Advancing diabetic foot care: Incorporating horizontal shear forces in orthopaedic insoles through generative design

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Purpose In Germany, people with diabetes mellitus receive excellent medical care, resulting in an increasing number of elderly diabetes patients. As of 2022, approximately 340,000 German adults were affected by type 1 diabetes, with almost 30% of them being over the age of 70. Additionally, about eight million people suffered from type 2 diabetes, with 25% of them being over the age of 75 (Zeyfang et al., 2022). Diabetes frequently co-occurs with polyneuropathy, which can result in reduced sensation of pressure and pain. This can lead to diabetic foot syndrome, a condition characterized by pathological changes in the foot. Morbach et al. (2021) reported that the likelihood of diabetic foot syndrome in individuals with diabetes ranges from 19%-34%. To prevent foot ulceration or necrosis, it is critical to identify and relieve calluses and pressure points in a timely manner. Diabetes patients are often fitted with orthopaedic insoles to relieve particularly stressed areas. Personalization of footwear is achieved through 3D impressions using plaster or impression foam, coupled with pressure measurements during walking using pedography. However, traditional podography only records vertical forces directed towards the ground, neglecting the horizontal shear forces that contribute to blistering caused by friction. The objective of this study is to investigate the feasibility of developing orthotic insoles that account for horizontal shear forces using generative design and additive manufacturing techniques. **Method** Generative design methodologies are used to develop a soft orthopaedic insole that targets stress points on the foot. Biomechanical load models are created to encompass various gait phases, including initial contact, loading response, mid stance, and terminal stance, factoring both vertical and horizontal forces. Autodesk Fusion 360 software allows for the creation of load cases for each gait phase, considering the corresponding force magnitudes based on Jacqueline Perry's 'Gait Analysis' (Perry, 1992). The insole's basic shape is initially adjusted using free-form surfaces. **Results and Discussion** This study demonstrates the feasibility of generative design for orthopedic insoles, considering horizontal shear forces. Generative design involves generating material based on applied load, force flow, material, and manufacturing process. The amount of material generated increases with the applied load (Garland et al., 2021; Zwettler, 2020), resulting in increased strength in heavily loaded areas of the insert. This, in turn, can counteract the relief of these areas. Additionally, the current approach to static analysis should consider the foot's dynamic behavior during walking to ensure optimal shock absorption and support. Generative design and additive manufacturing have the potential to enhance foot care for diabetics by accounting for horizontal shear forces that can reduce the risk of pressure points and foot ulcers. Additive manufacturing can reduce material consumption compared to traditional subtractive methods such as milling. Additionally, the use of bioplastics in additive manufacturing can improve environmental sustainability.

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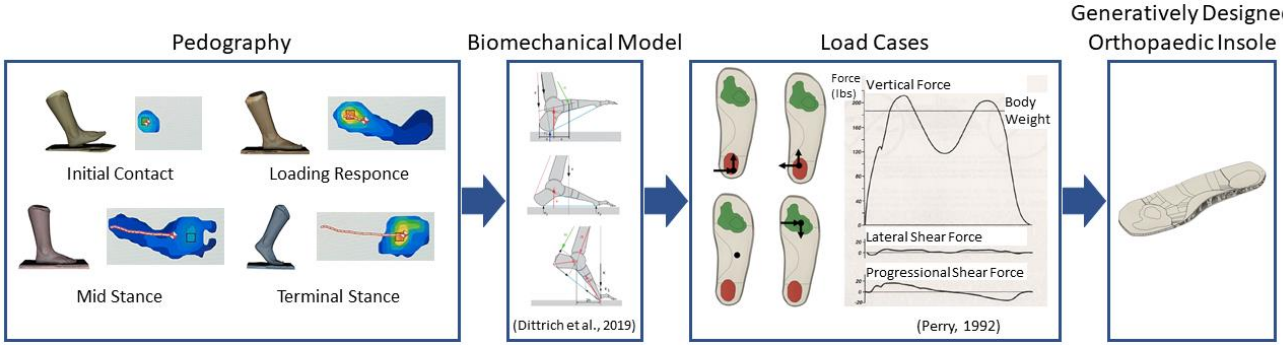

Figure 1. Design Process of an Orthopaedic Insole