DermaVision

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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].

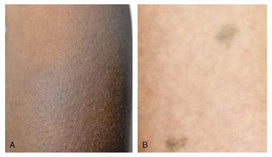


Figure 1. *A: Contusion on dark skin (Massey-Martin rating of 6). B: Contusions on light skin (Massey-Martin rating af 1) [5]*

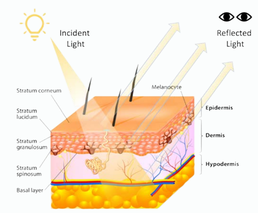


Figure 2. *Melanocytes and the Layers of the Skin.[6]*

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.

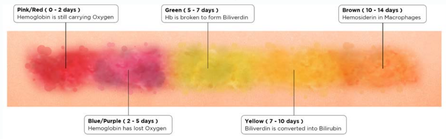


Figure 3. *Variance in Bruise Chromophores [7]*

Team Organization Chart

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

Legal	Clinical	R&D	Algorithm
Derek Nutz Gerald Lee Matthew Lo	Gerald Lee Alejandra Reyes Jazmin Arias Joseph Chei	Christine Ly Hao Ngo Siana Jimenez Jessica Lam	Matthew Lo Mitchell Frazeur Ashley Im
Document inventors, iteration developments, and invention specifics	*Develop clinical testing protocols and submissions*	*Design, assemble, and prototype device iterations*	*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.

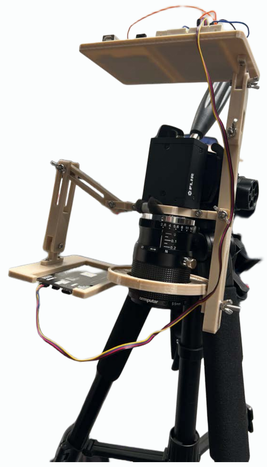
Measure
Critical-to-quality (CTQ): portable, wide range of wavelengths, easy-to-train functionality, non-invasive nature.

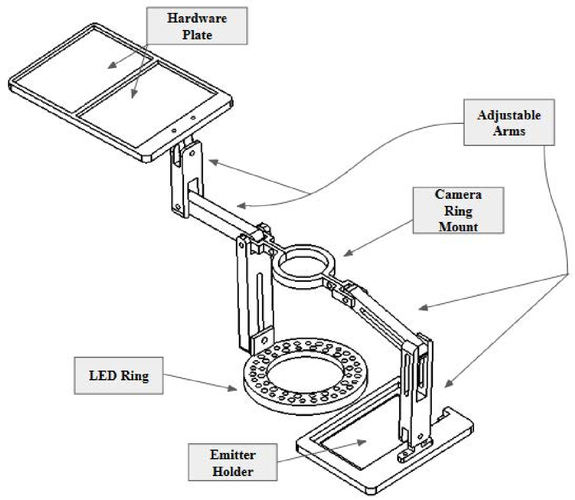
Analyze
Brainstorm design and consider feasibility, cost, and effectiveness; select optimal concepts.

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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Jiaxin Luo

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BEAMS LAB

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