

The EquiOx Study

Prospective Clinical Study of Pulse Oximeter Errors in Hospitalized Patients: Update after enrolling 479 patients

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The authors have no conflicts



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The EquiOx Study

Primary aim is to measure the bias in pulse oximeter SpO₂ measurements across a range of skin pigmentations among critically ill hypoxemic patients.

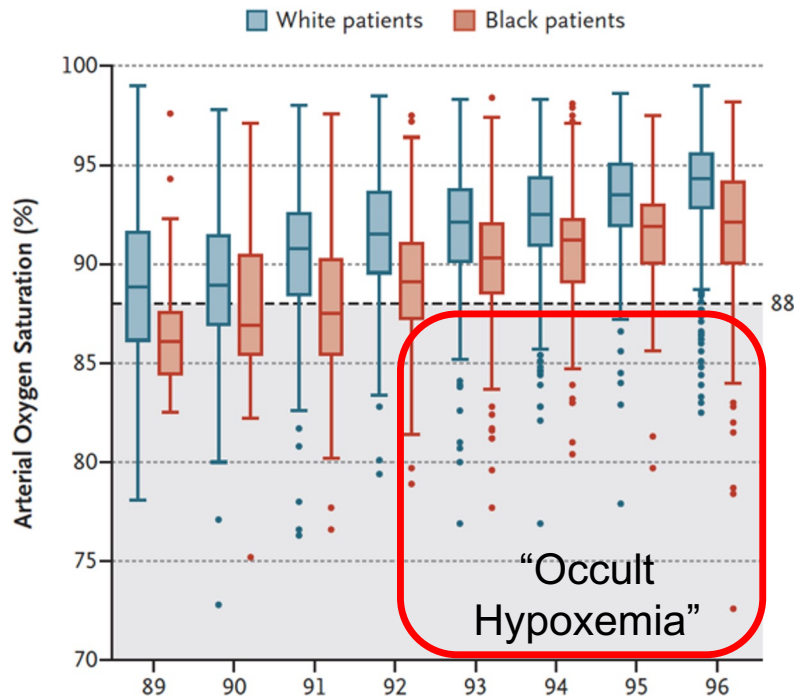


PI: Dr. Carolyn M. Hendrickson

EquiOx Secondary Aims

- Compare subjective skin pigment scales to objective spectrophotometer data to inform pulse oximeter performance studies.
- Relate skin pigmentation and race among patients hospitalized in San Francisco
- Test if previously described differences in bias between race categories is explained by skin pigment differences
- Determine if pulse oximeters performance in clinical use is similar to performance measured in controlled laboratory studies
- Test low perfusion as a mediator explaining differences in oximeter performance

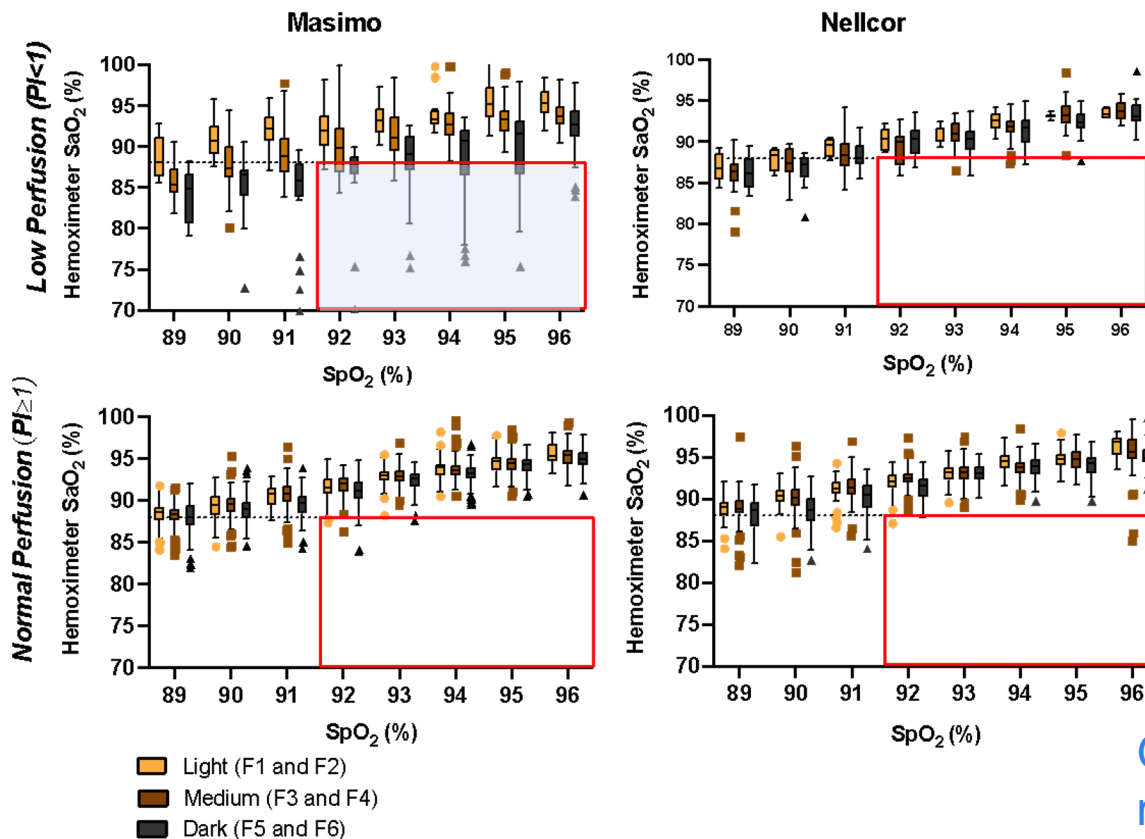
Why the EquiOx study?



- Imprecise pairing of SpO₂ and SaO₂
- Hemoximeter set to fractional not functional saturation
- Self reported race, no skin pigment data
- Interfering pigments
- Anemia
- Low perfusion
- Motion

Sjoding *et al.*, NEJM, 2020

Missed hypoxemia



Missed hypoxemia rate 30% (Masimo), 8% (Nellcor) among darkly pigmented subjects with low perfusion

Gudelunas et al.,
medRxiv 2022, A&A 2024

The EquiOx Study

Study strategies and advantages over retrospective studies

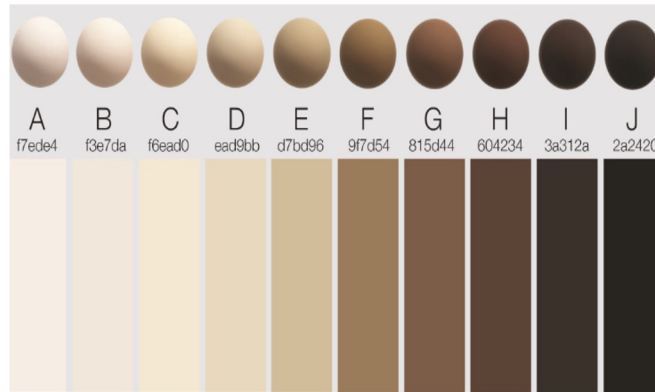
- Synchronous paired samples
- Functional saturation measured
- Skin pigment quantified (Monk, VL, FP, Konica-Minolta)
- Perfusion quantified
- Optical signals measured
- Inclusive Network of Collaborators/
Stakeholders, Statisticians
- Population with broad skin pigment range

Subjective Measurement Scales

- Categorical variable
- Von Luschan, Fitzpatrick, and Monk scales
- Measured at forehead, ear, nare, inner arm, fingers

	1	10			19	28
	2	11			20	29
	3	12			21	30
	4	13			22	31
	5	14			23	32
	6	15			24	33
	7	16			25	34
	8	17			26	35
	9	18			27	36

Von Luschan (VL) Scale



Monk Scale

0-6	Pale white skin Extremely sensitive skin, always burns, never tans Example: red hair with freckles	
Type I		
7-13	White skin Very sensitive skin, burns easily, tans minimally Example: fair skinned, fair haired Caucasians, northern Asians	
Type II		
14-20	Light brown skin Sensitive skin, sometimes burns, slowly tans to light brown Example: darker Caucasians, some Asians	
Type III		
21-27	Moderate brown skin Mildly sensitive, burns minimally, always tans to moderate brown Example: Mediterranean and Middle Eastern Caucasians, southern Asians	
Type IV		
28-34	Dark brown skin Resistant skin, rarely burns, tans well Example: some Hispanics, some Africans	
Type V		
35+	Deeply pigmented dark brown to black skin Very resistant skin, never burns, deeply pigmented Example: darker Africans, Indigenous Australians	
Type VI		

Fitzpatrick (FP) Scale

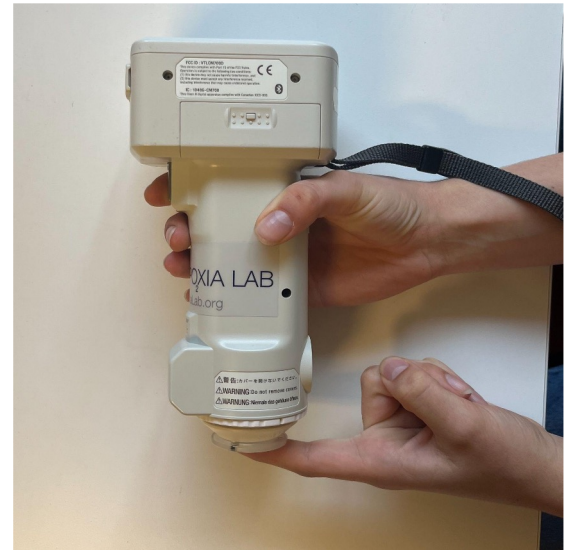
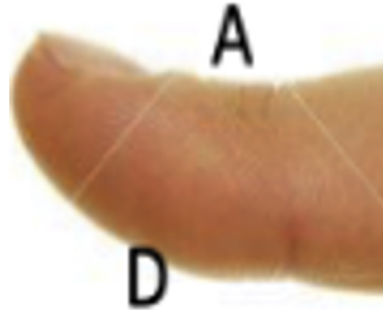
Objective Measurement Tool

Konica Minolta (KM) CM700d Spectrophotometer

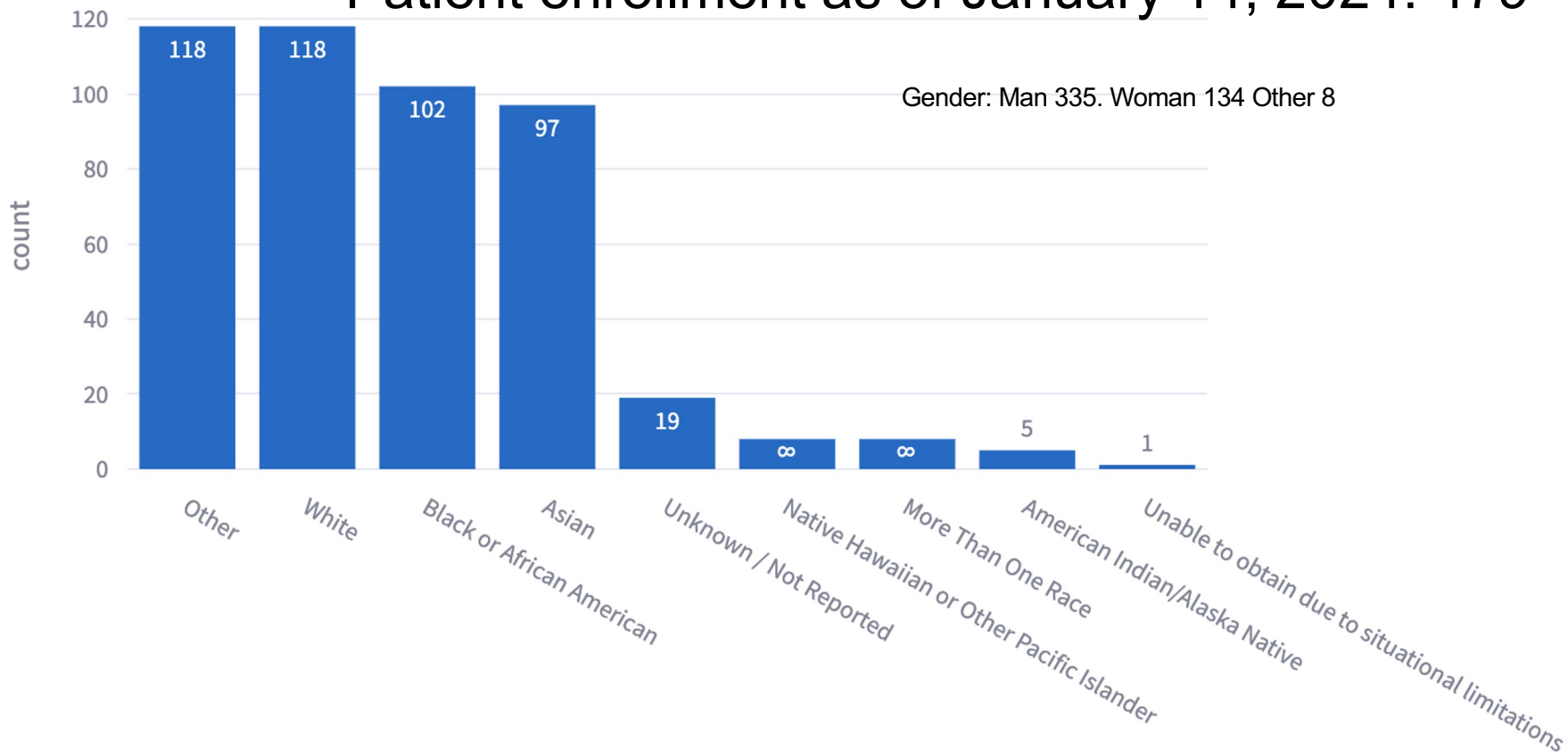
- Calibrated with manufacturer guidance

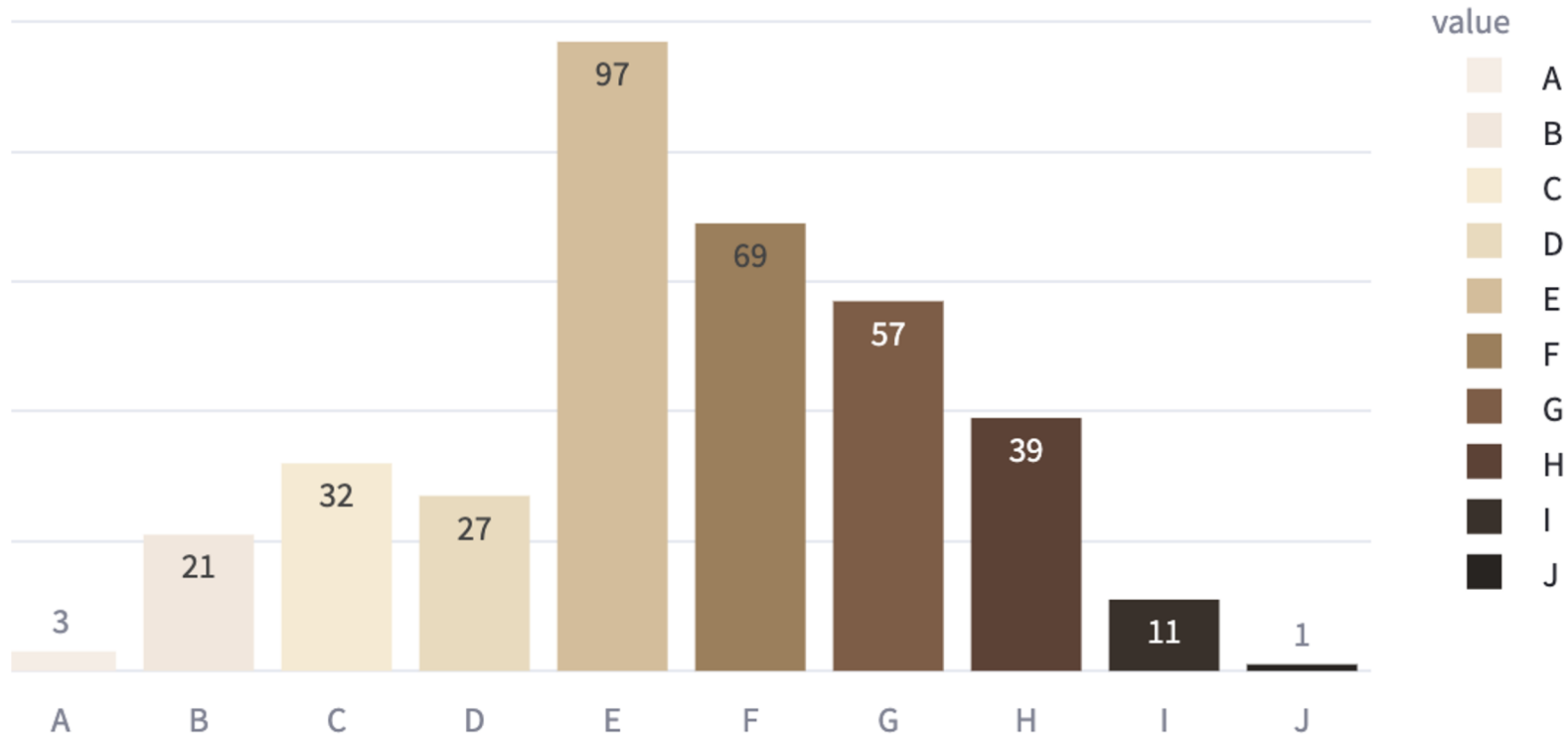


ITA: brightness, yellow/blue, red green



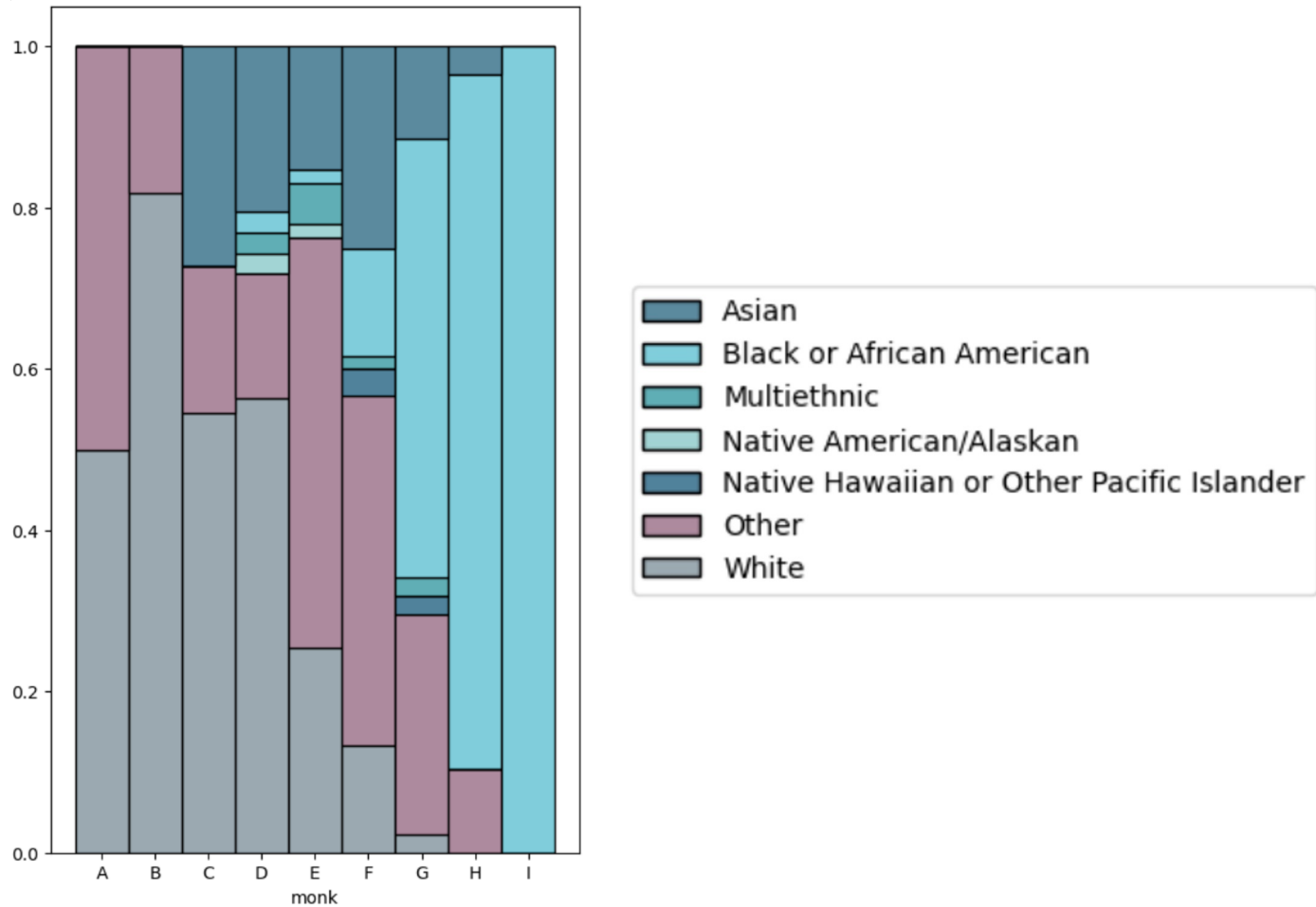
Patient enrollment as of January 14, 2024: 479



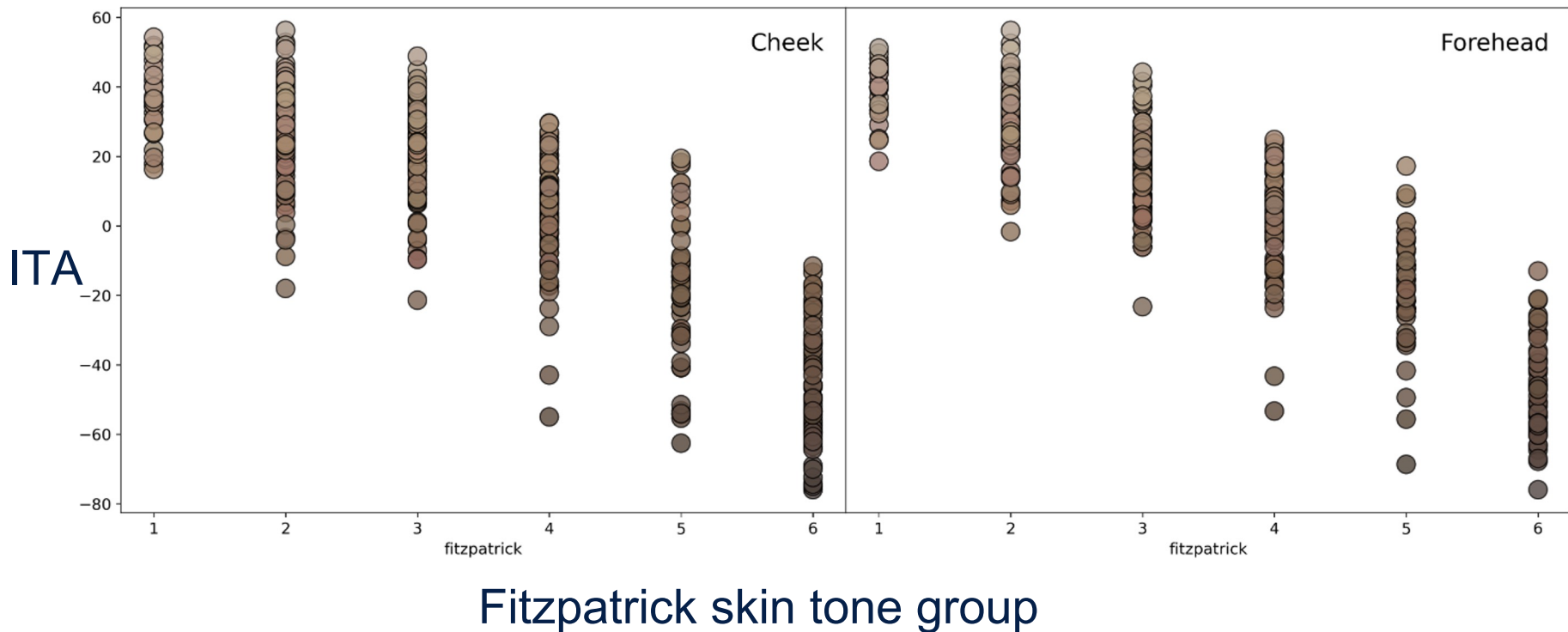


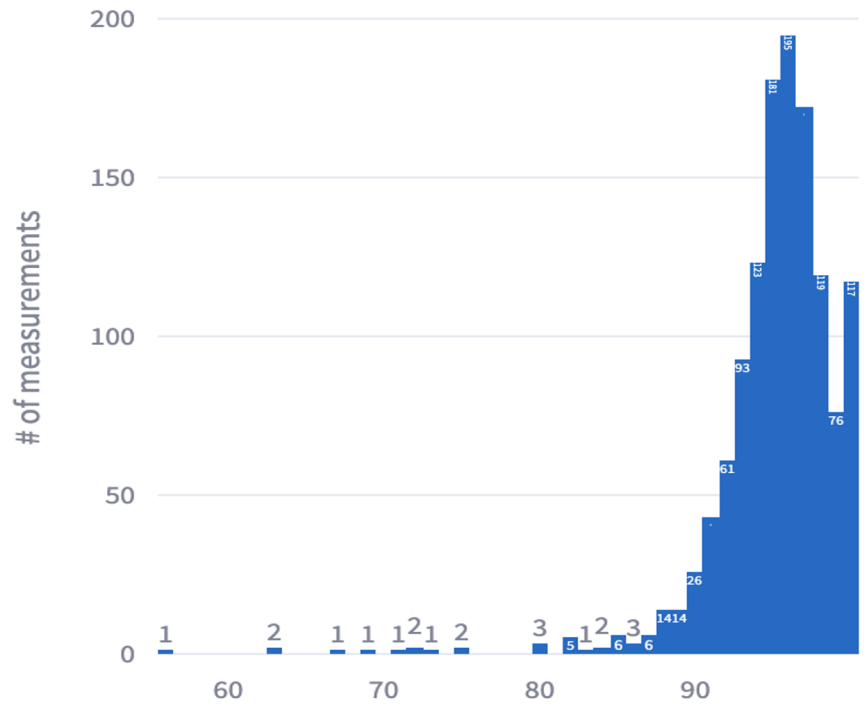
Skin tone varies within self-reported race categories

Proportion in each MST category

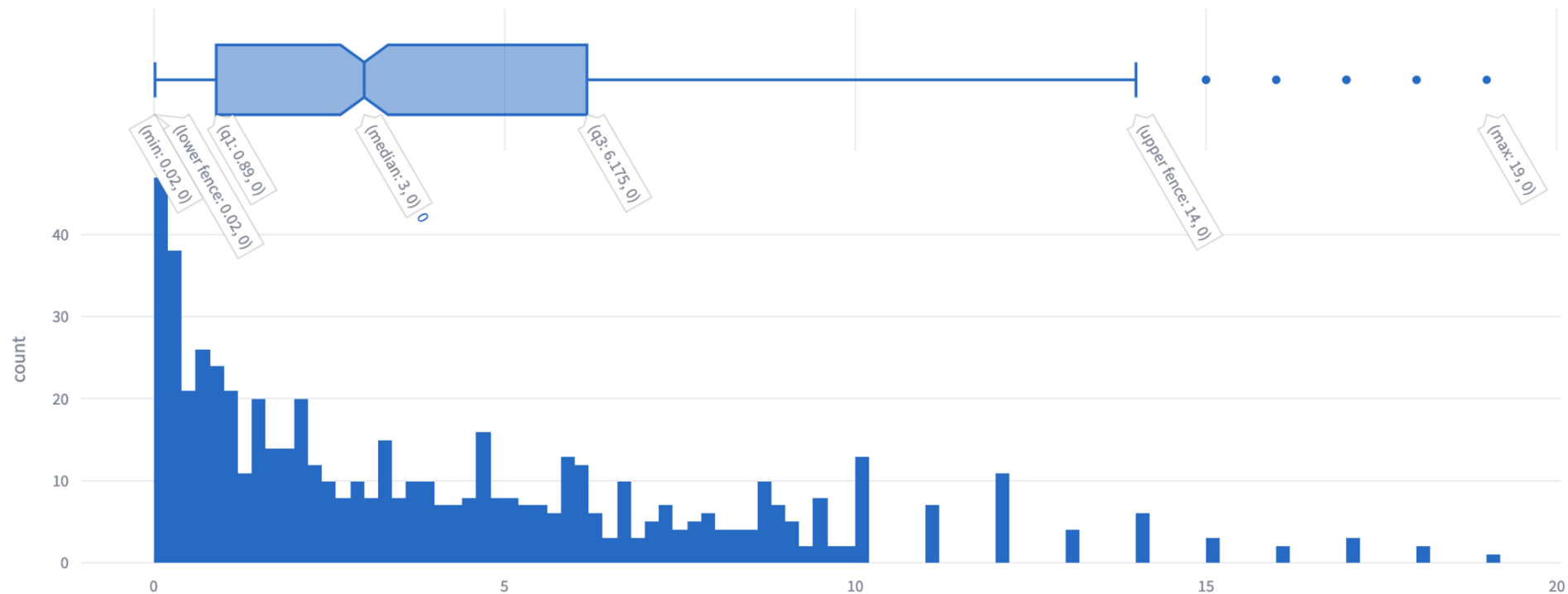


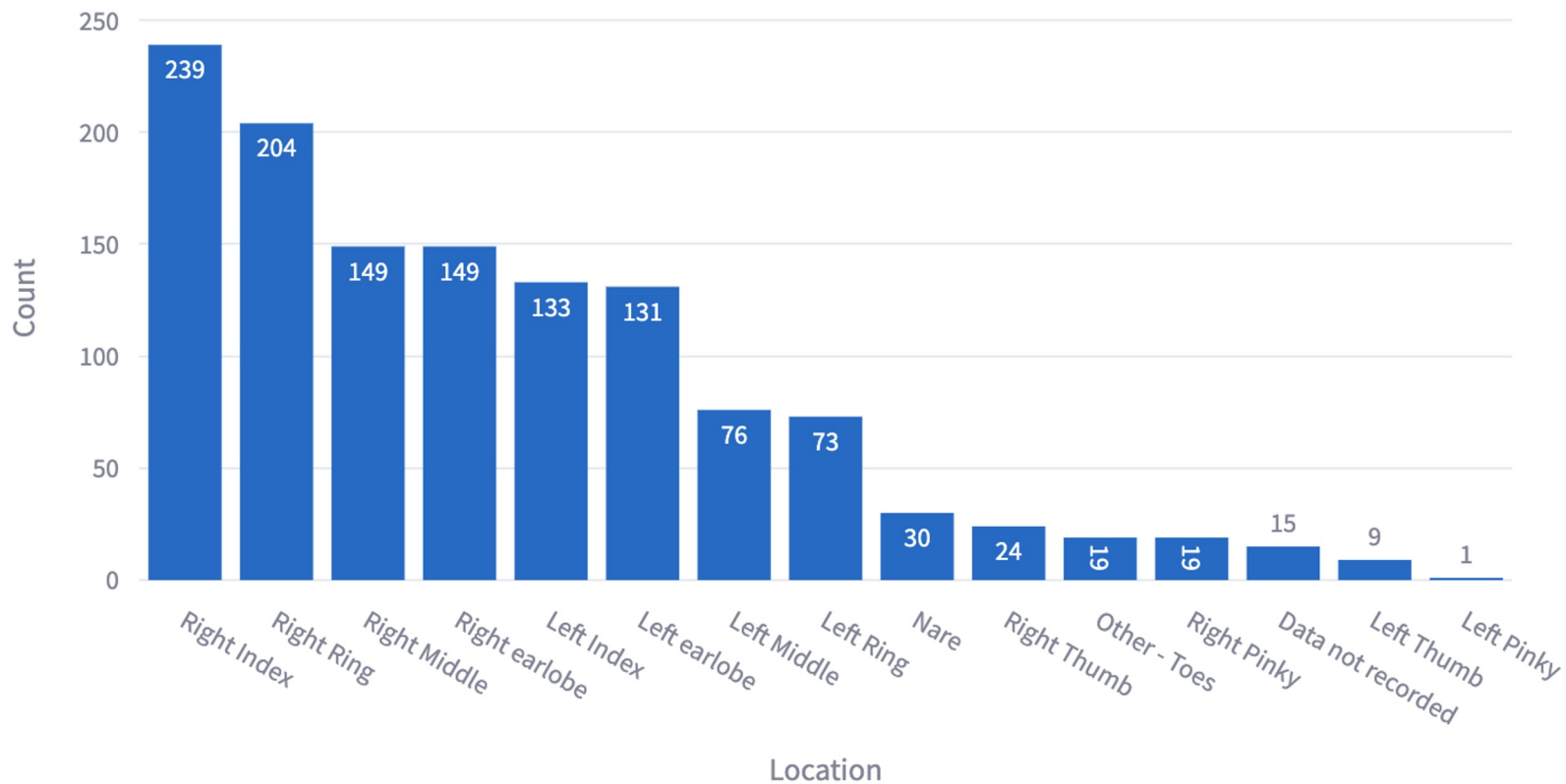
Objective assessment of skin pigment (ITA) versus subjective (Fitzpatrick)





Distribution of perfusion index values (Masimo)





Summary

- EquiOx is a real-world prospective study of pulse oximeter accuracy with detailed data collection
- Self identified race, subjective and objective skin pigment measurements, perfusion index, comorbidities, stability of SpO₂ data
- Most blood samples are at SaO₂>90%
- Perfusion index is low in most observations
- Probe location varies in a real-world setting



The Open Oximetry Project



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