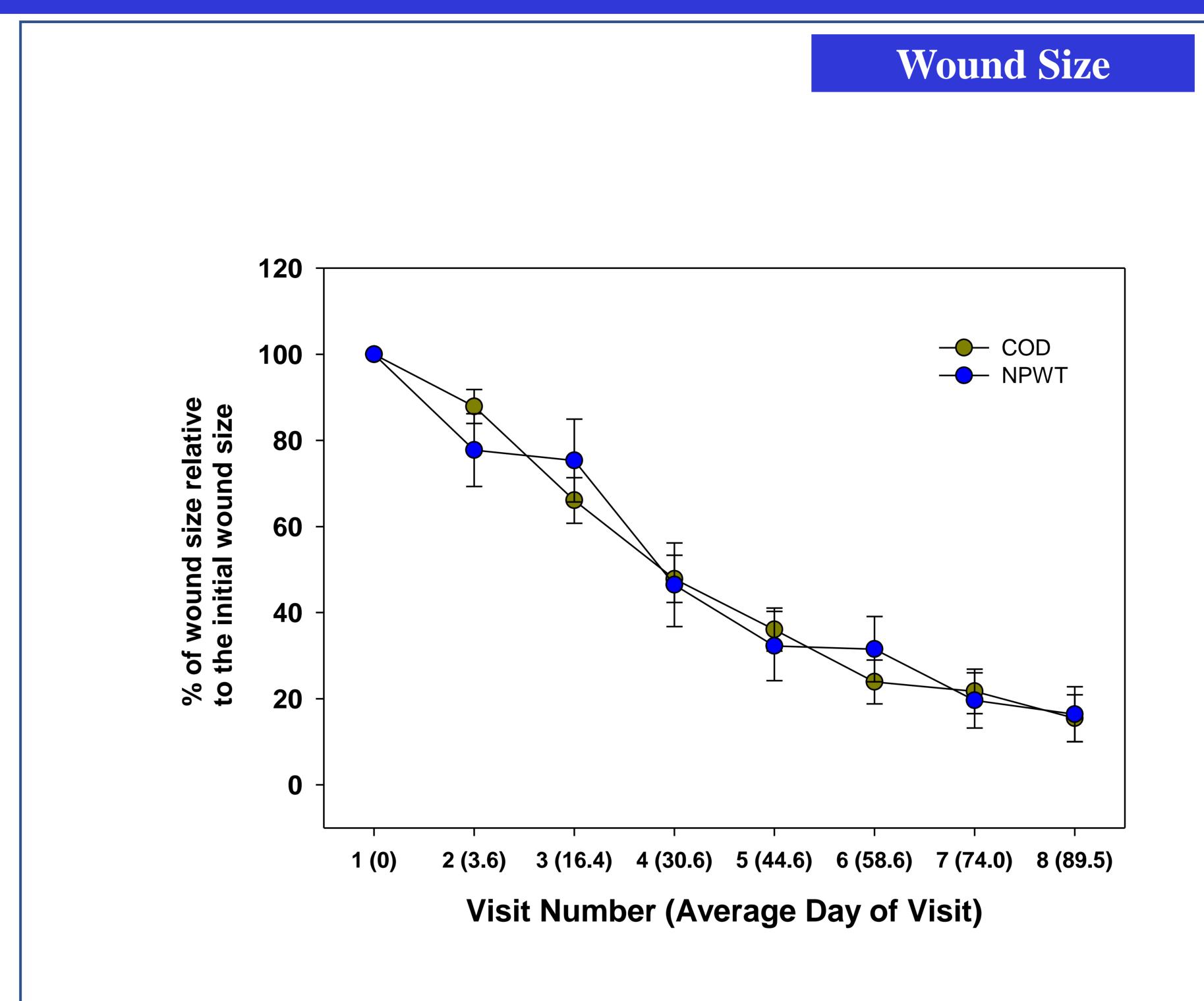
Results

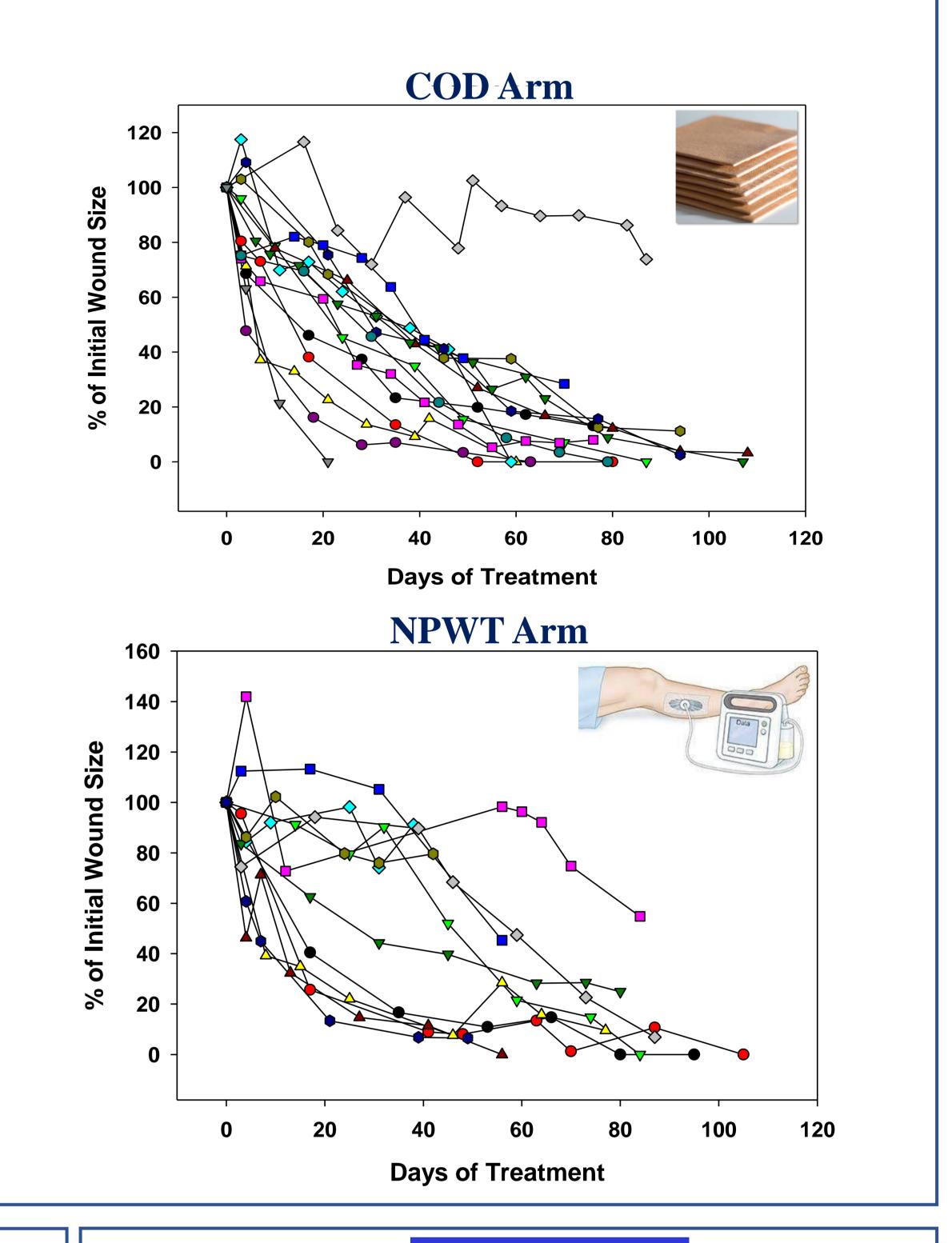
Initial wound area was 16.9 ± 17.4 and 14.2 ± 16.7 cm2 in the COD and NPWT arms, respectively (p=0.43). NPWT was used for 29.5 ± 15.4 days. 11 (52.4%) and 6 (31.6%) wounds were closed during the study in the COD and NPWT arms, respectively (P=0.18). Reduction of wound size was 61.5% and 41% after 1 month, in the COD and NPWT arms, respectively (p=0.04).

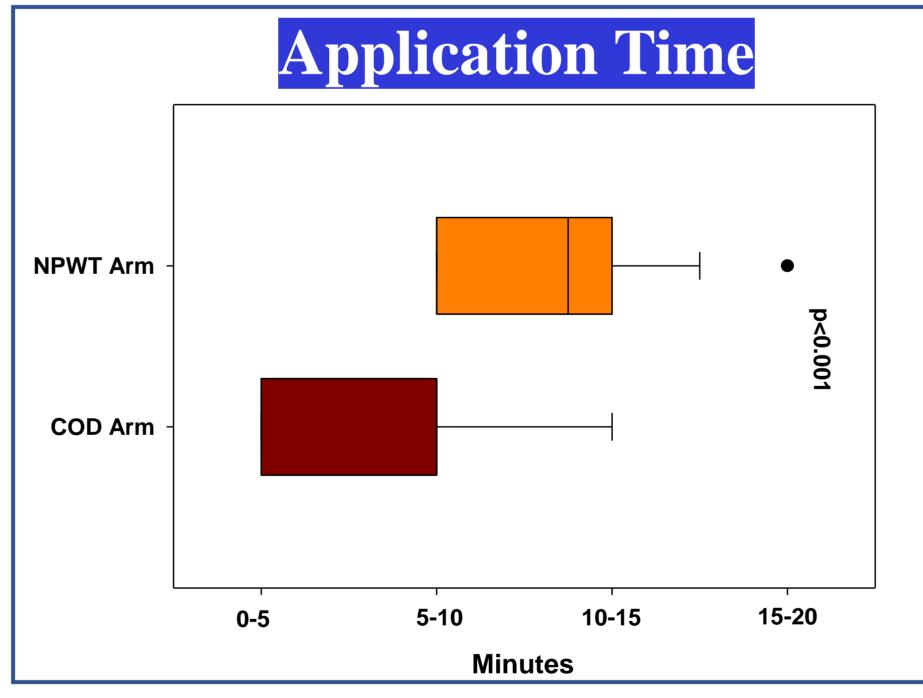
Analysis using a 20% margin shows a statistically significant non-inferiority of the COD Arm as compared to the NPWT Arm in terms of wound size reduction during the NPWT period (p=0.04). COD therapy was more convenient for the patients (Visual Analog Score [VAS] was 8.44 vs. 5.33; p=0.002) and the medical personnel (8.29 vs. 6.0; p=0.007), and less painful (1.15 vs. 2.19; p=0.67) in the COD arm compared to NPWT. Mean application time was shorter for the COD (8.5 vs. 13.25 minutes; p<0.001). Cost of COD is estimated to be 84% less than NPWT treatment.

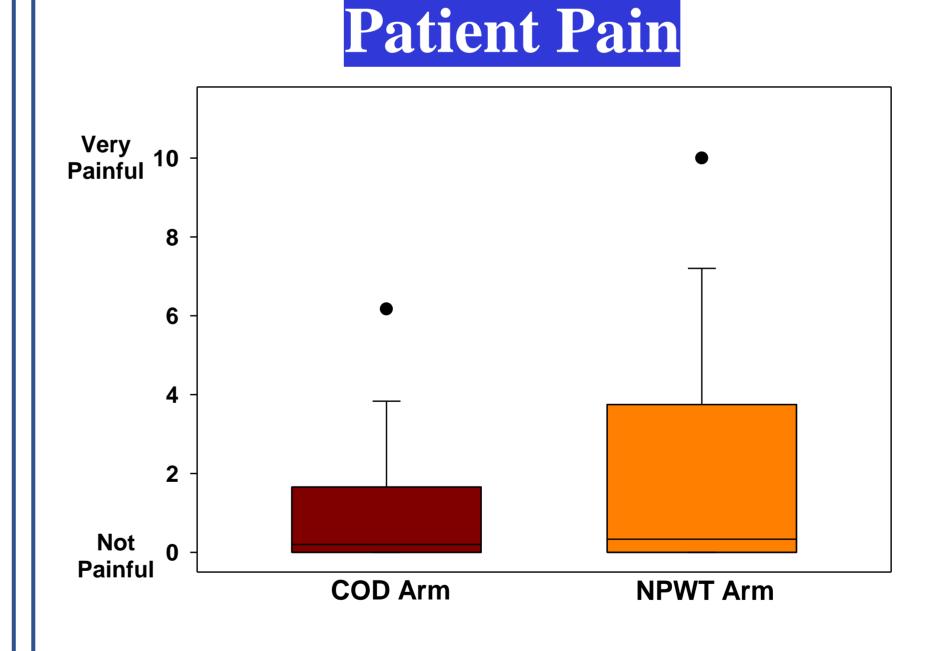
Conclusions

This RCT study indicates statistically significant non-inferiority of COD dressing therapy than NPWT in terms of wound healing rate of DFW. Better convenience and reduced costs in the COD arm, justifies initial copper dressing attempt in patients with diabetic foot wounds before NPWT treatment.

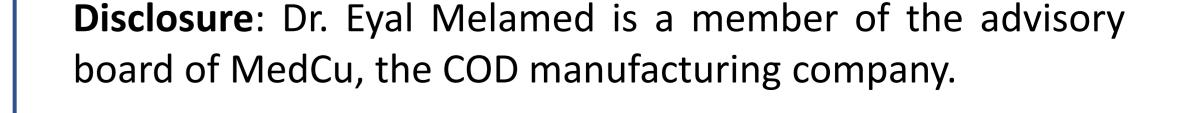




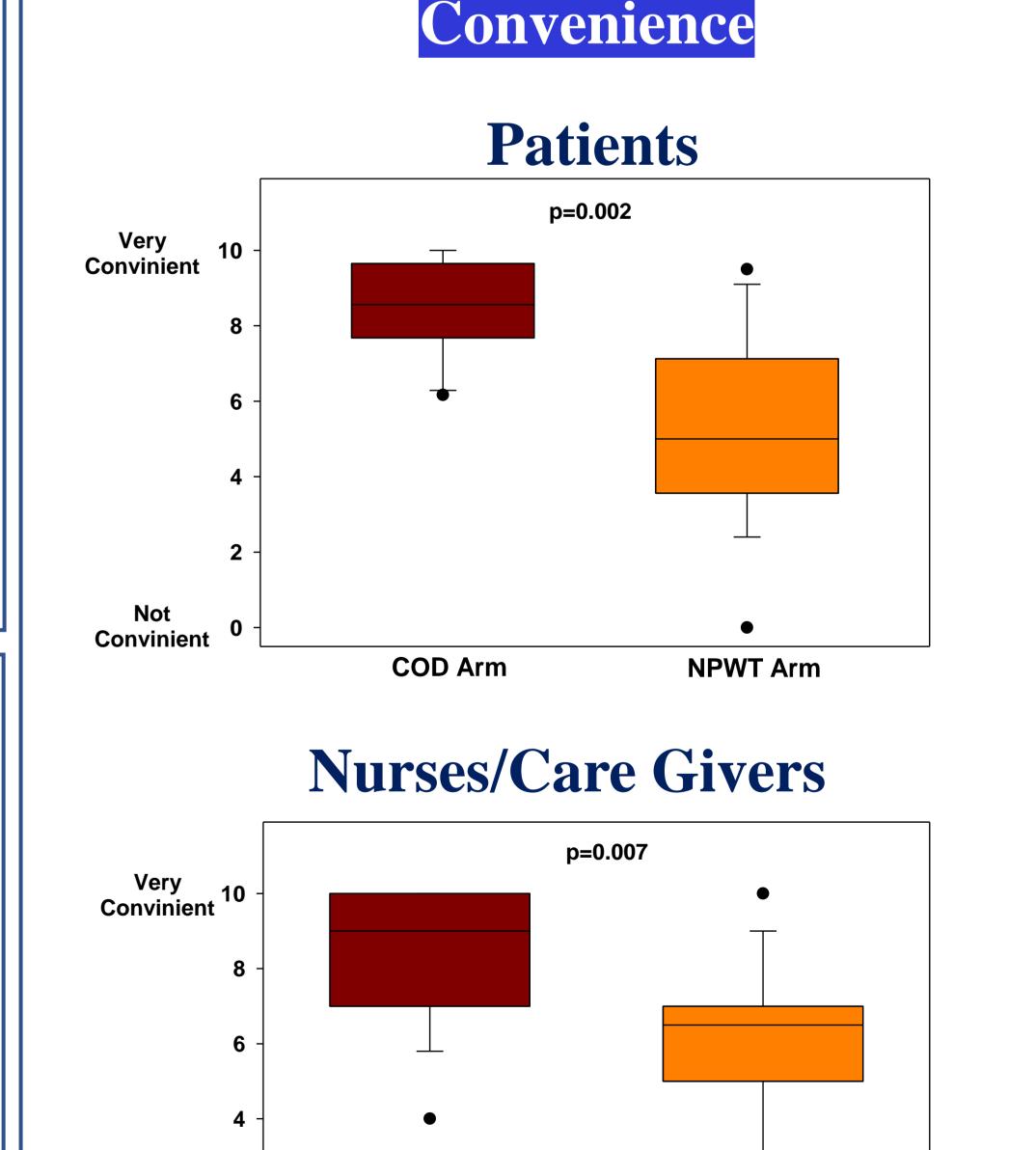








NPWT Arm



Patient No. 24. - COD Arm