THE STUDY AND DEVELOPMENT OF PERSONALIZED ORTHOTIC INSOLES THROUGH 3D PRINTING TECHNIQUE

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THE STUDY AND DEVELOPMENT OF PERSONALIZED ORTHOTIC INSOLES THROUGH 3D PRINTING TECHNIQUE (Abstract): The human foot is the main connection of the body with the environment. It has a complex anatomical structure allowing different movements, such as gait, orthostatic position or running, on different surfaces, without any pain or injuries occurring. Upon it, there are many types of impact forces acting, therefore, the human foot has to absorb and dissipate these forces. The study of plantar pressures and their distribution across the foot aid in diagnosing and treating different pathologies. The plantar analysis helps in creating personalized tools for treating pathologies associated with the foot. **Objective:** This paper aimed to create a personalized insole, 3D printed, made out of flexible materials that would be fitted for this study's participant. **Material and methods:** The study consisted in collecting data from 12 subjects, with no known pathologies and performing the plantar pressure analysis, both static and dynamic analysis, then, modeling and printing the anatomical insole, fitted for the participant of the study. **Results:** The result is an anatomical insole, personalized, 3D printed, using flexible filament, with different thicknesses along the arches of the foot and different infill densities for unloading uneven plantar pressures across the foot. **Conclusions:** After all the stages of the study, a personalized insole was printed. The insole strictly follows the participant's foot anatomy, takes into account the distribution of plantar pressures across the foot and the deformities that were noticed as a result of the static and dynamic plantar analysis. **Keywords:** PLANTAR PRESSURE, INSOLE, 3D PRINTING, FLEXIBLE FILAMENT.

People spend the majority of their time in orthostatic position, walking or engaged in other types of physical activities. In this case, the feet and all the surfaces walked on are in direct contact. The plantar forces, forces that are acting upon the feet can sometimes have an uneven distribution. This uneven distribution can lead to a series of issues that can affect the general health of an individual (1).

Since the foot is the main surface of interaction during gait or every other physical activity, it is important to quickly identify any types of pathologies and deformities in their beginning phases so they could be either treated, prevented or corrected. One of the easiest, fastest and most reliable sources to do so could be considered the plantar pressure analysis (2).

Plantar pressure and its measurement offer information about foot and ankle function in orthostatic position and during

physical activities. The data obtained during the analysis of the important parameters involved in these movements are important in evaluating different pathologies and deformities that can affect the feet (1).

There is a great relationship between plantar pressure and the posture and balance of human bodies (3).

There are a lot of advantages in using this technique to assess different issues upon the foot, such as the usage of complex software able to perform and evaluate gait analysis, in both static and dynamic regimes, distribution of the plantar pressures across the feet, support areas, mass repartition, body posture. All the information can be easily saved and viewed in a database. The method in itself is easy to perform for both the specialist and the patient, fully objective and it allows modelling and creating personalized insoles fitted for each patient and their issues. Performing the analysis and taking the measurements are, as mentioned before, easy to obtain, the more difficult part is interpreting and analyzing the results obtained after the measurements (4).

Inadequate support of the feet can lead to numerous injuries in the short or long term. For better support, an anatomical insole can be one great solution. To create a personalized insole, the morphology should be perfectly adapted to the patient's feet. 3D printing of the insoles is the newest and best technique to create solutions for treating or preventing deformities, to ensure an even distribution of the pressure across the feet for better support and better comfort (5,6).

For designing shoes and the components of the shoes, such as the insoles, a detailed analysis of the feet is a key point, considering the different characteristics that every individual has. Given the fact that the feet of every individual are so different, it is important to understand and recognize certain patterns to obtain products that are both supportive and comfortable enough (7).

As stated before, the foot has an anatomical structure that is different for every person, therefore, when the plantar analysis is taken, a series of other parameters and measurements are important, such as: the length of the foot, width at different points, the height of the hallux and other toes, along with some information about the patient: age, sex, height, weight, shoe size (7,8).

MATERIAL AND METHODS

In this study, plantar analysis was performed on 12 participants. The plantar analysis was performed for both the static and dynamic regimes. The participants had no diagnosed pathologies but had different ages, heights, weights and shoe sizes.

The data was collected using the pressure plate Footwork (AMCUBE) and was visualized using the associated software.

The first step of the study was collecting data from the participants: age, sex, height, weight and shoe size. All this information is relevant because they change the way the plantar pressure is distributed across the foot (9, 10). The next step was performing the plantar analysis. For the static analysis, the subjects were asked to stand in a natural position for 10 seconds, their arms on the sides of the body, looking ahead, feet shoulder-width apart, both feet on the pressure plate. For the dynamic condition, subjects were asked to take two steps before striking the plate, right foot first, then in the same way for the left foot. Once the data was collected, it was visualized and organized for better understanding

in tables. The data that was looked at was mean and maximal pressure for both feet, in both conditions, the forces chart and mass distribution.

TABLE I.
General data collected from subjects

Subject	Sex	Age	Height (cm)	Weight (kg)	Shoe size (EU)
S1	F	48	165	69	40
S2	M	19	168	60	42
S3	F	20	160	48	38
S4	M	20	182	110	46.5
S5	M	23	181	85	40
S6	F	19	165	54	38
S7	M	20	177	68	41
S8	F	20	160	36	37
S9	F	19	158	48	38
S10	F	20	165	54	37
S11	M	21	180	86	44
S12	F	24	173	59	40

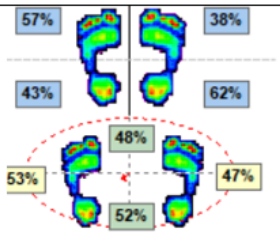
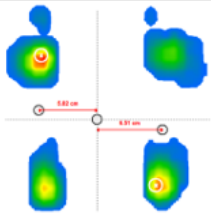
Fig. 1. Pictures taken during the scanning process.

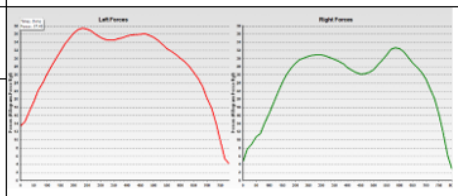
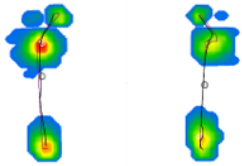
To create the insole, out of the 12 analyses, only one was chosen given the different deformities and the pressure distribution that were noticed on the subject. Table I displays the plantar analysis for the chosen participant.

Once the plantar analysis was chosen, the next step was to create the model of the insole for printing. Firstly, Gensole was used. Gensole made possible the creation of a template for the insole with all the dimensional parameters of the participant's foot, along with certain modifications on the thickness and heights across the insole, in accordance with the foot's deformities,

TABLE II.

Plantar pressure for static and dynamic analysis.

Static					
Mean Pressure (kPa)		**Maximal Pressure (kPa)**		**Mass Repartition**	**Plantar Pressure**
Left Foot	Right Foot	Left Foot	Right Foot		
56.53	51.66	151	125		

Dynamic					
Mean Pressure (kPa)		**Maximal Pressure (kPa)**		**Forces Chart**	**Plantar Pressure**
Left Foot	Right Foot	Left Foot	Right Foot		
186	198	306	301		

Autodesk Fusion 360 was used to modify the specific zones according to the plantar pressures. For this, the 3D model previously obtained and the plantar pressure for the subject were overlaid to create a support for the transverse arch, as well as to mark zones for decreasing plantar pressures in areas where high values were observed.

For the printing of the model, Prusa Slicer was used to modify the local densities and geometries inside the insole.

In the last phase, the obtained personalized insole was printed using PRUSA i3 MK3. The used material was Filaflex, a flexible filament from Recreus with great proprieties for this type of application.

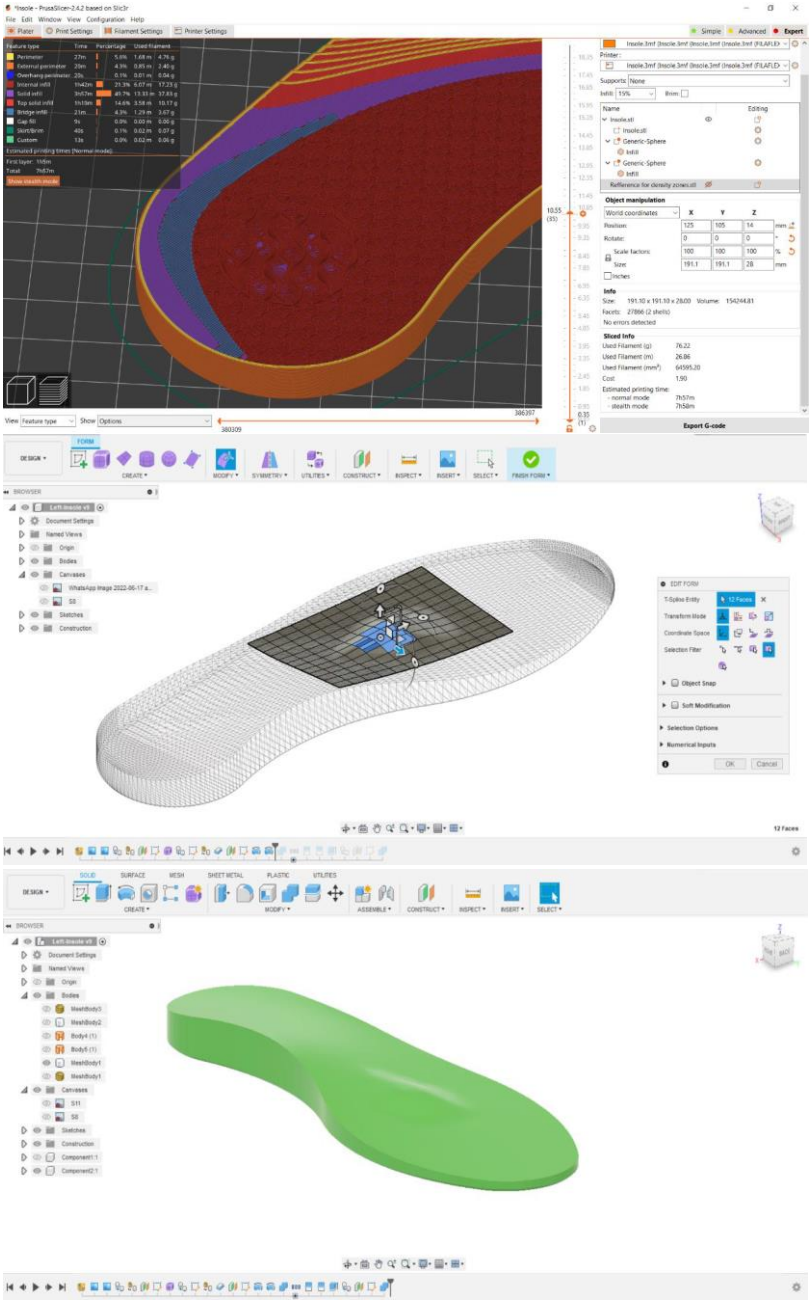


Fig. 2. Images during the modelling process.

RESULTS

After the 3D printing of the insole was performed, the result was a personalized insole, fitted for the study's participant. Different heights, thicknesses and heights were obtained across the plantar arches,

with the purpose of correction of pes cavus hindfoot valgus. Also, another advantage of the personalized insole is that it has zones of different infills that will serve as unloading areas of the high plantar pressures that were noticed in the first part of this study.

Fig. 3. Images of the personalized insole.

DISCUSSION

Over the last few years, the topic of personalized medicine, based on treating each patient individually and not the pathology itself has been presented as the future of the medical field. This type of approach has a series of advantages, such as the optimization of specific treatment schemes, better solutions fitted for every patient and lower final costs.

The study has presented such an application, a personalized solution for treating certain pathologies or for improving patients' comfort in their day-to-day life.

While many researchers have been working on creating customized insoles through various techniques and materials, the method presented in this paper has not been done before. Most of these papers were done regarding the study and comparison of thermoplastic elastomers. Mogan *et al.* (11) has conducted a series of studies regarding the proprieties that Filaflex has and the infill pattern impact on the mechanical proprieties of the final product and has concluded that this particular material has remarkable proprieties.

Zuniga *et al.*(12) developed a 3D printed insole, using two types of flexible filament, for comparison and evaluated plantar pressure distribution in walk trials. The development of the insole was, however, done using a 3D scanner along with the usage of Gensole and then printing the insoles. The authors have declared this method as being expensive. Also, their proposal was time-consuming compared to the method this paper presented.

Jandova *et al.* (8) have presented a study in which they developed a model of a 3D printed insole, which was based on specific parameters and characteristics of one of the three specific European feet, as they classified them, but their proposed method was not a personalized, custom made for patient application.

The method presented in this paper is a new method to design and create custom-made insoles to treat feet's pathologies or for better support and comfort. The combination of techniques that were used, such as the usage of just a pressure plate to identify the most affected areas across the feet, the usage of Gensole software to briefly design the template that was later used to shape and design different areas on the

insole in Autodesk Fusion 360 that would make the insole truly personalized and then the fabrication process, respectively 3D printing using a flexible material, Filaflex, a material with truly remarkable proprieties. All these methods combined have not been done before, making it possible to create a custom-made insole, perfectly personalized without needing a 3D foot scan, but only a pressure plate and the 3D printing machine.

CONCLUSIONS

This study's purpose was to create personalized insoles using flexible materials. Plantar analysis performed in both static and dynamic allowed for adequate data that was needed to use in the design and 3D printing of the insole. This technique has the potential of easing the technician's work through optimized and digitalized processes, with lower final costs and much quicker than using the standard methods, with better results for the patient as well.

CONFLICTS OF INTEREST AND FUNDING

Authors declare that there is no conflict of interests, and they received no funding for this study.

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