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Generative design for individual orthopaedic insoles: Optimisation of load distribution and additive manufacturing

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Abstract: Introduction: Generative Design (GD) is an intelligent process that uses algorithms to automatically create optimised, functional and material-efficient structures based on defined parameters and loads. This makes it a valuable tool for the customisation of orthopaedic insoles to suit individual load patterns. Conventional methods are frequently predicated on pressure data. However, force-based modelling has the potential to reproduce dynamic gait phases with greater accuracy. Additive manufacturing facilitates the production of such complex, customised designs. **Methods:** In this preliminary study, a comparison is made between different load definitions (pressure vs. force) and manufacturing constraints (additive vs. unrestricted) within GD. Pedographic pressure data is utilised to ascertain individual load distributions. The maximum value recorded during walking was utilised for the purpose of analysing the pressure load. In order to analyse the effect of force, a separate load case was defined for each gait phase, with the objective of mapping the application of force along the gait line as precisely as possible. **Results:** Within GD, forces can be positioned specifically for each gait phase, allowing structures to be generated with a precise fit. Conversely, pressures act over the entire surface and overlap when analysing multiple gait phases. The findings demonstrate that force-based modelling offers a more precise depiction of dynamic loads, consequently resulting in optimised insoles. Additive manufacturing constraints prove beneficial by removing the need for internal support structures, which are often hard to remove. However, thickened structures in the upper layer of the insole can compromise flexibility. **Conclusion:** The employment of GD facilitates the development of orthopaedic insoles that accurately reflect the patient's individual load distribution. Future research should investigate the impact of different design choices on flexibility and biomechanical performance. In addition, the identification and evaluation of suitable materials, is crucial for determining their effectiveness in the manufacture of foot orthoses.

Keywords: Generative Design, Orthopaedic Insoles, Additive Manufacturing, Dynamic Foot Load Distribution, Gait Analysis, Biomechanics, Material Optimisation, Pedography

1 Introduction

Foot deformities are a prevalent phenomenon in modern society, manifesting in a variety of shapes and forms. Causes can be varied: congenital, such as flat feet in children, caused by disease, such as diabetic foot syndrome in diabetes mellitus, or acquired over time, such as improper footwear contributing to the development of flat feet in adults. These misalignments can cause widespread effects throughout the musculoskeletal system, often leading to pain and improper loading of the knees, hips, or back. To alleviate these complaints, orthopaedists often prescribe customised orthopaedic insoles. These insoles are designed to address foot misalignments and enhance biomechanical functions, thereby reducing strain and improving walking efficiency [1]. The manufacturing process of orthopaedic insoles traditionally involves a combination of manual and mechanical procedures. However, the process is often time-consuming and costly, especially for customised insoles. Furthermore, the options for customisation are restricted by the limited choice of materials, meaning that pre-fabricated insole blanks are often simply modified [2]. Advancements in digitalisation are opening up novel possibilities in the design and fabrication of orthopaedic aids. In particular, generative design in CAD (computer-aided design) in combination with additive manufacturing processes (3D printing) offers innovative approaches for the production of highly customised foot orthoses. Computer-aided algorithms facilitate targeted optimisation of the insole geometry, ensuring that not only biomechanical requirements are met, but also material efficiency and wearing comfort are maximised. Dynamic pedography represents a central component of this optimised design. This technology captures in-depth data on the pressure distribution across different phases of the gait cycle, including initial contact, loading response, and the mid- and terminal stance phases. The determined gait line displays the course of the

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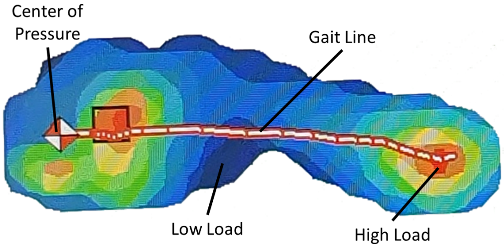


Fig. 1: Dynamic pedography of a flat foot

centre of pressure and facilitates precise identification of deviations in the gait pattern (see Figure 1).

Generative design (GD) is based on predefined parameters, including material, size, load, and manufacturing process, and generates load-optimised structures accordingly. The GD approach is characterised by its systematic consideration of force flows, with the objective of optimising the geometry of the insole to align with the unique requirements of each patient. The algorithm generates multiple design proposals that meet the specified requirements, enabling the comparison of different materials and structures to identify the optimal solution for the designated application [3, 4].

The aim of the project is to develop an orthopaedic insole that is customised to the user's specific needs. This is achieved by implementing GD, followed by 3D printing. In this preliminary study, the insole is divided into five functional zones, whose varying material stiffness is intended to provide relief or stability to different areas of the foot. As part of the exemplary design studies, one of the zones is analysed in more detail and loaded differently. The objective is to examine how each loading type influences the generated model. Subsequent research activities will concentrate on the experimental validation of the resulting designs.

2 Methods

The insole is designed on two levels: On the one hand, the geometry is customised to the patient's foot, and on the other, different material stiffnesses are used to define specific functional areas. The present preliminary study investigates the influence of the choice between pressures and forces as the basis for generative structure generation. The development process employs Autodesk Fusion 360 software. The prototype addresses the flexible adult flat foot, caused by tibialis posterior tendon dysfunction. This leads to hindfoot valgus, flattening of the medial arch, and forefoot abduction and pronation [1, 5].

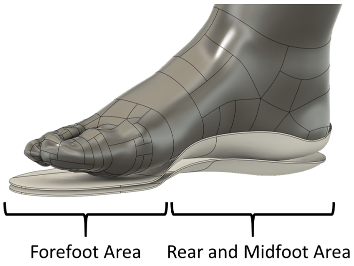


Fig. 2: Geometric design of the insole: flat forefoot area and customised midfoot and rearfoot areas

2.1 Geometric design of the insole

The insole's basic shape is designed for easy placement inside a shoe. Its geometry is based on a 3D scan of the foot in an unloaded state. Two primary regions are distinguished (see Figure 2):

- **The rear and midfoot area (rear 2/3 of the insole):** This area is adapted to the foot contour using free-form surfaces. The insole is given increased edge guidance in the heel area, while medially the support for the longitudinal arch is reinforced. The objective of this design is to stabilise the heel and the medial longitudinal arch, thereby preventing the joint axis from buckling and the arch from dropping further.
- **The forefoot area (front 1/3 of the foot insole):** The insole is designed to be flat in order to provide sufficient space for the forefoot and toes. This configuration enables a natural spread during contact with the ground during the middle and terminal stance phase.

2.2 Functional design of the insole

The functional design is based on dynamic pedography, which visualises the pressure load on the foot during walking. Using this data, the design delineates five zones characterised by different levels of material stiffness. The objective is to provide targeted relief to areas of particular stress within the foot by incorporating soft zones within the insole, while providing support to other areas with firmer zones:

1. **Heel area:** During initial contact, the heel makes contact with the ground first. A teardrop-shaped structure has been designed to optimally distribute forces, prevent plantar tendon irritation, and guide the roll over the lateral arch. This area is subdivided into four zones, each with a graded stiffness. The centre bears the highest load and is softer than the surrounding areas, which gradually stiffen to facilitate a smoother, more comfortable transition.

2. **Metatarsal area:** During mid stance, the load is distributed evenly over a larger area, so that no pressure peaks occur at certain points. This area is therefore designed with a uniform stiffness. The shape is based on the aponeurosis plantaris and the joint line of the articulationes interphalangeae.
3. **Ball area:** During terminal stance, peak forces occur as the foot pushes off. The design is informed by the consideration of key anatomical structures, and, in a manner analogous to the heel, subdivides the ball area into four subzones. The highest load is absorbed at the transverse arch centre, with surrounding zones ensuring a smooth transition.
4. **Big toe:** The optimal rolling process takes place via the big toe, which is why high loads occur here. Due to the comparatively reduced contact area, this area is divided into two subzones with graduated material stiffness.
5. **Remaining toes (toes 2-5):** These toes are primarily responsible for balance during walking and thus transmit only low forces. Consequently, this region exhibits a uniform material stiffness, with no further subdivision.

The surrounding area exhibits uniform stiffness, determined by body weight rather than pedography. This uniform stiffness ensures uniform support throughout the body, thus avoiding pressure peaks or soft spots outside the functional zones.

2.3 Generative design of the insole

Pressure is defined as the ratio of a force acting vertically on a surface to its area [6]. In GD, *pressure* is defined as the application of uniform vertical loads on a defined surface, whereas a *force* is defined as acting at a specific point and varying in impact depending on its position. In the context of insole design, it is important to consider all phases of gait, which is achieved by defining separate load cases for each phase. Using pressure distributions could result in overlaps, thereby concealing only the most substantial load. In contrast, forces can be positioned along the gait line in different phases, ensuring a more accurate load representation. In GD, material generation is based on applied loads, with higher loads creating firmer structures. This is in direct opposition to the insole's objective of relieving pressure with softer areas. To address this discrepancy, dynamic pedography loads are inverted. The mean of the highest and lowest values is calculated and the deviations from this mean are reversed. The objective of this approach is to achieve a more uniform distribution of pressure across the entire surface of the foot by means of the insole. The validity of this concept and its capacity to meet the diverse needs of users will be examined in subsequent studies. The conversion of pressures into forces is based on insole zones, with separate load cases designated for each gait phase, positioned along the gait line (see Figure 4). The GD process is applied separately to the zones of the insole in order to realise different stiffnesses. It employs *unrestricted* and *additive* manufacturing to define flexible materials, ensuring optimal material distribution. The insole's lower part is fixed to simulate a secure fit in the shoe.

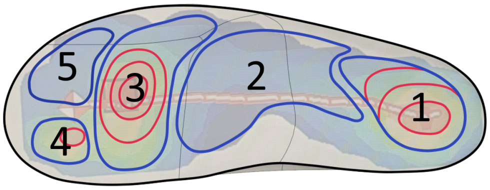


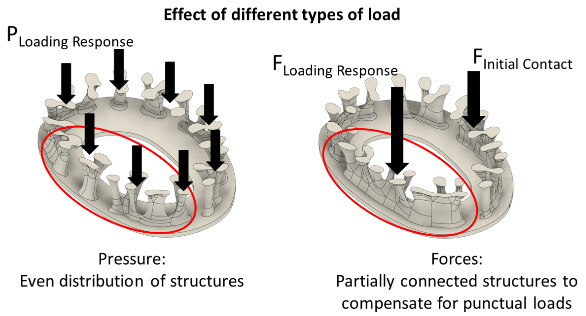
Fig. 3: Functional main zones of the insole (blue) and integrated subzones (red): 1 - heel, 2 - midfoot, 3 - ball, 4 - big toe, 5 - remaining toes

3 Results and Discussion

This preliminary study demonstrated the feasibility of using GD to design an orthopaedic insole that accounts for individual foot loads. Two key findings are detailed in this study: firstly, a comparison of pressure versus force as load parameters, and secondly, the impact of additive versus unrestricted manufacturing. A ring-shaped element in the heel area, surrounding the highest heel load, illustrates these effects across different gait phases. However, the subject of future studies will be the experimental verification of the created designs. When designing an orthopaedic insole, it is crucial to verify the dimensions and positioning of the loads defined in the generative design tool. In this study, these loads were initially determined by inverting the pressure distributions measured using pedography. However, it is unclear whether this procedure adequately reflects the actual needs of the user, and this should be clarified in further studies.

3.1 Pressures vs. Forces

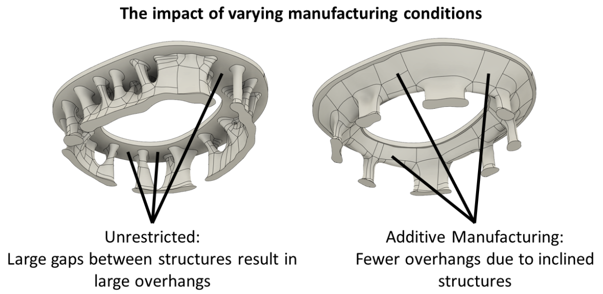
As demonstrated in Figure 4, the left insole element was subjected to pressure, while the right experienced forces. With the covers removed for the purpose of clarity, the differences become evident: the pressure-loaded element has a uniform material distribution, while the force-loaded one features cohesive structures for better load compensation. This finding underscores the efficacy of utilising forces over pressures in GD for more precise representation of foot loads. However, further studies are needed to assess its practical effectiveness.



Pressure:
Even distribution of structures

Forces:
Partially connected structures to compensate for punctual loads

Fig. 4: Ring-shaped element, designed with different loads using the GD tool in Autodesk Fusion 360; unrestricted manufacturing method in each case



Unrestricted:
Large gaps between structures result in large overhangs

Additive Manufacturing:
Fewer overhangs due to inclined structures

Fig. 5: Ring-shaped element, designed with different manufacturing conditions using the GD tool in Autodesk Fusion 360; force as a load in each case

3.2 Additive vs. Unrestricted Manufacturing

The present study sought to compare two distinct methodologies: additive manufacturing and unrestricted structure generation. In the context of additive manufacturing, the model is optimised for production, with parameters such as orientation, overhang angle (up to 45° without support) and minimum structure thickness, depending on the print nozzle. In contrast, unrestricted production is characterised by the absence of constraints related to production. As demonstrated in Figure 5, the model depicted on the left, characterised by its absence of production limits, exhibits substantial gaps and overhangs, necessitating the use of additional support material. Conversely, the model on the right, optimised for additive processes, utilises additional material, particularly in the lid area, where angled, tree-like structures are employed to eliminate the requirement for supports. The study suggests that restricting production to additive methods is beneficial for designing orthopaedic insoles, ensuring no need for support structures, which is particularly helpful for internal areas. However, further research is needed to understand how the thickened structure in the lid affects flexibility and to optimise the balance between manufacturability and functionality.

4 Conclusion

This study shows the potential of generative design (GD) for the development of customised orthopaedic insoles that precisely adapt to the individual load distribution of the foot. The comparison of different methods - in particular pressure vs. force data and additive vs. unrestricted manufacturing - shows that the use of forces instead of pressures allows a more accurate mapping of the dynamic load during gait phases. In addition, the restriction to additive manufacturing improves manufacturability by eliminating the need for support structures that are difficult to remove.

Future research should focus on the influence of different design choices on the biomechanical performance of the insole, in particular the effect of the thickened cover structure on flexibility and function. The choice of materials is also critical to the comfort and durability of the insole. The use of bio-based materials as a sustainable alternative remains to be explored and further research is required to determine their suitability. By optimising material properties, design parameters and manufacturing processes, GD can contribute to more efficient and environmentally friendly orthopaedic solutions.

Author Statement

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