



A Finite Element Method to support the materials selection phase during the insole design process

M. Mandolini^(a), M., Germani^(a), R. Raffaeli^(b)

^(a) Università Politecnica delle Marche, Department of Industrial Engineering and Mathematical Sciences

^(b) eCampus University, Engineering Faculty

Article Information

Keywords:

Custom Made Insole
Insole Design
Footwear
Insole Material Selection
Finite Element Analysis

Corresponding author:

Marco Mandolini
Tel.: 0039 071. 220.4797
Fax.: 0039 071.220.4801
e-mail: m.mandolini@univpm.it
Address: Università Politecnica delle Marche, Department of Industrial Engineering and Mathematical Sciences, via Brecce Bianche 12, Ancona, 60131, Italy

Abstract

Purpose:

The paper aims to define a method to support the materials selection phase during the insole design process. The proposed scientific approach is pursued adopting a finite element method to simulate the mechanical behaviour for combinations of materials to create customized insoles. The paper presents also two processes, one to design the custom made insole and the other to select the insole materials combinations with the aim to uniform the foot plantar pressure.

Method:

The insole design and the materials selection processes are based on the use of software tools to manage the materials properties, in order to make them as scientific as possible. A Finite Element Method is used to calculate the stress-strain relationships of a custom combination of multiple layers of materials. The contextualization of this method into the insole design process allows the proposed idea to be successfully implemented.

Result:

The error committed by the Materials Combinations Simulator has been verified with a large set of materials (EVA, PU and rubber). Experimental tests have been performed to evaluate the deviation with the results of the simulation model, highlighting an error less than 10%.

Discussion & Conclusion:

This work is a step toward a more scientific design process for custom made insoles. The possibility to simulate the mechanical behaviour of a combination of multiple materials lead to the elimination of the physical tests. The integration of the proposed Materials Combinations Simulator system with an Insole Design software tool will represent a further innovation respect the state of the art

1 Introduction

High values of foot plantar pressure are considered critical for those patients suffering of diseases such as diabetes, plantar fasciitis or rheumatoid arthritis. According to the survey conducted by the "International Working Group on the Diabetic Foot", for example, in 2011, 366 million people worldwide are estimated to have diabetes, representing roughly 8.3% of the global adult population (20-79 years of age). This number is expected to reach approximately 552 million by 2030, representing 9.9% of the global adult population. Up to 85% of amputations are avoidable if foot ulceration is prevented through the use of suitable insoles with a preventive function.

Several studies reported dramatic reductions in heel pressure (measured inside the shoes) of patients wearing insoles that were more conforming to heel-pad geometry [1]. For this reason, the role played by the custom-made insoles is increasingly recognized as important to prevent or treat specific foot pathologies. Their use goes beyond the traditional medical sector, since they are also used within sport and safety shoes. Many studies have found a growing demand for plantar orthotics (The 2009-2014 World Outlook for Orthotic Insoles, The 2011-2016 World Outlook for Orthotic Insoles, The 2009 Report on: World Market Segmentation by City).

This context led many researchers to present new methodologies and software tools to support the insole design phase, anyway, most of the custom-made insoles are nowadays manufactured using manual techniques according to the tacit knowledge of experienced technicians. The first reason since these tools are poorly used, is due by the low ease of use and by their poor capability to replicate the tasks manually done by the technicians.

The insole design phase consists in the definition of its geometry and set of materials. While lots of methodologies and software tools are existing to support the first design outcome, for the material selection phase there are few contributions. In this context, the paper aims to define a method to support the materials selection phase during the insole design process. The proposed scientific approach is pursued adopting a Finite Element Method to simulate the mechanical behaviour for combinations of materials to create customized insoles.

2 State of the art

Many factors contribute to the effect of footwear on foot complications such as ulceration for diabetics (e.g., plantar foot pressure, foot movement in the shoe, lacing of the shoe, moisture permeability, insole geometry, stiffness and shock absorption properties, sole depth, pitch, stiffness and how these alter over the length of the

shoe). Some studies [2] and [3] show that higher pressures are related to the risk of ulceration.

The necessity of customized footwear insoles to reduce the foot plantar pressure has been recognized almost 20 years ago, as demonstrated by Lavery et al. [4]. Their results show that in-shoe foot pressures are significantly lower when insoles are used, compared to measurements without insoles, in particular under the first metatarsal, the lesser metatarsals and the heel. The latest research have had the aim to study the biomechanical relationships between the insole and the foot, from a clinical point of view. This study suggested that quantifying the reduction of soft tissue strain is an essential design requirement for orthotic insoles since plantar pressure may not be a sufficient indicator of the effectiveness of an insole in preventing ulcer initiation [5].

Lots of research available in literature highlight the importance of a scientific approach during the insole design [6], which has to include the identification of areas of excessive plantar pressure and the utilization of appropriate insole materials.

The reduction of the excessive plantar pressure pass through the identification of the relationship between the pressure and the insole comfort [7]. The effect of orthopaedic insole for a plantar pressure reduction has been deeply investigated in [8] and [9]. In particular, Cavanagh [10] demonstrated that uncomplicated plantar ulcers should heal in 6 to 8 weeks with an adequate off-loading.

The most widely used solution to implement the off-loading techniques consists in the removal of material under high-pressure areas and the build-up of material at other locations. In this way, the custom-made insoles significantly reduce the peak pressures in the heel and in first metatarsal head regions while pressures significantly increases in the medial midfoot region compared with flat insoles. The implementation of the experimental conclusions is carried out through specific "load transfer algorithms", used to calculate the insole geometry in order to transfer the load between the heel and midfoot regions, for the significant correlation between load loss and gain in these regions (-0.8) [11]. The most important offload solution, from a geometric point of view, is represented by the metatarsal dome, whose positive effects have been evaluated in [12].

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 stiffer material at other locations. The aim of the study related to this technique consists in the investigation of the amount of pressure reduction for different padding and insole materials commonly used in the podiatry clinic. In [13] four insole materials have been investigated: SRP (Slow Recovery Poron[®]), P (Poron[®]), PPF (Poron[®] +Plastazote) and PPS (Poron[®] +Plastazote soft). The authors concluded that all the four commonly used insole materials were able to reduce pressure across the whole foot with PPF achieving significance. Off-loading the 1st metatarsophalangeal joint would still be best achieved with the commonly used plantar metatarsal pad of semi-compressed felt with the aperture cut-out design. Begg and Burns [14] have also investigated the effect of various medical grade insole materials on plantar pressure and comfort in a neuroischaemic diabetic patient at risk of foot ulceration. The authors concluded that the multidensity insole was the most effective at reducing peak pressure and pressure-time integrals compared to the shoe only condition.

In order to define a scientific customized insoles design process, their effect in reducing the plantar pressure have been also investigated using Finite Element Analysis approaches. The first studies date back nineties, when the design of these orthoses have largely been a trial and error process. Lemmon et al. [15] investigated the pressure alterations under the second metatarsal head as a function of insole thickness and tissue thickness. The techniques presented represent a promising approach to understanding plantar cushioning and the principles involved in the design of therapeutic footwear for insensate feet. Several 2D and 3D simulation models have been presented in literature, even more accurate in the representation of the human foot and insole materials. In [16] a two-dimensional plane strain finite element modelling has been used to investigate several insole designs. Combinations of three insole conformity levels, three insole thickness values and three insole materials were simulated, obtaining a low uncertainty. A 2D simulation model is also presented in [17], where the heel has been modelled through an axisymmetric element. The aim of their study was to estimate the stress, strain and strain energy density fields produced in the pedal tissues.

Using 3D simulation models, instead, it is possible to estimate the plantar pressure distribution on the foot, once it is in contact with a custom made insole. In [18] a computational model of the foot and footwear has been proposed in order to provide an efficient evaluation of the different combinations of structural and material design factors on plantar pressure distribution. In this study, a combined finite element and Taguchi method was used to identify the sensitivity of five design factors (arch type, insole and midsole thickness, insole and midsole stiffness) of foot orthoses on peak plantar pressure relief. The effect of material stiffness of flat and custom-molded insoles on plantar pressures and stress distribution in the bony and ligamentous structures during balanced standing have been also investigated by Jason et al. [19]. The aim was to establish also the influence of the custom-molded shape and the materials choices in reducing peak plantar pressure. A similar Finite Element Model has been also presented in [20].

The review on how the insoles are able to prevent ulceration in the diabetic neuropathic foot appear to be of some value and should be considered within the prevention strategy for the diabetic neuropathic foot [21]. However, the authors concluded also that no recommendations cannot be made at this time regarding the type and specification of insole best suited for purpose. This conclusion means that further researches are needed to formalize and make scientific the insole design process.

A critical analysis of the state of the art proposed above allows the authors to outline the following limitations and justify the paper objectives. The simulation models presented to predict the plantar pressure distribution using orthopaedic insoles are difficult to integrate within the design process of customized insoles for the following reasons:

- a FEM system can be used only by technicians with very specific skills;
- the time required to customize the simulation model on each patient feet is not compliant with the design process time.

A more profitable use of the FEM systems within the insole design process consists in the simulation of the mechanical properties of a combination of two or more layers of materials. Since a customized insole is generally

made at least of three layers of different materials, a simulation model to estimate the resulting mechanical properties is recognized as useful by the designers. The properties resulting from the simulation phase, and stored into a specific database, can be retrieved by the designers in order to set-up the best customized insole. In conclusion, none of the papers in literature contextualize the use of a FEM system during the insole design process.

3 Method

The design process of a custom-made insole consists in the geometry modelling and the materials selection. When the aim of the customised insole is to distribute the foot plantar pressure (i.e. in case of a diabetic foot), the effects given by a good combined choice of geometry and materials is essential. In particular, this is important in case of multi-layered insoles, obtained with vacuum techniques, where materials with very different properties (biomedical, mechanical and physical) are combined to meet several foot requirements. While in literature lots of papers are focused on mathematical algorithms and rules to model the insole surfaces in order to distribute the plantar foot pressure, few works are related to the selection of the best combination of materials. For this reason, the following chapters are focused on the materials selection topic.

3.1 The insole design process

The design process of a customised insole starts from the analysis of medical and clinical factors. A specific design workflow has been formalised to obtain a customised insole using patient biomechanical parameters as inputs (Fig. 1). The first activity consists in the measurement of the biomechanical parameters of the patient's feet using a 3D foot scanner, a baropodometric platform and a gait analysis system. Doctors and clinicians assess the foot geometry, the foot plantar pressure and foot movements during the gait. After the feet diagnosis phase, the shoe last is modelled starting from the feet 3D geometry and a reference last, retrieved from a repository of the footwear company. A typical example of this process is described in detail in [21] and it is focused on diabetic patients.

In parallel with the shoe last design activity, another preliminary step is required before design the insole: it consists in the analysis of the plantar pressure distribution and in particular on the calculation of the isobar curves of the foot pressure maps during a complete gait. An example of how this step is carried out is presented in [23]. Also in this case, the presented method and tool have been tested on diabetic patients. The isobar curves coming out during this step are fundamental during the insole design phase since this information guides the designer during the insole modelling and materials selection. This approach is essential for a scientific insole design process. Firstly, these curves, bounding a foot region where the pressure plantar is included in a range, are used by designers as the outline of the foot area to offload. Secondly, the offload procedure can be realized removing material or selecting a softer material in the most loaded areas. By selecting a less rigid material for the area to offload, the plantar load will move toward the neighbouring regions, with the aim to level the plantar pressure, avoiding any peak.

The custom made insoles are generally made combining multiple layers of different materials (polymeric materials, usually cellular or foamed materials): semi-rigid supporting and soft accommodative. The materials can be classified according to their polymeric nature: polyurethane, ethylene vinyl acetate, polyethylene, polyvinylchloride, vulcanized rubber, etc. These materials can be also classified into three types depending on their function in the insole: *adaptation*, *cushioning*, and *filling* materials [24]. The *adaptation* material is in direct contact with the foot, and it must be able to conform to the sole to homogenize the plantar pressures, thus avoiding high pressure points that may cause ulcerations in the feet of patients with diabetes. The *cushioning* material is under the adaptation material and it is aimed at absorbing the impact energy during gait. In addition, it should also be able to absorb humidity produced inside the shoe and be resistant to perspiration. The *filling* material is under the cushioning material so that the insole perfectly fits the shoe shape. This material has to be hard and stiff enough to provide stability to the insole.

In order to select and combine the materials able to respect the requirements given by the foot pathology, a materials database and a list of rules are required at this stage. The materials repository, which will be deeply explained in the following chapters, mainly consists of two set of data: mechanical, physical and chemical properties of each material and mechanical properties (stress-strain curve) relative to a combination of many materials. The first set of data is defined through the datasheets of the commercial materials and laboratory tests to evaluate those unknown properties. The second data set, instead, is build using a materials simulator, which elaborates the mechanical properties of each material layer.

The materials database population has to be considered as an activity parallel to the insole design process, carried out by a material engineer or by someone else with a background on footwear materials. The Materials Combinations Simulator is thought to substitute the experimental tests on specimens made of two or more materials layers. This is possible since the main mechanical and physical properties of each material have been obtained with experimental tests. Using a simulator tool, a very wide range of materials combinations can be characterized, without setting up any testing machine. The comparison between the simulation tool and the experimental tests lead to a time and costs saving since:

- no testing machines have to be equipped;
- no specimens have to be built;
- no long measurements have to be carried out;
- no expert technicians are required to perform the physical measurements;
- no laboratory tests are required.

These advantages increase as the number of materials rises, and they allow the footwear companies (or orthopaedic shops) to have a very large set of materials combinations and a very wide set of materials possibilities for the custom made insoles. This scenario increases the possibility that the insole fits the foot biomedical requirements. The materials data stored into the repository are proposed to the designers through a specific tool used to query the database. The selection of the best materials combination is supported by an algorithm proposed in the following chapter.

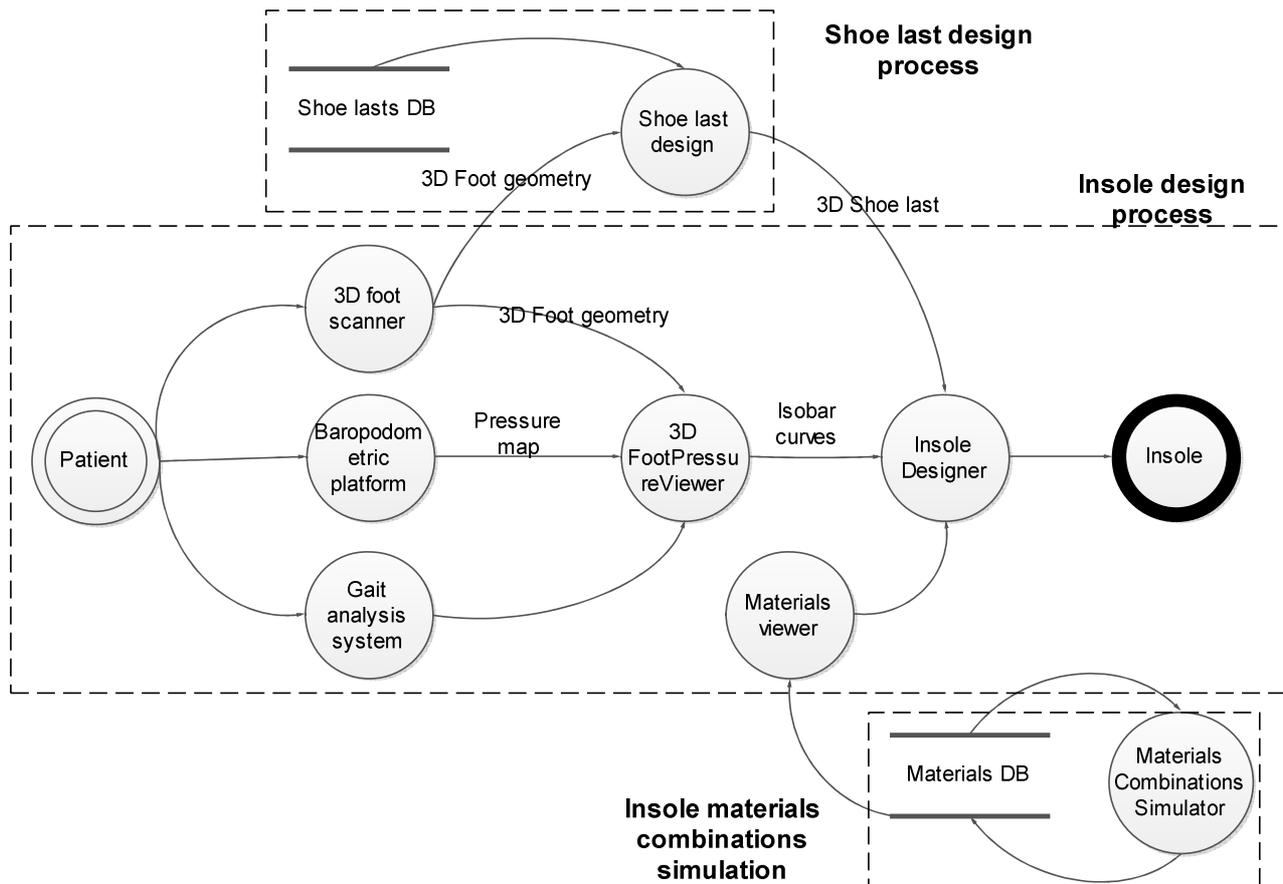


Fig. 1 Insole design process

Once the insole materials and the shoe last have been respectively selected and designed, the designer proceed with the insole modelling, supported by software tools such as *Canfit™ Insole Design* (by Vorum) [25]. Finally, the insole is manufactured following one of the possible techniques:

- milling a multilayered polymeric sheet where the materials combination is provided by the Materials Combinations Simulator and the geometry by the insole designer tool;
- cutting different mono-material polymeric sheets (one material for each layer to make the insole) where the outlines are the plantar pressure isobar curves. Then, overlapping, gluing and shaping the material pieces through vacuum machines.

3.2 How to choose the insole materials

The material selection is a fundamental phase of the insole design process. In order to standardize this critical step, the definition of a workflow is very important. Only with a scientific approach it is possible to design custom made insoles able to prevent or heal a particular foot pathology with the maximum effects.

The process shown in Fig. 2 starts with the calculation of the isobar curves of the plantar pressure map as presented in [21]. The curves identify the areas where the plantar pressure is uniform and the regions with the same combination of materials layers. The number of levels and curves control points depend by the accuracy the insole designer wants to achieve. High values for these parameters lead to an insole with lots of regions with specific materials combinations, aiding to obtain a best

fitting insole. Since the curves are a result of an automatic procedure of a specific software tool, the insole designer has the possibility to adjust them. Once these preliminary activities have been completed, the materials selection process starts. This process is supported by the materials database, explained in chapter 4.

First of all, the designer sets the information (material and thickness) for the adaptation and filling layers. The selection is carried out examining specific material properties as the compression set, compression fatigue and perspiration for the adaption layer. The next step consists in the set of the maximum number of materials layers for the cushioning region.

The process continues following one of two ways according to the kind of insoles to design: insole with a uniform or variable thickness. In the first case, the designer sets the thickness for the insole cushioning volume (T_c) and the tolerance on the materials stiffness used during the selection of the materials combination. The combination is chosen scanning all the solutions contained into the database. While the layer thickness must to be equal to the value previously defined (T_c), the stiffness has to be included within a tolerance. The stiffness strictly depends by the plantar pressure. During this scanning, three scenarios are possible: one, none or more materials combinations respect the selection criteria. In the first case, the combination is chosen, and the selection process pass to the next step. If more materials combinations respect the criteria, these ones are considered during a further selection.

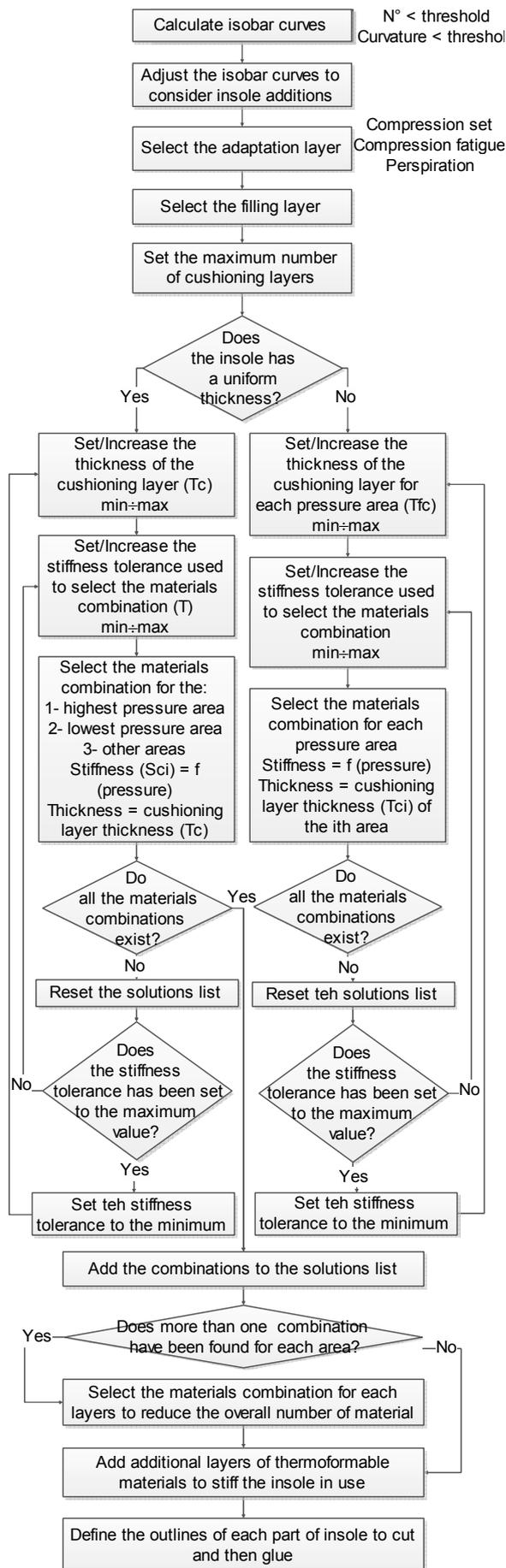


Fig. 2 Process to select the insole materials combinations

If no combinations are found, a new selection process has to be started again. The list of the solutions defined up to now has to be initialized, then, the stiffness tolerance is increased and a new selection process is started again trying to find a combination for those areas still without a solution. If the tolerance exceeds the maximum value, this is set to the minimum, the thickness of the filling layer is increased and, finally, the selection process is started again as described above.

In the case of an insole with a non-uniform thickness, the materials combinations selection phase proceeds as follows. First of all the thickness of the cushioning region is set for each area (the thickness depends by the off-load procedure). Then, the selection is performed as described above; the only difference is given by the fact that the materials combination of each area must to have its specific thickness.

Once the selection process is completed, if more combinations have been found for each area, a refinement is required to set a materials combination for each layer. This selection is done with the aim to minimize the number of materials used to make the insole.

Optionally, the designer can also define a further layer, required to stiff the insole after the thermoforming process. Finally, the outlines curves and the information related to the materials combination for each layer are used as input data of the insole manufacturing process, and, in particular, of the cutting activity (Fig. 3).

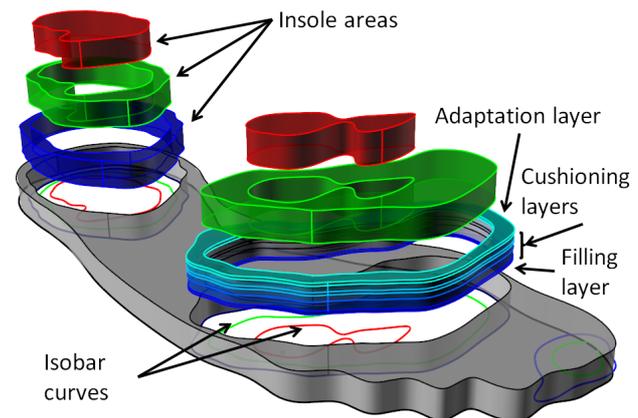


Fig. 3 Example of custom made insole following the proposed material selection process

4 The Materials Combinations Simulator

The insole design process presented in the previous chapter is made possible through a set of CAD tools and databases, specially thought to design custom made insoles. Since this paper presents an approach to select the most suitable combination of materials for customized insoles, only the tools supporting this aim are described: these are the Materials Combinations Simulator and the relative database. Examples of the other tools supporting the entire insole design process as the shoe last designer, the insole modeller, the foot isobar curves calculator are described in [21], [23] and [25].

4.1 The simulation model

The simulation model implemented in Ansys has been defined in order to accomplish both material and

geometric non linearity. The first one is due to the non linearity between stress and strain within the elastic field, whereas, the second one is due to the high deformation values the insole materials have been able to resist without any plastic deformation. With non geometric linearity, the assumption that the initial and final configurations are the same cannot be done. Considering the high computational effort in case of these non linearity conditions, the geometry has been defined as simple as possible (Fig. 4).

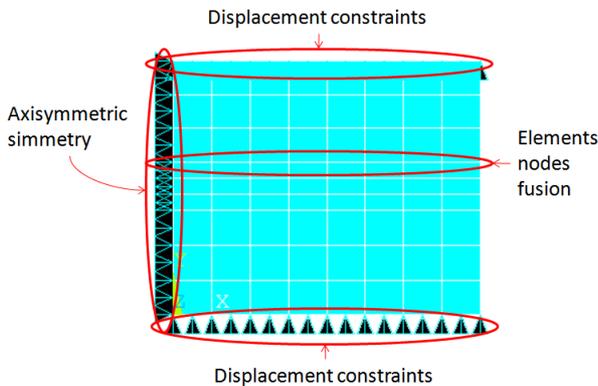


Fig. 4 Boundary conditions of the simulation model

Using a cylindrical sample, it is possible to run an axisymmetric analysis, simplifying the simulation task, from a three dimensional to a two dimensional model. In this way, the number of elements will be an order of magnitude less, speeding up the entire simulation process. Performing an axisymmetric simulation, the geometry is a rectangle whose dimensions have been chosen according to the real specimen used for the laboratory tests. While the diameters have been generally around 12 mm, the thickness depends on the combination user wants to simulate. In case of a multilayer materials, more than one rectangle will be modelled, one over the other.

Considering the behaviour of the materials used for insoles, a simplified simulation model, based on a multilinear elastic material model, has been defined. The Multilinear Elastic material behaviour describes a conservative (path independent) response in which unloading follows the same stress-strain path as loading. Thus, relatively large load steps might be appropriate for models that incorporate this type of material nonlinearity. Behaviours like viscosity cannot be taken into account due to the lack of experimental data, which require a specific testing machine. For the same reason, it has not been possible to consider an hyperelastic simulation model, since the following tests are required: uniaxial, biaxial and planar/shear. Using the proposed material model, during the simulation, it must be verified that the deformation value in each node is less than the maximum deformation given to the material, during the experimental test, because the simulation engine does not know material behaviour beyond this threshold.

The *PLANE82* (Ansys element) has been chosen as finite element since it provides more accurate results for mixed (quadrilateral-triangular) automatic meshes and can tolerate irregular shapes without loosing so much accuracy. The 8-node element is defined by eight nodes having two degrees of freedom at each node: translations in the nodal X (radial direction of the sample) and Y (axial direction of the sample) directions. The element may be used as a plane element or as an axisymmetric element.

During meshing phase, each area is meshed using the same number of elements. Considering the element used (8 nodes, three along Y axis), three elements for each layer on its thickness is enough. On the radius, instead, 8 elements is a compromise between simulation speed and accuracy.

Once meshing phase is completed, boundary conditions are applied. They depend on:

- The kind of simulation to do. In a controlled force simulation, a force will be applied to the upper face of the sample, increasing its value up to a threshold value. In a controlled displacement simulation, instead, a displacement will be applied to the upper face of the sample, increasing its value in order to compress the specimen till a specific thickness;
- The kind of glue used to connect one material layer to the next one;
- The friction between materials.

In particular, the followings boundary conditions have been applied:

- *Axisymmetric symmetry*: simulation software automatically applies these boundary conditions, in case of axisymmetric simulations;
- *Elements node fusion*: nodes on the lines connecting two layers are merged in order to avoid redundant nodes. This operation means an infinite friction coefficient between layers. This assumption is possible considering the kind of glue used to joint the material layers;
- *Displacements of the nodes of upper layer*: the nodes of upper layer are constrained to move along y-axis with the same values, in order to maintain planar and horizontal the upper face;
- *Displacements of the nodes of lower layer*: no friction has been taken into account between simulated combination of materials and external environment, because friction depends by materials in connection. Stress-strain curve for a material must not depend on boundary conditions, then, for this reason, no friction has been considered. Nodes are constrained to move only along x-axis, in order to maintain the bottom face horizontal and planar;

Simulations have been done considering geometric nonlinearity, due to the large strain and deflection the sample is subjected. Because of large strain, simulation is done by splitting deformation in a finite number of sub-steps and the couple of stress and strain values are used to build the characteristic curve of the simulated sample (the maximum sub-step number is fixed to 100).

4.2 The simulation system

The Materials Combinations Simulator is a software tool used by a Materials Engineer with the aim to populate the materials database, used then by the Insole Designer during the design phase. This tool is an element of a wider architecture, as shown in Fig. 5, made of two other modules, the simulation Engine (*Ansys* by *Ansys Inc.*) and the materials database (*Access* by *Microsoft*). The insole designer defines the simulation parameters through the graphical user interface of the Materials Combinations Simulator, which generates several code scripts, required to automatically set up the simulation model. Once the simulation is finished, the user checks the simulation results, having also the possibility to store them into the relative database.

Henceforward, the above-mentioned workflow of the software is presented in detail:

- 1) The user defines a combination of materials to simulate. In this phase, the list of materials and relative thicknesses has to be defined by choosing them from the materials database. It is also possible to retrieve data relative to a combination of materials previously simulated;
- 2) The Materials Combinations Simulator generates the simulation scripts for Ansys. The software automatically configures the scripts required to run the simulation. These scripts take care to define the geometry, the materials properties, the boundary conditions and the elaborate and format the results in order to input them directly into the Materials Database;
- 3) The user runs the simulation using the simulation scripts;
- 4) Read the simulation results (stress-strain curve). Once the simulation is completed, the user runs a command to read and watch the simulation results (stress-strain curve) exported by Ansys in a textual file (Fig. 6);
- 5) Save the results into the Materials Database. The Materials Combinations Simulator saves the data into the Materials Database, so these results can be used later for other simulations or during the insole design phase.

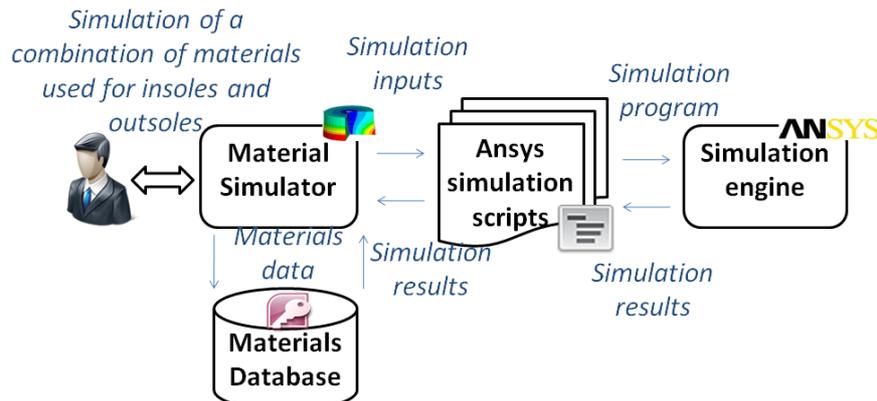


Fig. 5 Architecture of the Materials Combinations Simulator

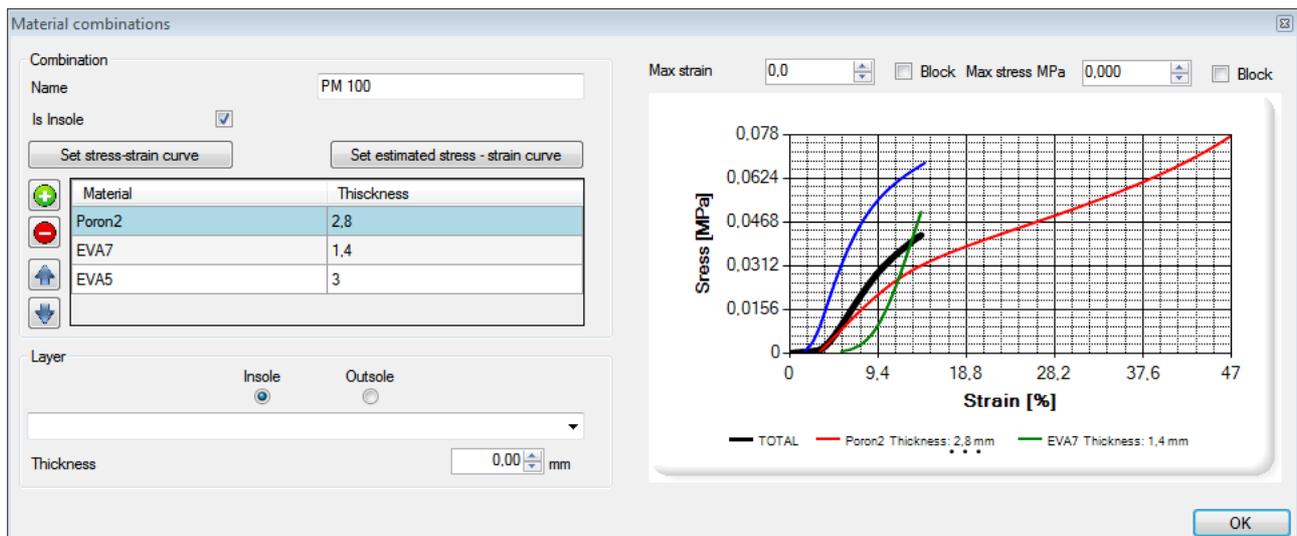


Fig. 6 Graphical User Interface of the Materials Combinations Simulator

4.3 The Materials Database

The Materials Database is a Relational Database with the aim to store data related to each insole material or a combination of them (Fig. 7).

The database mainly consists of two datasets: one to store the data relative to a single material, the other, for a combination of them. The first dataset is represented by a table containing, for each material, all the principal properties recognized as useful by designer during the material selection (properties collected through experimental tests or datasheets):

- Commercial name;
- Supplier;
- Chemical nature;
- Material picture;

- Supplier Technical Sheet;
- Material function: adaptation, cushioning, filling;
- Thickness [mm];
- Density [kg/m³];
- Hardness [°ASK C] -
- Stress-strain curve;
- Compression set at 23°C [%];
- Compression fatigue [%] (after 25.000 cycles);
- Rigidity [kPa];
- Resilience [%];
- Perspiration [mg/cm²];

The results of the Materials Combinations Simulator, instead, are stored into another table, linked to the previous one. For each combination, the table identifies list of materials layers with relative code and

manufacturer. For each layer, the material name and thickness are stored.

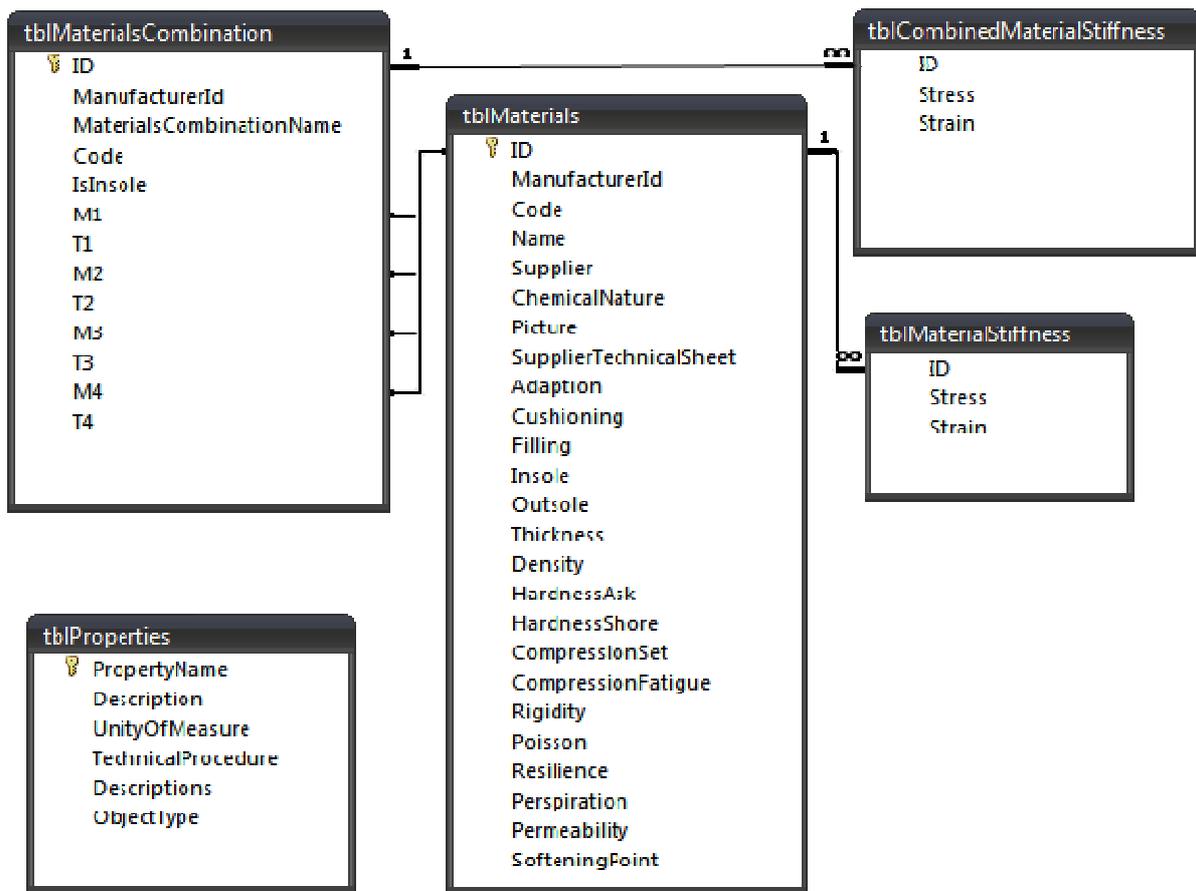


Fig. 7 Materials Database architecture

In order to aid the designer during the material selection phase and the understanding of each property, another table has been defined. It contains the list of the properties managed for each material, and, for each property:

- the documents describing the meaning of the property;
- the procedure followed during the experimental laboratory tests to measure each property.

5 Results discussion

The Materials Combinations Simulator has been tested in order to verify the uncertainty of the results calculated by the implemented simulation model. The results calculated by the Materials Combinations Simulator has been compared with the data obtained with laboratory tests on specimens made of a single material (Fig. 8) or a combination of multiple layers (Fig. 9). During the test, a wide set of materials have been considered, as EVA (Ethylene Vinyl Acetate), PU (polyurethane) and rubber.

The results analysis highlighted the following conclusions:

- the simulation model exactly represents the behaviour of a real material, when a specimen of a single material is simulated. The error is close to zero (Fig. 8);

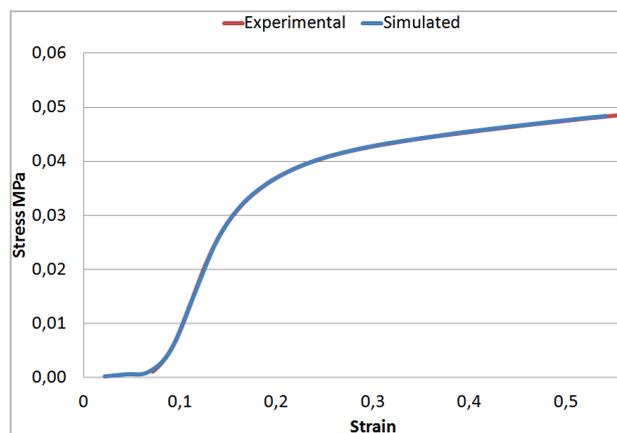


Fig. 8 Experimental vs simulated stress-strain curves for a specimen made of a single material

- the average error committed during the simulation of a combination of multiple layers of material is less than 10% (Fig. 9). The experimental data outcoming from the testing machine have been also weighted by specific parameters (intrinsic of the machine) in order to consider the friction between the specimen and the

machine plates. The deviation is firstly due by these parameters and secondly by the boundary conditions used to model the glue between the materials layers.

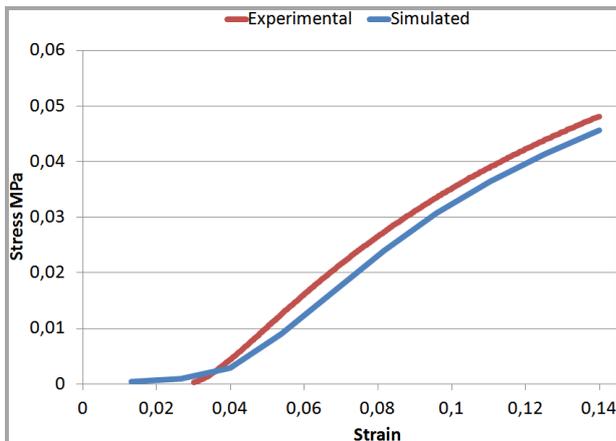


Fig. 9 Experimental vs simulated stress-strain curves for a specimen made of a combination of multiple materials

The proposed process for the insole materials selection is still under test, so, the related advantages, compared with traditional practices, will be presented in further papers.

6 Conclusion

The paper presents two processes, one to design the custom made insole and the other to select the insole materials combinations with the aim to uniform the foot plantar pressure. The second process is supported by a system for the simulation (based on a FEM software) and storage of the mechanical properties of materials used for custom made insoles.

The presented work is a step toward a more scientific design process for custom made insoles. Nowadays, in fact, the materials selection phase is delegated to the expertise of each technician, without any kind of support aimed to standardize this part of the insole design process. The definition and the development of a simulation system permits the footwear companies to gain a set of advantages, as the elimination of the physical tests to characterize the mechanical behaviour of a combination of materials and the related time saving for preparing equipments and for performing the tests.

Moreover, the materials selection process represents a support for inexperienced insole designers during the insole materials definition process. The proposed workflow mainly aims to uniform the plantar pressure, selecting materials with specific stiffness: softer materials for the most stressed areas and vice versa, stiffer materials for the low loaded areas.

The laboratory tests confirmed a good reliability of the results calculated by the Materials Combinations Simulator during the simulation of a combination of multiple materials. Further research studies are required to model the interface behaviour between two layers of different materials. The characterization of the relationships between the different kind of materials applying several type of glues is a preliminary step to improve the simulation model. In addition, the integration of the proposed Materials Combinations Simulator system with an Insole Design software tool will represent a further innovation respect the state of the art. In fact,

there are no software tools able to combine geometry and materials at the same time, during the insole design process.

References

- [1] Bus S.A., Ulbrecht J.S., Cavanagh P.R. Pressure relief and load redistribution by custom-made insoles in diabetic patients with neuropathy and foot deformity. *Clinical Biomechanics* 19 (2004) pp 629–638.
- [2] Armstrong D.G., Peters EJ, Athanasiou KA and Lavery LA. Is there a critical level of plantar foot pressure to identify patients at risk for neuropathic foot ulceration? *The Journal of Foot and Ankle Surgery* 37, 4 (1998) pp 303–307
- [3] Lavery L.A., Armstrong DG, Wunderlich RP, Tredwell J, Boulton AJ. Predictive value of foot pressure assessment as part of a population-based diabetes disease management program. *Diabetes Care* 26 4 (2003) pp 1069–1073.
- [4] Lavery L. A., Murdoch D. P., Frolich M., and Lavery D. C. Effectiveness of Diabetic Insoles to Reduce Foot Pressures, *The Journal of Foot & Ankle Surgery* 36,4 (1997) pp 268-271
- [5] Musab Ibrahim, Rana El Hilaly, Mona Taher, Ahmed Morsy. A pilot study to assess the effectiveness of orthotic insoles on the reduction of plantar soft tissue strain, *Clin. Biomech.* (2012), article in press.
- [6] Janisse D. J. A scientific approach to insole design for the diabetic foot. *The Foot* 3,3 (1993) pp. 105–108.
- [7] Che H., Nigg B. M. and de Koning J. Relationship between plantar pressure distribution under the foot and insole comfort. *Clinical Biomechanics* 9,6 (1994) pp. 335–341.
- [8] Hinz P., Henningsen A., Matthes G., Jäger B., Ekkernkamp A. and Rosenbaum D. Analysis of pressure distribution below the metatarsals with different insoles in combat boots of the German Army for prevention of march fractures. *Gait & posture* 27,3 (2008) pp. 535–8.
- [9] Raspovic a., Newcombe L., Lloyd J., and Dalton E. Effect of customized insoles on vertical plantar pressures in sites of previous neuropathic ulceration in the diabetic foot. *The Foot* 10, 3 (2000) pp. 133–138.
- [10] Cavanagh P. R. and Bus S. Off-loading the diabetic foot for ulcer prevention and healing. *Journal of vascular surgery* 52, 3 (2010) p. 37S–43S.
- [11] Bus S., Ulbrecht J. S. and Cavanagh P. R. Pressure relief and load redistribution by custom-made insoles in diabetic patients with neuropathy and foot deformity. *Clinical biomechanics* 19, 6 (2004) pp. 629–38.
- [12] Guldemond N. A., Walenkamp G. H., Leffers P. and Nieman F. The effect of insole configurations on plantar pressure

- in diabetic patients with neuropathic feet. *Clinical Biomechanics* 23,5 (2008) pp. 662–720.
- [13] Tong J. W. K. and Ng E. Y. K. Preliminary investigation on the reduction of plantar loading pressure with different insole materials (SRP--Slow Recovery Poron, P--Poron, PPF--Poron +Plastazote, firm and PPS--Poron+Plastazote, soft). *The Foot* 20 (2010) pp. 1–6.
- [14] Begg L. and Burns J. A comparison of insole materials on plantar pressure and comfort in the neuroischaemic diabetic foot. *Clinical Biomechanics* 23,5 (2008) p. 662720.
- [15] Lemmon D., Shiang T. Y., Hashmi A., Ulbrecht J. S. and Cavanagh P. R. The effect of insoles in therapeutic footwear-a finite element approach. *Journal of biomechanics* 30,6 (1997) pp. 615–620.
- [16] Goske S., Erdemir A., Petre M., Budhabhatti S. and Cavanagh P. R. Reduction of plantar heel pressures: Insole design using finite element analysis. *Journal of biomechanics* 39,13 (2006) pp. 2363–70.
- [17] Luo G., Houston V. L., Garbarini M. A., Beattie A. C. and Thongpop C. Finite element analysis of heel pad with insoles. *Journal of biomechanics* 44,8 (2011) pp. 1559–65.
- [18] Cheung J. T.-M. and Zhang M. Parametric design of pressure-relieving foot orthosis using statistics-based finite element method. *Medical engineering & physics* 30, 3 (2008) pp. 269–77.
- [19] Cheung J. T.-M., and Zhang M. A 3-dimensional finite element model of the human foot and ankle for insole design. *Archives of physical medicine and rehabilitation* 86, 2 (2005) pp. 353–8.
- [20] Chen W.-P., Ju C.-W., and Tang F.-T. Effects of total contact insoles on the plantar stress redistribution: a finite element analysis. *Clinical Biomechanics* 18, 6 (2003) pp. S17–S24.
- [21] Paton J. Bruce G. Jones R. and Stenhouse E. Effectiveness of insoles used for the prevention of ulceration in the neuropathic diabetic foot: a systematic review. *Journal of diabetes and its complications* 25 (2011) pp. 52–62.
- [22] Germani M., Mandolini M., Mengoni M., Nester C. and Raffaelli R. Tools for design and validation of shoe lasts for diabetic patients. *Footwear Science* 4:3 (2012), pp. 37–41.
- [23] Davia M., Germani M., Mandolini M., Mengoni M. and Montiel E. Shoes Customization Design Tools for the 'Diabetic Foot'. *Computer Aided Design & Applications* (2011) pp. 693–711.
- [24] Faulí A. C., Andrés C. L., Rosas N. P., Fernández M. J., Parreño E. M. and Barceló C. O. Physical evaluation of insole materials used to treat the diabetic foot. *Journal of the American Podiatric Medical Association* 98, 3 (2008) pp. 229–38.
- [25] <http://www.vorum.com/english/footware/insoledesign.php>, accessed 20 Jan. 2013.