2021 43rd Annual International Conference of the
IEEE Engineering in Medicine & Biology Society (EMBC)
Oct 31 - Nov 4, 2021. Virtual Conference

FootAssure: A multimodal, in-home wound detection device for diabetic peripheral neuropathy

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***Abstract*—Currently, there is no single technology capable of assessing all the multitude of factors associated with peripheral complications of diabetic neuropathy. In this work, a multimodal wound detection system is proposed to help facilitate in-home examinations, utilizing a combination of thermal, multi-spectral 3D imaging modalities. The proposed system is capable of the 3D surface rendering of the foot and would overlay thermal, blood oxygenation, besides other skin health information to aid with foot health monitoring. Examples of biomarkers include pre-ulcer formation, blood circulation, temperature change, oxygenation, swelling, blisters/ulcer formation and healing, and toe health.**

Keywords: Diabetes, Neuropathy, Foot Ulceration, Multimode Wound Assessment, Telehealth

I. Introduction

According to the CDC, as of 2018, 10.5% of the US population were affected with diabetes mellitus. Complications associated with diabetes include peripheral neuropathy, a type of nerve damage within the peripheral nervous system caused by high blood glucose and triglyceride levels [1]. Peripheral vascular complications include peripheral arterial disease which is characterized by atherosclerotic occlusive disease of the lower extremities. This leads to the blockage or narrowing of the arteries, leading to restricted blood flow to the legs and feet. Patients with diabetes are more susceptible to ischemic events and impaired functional status compared to patients without diabetes [2]. Left untreated, these foot complications can develop tissue necrosis which can necessitate amputation. These complications account for the majority of nontraumatic lower-limb amputations, with the risk of amputation being up to 46 times higher in diabetic patients [3]. Though early detection of foot ulcers can prevent up to 85 percent of these amputations, studies have shown that foot examinations of diabetic patients are often infrequent and inadequate [3]. Furthermore, the subjectiveness associated with nurse assessments can result in the loss of critical clinical information.

The management of diabetic foot ulcers (DFUs) costs \$9–\$13 billion in the United States, with an expected 6.6% annual growth rate of the DFU market by 2024 [4]. Chronic wound healing is a lengthy process with months, or even years, of treatment time. Throughout the healing process, patients may have to pay countless visits to clinicians for checkups.

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This introduces tremendous challenges for the aging patients who are often incapacitated. With the ever-increasing healthcare costs and the likelihood of early discharge to home carepatients are highly vulnerable to complications due to the lack of routine checkups or personalized care. Unfortunately, the absence of personalized attention could easily cause infections and complications and 14-24% suffer from amputation [4].

The wake of the COVID-19 pandemic underscored the hurdles that these patients face when seeking care to treat their foot ulcers. Since wound centers where thousands of podiatrists provide care for diabetic foot ulcers have closed or reduced their hours, and in many states, diabetic foot ulcer procedures/surgeries have been mistakenly categorized as "non-essential", increased amputations and death have and will continue to follow. It is unthinkable that this extremely vulnerable population could be at increased risk due to clinic accessibility concerns. As such, the COVID-19 pandemic introduced the notion of podiatrists adapting to a telemedicinal system of care from which diabetic patients suffering from foot ulcers may benefit tremendously.

There are currently a few products with foot scanning capabilities that target diabetic patients. Most of the optical imaging products are non-contact and a mixture of handheld and console (including smart pad) systems. HyperMed, for instance, is a company that has developed and commercialized a wide-field optical imaging device called the HyperView™ (previously, OxyVu™-1) for assessment of tissue oxygenation [5]. The system uses homogenous models to quantify tissue chromophores using visible light data only. This means that measured Oxy-Vu signals originate primarily from superficial regions and provide only a 2D view of the foot, limiting its ability to identify deep foot ulcers. SnapshotNIR by Kent Imaging and Clarifi™ by Modulim have shown success on perfusion and tissue oxygenation measurements [6][7]. Thermetrix, has employed a thermochromic liquid crystal sheet that changes color with temperature and a camera is used to record the images [8]. Orpyx and The Smart Bathroom Mat (Mateo) does only thermal and pressure imaging using sensors inserted in shoe insoles [9][10].

None of the above-mentioned technologies can assess all these factors in one device. The multimodal wound detection system proposed will combine multiple imaging modalities and will be capable of developing a 3D RGB and thermal image model for foot wound exams.

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II. METHODS

A. FootAssure

The University of North Dakota (UND) Biomedical Engineering Program is developing and evaluating, a multi-mode optical imaging technology, FootAssure™, to identify early-stage pressure ulcers in collaboration with WoundExam Corp. This inexpensive, non-invasive, and portable technology is based on the detection of abnormalities using multimode mapping of the foot characteristics via spectral multi-mode and thermal imaging techniques, which allows for in vivo 3D evaluation of multiple biomarkers: pre-ulcer formation, blood circulation, oxygenation, swelling, blisters/ulcer formation, and healing, and toe health. As shown by Khan et. al. in 2018, a reflectance-based oximeter can be used to monitor oxygenation of tissues and wounds, eliminating the limitations posed by traditional transmission-mode pulse oximetry [11]. In addition, a temperature difference above the 2.2 ^{o}C threshold between similar regions in the two feet on two consecutive days could be an indication of ulceration, allowing for abnormality detection based on thermal imaging [12].

FootAssure™ will be a robust technology available for assessment of existing wounds, and for prevention through evaluating the risk of developing ulcers. Using a simple foot scanning unit at the clinic or at home, the patient receives a molecular, physiological, and visual analysis of their feet's skin and underlying structures to assess skin health and improve their quality of life. The system operates using telehealth, and clinicians receive an easy-to-understand report that can help spot problems immediately and track health progress. The FootAssure technology differentiates itself from competitors in three key factors. First, The FootAssure™ technology (Fig. 1) is designed as an all-in-one portable assessing system. Circulation issues through a combination of spectral and thermal imaging; tissue oxygenation and pre-ulcer formation; and other biomarkers of blisters, cuts, bruises, redness, and swelling. Assessment of all these factors in a single system is an innovative feature and an important step toward remotely optimizing a prevention and treatment plan at the point of care in a fully integrated, calibrated telemedicine device. Second, FootAssure offers a solution to monitor patients in in-care facilities or their private homes. For patients at risk of developing foot ulcers, constant manual assessment of their feet is necessary to prevent wound progression and the ultimate risk of amputation. By using a simple foot scanning unit, the FootAssure imaging system provides vasculature, tissue oxygenation, metabolism, and infection images that cannot be seen with the naked eye. Elderly patients with diabetes tend to have an even more difficult time, monitor their feet regularly, reducing their chance to detect problems. For them, FootAssure is a life-changing technology with great potential to alleviate possible foot wound threats and ulcer development.

Third, FootAssure expedites clinical response time through the integration of hardware, software, and telemedicine. Connectivity for immediate treatment decisions via telehealth consultation, such as wound debridement and choice of dressing or need for immediate intervention form a new approach to identify foot problems and early-stage pressure ulcers in patients suffering from diabetic neuropathy. Identifying problems in foot health and pre-ulcers improves the ability to pre-empt problems and ensure the best possible foot health.

B. Imaging Stage

The current version of the imaging stage (Fig. 1) is built within an optical enclosure consisting of a metal frame lined with non-reflective foam. In the future, the enclosure will be moved into the Pelican 1690 Protector Transport case (dimensions: 30.1” × 25.1” × 15.4”). This ensures compatibility with the camera track used and allows for portability of the final device between the research lab and patient clinic. The camera track in use is the Waterbird Multislider Pro 47”. Currently, each scan on this stage takes 30 seconds to complete. The track is placed within the base of the enclosure in a semi-circular formation to allow for maximal exposure of the foot. Two imaging modalities are currently used for data acquisition: digital and thermal.

Fig. 1. RGB and Thermal Camera mounted on the Waterbird Track. The entire imaging stage is enclosed within the optical enclosure. A raised platform in the center serves as the platform for patients to place their foot upon for imaging.

The USB3 RGB camera in use is the Allied Vision Alvium 1800 U-319. The camera is equipped with an IMX265 CMOS sensor and can acquire at 2064x1544 pixels with a maximum frame rate at full resolution of 53 fps. The settings used for digital image acquisition are as follows: frame size of 2064 x 1000, frame rate of 30 fps, and an exposure of 20000. The lowered frame rate and frame size settings help accommodate a higher exposure setting, allowing for greater illumination of the foot. Digital imaging acquisition is performed through a Python pipeline after applying the previous camera settings utilizing the included Vimba software. The final video files are stored in the MPEG-4 format and parsed to extract frames to be used in image reconstruction.

The current thermal sensor in use is the FLIR A65 with a f=13mm lens. The sensor is 8-bit monochrome capable of recording at 30 Hz with an image resolution of 640x512 pixels. The object temperature range of the camera is -12 degrees F to 275 degrees F which is suitable for this use case. Data acquisition are performed using FLIR's ResearchIR software which records images in a *.seq* format and allows for easy analysis of temperature on a frame-by-frame basis. These images can be exported as video files for analysis by an external algorithm. The Alvium digital and FLIR A65 thermal cameras are mounted onto the Waterbird track using a flexible camera mounting arm. The track can be controlled using a mobile app and allows adjustment of the start and end positions of the cameras along with the rotational speed. A rotational speed of 50% was used for all imaging analysis to allow sufficient clarity in the acquired images, which each scan taking approximately 30 seconds.

C. Data Acquisition

The foot is imaged in two positions to allow for maximal coverage of all surfaces. First, the foot is placed in a horizontal position, with the plantar surface on the floor of the stage. One scan is performed in this position to acquire data on the dorsal surfaces of the hindfoot, midfoot and forefoot. A second scan is performed by placing the plane of the foot normal to the imaging stage, exposing the plantar surface of the foot. Imaging was performed utilizing a mannequin first to adjust focal length and imaging field of views to ensure the entirety of the foot was visible. Further tests were also performed after cooling the mannequin via placement in an ice bath and after heating it up through placement in a hot water bath. These tests were performed to confirm functionality of the thermal sensor. After these initial tests, imaging was performed upon human subjects to determine the efficacy of this system in a patient environment. Tests were performed on subjects with varying skin tones to ensure relativity across a wider patient population.

III. RESULTS

A. RGB Volume Rendering- Zephyr

Volume rendering was performed using two different toolsets. First, the open-source, 3DF Zephyr toolbox was utilized to generate a point cloud render of the previously acquired subject video. In this case, a selection of 21 frames were extracted from the RGB video. Zephyr is capable of automatically extracting frames with a video input with the user specifying the number of frames to be extracted. In the future, the goal is to automate the processing and 3D rendering by making use of the Zephyr API. In the case of this prototyping step, the selected frames were selected to allow for a slice rendering of the foot to confirm the efficacy of this pipeline. ImageJ, another open-source toolbox, was utilized to segment the extracted frames so that only the foot was visible. Segmentation was performed via the Trainable Weka Segmentation method. Segmentation generated masks for each frame, which were then binarized within MATLAB and further processed to remove outliers present from the previous steps. Morphological operators were used for this step, removing all connected components that had fewer than 1500 pixels and less than six faces of connection. Fig. 2 shows the transformation of the initial image to the final mask, along with a representation of the final masked image. This process was repeated for all 20 extracted frames and the final set of masked images were used with 3DF Zephyr toolbox. Zephyr was then used to compute a 3D point cloud model with mesh rendering. The internal camera parameters were automatically extracted to calibrate the frames. The reconstruction presets were set to human body for both the dense cloud creation and the surface reconstruction. Reconstruction took approximately 5 minutes, with an input of 21 frames, and resulted in a 3D slice rendering of the foot. However, artifacts were still present from inconsistent segmentation, so the selection and triangle removal tools were utilized to ensure only the foot was visible in the final rendering. Fig. 3 shows the 3D rendering before and after the cleaning steps, along with their respective point cloud reconstructions. The final models were then exported as .obj files for use in final rendering where information from multiple modalities will be combined.

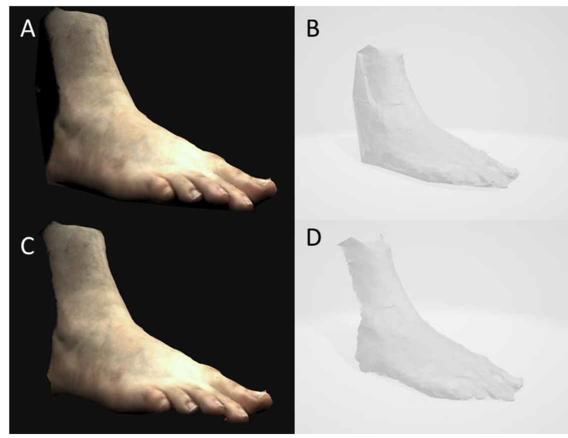

Fig. 3. Volume rendering of slice using Zephyr toolbox A) before removing of artifacts B) mesh model before removal of artifacts C) after removal of artifacts D) mesh model after removal of artifacts.

B. RGB Volume Rendering- Eva Lite

A second rendering of a wound mannequin model was performed using the Eva Lite 3D scanner. In this case, the mannequin was placed upon a rotating platform and the scanner was held at various angles to ensure capture of the entire foot surface. Due to the flexibility of the scanner, the mannequin was also flipped to scan the opposite side. This allowed for generation of a complete 3D model by combining the models for each individual scan. The goal with this mode of rendering is to use the scanned foot model as a base to overlay patient specific information such as skin temperature and blood oxygenation levels. Figure 4 shows the two scans

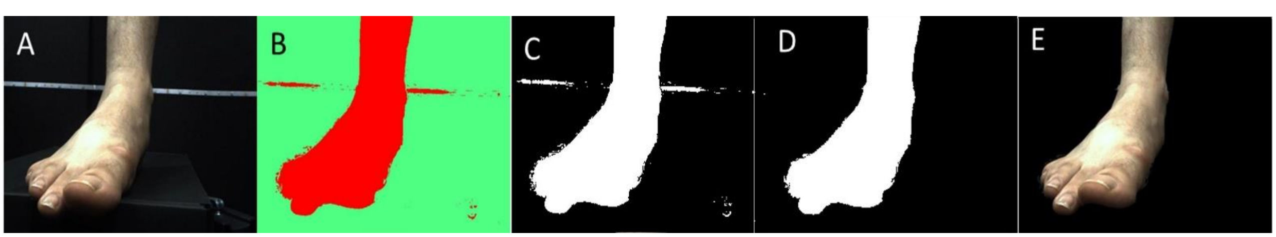

Fig. 2. Preprocessing of extracted frames from RGB video A) original frame, B) after ImageJ Trainable Weka Segmentation, C) after binarization in MATLAB, D) after removal of outliers, E) final segmented image.

captured with the tool along with a point cloud and textured rendering of the mannequin.

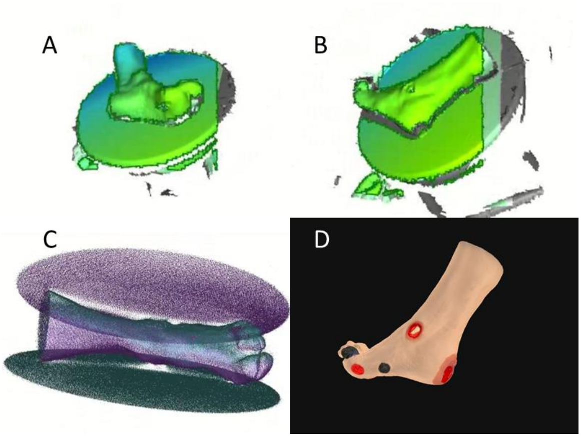

Fig. 4. Visualization of Eva Lite scanner, A) Scan 1 of side of medial side of the foot, B) Scan 2 of the lateral side of the foot, C) Combining point cloud renders of Scans 1 and 2, D) Final, textured 3D render of mannequin.

C. Comparison of two methods

While the Eva Lite model can generate a more detailed model, the device requires manual handheld operations which increases the variance between patient datasets. The software is also proprietary and incapable of being integrated into an automated pipeline; each patient scan would have to be manually processed to generate a final 3D rendering. The Zephyr allows for fixed position image acquisition and automation through the provided API. The technology within the Eva Lite scanner is also expensive and would greatly increase the final cost of the FootAssure, while the Zephyr toolset integrates with the USB3 Allied Vision camera. For these reasons, the Eva Lite model will be used as a baseline to develop the processing pipeline while the Zephyr toolset will be used to generate models for individual patients.

IV. Discussion

A. Thermal Data Overlay

The next step for FootAssure is overlaying the recorded thermal information onto the 3D RGB rendering. Achieving this will add an additional layer of functionality to the device and provide a pipeline which can be used to add additional information such as blood oxygenation level. To this end, two methods have been proposed. First, the co-registered thermal and RGB frames will be used to generate a composite image consisting of information from both modalities. An issue of attempting volume rendering from thermal data alone is the lack of texture and feature information on the foot surface. Image fusing techniques should allow for generating frames that contain both thermal information and the texture and feature data present with the RGB images. These composite frames will then be passed through the Zephyr toolbox to generate a 3D volume render that includes thermal information. A second method will be to import the volume render of the RGB images as a 3D point cloud matrix into MATLAB. The thermal data will also be imported as a 2D matrix for each frame. For prototyping purposes, only a few regions on the foot will be selected for thermal information overlay. The 2D matrix from each frame will be co-registered to the 3D point cloud matrix and an intensity parameter will be added to the points within the region of interest to indicate the thermal information. In the final model, thermal data will be visualized as a color gradient at each point of interest. The difficulty of this method lies in the ability to co-register the 2D frames onto the 3D-point cloud matrix. As this is a more complex methodology, this will be attempted as an alternative to the composite frame method outlined previously.

B. Future work

Once the ability to overlay thermal information is achieved, the next step for FootAssure will be to add skin biomarkers measurement capabilities. To this end, LED rings of differing wavelengths are currently being developed. These rings will be placed behind the camera modules and illuminate the subject in a staggered manner. The frame-to-frame differences will then be used to compute the oxygenation information. Once these components are in place and have been prototyped, the imaging stage will be moved into the Pelican 1690 Protector Transport case previously mentioned so the device can be used in a clinical setting to acquire real patient data.

V. Acknowledgment

We would like to appreciate *WoundExam* Corp for partially supporting this research.

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