DEVELOPMENT OF ADVANCED DIABETIC ORTHOTICS: FROM FINITE ELEMENT MODELING TO PRESSURE SENSOR IMPLEMENTATION

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ABSTRACT

Within the Orthotics and Prosthetics Industry, there exists a lack of integrated sensing methods, which are accessible for patients and cost effective for the industry. This is especially true with diabetic orthotic interventions, where retroactive outcomes are used in lieu of quantitative data **[1]**. Pressure sensing is crucial for diabetic patients in offloading orthotics, compounded by underlying orthopedic conditions, making standardized sensor arrays impractical. Here, we demonstrate Finite Element Models (FEM) aimed at modeling pressure sensing for patient-specific, diabetic offloading orthotics. This model is developed to replicate the forefoot loading condition during "toe-off" in a normal gait cycle. The model is compared against data acquired from a fully characterized commercial piezoresistive sensor array system. The system is ultimately assessed for insole response to gait exerted pressures. Further development efforts of customized microsensor-arrays for diabetic orthotics are underway currently.

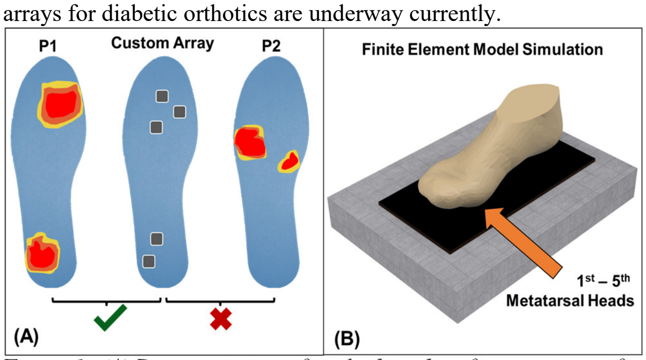

Figure 1: (A) Representation of method to identify patient-specific sensor arrays for development and incorporation into diabetic orthotics. (B) Customized finite element modeling representation.

KEYWORDS

Finite Element Modeling (FEM), Pressure Sensors, Microsensor Array, Offloading, Orthotics, Diabetic Foot Ulcer.

INTRODUCTION

Diabetic foot ulcers (DFU) are a wound classification occurring in 19-34% of all patients with diabetes **[2]**. Of these, 50-60% will result in complications and nontraumatic, lower-extremity amputations **[3, 4]**. Offloading orthotic treatments are widely utilized, but compliance with the prescribed orthotic is crucial to desired positive outcomes **[5, 6]**. There are research proposals using standard arrays of RF-sputtered AlN piezoelectric sensors **[7]**, and electromagnetic models **[8]** for the diagnostic of foot ulcers. These approaches are important to improve early detection, but customized integration is still missing. Development of a foot plantar measurement system with piezoresistive sensors has been explored through FEM **[9]**, but sensor response was tested for static conditions onto the array only. Dynamic pressure sensing thus becomes vital, as a method for providing feedback to patients and practitioners on the compliance with, and offloading efficacy of the prescribed orthotic. Plantar surface sensing technologies exist in more standard and clinical settings, such as for gait analysis from healthy individuals. However, customized point-of-care options for diabetic patients are non-existent. Further, advanced stages of diabetes often cause underlying orthopedic conditions, requiring clinical monitoring **[10]**. The development of a predictive FEM for industry to use in microfabrication of custom orthotic solutions will thus enable the development and integration of pressure sensing architectures in a patient-specific manner (**Figure 1**).

MATERIALS AND METHODS

For FEM development, and due to model limitations between software programs, pressures were applied to two systems with comparable structures: an NIH CAD foot model, and a 3D scanned foot from a volunteer obtained using the Luma 3D scanner (Vorum, USA). FEM was executed in COMSOL (COMSOL Multiphysics 5.4, Sweden) and Fusion 360 (Autodesk, USA) to validate and compare deformational reaction and visualize stresses, upon foot standing. Modeling material properties (Density (r), Young's modulus (*E*), Poison ratio (n)) for a commercial foam (7mm thick, P-Cell) were calculated from datasheets, and literature information **[11, 12]**. Applied pressures (4, 6, & 8 psi) were selected to align with the experimental capabilities of the Pressure Guardian™ system and representing persons weighing 100, 150, and 200 lb. respectively. Experimental pressures were applied with the scanned volunteer and measured using the Pressure Guardian™ system. Piezoresistive sensors (Flexiforce, USA) to measure change in resistance upon deformation were placed below the area of forefoot loading, on or between the 1st - 5th metatarsal heads, and recordings were obtained.

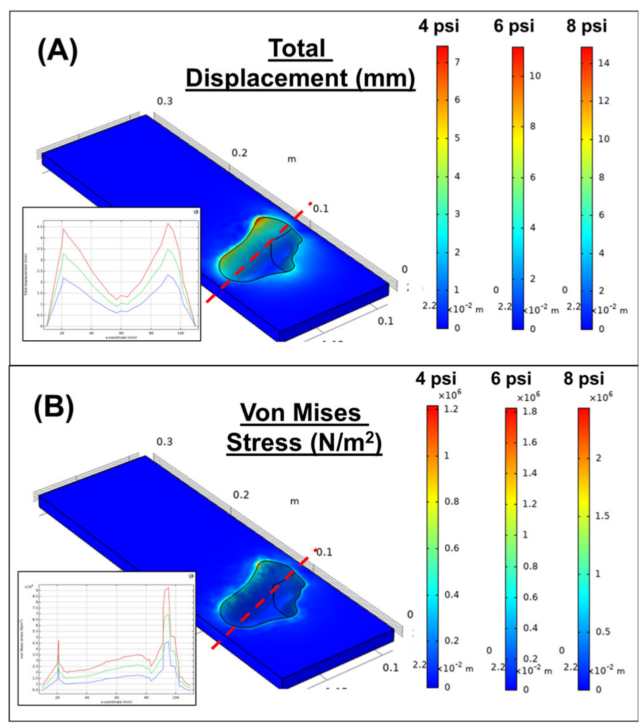

Figure 2: COMSOL deformation (A) and stresses (B) at 4, 6, and 8 psi (to represent 100, 150, and 200 lb. patients). Inset details numerical changes to deformation and stress along defined axis.

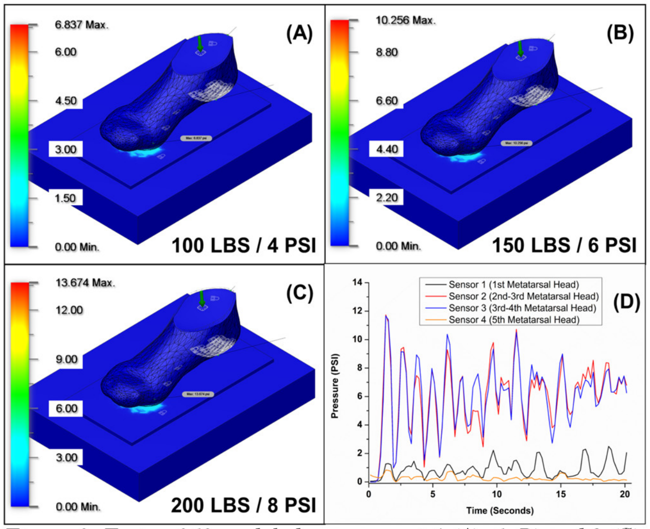

Figure 3: Fusion 360 modeled pressures at 4 (A), 6 (B) and 8 (C) psi. (D) Experimental gait cycle, pressure data from 180 lb. volunteer, mirroring the modeled data (between B-C as expected).

The subject of interest weighed approximately 180 lb., and recordings were procured during a normal gait cycle (N=5), for 20 seconds. The piezoresistive sensors were subsequently cross-sectioned and characterized to aid in future microsensor array fabrication efforts that are ongoing.

RESULTS

Figure 2 details the simulated deformational performance and von Mises stress on the selected foam for each area of interest under the conditions experienced. The maximal deformation and stresses expected at 8 psi were calculated to be ***4.5 mm and 9.0x10^5 N/m^2***.

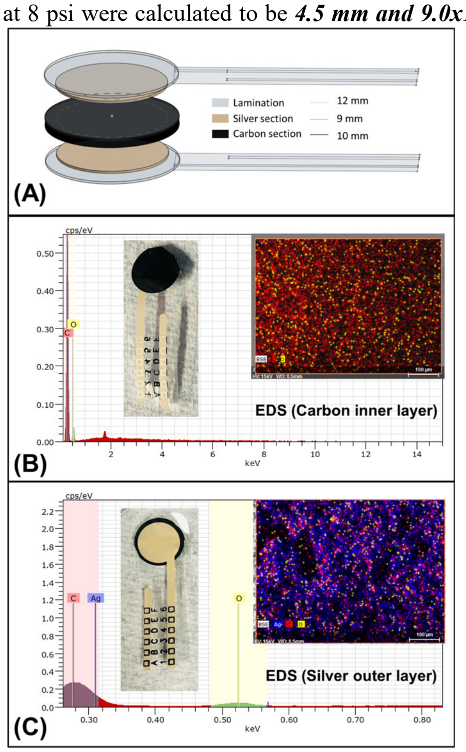

Figure 4: (A) Multilayer commercial piezoresistive sensor structure. (B-C) Optical imaging and Energy Dispersive Spectroscopy (EDS) characterization detailing sensor's composition: carbon piezo-material, and silver packaging electrodes.

Complementary models to expand on expected results were performed in the FEM module for Fusion 360 (**Figure 3**). As was modeled with the same loading conditions as described previously, the resulting pressures experienced centrally between the 2nd and 4th metatarsal heads of the forefoot were calculated to be *6.3, 10.3, and 13.7 psi* (from 4, 6 & 8 psi loading pressure respectively). It was thus expected that a 180 lb. person would experience between ***10.3 and 13.7 psi*** maximum during forefoot gait loading experimentally. Pressure data (**Figure 3**) from the scanned patient did indeed show the highest observed forefoot pressures on the sensors placed between the 2nd and 4th metatarsal heads, with averaged maximal pressures of ***12.2 ± 1.2 psi*** (within the expected range). Peak values at the 1st and 5th metatarsal heads averaged ***1.4 ± 0.4 psi*** likely due to the volunteer's individual gait loading pattern. The performance of the practical foam deformation mirrors the simulated FEM closely. **Figure 4** depicts characterization results of the commercial sensor used in the measurements. Future works include further tailoring the parameters of the model to better replicate the hyper-elastic nature of foam materials, as well as testing anonymous patient-derived models. ***The ultimate goal of this effort is the development of piezo-actuated microsensor pressure arrays, for orthotic diabetic offloading, through the implementation of full pressure mapping model and commercial sensors.***

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