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Shoes Customization Design Tools for the "Diabetic Foot"

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ABSTRACT

Diabetes is one of the main causes that generate foot health related diseases. It impacts on a large percentage of world population and is expected to grow in next 20 years. Good footwear is fundamental for influencing foot health status in particular when foot can be subjected to many serious problems as in case of diabetic patients. This research work faces this problem by defining an approach and related computer-aided technologies in order to properly design customized shoes for people suffering from diabetes. Design rules have been fixed by formalizing knowledge that expert podiatrists use to prevent foot diseases. Studied and implemented technologies interest the whole footwear design process: foot scanning, foot dynamic pressure measurement, design of last, insole and outsole. This paper is focused on the description of design software system structure and related tools, and, then, it reports preliminary experimental results on 20 case studies.

Keywords: diabetes, footwear customization, CAD modeling.
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1 INTRODUCTION

Diabetes is a growing health problem around the world. WHO (World Health Organization) estimates that in 2030 more than 334 millions of persons will suffer from diabetes [1] (in 2009 diabetes affects 220 millions of persons). Diabetes is a lifelong condition that seriously affects a person's quality of life. In these years, the progress of medical treatments for curing diabetes has fortunately implied a considerable lengthening of life expectation for many sick persons.

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". The people with diabetes mean probably people with foot ulcers, a common side effect of the disease. It is estimated that 15% of diabetic patients are affected by this complication along their life, but this value will probably grow due to the modifications of life style in many parts of the world, especially in the emerging Countries.

Diabetic foot is a complication that often leads to amputation. This is a problem that is difficult to overstate, not just for individuals who have lost limbs, but for the society. 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. These pressures may be present as a result of compromised foot function, such as in hind foot tendon disorders and diabetic Charcot foot.

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 (shape and materials) that avoid the causes of ulcer. For example, studies have shown that foot morphology (calcaneal pitch angle) affects peak plantar pressure and plantar pressure is related to ulceration. The averted calcanei were associated with medial metatarsal head ulcers, while inverted calcanei were associated with lateral metatarsal head ulcers. Foot deformities, such as hammer/claw toe deformity or hallux limitus, have been significantly associated with ulcer incidence in a univariate analysis. Distribution of the internal foot geometry for given population is indicator of the foot deformity, ageing, and body growth anomaly and many others.

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 and sole (insole and outsole) and manufacturing methods. These factors affect cost, higher than traditional ones with same functionalities and style, availability on the market (35-45 days for bespoke shoes and 5-7 days for insoles), and, finally, variety in terms of aesthetics coupled with custom lasts.

In order to investigate this problem, a research program (SSHOES) was started. It has been funded within the Seventh European Framework Program (FP7-NMP-2008-SME). 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 and biomedical as well as style and aesthetics aspects, adaptive production processes and technologies, innovative high-performing materials with self-adaptive capabilities to optimally fit consumers physique and ergonomics, 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 behavioral data, to provide as output a set of shoe design parameters and finally developing virtual models of main customized shoe components.

2 RESEARCH BACKGROUND

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 industrial CAD systems to create 3D virtual models of shoes have been employed in the industry. 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. Trials to design parts limited to the uppers for orthopaedic shoes using existing CAD systems have been conducted from early ’90 with successful results also for the “diabetic foot” [3]. However, base last volumes were traditionally obtained and digitized. In the area of industrial CAD systems, the product conceptualization is basically limited to the aesthetic evaluation neglecting the desired shoe functions, the achievable comfort and the shape customization.

The creation of customized shoes has been investigated in several research activities [4-9]. 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 [10] or a set of meaningful of cross-section measurements [11]. 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* [12], *Yeti* by *Canfit*, *ERGOscan* by *Creaform*.

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. Computational systems have being proposed to design shoe-last on CADs with specific functionalities to create different toe styles, heel heights and heel bottom styles.

In particular, possible approaches can be summarized into the following categories:

- Retrieving the best fitting shoe last from the available shoe last library or database based on the 3D foot scan of the customer through geometric similarity comparison [11, 13-14];
- Deforming an existing shoe last into the customized one that matches with the scanned foot data through free-form deformation [15], amendment of distance map or some other methods [4];
- CAD systems which can be used for designing ex-novo customized shoe last tailor-made for the customer's foot and the chosen style [8]
- Deforming the base shoe last with the customer's chosen style into the customized shoe last that fits the scanned foot data based on the customer's foot features while maintaining the style of the base shoe last [9]

The limitation of such methods for the case of the "diabetic foot" is that style and comfort feature must be embedded in the system in aprioristic manner.

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 [16] and [17].

It is worth underlining 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 for the whole design and production cycle, causing 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.

Main critical aspects emerged from available systems analysis 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 [13];
- the definition of anatomical landmarks to facilitate foot acquisition and its surface reconstruction [18];
- 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.

Diabetes introduces additional issues. 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.

Extracting pressure parameters and insole design has being also found in the literature in the area of the "diabetic foot" [19]. The objective of the study was to establish a 3-dimensional (3-D) finite element model of the foot and ankle, using actual geometry of the foot skeleton and soft tissues in contact with an insole support.

However, pressure is usually evaluated by commercial baropodometric platforms such as F-Scan System (*by tekscan*), Parotec (*by Molinari*), that provide a 2D representation of the patient's foot pressure but neglect the 3D shape of foot during the dynamic movement. Academic researches concerning plantar pressure analysis, such [20] and [21] refer about methodologies to make custom insoles starting from plantar pressure maps and isobar curves, but the foot geometry is not taken into account. Other scientific research have been done to overcome previous limitations, as discussed in [22], proposing a method to combine 3D foot geometry and plantar pressure distribution data in only a single graphical representation.

Another study presents the simulating physical tests that predict the interaction between shoe and user in order to obtain an estimation of several performance ratings without the necessity to manufacture and validate physical prototypes [23]. The aim is the simulation of the behavior of footwear components and the interaction between shoe and user in order to derive a predictive estimation of the fitting, thermal comfort and performance ratings without the necessity to manufacture and validate physical prototypes.

The limitation of the last cited studies is that they do not take in to account the behaviour of the person that changes loading of the foot in response of his sensations. In case of diabetes, the compromised perception of pain makes the situation even more complex.

Finally, changes of footwear performance over time and/or patients' use and ways to move can affect the clinical efficacy of footwear. Some 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 open 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 software solutions are proposed in order 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 and 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 measurement 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 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.

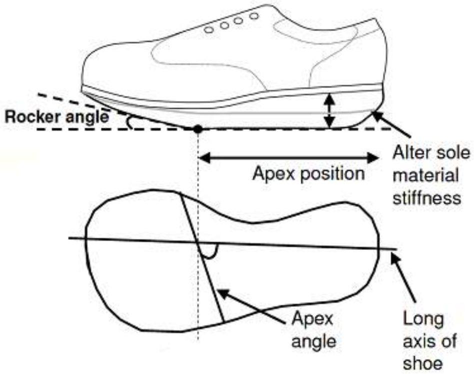

Fig. 1: Diabetic footwear features.

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 regard:

- *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, that 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.

3.1 Research framework description

The flowchart in Fig. 2 represents main activities in order to improve the diabetic footwear design, data being involved and systems to be developed. In this section the main steps of are highlighted and briefly described.

3.1.1 Patient Data Gathering

Patient data are gathered from medical diagnosis and shoes lifecycle. Clinics and orthopedic stores are used as data acquisition points for retrieving useful information for driving custom footwear design.

One of the main goals of the research is the development of a portable gait analysis laboratory (called "Minilab") with limited overall dimensions and designed for sensing meaningful data in a diabetic foot. This measurement tool integrates a foot scanner, a baropodometric platform and gait analysis system. Scanner innovation concerns the possibility of acquiring foot geometry in a correct heel height position and simultaneously getting plantar pressure data. The resulting foot shape is represented by a mesh model from laser scanner point cloud and a pressure map of the foot sole.

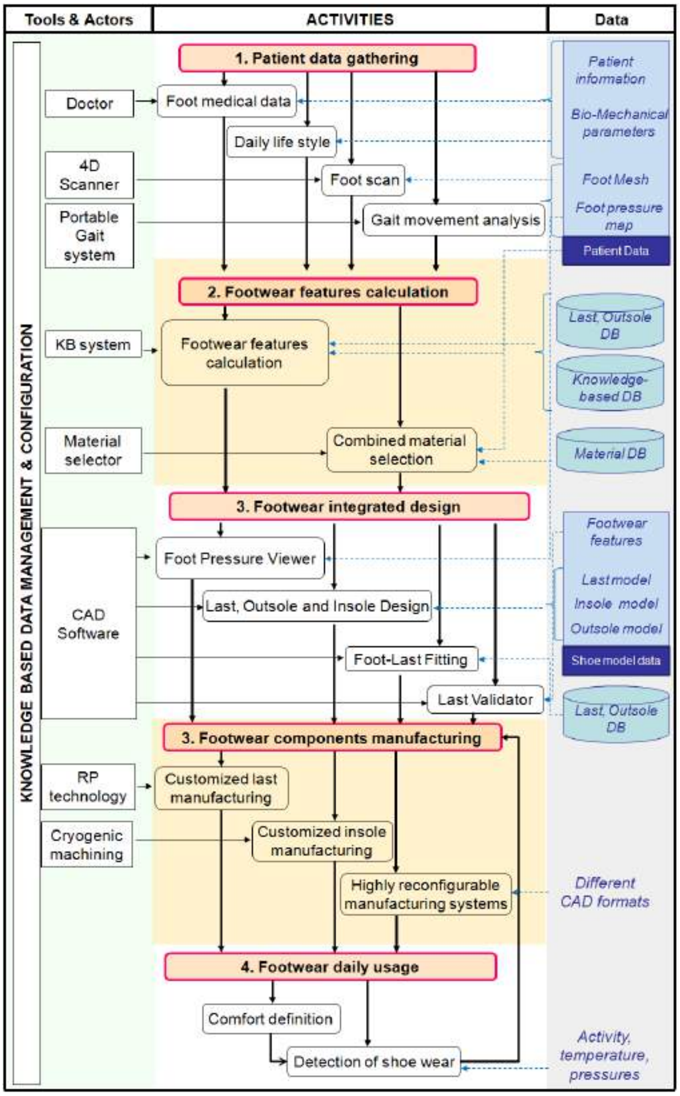

Fig. 2: Activities and tools for realizing customized shoes for diabetics.

3.1.2 Footwear Features Calculation

As next step, bio-mechanical parameters are transformed to footwear features, used to design the shoe with its components (outsole, insole, upper, etc.) by two software tools.

The first one is a knowledge based tool (KB system) that reads from a database a set of rules. They drive orthopedic technicians in the shoe design process. Rules match features to comfort and result from experimental tests on diabetic people. In fact, footwear features, in particular last and outsole geometry, influence patient comfort during daily usage. Comfort is here defined as the control and possibly reduction of new foot ulcerations.

Footwear features also include materials used for insole and outsole. The second software module helps user selecting layer materials combination. Rigidity properties of materials combined in layers have been calculated through FEM simulations and stored in a database. The stress-strain curves are available to seek for best outsole and insole load absorption properties.

3.1.3 Footwear Integrated Design System

The objective of this activity is to develop a single environment, i.e. a dedicated modular biomechanical CAD system, to accomplish shoe components design and validation. These modules read and write on the XML file in order to share the same data.

The prototypal system has been developed on the 3D CAD Rhinoceros by McNeel Inc. This general purpose CAD functionalities can be expanded by custom plug-ins developed for specific needs. In particular three modules have been studied for modeling last, insole and outsole. Two other additional plug-ins are used to compare foot with last and last with required general footwear features. As depicted in Fig.3, modules exchange data and store elaborated models in the XML data file, in order to have a single repository for each pair of shoes.

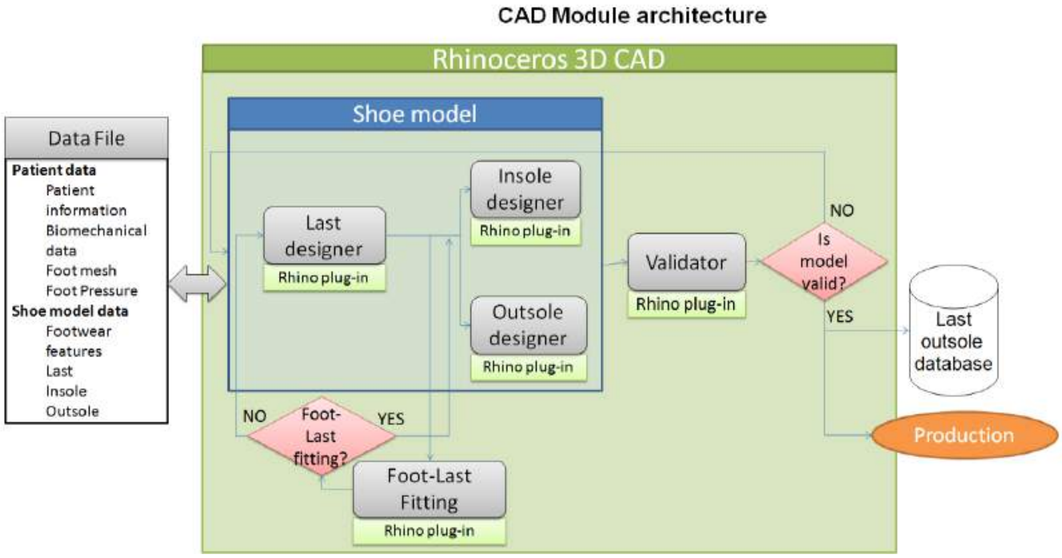

Fig. 3: Shoe components design modules.

First module concerns last modeling (*Last Designer* plug-in). It employs dedicated functionalities to handle lasts for diabetic feet also starting from an already existing physical last. Some functionalities are general purpose (for instance, heel height modification), while other ones are specific to diabetic shoes, such as apex angle variation, apex positioning and rocker angle modification.

Last geometry is defined under some constraints satisfaction. They concern fitting criteria among a set of predefined last measurements (known as ball girth, instep girth, foot length and other custom circumferences) and a corresponding set on the feet. Foot and last are compared in the same software environment in order to guarantee coherent positioning of measurement points. Foot and last are overlapped in a semi-automatic way, by algorithms that embed mostly diffused practice of technicians.

As soon as last is designed and validated, two parallel flows can start for the definition of insole and outsole. In fact, outsole and insole geometry are strictly connected to lower last surface and required footwear features. *Insole-Outsole Designer*, as further input, takes isobar curves calculated by

Foot Pressure Viewer. It is a software tool properly developed for viewing and elaborating foot pressure maps. It allows 2D pressure maps analysis but also to combine pressure data on 3D foot mesh, and elaborate isobar curves and maximum pressure points.

In this way, insole and outsole can be fully customized according to patient foot characteristics and modeled with the aim to distribute pressures on the whole sole avoiding ulceration generation or propagation.

A second validation step is employed to verify if last, outsole and insole models respond to footwear features defined by the knowledge-based system. Once again a set of discrete and meaningful measurement is used as means for comparing geometries. If deviations greater than fixed thresholds occur, the entire shoe model can be revised. Otherwise, the design process is completed, and defined model are stored within a database. Such models could be used for a new pair of shoes or for other patients.

3.1.4 Footwear Components Manufacturing and Daily Usage

When shoe models have been defined and materials for outsole and insole have been chosen, footwear components manufacturing can start. Here, the main objectives of the research concerns with the use of innovative and flexible technologies and materials, such is rapid prototyping, cryogenic machining of soft materials, casted PU materials, to shorten customized components realization time. The target has been fixed in 1 hour time for a pair of shoes.

One of the critical aspects is the possibility to export files that can be recognized by the manufacturing technologies out the data stored in the XML file. Moreover technologies should be sufficiently open to accept standardized file formats.

The ultimate objective is to match patients' needs with biomedical and biomechanical specifications. This goal includes criteria for the assessment of footwear and patient behavior after he leaves the clinic. This answers to a "*fit for purpose*" concept that is the assessment of products on long time frames.

Some testing shoes will be provided with on-board pressure sensors, in order to evaluate foot pressure distribution during daily usage. The objective of this sensor is twofold: it has to evaluate if shoe is able to fit patient's needs and to indicate when the shoe is no longer valid, because, for instance, too much insole wear has leaded to a non-uniform foot pressure distribution.

4 FOOTWEAR DESIGN SYSTEM IMPLEMENTATION

The core of the proposed diabetic footwear design process is the biomechanical CAD (B-CAD). It embeds the footwear integrated design system outlined in the previous section (points 2 and 3 of Fig. 2) and drives the product components geometries and materials definition providing data for adaptive manufacturing technologies.

B-CAD composes of a knowledge-based (KB) system, a material selector for insole and outsole and a proper CAD environment. KB manages and configures footwear from initial patient data gathering, to shoes design, till manufacturing and usage. The CAD environment will be described focusing on *Foot Pressure Viewer*, *Last Designer* and *Foot-Last* fitting modules. Insoles and outsoles modules are under development together with the material selector system since they are strictly interrelated. Insole and outsole shapes will be based on design criteria deriving from the combination of measured foot pressure and material behavior.

To deal properly with all involved geometry elements (mesh, curves, NURBS surfaces, …) the Software Development Kit of a low-cost commercial CAD software (Rhinoceros v.4.0 by McNeel) has been employed. It provides access to the CAD geometric kernel and it allows the implementation of new specific modeling functionalities. Dedicated software applications has been developed using the programming language MS Visual Basic.NET. The usage of a common platform for the set of required modules allows a homogenous environment and high data exchange capabilities.

4.1 Knowledge-based System Module

The first implemented module of the B-CAD system enables specialists to fix shoes design parameters accordingly to the specific patient needs. This module drives the footwear designer in finding appropriate geometric solutions by applying decision-making rules based on experience, medical data and measurements of the most significant biomechanical variables of the patient.

System inputs are both geometrical and non geometrical as summarized in table 1. Geometrical parameters are represented by foot shape in static and dynamic conditions, foot motion in gait and elaborated foot pressure maps. Geometries are mainly employed in shoe components design phase but, at this stage, they provide additional clinical variables as global foot deformity and pressures concentration level.

Besides, foot motion data are used for driving 3D dynamic foot geometry simulation by the foot dynamics simulation module. 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 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.

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

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 built from evidences from the literature and real test cases. The first type of knowledge is implemented in algorithms that basically filter the possible range of design parameters on the basis 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.

4.2 CAD Software

Three of the main modules forming the B-CAD system are here described with outlooks on geometrical algorithms implementation.

4.2.1 Foot Pressure Viewer

The portable "Minilab" measurement system will be constituted by a 3D laser scanner, baropodometric platform and a gait tool for static and dynamic analysis. Outputs of Minilab will be a sequence of foot pressure maps (*.bmp* or *.csv* files) and foot geometries (*.stl* mesh). The pressure maps sequence will be acquired during foot scanning, so pressure distribution over time will be analyzed. In fact, during scanning time span, patient could slightly move his body and pressure distribution changes.

Foot Pressure Viewer firstly reads a sequence of pressure maps from the baropodometric platform and extracts the one that maximize the extension of foot plantar pressure map. Pressure map is acquired in a discrete way and converted to point cloud. Only points whose pressure values are above zero are actually included. X and Y coordinates correspond to pressure sensor cell midpoint while Z represents pressure value.

The selection of the best pressure map is based on the following algorithm (see Fig. 4):

- *Foot axis calculation*, as the line that minimizes deviation among pressure points (points are projected on XY plane). Linear least squares is used to this purpose. This line represents the x axis of a local reference system used for the calculation of the following points;
- *Extraction of 1st and 5th metatarsal points*. These points are calculated as the most external points of pressure map in the local reference system. In case of multiple points lying on the most prominent region (under a certain tolerance fixed to be the grid spacing) a mean point is computed;
- *Medial metatarsal point* is the midpoint of the metatarsal points. Heel point is then computed as the most prominent point along the foot axis. Between the two possible points (toe point and heel point), the one that is more distant from medial metatarsal point is chosen.
- *Centre of pressure (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.
- Best pressure map is identified as the one that minimize distance between COP and barycentre.

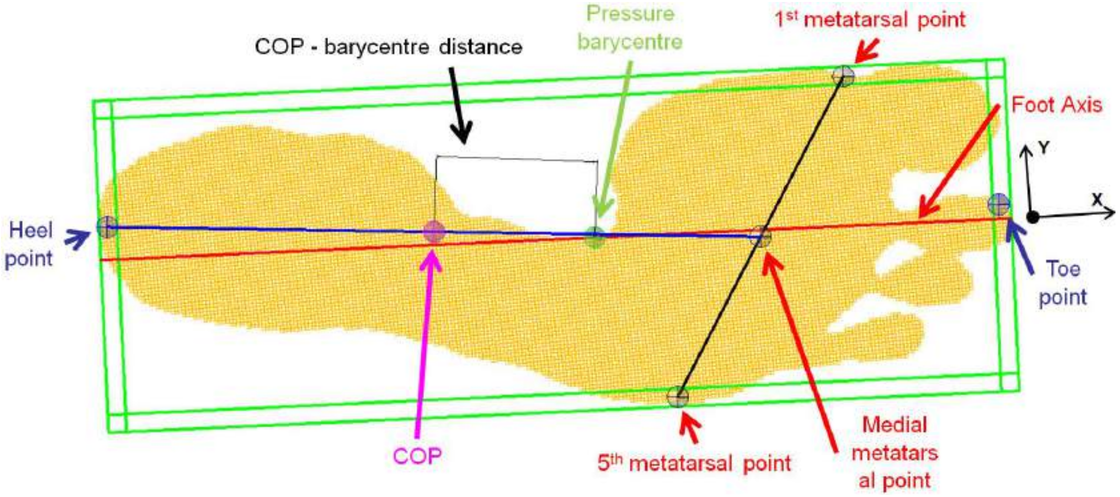

Fig. 4: Geometrical construction of characteristic points of a pressure.

Second main functionality of *Foot Pressure Viewer* concerns the automatic alignment of foot mesh with pressure map, since these geometries are expressed in different reference systems. The transformation matrix for overlapping pressure to geometry is calculated from the alignment of the

convex-hull curve of foot sole mesh and the one of pressure map. This approach has shown good reliability and efficiency.
Here are basic algorithm steps:

- Foot mesh comes from the scanner in a standard reference system (foot aligned along X axis and its sole lays on XY-plane);
- A set of points for drawing foot sole curve is built from vertices whose Z coordinate is less than a threshold value fixed to be 10 mm. Additionally only vertices belonging to facets whose normals have a negative Z component are selected. Selected points are projected onto XY plane;
- Foot sole curve is computed as the 2D convex-hull of the set of points. *Gift wrapping algorithm* developed by Jarvis [24] has been implemented for this purpose. Points are sorted along the x axis and then curve is obtained connection points after of a comparison of their polar angles;
- Pressure map curve is build from an analog convex hull of pressure point cloud;
- Curves alignment is based on an Iterative Closest Point (ICP) algorithm (Fig. 5). For a correct and fast result a rough pre-alignment algorithm is needed. Pressure map curve is pre-aligned to foot mesh curve thanks to a roto-translation drawn from the characteristic points previously extracted from the pressure map.
- ICP works on points clouds derived from uniform curves sampling (200 samples). A corresponding set of point is found on the other curve by calculating the closest points for each sample. Overlapping transformation is computed as the roto-translation that minimize the distance between the two sets of points. Best approximating transformation is computed using Moore–Penrose pseudoinverse matrix. The process is iterated until curves sample points deviation stabilizes.

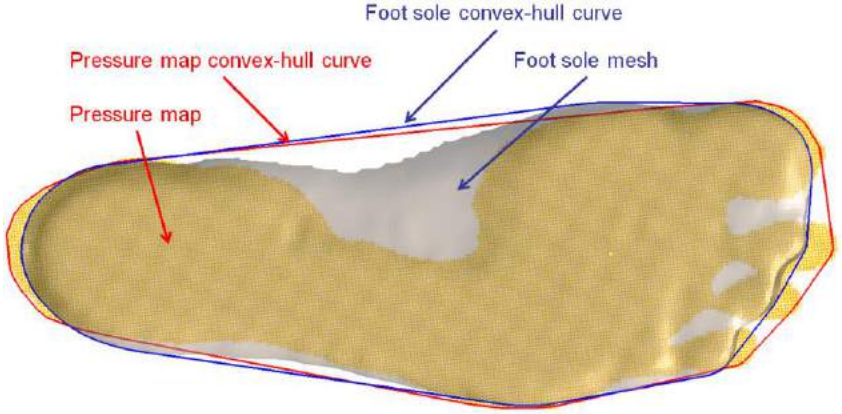

Fig. 5: Pressure map with foot geometry alignment by ICP applied to convex-hull curves.

As alignment has been reached, pressure map is projected on the foot sole mesh (Fig. 6). 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.

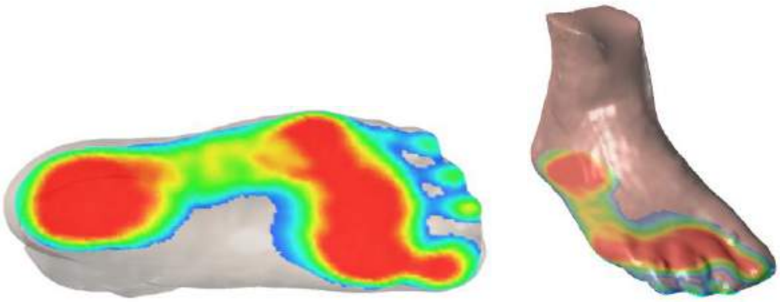

Fig. 6: Foot pressure projected on sole foot mesh.

Isobar curves have been calculated from a NURBS surface obtained from pressure map. Curves are calculated slicing this surface with parallel to XY and equidistant planes (Fig. 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.

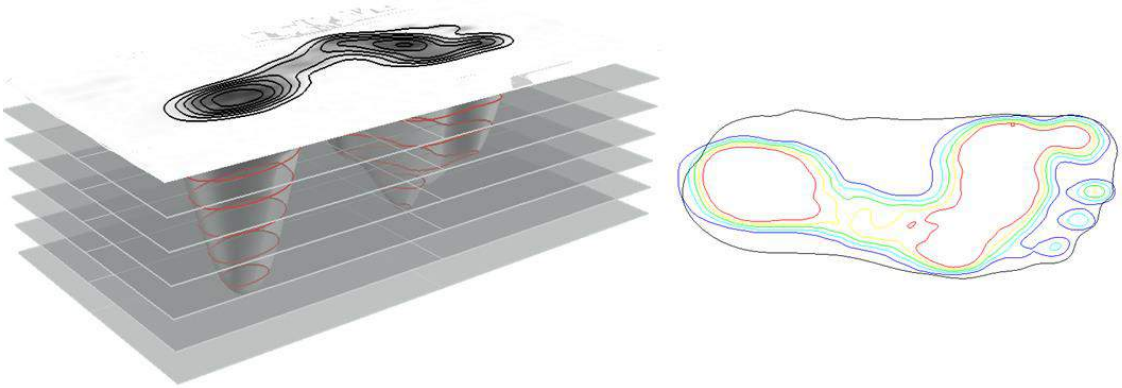

Fig. 7: Pressure surface from pressure map to be used for isobar curves calculation. In black feet profile from 3D mesh is drawn.

4.2.2 Last Designer System

Once geometrical data about foot and pressure has been acquired and elaborated, next step regards the definition of the model of a customized last. As a consequence of the complexity of the patient pathology, customized last shape must be drawn in order to cope with medical prescriptions, but also, if possible, with fashion dictates.

A set of modeling functionalities has been implemented in the *Last Designer* module. They regard foot and lasts points cloud data importing, lasts geometry creation as NURBS surfaces, modifications, exporting to milling devices and unrolling for leather cutting (Fig. 8).

The main contribution of *Last Designer* system to the state of the art is the possibility to cope with highly non standard last shapes that are required for feet affected by diabetes from a long time, e.g. amputations. Here main distinguishing features from previously proposed last modeling CADs are highlighted.

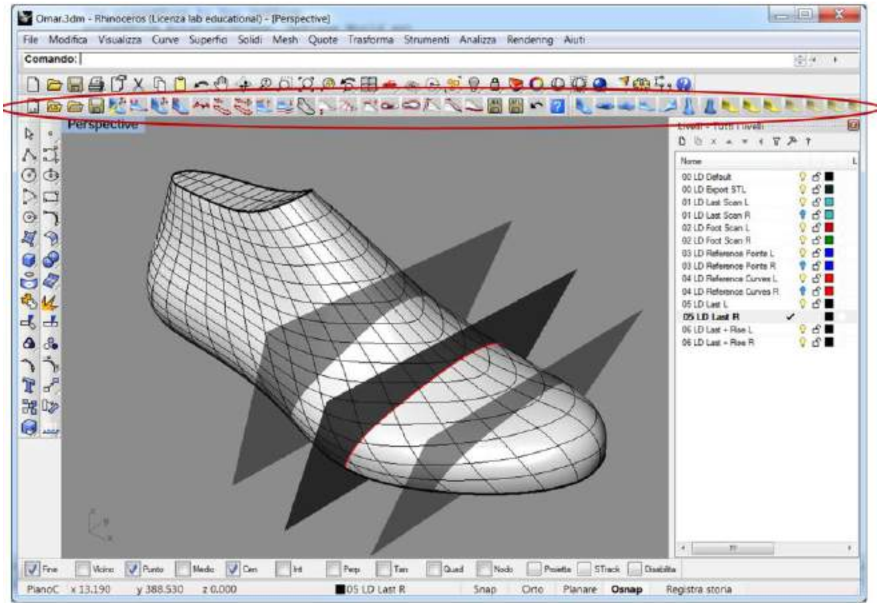

Fig. 8: LastDesigner user interface. A set of last modeling dedicated commands has been added to Rhinoceros environment.

Firstly, a triangulated mesh representing the last geometry is obtained from points cloud data. There are no limitations concerning the scanning system as long as a STL model is provided as output. Minolta V9i laser 3D scanner has been chosen for the current implementation. The main advantage of such system is the possibility to maintain acquisition quality also for highly non standard last shapes.

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 are available through macros of existing commands of Rhinoceros.

A standard last reference coordinate system has been fixed. The user 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 by fitting of the point clouds.

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, semi-automatic surfaces reconstruction has been accomplished and it is available also to operators with poor reverse engineering knowledge.

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 (Fig. 9). 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 basis of suitable deformation functions.

Modifications that target diabetic feet necessities are addressed by a sequence of deforming functions. The achieved last shape 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.

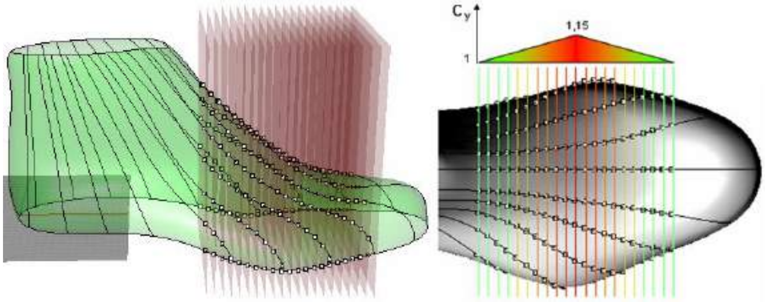

Fig. 9: Example of last virtual modification. Control vertices displacement linearly decreases from a mid target plane.

4.2.3 Outsole Design System

Analyzing results provided by the foot pressure viewer software, an orthopedic technician is able to identify three values defining the input parameters for the outsole prototype design. These parameters are: *Apex Position*, *Apex Angle* and *Rocker Angle* (Fig. 10), which clearly characterize the morphology of the upper zone of the outsole to build prototype incorporating bio-mechanical information necessary for the proper development of the dynamic features of the foot patient. The outsole bottom base curve that defines the main body of the outsole design is modified according to the input parameters mentioned above. Parametric modification of the parameters involves a recalculation and automatic regeneration of the surfaces that conform the outsole prototype, generating in an automatic way the parametric model. The final outsole surfaces are generated thanks to links between upper and bottom outsole base curves. These links are parametrically defined and the rectification of base curves involve the automatic regeneration of them.

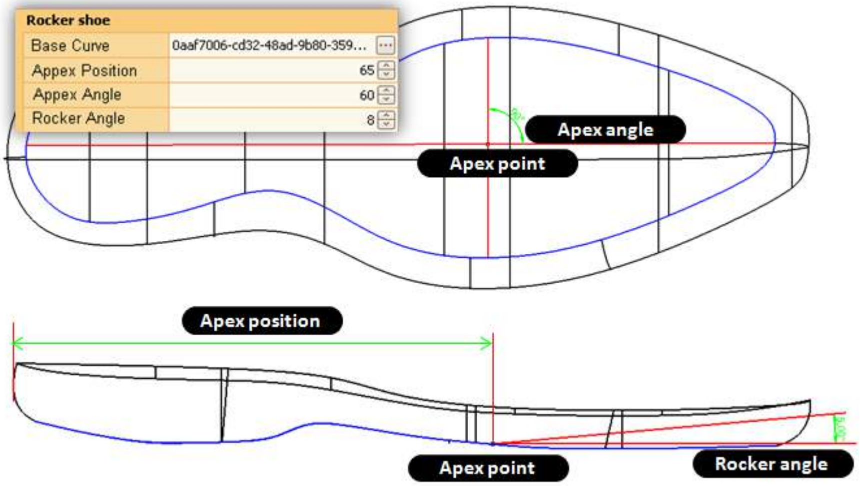

Fig. 10: Outsole geometry for a diabetic patient with characteristic features (*apex angle*, *apex position* and *rocker angle*).

4.2.4 Foot-Last Fitting

The aim of this module is to measure a foot and its last, when they are both oriented using the same procedure. This 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 characteristic points (1st , 5th metatarsal points for instance). This module is used to import last and foot, both as *stl* meshes and pre-aligned respectively by the last design module and software scanner.

Alignment procedure is made by following steps (Fig. 11):

- *Foot or last alignment with XZ plane*: the rear most prominent point of mesh, along x axis, is firstly calculated. 1st and 5th metatarsal points are then calculated as the most prominent points along y axis. The axis connecting HL and CL points (CL is the medium metatarsal point), called foot or last axis, has to be aligned with x axis;
- *Insole foot axis or insole last axis tangent with the x axis in SPL point*: first of all the foot insole axis and last insole axis must be calculated (they are two curves). they are calculated projecting respectively foot and last axis on the insole geometry of foot and last mesh. SPL point is calculated projecting CL on the foot or last insole axis. Foot or last insole axis must be tangent to x axis on SPL point;
- *Foot or last heel tangent to Z axis*: the rear most prominent point must be located on z axis;
- *Foot or last geometry symmetry on XZ plane*: the curve calculated sectioning the mesh with a plane parallel to YZ passing on CL has to be symmetric respect XZ plane. Symmetry is guaranteed with a rotation around HL-SPL axis till D1 is equal to D2;
-

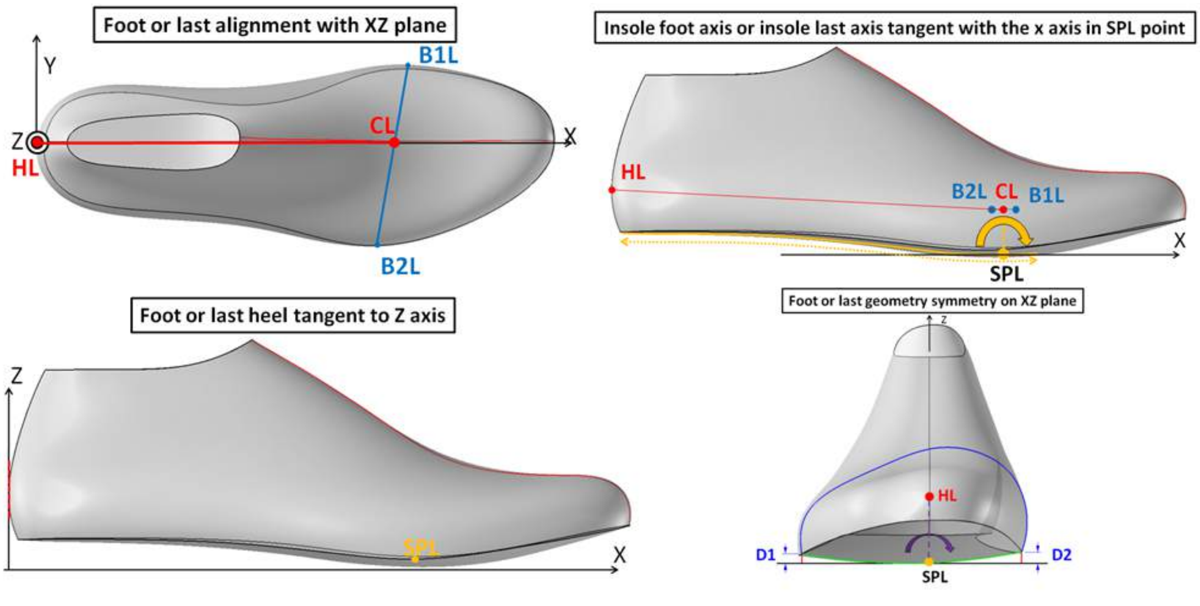

Fig. 11: Criteria for the orientation of foot and last in univocal manner.

Once geometries have been aligned, the measuring phase will begin. First of all, foot and last basic points are computed, then, measurements are calculated as distances among points or curves length, sectioning foot or last with specific planes. Some typical measures are: 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.

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).

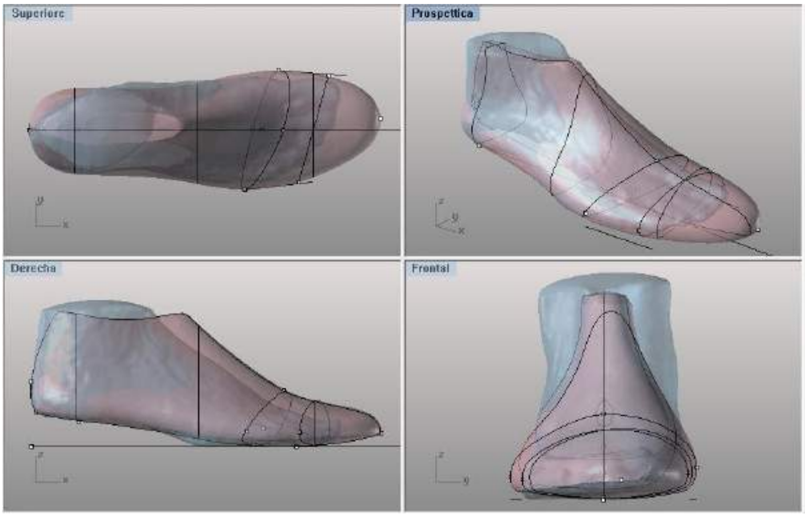

Fig. 12: Module to compare last and foot.

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 table form 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 RESULTS

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 (Fig. 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.

Fig. 23: 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.

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.

	Traditional process [minutes]	Proposed process [minutes]	Improvement [minutes]
Patient data gathering			
Foot pressure and geometry measurement and preliminary data elaboration	15 (foot geometry is manually measured and foot pressure is reported in 2D files)	3 (for this phase the new process proposes a traditional 3D scanner and a baropodometric platform; the "Minilab" is not still experimented)	-12
Footwear features calculation			
Footwear features calculation	20	4 (material selector is not still experimented)	-18
Footwear integrated design			
Foot pressure visualization	-	2	+2
Last	40	20	-20
Insole-Outsole	25	20 (the current advantage is due to the data deriving from the pressure viewer tool: the benefits of the Insole-Outsole Designer module are not considered))	-5
Foot-Last fitting	35	2	-33
Total time	135	51	-86

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

This table presents process time by using proposed software tools, these ones are compared with the traditional shoe design process. During patient data gathering, foot scanner, baropodometric platform and gait analysis are three separated systems and they are not integrated in a single portable laboratory. For footwear features calculation, in a traditional process there is not any knowledge-based software tool, able to help orthopedic technician during shoe design.

The adopted systems, even if the experimentation is still limited (only one company and two operators involved), seems very usable and saved time is really relevant (-64%). Anyway, more meaningful results will be achieved when the whole design and manufacturing framework will be implemented. In that case the validation will imply both the system performance measurement and the quality of developed shoes in terms of medical results (prevention of ulcers).

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 valuator). In parallel many efforts will be done to completely develop the whole framework and relative adaptive manufacturing systems.

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