IMPLEMENTING RAPID PROTOTYPING TECHNOLOGIES FOR CORRECTIVE INSOLES

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Abstract: The paper presents a technological method suitable for the fast manufacturing of personalized orthoses, namely insoles. After obtaining the model by help of various modelling softwares, the production time may be considerably shortened by help of a rapid prototyping method. Manufacturing of personalized corrective insoles is presented as an example of using rapid prototyping technology in obtaining personalized orthosis. The corrective insoles are designed and manufactured for two of the most encountered foot deformities, namely flat foot and hollow foot. The result is an accurately adapted orthosis to the individual requirements (anthropometrical dimensions, type of deformity etc.) and a short manufacturing period.

Key words: Rapid prototyping, insole, corrective, technology, material deposit.

1. INTRODUCTION

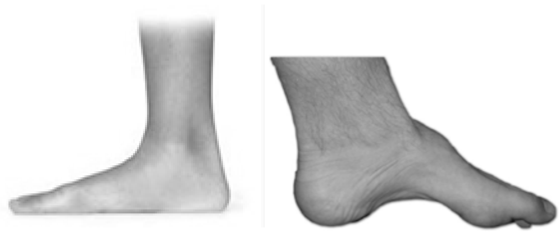
Orthotic devices are designed to align, support, or correct deformities, or to improve the movement of joints or limbs. They are usually fabricated based upon predefined dimensions, in various sizes like small, medium or large, (5). Then some fitting operations are required in order to adapt the device to the patient.

There are also several possibilities to use some CAD programs or other biomechanical modelling software in order to obtain the virtual model for most of the orthotic devices. This way they can be further tested to the corresponding loads and studied if subjected to the effect of mechanical stress upon the modelled item.

All these procedures take time but once the methodology established, the information for each new patient can be obtained by a simple change in the data used for processing.

The problem is the physical result of the determined model. Due to the large range of dimensions characteristic for each individual, a mass production is out of the question, (Cotoros, D., et al, 2011). For this reason it is necessary to consider another approach, meaning the rapid prototyping technology, respectively prototyping technique based upon deposits of melted material in the areas requested by the prior established configuration (FDM – *Fused Deposit Modeling*). This way we can start from a predetermined shape and individualize it very fast according to the current patient.

As most of the foot deformities are the results of over-pronation - or rolling inwards of the feet and ankles, and collapsing of the arches, (Baritz, M., 2011), we took a special interest in proposing a fast and personalized technology for two of the most encountered foot problems: orthotic insoles for flat foot (figure 1a) and hollow foot (figure 1b), (7).



a) flat foot b) hollow foot

Fig.1. Foot deformities

Orthotic insoles are designed to control over-pronation and to restore the natural foot function.

Orthotic insoles re-align the foot and ankle bones to their natural position, thereby restoring proper foot movement, (Baritz, M., et al., 2009), (Radu, C., 2006), (Perttunen, J., 2002).

2. GENERAL ASPECTS CONCERNING THE RAPID PROTOTYPING PROCESS

Rapid prototyping is in fact an "adding manufacturing" technology used to manufacture high-quality parts in a small number and short time. Nowadays, around 8,8% of the rapid prototyping technologies are used for medical industry, proving the fact that in many situation the personalization of some medical devices should be the deciding factor when choosing a manufacturing technology type.

The equipment used in the rapid prototyping process is a **Dimension Elite Printer,** shown in figure 2, which is part of the research equipment of the Advanced Mechatronic Systems research department.

Fig.2. Dimension Elite Printer equipment

The working principle of the installation Dimension Elite Printer is based upon the heating of the material to be deposited until near its melting point an then depositing the fused material in the required areas in order to obtain the designed model, (6). The success of the procedure strongly depends on the accurate control of the heating and maintaining the material during the depositing operation.

The rapid prototyping machine consists of the following main components: electronic control block (control equipment), heating-extrusion head and working platform.

Electronic control block (figure 3) is the component designed to take the information from the computer and controls the displacement of the heating-extrusion head in the xOy plane and also of the working platform along the axis Oz. This component is the one maintaining both the construction and the support material heating temperature near the liquefaction temperature and maintains the temperature of the working area at a prior established temperature.

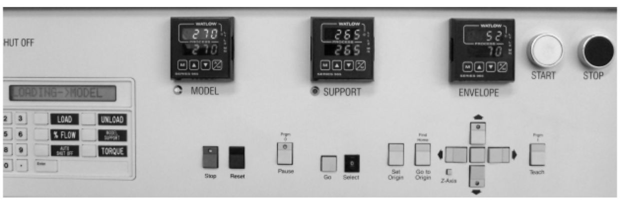


Fig.3. Electronic control block

Heating-extrusion head is the component of the prototyping machine inside which the heating material takes place, reaching a temperature near the liquefaction point and also deposits the melted material filament along the tracks calculated by the dedicated software Catalyst. The heating-extrusion head moves in a plane which is parallel to the machine working platform. This motion is assured by some step by step motors and is controlled by the electronic control block of the machine.

The extrusion-heating head is provided with two extrusion nozzles, one is assigned to deposit the main construction material, while the other deposits the support material.

The material is usually a filament or a wire, with an approx. 1,8*mm* diameter. It is introduces by means of the the drive rollers inside the heating chamber. Here, the material is heated until it reaches a paste state and then it is deposited by help of the extrusion nozzle. The solid filament acts like some kind of piston during the extrusion process.

Working platform is that part of the machine which performs the motion along Oz axis. This motion is assured by some ball screws driven by stepping motors. In their turn the motors are controlled by the electronic control block.

There is a special shape tray on the machine working platform used to hold a plate made of foam (figure 4).

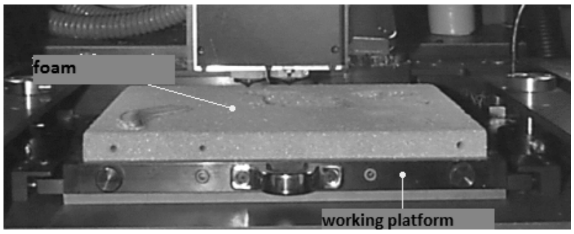


Fig.4. Working platform

Before starting the actual construction of the desired part we need to create the so called „basis”, which represents the connection element between the platform and the part during the construction. The displacement increment of the platform along the Oz axis is 0,0127*mm*. If the distance between two consecutive cross sections through the virtual model is not a multiple of this value, then during the section materialization process the machine will compensate this difference, practically we get another value of the deposited filament section than the one initially considered.

The rapid prototyping system is able to use several types of construction materials, such as:

- ICW-05 – Investment Casting Wax (wax used for easy fusible models);
- MW-01 – Blue Machinable Wax (special wax that can be machined);
- P200 – Plastic Material (Polyolefin);
- P301 – Plastic Material (Polyamide);
- P400 – Plastic Material ABS (Styrene Acrylonitrile Butadian).

The material used for the present process was an ABS Plus wire (filament). The plastic was heated at 270^{0}C, when the material gets into a semi-liquid state. It can be extruded next through a very small diameter nozzle and immediately deposited where the structure requires. The nozzle used for the extrusion of semi-liquid material can be moved together with the heating-extrusion head. The operation principle of the described equipment is shown in figure 5.

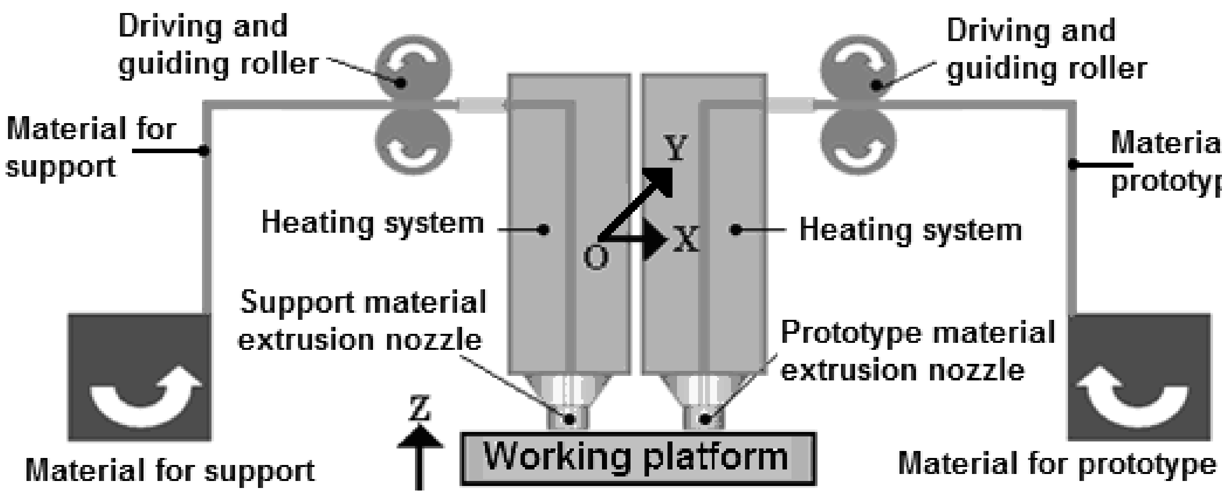


Fig.5. Operation principle of the rapid prototyping system

At the same time with the physical model, the support model is deposited by the second nozzle. Of course the support will not be part of the final model but it is necessary to hold the model material during the manufacturing process, especially in the areas where the model presents a complex configuration and interior holes. The support material is also ABS plastic only its properties are different from those of the construction material.

This way, it is possible to obtain a physical representation of the virtual model by depositing material in places required by the configuration. The important thing is that the period elapsed during the accomplishment of the virtual CAD model and the manufacturing of the physical model that may be further used in other manufacturing processes or used directly as a functional part, is very short in comparison to the classical manufacturing processes.

The dimensional accuracy of the models which are manufactured using this procedure is about 0,125mm on the axes Ox, Oy, Oz within a working volume of 205x205x305 mm.

3. RAPID PROTOTYPING OF CORRECTIVE INSOLES

The process of manufacturing the physical model consists of three stages: preprocessing stage, actual construction of the prototype and postprocessing stage.

3.1 Preprocessing

The first step of this stage is importing the *.STL* (file format native to Stereolithography CAD software) models of the virtual insoles for both the flat foot and hollow foot. The virtual models were created using the EasyCAD software and saved as *.STL* files, in order to be imported by the control code of the prototyping machine.

The virtual model of the insole is provided with the required orthosis elements according to the supported deformity and then it is optimized, as shown in the image in figure 6.

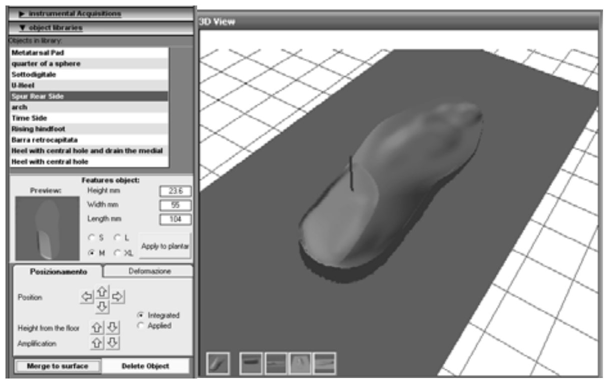


Fig.6. Introducing the orthotic elements

Then, the model is saved in *.STL* format file in order to be accessible for the rapid prototyping machine, as in figure 7.

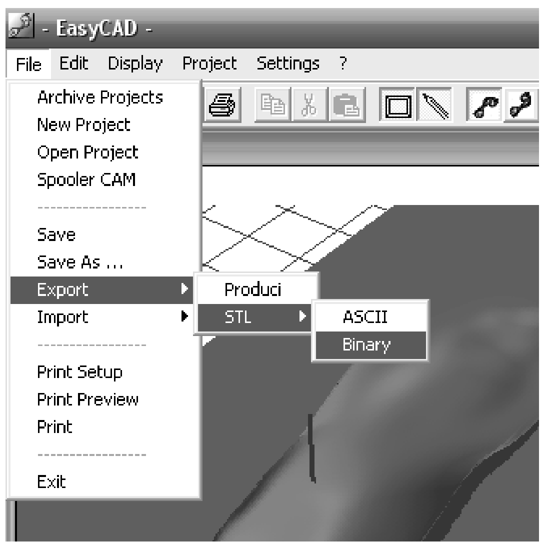


Fig.7. Creating the *.STL* file

After reading entirely the .*STL* models, the next step was to orient them in the machine working space, so that the models' construction is optimal from the point of view of working period and of material consumption. This orientation is performed by help of specialized functions (rotation, translation, mirroring etc.) of the machine program.
Following the .*STL* models orientation, these were sectioned by planes (slices) which are parallel to the machine working plane (horizontal planes), operation that delivers an assembly of level curves, also called perimeters, as shown in figure 8.

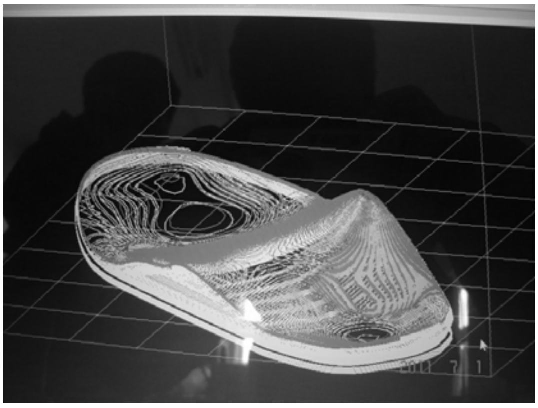


Fig.8. Discretization of the virtual model in horizontal slices

Each horizontal slice will be extruded in the form of a material layer by the prototyping machine, when creating the physical model.
The sections pitch (along the Oz axis) was given according to the type of used material and diameter of the fused material extrusion nozzle. Considering the normals that form the .*STL* models, the machine program determins on which side of the curves should the tracks be generated for the extrusion head in order to be able to materialize a section through the manufactured part.
Due to the relative small size of the orthosis (insole) and the complex geometric configuration, the layer thickness was chosen at 0,1778*mm*.
When all the tracks (also known as "roads") to be followed by the extrusion head are generated, the preprocessing operation is finalized by saving the information in a control file (type **.SML* – Stratasys Modeling Language) and by transmitting them to the control equipment of the machine in order to start the processing stage (actual construction of the protoype).

3.2 Actual construction of the prototype

During the actual construction of the prototype, the physical model of the insole was obtained layer by layer, as follows:
The heating-extrusion head of the machine deposited a thin filament of construction material along the curves that define the section perimeter (figure 9).

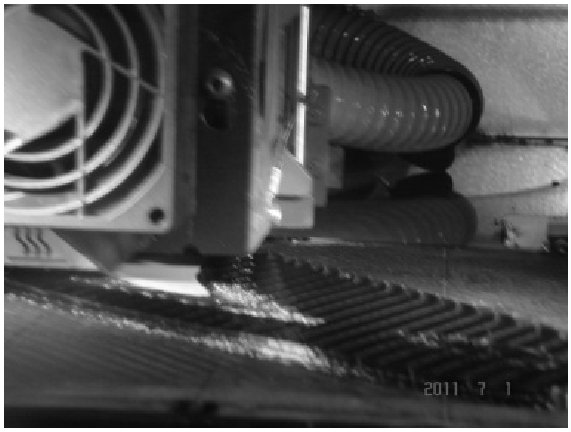


Fig.9. Deposit of a filament of construction material

After the perimeters materialization, the construction material was deposited in the areas corresponding to the full areas of the models (figure 10).

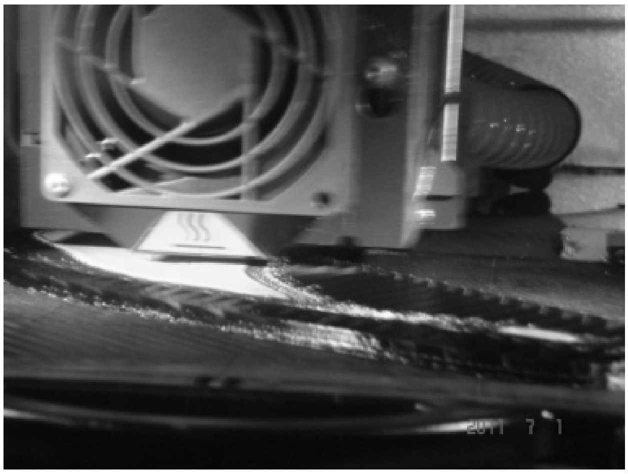


Fig.10. Depositing construction material

Through the second nozzle of the heating-extrusion head, the support material is deposited (figure 11).

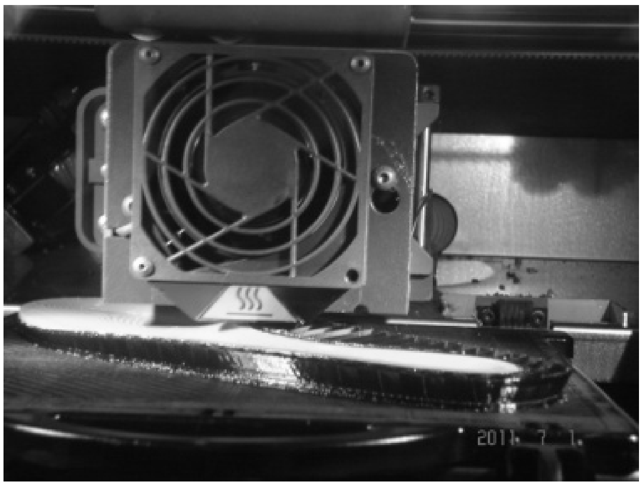


Fig.11. Depositing support material

After materializing the entire current section, the machine platform descends along a distance equal to the sectioning pitch of the virtual model (figure 12).

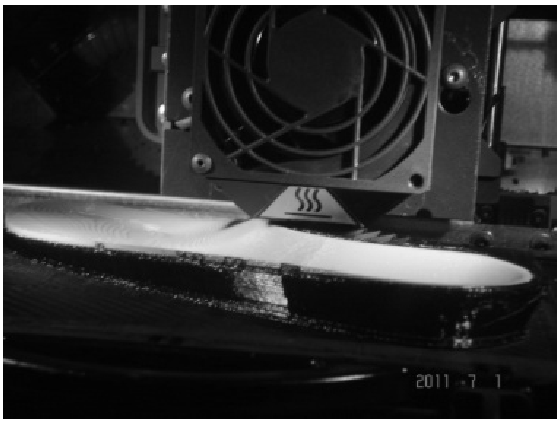


Fig.12. Platform descends for the next pitch

For the next section, the same procedures were followed, creating the physical model layer by layer (figure 13).

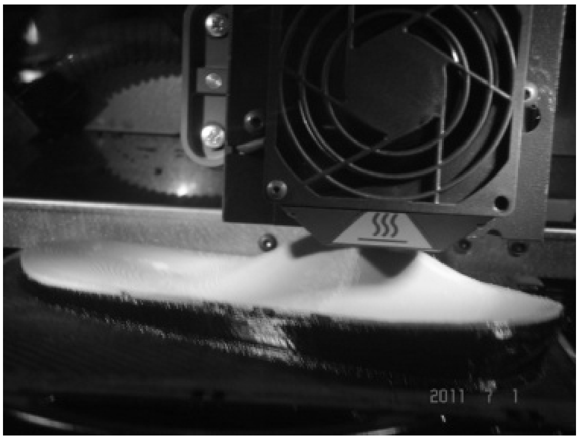


Fig.13. Intermediate stage of the physical model

The procedures were applied for both types of orthotic insoles, meaning the one for flat foot and the other for hollow foot.

The above mentioned processes took place automatically, without the intervention of an operator. The actual construction of the prototype stage was finished after the materialization of the last section of the insole virtual model (figure 14).

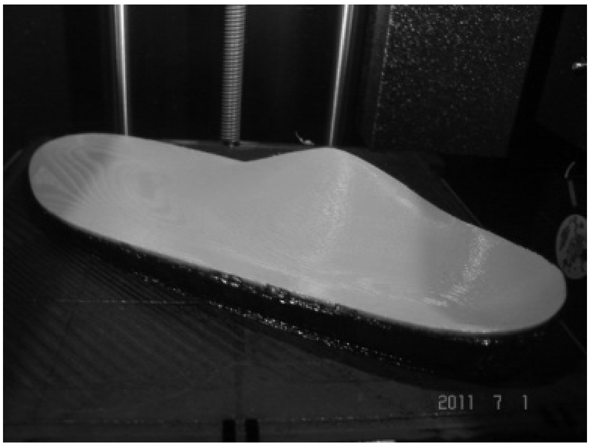


Fig.14. Physical model after final layer

(insole for flat foot and insole for hollow foot) we chose the same type of material ABS Plus, in filament shape with the diameter of 1,8 *mm*. The melting temperature of the working material and of the support material was set at 270°C on the electronic control block of the machine. As far as the optimal temperature in the machine working chamber, the setting was at 70°C. Processing time for each insole was approximately 6 hours.

3.3 Postprocessing

The postprocessing stage for the manufactured physical models consisted of several procedures, as follows:

-Separating the physical models (corrective insoles) from the construction platform;

-Removing the basis of the physical models (connection element between the actual part and the construction platform);

-Removing the support material;

The removal of the support material is done by help of a pickling bath at a temperature of 80˚C . The exposure time to the pickling solution was about 48 hours for each prototype.

Finishing physical models (by polishing, priming, painting or other finishing procedures).

Finally we obtained smooth surfaces, without burrs, having compact texture and corresponding to the designed dimensions.

The final products are shown for both types of insoles in figures 15 and 16.

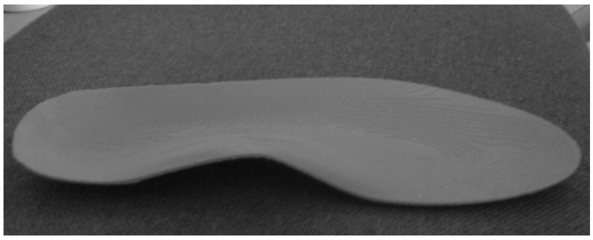


Fig.15. Final product (corrective insole for flat foot)

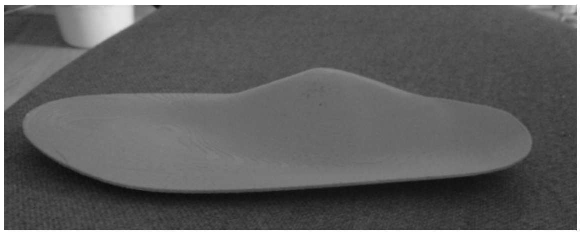


Fig.16. Final product (corrective insole for hollow foot)

Next, it is important to test the new obtained insoles with the plantar surfaces of the patients in order to establish their functionality [2]. Using the rapid prototyping technology, it is very easy to correct the possible errors, either by adding supplementary layers or by polishing in order to reduce dimensions if necessary.

The patients will be asked to position their foot so that the plantar surface takes the normal disposition and to assess the way they feel during normal walking and even running or jumping [1]. The assessment of the corrective insoles on the patients's feet is shown in figure 17a and b.

a

b

Fig.17. The assesment of the corrective insoles:
a- Compatibility assessment for flat foot;
b- Compatibility assessment for hollow foot

4. CONCLUSIONS

As a main conclusion we may say that the rapid prototyping technology is a fast, revolutionary method in the medical industrial field and can be used in manufacturing any orthotic or prosthetic element, made of various materials, like: plastic, metals etc. The products obtained by help of this technology rigorously match the required shapes and dimensions and need a short manufacturing time (starting from CAD models and reaching the physical models), meaning that we can get individualized aiding elements.

They can be made for each and every patient according to his/her own anthropometric dimensions in order to enhance the quality of life and also to allow them to function as close as possible to a healthy person.

One major disadvantage of the models obtained by rapid prototyping, regardless of the procedure we use is related to the surface roughness. This is why, in order to obtain a suitable roughness, the postprocessing stage is absolutely necessary.

Anyway, this parameter, whose importance cannot be denied can be at some extent controlled during the rapid prototyping process if we take into account the fact that it is highly influenced by the accuracy of the STL model, the orientation of the model within the working area, the diameter of the material extrusion nozzle, sectioning pitch of the virtual model, prototype dimensions, the complexity of the modeled configuration and the type of material.

The corrective elements can be obtained without exaggerate costs, even if mass production is out of the question. The model will be obtained fast by computer, using the existing dedicated software and the "adding" procedure is starting from predetermined shapes in order to speed up the process.

The procedure can be made available for every person requiring it and the results will suit each individual as it is modeled exactly according to his personal characteristics. Besides, the product can be checked out before purchase, avoiding ulterior problems and discontents.

5. ACKNOWLEDGEMENT

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