Tissue mimicking material selection and finger phantom design for pulse oximetry

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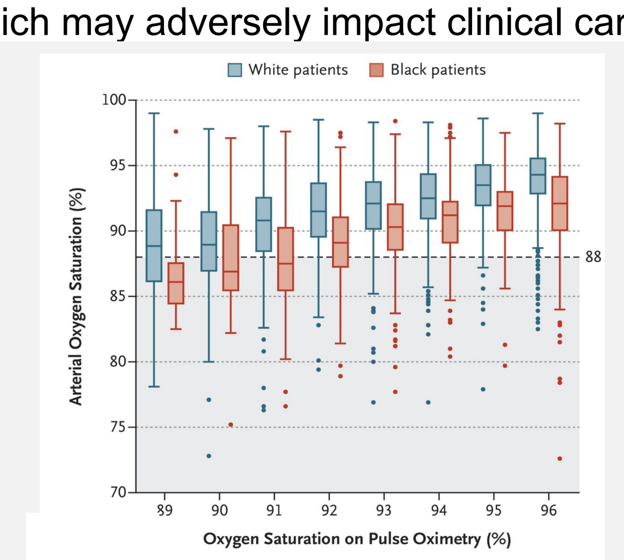
Introduction

Pulse oximetry is a widely used optical sensing technology that was cleared by FDA for noninvasive measurement of arterial blood oxygen saturation. In recent years, it has become increasingly used by clinicians as a threshold diagnostic for treatment (e.g., oxygen therapy for COVID-19).

Kyriacou et al., Academic Press 2021
Chatterjee et al., Sensors 2019

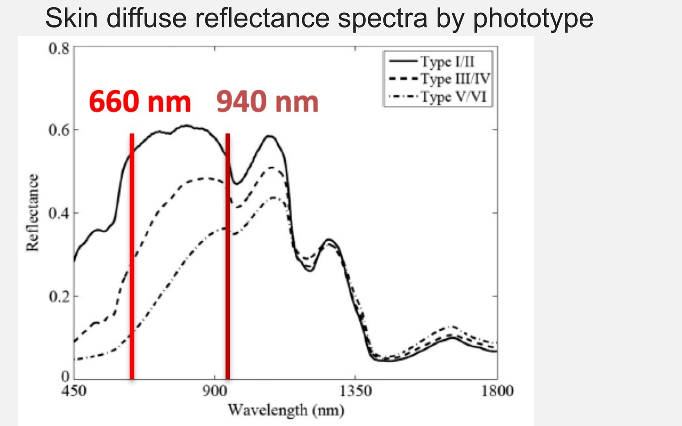
Recent pulse oximetry studies have indicated an overestimation of SaO_2 in subjects with strong skin pigmentation, which may adversely impact clinical care.



Sjoding, M.W., et al. *NEJM* 2020

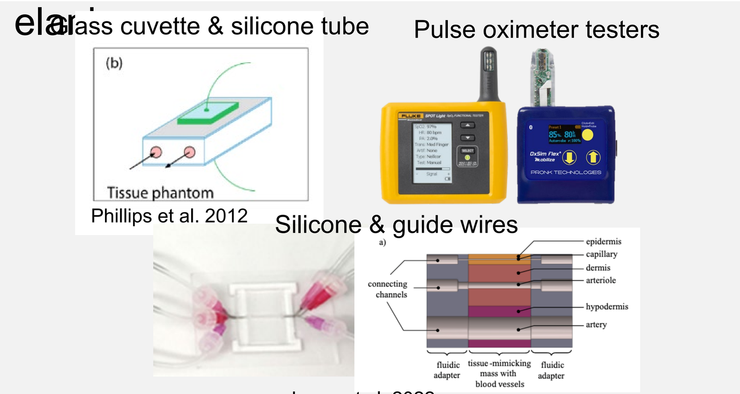
Epidermal melanin is well known to act as a dominant absorber in the skin, strongly reducing detected signals, especially at visible wavelengths.

Skin diffuse reflectance spectra by phototype



Mendenhall et al., Appl Opt 2015

Tissue-mimicking phantoms provide tools for elucidating mechanisms, studying error sources and characterizing device performance. However, prior studies have not been successful in developing practical, realistic, validated pulse oximetry phantoms or using them to elucidate the effect of ela



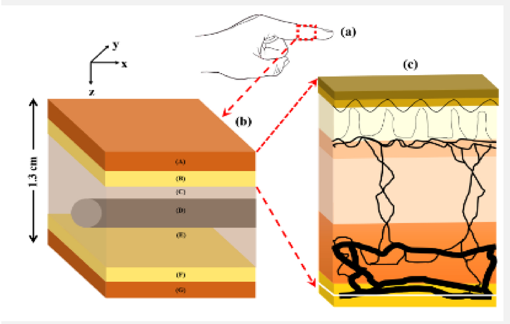
Phillips et al. 2012

Jenne et al. 2022

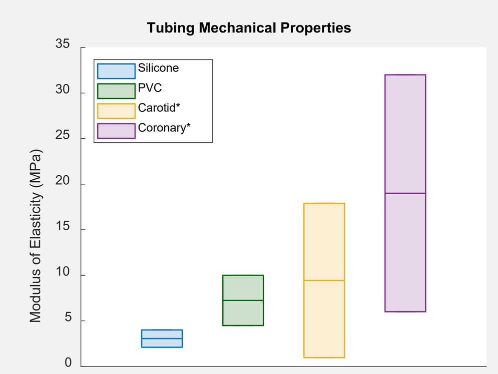
Materials and Methods

Purpose: Develop pulse oximetry phantoms with bio-relevant geometry, optical, and mechanical properties

Target Properties



Chatterjee, S. et. al. *Sensors* 2019



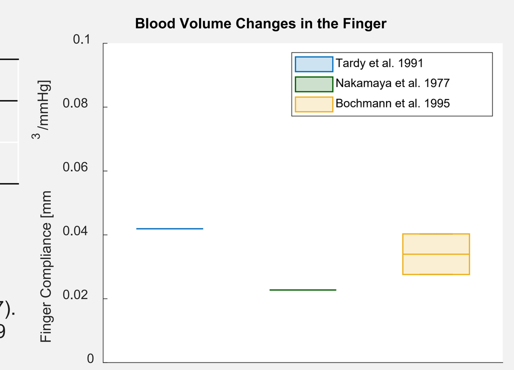
*Yazdi, Sina G., et al. *Annals of Biomedical Engineering* 2018

Target Optical Properties

Wavelength (nm)	μ_a (cm^{-1})	μ_s' (cm^{-1})
660	0.9	14.7
940	1.1	9.8

Target 2% blood volume change as shown in human blood vessels

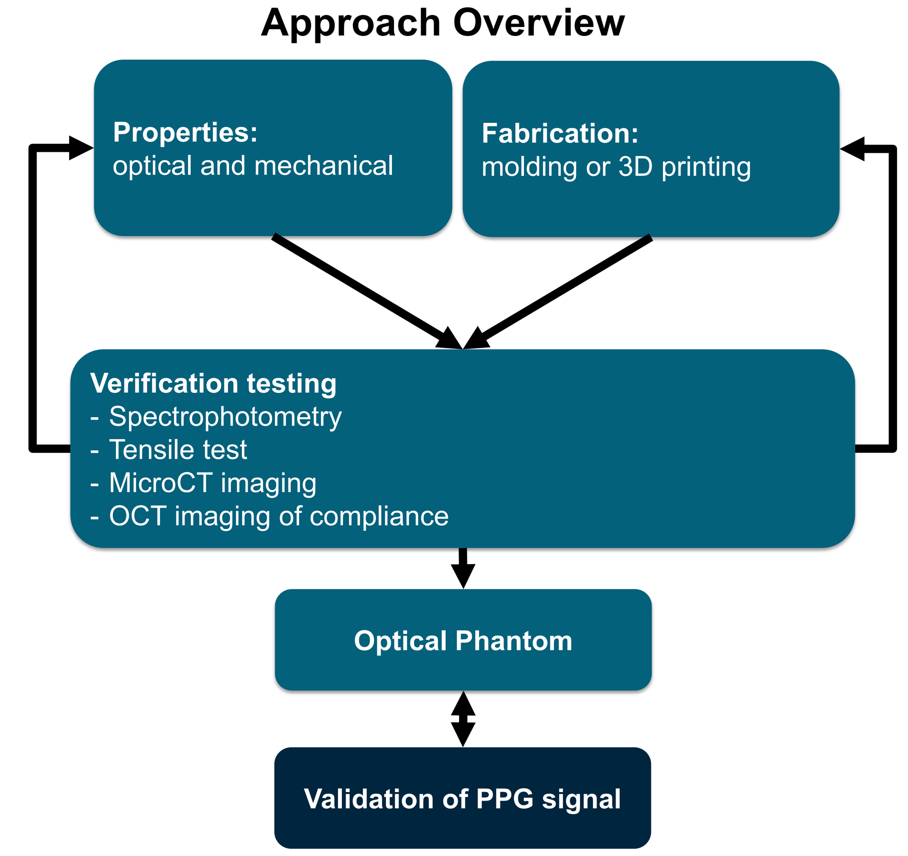
T. Khamdaeng et al., Ultrasonics 52(3), 402–411 (2012).
C. Giannattasio et al., Eur. Heart J. 18(9), 1492–1498 (1997).
C. Giannattasio et al., Arterioscler. Thromb. Vasc. Biol. 1999



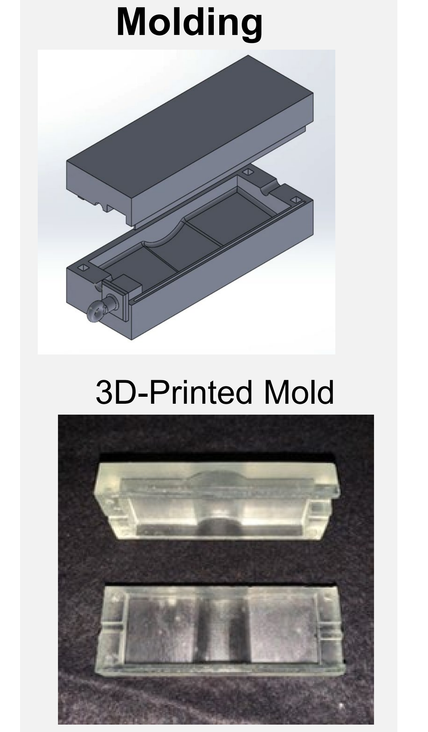
Goals:

(1) To identify/develop suitable composite materials.
(2) Fabricate phantoms that fit pulse oximeter sensors and provide adequate hemodynamic volume changes.
(3) Connect geometries to fluidic systems and generate PPG signals

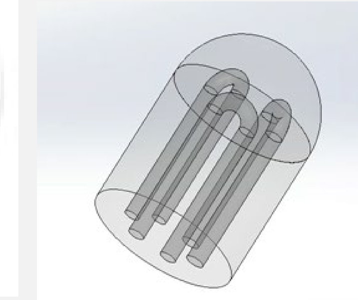
Approach Overview



Molding



3D Printing + Hollow Channels



FormLab's Elastic 50A

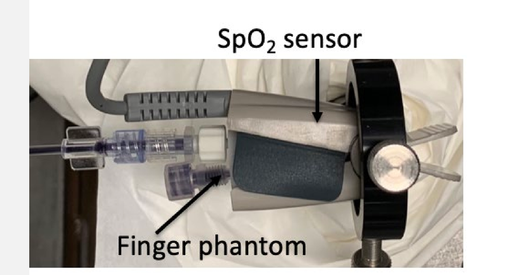
SLA 3D Printer
Form 2 (FormLabs, MA)
250mW violet laser (405 nm)
Layer thickness (axial resolution): 25,50,100 µm
Print time – full tray – 7-10 hrs.

3dprint.nih.gov

Controlled scattering coefficients with TiO_2 - hand/machine mixed -sonicated -degassed

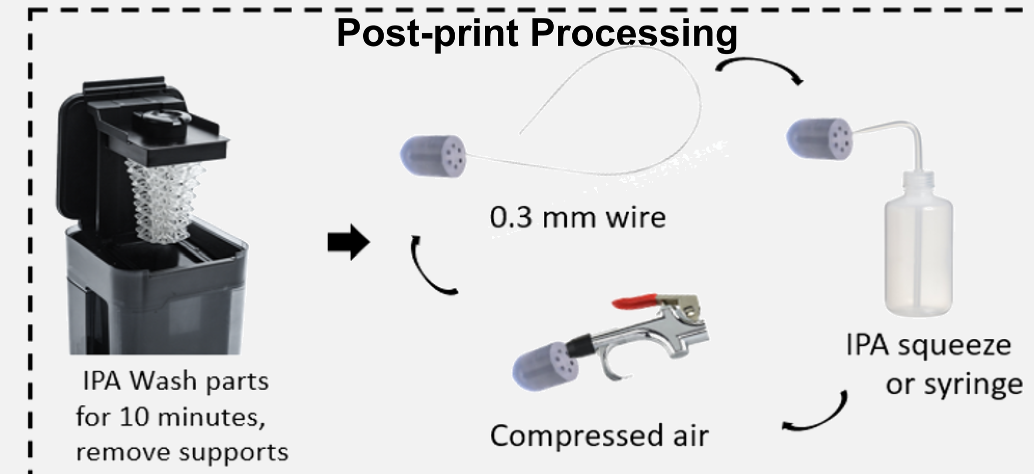
PPG Testing with Pulsatile Flow

Pressure Pulse Generator & Attenuation Testing Device (PPG-601A, Flometrics, CA)



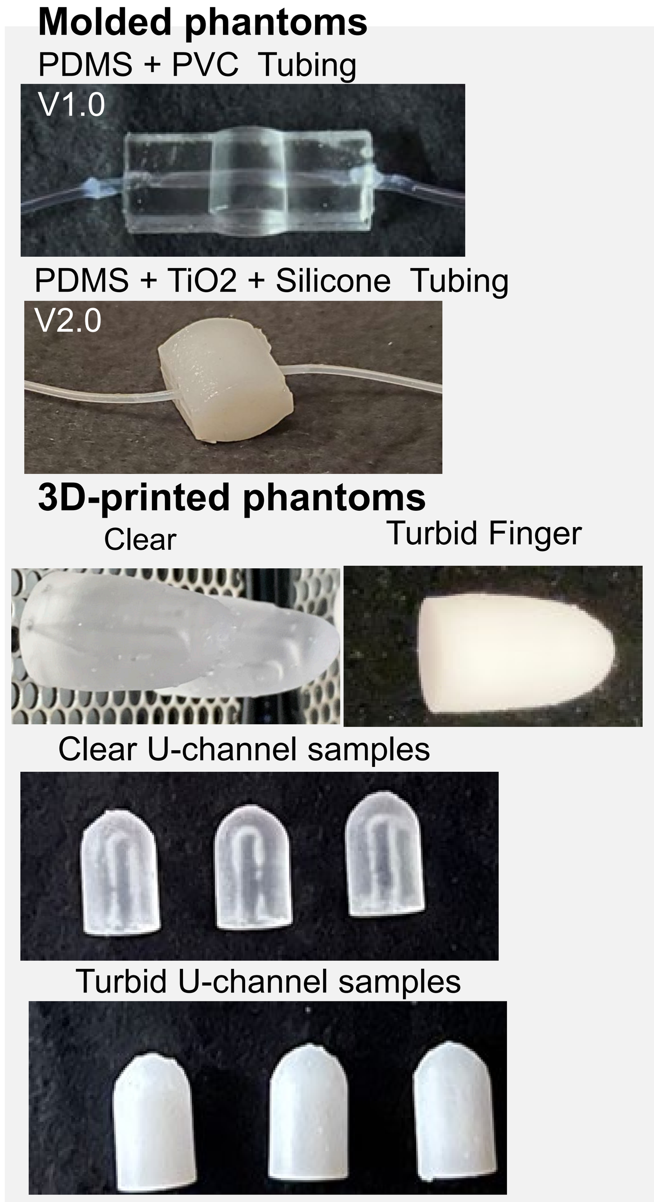
Pulse Oximeter Evaluation Module (Texas Instruments, TX). Tube filled with nigrosin solution at blood-relevant μ_a

Post-print Processing

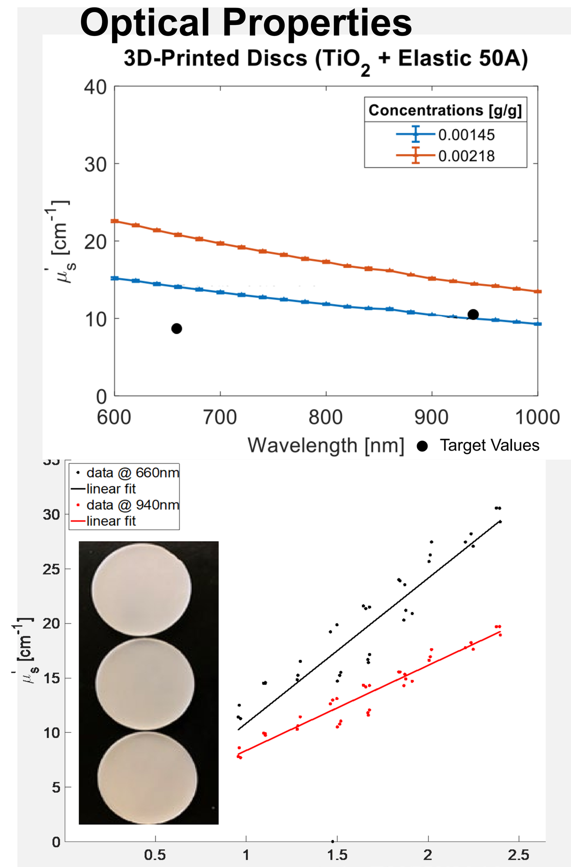


Results and Discussion

Molded phantoms



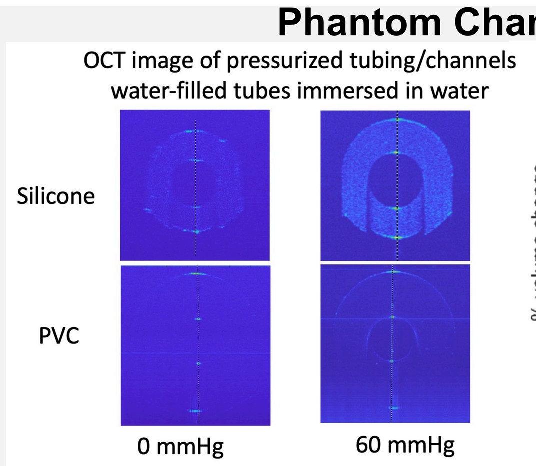
Optical Properties

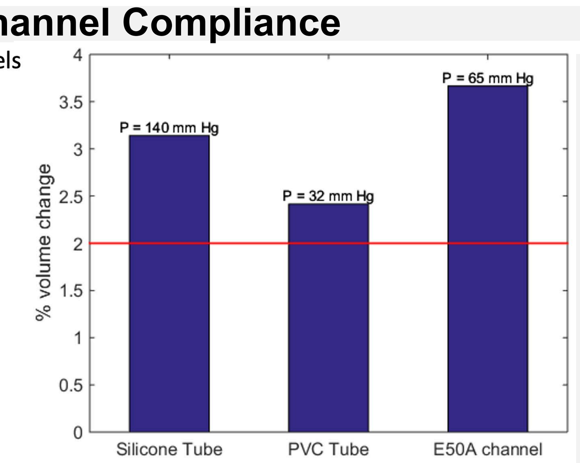


3DP Channel Patency and Diameter

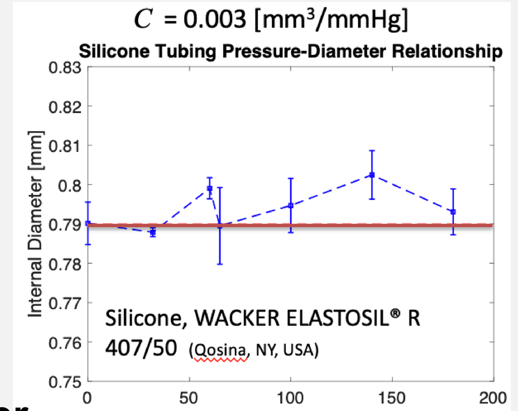
	ID = 1.0 mm	ID = 1.1 mm	ID = 1.2 mm
Elastic 50A	◉ ◉ (red)	⊛ ⊛ (green)	◎ ◎ (green)
Elastic 50A + TiO2 #1	◉ ◉ (red)	⊛ ⊛ (green)	⊛ ◎ (green)
Elastic 50A + TiO2 #2	◉ ◉ (red)	⊛ ⊛ (red)	⊛ ⊛ (green)
Elastic 50A + TiO2 #3	◉ ◉ (red)	⊛ ⊛ (red)	⊛ ⊛ (green)
Elastic 50A + TiO2 #4	◉ ◉ (red)	◉ ◉ (red)	◉ ⊛ (yellow)

Phantom Channel Compliance

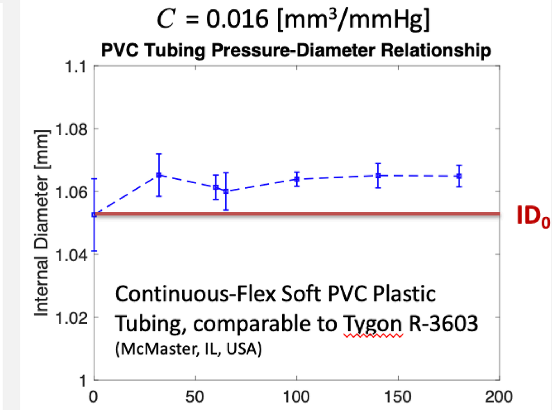




$C = 0.003$ [mm^3/mmHg]



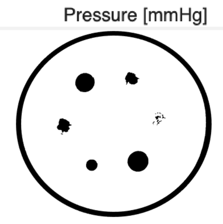
$C = 0.016$ [mm^3/mmHg]



Phantom Patency

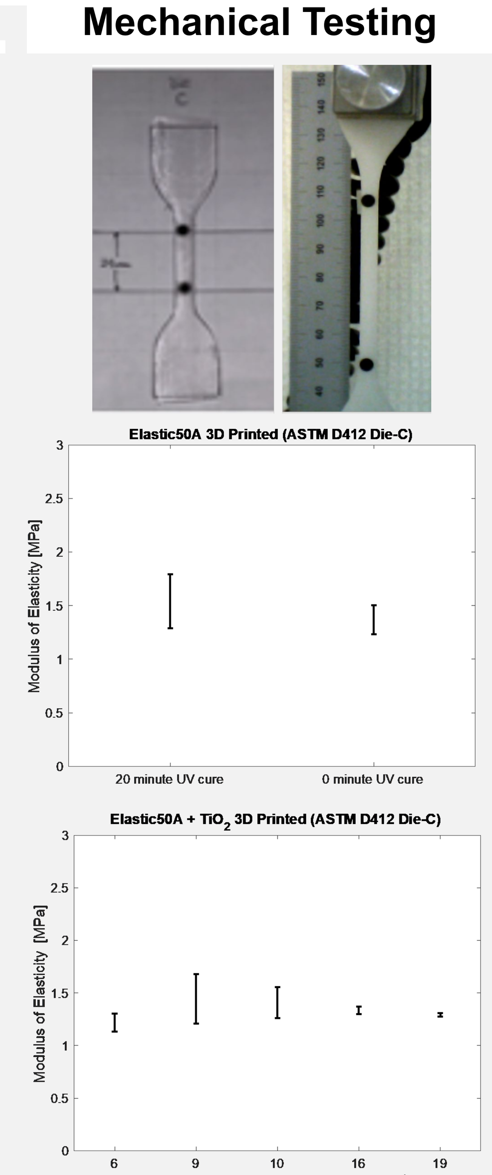
- Blocked (red)
- Partial (yellow)
- Open (green)

◎ - Fully open
⊛ - Channel reduction
◉ - Fully closed

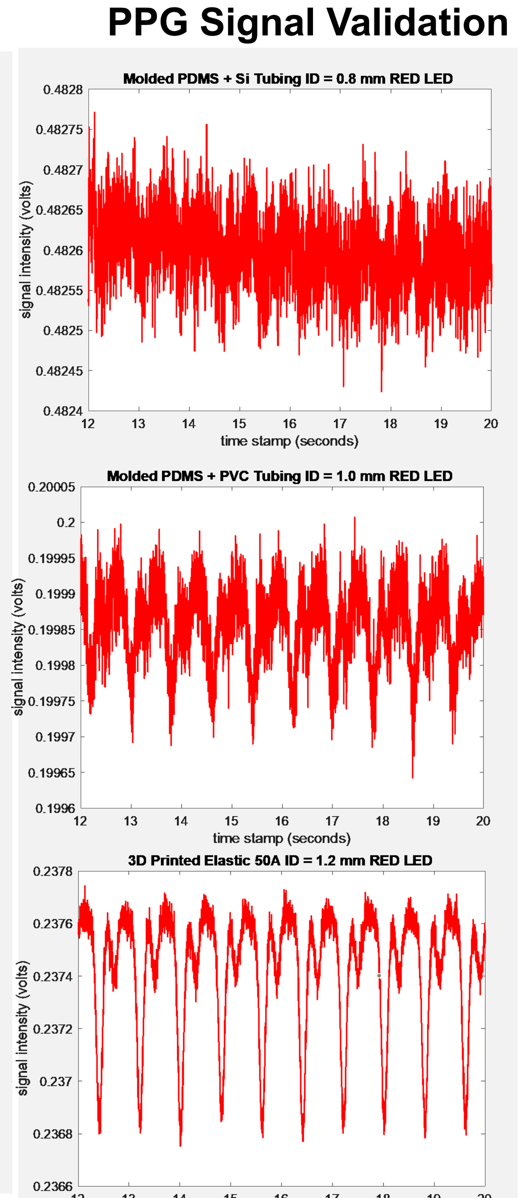


MicroCT Scanner - μCT 100
(SCANCO Medical AG, Brüttisellen, Switzerland)

Mechanical Testing



PPG Signal Validation



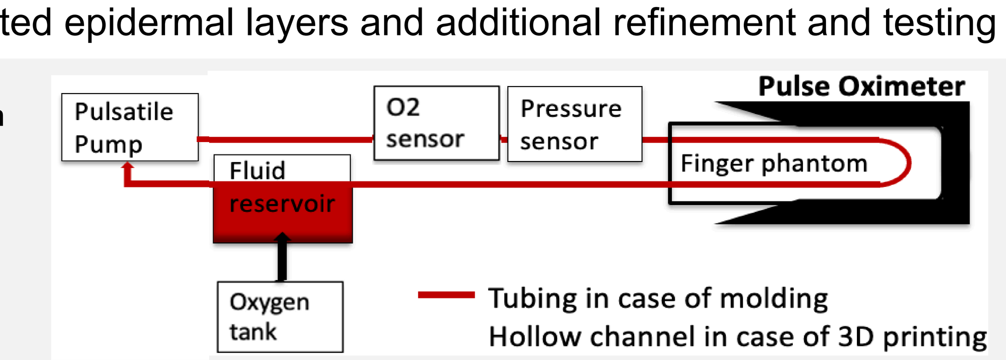
Conclusion

- Preliminary results indicate that the phantoms show strong potential to be developed into tools to evaluate pulse oximeter performance
- Both silicone molding (with tubes) and 3D printing appear viable, providing biologically-relevant optical and mechanical properties
- Minimum vessel inner diameter - 3D printing with Form 2: 1.2 mm - Tubing: 0.8 mm (silicone)
- Silicone and PVC tubes show compliance lower than target range, with the latter showing higher compliance
- Both tubing and 3D printed channels tested show bio-relevant volume changes and can generate dynamic, pressure-driven changes in optical signals (i.e., PPG), although % modulation levels are lower than realistic
- 3D printing facilitates fabrication/modification of bio-mimetic finger geometries

Future work will incorporate pigmented epidermal layers and additional refinement and testing with a closed loop pulsatile system.

Epidermal melanosome volume fraction

Afshari, Ali, et al. *BOE* 13.5 (2022): 2909-2928.



Acknowledgements

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