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RESEARCHES ON USING ABS COMPOSITE AND SILICONE TO BUILD INSOLES BY 3D PRINTING

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Abstract: *The insole used for medical purposes are the constructive variants with good efficiency in posture recovery procedures and the quality of human subjects' walking. In this paper, the variants of the insole that allow the obtaining of correct posts in different activities, but also the ways of realization from different materials are analyzed. In the first part of the paper, the theoretical aspects regarding the configuration and the structure of an insole, followed by the experimental considerations regarding the testing of the forms of the insole under the effect of the different conditions of use are presented. From the conclusions of these analyzes, it has been possible to use rigid support insole made by 3D printing, to which is added a flexible silicone structure with a protective and effective purpose for the uniform distribution of forces on the plantar surface. Measurement of this distribution has been achieved by means of pressure sensors embedded in the insole structure and displaying values on a computer. In the final part of the paper, the results and conclusions of these tests are presented.*
Keywords: *insole, silicon, 3D printing, composite materials*

1. INTRODUCTION

Insoles are composite structures that are inserted into any kind of footwear and for any purpose of use in order to protect the plantar surfaces of the subject's leg and to achieve a postural comfort, both in the static position of the biped position and in the dynamics of the walking cycle.
The manufacturers of these systems have developed integral or partial variants, flexible or not, of variable and integrals dimensions inside the footwear, starting from the principle that the plantar foot surface must be protected from impact with the ground and must be provided with thermal and hydrophobic protection. [1,2]

Figure 1: Insole variants for different high heel, plantar surface, complete or partial shape [1,2,]

Additionally, if these systems are used for medical recovery procedures or for patients with different pathologies of the locomotor system, the shape, structure and materials of the insoles can be adapted and supplemented with solutions, medications, extra pieces (magnets) or specific substances that act on wounds or inflammation of the plantar surface or ankle area. [3,4]
From the point of view of the most widespread pathology that can occur at the level of the plantar surface and as shown in the paper [5] "diabetes mellitus (DM) is one of the most common and rapidly increasing health problems worldwide. The number of people in the developing world with diabetes will increase by more than 2.5-fold, from 84 million in 1995 to 228 million in 2025. With the rise in prevalence of DM, the burden of this disease to society becomes progressively greater.
Pathologies of the foot due to DM are a significant contributor to the economic burden. An estimated 25% of DM patients developed foot problems, and about 20% of diabetic patients entering the hospital are admitted because of foot problems. Studies showed that complications of DM, such as changes in bony structures, limited

joint mobility, callus formation, and arterial in sufficiency, may cause locally elevated plantar pressures. Repeated applications of such high pressures make the foot more susceptible to the development of ulcers."

Therefore, medical intervention through medicinal substances is beneficial to the patient and is a method of assessing both the pathology evolution and a method of improving the functional parameters of the posture or the walking cycle.

Other research has been directed towards determining the appropriate forms of the patient's insole forms according to the anatomical form and the pathologies developed at the plantar level due to various sports or professional activities. As shown in the studies [3] conducted on patient samples in the USA, Australia or the UK "plantar heel pain (PHP), also known as plantar fasciitis, jogger's heel, tennis heel, and policeman's heel, is a painful syndrome that occurs around the calcaneus. Although the term itself might be vague, the chronic pain that originates at the plantar fascia following weight bearing is the unfortunate reality of many. The pain, which could lead to a reduction in sporting and everyday activities, has been described as burning, aching, and occasionally lancinating. It is the most common foot musculoskeletal disorder encountered by health professionals that has a negative impact on health-related quality of life in those who experienced it. This condition occurs in approximately 2 million Americans per year, while the prevalence rates in UK and Australia are 4.6 and 17.4%, respectively."

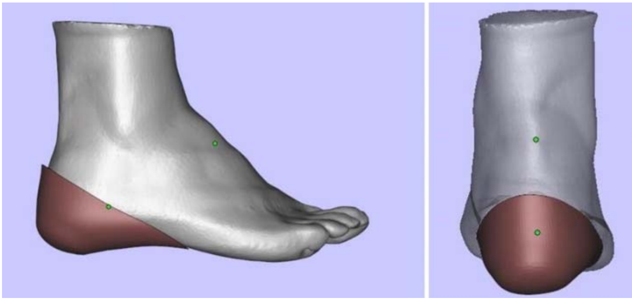

Figure 2: Insole variants for plantar heel pain (PHP) [3]

These forms of medical devices are made by 3D printing following a 3D scan process of the ankle area and the plantar surface and direct transfer to the printing machine.

Another important aspect identified in the research on the shape and structure of the insole is their realization from materials with different density and rigidity present on the plantar surface in order to give the patient comfort in displacement or bipodal position. In these researches it was assumed and proved that "a decrease in the insole density could increase the activation time distribution on the foot during fast walking", especially in patients with flat feet or with problems of continuity at the level of the plantar surface.

Other experimental researches have focused on highlighting aspects of the biomechanical parameters of the plantar area (fascia) measured on the walking cycle using insoles with embedded sensors and positioned in different areas of the foot plantar surface. [7]

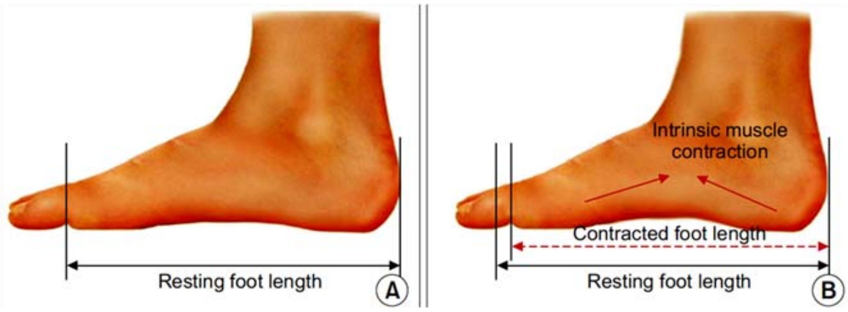

Figure 3:"Description of arch building gait (A) Resting foot (barefoot), (B) Contracted foot (arch building)" [7]

Evaluation of the contact surface size and / or distribution of the pressing force on the ground different areas of the plantar surface (tarsal, metatarsal, heel) foot in the relaxed situation - bipodal stance static (rest) or foot walking cycle (Fig. 3) can highlight points and over-or overloaded areas that constitute pressure and voltage transducers transmitted throughout the locomotor system in the form of pain or difficulty in action. [7] Therefore, experimental research is aimed at obtaining detailed and localized information on the distribution of pressure and tension concentration points to identify ways to mitigate their effects on postural comfort. [8,9,10]

Another very important aspect of the conception, construction and development of these systems with medical action is the type of materials and the technology of realization. The natural materials (leather, wool, cotton, linen, natural fibers etc.) were the first options in the construction of these insoles, but they were often

ineffective if they were used alone (due to wear, absorption water, or residual deformations), or even in combination. Artificial materials based on polyurethane foam, plastic or silicone have formed another set of materials to make corrective inlays.
Combined natural and artificial materials are often used in varying proportions and on different surfaces, plus auxiliary elements (magnet pieces, pressure sensors, air cavities, or drug-stuffed ones) to increase utility and performance.
From the point of view of personalized development of corrective insoles, it is now preferred to use the foot scanning technology and 3D printing technology to obtain the shape best suited to the plantar surface and the type of shoe that the subject / patient will use (for general use, military, sports, medical). In addition to the variants of insoles made possible by 3D printing technology, the same technology has been successfully used in the achievement of integral foot prostheses (Fig.4), the beneficial effects being reduced in weight, much better compatibility with the human body, easy maneuverability and relative downward trend costs.

Figure 4: Multi-Material Foot builds by 3D printing method [12]

According to the experts from the field "three-dimensional (3D) printing, one of the most recent forms of CAM, has proven efficacy in the fabrication of ankle foot orthosis (AFO) with reports of excellent dimensional accuracy, good manufacturing precision, and performance that is at least equivalent to hand-crafted AFO's. Recent studies report positive subjective comfort ratings and similar biomechanical gait parameters with the use of orthosis manufactured using 3D printing in comparison to orthosis fabricated using traditional means." [11]

2. EXPERIMENTAL SETUP

The experimental system, designed for the development of the procedure for the achievement of the 3D printing and use for the purpose of determining the pressure distribution mode, consists of several modules corresponding to the stages of activity. The activity steps are marked by specific working modules in the general scheme of the 3D prototyping prototype development process. Thus, according to the block diagram of Fig. 5, the scaled form of the plantar surface of the subject's foot is corrected and completed by dedicated software and transmitted to the 3D printing machine via the compatibility software module.

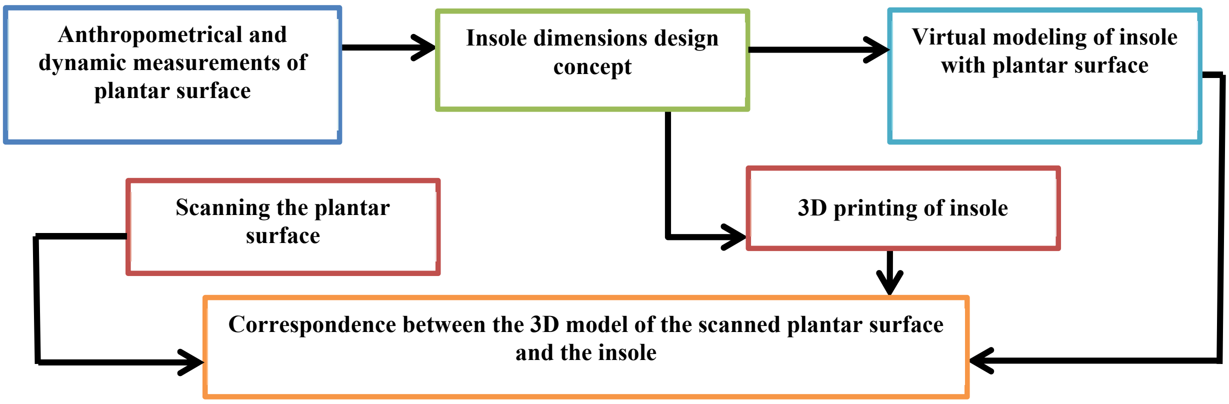

Figure 5: Block diagram of design and manufacturing of insole by 3D printing procedure

Catalyst software is the program by which, starting from the *STL* model of the insole prototype, the command code (the **.SML*) file of the 3D printing machine is generated. With this software application, the *STL* virtual

model is discretized in "horizontal slices", and then each slice is extruded as a layer of material by the installation to achieve the physical model. After processing the *.STL* virtual model, the 3D printer will physically begin to build the insole previously designed.
After the scanning procedure of the plantar surface to which the insole is to be adapted and for the achievement of its model, the material (natural or synthetic) from which the insole, the model, the shoe size and the identification elements of the subject are to be made.

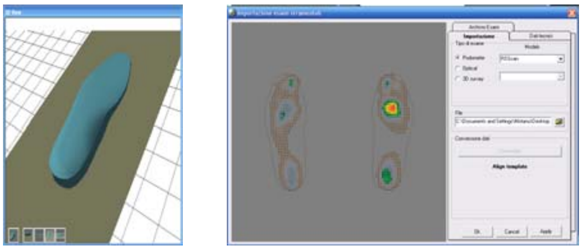

Figure 6: Correlation between insole virtual models with RSscan recordings of plantar surface

To create an insole profile, it will choose the module software **EASYCAD** option **self-modeling** where the parameters are set: plantar border height, the size and shape of the plantar vault, and after this command, the dynamic recordings on the RSscan board are correlated, through digital embedding with the virtual insole model to compensate the areas high plantar pressure (fig.6).

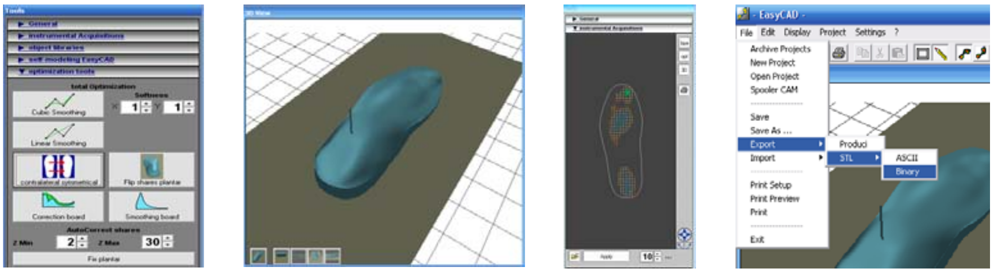

Figure 7: Importing static image from RSscan, framing on the insole and export for 3D printing [13]

The last step is the optimization of the insole shape, the virtual application of the load mode on the plantar surface and the saving of the model created as *.STL* file for the next 3D printing process (fig.7).

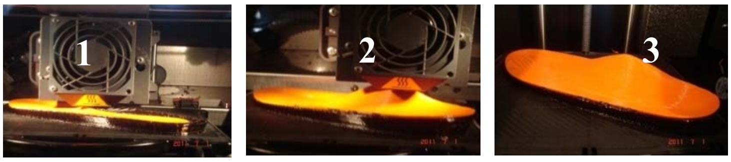

Figure 8: The main stages of 3D printing process

The main steps of 3D printing process of the rigid insole are shown in Fig.8. Instead of this form, it is envisaged to introduce in the high plantar pressure areas, some soft silicone surfaces that adhere to the insole surface and at the same time to offer the possibility of recording, during the gait cycle, the dynamic response.

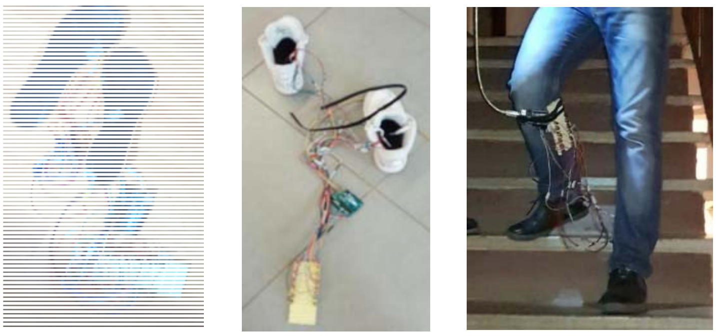

Figure 9: The sensorial system for measuring the ground force applied by human body to the insole [14]

The system by which the pressure of the foot plantar surface, through the insoles, can be recorded is shown in Fig. 9 and consists of a set of force sensors placed in silicone modules in the areas identified to be loaded more much of the records on the RSscan plate. These silicone modules are attached to the 3D printing insoles form and are coated with a smoothing material and also to provide a touching, thermal and hydrophobic comfort to the patient's foot.

3. RESULTS

The results of the recordings on the RSscan plate of the subject gait cycle for which the composite material insoles was made reveal important aspects regarding the way of walking, the level of contact forces with the ground of the left / right foot, in the case of wearing and not wearing shoes where is the sensorial insole.

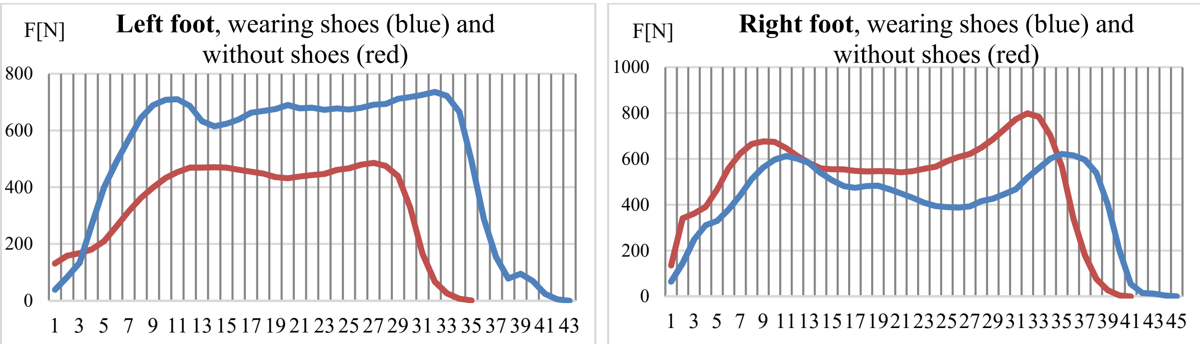

Figure 10: The recordings of force level from RSscan plate wearing shoes (blue) and without shoes (red)

From Fig. 10 it can be seen that in the case of the subject registered on the RSscan plate, the force developed at the level of the plantar surface in contact with the ground differs for the left foot from the same size measured at the right foot, under the same conditions, with up to 16% when wearing shoes and up to 36% without shoes.

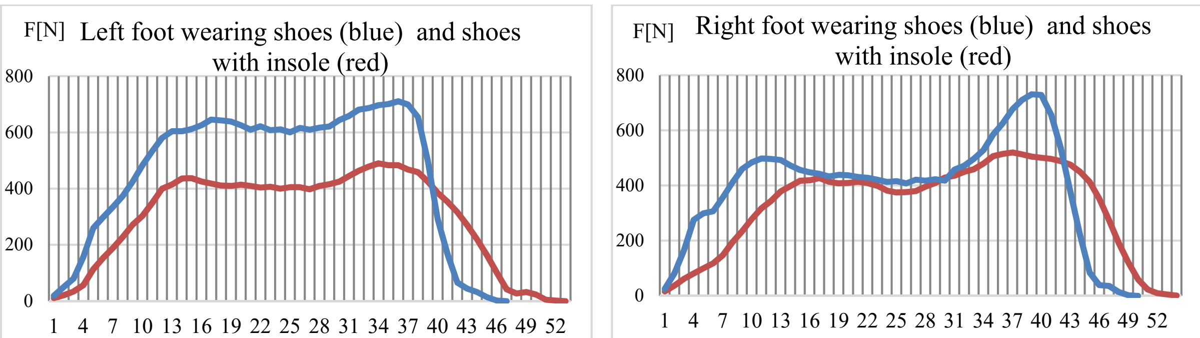

Figure 11: The recordings of force level from RSscan plate wearing shoes (blue) and shoes with insole (red)

If the same subject wearing the sensory insole is recorded on the RSscan plate (fig.11), the percentages change in order to establish approximately the same level of ground force on both plantar surfaces (left / right) when wearing shoes with composite composite material.

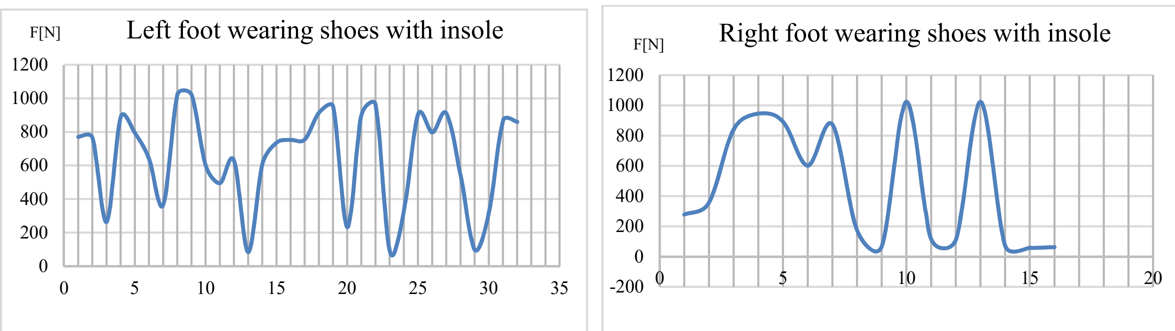

Figure 12: The recordings of force level from sensorial board wearing shoes with insole

In case the compare wearing insole for shoes with and without, the difference is evaluated in percent in the same range for both plantar surfaces (about 25% for the left foot and 7% for the right foot).

At these recordings are added the signals acquired from plantar sensors in insoles indicating the same distribution of plantar force when the subject walks on the flat surface, with shoes with sensorial insoles mounted inside.

4. CONCLUSION

In this experiment, it was made to emphasize the pressing force of the plantar surface of the left / right foot on the ground, in the situation where the subject is wearing or not appropriate footwear for the anthropometric dimensions. Also, the evaluation of the force of pressing on the ground was determined, in the second part of the experiment, at the same time with the help of the sensorial insoles mounted in the appropriate shoe, demonstrating the obtained values a similarity of the measurements.

In addition, the 3D printing technology of manufacturing the rigid insoles, has enabled to obtain a personalized form of plantar support composite with silicone material. This form induces a much better postural comfort in the subject and allows for fast recordings made with a portable system.

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