Racial Bias in Pulse Oximetry: Clinical Consequence & Strategies for Gathering Real-World Data

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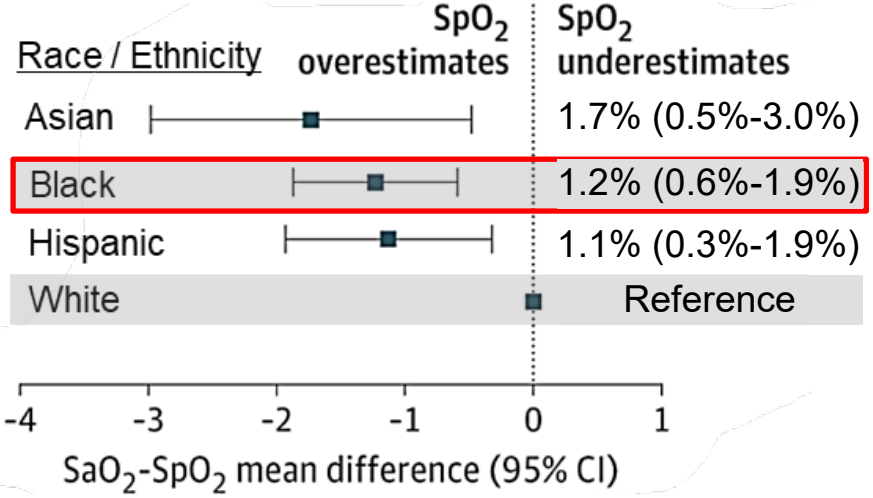
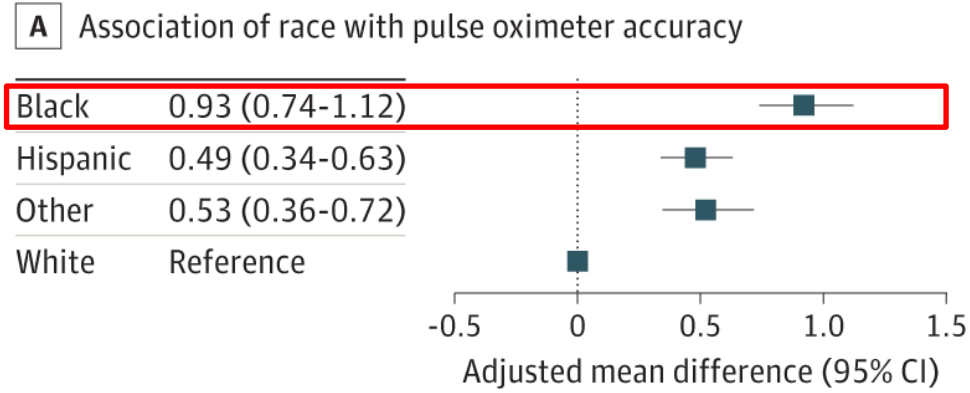
Disclosures: Nothing to disclose

Average Pulse Oximeter Error Seems Numerically Small



Fawzy et al. "Racial and Ethnic Discrepancy in Pulse Oximetry and Delayed Identification of Treatment Eligibility Among Patients With COVID-19" *JAMA Internal Medicine*, 2022

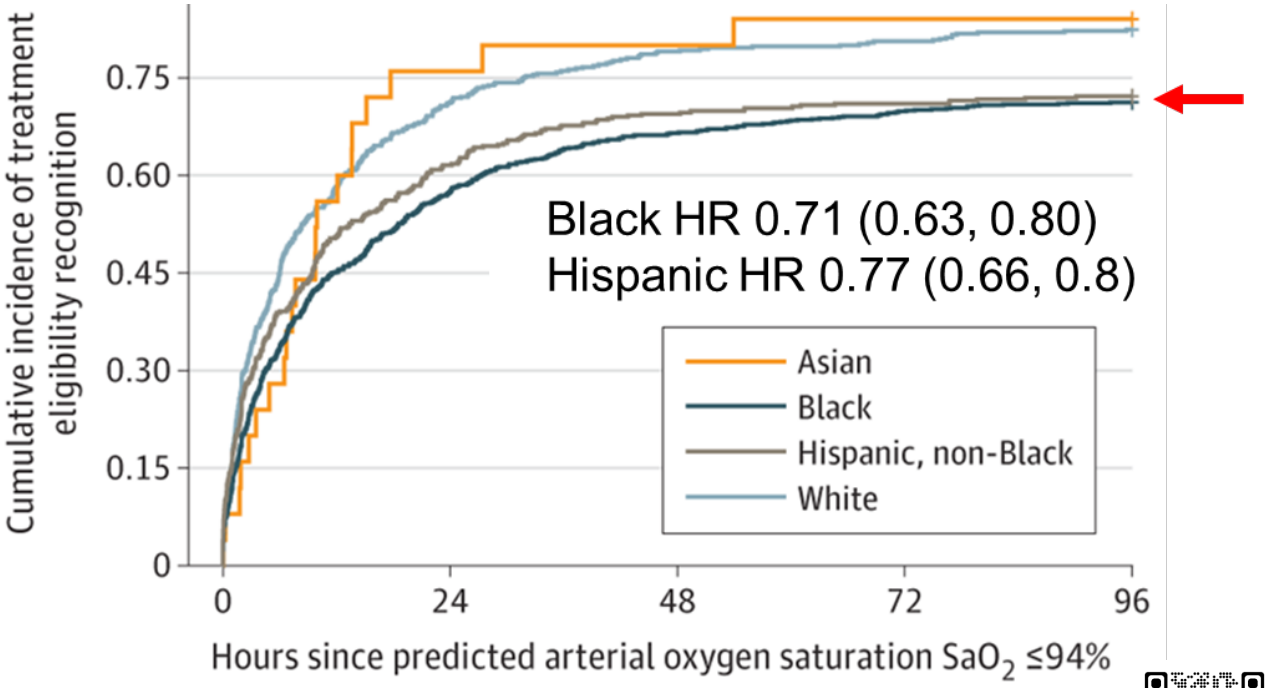


Fawzy et al. "Clinical Outcomes Associated With Overestimation of Oxygen Saturation by Pulse Oximetry in Patients Hospitalized With COVID-19" *JAMA Network Open*, 2023

Impact on Clinical Outcomes

Need for COVID-19 Treatment Not Recognized

Race	N (%)
Asian	4 (0.9)
Black	**247 (54.8%)**
Hispanic	122 (27.1%)
White	78 (17.3%)



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Impact on Clinical Outcomes

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Table 2. Median Time to COVID-19 Therapy and Adjusted Hazard Ratios of Timeliness of COVID-19 Therapy Stratified by Race and Ethnicity

Characteristic	Time to therapy, median (IQR), hours		Adjusted hazard ratio (95% CI)	*P* value[a]
	Unrecognized	Recognized		
Overall	7.3 (2.8-23.4)	6.5 (2.0-21.3)	0.90 (0.83-0.98)	.02
Race stratified				
Black	9.5 (3.6-27.6)	7.4 (3.0-24.7)	0.88 (0.72-1.07)	.45
Hispanic	6.4 (2.6-20.8)	5.0 (1.5-16.3)	0.83 (0.71-0.96)	
White	7.1 (2.8-24.8)	7.2 (2.6-23.6)	0.96 (0.85-1.10)	
Other[b]	6.8 (2.3-13.0)	6.1 (2.1-18.4)	1.00 (0.77-1.29)	

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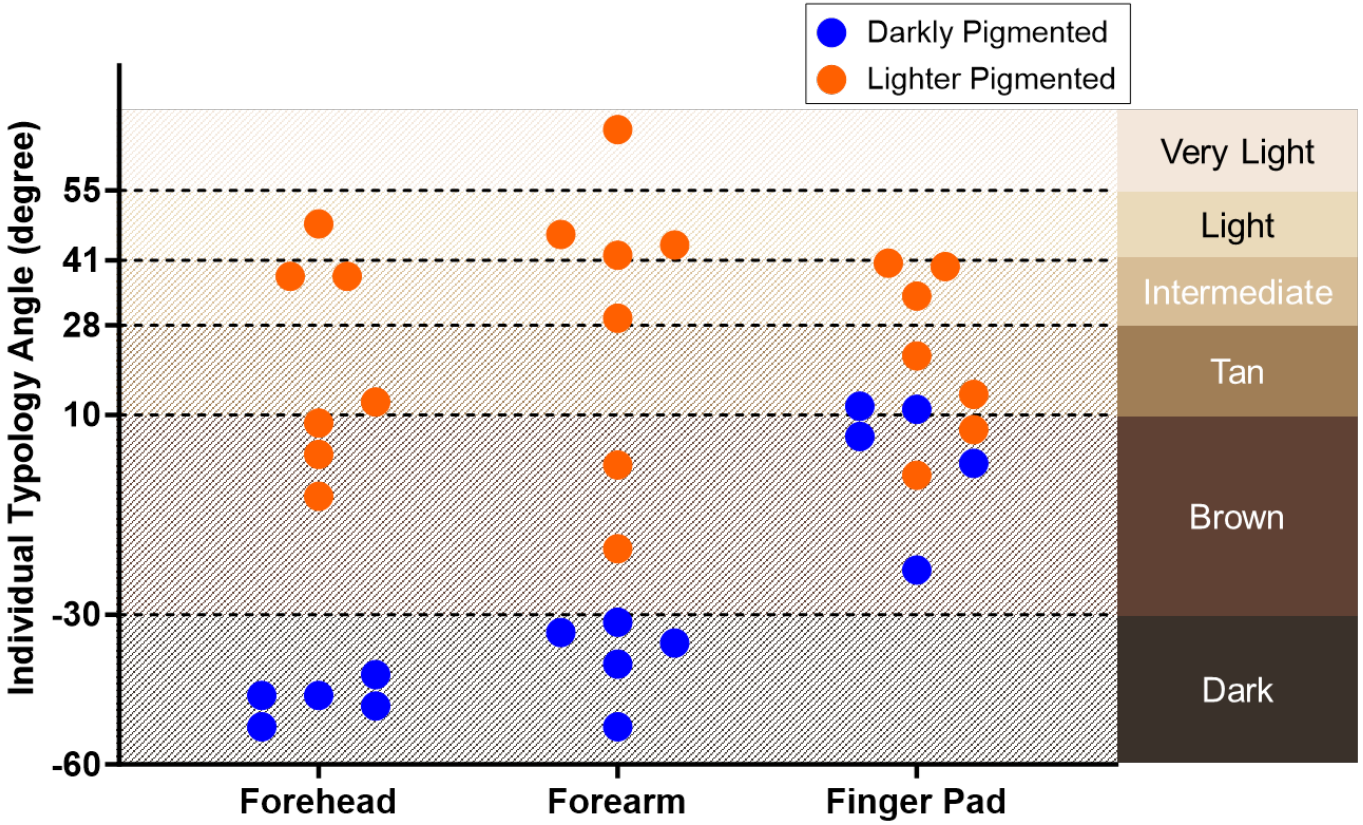
Prospective Study Population



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Prospective Study Methods

- Clinical arterial blood gases with exact time of blood draw identified
- Matched to pulse oximeter readings during that period (recorded every 2 seconds)
- More likely to capture occult pulse oximeter errors compared with research arterial blood gases
- Better reflects real-world pulse oximeter performance
- Reduces participant and research staff burden

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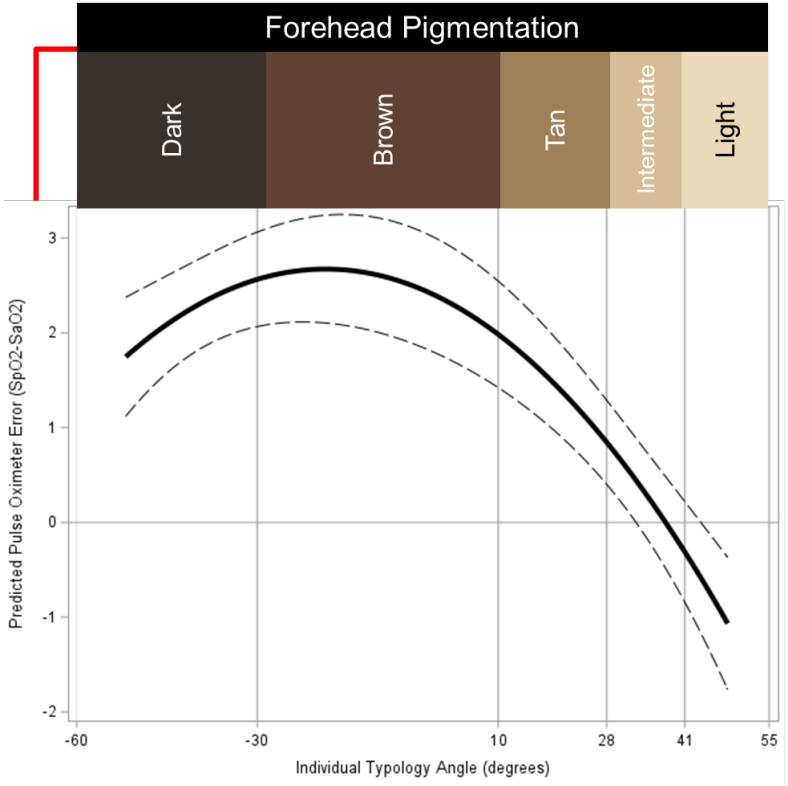
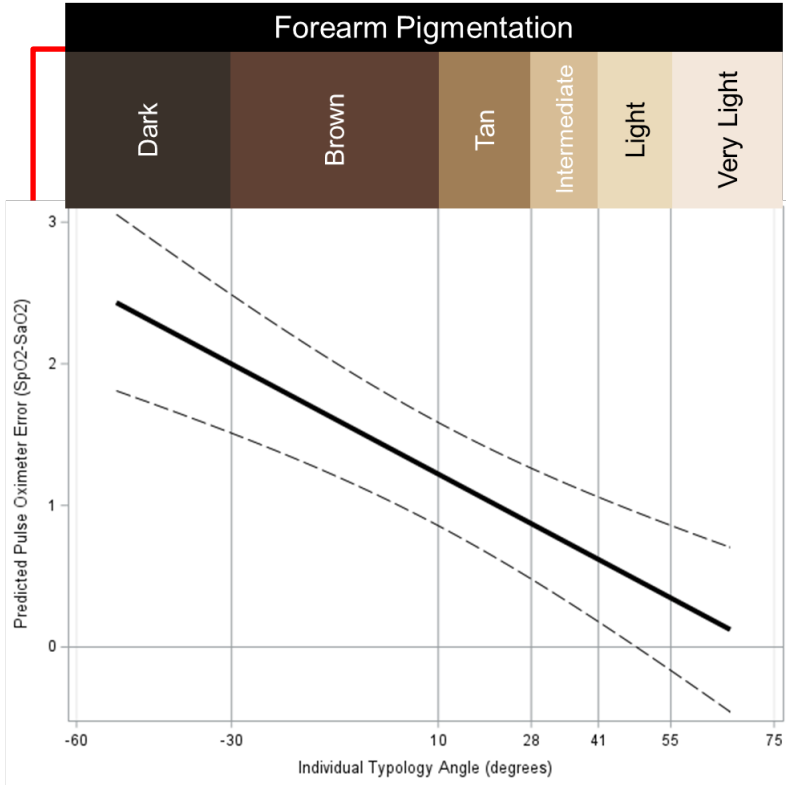
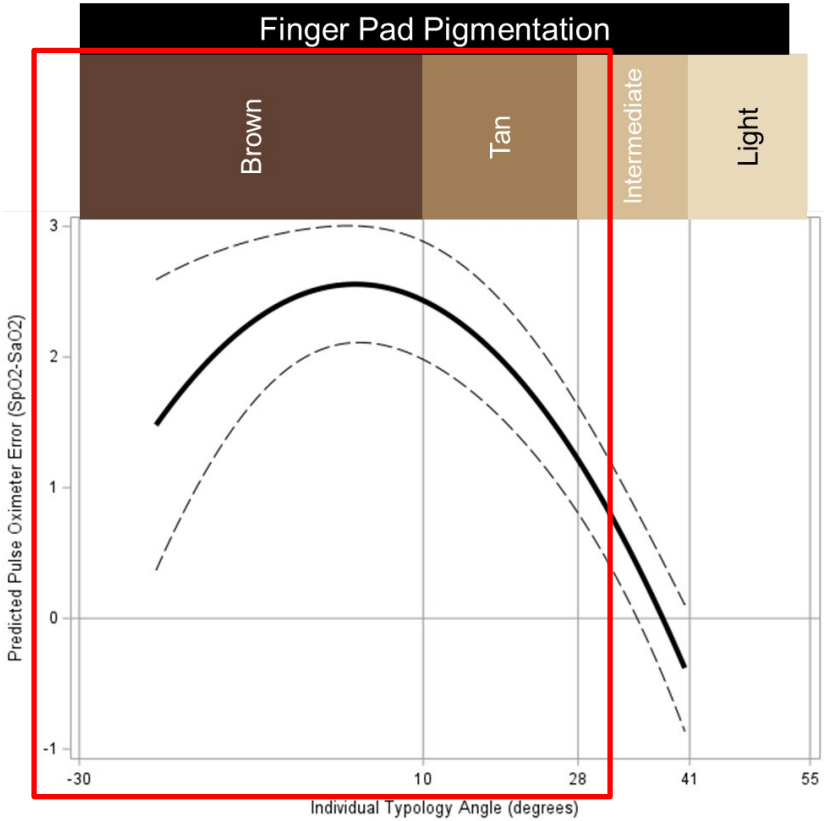
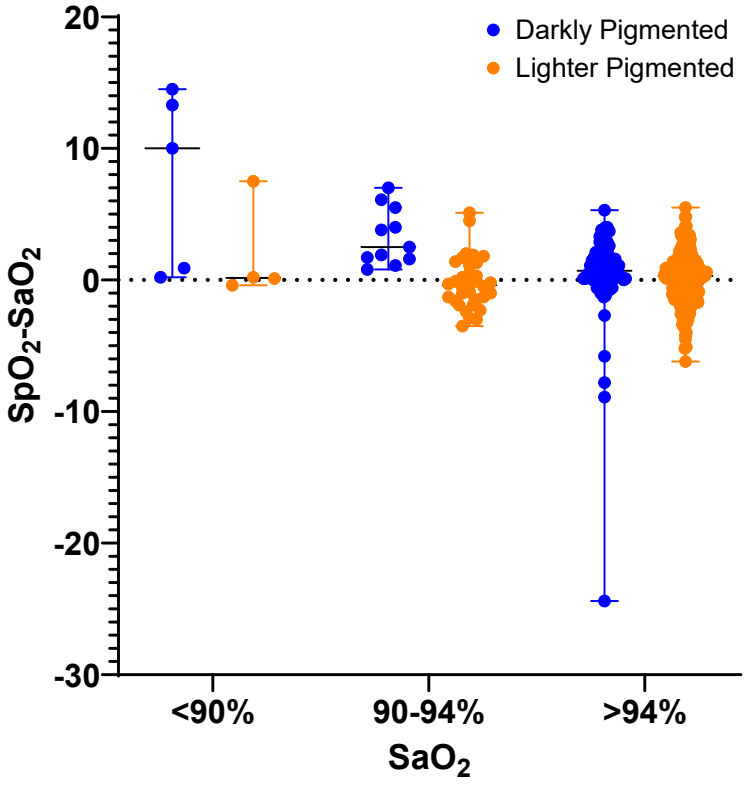
Prospective Study Results





Prospective Study Results





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Prospective Study Results

Overall A_{RMS} = 2.75%

Darkly Pigmented A_{RMS} = 4.15% (95% CI 2.35-5.72%)

Lighter Pigmented A_{RMS} = 1.97% (95% CI 1.76-2.17%)

Pulse Oximeter: Masimo SET Neo-3 wrap oximeter

Monitor: GE Carescape B850

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Summary & Recommendations

- An FDA cleared pulse oximeter would not have met regulatory criteria if tested on darkly pigmented critically ill patients
- Overestimation of oxygen saturation by pulse oximeters has important clinical consequences
- Pulse oximeters should be tested in a diverse population of patients using actual clinical data and objective skin pigmentation measurements

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