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FOOT PLANTAR PRESSURE OFFLOADING: HOW TO SELECT THE RIGHT MATERIAL FOR A CUSTOM MADE INSOLE

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Abstract

The custom-made insole is largely recognized as the most important orthotics for decreasing the foot plantar pressure, using additions or cutouts, which modify the geometry of the insole. This paper proposes a procedure for supporting the clinicians in prescribing innovative custom made insoles for offloading the plantar pressure by using specific combinations of materials for the foot peak-pressure areas, without modifying the geometry of the insole. The process starts with the acquisition of the plantar pressure map of the customer and ends with the definition of the customised insole. The aim of the procedure is choosing the best combination of materials for each foot anatomical area for reducing the plantar pressure peaks below a maximum admissible pressure value decided by the physician. The positions and dimensions of the inserts are defined through analyzing the customer plantar pressure while the inserts materials are defined using FEM simulations of the insole-foot interaction. The case study showed a plantar pressure reduction congruent with the FEM simulations results. This procedure is applicable both for subtractive and additive manufacture techniques.

Keywords: Custom made insole, Pressure offloading, Biomedical design, Design process, Simulation

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1 INTRODUCTION

Several medical studies highlighted that elevated foot plantar pressure is the cause of skin breakdown and the consequent formation of plantar ulcers. In diabetic people, such a condition is the precursor of lower extremity amputation (Ibrahim et al., 2013).

Therapeutic footwear plays an important role in plantar pressure relief and the prevention of foot ulceration for diabetes (Cheung and Zhang, 2008). The reduction of plantar pressure by offloading helps the prevention and treatment of diabetic (Kato et al., 1996) and neuropathic ulceration (Actis et al., 2008). In particular, the foot plantar pressure offloading can be achieved by using orthotic insoles.

However, it is not scientifically determined which design factors contribute most in reducing peak plantar pressure (Ibrahim et al., 2013). Due to the large variations of prescribed footwear and the uncertainty in the reliability and validity of assessment and intervention methods, consistent outcomes are yet to be achieved and thus conflicting results are common in terms of functionality of therapeutic insoles.

The most widely used techniques for the plantar pressure off-loading consists in removing material under high-pressure areas while building-up material at other locations. A different offloading technique consists in the right selection and combination of materials on different areas of the insole, selecting soft materials under high-pressure areas and stiffener material at other locations (Mandolini et al., 2013). The second approach guarantees several advantages compared to the first one. For instance, following the second strategy clinician can prescribe full-contact insoles, required for controlling the shearing forces or treating the plantar skin with healing products. However, there is not any scientific approach which suggests how to select the materials combination for the best offloading.

The paper proposes a procedure for supporting clinicians in prescribing innovative custom made insoles with the aim to offload the plantar pressure with the right combination of materials. This procedure contains also an optimization process for offloading the foot by selecting the best material for peak-pressure areas, without losing the overall support given by the insole. The procedure leverages on software systems for the plantar pressure analysis and Finite Element Analysis for the simulation of the insole-foot interaction.

2 STATE OF THE ART

The need of custom-made insoles to reduce the foot plantar pressure and the importance of a scientific approach during the insole design are highlighted in a great number of researches available in literature. Nowadays the plantar pressure offloading consists in the identification of the plantar areas with pressure peaks and the design of appropriate personalized insoles in terms of geometry and materials. Although the design and manufacturing of insoles vary among practitioners and manufacturers, the plantar pressure offloading is generally achieved through the use of pads (e.g. metatarsal bar, metatarsal dome, heel pad), cavities, cuts out or combining layers of different materials in different plantar areas.

Several studies investigated the amount of pressure reduction for different padding and insole materials commonly used in the podiatry clinic. In Tong and Ng (2010) four insole materials were investigated: Slow Recovery Poron®, Poron®, Poron® + Plastazote Firm and Poron® + Plastazote Soft. In addition, semi-compressed felt (SCF) padding with a 1st metatarsophalangeal joint (MTPJ) aperture cut-out bilaterally was investigated. Authors concluded that all four commonly used insole materials were able to reduce pressure across the whole foot, with Poron + Plastazote Firm achieving significance. Off-loading the 1st MTPJ would still be best achieved with the commonly used plantar metatarsal pad of SCF with the aperture cut-out design. Also in Rogers et al. (2006), authors found that both Poron® insoles and Poron®/Plastazote® insoles are effective at reducing pressure peaks. Others insole materials (e.g. EVA with different shore A, silicone) comparing evaluations are reported in Sun et al. (2008), Healy et al. (2011) and Tang et al. (2014).

Moreover, several 2D and 3D simulation models have been presented in literature, accurate in the representation of the human foot and insole materials, for analysing the effects of geometrical and material variations of customized insoles. The results showed that the change of insole design and the use of different materials can significantly redistribute the stress/strain on the plantar surface (Cheung and Zhang, 2005; Cheung and Zhang, 2008; Luo et al., 2011).

Nevertheless, none of the works present in literature explains how to choose the appropriate material for particular plantar areas of excessive pressure.

Several CAD-based solutions are available both in literature and on the market for the design of custom-made insoles. In Li et al. (2009), Huang et al. (2011) and Mandolini et al. (2015), the target is related to the insole modelling, considering the foot plantar pressure and insole geometry, but there is no software system that scientifically defines a method or rules for the material choice. A precise relation between plantar pressure and insole material still not exists.

Moreover, the manufacture of custom-made insoles is still relied on computer numeric control (CNC) milling machines while the CAD systems described can feed also additive manufacturing (AM) machines. For this reason, in order to offload the plantar pressure peaks with the best combination of insole materials, it is desirable to fabricate insoles with AM techniques. Among the available AM techniques, stereolithography, PolyJet, selective laser sintering and three-dimensional printing have been used for foot orthoses (Pallari et al., 2010) and sports footwear prototyping. In Manoharan et al. (2013) a five-point scoring system was used to rate the performance of AM techniques in terms of accuracy, surface finish, range of materials supported and building time. Results showed that AM techniques can effectively be employed for use in the sports footwear industry for faster product design cycle and customisation. In case of orthotic insoles, although cost and fabrication time are two key barriers to the adoption of AM, better designs will ensure a better material use and the minimization of manufacturing time.

The procedure presented in this paper overcomes several of the issues previously cited. In fact, through this method, the insert material choice can be scientifically defined because the procedure takes into account the customer plantar pressure, the materials properties and the insole-foot interaction. Moreover, this design method can be easily integrated into CAD systems for the insole design and can be used both with subtractive and AM techniques.

3 MATERIALS AND METHODS

3.1 Method introduction

The most important drivers for an improved offloading are the insole shape and materials (Ibrahim et al., 2013). This paper presents an innovative procedure for designing and manufacturing customised multi-material insoles, in order to achieve the plantar offloading, by changing the materials combinations rather than the insole geometry. Indeed, this procedure permits the development of personalised insoles for offloading the pressure peaks through inserts, available in several materials, incorporated in the main shell. It is not about multi-material stratified insoles nor about additions and cavity, which modify the shape of the insole (Figure 1.a). It is about a ‘spot’ combination of materials that allows the insole surface to remain uniform without hollows or protrusions (Figure 1.b).

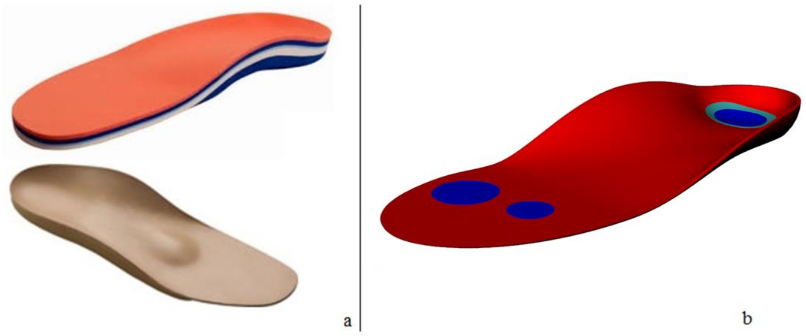

Figure 1. Comparison between traditional insoles (1.a) and innovative one (1.b)

This process starts with the acquisition of the plantar pressure map of the customer through the baropodometric analysis and ends with the definition of the customised insole, both in terms of main shell and inserts (materials and dimensions). This method is mainly oriented to podiatrists and orthopaedists who nowadays still base their choices about insole design, materials and composition on their experience and know-how, without the use of precise guidelines (Mandolini et al., 2016). In particular, the choice of materials is not accurate and personalised. Using the proposed approach, the foot doctor will have just to insert the plantar pressure map of the patient and specify the limit pressure threshold (that permits the pressure peaks offloading); the method will suggest the insert dimensions and related materials.

Moreover, this procedure has been thought both for traditional manufacture techniques (subtractive manufacturing, milling) and innovative ones (additive manufacturing, 3D printing). For this reason, in view of industrialisation, the inserts have been designed with standard shapes and dimensions. Even if it seems a limitation, such a solution meets the constraints fixed by subtractive manufacturing processes, which ask for a finite number of inserts.

The method, made by eight steps, is based on a database of simulations for the characterization of the insole-foot interaction. Hereunder the description of the insole materials characterization and the workflow of the method for the design of multi-material insoles.

3.2 Foot - insole contact characterization

The study of the interaction between foot and insole is necessary for selecting the right material. For this aim, the first step is the characterization of materials with compression tests to determine the stress-strain curves. The most common materials used for custom made insoles are elastomeric foams, in particular Poron® (Rogers Corporation, Connecticut, U.S.A) and Nora® (Freudenberg, Germany), in different densities. Poron® is an open-cell polyurethane foam, while Nora® is a close-cell Ethylene Vinyl Acetate (EVA) foam. The performance of each material has been evaluated using Dynamic Mechanical Analysis (DMA) in order to know the individual properties of each material for insole. From the tests carried out with compression clamp, a strain-stress curve of the materials has been obtained. The second step consists in simulating the foot-insole interaction, by using the Finite Element Method. The foot has been modelled using materials characterization available in literature for bony structures, cartilage, ligaments and soft tissue (Cheung and Zhang, 2006). The insoles materials (hyperelastic and incompressible) have been modelled using the Mooney-Rivlin 3p model (*Ansys v.15, by Ansys Inc.*). The boundary condition between the foot and the insole is a frictionless contact. The result got by the simulations is a pressure map, which plots the normal stress between foot and insole. As shown in Figure 2.a, the obtained pressure peaks correspond to the anatomical foot areas (metatarsals and heel) where the pressure loading is usually higher than other areas.

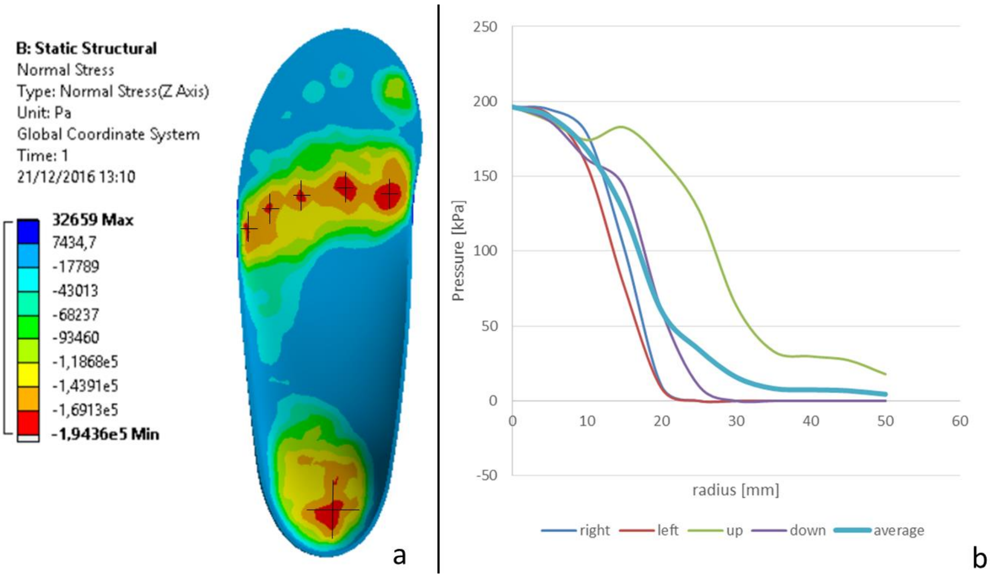

Figure 2. a) Simulated pressure map for a mono-material insole; b) Pressure curves around the peak pressure point

With the aim to get an average pressure behaviour around the peak pressure point, the third step consists in plotting the pressure values along four directions, aligned with the foot axis and its perpendicular (right, left, up, down, Figure 2.a). The results consists of an average pressure curve (average, Figure 2.b) for each anatomical foot area.

The aforementioned simulation and calculation process refer to a "standard", non pathological foot (one size) and the relative insole (flat and mono-material). However, for a more complete scenario, authors considered the combination of 3 foot sizes with 5 insoles materials (2 kind of Poron® and 3 kind of EVA Nora®). In addition to the previous set of simulations, authors simulated also the contact between the foot (3 sizes) and a rigid plane, with the aim of reproducing the actual contact between a healthy foot and baropodometric platform.

The last step consists in storing the results previously calculated into a database. It contains the average pressure curve for each anatomical foot area, for each foot size, for each insole material and for the rigid plane. The database will be used later on by the method for selecting the best offloading material.

3.3 How to design multi-material insoles

The procedure for designing multi-material insoles strictly depends by the data available about customer and materials, the technology chosen for the production and the biomedical requirements. The section hereunder analyses these aspects while presenting a workflow for the design of the insole inserts. Moreover, the method proposed in this paper is valid only for feet without deformities.

3.3.1 Definition of the input data

The workflow inputs are:

- Patient's static pressure map;
- Main shell design (defined following the insole prescription guidelines in Marinelli et al. (2015));
- Database of FEM simulations.

The first result is achieved by using a baropodometric platform, which provides also specific information about the anatomy of the patient's foot.

The FEM analysis are required because they represent the interface between the foot and the insole. Since such simulations need specific skills and long time, the FEM simulations, previously calculated, are stored within a specific database, as described in Chapter 3.2.

3.3.2 Offloading optimization for the fulfilment of technological and biomedical constraints

The aim of the procedure is to choose the hardest insert material that is still able to reduce plantar pressure peaks below a maximum admissible pressure value (MAPV) decided by the physician. The hardest material is for supporting the foot, since a too soft material would result in an uncomfortable insole.

The procedure has to fulfil several constraints, which mainly depend by the insole manufacturing technology and the biomedical requirements.

The subtractive manufacturing process is the most common technology used in industries for the production of foot orthosis. Standard insoles are produced from EVA or polyurethane blocks, using 3-axis CNC carving machines. In order to realize a custom insole as the one shown in Figure 1.b, using this technology, it is necessary firstly to carve out the insert from a mono-material block. Secondly, there is the necessity to carve the insert slot in another mono-material block, which will be the main shell for the custom-made insole. After that, the insert is glued with the carved block. At last, the multi-material block is milled for obtaining the insole surface. This technology implies difficulties in working inserts with particular shapes and small dimensions, because they require long machining times and are difficult to handle. Since this process can be time consuming, the following constraints are defined in order to speed it up:

- Round shaped insert, for simplifying their cutting (use of a finite number of round punches) and gluing;
- Predetermined inserts dimensions: "small", "medium", "big", respectively 10mm, 15mm and 20mm radius. In this way, it is possible to create a warehouse of inserts;
- Maximum of two materials per insert (only for "medium" and "big" sizes). In particular, a bi-material insert is made of two glued parts, the inner one with a circular shape, and the outer one with an annulus shape. If the insert is "small", then it is mono-material. In this way, there are not inserts that are too small for machining;
- For bi-material inserts, the inner part radius (IPR) must assume only predetermined values. These values are 25%, 50% and 75% of the entire insert radius;

Beside technological constraints, there are also biomedical constraints. In particular:

- Final peak pressure inferior to a maximum admissible pressure value (MAPV), defined by the physician (generally between 180-200kPa).

The variables of the procedure are the inserts materials, which have to be chosen within the materials available in the database, previously tested, as described in chapter 3.2.

3.3.3 Procedure description

The procedure was designed taking into account inputs, constraints, variables and aim previously described. The result is shown in Figure 3.

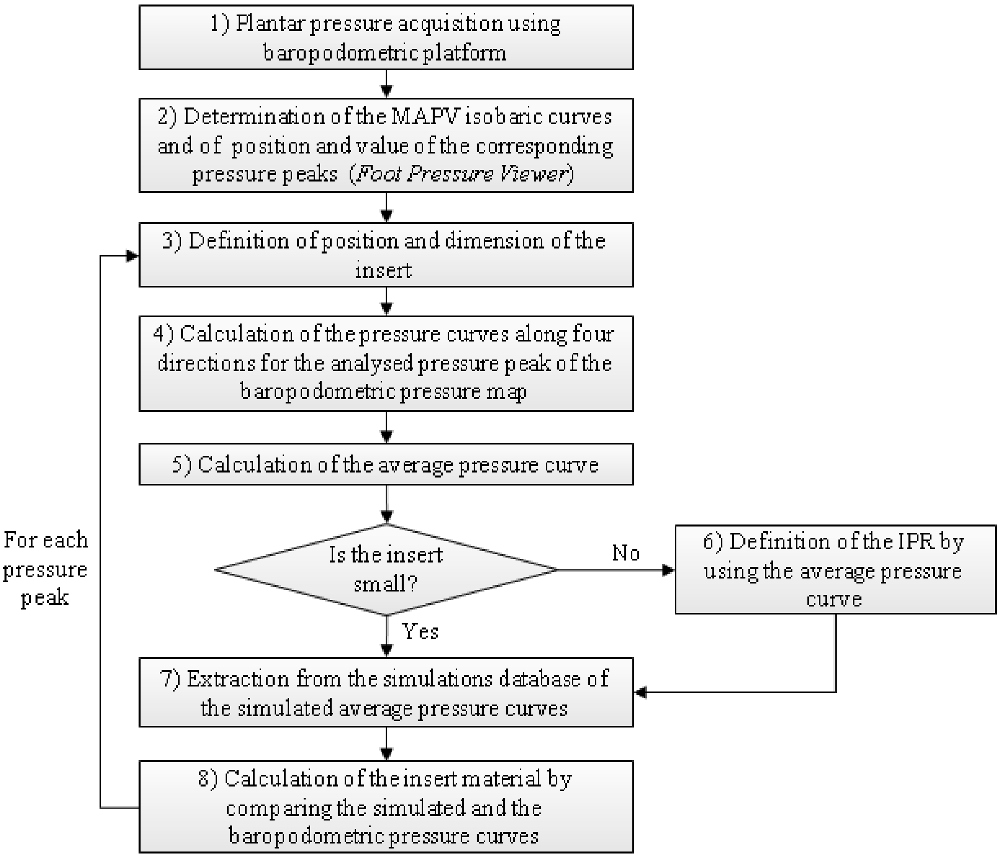

Figure 3. The method workflow

The first step entails the static acquisition of the foot pressure map, using a baropodometric platform. The second step consists in sketching, over the pressure map, the isobar curves at the admissible pressure value, for each pressure peak. The *Foot Pressure Viewer* software tool (Germani et al. 2011) was used for this aim (Figure 4).

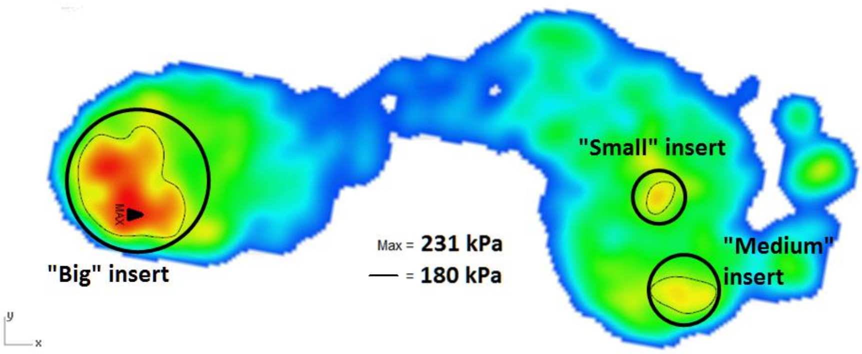

Figure 4. Choice of inserts position and dimensions (step 3)

The isobar curves allow, in the third step, the definition of the position and the overall dimensions ("small", "medium", "big") of the inserts, which must be big enough to cover the whole curve, previously computed. During the fourth step, the method calculates the pressure curves along four directions for the analysed pressure peak of the baropodometric pressure map, following the same procedure defined in Chapter 3.2 for the simulated maps; then in the fifth step the method calculates the average pressure curve.

The sixth step of the process depends by the size of the insert. For the "medium" and "big" cases, indeed, the insert is made by two different materials, according to the technological constraints (§ 3.3.2). In these cases, the method has to determine the inner part radius (IPR) and the materials for both the areas. The IPR is calculated using the average pressure curve for the current peak pressure point. The method determines the minimum pressure in the insert area (which is at the insert outline) and the distance from the anatomical foot area where the pressure is 25% lower than the peak pressure (Figure 5). Hence, IPR is determined so that it is greater than the distance just calculated (50% for the example in Figure 5). The constant value of 25% has been defined empirically since it is a good compromise to distribute the pressure between the two insert areas. For small inserts size, IPR is not applicable.

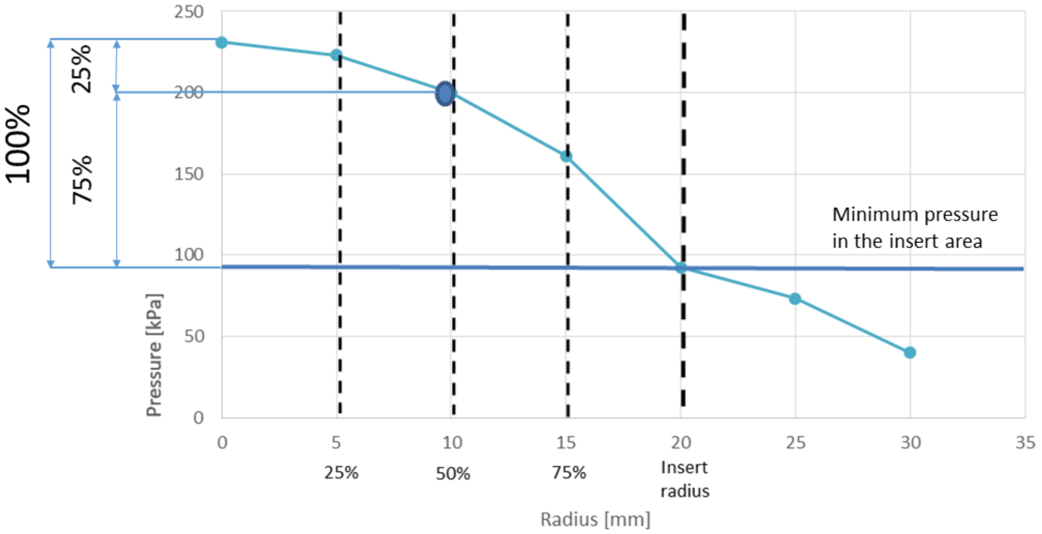

Figure 5. IPR determination, for "medium" and "big" inserts

For each anatomical foot area, during the seventh step, the method extracts from the simulations database the simulated average pressure curves (one for each insole material) relative to the "standard" foot.

Finally, the eighth step calculates the materials of the insert through an analysis of the following curves (Figure 6):

- Rigid surface: simulated pressure curve, at the specific anatomical foot area, for the foot on a planar surface;
- Baropodometric pressure curve: pressure curve of the customer, at the specific anatomical foot area, on the rigid surface of the baropodometric platform;
- Estimated pressure map: simulated plantar pressure curve, at the specific anatomical foot area, in case of customized insole insert.

Although the boundary conditions (pressure levels, shape of pressure distribution) between baropodometric and simulated pressure curves are different, the deviation is acceptable because it is within a certain threshold, since only patients with non-deformed feet are considered. Moreover, given the variability between the pressure trends of the customers and the pressure trends of the simulations in terms of pressure peak and radius, the curves obtained from simulations are scaled along the two axis; the scaling coefficients are found by trying to overlap the curve from the foot-rigid surface simulation and the one from the baropodometric map.

For the inner part of the insert, the method selects the hardest material with the curve below the maximum admissible pressure value (MAPV). Similarly, the method calculates the material for the outer part of the insert (it is admissible having the same material for both insert areas). In the example shown in Figure 6, the method selected Poron L32 for the inner part and Nora SL for the outer one. In this way, the foot plantar pressure is always lower than MAPV.

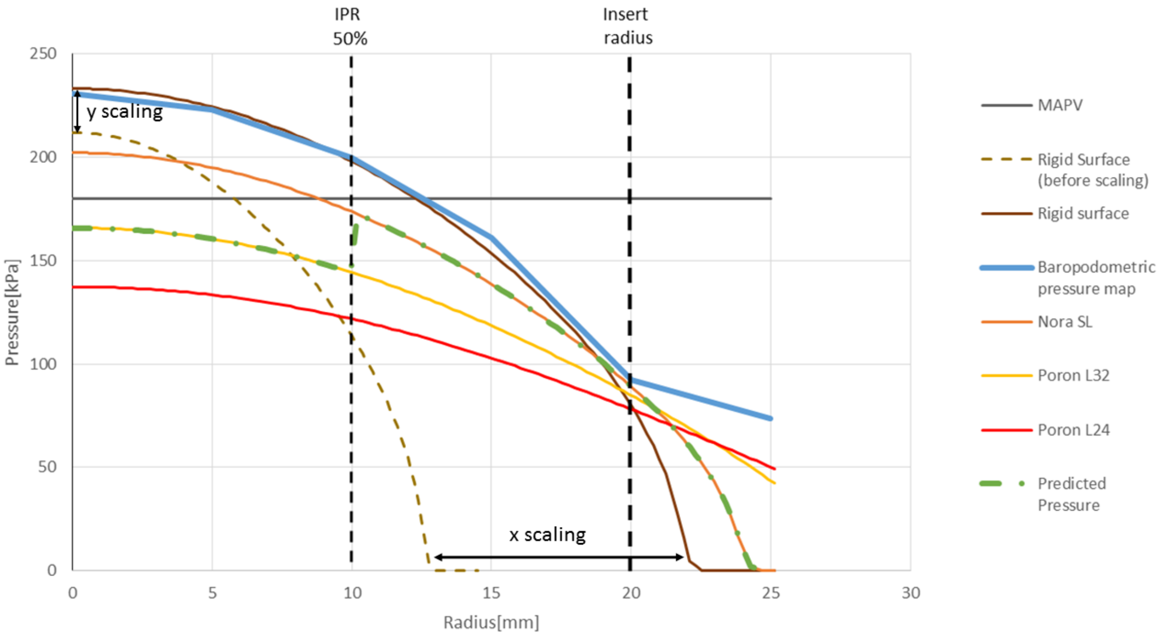

Figure 6. Materials selection for "medium" and "big" inserts

For "small" inserts the material choice is simpler since they are mono-material. From this last step, an iterative loop analyses all the anatomical foot areas where the pressure is higher than the MAPV and calculates the dimensions and materials of the inserts for each pressure peak.

3.4 Additive manufacturing contextualization

The procedure presented in this article can be simply adapted for AM. The use of this technology has several advantages respect to traditional manufacturing, since it allows to realize complex geometries without material losses. Furthermore, by changing the percentage of infill pattern, it permits to obtain areas of the insole with different stiffness using the same material and thus not requiring time consuming operations such as cutting and gluing the inserts.

For these reasons, some of the technological constraints considered in the article can be removed, such as the cylindrical shape of the inserts, the predetermined inserts dimensions ("small", "medium", "big") and the predetermined values of the IPR. Using AM, in fact, there is no need to build a warehouse of inserts; thus, isobar curves calculated on the baropodometric pressure map can be used in order to determine the shape of offloading areas. The range of FEM simulations, however, must be extended with suitable materials for AM insole production. In particular, in the new simulations the percentage of infill must be considered as a new variable, in order to obtain softer or harder areas.

4 CASE STUDY AND RESULTS DISCUSSION

The procedure proposed in this paper has been tested in order to evaluate its accuracy from scientific, technical and biomedical points of view.

The case study refers to a 27 years old, healthy woman and an insole with the main shell made of Nora AL. Firstly, using a baropodometric platform, the static pressure map (Figure 7.a) has been acquired in order to evaluate position and value of pressure peaks and to determine the MAPV isobar curves. The dimensions and the position of two inserts have been defined: the first one, of small size, had to be positioned under the fourth metatarsus while the second one, of medium size, had to be placed under the heel. For the 'medium' insert, the IPR has been calculated as the 50% of the insert radius. Following the method described in Section 3.3.3, the inserts materials have been calculated:

- 18 Shore A Polyurethane for the 'small' insert;

- 30 Shore A EVA for the annulus part of the 'medium' insert;
- 25 Shore A EVA for the circular part of the 'medium' insert.

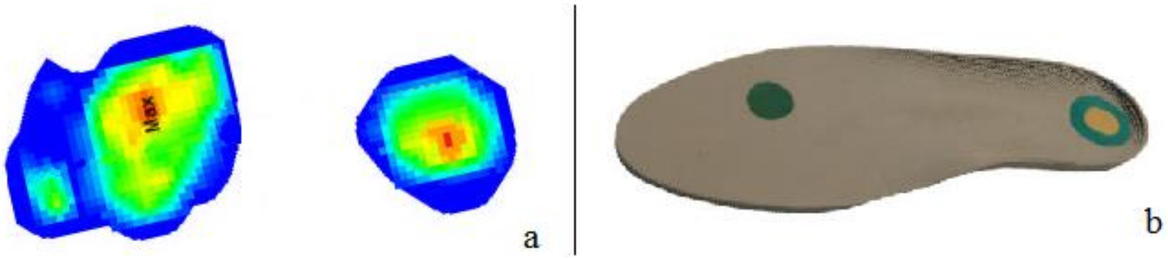

Figure 7. a) Trial static pressure map; b) Trial custom made insole with the right combination of inserts materials

It is evident that the hardness of the materials is consistent with the pressure to offload: indeed the softest and most accommodating material is under the maximum pressure peak.

With the custom made insole, realized by an Italian orthopaedic footwear factory and showed in Figure 7.b, a pressure analysis has been fulfilled using in-shoe pressure sensors, in order to evaluate the results of the offloading through the materials combination.

Comparing the pressure values measured with the baropodometric platform (barefoot) and those ones with in-shoe pressure sensors (wearing the custom made insole), the results showed a 30% reduction of the pressure peak under the fourth metatarsus. It was around 20% under the heel. These outcomes are congruent with the results achieved with FEM simulations, suggesting the accuracy and effectiveness of the procedure for the choice of the inserts materials combination.

5 CONCLUSION

The paper presented a method for the plantar pressure offloading by selecting the right material for foot anatomical areas. A fundamental feature of the presented procedure relies on its objectivity. Hence, the custom-made insole will depend less and less on the subjectivity of the clinician, while the design can be easily automated. Although the procedure is based on data related to FEM simulations, it is not necessary that the final user had such a software or competencies. Indeed, the simulations are not performed in real time, rather their results are stored into a specific archive. This storage of simulations can be enriched over time, improving the output quality of the process. The archive can be increased adding simulations of further materials and foot anatomies for considering additional pathologies (e.g. amputations, malformations, ulcers and flat or cavus feet).

The presented method for the inserts materials choice allows the development of custom made insoles more responsive to patient needs, both in terms of pressure offloading and footwear comfort. Therefore, the simplicity of the procedure and the greater automation of the insole prescription phase permits the reduction of the non-compliant custom made insoles.

Moreover, the present workflow is compatible with the additive manufacturing technology for custom-made insoles, simply by replacing the insert material choice with the percentage of infill pattern choice. In future works, the present workflow will be improved for additive manufacturing by removing the technological constraints for the subtractive processes and by characterizing the stress-strain curves for printable materials with different percentage of infill.

An additional future work will consist also in automating the proposed method by using a specific software tool. This is the way for providing a tangible support for clinicians during the custom-made insoles prescription process.

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