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Digital personalized medical insole process

A step forward to more personalized medical support.

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Abstract: Medical insoles are used to correct patient's foot malpositions or to relieve certain foot areas from pressure. The required insole type depends largely on the presenting clinical picture and the individual's needs. Accurate fit of medical insoles is critical to wearer acceptance, which is a necessary precondition where further serious injury is to be prevented. An end-to-end digital process offers the potential to better adapt insoles to the personalized patients' foot geometry and pressure load. Furthermore, the whole gait-cycle could be included in the digitalization process and the adaption could consider special needs of different gait phases. This hasn't been done, yet.

For this purpose, a digital process chain was developed and prototypically tested in collaboration with an orthopaedist. 3D scans of the foot geometry in various loaded conditions were compiled and the corresponding gait analysis images were mapped. Both results were overlaid in a CAD program to create a model and identify the clinical picture. Adapted to the geometry of the foot, a volumetric model of the medical insole was built, individual stress zones were separated and filled with lattice structures of different parameters. The insole was 3D printed. The results of the present examination show benefits in using the loaded foot scan to model insoles, as malpositions can be checked automatically via standard (digital) tests. While it is possible to model and print medical insoles in one piece with differing strengths, there is limited information about the influence of the designed lattice structure on a specific printing result (i. e. the material behaviour).

Keywords: development of medical plantar insoles, digitization process, additive manufacturing

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1 Introduction

Basically, three types of insoles can be distinguished: Arch support, bedding and corrective insoles [1]. However, it may be that a combination of insoles is necessary for a particular patient. Nowadays, insoles are usually manufactured in layers of varied materials, which are produced separately by milling and then glued to obtain the desired material properties. New developments in digitization technologies, innovative materials, and the possibility of producing free-form surfaces using additive manufacturing processes enables new ways of developing insoles purely digitally and for direct manufacturing. In addition, there are CAD features that uses lattice structures to fill volumes, which were originally used to design lightweight structures. Nowadays, with the availability of 3D-printed thermoplastic elastomers, plastic structures with flexible elements in combination with free-form surfaces can be manufactured that offer new applications, especially in orthopaedics.

The pressure load during walking is usually recorded using dynamic pedography. This method produces an overall picture that also shows the rolling behaviour of the foot, that is the basis for developing and manufacturing orthosis. The pressure load on a foot varies when walking. This is represented in a person's gait phases. Perry [2] distinguishes eight different gait phases, with varying pressure load on the foot.

2 Market research and literature review for printed medical insoles

Studies show that a digital process for insoles is feasible, especially with the industrialisation of 3D. Selective laser sintering (SLS) and/or fused deposition modelling (FDM) can be used as 3D printing processes for those polymers. However, the digital process chain is still associated with a lot of system breaks [3, 4, 5]. In [6], an insole was manufactured using a 3D-printing process. The insoles were found to be too firm, and additional padding was necessary. In [3], no quality differences were found between manufacturing based on plaster casts versus 3D scans. The fast adaption in iteration loops was identified as an advantage of the digital process, but adaptation to personal needs was not addressed.

Personalized 3D-printed insoles have already been realized by Aetrex, but the patient`s data is statically recorded [7]. Together with GeBioM GmbH, Covestr AG has developed materials for 3D-printed insoles. Here, too, lattice structures are used to define different strengths [8]. In [9], a method has been developed that simulates the effects of an insole on a diabetic foot. Using FEM software, for quasi-static simulations were carried out in which the model of the foot was placed on the model of the insole at different angles corresponding to relevant gait phases. [10] addresses the design of an orthopaedic insole, consisting of a special (Voronoi) lattice structure.

However, so far there is primarily only a static measurement for the design of insoles. Also, patient needs and habits are not sufficiently integrated into the insole design process. Likewise, there is need for a feedback loop with simulation that is comprehensively integrated into the digital process. Continuous improvements in 3D printing processes, as well as the ability to print thermoplastic elastomers, make it possible to produce insoles from a single piece that have a certain degree of elasticity. To enable different degrees of elasticity, lattice structures are partly used. In Fusion 360 / Autodesk, for example, there are different lattice structures with different focuses (see Fig. 1). Every single lattice structure has good or less good strength properties in certain directions, has a high load-bearing capacity or is self-supporting.

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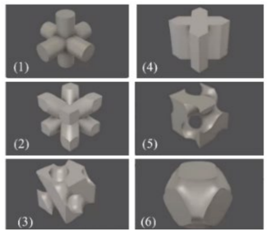

Figure 1: (1) cross (2) X-cell (3) black D (4) 2,5D-X-cell (5) gyroid, (6) black P (source Autodesk/Fusion 360).

3 Methodology: Digital process chain

In the following, the concept of a new digitization process is illustrated using the example of a flat foot (see Fig. 2). First, the foot is dynamically digitized in various gait phases: initial contact (Fig. 3), loading response (Fig. 4), mid stance (Fig. 5), terminal stance (Fig. 6) and swing phase. The novelty is that now the foot is scanned in a loaded state.

1. **Initial contact**

The foot touches the ground for the first time. This is usually done with the heel. The foot is positioned at an angle of about 90 degrees towards the lower leg and is inclined accordingly. Since the weight is initially still on the other foot, the pressure applied to the heel is still low.

Figure 3: Geometry and load during the first contact of the foot when walking.

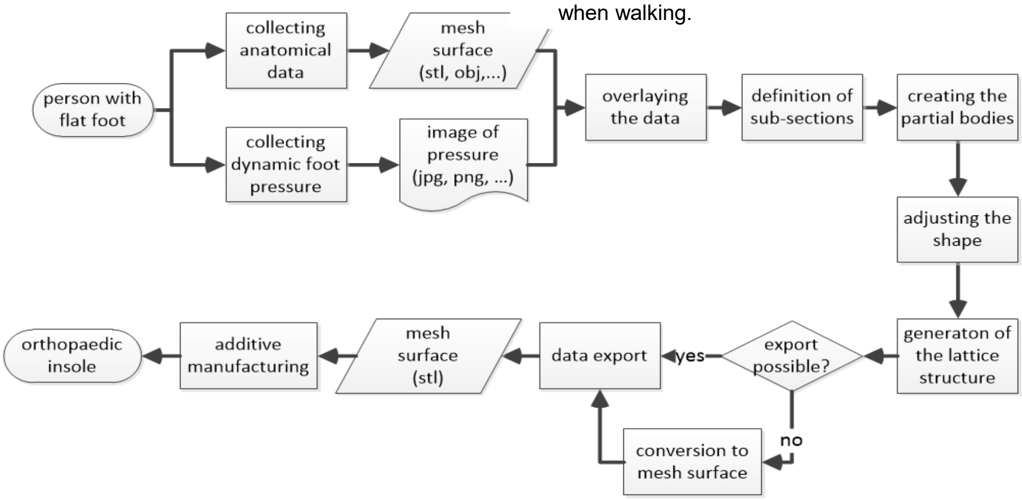

Figure 2: Concept of a digital process chain.

2. Loading Response

In the loading response, both feet are in contact with the ground. 60 % of the body weight is transferred to the second foot. This causes a torque around the ankle. Since the centre of gravity is still behind the ankle, the greatest pressure is still on the heel. Nevertheless, the midfoot and forefoot are also are also taking weight.

Figure 4: Load when stepping on the foot.

3. Mid Stance

During the mid stance, the swing leg is raised. The weight must be stabilized on the stance leg alone. The foot rests and the lower leg is almost perpendicular to the foot.
The body weight is now distributed over the entire foot. The greatest application of force (highlighted by the square) gradually moves toward the forefoot.

Figure 5: Load during whole surface loading.

4. Terminal Stance

In the terminal stance, the heel is lifted off the ground. As long as the foot of the swing leg is in the air, the forefoot must now support and stabilize the entire body weight.

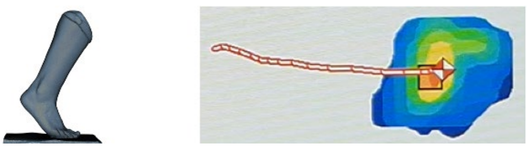

Figure 6: The body weight rests entirely on the forefoot.

5. Swing phase

During the swing phase, the foot is in the air and therefore does not have to bear any body weight. For the design of an orthopaedic insole the individual phases of this particular associated movement are of no further relevance.
At the end, the data from the scan is exported to the corresponding CAD software in .stl-format and the pressure image is imported as .png/.jpg. For the design of the insole, the pressure images of the different gait phases are combined to form an image of the pressure peaks.

4 Implementation: Shaping process of the insole

A hand-held scanner (Shining 3D), in this case using white structural light, is used to digitise the shape of the foot. The resolution of the scanner is 0.5 - 3 mm, the accuracy is 0.05 mm.
For the redesign of an orthopaedic insole, plantar foot pressure measurements are also relevant. The distribution of pressure during walking or standing is represented by means of a colour scale. To record the foot pressure, the PrestoSCAN measuring plate from the manufacturer Savecomp Megascan is used. The measuring plate has a size of 440 mm x 370 mm and measures with a frequency of 40 Hz. The foot pressure is measured over a total of 2288 measuring points (corresponds to 1.4 measuring points per cm²) and transferred directly from the associated software via cable.
The shaping process is composed on different steps (see Fig. 9). First the data is superimposed (1). For the basic shape of the insert, the outline of the print image is reproduced in a sketch by means of a spline (2). Additionally, the colour-differentiated pressure areas are outlined individually. Then the areas of the printed image are extruded (3).

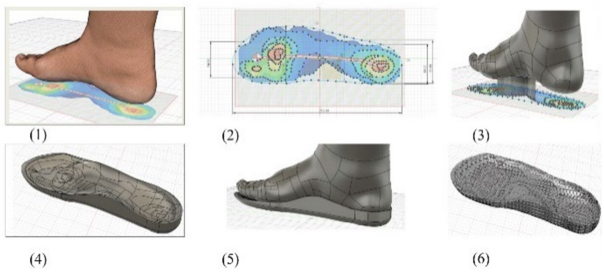

Figure 7: (1) superimposed data (2) splines for colour/stress areas (3) extrusion (4) solid bodies (5) adaption process (6) filled with lattice.

After cutting, an orthopaedic insole is created, which is composed of several solid bodies (4) and the surface of which is adapted to the foot (5). In order to obtain an orthopaedic insole with its strengthened adapted to the pressure pattern of the human gait phases, the individual areas of the insole are equipped with individual lattice structures (6). The choice of the respective cell type and its dimensions are based on the pressures measured in pedography, which are generated during walking. The 3D model is then converted into a mesh and the data is sent to the 3D printer in .stl format. In this study FDM was used, because it is more suitable to produce filigree structures with TPU (thermoplastic elastomer).

5 Results: Innovative insole and digital illness diagnosis

It is possible to design orthopaedic insoles that consider people's gait phases. Thanks to the digitisation process and additive manufacturing, insoles can be made that take note of the foot pressure of the different gait phases. It is possible to manufacture the insole in one piece and generate different strengths at the same time.

With support from the superimposed data, it is possible to derive clinical diagnoses (here: flat foot). For this, a scan of the foot in the loaded state is absolutely essential. Diagnosis might be automated by measuring, for example, the angle of the hindfoot axis. For this purpose, the axes of the hindfoot are aligned at prominent points. Deviations from the target value, e.g. a maximum angle of the hindfoot axis, can thus be diagnosed automatically.

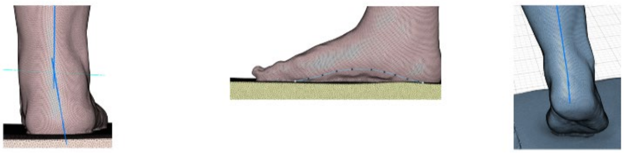

Figure 8: left: axial relationship between lower leg and calcaneus of a right foot, dorsal view middle: lowered medial longitudinal arch of a right foot, view from medial right: heel rise test, view from dorsal.

6 Discussion

In this study a common CAD-Software package (in this case Autodesk Fusion 360 was used. Accordingly, no special medical software is required for the development of orthopaedic insoles. Currently, static measurements of foot pressure while standing are used to design orthopaedic insoles. However, normally the load pattern oscillates around the patient's centre of gravity when walking and is related to his body weight. The gait pattern shows increases in heel strike and rolling over the ball of the foot. These areas of increased pressure often need to be relieved to prevent pain. Dynamic measurements offer the benefit that the rolling behaviour of the feet and the pressure distribution during walking can also be considered and thus diseases can be represented and analysed virtually in advance of the printing process.

The use of additive manufacturing makes it possible to design the insole individually with regard to the pressure areas and additionally manufactured in one piece. However, for a correct choice of the corresponding lattice structures, further studies have to be carried out.

7 Conclusion and outlook

In principle, it was found that it is possible to establish a digital end-to-end process that describes the efforts of a dynamic foot pressure measurement and scans across the different gait phases. Today's CAD systems offer the possibility to work with layers and to overlay data. By integrating the gait phases, wear patterns can be better integrated into the insole development and the patient's clinical picture can be better addressed. However, it is important to establish a feedback loop to a simulation model of the patient`s data via personalized models in order to repeatedly compare the digital insole results to the virtual simulations. Another problem is, that at the moment it is not possible to create an insole which maps a given structural behavior, because there is data of the combined lattice-material-behavior. For this purpose, libraries with material behaviour have to be created, which better represent the material/structural behaviour.

Author Statement

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