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Plantar pressure relief under the metatarsal heads – Therapeutic insole design using three-dimensional finite element model of the foot

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ABSTRACT

Therapeutic footwear with specially-made insoles is often used in people with diabetes and rheumatoid arthritis to relieve ulcer risks and pain due to high pressures from areas beneath bony prominences of the foot, in particular to the metatarsal heads (MTHs).

In a three-dimensional finite element study of the foot and footwear with sensitivity analysis, effects of geometrical variations of a therapeutic insole, in terms of insole thicknesses and metatarsal pad (MP) placements, on local peak plantar pressure under MTHs and stress/strain states within various forefoot tissues, were determined. A validated musculoskeletal finite element model of the human foot was employed. Analyses were performed in a simulated muscle-demanding instant in gait.

For many design combinations, increasing insole thicknesses consistently reduce peak pressures and internal tissue strain under MTHs, but the effects reach a plateau when insole becomes very thick (e.g., a value of 12.7 mm or greater). Altering MP placements, however, showed a proximally- and a distally-placed MP could result in reverse effects on MTH pressure-relief. The unsuccessful outcome due to a distally-placed MP may attribute to the way it interacts with plantar tissue (e.g., plantar fascia) adjacent to the MTH. A uniform pattern of tissue compression under metatarsal shaft is necessary for a most favorable pressure-relief under MTHs.

The designated functions of an insole design can best be achieved when the insole is very thick, and when the MP can achieve a uniform tissue compression pattern adjacent to the MTH.

1. Introduction

Therapeutic footwear with custom insoles plays a major role in the prevention of plantar ulceration in diabetic foot (Albert and Rinoie, 1994; Arts et al., 2012), relieving painful forefoot syndromes (e.g. metatarsalgia) (Postema et al., 1998), and accommodating structural deformed foot in rheumatoid arthritis (Silvester et al., 2010). These specially-designed insoles are purported to function by alleviating high pressures from areas beneath bony prominences of the foot, in particular to the metatarsal heads (MTHs).

The principle design features of a therapeutic insole may include the thickness, the geometry contour, and other forms of variations such as the metatarsal pad (MP). In addition to the material's stiffness (which is strictly limited by commercial availability (Praet and Louwerens, 2003)), these features directly alter interfacial interactions between the foot and the shoe, and potentially offer a most effective approach to the pressure reduction in the foot's tissue (Bus et al., 2004; Mueller et al., 1997; Owings et al., 2008).

In the literature, increases in foot's contact area, decreases in peak plantar pressure and force-time integrals have been documented for Total Contact Insole (TCI) used in people with diabetes and peripheral neuropathy (Ashry et al., 1997; Bus et al., 2004; Mueller et al., 1997). However, because of concern over TCI's effectiveness on local pressure relief, a combination design is occasionally built where a MP component is constructed directly into an insole (Bus et al., 2004). The MP seeks to achieve enhanced pressure-relief to the bony prominences under MTHs. Unfortunately, according to Owings et al. (2008), the design of such devices could be intuitive and mostly based on the past experience of the pedorthists. A number of studies using pressure measurement have shown variations in MP placement may lead to unwanted outcomes (Hastings et al., 2007; Hsi et al., 2005). For example, a MP placed more distal than as little as 1.8 mm from the MTH leads to an increased peak plantar pressure (Hastings et al., 2007). Other studies comparing insoles with and without a MP in healthy subjects showed the pressure-relief effects of a MP seem to be varied and dependent on subject characteristics (Brodtkorb et al., 2008; Holmes and Timmerman, 1990).

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When optimal plantar pressure relief is the goal, the efficacy and mechanism of the effects of insole design on foot structures must be quantified. Spiral Computed Tomography (CT) has been used to examine how a specific MP could affect tissue compression in the forefoot (Mueller et al., 2006, 1997). However, deviation in device location, such as the difficulty in consistently placing a MP during experiments, poses a challenge to obtain reliable data. Importantly, stress/strain distributions could have been modified throughout the foot by different insole conditions. The insole may induce a complex interplay with the foot skeleton, muscles, ligaments, and fascia structures, many of which has not been extensively investigated, and thus are largely unknown (Mueller et al., 2006).

Finite element (FE) modeling of foot and footwear offers a unique computational tool, as it allows multiple insole design variables to be evaluated in a more controlled and efficient manner than traditional experiments. Foot FE models have been employed to investigate the effects of insoles thickness on peak plantar pressure under the 2nd MTH (Lemmon et al., 1997), the influence of midsole plug's material on pressure distributions (Erdemir et al., 2005), and efficacy of a modified TCI on MTH pressure reductions in diabetic foot (Actis et al., 2008). However, the primary problem with these models is lack of geometrical details as only 2D sections of the foot were analyzed. A few have attempted 3D foot–insole FE analysis (Chen et al., 2003; Cheung and Zhang, 2005). These have incorporated anatomical-accurate foot structures, but they often do not consider auxiliary muscle action in the analysis, and focus mostly on standing.

In this study, we presented a 3D FE musculoskeletal model of the foot to be applied for therapeutic insole design. More specifically, we aim to establish relationships between insole modification, including thickness and MP placement, and stress distributions under metatarsal heads (MTH). Precise determination of such relationships may shed new light on the underlying mechanism of foot–insole interaction, and will eventually enhance the scientific basis of therapeutic footwear design and testing.

2. Methods

2.1. Finite element model of the foot

A three-dimensional FE model of the musculoskeletal human foot was employed (Fig. 1). Thirty bony parts, including sesamoids, were created individually and enveloped by soft tissue. The complete element mesh involves about 400,000 elements and 1,300,000 degrees of freedom. Relative articulating movements were modeled in the foot, with surface-to-surface contact elements created for the potential contact regions (i.e., articular surfaces) of the bony joints. The curved joints had a thin cartilaginous layer to allow a normal joint loading transfer during contact. The thickness of the cartilage ranged from 1.0 to 1.5 mm in accordance with the reported measurements (Shepherd and Seedhom, 1999). The bony joints were passively stabilized by 134 major ligaments and a fan-like plantar fascia. The ligaments were represented by spring elements with a 'no compression' option, in accordance to their physiological function. A 3-D geometry of the Achilles tendon was constructed and incorporated into the extreme posterior of the calcaneus. This approach ensures realistic joint moments to be produced by the Gastrocnemius and Soleus muscle forces. The long tendons of other five extrinsic flexor muscles were incorporated into the model at their corresponding anatomical attachment sites. The plantar soft tissue was modeled by an incompressible Ogden hyperelastic material (Fig. 2A). Isotropic linear elastic material properties were assigned to the ligaments and cartilages in consistent with other researchers (Cheung and Zhang, 2005; Garcia-Gonzalez et al., 2009). The details of the material parameters used in the model were given in Table 1. All 3-D structural components of the model were meshed by tetrahedral elements, and optimal mesh density was determined based on model convergence analysis. The tolerance level was set as the change in total strain energy by less than 5%. This resulted in a final mesh with characteristic edge length of 2.3 mm used in the current model. The FE model was previously validated for plantar pressure distributions and metatarsal bone strains, and has been described in detail elsewhere (Chen et al., 2010, 2012).

2.2. Footwear conditions

A therapeutic footwear model was specifically created, which lies right underneath the plantar aspect of the forefoot. The top layer of the footwear material was an insole with a combined metatarsal pad (MP), and the bottom layer represented the midsole which accommodated insole. All-hexahedral element meshes were constructed for the model. The MP component was built by projecting the boundary nodes onto a curved surface that represents the geometrical shape of an actual MP used clinically (Foot in Motion, USA). The size of the MP was 76 mm in length, 55 mm in width, and 9 mm for the maximal dorm (i.e., apex) height. The orientation and configuration of the MP would sufficiently cover the three central metatarsals (second, third and fourth). The thickness of the midsole is 12.7 mm. The insole, made from highly-deformable foam (Plastazote) providing the primary cushioning, and the midsole as a firm base (Microcell Puff), was modeled as compressible hyperfoam materials (Fig. 2B). The values of the elastomeric foam parameters were obtained from the literature (see Table 1). Frictional contact interaction between the plantar surface and the insole was defined using a coefficient of friction of 0.5 (Lemmon et al., 1997). The midsole was fully constrained to the ground throughout simulation.

Various insole designs were modeled and studied (Fig. 3). These include five different thicknesses (t) of the insole: 2.5, 5.1, 7.6, 10.2, and 12.7 mm. The insole thickness chosen was based on range of the commercial-available insole sheet (Foot in Motion, USA). Each insole thickness was analyzed with each of the four MP placements: none (insole-only), the distal (P1), the proximal (P2), and the most proximal positions (P3). The distal-to-proximal placements of a MP were defined according to the longitudinal distance in relation to the 2nd MTH. In P1 condition, the frontal aspect of the MP just covers the distal perimeter of the 2nd MTH, with dorm apex 6.5 mm proximal to the center of the MTH. The MP was then moved proximally (distance with respect to P1) by 13 mm and 20 mm to achieve at P2 and P3 conditions, respectively.

2.3. Simulated musculoskeletal loads

We analyzed the foot–insole interactions at a time during the gait cycle when the forefoot force reaches a peak, i.e., the second peak of the ground reaction forces (GRF) associated with walking. This loading protocol has previously been established in our foot FE model (Chen et al., 2012), which mimicked the manipulations in a cadaveric foot model conducted by Sharkey et al. (1995). In brief, a targeted maximum vertical GRF (i.e., 623.1 N for a subject with a body mass of 60.5 kg) was generated solely by contracting plantar flexors at a prescribed kinematic configuration

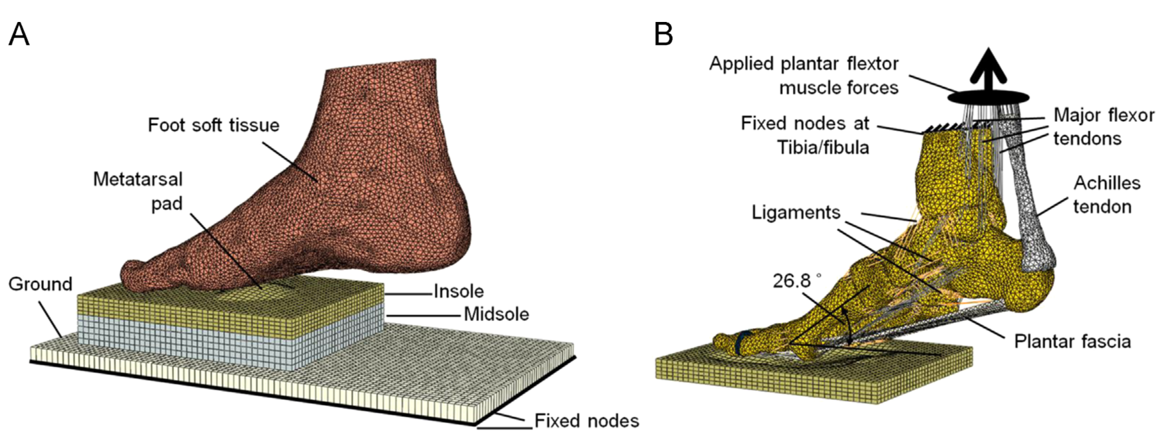

Fig. 1. Finite element models of the human foot, and the supporting surface consisting of metatarsal pad, insole and midsole (A). The applied loading and boundary conditions to simulate a muscle-demanding instant in gait (B).