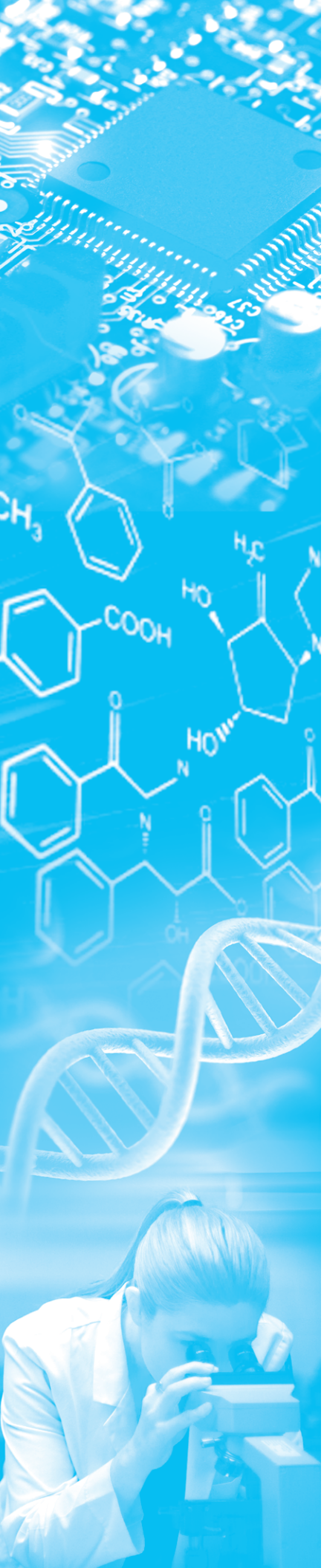

NSU Florida
NOVA SOUTHEASTERN UNIVERSITY

Alternative Light Source for Detecting Tissue Damage

According to the Agency for Healthcare Research and Quality, each year pressure ulcers (bed sores) costs the healthcare system $9.1 to $11.6 billion and individual patient care costs range from $20,000 to $151,700 for each pressure ulcer. Considering this socioeconomic burden of pressure ulcers and the difficulty to treat an ulcer efficiently once it has become larger, developing a method for early detection is essential for better treatment, quality of life and saving healthcare costs. Moreover, currently there are no clinical tools suitable for early detection and prevention of pressure ulcers. The current standard of care for prevention of ulcers implements risk assessment scales to predict which patients are more likely to develop ulcers. However, all of these scales (Braden, Cubbin and Jackson, Norton and Waterlow scales) lack adequate specificity and sensitivity. To offer a solution for this unmet need a researcher at NSU has developed a method that utilizes various wavelengths of light as an alternate light source (ALS) to detect tissue trauma associated with pressure ulcer pathophysiology.

Technology

Dr. Heather Hettrick has developed this novel ALS technology by modifying a visualization tool that was originally designed to be used by forensic experts for the detection of localized damage to skin and/or soft tissue lying immediately underneath it. The device consists of a powerful ALS capable of emitting light in the visible spectrum, UV and IR. The device is designed to filter light into wavelengths to visually enhance evidence of tissue damage by different light interaction techniques such as absorption, fluorescence and oblique lighting. The examiners are also provided with goggles of different colors that act as filters and further enhance visualization of tissues. This system equipped with wide range of wavelengths will enable accurate detection of tissue damage associated with pressure ulcer pathophysiology well before it is detectable by the unaided human eye. This early detection will lead to improved treatment, enhance a patient's quality of life and save significant healthcare expenses. According to external regulatory consultants, this product is most likely to be classified as a Class II device and will require a De Novo submission for 510(k) regulatory clearance.

Application

This clinical tool will enable health professionals to identify tissue trauma and areas at risk of developing pressure ulcers even when they are not visible to the naked eye under normal white light.

This will offer much earlier and accurate detection of tissue trauma, which will allow the opportunity of earlier therapeutic intervention.

ALS can also be used to screen sites of previous injury that might be at higher risk of subsequent tissue damage so that patients can take appropriate precautions to protect the vulnerable areas.

Advantages/Benefits

Detects damaged tissue much earlier than current procedure of checking with naked eye. ALS will also offer higher specificity than the currently used risk assessment scales.

ALS implements various wavelengths of light, which allows visualization of possible tissue damage that, cannot be seen with only white light.

This device will offer a simple, noninvasive and portable method for detecting tissue trauma. Currently there are no approved clinical tools suitable for this purpose of early detection of pressure ulcers.

Status of Development

In an IRB approved clinical study at a long-term care facility, 10 subjects were monitored for 6-weeks to evaluate the efficacy of this ALS device. The findings from this study indicate that ALS is capable of detecting tissue damage that is not possible to be identified by visual examination with naked eye under normal white light.

Currently researchers at NSU are in the process of initiating a larger clinical study based on the findings of this preliminary study so the device might be further modified to make it ideal for intended clinical applications.

Patent Status

Patent Application published on 09 March 2017.

Information on Inventor

Dr. Heather Hettrick is an Associate Professor at NSU's Department of Physical Therapy. Dr. Hettrick is a Certified Wound Specialist from the American Board of Wound Management (ABWM) and a Certified Lymphedema & Wound Therapist from the International Lymphedema and Wound Training Institute (ILWTI).

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