



The effect of Continuous Diffusion of Oxygen on Breast Tissue – Updated Results From a Pilot Randomized Clinical Trial

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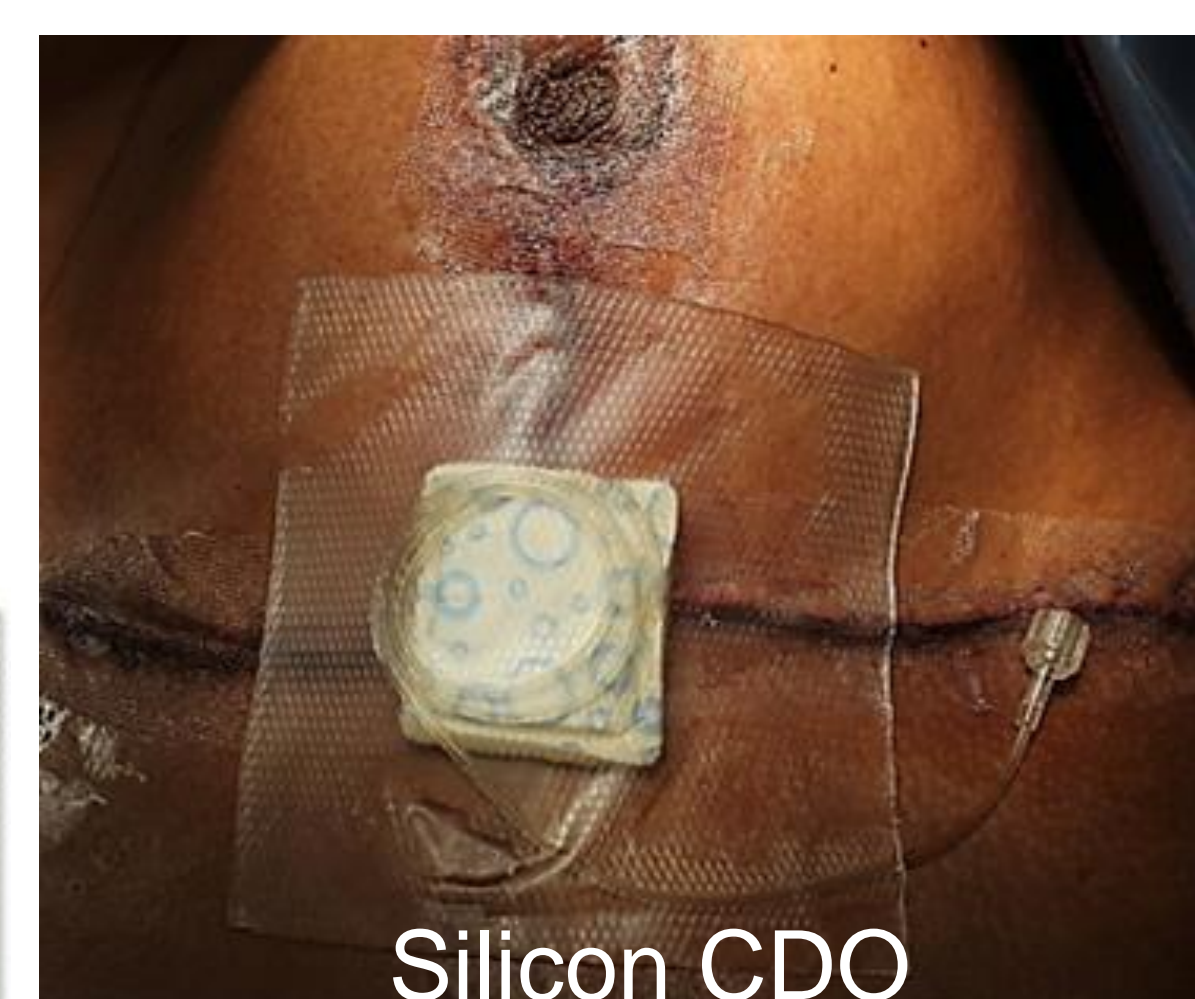
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INTRODUCTION

- Bilateral Reduction Mammoplasty (BRM)^{1,2} requires an upside down “T”, high-tension incision (T-Junction)³ with a predicted 10 – 39%^{4,5} complications related to breakdown.
- Continuous Diffusion of Oxygen (CDO) has shown to improve surgically closed wound outcomes in cervicotomies.⁶
- We examined the CDO effectiveness to improve tissue oxygenation and reduce wound dehiscence at the T-junction in women status post BRM.

METHODS

- 4-week pilot RCT in women undergoing BRM.
- **Inclusion criteria:** Macromastia, scheduled for BRM, 18-85y/o
- **Exclusion criteria:** Malignancy, Breast proliferative disease,
- Group allocation (internal randomization, right/left)



- Standard of Care (SOC) (n=20): Topical skin Adhesive covering all incision
- Direct CDO (dCDO) (n=10): CDO to T-junction + skin adhesive to rest of incision
- CDO + Silicon sheet (sCDO) (n=10): Skin adhesive covering all incision + CDO at T-Junction covered by a silicon sheet

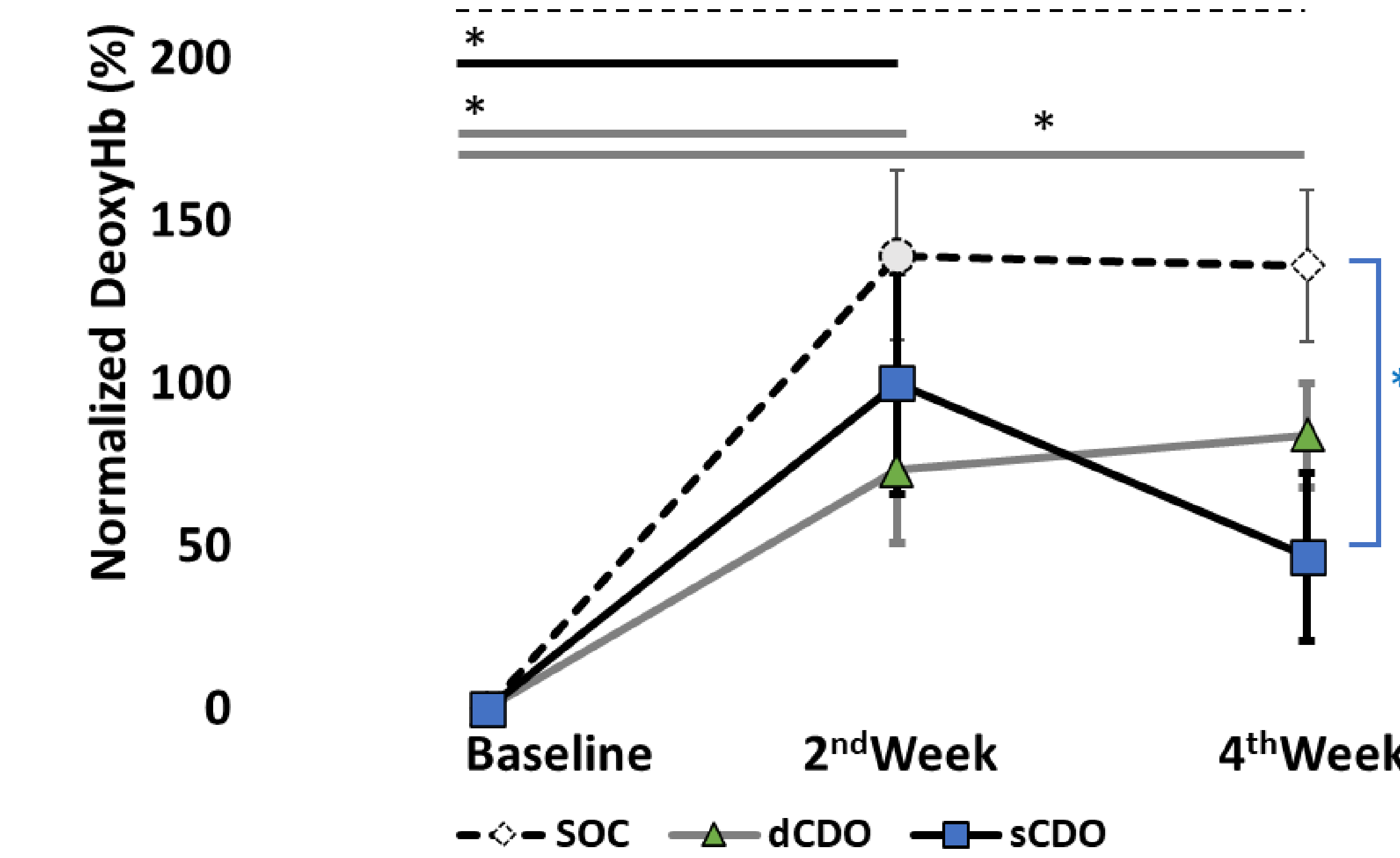
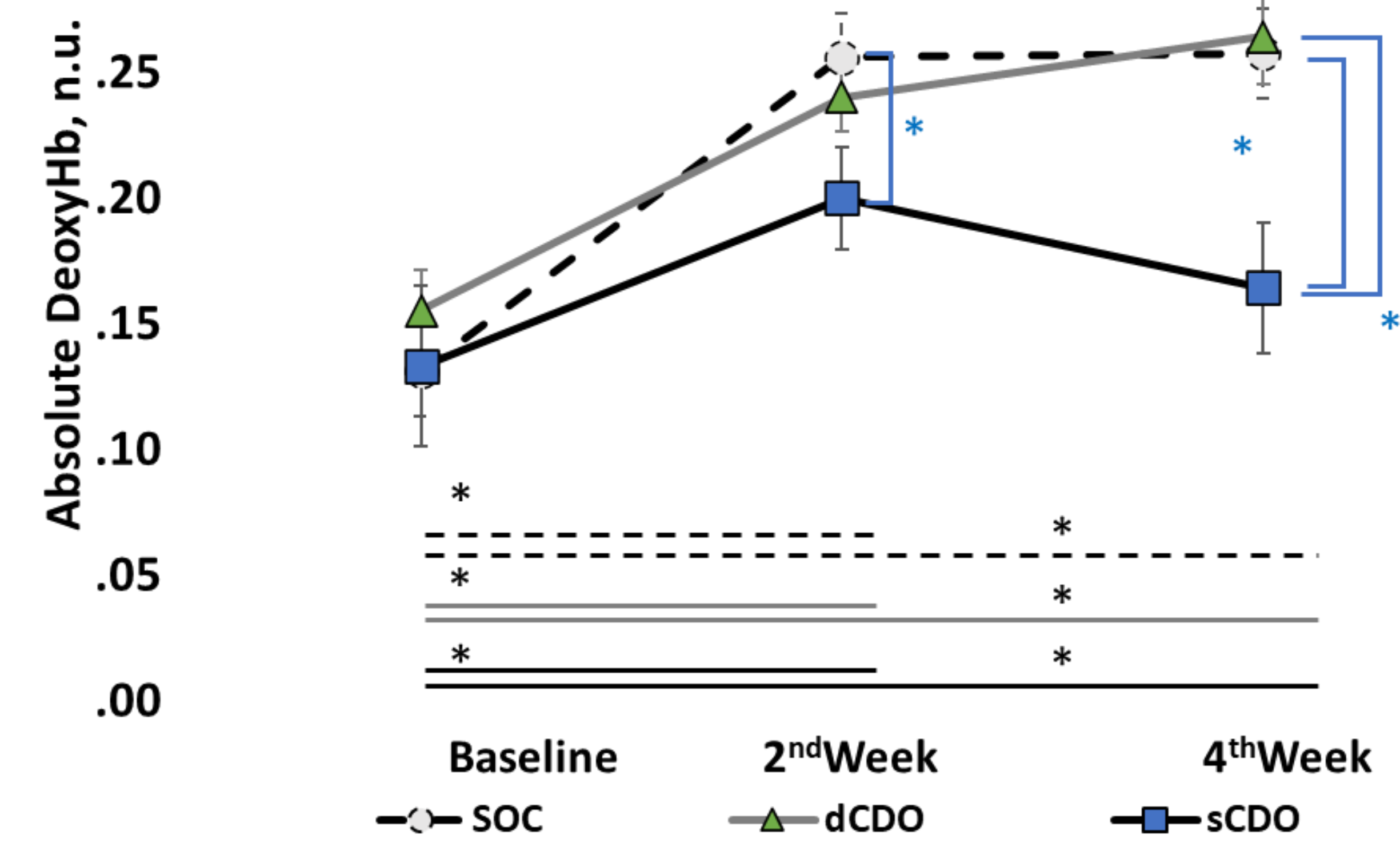
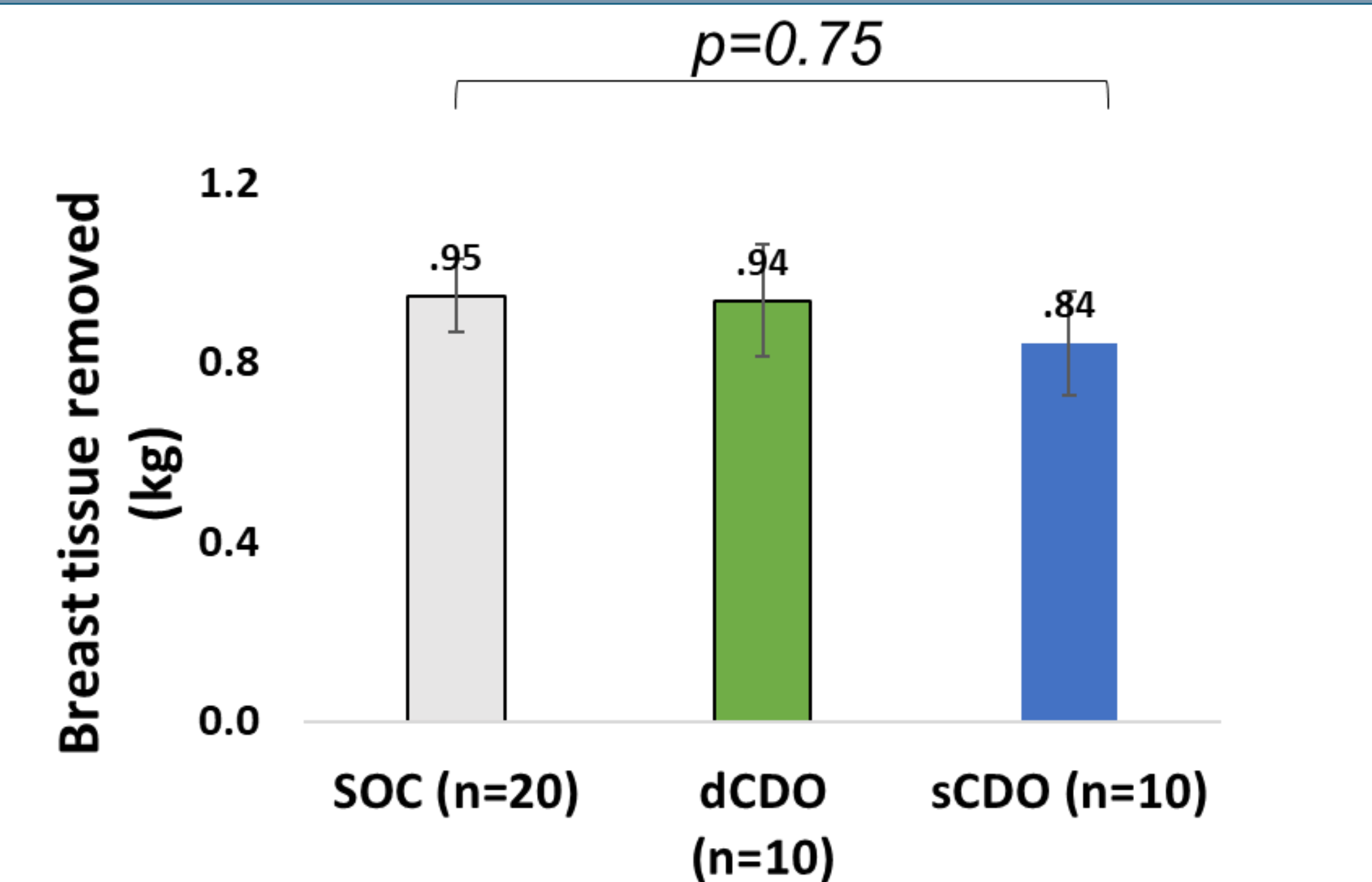
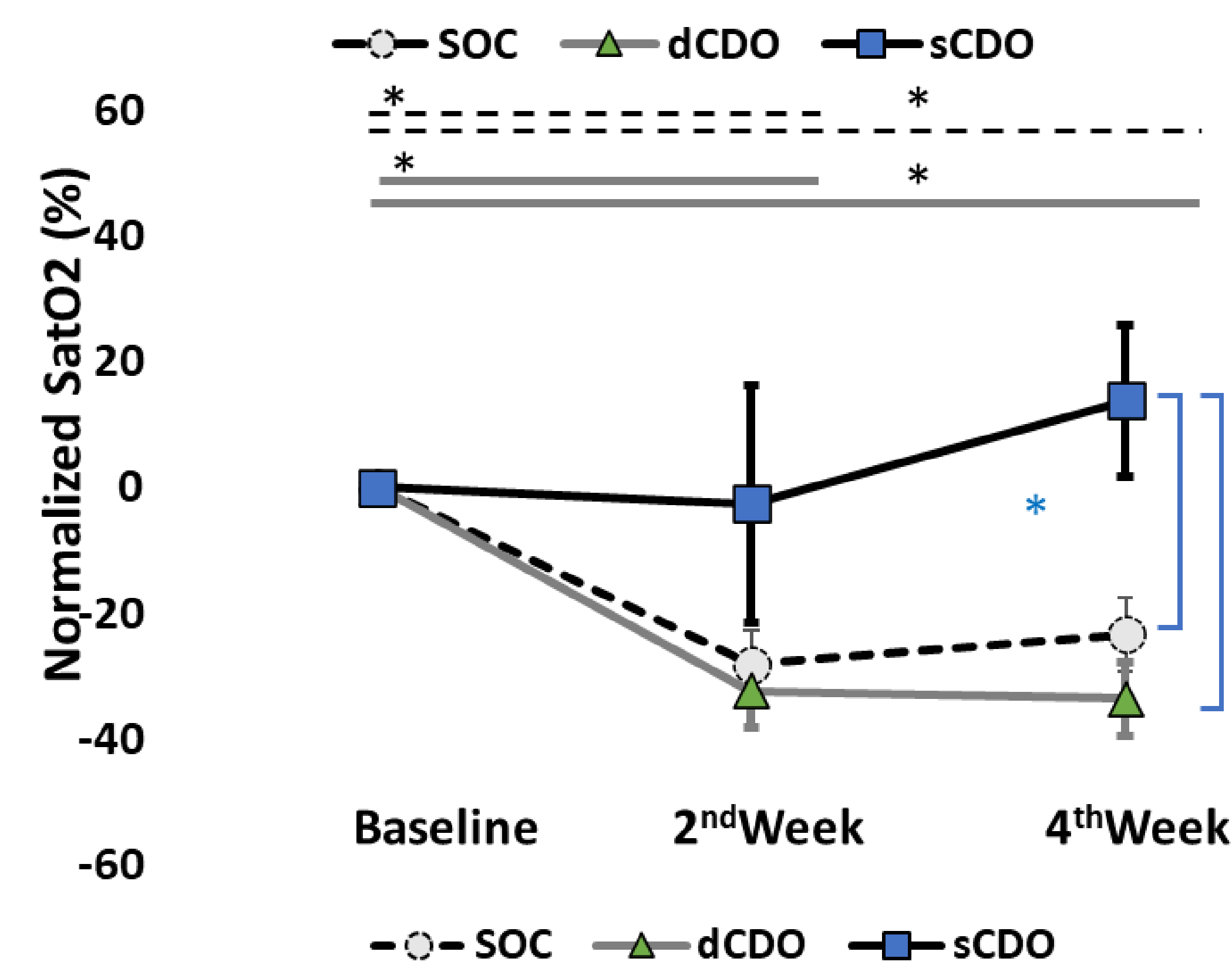
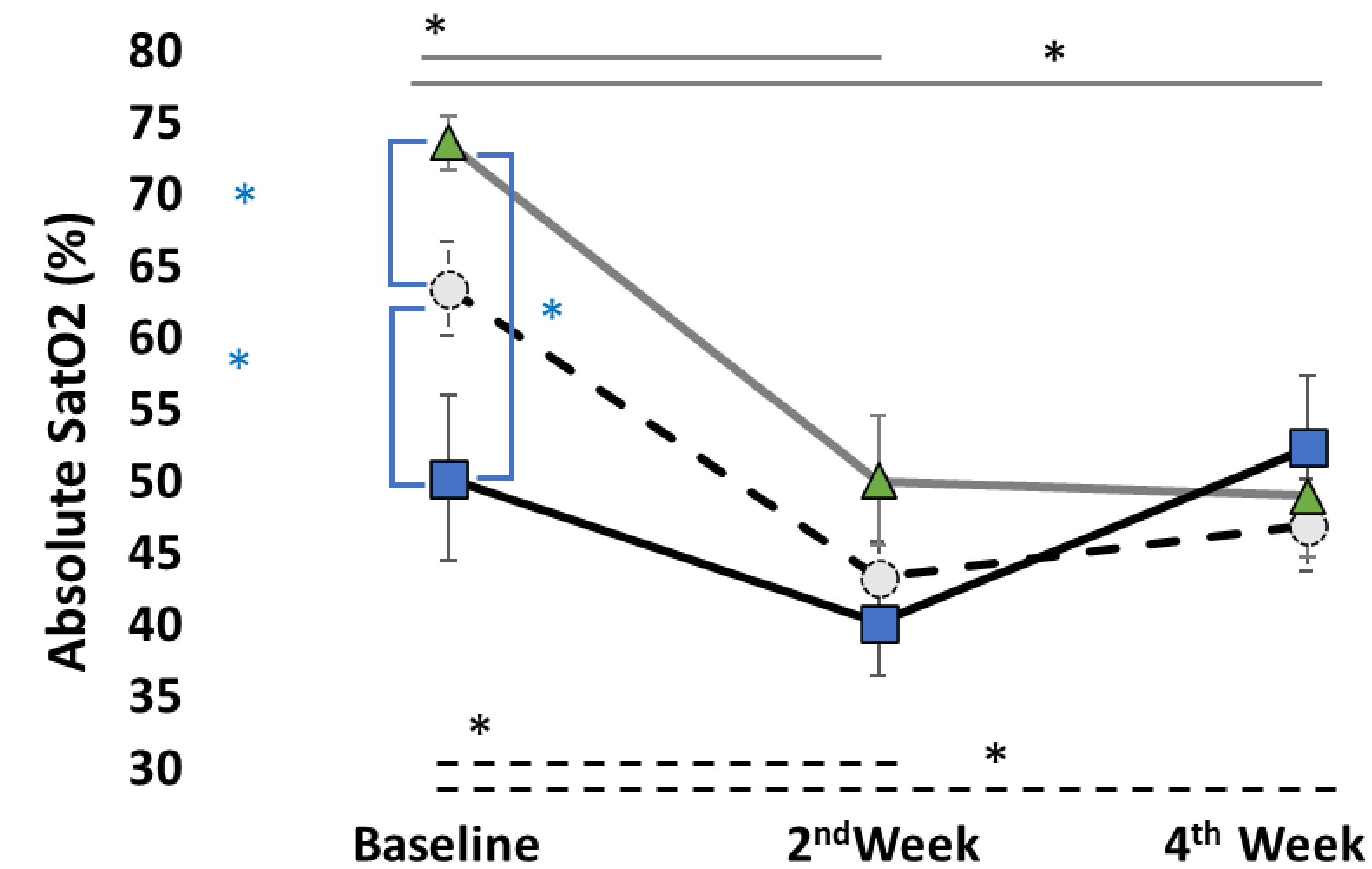
- Outcomes:
 - Wound dehiscence
 - Oxygen Saturation (SatO₂%)
 - Deoxyhemoglobin

Continuous Diffusion of Oxygen Device. All groups were set to receive 15mL/h of oxygen



RESULTS

Baseline characteristics (N=20)	
Age, mean SD	35 ± 10
BMI (kg/m ²), mean SD	34 ± 5
Breast tissue removed (kg), mean SD	0.96 ± 0.38



- sCDO showed a lower trend for T-Junction wound dehiscence compared to breasts undergoing SOC
- sCDO showed a higher T-Junction SatO₂ compared to breasts undergoing SOC and dCDO
- SOC and dCDO showed a significant decline in SatO₂ from baseline to 4-week
- sCDO did not show decline in SatO₂ (p>0.05).

DISCUSSION

- **Summary of results:** CDO with an adjunctive silicon sheet resulted in significant increase of T-Junction SatO₂ at 4 weeks.
- This modality showed a not statistically significant lesser wound dehiscence trend compared to standard of care.
- **Limitations:** These findings should be explored in a larger sample size.
- **Future direction:** Known confounders for breast surgery (such as surgical-ipsilateral dominant arm motion) should be investigated.

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