

Design and Development of a Novel Diabetic Foot Risk Screening Device

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Abstract

Background: Neuropathic diabetic foot ulcers (DFUs) are a complication of uncontrolled diabetes and can lead to serious consequences. Self-examinations and existing solutions often result in identification of DFUs after subcutaneous hemorrhage has occurred. Hence, there is an unmet clinical need to screen for early-stage neuropathic ulcers. Previous studies have reported callus formation and local relative inflammation of 2.2 °C as indicators of potential ulcers.

Methods: A floor mat was developed with multimodal sensors strategically placed at three high-risk ulceration locations per foot (Fig. 1A). Each custom-designed sensor consisted of a 3D-printed frame, aluminum ball bearing, force-sensitive resistor, load cell, and thermistor array (Fig. 1B). Hertzian spherical indentometry and thermometry were leveraged to measure tissue moduli and local temperature, respectively. Plantar surface characteristics were compared to contralateral foot areas and prior timepoints. Data was displayed on a screen and stored in a secure web-based platform.

Results: Testing was performed using silicone tissue-mimicking phantoms with moduli equivalent to diabetic foot skin (1.07 MPa) and callused diabetic foot skin (2.16 MPa) as well as heated socks. A qualitative three-tiered ulcer risk severity color classification was generated at each location based on a research-informed decision matrix (Fig. 1C). Data from four sets of 16 trials indicated high sensitivity in detecting pathological tissue moduli and temperature levels (Fig. 1D).

Conclusion: This novel innovation considers the interplay between different biomarkers to create a comprehensive assessment of diabetic foot health. Remote patient monitoring technology offers a promising approach for at-home DFU screening, promoting early detection and reducing the incidence of invasive interventions.

KEY WORDS: Diabetic foot ulcers; screening tool; remote patient monitoring; peripheral neuropathy

Figures:

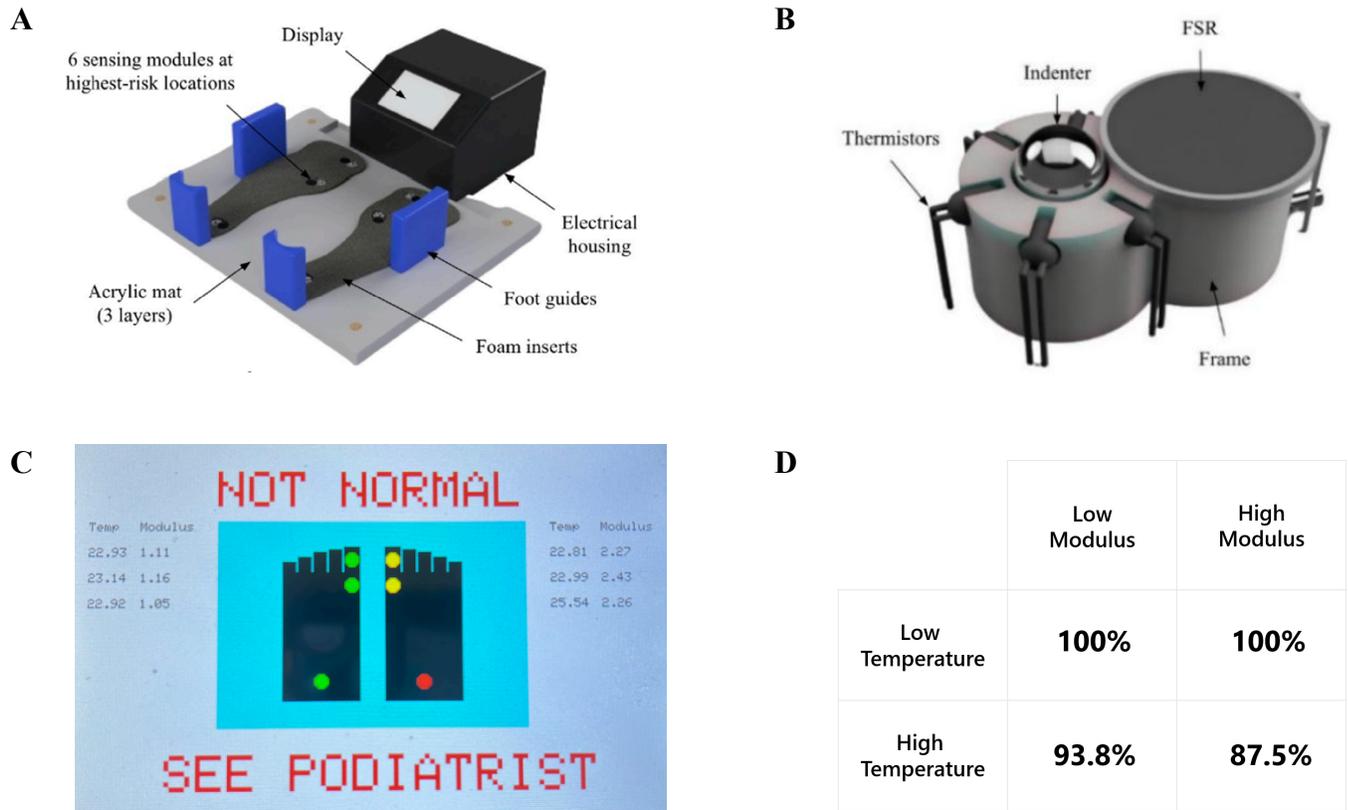


Figure 1. Device overview. (A) Schematic with labeled parts. Foot guides along the contour of the sensing area ensure reproducible alignment. Sensors are located at the hallux, first metatarsal head, and the heel regions. (B) Multimodal sensing module components. Note that the force-sensitive resistor is along the same plane as the ball indenter. (C) Display output of example test case with stiffer right phantom and localized heating applied to the heel region. “Red” indicates local inflammation irrespective of tissue modulus, “yellow” indicates increased tissue modulus within a normal temperature range, and “green” indicates no abnormal symptoms. (D) Preliminary testing outcomes.