Methods and tools dedicated to shoes customization for people with diabetes

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Abstract

Purpose:
Study and development of innovative tools in order to support the design and manufacturing of customised shoes for people with diabetes.

Method:
The approach is based on the identification of main critical stages of footwear customisation when patient parameters have to be properly used; medical knowledge formalisation is translated in new software design tools that interest the footwear shape and the suitable materials.

Result:
Rapid customisation of preventive shoes for people with diabetes

Discussion & Conclusion:
"Diabetic foot" in one the main effects of diabetes; it is important to develop shoes able to prevent this kind of complication. This paper reports an approach and related design tools that allow customising shoes on the basis of patient features. Rapid manufacturing technologies have to be still analysed in order to complete the whole process.

1 Introduction

Diabetes is a growing health problem around the world. World Health Organization estimates that in 2030 more than 334 millions of persons will suffer from diabetes [1]. Today, main problems for people with diabetes are due to the complications that such sickness generates. One of the most relevant complications is called "diabetic foot". It often leads to amputation. Peripheral neuropathy, a loss of feeling in the extremities, renders these individuals unaware of sores that develop on their feet until the wound becomes infected. Then, because of other diabetes-related complications, the infection often defies healing and eventually leads to amputation. The main cause of foot ulceration in the adult neuropathy diabetic is thought to be the presence of abnormally high plantar pressures secondary to neuropathy. It is evident that reduction of amputations can be achieved if it is possible to effectively prevent the foot ulceration. Early diagnosis through a continuous foot monitoring can be applied. But the best approach is to wear suitable personalized shoes that avoid the causes of ulcer. Despite needs, there is not a full user-centered footwear development due to the difficulty to simultaneously take into consideration multiple design aspects such as foot shape and biomechanics, materials performance for upper, insole and outsole, manufacturing methods. These factors affect cost, availability on the market and variety in terms of aesthetics. In order to investigate this problem, a research program (SSHOES) was started. It has been funded within the Seventh European Framework Program. It aims at developing a new paradigm and implementing infrastructure for the creation of diabetes-oriented footwear, based on demand product differentiation and personalization in order to achieve high quality and customer satisfaction. Specific addressed research topics are: 3D foot digitalization systems, footwear design tools dedicated to personalized biomechanical as well as aesthetics aspects, adaptive production technologies, etc.

This paper is focused on the adopted footwear design approach and the results regarding with the implementation of the supporting software systems. After a brief review of tools dedicated to shoes customization, the design approach will be described. A prototypal design system implementation will be proposed in order to support personalized shoe development. Main developed features consist of the possibility to input data from dedicated sensors such as foot scanners and pressure measuring systems, to elaborate patient medical and behavioural data, to provide as output a set of shoe design parameters and finally developing virtual models of main customized shoe components.

2 Related works

Advanced Computer-Aided solutions can highly improve the efficiency of footwear industry internal and external processes. Dedicated CAD (Computer Aided Design), Reverse Engineering and Rapid Prototyping systems are examples of tools usable in order to reduce shoes development time and product cost [2].

Various specific CAD systems to create 3D virtual models of shoes have been developed [3-4]. They are mainly oriented to manage manufacturing processes such as upper cut, shoe sole molding, etc., or to marketing purposes, thanks to 3D rendering tools. The product conceptualization is basically limited to the aesthetic evaluation neglecting the desired shoe functions, the achievable comfort and the shape customization. These
aspects are ever more important in order to satisfy the specific customer requirements. The creation of customized shoes has been investigated in several research activities [5-6]. They face the digitalization of customer’s feet by adopting non-contact 3D scanning systems and the related range data elaboration software tools in order to provide a virtual foot model [7] or a set of meaningful of cross-section measurements [8]. The most adopted 3D acquisition tools are based on the triangulation principle by laser scanning and structured light measurements. Examples of contact digitizers are Amfit Digitizer by Amfit and Orthofit scanner by Foot Clinic. Examples of laser-based scanners dedicated to custom shoes for patients with special feet diseases are Lightbeam 3D by Corpus, Yeti by Canfit, ERGOscan by Creaform, etc.[9]. Once feet models have been obtained, a digital model of the last is necessary as it is the base over which the shoe components are designed. Generally the most suitable last can be selected from a database of possible ones and its shape deformed accordingly to the designer intent.

The aim of other research activities was to set efficient manufacturing systems based on the automation of phases when a high number of possible productive variables have to be managed as in shoes customization occurs. Some interesting solutions are described in [10] and [11].

It is worth to underline that such technologies are only partially implemented in the majority of industrial contexts. Main reason for that can be found in footwear commercial systems that often lack of robust functionalities that cause inefficiencies and waste of time. In these cases, operators should use workarounds to achieve the desired results. Furthermore, customers complain absence of tools to support the implementation of their specific processes. Resuming the main critical aspects of this set of systems regard:

• the integration between the SW adopted to manage the digitalization and the CAD-based systems used to elaborate the geometry according to the chosen last, the medical parameters, the manufacturing technology, etc.;
• the formalization of rules that experienced shoemakers use for achieving a right footwear components design (last, insole, outsole, etc.);
• the adopted methods to enable footwear fit quantification according to the scanned foot dimensional parameters [10];
• the definition of anatomical landmarks to facilitate foot acquisition and its surface reconstruction [11];
• lack of tools to interface different software solutions present in the design and manufacturing cycle, often required to cope with non standard shapes. In fact, different proprietary file formats, linked to the specific CAD solution, have arisen during the last years, in order to maintain own market share. This has caused high costs, low integration possibilities with other systems, and consequentially lost of efficiency. The result has been that many companies rely on traditional processes still employing 2D CAD systems;
• time and feasibility of 3D scanning in orthopedics and shoes stores.

Speaking of shoes for people with diabetes additional issues arise. Apart from the disease intrinsic factors, many extrinsic factors related to foot and footwear can influence diabetes progression and health (e.g. foot pressure, movement of the foot 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). Each of these extrinsic aspects requires data and information from the specific patient in order to enable appropriate footwear personalization.

Furthermore, changes of footwear performance over time and/or patients’ use and ways to move can affect the clinical efficacy of footwear. Several commercial systems (e.g. Vorum by Canfit, FootWizard by Otto-Bock, SOLETEC by Shoemaster, etc.) try to achieve a full customization of shoes and insoles for people with special diseases. Systems interoperability, integration, performance, implementation of biomedical and biomechanical features and ease-to-use for non-expert users (e.g. health care professionals who work with patients with diabetes, orthopedics, etc.) are only some problems limiting their application. Main practical problems to be faced are listed here:

• lack of suitable 3D modeling strategies of deformation to modify the last shape as the experts manually do;
• lack of criteria to model the insole and the whole shoe in according to the medical criteria;
• lack of advanced tools in order to manage heterogeneous geometric and non geometric data (clouds of points, surfaces, images, pressure maps, disease characteristics, etc.)
• the impossibility of capturing foot in the desired position set up by the orthopedic technician;
• the right combination between the acquired foot geometrical data and the plantar foot pressure;
• the difficulty to design a proper insole in terms of shape and materials in order to unload specific foot zones.

In this paper several software solutions are proposed dedicated to support the design phase, while future work will be dedicated to integrate foot scanning with plantar pressure measurement and to improve manufacturing technologies.

3 Footwear design approach

The proposed approach is based on an integrated product design framework for enabling the management of the whole life cycle of shoes for diabetic people. The approach is based on a set of integrated software systems. Such systems exchange information through a unique XML file containing patient as well as manufacturing data involved in the entire shoe lifecycle. A diabetic patient needs at first specific analysis, in order to evaluate important bio-mechanical parameters (first MPJ motion & torque, plantar pressure, ankle dorsiflexion, dorsal geometry, foot pronation, etc.). These data are later used to design the best shoe required to fit his/her specific needs. In order to measure above parameters, commercial solutions could be insufficient or not sufficiently integrated. Therefore, new measurements devices and the integration of already existing ones in portable systems are going to be investigated. These integrated systems mainly concern foot geometry and pressure acquisition during a complete gait cycle.

During subsequent shoe design phase, mentioned bio-mechanical parameters are converted in footwear features. In case of diabetic shoes they are: rocker angle, heel height, apex position, apex angle, sole stiffness, etc., as shown in figure 1 Fig. 1. These parameters define the geometry of a diabetic rigid sole. A rigid sole is designed for a corrective gait and helps preventing feet ulceration.
Data coming from measurement system can be stored in the XML data file. Such file is divided in two parts, the first one concerning patient data, while the second one concerning shoes.

Main patient data regards:
- Patient information: general patient personal data;
- Bio-mechanical parameters: values of those parameters, which should be used for designing an ad-hoc pair of shoes;
- Feet mesh: feet dynamic shape acquired during a complete gait cycle. Foot shape variation during walking is combined with the static one relative to single foot geometry digitized when the patient is standing;
- Feet pressure maps: for each foot during a complete gait cycle. Pressure distribution changes during gait cycle in relation to foot geometry. From maps elaboration, isobar curves or maximum pressure points, are extracted and stored.
- Second part of the XML file defines the shoe:
  - Footwear features: list of parameters which drives footwear component design;
  - Last model: file contains information about lasts geometry, which are used during shoes manufacturing phase;
  - Outsole model: outsole geometry derives from the last and other patient specific parameters. Geometry of several outsole layers and relative materials are stored;
  - Insole model: this part of shoe is strongly customized on patient and it is derived from foot pressure distributions. Geometry of insole layers and relative materials are written in the file.

In the following sections the dedicated CAD system is described in more detail.
provide additional clinical variables as global foot deformation and pressures concentration level.

Besides, foot motion data are used for driving 3D dynamic foot geometry simulation. It employs data points from the foot surface measured during the gait cycle to drive corresponding data points in 3D geometric foot surface model derived from laser scanning system. The simulation is used to identify ideal flexion line in the shoe, foot girths values and fluctuation during motion and also insole profile curves.

On the other hand, non geometrical parameters, also referred as clinical variables, have been identified in order to be: user activity level, types of activities undertaken, vascular status, neuropathy status, plantar soft tissue properties, sweat production, site and nature of skin lesions, range of joint motion, muscle shortening. These parameters are assessed by the orthopedic specialist and each one ranked on a scale from 1 to 10.

<table>
<thead>
<tr>
<th>Biomechanical variables</th>
<th>Assessment</th>
<th>Type of data</th>
</tr>
</thead>
<tbody>
<tr>
<td>Activity level</td>
<td>Orthopedic specialist</td>
<td>Rank 1 to 10</td>
</tr>
<tr>
<td>Types of activities undertaken</td>
<td>Orthopedic specialist</td>
<td>Rank 1 to 10</td>
</tr>
<tr>
<td>Vascular status</td>
<td>Orthopedic specialist</td>
<td>Rank 1 to 10</td>
</tr>
<tr>
<td>Neuropathy status</td>
<td>Orthopedic specialist</td>
<td>Rank 1 to 10</td>
</tr>
<tr>
<td>Plantar soft tissue properties</td>
<td>Orthopedic specialist</td>
<td>Rank 1 to 10</td>
</tr>
<tr>
<td>Sweat production</td>
<td>Orthopedic specialist</td>
<td>Rank 1 to 10</td>
</tr>
<tr>
<td>Site and nature of skin lesions</td>
<td>Orthopedic specialist</td>
<td>Rank 1 to 10</td>
</tr>
<tr>
<td>Range of joint motion</td>
<td>Orthopedic specialist</td>
<td>Rank 1 to 10</td>
</tr>
<tr>
<td>Muscle shortening</td>
<td>Orthopedic specialist</td>
<td>Rank 1 to 10</td>
</tr>
<tr>
<td>Foot geometry</td>
<td>Foot digitizer</td>
<td>3D mesh model</td>
</tr>
<tr>
<td>Foot deformity</td>
<td>Foot digitizer</td>
<td>Rank 1 to 10</td>
</tr>
<tr>
<td>Pressures map</td>
<td>Foot digitizer</td>
<td>Pressures map</td>
</tr>
<tr>
<td>Pressures concentration</td>
<td>Foot digitizer</td>
<td>Rank 1 to 10</td>
</tr>
<tr>
<td>Ideal flexion line</td>
<td>Dynamics module</td>
<td>Numeric value</td>
</tr>
<tr>
<td>Foot girths values and fluctuation</td>
<td>Dynamics module</td>
<td>Numeric intervals</td>
</tr>
<tr>
<td>Insole profile curves</td>
<td>Dynamics module</td>
<td>Profile curves</td>
</tr>
</tbody>
</table>

Tab. 1 Clinical and biomechanical variables.

The whole clinic and biomechanical variables system is elaborated by the knowledge based software in order to elaborate appropriate footwear components design parameters (FCDP). In particular outputs refers to last selection, last typical measurements and girths, upper materials selection, shoe components options, heel height and shape prescriptions.

The software that matches biomechanical parameters with design parameters is based on a knowledge base repository represented by evidences from the literature and a wide selection of real test cases. The first type of knowledge is implemented in algorithms which basically filter the possible range of design parameters on the base of the specific patient data when explicit rules can be formulated. On the other hand real test cases are stored as a set of design solutions which experience and practice have shown to be optimal for certain patient categories.

4.1 CAD system

The input for designing insole and last is given by the results of a dedicated measurement system constituted by a 3D laser scanner, baropodometric platform and a gait tool for static and dynamic analysis. Outputs of this systems are a sequence of foot pressure maps (.bmp or .csv files) and foot geometries (.stl mesh). The pressure maps sequence is acquired during foot scanning, so pressure distribution over time can be analyzed. In fact, during scanning time span, patient could slightly move his body and pressure distribution changes.

Foot Pressure Viewer reads a sequence of pressure maps and extracts that one which better represents foot plantar pressure, following a specific algorithm that maximizes the quantity of information that is available on the map.

Pressure map is acquired in a discrete way and represented by a cloud of points. Only points whose pressure value is not zero are included. Map point X and Y coordinate correspond to pressure sensor cell midpoint while Z represents pressure value.

An algorithm works on the point cloud in order to extract characteristic points, such as 1st and 5th metatarsal points, most prominent points on heel area, medial metatarsal point, centre of pressure (COP) and pressure map barycentre (figure 3). Foot axis is also calculated, as the line that minimizes deviation among pressure points (points are projected on XY plane). 1st and 5th metatarsal points are calculated as the most external points of pressure map. Medial metatarsal point is the midpoint for the two previous ones. Most prominent points are computed in a local reference system that is aligned with the foot axis. Between two possible points, is chosen that one which is more distant from medial metatarsal point. COP is defined as midpoint between most prominent and medial metatarsal ones. Barycentre is calculated as a weighted average point, where pressure value is used as weight.

Fig. 3: Extraction of characteristic points of a pressure map

Foot Pressure Viewer has also a functionality to automatically align foot mesh with pressure map, since these data are generally expressed in different reference systems. The transformation matrix necessary to overlap pressure to geometry is calculated from an alignment process of the convex-hull curve of foot sole mesh and convex-hull curve of pressure map. This approach has shown good reliability and efficiency. First curve is generated as follow: from foot mesh, a new one is generated from facets with vertices Z-coordinate less than a threshold value (foot scan is generally aligned along X axis and its sole on XY-plane). XY plane projected...
silhouette of this mesh is calculated and then the convex-hull of obtained curve is derived. On the other hand, the second curve is build from the convex hull of pressure point cloud.

Curves alignment is based on an Iterative Closest Point (ICP) algorithm (figure 4). For a correct and fast result a rough pre-alignment algorithm is used. Pressure points bounding box is overlapped to foot sole mesh bounding box. In this phase, foot orientation is guaranteed by considering pressure map characteristic points. In fact, it must be avoided to overlap toe of foot mesh with pressure map heel zone. ICP works on points clouds derived from uniform curves sampling. Each iteration transformation is computed using a Moore–Penrose pseudoinverse matrix.

![Fig. 4: Pressure map with foot geometry alignment by ICP applied to convex-hull curves.](image)

As alignment has been reached, pressure map is projected on the foot sole mesh (figure 5). Result of this operation is a new mesh corresponding to foot sole with colored vertices. Projection is created from a planar quadrilateral mesh, with a texture representing pressure map applied on it. The texture is created from pressure point converting Z coordinates in color information. In particular, maximum pressure level has been converted in red, while minimum one in blue. During this phase, also an improvement of texture image resolution has been performed in order to improve final quality of projection result. In fact baropodometric platforms have low resolutions, generally 2÷4 sensors for square inch.

![Fig. 5: Foot pressure projected on sole foot mesh.](image)

Isobar curves have been calculated from a Nurbs surface obtained from pressure map (figure 6). Curves are calculated slicing this surface with parallel to XY and equidistant planes (figure 7). The number of curves is specified by user. A control points grid is defined on the XY-plane and points elevation (z-coordinate) is set accordingly to color information: point with red color have maximum elevation, while blue points have zero elevation. As input parameters grid resolution and maximum points elevation can be specified. Higher number of points means higher accuracy of final isobar curves while decreasing grid resolution curves are smoother.

![Fig. 6: Pressure surface from pressure map to be used for isobar curves calculation.](image)

![Fig. 7: Examples of isobar curves. In black feet profile from 3D mesh is drawn.](image)

Once geometrical data about foot and pressure has been acquired and elaborated, next step regards the definition of the model of a customized last. Last shape must be drawn in order to cope with patient pathology, medical prescriptions, but also, if possible, with fashion dictates. The result of the process consists of a set of NURBS surfaces. They are afterwards used to physically produce the lasts by milling and to be unrolled to pieces which can be cut from leather.

A set of modeling functionalities has been implemented in the Last Designer module. They cope with foot and lasts points cloud data, lasts geometry editing, modifications and exporting to milling devices and leather cutting. Figure 8 shows the sequence of operations to carry out in order to obtain a customized last. Firstly, a triangulated mesh representing the last geometry is obtained from points cloud data. Minolta V9i laser 3D scanner has been chosen for 3D last digitisation. The main advantage of such system is that it can be successfully employed also for acquiring textures.

![Fig. 8: Last Designer functionalities and flowchart](image)

The digitization may lead to some errors in the STL model and some corrections must be performed: holes filling, non manifold faces deleting, noise reduction, mesh decimation, isolated triangles deleting, etc… All these operations have been implemented through automated commands, easy in using also for non-skilled operators.
Standard reverse engineering algorithms have been used and optimal parameters selected on the base of the specific application.

A standard last reference coordinate system has been fixed. The operator identifies some conventional points on the last scan in order to fix styling and space references. The last is then positioned in a predefined coordinate system.

Then, last base-curves can be drawn. These curves include base edge curves and ankle curves; they are necessary for the subsequent phase of surface reconstruction. A semi-automated approach has been followed. Through curvature analysis, the software extracts sub-clouds of points with higher curvature. The curves are then obtained fitting the point clouds (see figure 9).

An additional curve network is generated as sections of mesh and conveniently trimmed and smoothed. An algorithm that uses base-curves to position and orient section planes performs this operation. The curve network is then used to build NURBS surfaces as ordinary lofts.

In this way, a sort of automatic reverse engineering process has been obtained. This approach is particularly convenient for lasts. In fact, surface reconstruction has to be rapidly repeated many times, and automation makes it easy also for operators with poor reverse engineering knowledge.

![Fig. 9: Automatic Reverse Engineering process. Reference curves from mesh curvature and curves grid from mesh sections](image)

Once a NURBS surface has been obtained, it can be modified in order to meet specific patient needs. A number of standard modifications have been identified from manual operators’ expertise. Typically, these modifications refer to heel height variation, length or width increment, profile curves redrawing (figure 10). In order to preserve the styling and aesthetic shape, the amount of surfaces distortion has to smoothly vary from a maximum corresponding to a target section decreasing toward the areas where deformation is not needed. The algorithm is based on the simultaneous displacement of curves and surfaces control vertices on parallel planes on the base of suitable deformation functions.

Analogous approach has been followed for other modifications that target diabetic feet necessities. The operator uses these functions in a proper sequence in order to achieve the required last shape that can considerably vary from the starting one.

Eventually, NURBS surfaces can exported in IGES format to milling machines to obtain a physical last or to other software packages for leather pieces preparing.

![Fig. 10: Example of last virtual modification. Control vertices displacement smoothly decreases from a target plane](image)

The further software module is used when last design phase is completed. It is composed of three main groups of functionalities: the first one is used to position and align foot with last, the second one to measure foot and last and the third one to export measures and geometries defined during the measurement process.

Lasts and feet are both characterized by a set of basic points. The definition of some of them corresponds between foot and last. The module imports both last and foot and user specifies if foot has been digitized with the sole on the ground or using a raised heel.

After import procedure, Foot Last Fitting module automatically aligns geometries on the base of a quite complex procedure. As first step, a set of four axes are calculated: foot axis, last turning axis, foot and turning sole axis (projection of previous axes respectively on foot or last sole surface). Foot axis is defined as the line passing through most prominent and medial metatarsal points (respectively HL and CL in Fig. 11). Turning axis, instead, is the line passing through the two most prominent points of a last, one in the heel zone and the other one in the toe zone.

Orientation procedure is based on the following set of geometrical criteria: foot and last axis is aligned along X axis, symmetry plane corresponds to XZ plane, most prominent points are on positive Z axis, foot and last sole are on XY plane, foot and last axis are tangent to X axis on a specific point (projection of medial metatarsal point on foot and last sole axis).

![Fig. 11: Criteria for the orientation of foot and last in univocal manner.](image)

Once geometries are aligned measuring phase is performed (figure 12). At first foot and last basic points are computed. Then, measurements are calculated as distances or extracted curve lengths. They include: foot and last width, length, 1st and 5th metatarsal distance and angle, insole length, waist length, big toe tip movements, big toe tip vertical compression, etc.

Other typical measures are relative to following sections: heel, high instep, medium instep, ball, toe, toe perpendicular and any other user defined section. For each section, section plane can be visualized (inclination
and torsion) as well as section curve and its bounding box.

Fig. 12: System in order to compare last and foot.

The third group of functionalities is used to export and report measurements. Each section curve and basic points can be exported in a standard geometrical exchange format such as .igs.

Measurement values are exported in ascii or .csv format in order to respectively highlight measurement of foot, last and relative deviation. Analyzing deviation column, it is possible to provide a rough judgment about foot last fitting. For an exact validation, also geometry is considered during measures deviation analysis.

5 Example of results

The experimental results achieved till now concern footwear features calculation and footwear integrated design, two main activities of the workflow proposed in section 3. However, such systems have been applied in order to design a set (20 pairs) of shoes for people with diabetes (figure 13) together with the traditional tools for performing the other main phases of process. In this way it has been possible to verify the developed systems usability and applicability. In particular time saving has been measured in order to estimate the possible time to market improvement.

Testing phase has been leaded recruiting 100 diabetic subjects (50 in the UK, Salford University, Faculty of health and social care and 50 in Germany, German Sport University, Cologne) and 100 healthy subjects (50 in the UK and 50 in Germany). Each of these subjects have attended for 1 or 2 laboratory testing session in which technicians assessed foot biomechanics and in-shoe plantar pressure. For the biomechanical assessment technicians have required subjects to walk barefoot whilst during kinematic, force and pressure data collecting.

During data acquisition, each subject walks in 20 different pairs of shoes whilst equipped with in-shoe pressure measurement to quantify the pressure under the 1st MTP joint (Metatarsophalangeal Point). Each of the different pairs of shoes have a different combination of design features and the orthopedics involved in testing phase ensure that developed shoes are able to cover the range of footwear designs which have the capacity to reduce 1st MTP joint pressure. Figure 14 shows how a footwear design feature (apex angle, for instance) influences the 1st MTP joint pressure (four values for apex angle have been tested, for instance).

With experimental data for an individual subject will be defined a link between foot biomechanics and optimal footwear design. This link will then be entered into the database and the process repeated for all the different subjects.

Fig. 13: Example of a diabetic shoe designed using innovative process and tools

Even if the most important benefit of a knowledge based system for footwear features calculation is qualitative (improvements of shoe quality), time saving is possible thanks to the lack of human interpretation of patient bio-mechanical parameters which need lot of time and generally can generate process iterations due to the inexperience of novice operators.

This is the case of the insole design phase. Using the results of the Foot Pressure Viewer (§ 4.1), especially isobar curves, an orthopedic technician, during design phase, can easily define insole areas where remove or add material in order to release too loaded foot regions. Perimeter of these area are exactly the just mentioned curves, without any subjective interpretation (figure 15). Similar case occurs during the insole material choice. Insoles are generally constituted by two or more different materials, that opportunely combined allow a right pressure distribution on the foot insole. Using isobar curves, then, it is possible to choose the best materials combination for those areas where pressure values could
determine foot injuries. 1st Joint will be generally characterized by soft materials (low stiffness), in order to redistribute insole forces on close areas.

Most interesting results concern the integrated shoe design phase, in fact, the definition of a single CAD platform for shoe components design allows increasing efficient collaborative design among companies with different competencies (last, insole and outsole). Shoe data sharing and use during design phase of components has been improved by the definition of XML datafile. Each CAD module can directly read and write from this file, allowing to transmit from one module to another one as more information as possible. In this way, it will be also possible to make parallel some design phases, such as insole and outsole design.

CAD module is based on dedicated commands for diabetic feet speeding up designing phase. An operator can start from the most suitable last and he/she can modify it in order to respect footwear features for the specific patient. Insole and outsole design is faster by using the proposed process because some useful information, like isobar curves, have been calculated during patient data gathering phase. The insole-outsole design system used for experimentation does not adopt the material selector and the automation of insole-outsole modeling, thus further improvements will be surely achieved. Foot-last fitting module allows the standardization of procedures used to compare foot and last, in order to establish how a last is fitting a foot. By using this software an objective evaluation is done, rather than a mere qualitative one. In few seconds, a technician is now able to know more than one hundred of measures for foot and last; otherwise, a manual measurement procedure requires about a few tens of minutes. Average time measured for carrying out the main phases of personalized shoe design on 20 pairs of shoes are summarized in table 2.

<table>
<thead>
<tr>
<th>Traditional process (minutes)</th>
<th>Proposed process (minutes)</th>
<th>Improvement (minutes)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient data gathering</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Foot pressure and geometry measurement and preliminary data elaboration</td>
<td>15 (foot geometry is manually measured and foot pressure is reported in 2D files)</td>
<td>3 (for this phase the new process proposes a traditional 3D scanner and a bodpodometric platform; the &quot;Minilab&quot; is not still experimented)</td>
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<tr>
<td>Footwear features calculation</td>
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<tr>
<td>Footwear features calculation</td>
<td>20</td>
<td>4</td>
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<tr>
<td>(material selector is not still experimented)</td>
<td></td>
<td></td>
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<tr>
<td>Footwear Integrated design</td>
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<tr>
<td>Foot pressure visualization</td>
<td>40</td>
<td>20</td>
</tr>
<tr>
<td>Last</td>
<td>20</td>
<td></td>
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<tr>
<td>Insole-Outlet</td>
<td>25</td>
<td>20</td>
</tr>
<tr>
<td>(the current advantage is due to the data deriving from the pressure viewer tool: the benefits of the Insole-Outlet Designer module are not considered)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Foot-Last fitting</td>
<td>35</td>
<td>2</td>
</tr>
</tbody>
</table>

Table 2: Time for data gathering and footwear design for comparing traditional and developed systems (average measured time for a pair of customized shoes)

The most important innovations proposed by this research project are summarized in:

- **Integrated framework of CAD systems for insole, outsole and last design for diabetic patients:** the integration of last, insole and outsole design software toward a special framework using the same CAD system (Rhinoceros); it allows the transparent data flow from one system to the other one. In this way, information generated by a framework module are easily used by another software as input data. The example is given in § 5, where isobar curves calculated by Foot Pressure Viewer are gathered by the Insole designer, in order to build insole geometry;

- **Definition of links between footwear design features and biomechanical parameters:** in this project has been defined a last that can be used in case of diabetic people with a set of outsoles. These ones, have been parameterized by four main footwear design features (apex angle, apex position, rocker angle and sole stiffness), which are the most important in terms of pressure reduction on 1st Point joint. Links between footwear features and mechanical parameters are stored within a database, which, using specific Neural Networks Algorithms, they allow the definition of the best shoe for a specific patient;

- **Definition of criteria which allow the orientation in the space of feet and relative lasts in an objective way:** a set of criteria for relative last and feet orientation has been defined (§ 4.1) in order to position them in a rational way, before take measures. Using such criteria, feet and lasts measure can be compared during last design or verification phases.

- **Definition of measure on lasts and feet in order to compare them:** a set of measures and relative rules for their revelation on a geometry (feet and lasts) have been defined.

- **Definition of rules for insole materials selection:** insole and outsole common materials have been tested within laboratories with the aim to define their mechanical properties (stiffness above all). The rules allow the definition of link between biomechanical parameters (only foot pressure till now) and insole materials, as already defined in § 5.

### 6 Conclusions

Literature overview shows that there is a need of dedicated systems to support the development of shoes for people with diabetes and on the contrary, there are not available technologies to effectively overcome all problems implied in footwear customization, flexibility, rapidly and quality.

A general framework based on a KB system for managing the whole shoes development cycle is defined. It sets the basis for innovating the whole process from design, to manufacturing and retailing. The paper is focused on the description of the adopted approach to define the design framework and on the preliminary results about the implementation of the CAD-based platform for customized shoes design. Developed modules (KB system, foot pressure viewer, last designer
and foot-last validation tool) are only a part of the whole system but they showed interesting advantages respect to the traditional shoemakers way of doing. The proposed system framework tries to integrate in a single tool the digitalization and the CAD functionalities used to elaborate the geometry according to the chosen last, the medical parameters, etc. It allows to effectively combine the foot acquired geometrical data and the plantar foot pressure map. Finally it is based on expert shoemakers knowledge in order to model the last (and in the near future also insole and outsole) within a highly usable 3D dedicated CAD system.

Future research will be concentrated both on the development and optimization of hardware tools for simultaneously acquiring the dynamic 3D foot shape and the related variable plantar pressure and on the implementation of further design modules (insole-outsole, material selector, last valuater). In parallel many efforts will be done to completely develop the whole framework and relative adaptive manufacturing systems.

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### References

[1] www.who.int/diabetes