

DermaVision

Team members: Ashley Im¹, Alejandra Reyes¹, Mitchell Frazeur¹, and Hao Ngo¹ Project Advisor: Elliot Botvinick, Ph.D.

UCISamueli School of Engineering University of California, Irvine

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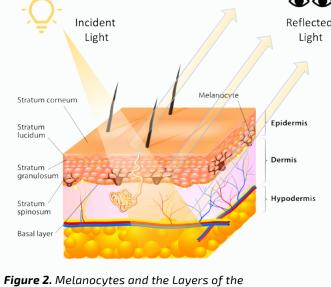
Project Goal:

An estimated 10 million people in the United States experience domestic violence (DV) every year, with 4 out of 10 cases affecting people of color [1][2]. Law enforcement and healthcare providers visually inspect injuries and document bruising using a commercially available camera. While this method is highly effective on lighter skin tones, it fails to account for pigmentation levels on the skin (Figure 1).

Increased melanin concentrations make it more difficult to detect bruising on darker skin tones (Figure 2), which can lead to unreliable measurement and thus disparities in legal and medical outcomes. Without firsthand evidence to identify when the bruising event occurred, the age cannot be reasonably determined earlier than 18 hours [3][4].



6). B: Contusions on light skin (Massey-Martin rating of 1) [5]



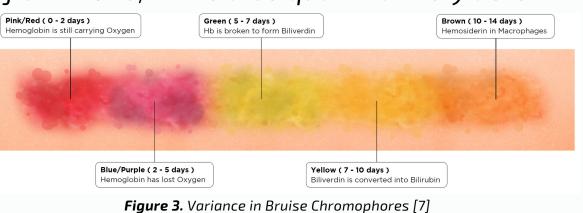
Objectives:

- 1. To develop a reliable imaging tool capable of detecting bruise injuries across all skin tones.
- 2. To incorporate a quantitative measurement of the age of the injury.

Solution:

Employ multi-spectral imaging techniques to capture and process images across a wide range of wavelengths. This method generates a spectral signature or "fingerprint" of the chemical components of blood present in bruises (Figure 3).

As these components vary in concentration during the healing process of a bruise, the device can effectively detect bruise injuries regardless of skin tone, while also quantitatively determining bruise age.



Team Organization Chart

Project Mentor: Elliot Botvinick, PhD **Project Managers:** Christine Ly, Matthew Lo, Gerald Lee

R&D

Design, assemble, and

prototype device

iterations

Legal

Derek Nutz Gerald Lee Matthew Lo

Document inventors iteration developments, and invention specifics

Clinical

Gerald Lee Alejandra Reyes Jazmin Arias Joseph Chei Jessica Lam

Develop clinical testing protocols and submissions

Algorithm

Christine Ly Matthew Lo Hao Ngo Mitchell Frazeur Ashley Im Siana Jimenez

> Process preliminary data, provide feedback to R&D, create software

Project Design and Device Validation/Verification Plans

FDA Standard: Class 1 Medical Device, CPC subclass A61b/0075, and 510(k) exempt In compliance with: ISO 14971, ISO 1099, IEC 60601

DMADV

Define

Develop a portable device for precise imaging of skin bruising, focusing on higher skin pigmentation cases.

Measure

Critical-to-quality (CTQ): portable, wide range of wavelengths, easy-to-train functionality, non-invasive nature.

Analyze

Brainstorm design and consider feasibility, cost, and effectiveness; select optimal concepts.

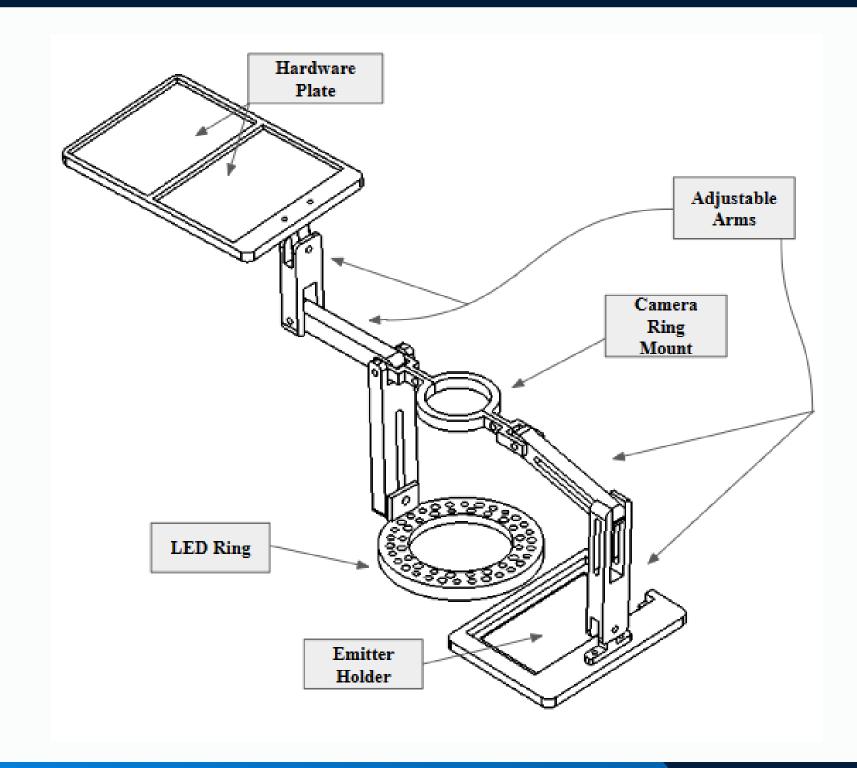
Design

Develop a prototype incorporating chosen design concepts, ensuring it meets all CTQ parameters.

Verify

Test prototype with phantom model and different skin tones; verify image accuracy and non-invasiveness.





Once verified, the prototype will be validated through testing by imaging clinical patients in a hospital setting. Ensure that the prototype meets the criteria outlined in the CTQs. Thoroughly assess the performance against the intended objectives using real-world clinical data. Use the results to inform any necessary refinements or improvements before making decisions about scaling up the design for production.

Timeline

Activity	Fall 2023										Winter 2024										Spring 2024									
	W1	W2	W3	W4	W5	W6	W7	W8	W9	W10	W1	W2	W3	W4	W5	W6	W7	W8	W9	W10	W1	W2	W3	W4	W5	W6	W7	W8	W9	W10
Test images with various LED setups																														
Process/compare initial image sets																														
Develop clinical device: CAD modeling, circuit design, prototyping																														
Develop smartphone attachable miniaturized device																														
Submit IRB proposal for imaging human subjects																														
IRB revisions, clinical protocol																														
Collect clinical bruise image sets, verify clinical device																														
Process clinical image sets																														
Develop algorithm that correlates spectral data to bruise marker																														
Supplemental algorithms, developing time-to-injury correlation																														
Conduct customer discovery interviews with law enforcement personnel,																														

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Dr. Christine King Dr. Tibor Juhasz Sina Javadzadeh No Jiaxin Luo

Contact Information

Dr. Elliot Botvinick: ebotvini@uci.edu Mitchell Park Frazeur: mfrazeur@uci.edu Hao Ngo: chngo2@uci.edu Ashley Im: ashleyji@uci.edu Alejandra Reyes: reyeschm@uci.edu



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