Detecting early stage pressure ulcer on dark skin using multispectral imager

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Abstract:

We are developing a handheld multispectral imaging device to non-invasively inspect stage I pressure ulcers in dark pigmented skins without the need of touching the patient's skin. This paper reports some preliminary test results of using a proof-of-concept prototype. It also talks about the innovation's impact to traditional multispectral imaging technologies and the fields that will potentially benefit from it.

Introduction:

We are developing a hand held multispectral imaging device to non-invasively inspect Stage I Pressure Ulcers. Our long-term goal is to fill the hole existing in the medical imaging market with a product that has the combination of the following features including: miniaturized, low cost, convenient to use, without the need to touch the patient's skin, real time output, standing alone, etc [1].

Pressure ulcers have high prevalence in all health care settings and are costly secondary complications for people with impaired mobility and sensation. Meanwhile pressure ulcers are preventable with simple care if accurate detection in the early stage is readily available. The state of art in clinical practice for early stage pressure detection is by visual inspection of skin which is problematic in persons with darkly pigmented skin as the melanin masks the visual indications and detection is dependent on the clinician's ability to detect subtle palpatory changes.

Pressure ulcers have an average prevalence of 15% in the acute care patient setting and a greater incidence in the long term and home care settings and have been a bane to the health care continuum for decades. The cost to heal a pressure ulcer that requires surgical intervention is estimated to be $40,000. Associated health care costs related to treating pressure ulcers exceeds $8 billion annually to the medical system. Pressure ulcers are one of the three primary concerns identified by the federal government within the Healthy People 2010 initiative and the National Quality Forum and are one of several "never events" that the Center for Medicare and Medicaid Services (CMS) refuses to reimburse for treatment if the ulcer is acquired while the patient is being treated at the facility .

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Early detection is the most effective strategy for the prevention of bedsores by clinicians and caregivers. If pressure ulcers are detected in the earliest stage of development (stage 1), simple care of the tissue can allow the skin to remain intact and heal without scarring or the need for surgical intervention. Visual inspection is the basic tool used for early detection. This can be subjective and inaccurate for the unskilled observer. In dark skinned individuals the melanin at the surface of the skin masks important findings to the point where inspection can easily miss significant tissue deterioration. (Figure 1).

The ideal detection device needs to be hand held, portable, and easy to use. Point of care for detection will include the acute, home, long term care facilities, and clinics where operators may not be skilled in detecting subtle changes without the assistance of a point of care technology. The images this device will create can be easily sent to others for interpretation or archiving to a medical record.

Multi-spectral imaging as an imaging tool has matured into a technology with many applications. These include defense applications, produce sorting, precision farming in agriculture, quality inspection in manufacturing, food contamination detection, remote sensing in mining, atmospheric composition monitoring in environmental engineering, and early stage diagnosis of cancer and tumors. Multi-spectral imaging is quickly replacing other visually-based diagnostic methods as the most powerful diagnostic tool in medical imaging. Our prior research work has approved the technology is valid in diction of early stage pressure ulcer [2]. But current technology has been incompatible with the requirements of a handheld point of care clinical tool. Existing multispectral devices are either non-portable, require multiple exposures or require significant post-processing time. Thus, the basic platform technology would have a significant strategic competitive edge over other multi-spectral imaging devices currently in use which in turn will help drive adoption rates.

There is a large market for a handheld device that can reliably detect stage 1 pressure ulcers in an acute care, long term care and home care setting. The device will replace unreliable (manual palpation) and/or expensive diagnostic techniques (tissue biopsy and radiological imaging) and improve diagnosis and treatment. This will provide better patient outcomes for millions of people at risk for developing pressure ulcers and those with arterial, venous, diabetic, lymphatic and collagen vascular disease. Our new multispectral imager will be a robust low cost point of care technology for many clinical conditions in a variety of patient care settings. This will facilitate early detection of skin changes in all colors of skin and lower the high costs associated with treating pressures ulcers along the health care continuum in America today.

<u>This innovation can make many fields utilize multispectral imaging technology without cost and portability issues any more:</u>

- The immediate application is early stage pressure ulcer detection, which will accommodate all skin tones especially darkly pigmented individuals, at the stage when simple care can prevent progression to an open ulcer. The corresponding market

including hospitals, nursing homes, homecare, remote care, tele healthcare, long term care, etc.
- The same technology can also be used to accurately and conveniently monitor wounds.
- The core technology can be applied in modern scientific research including a) to develop a handheld quantum dot detector for cancer study and targeted drug delivery, b) reconstruct the Hartman interferometer to make it simultaneously detect multi epidemic diseases and monitor virus concentration in real time, c) to develop lens microarrays and multi-spectral focal plane arrays
- The core technology also has rich non-medical related applications in the traditional industries including inspection of agricultural products and food manufacturing, military target search, etc.

Technology:

We have designed and developed a breakthrough technology to reduce the cost and size of multispectral imaging systems by placing a miniaturized filter mosaic immediately in front of the focal plane of CMOS/CCD imaging sensors to produce an economic and compact skin disorder imager (Figure 2). The core technology including the micro-manufacturing process for fabricating filter mosaic and the microsystems packaging procedures to integrate the filter mosaic with commercial CCD/CMOS imaging sensors greatly facilitates multispectral imaging technology entering practical applications especially at point-of care clinical fields [1]. Integration procedures have been established to laminate the filter of a certain cell size with commercial CCD and CMOS imaging sensors of different pixel sizes (Figure 3).

The filter mosaic allows light of specific wavelengths centered at λ_1=540, λ_2=577, λ_3=650 and λ_4=970 nm with bandwidth of 30nm to pass through, in order that the resulting imager can be best tuned to the characteristic chromospheres existing in pressure ulcers. 540 nm and 577 nm correspond to the hemoglobin absorption peaks; 650 nm gives us a melanin or background image, and 970 targets the water peak plus it gives deep penetration. The area of a single wavelength cell of the current prototype is 20.8 x 20.8 μm^2 with spacing between individual filter cells about 1-2 μm (Figure 4).

The prototyped multispectral imager is used to detect early stage pressure ulcers. With a single shot, the integrated multispectral imager produces in real time four images corresponding to wavelengths 540, 577, 650 and 970 nm where the erythema becomes visible, although not very clearly. The real time fused image is shown in Figure 5, where the erythema is more apparent than in the single multispectral image, but still needs to be refined in order to produce better image quality required by clinical applications.

Results from preliminary test:

The real time erythema imager has passed bench test before delivering to clinical trial. Results showed that for white/Caucasian, Asian and black/African-American, the imager can real time detect erythema effectively (Figure 5).

From Figure 5, people can find the erythema on the skins of white/Caucasian and Asian is not hard by using visual inspection. However, for black/African-American, skin pigmentation can mask the visual indication of erythema, thereby hindering clinical assessment in people with darkly pigmented skin

Future work:

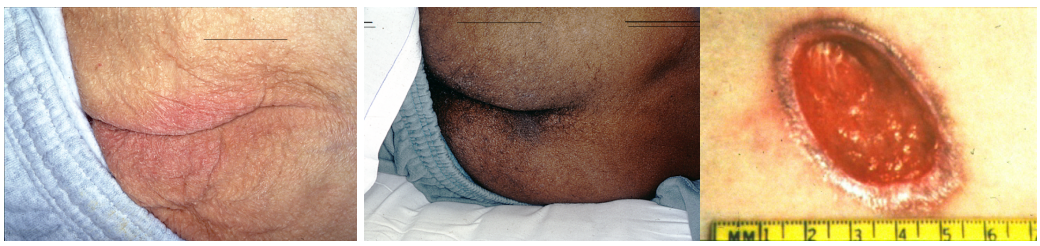
The further work is being done to refine the technology to achieve better image quality. Major milestones are to design and deploy the illuminating field to permit imager use under clinical conditions with different ambient lighting, specular reflection, body curvature, etc. We also need to improve the calibration procedure to overcome miss-alignment between the filter mosaic and the underlying CMOS/CCD imaging sensors.
Simultaneously we are going to develop and implement algorithms able to deconstruct the mosaic image into an image that contrasts the intensities of the different wavelengths. We will also refine the technical specifications for the next generation filter mosaic and imager and have develop a R&D plan in the next stage during which multiple prototypes will be fabricated and deployed to assess the clinical validity in detecting incipient pressure ulcers.

References:

1. Kong, L., Sprigle, S., Duckworth, M., Yi, D., Caspall, J., Wang, C. and Zhao, F. "Handheld erythema and bruise detector," Proc. SPIE **6915**, 69153K (2008)

2. Sprigle, S., Zhang, L. and Duckworth, M. "Detection of skin erythema in darkly pigmented skin using multispectral images," Adv. Skin Wound Care **22**(4), 172–179 (2009).

Figures:



Erythema in light and dark skin Stage 3 Pressure ulcer

Figure 1. Top: Early stage erythema in light and dark skin. The latter case is hardly visible.

Bottom: Stage 3 pressure ulcer.

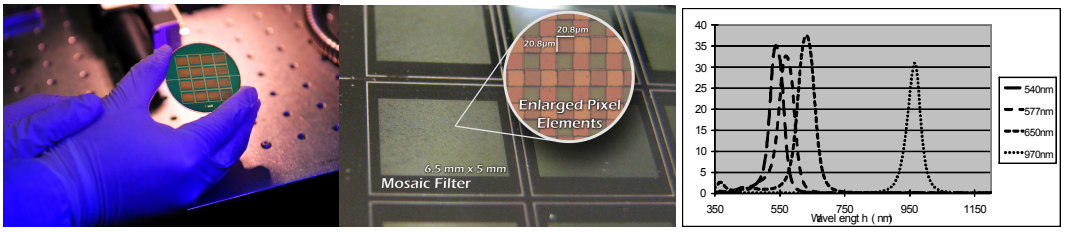


Figure 2. *Left:* One waffle by mass production containing 16 multispectral narrowband filter mosaic with our current manufacturing procedures. We can produce 24 such waffles within one batch production. *Middle*: A section of the prototype mosaic filter for the set of wavelengths $\lambda_{[1,2,3,4]}$ = 540, 577, 650 and 970 nm, respectively. The image shown was taken from a CCD microscope. *Right:* Transmittance of the four wavelengths through the filter array.

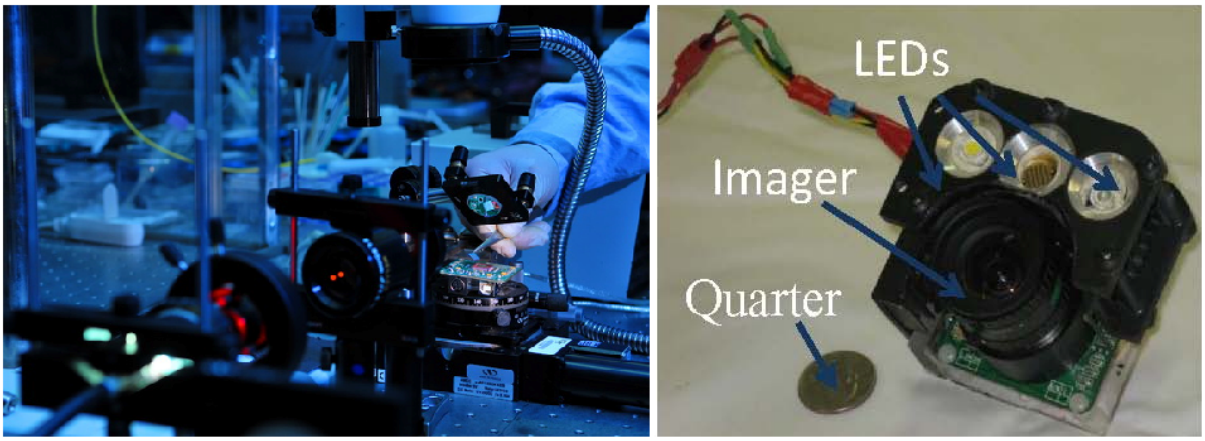


Figure 3. *Left*: Integrating filter mosaic with a CMOS imaging sensor (e.g., a Mightex USB2 camera's monochromic CMOS sensor (MT9M001C12STM). *Right:* a compact erythema imager with three LED lighting sources.

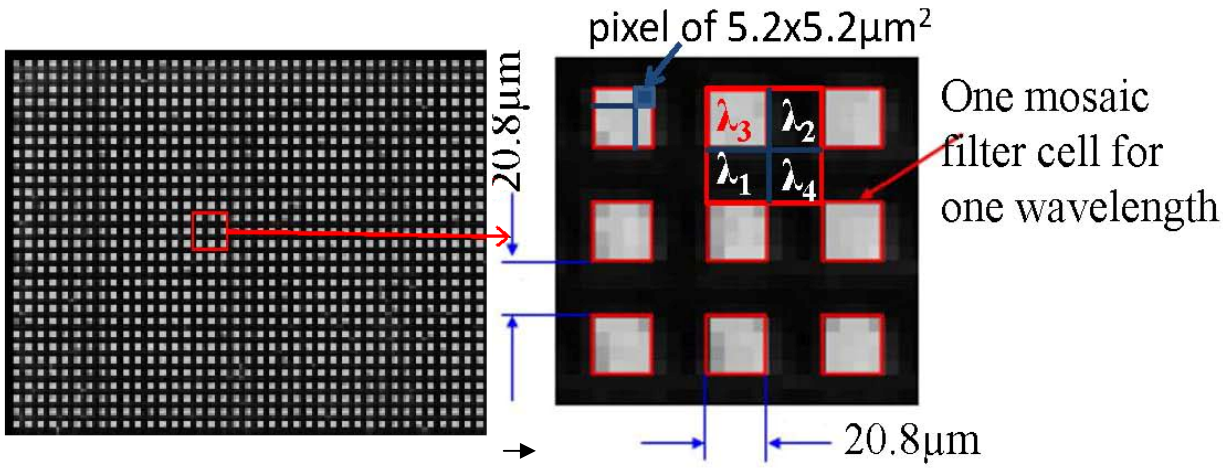
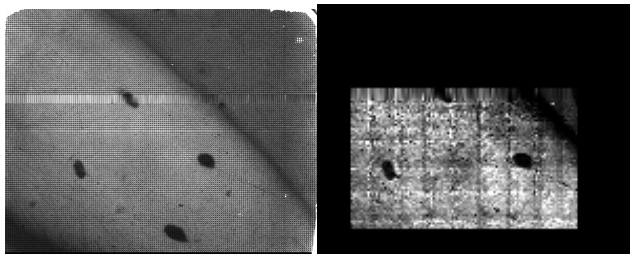
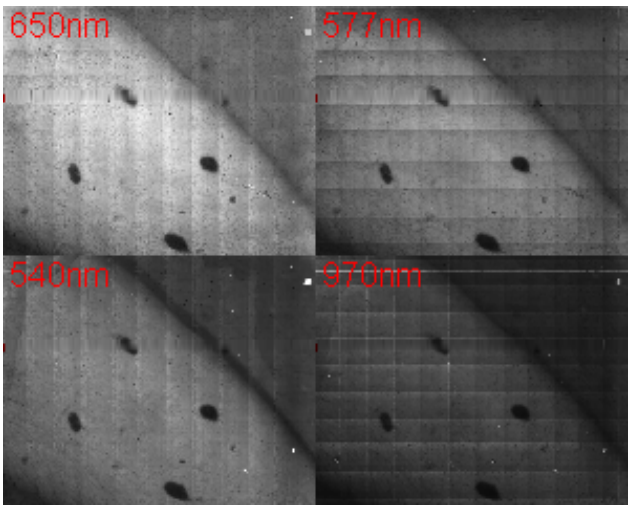


Figure 4 Left: A raw image of a flat sheet illuminated by green light of wavelength centered at 650nm produced by the prototyped erythema imager. As expected, only cells that correspond to the spectral component of wavelength 650 nm are light up, leaving cells of other spectral components (λ_1=540, λ_2=577, and λ_4=970 nm) at rather low intensity. Right: An enlarged version of a few filter mosaic cells which illustrates the size of one wavelength cell for the current prototype is 20.8 x20.8 μm^2.

white/Caucasian

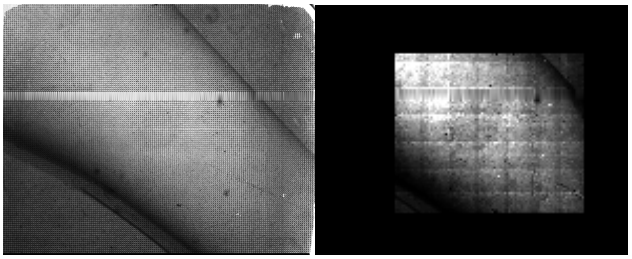


White-(a) White-(b)

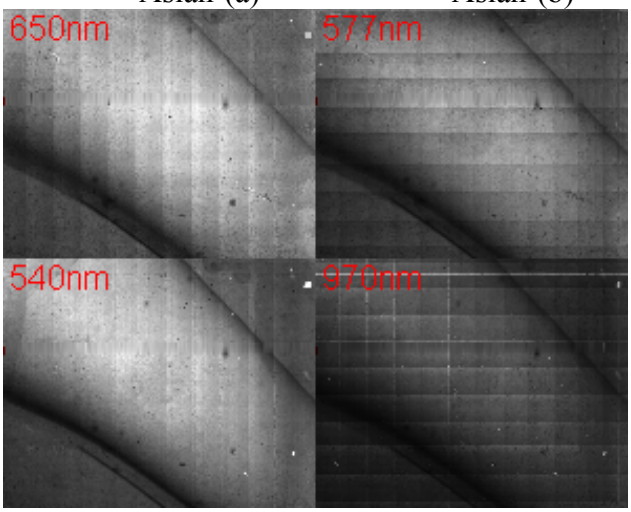


White-(c)

Asian

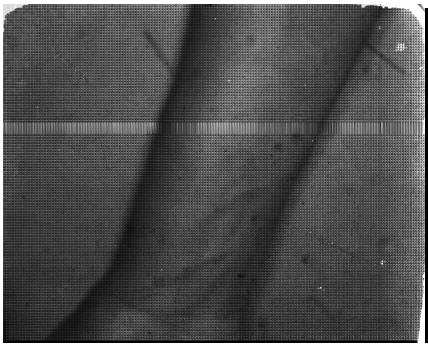


Asian-(a) Asian-(b)

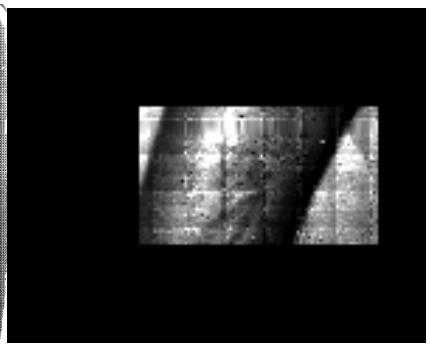


Asian-(c)

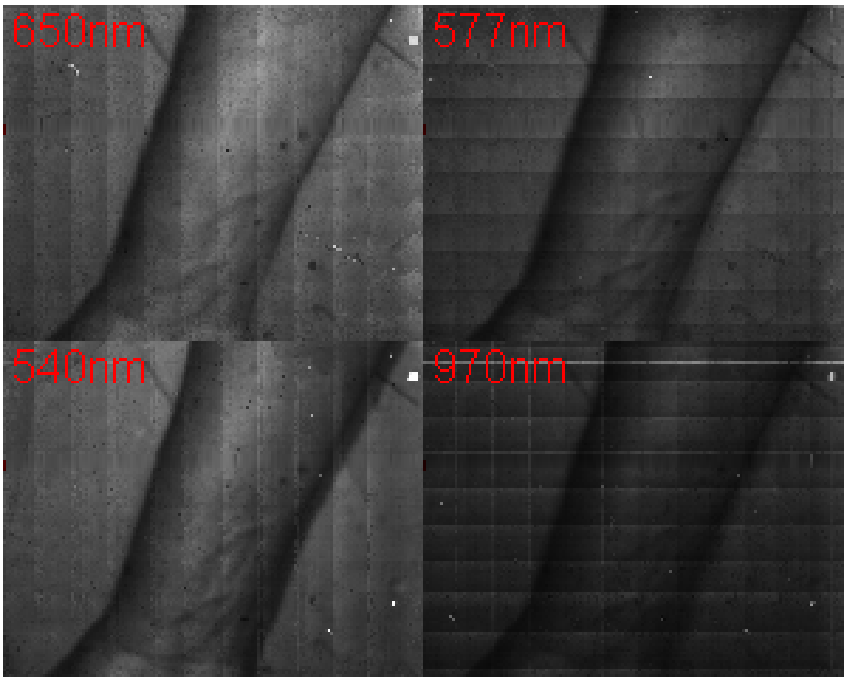
black/African-American



Black-(a)



Black-(b)



Black-(c)

Figure 5. For white/Caucasian, Asian and black/African-American **a)** real time acquired images of an erythema (artificially pressure induced) (b) fused view of the erythema (c) four images correspond to four different wavelengths $\lambda_{[1,2,3,4]}$.