



## A CAD Tool to Design Bespoke Insoles for Severe Orthopaedic Treatments

Marco Mandolini<sup>1</sup>, Massimiliano Carloni Vitali<sup>1</sup>, Alessandro Macchione<sup>1</sup>, Roberto Raffaelli<sup>2</sup> and Michele Germani<sup>1</sup>

<sup>1</sup>Università Politecnica delle Marche, [m.mandolini@univpm.it](mailto:m.mandolini@univpm.it), [m.carloni@univpm.it](mailto:m.carloni@univpm.it),  
[a.macchione@univpm.it](mailto:a.macchione@univpm.it), [m.germani@univpm.it](mailto:m.germani@univpm.it)

<sup>2</sup>Università degli Studi eCampus, [roberto.raffaelli@uniecampus.it](mailto:roberto.raffaelli@uniecampus.it)

### ABSTRACT

Patients affected by serious foot pathologies often require special orthotics to stand and walk correctly. Skilled operators obtain such insoles on the basis of manual procedures and following the prescriptions of orthopaedic technicians. The process is handicraft and time consuming. The paper presents a virtual prototyping approach which is based on dedicated foot scanners, CAD-based design tool and milling machines to obtain the bespoke footwear orthotics. The major contribution is a geometric procedure to design complex insole shapes starting from the foot scan and highly customized shoe lasts which are required in case of important deformities.

The approach has been tested on several patients thanks to the collaboration with a partner insole producer and some orthopaedic centers. Patients have generally reported positive feedbacks on the comfort and functionality of the insoles.

**Keywords:** insole design, orthopaedic custom-made insoles, foot orthotics.

### 1. INTRODUCTION

During the last decades, the footwear sector was characterized by a strong computerization of the product development process, from the foot diagnosis to the manufacturing of the shoe. In such trend three main moments of intervention emerge:

- a foot diagnosis stage, in which dedicated 3D scanners are more and more used to achieve the virtual geometry of the foot;
- a footwear design stage, where the footwear and related accessories (last, upper, insole and outsole) are designed by customized CAD systems;
- a production stage, where CNC machines are employed to manufacture the shoe components.

For the orthopedic footwear sector, this changeover is more complex than the non-orthopedic one, due to the variability of footwear customizations to meet the foot pathologies. Many shoe pathologies are prevented or treated with custom made shoes and custom made insoles. A custom made shoe is realized on the basis of a bespoke last. The last is a wooden or plastic shape, resembling a foot, which provides the final volumetric shape to the shoe. The last is therefore important to provide an aesthetic value as well as comfort and health to the foot. The literature around

last customization and relative design tool is vast [2], [14], [11] and [7].

The role played by the insole is recognized as the most important for the majority of the foot pathologies, so relevant work is focused on this component. The research seeks to replicate in software design tools the manual operations carried out by experienced shoemakers. The literature of the last years presents frameworks of CAD [8] and CAM systems for customized insole [5]. In these works, the target is set on the insole modeling, considering the foot plantar pressure and foot geometry. However, the 3D shape of a bespoke shoe last is neglected.

More advanced design systems are proposed in [1] and [10]. However, the foot pathologies addressed by the resulting insoles are limited. For instance, there is no possibility to model insoles for severe deformities such as amputated feet or clubfeet. Additional insole design approaches are presented in [4] and [15], where CAD and CAE systems are combined together. Finite Element Methods are used to simulate the interaction between the insole and the foot, in order to achieve the best geometry and materials combination.

From an industrial point of view, some CAD-based solutions are offered on the market. They consist of software tools to design custom-made insoles and aiming at replacing the manual manufacturing

processes. The most popular ones are *Correct and Confirm*<sup>®</sup> (by Amfit) [6], *OrthoModel*<sup>®</sup> (by Delcam) [12], *Canfit InsoleDesigner*<sup>®</sup> (by Vorum) [3], *Insole-Designer*<sup>®</sup> (By Pedcad) [9] and *paroContour-System*<sup>®</sup> (by Paromed) [13]. The major limitation of such software is the substantial inapplicability to the orthopaedic field addressed in this paper. In fact, the tools have been conceived to design insoles for non-pathologic feet (clubfoot or amputated foot). In these cases a custom made shoe last is not required as input to the design process Fig. 1(a). A typical case of applicability for such a system is related to the design of preventive insoles for the diabetic foot. The objective is to uniform the foot plantar pressure to avoid ulcerations due to the lack of sensitivity to pain of the diabetes sufferer. As the literature highlights, a shoe for the diabetic foot do not generally need a customized shoe last. As a consequence, the existing tools do not consider the shoe last during the insole design workflow.

Generally speaking, insoles play a key role for the correct gait of the patient and they have to be designed starting from a custom made shoe last. In case of complicated pathologies, as in the case of amputated feet or clubfeet, the insole has the delicate task of supporting the foot in a correct position (Fig. 1(b)). In fact, the foot may be deformed, blocked or unable to assume natural shapes. In such cases, the manual procedure to realize a custom insole need to be carefully analyzed and formalized in a set of geometric operators to reproduce in a CAD environment the steps actuated by experienced technicians. The presented software is not an improvement of the solutions/prototypes already existing in the market/academic domains, but it is completely different since the insole is modeled considering the geometries of the foot and shoe last.

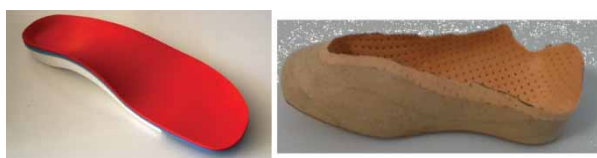


Fig. 1: An example of two kind of insoles: (a) for “normal” feet, and (b) for feet with serious deformities.

The aim of the present work is to develop a knowledge-based design tool to reproduce in a CAD environment the complex steps of realizing insole for severe foot pathologies. Thanks to a set of dedicated geometric operators, the user is able to model an insole following the anatomical characteristics of the foot. The obtained model is the produced thanks to milling machines. The ultimate goals of the research are the formalization of the technicians’ knowledge, the possibility of train novice operators on more

appealing working tools and standardize insole production procedures overcoming the traditional handcraft approach.

## 2. APPROACH AND PLATFORM DESCRIPTION

The previous section highlighted the lack of software tools to be used for the production of custom made insole for sever foot pathologies, so that the manufacturing companies of insoles, or the orthopaedic centers, are forced to use handcraft procedures. In this scenario, the paper presents a CAD tool to design bespoke footwear orthotics, fully integrated with the other devices of an innovative production process. It aims to transform the traditional process, based on manual activities toward a more technological development, leveraging the advantages given by electronic files, software tools and CNC machines. The following section presents the nowadays production process used for the kind of orthotics discussed in this paper and the innovative alternative based on the use of the Insole Designer software tool. The second section describes the CAD tool architecture and procedure followed for the insole modeling.

### 2.1. Insole Production Framework: The Status Quo and the Proposed Concept

The traditional insole development process, described in Fig. 2(a), starts when the podiatrist takes the cast of the foot using a foam box. A very important stage where the doctor needs to manually block the foot in a specific position to correct its pathology (i.e. adjust the crimping profile, pronation or supination). The foot negative shape is used to create the positive one using the casting plaster process. The plantar surface of shape achieved so far is then modified by the expert in order to include additions to functionalize the insole. Hence, the manufacturing process starts using sheets of thermoforming materials, glued among them to achieved the required insole thickness and hardness. Once the sheets have been heated, a vacuum machine is used to shape them on the foot cast plaster. Finally, a sander is manually used to finish the insole. The presented process does not consider any software tool or numerical control machine. The main drawbacks of such a procedure consist in the need of expert technicians for each stage, the use of physical prototypes for the foot geometry and the high lead time (as demonstrated in chapter 3).

The CAD tool presented in this paper needs to be contextualized in a completely new process based on the use of a foot scanner, software tools and numerical control machines, as depicted in Fig. 2(b). The foot scanner thought and developed for this process is based on a new concept, not available among the commercial solutions (*Contact digitizer*<sup>®</sup> by Amfit, *Footclinic*<sup>®</sup> by Footclinic and *Podoprofil*<sup>®</sup> by LuxOrtho).

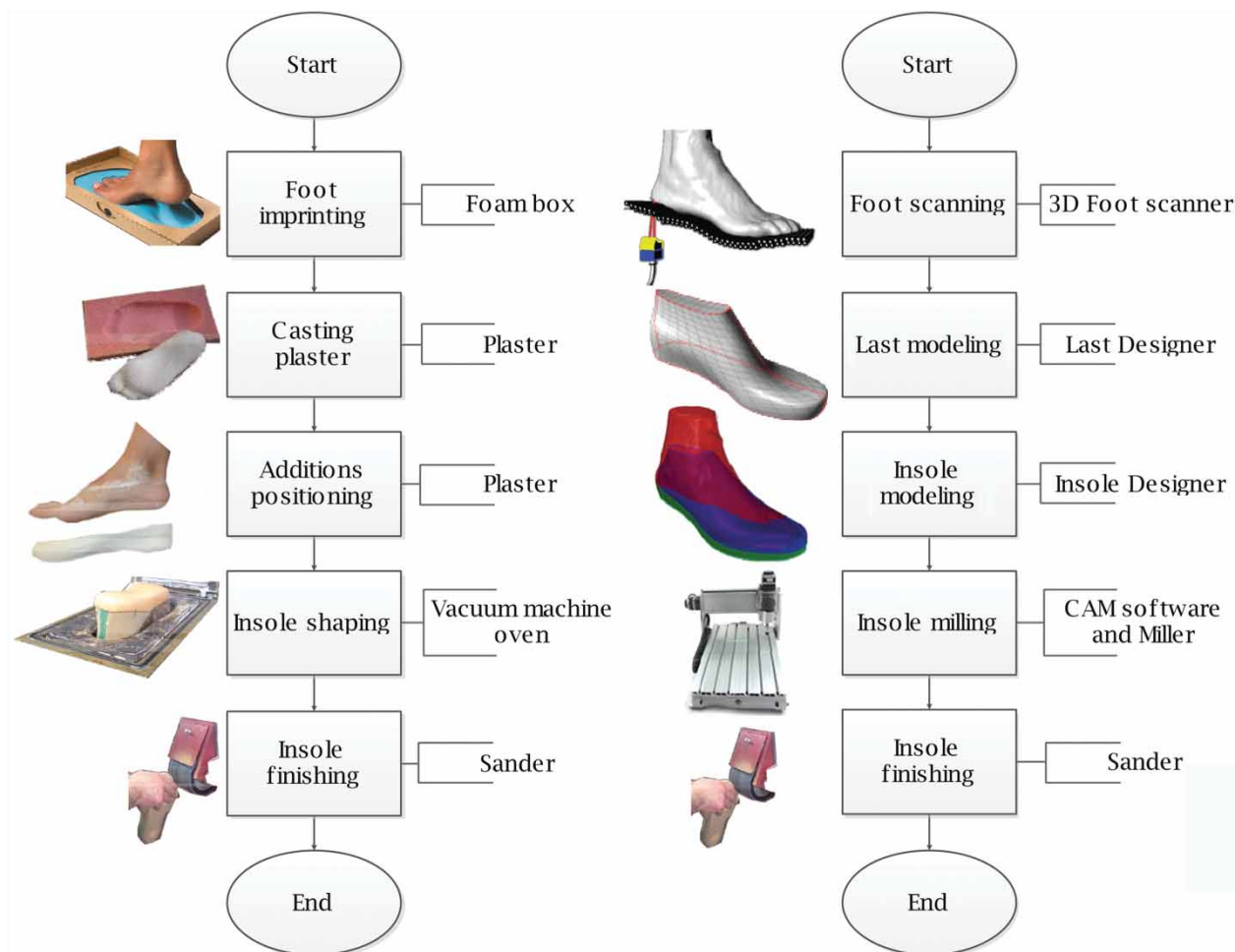


Fig. 2: The production processes of a custom made insole: (a) procedure used so far, based on a handmade approach (b) procedure proposed and supported by a foot scanner, CAD-CAM tools and CNC milling.

The foot is fully supported by a sequence of a rototranslating bars, whose axis is perpendicular to the foot, to adjust the foot crimping profile and pronosupination. Using such a device, the podiatrist is able to digitize the foot in the real orientation it will have once inside the shoe. The main advantages of this scanner consists in the real sensation given to the patient and in the better quality of final foot geometry. The last point is very important since the foot shape could be easily overlapped with the shoe last (the foot and shoe crimping profiles are considered being equals). Traditional scanners digitize the foot standing on a flat surface.

The next step of the proposed procedure consists in designing the shoe last, using a dedicated CAD tool [2]. The achieved volume is designed to contain the foot and insole volumes. The shoe last and foot geometries are then used to model the insole, as described in the following section. Once the 3D insole geometry is ready, a CAM tool is used to calculate the tool path of a miller, which will be used for the manufacturing. In the case of insoles for amputated

feet, the products is decomposed in several parts machined separately and then glued. Since the number of required grips for these cases, required to fully machine the workpiece, a final manual finishing operation is required. In this procedure, the CAD (LastDesigner<sup>®</sup> and InsoleDesigner) and CAM tools are part of a same platform (*Rhinoceros*, by McNeel Inc.) to favour the data exchange.

## 2.2. System Architecture

The general purpose 3D CAD system *Rhinoceros* version 5 (by McNeel Inc.) has been used to implement the design tool described above. A plug-in, namely *InsoleDesigner*, has been developed using the VB.NET language leveraging the availability of the *Rhino\_DotNET* Application Programming Interface (API). The plug-in defines new commands triggered through controls of a panel added to the User Interface. New commands are created combining the native ones and algorithms developed on purpose.

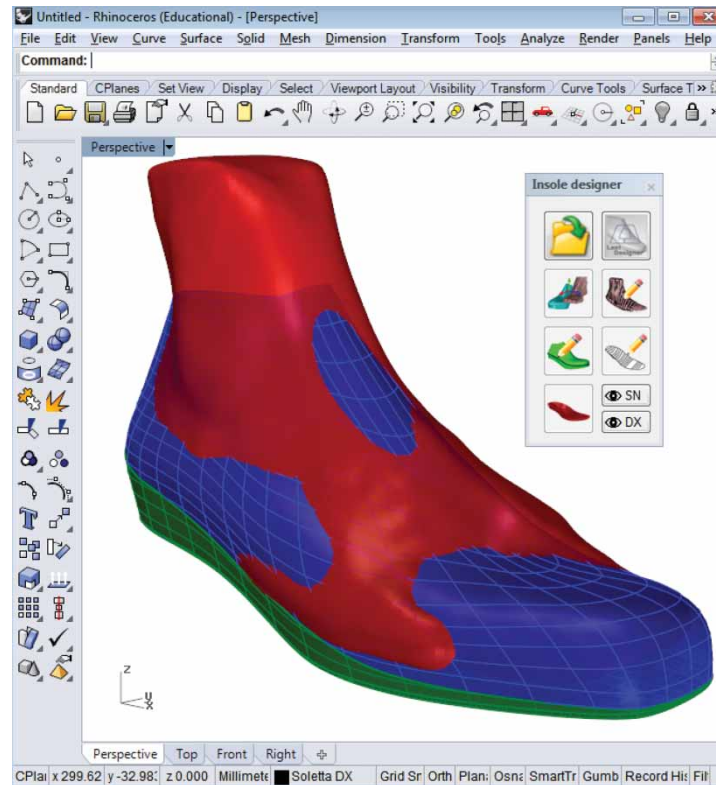


Fig. 3: Insole designer user interface. The panel with the six modeling steps is visible on the right. In the graphical area the overlapping of the foot scan (red) with the last model (blue) is shown. A standard custom made insole is shown in green.

The geometric definition process of an insole follows six main steps, a design wizard which is evident in a dedicated panel on the program user interface (Fig. 3):

1. Foot scan and last surface loading
2. Alignment of the foot with the last
3. Section curves creation from the sole of the foot
4. Definition of the insole lateral profile
5. Creation of the curve network of the insole surface
6. Insole volume generation

The following Fig. 4 depicts the main geometric elements on which the hereafter described procedure is built. The resulting insole volume will be finally composed of three surfaces:

- the top surface in contact with the foot, i.e. the *insole sole surface*;
- the bottom surface which is in contact with the outsole and matches the last bottom surface;
- the lateral surface which delimits the insole volume in order to be contained inside the last, i.e. the *insole lateral surface*.

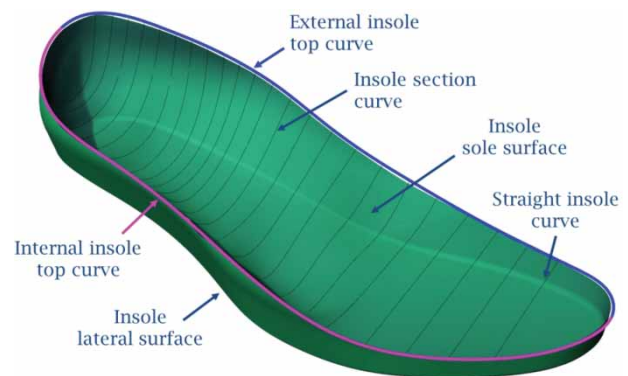


Fig. 4: Main geometrical elements involved in the definition of the insole model.

The design steps and the relative geometric algorithms are described in the following paragraphs.

### 2.2.1. Foot scan and last surface loading

The software has been conceived to operate on both the left and right foot. The following description focuses on only the right side, since the left side is similar.



Foot is imported from a digitalization process by laser or optical system in \*.stl format. Depending on the available technology and the pathology of the foot, the orthopaedic technician could choose for a direct acquisition of the foot or a negative copy of it, such as a plaster cast or a foam impression. Scanning systems software or standard Reverse Engineering software is used to create the mesh of the foot through registering and merging the single scans if necessary. Indeed, only the lower part of the foot shape is necessary to realize a correct insole, so the foot scan does not necessary need to be complete. Typical scanning imperfections, such as holes, degenerate and/or crossing facets, are tolerated and to a certain extent do not compromise the approach.

The last is input by three surfaces, namely the sole, the upper and the top. Possible formats include \*.igs and \*.3dm, i.e. the Rhinoceros native format. The last is modeled adopting a suitable orthopaedic design tool, such as the one described in Bernabéu et al.[2]. The main characteristic of the last is the presence of a volume to accommodate the insole. At the end of the process, the last shape should result as the union of the insole and the foot volumes.

### 2.2.2. Alignment of the foot with the last

The alignment of the foot within the last volume is a critical step. The last shape does not necessary reproduce the shape of the foot and some significant deviations are clearly visible in Fig. 3. The last usually bounds the shape of the foot in the lower region, even if sometimes the foot is wider than the last in the metatarsal area. Also in the ankle area the last is much smaller than the foot. In fact, the shoe materials are flexible and it is reasonable to have some parts to act as a containment of the foot.

In [2] a method is described to obtain repeatable and consistent alignment. The algorithm is based on some key points and ensures that the foot is centered in the last. The two volumes are laid on the x-y plane and aligned along the reference x axis. Then, the foot is moved up to leave thickness for the insole as specified by the orthopaedic technician. Small manual adjustments are possible to improve the relative positioning.

### 2.2.3. Section curves creation from the sole of the foot

In this step parallel section curves of the foot are created. The geometry of such curves is reworked to obtain the upper surface of the plantar, the *insole sole surface*. Such surface shape should be adherent to the foot sole morphology to guarantee comfort to the patient. However, the resulting surface should be smooth and filter the noise due to the scanning imperfections.

The section curves are obtained as follows. A bounding box of the foot mesh is firstly computed

to have the extension of the foot along the x axis. The foot is intersected with a set of vertical planes which are normal to the x axis starting from the back of the foot until a certain percentage of its length. The user controls the procedure with two factors: the portion of foot being sectioned and the distance between two consecutive sections.

The first parameter is important to determine the portion of the insole which needs to follow the sole of the foot. In fact, in the front region, usually the shape is flat and does not copy the shape of the foot toes. The step of sectioning can be varied as it acts as smoothing factor, since higher steps means a lower definition in the foot sole shape capturing. As default option, the foot is sectioned using 7 mm step in the heel area, where the curvatures are higher, and then every 15 mm.

Each intersection of the foot mesh with a plane is reworked as follows:

- Each intersection produces one or more poly-lines due to the discontinuities and the holes in the mesh. Polylines are joined together with pieces of Hermite curves covering the gaps between the closest open ends of the polylines. The result is a continuous curve.
- The curve is sampled at 100 points which are equally spaced. Spline curves are then interpolated through the points. The number of the samples can be varied to control the smoothness of the resulting curves.

### 2.2.4. Definition of the insole lateral profile

The lateral profile, i.e. the height where the insole ends, is specified by the orthopedic technician on the basis of the necessary supporting function on the foot. Typical profiles are available depending on the desired grade of wrapping of the insole around the foot. In order to guarantee flexibility, the user has the possibility of choosing standard profiles from a database or drawing custom inner and outer profiles on lateral views. In the first case profiles are imported as curve pairs which are scaled on the foot length.

The two profiles are positioned on the sides of the last and are used to create a loft surface, namely the *delimit loft surface* (Fig. 5). The surface connects the two profiles linearly. Such surface is intersected with the last lateral surface, i.e. the upper surface, to obtain the insole upper curve. Such curve is offset by a small distance to take in account numerical problems which may emerge in the following steps. The offset curve is finally split in two halves by the extreme points along the x axis. The resulting curves are named as *external insole top curve* and *internal insole top curve* respectively Fig. 4.

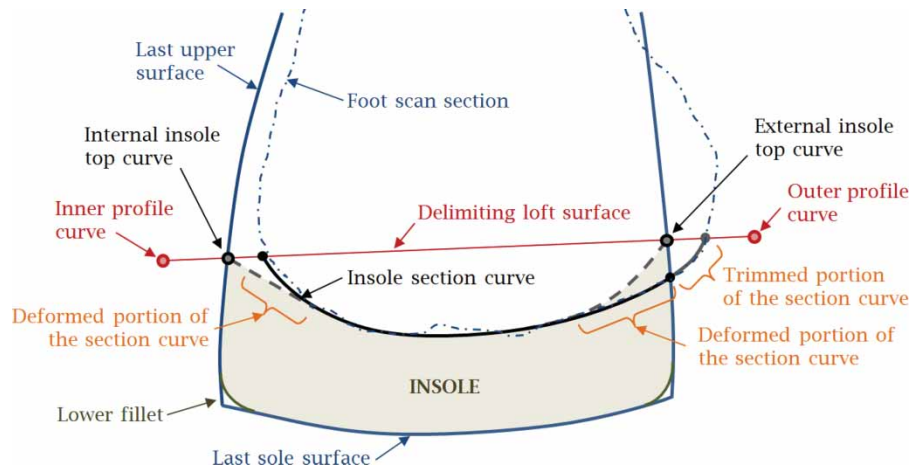


Fig. 5: Representation of the geometric elements taking part of the insole construction in a generic section normal to the x axis.

### 2.2.5. Creation of the curve network of the insole surface

In the third step, the set of foot section curves is elaborated to generate a surface. Initially, each interpolated section curve is split in two parts, a lower and an upper one, by the intersection with the delimiting loft surface. The upper half is deleted. Then the end points of the lower portion are connected to the two insole top curves. Two sub-phases have been introduced.

At first, the section curves are further delimited by the last upper surface. As previously highlighted, two opposite cases are possible. In some areas the foot is contained in the last while in others the foot exceeds the last. Therefore, if a section curve exceeds the last in any or both the sides, it is trimmed by the last border.

Secondly, the end points of the section curves are connected to the insole upper curve. The extreme

portion of the curve is smoothly modified so that the end of the curve becomes the intersection of the insole top curve with the plane originally used to compute the section.

Fig. 6 depicts the algorithm used to modify the extreme portions of the curve to meet the new end point.

The first input to the algorithm is a given by the new end point and a region to be searched for sending a tangent line from the new end point to the curve. The tangency search region is given as a percentage of the curve length. Then two cases are distinguished. In a first case, the tangent is found in the search region as in Fig. 6(a). In this case the Control Vertex (CV) points between the curve end point and the point of tangency are translated on the line respecting the original distribution. If the tangent line cannot be found (Fig. 6(b)), a second parameter is introduced, i.e. the ratio of the affected region. The CVs included in

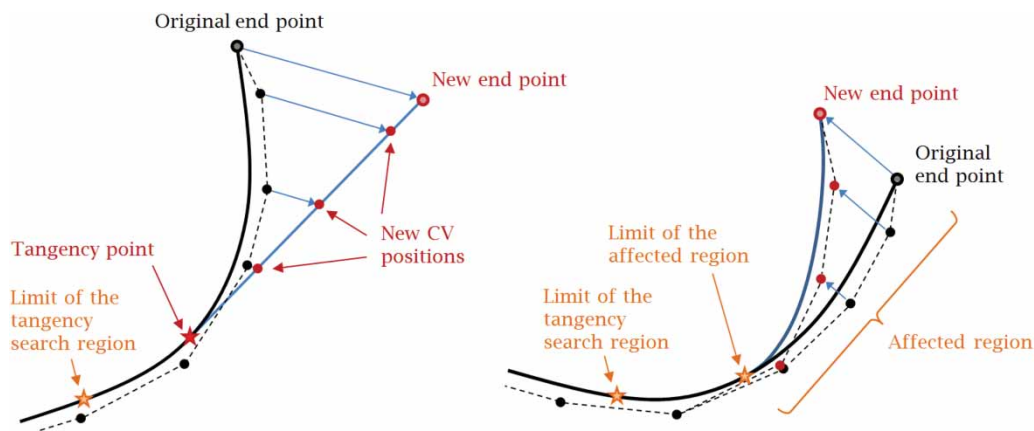


Fig. 6: Curve end point modification algorithm: on the left (a) the CVs of the curve extreme portion are aligned on a tangent line from the new end point; on the right (b) the CVs are deformed proportionally to the end point translation.

this region are translated by the end point translation mitigated by a factor. The factor varies from 0 at the limit of the affected region to 1 at the end point, proportionally to the curved abscissa.

In the front part of the insole, between metatarsal and toe, foot section planes have not been generated. There, the remaining section curves are covered with straight lines.

### 2.2.6. Insole volume generation

In the last step the insole sole surface is created from a curve network. The foot section curves from the previous step are used in conjunction with the external and internal insole top curves.

The obtained surface is used to split the last upper surface. The lower portion is used as the lateral surface of the insole. The insole sole surface is then delimited to eliminate the exceeding portion due to the offset of the top profile curves. The last sole surface is finally used to close the insole at its bottom once its normal orientation is reversed.

The lateral and the lower surfaces of the insole are blended to form a fillet around the circumference. This helps the insole to be accommodated in the shoe. Finally, the four surfaces, i.e. upper, lateral, blend and lower, are joined to form a close watertight volume.

## 3. EVALUATION OF THE DESIGN SYSTEM

The proposed approach has been tested within an Italian orthopedic footwear company, aiming at changing the traditional manual manufacturing processes with more innovative ones, based on the use of 3D foot digitizers, design software tools and milling machines for the shoe components manufacturing.

The partner company is a leader in the field of orthopaedic footwear manufacturing. Its production ranges from therapeutic and prepared shoes for children and adult to customized shoes for foot affected from specific pathologies. Thanks to the know-how of the most experienced technicians, the company provided important guidelines about the functionality of the insole design tool. Indeed, it has been possible to evaluate on real test cases the results achieved with the developed software tool.

### 3.1. Experimentation Campaign

The main purpose of the validation phase was the determination of the results achieved with the introduction of the "Insole Designer" in the design and manufacturing process of the insole. At first, the reduction of the production time compared to the traditional manufacturing process was evaluated. The main benefit is the availability of a digital model of the insole to be machined with a milling machine. This basically allows the traditional manual manufacturing process to be transformed in an automated

one. The second objective of the testing activity was the assessment of the functional and comfort characteristics of the insole created with the new approach compared with the traditional one. The main aims of the campaign were the assessment of the comfort, the acceptability of the patient, the capacity of the orthotics to maintain its function, shape and consistence after a period of use.

The tests were carried out with the help of some orthopaedic centers, customers of the partner company, which recruited some patients in order to make experimentations. 20 people (10 man and 10 women) were selected in total. They were identified from a medical point of view, gathering data on the clinical history and evolution of the foot pathology. Patients were chosen to have heterogeneous distribution of sex, age and pathology as reported in the Tab. 1. This reference group provided a wide base of different design situations, which allowed the introduced design tools to be deeply tested. The patients have been selected to represent the main pathologies of the feet. The experimentation has been principally carried out to evaluate the impact of the proposed software tool within the insole development process of an orthopaedic footwear company. Even if this experimentation is too small to be classified as clinical validation (just 20 people) it is sufficient to get the preliminary impression from the patients. The industrial partner is using the CAD system during the insole production and the authors foreseen a future paper focused on the clinical validation.

The insole production process starts scanning the feet, using a dedicated 3D optical scanner and/or the traditional foam boxes. In this way, both digital and traditional data were available to proceed with a comparison of the standard and the proposed manufacturing processes. The insoles were produced thanks to the company facilities and operators. Four technicians were involved in the activity. Two of them realized the insoles manually, using the standard procedures commonly adopted. Both last and insole were obtained from the manual measurements of the patient feet and the foam impressions. The insoles were realized by thermoforming and carving the material (Ethylene Vinyl Acetate and cork).

The other two technicians have experimented the digital design and production process. Firstly, they have modeled the last using *LastDesigner* software system, available within the company. The *InsoleDesigner* was then used to combine the shape of the last and the foot to achieve the insole geometry as described in the previous section. The physical orthotics were obtained by a milling machine with the same type of material. A CAM software (*RhinoCAM* by *MecSoft Corporation*) was used to define the working schedule which was finally used by a milling machine to manufacture the insoles (*Tecnocnc Professional 36-600*, by *Creostamp*).

Age	Men (10 patients)			
	15-30	31-45	46-60	Over 60
Number of patients -(range of BMI)	2 - (19-24,99)	2 - (19-24,99)	1 - (19-24,99) 2 - (25-29,99)	1 - (19-24,99) 2 - (25-29,99)
Number of patients -(kind of activity)	1 - (Active) 2 - (Low)	1 - (Active) 1 - (Normal)	1 - (Normal) 2 - (Low)	1 - (Normal) 2 - (Low)
Number of patients -(Disease)	1 - (Flat foot) 1 - (clubfoot)	1 - (Pes cavous) 1 - (Hammer toes)	1 - (Pes cavous) 1 - (Hallux valgus) 1 - (Diabetic foot)	1 - (Flat foot) 2 - (Diabetic foot)
Sensations of the patients	Both of them said that the difference between the insole made by old and new method is very small. In particular, the insoles made by new method are little harder than others.	The patient affected by "pes cavous" said that the traditional insole fits better the foot arch	The three patients report that the insoles are comfortable. The orthotics made by the new method results rougher than the others.	Both patients with diabetic foot felt a little difference on the surface of insole. The orthotic made by new method is softer than the others.
Age	Women (10 patients)			
	15-30	31-45	46-60	Over 60
Number of patients -(range of BMI)	2 - (19-24,99) 1 - (25-29,99)	2 - (19-24,99)	1 - (19-24,99) 1 - (25-29,99)	2 - (19-24,99) 1 - (25-29,99)
Number of patients -(kind of activity)	2 - (Active) 1 - (Low)	2 - (Active)	1 - (Normal) 1 - (Low)	2 - (Normal) 1 - (Low)
Number of patients -(Disease)	1 - (Hammer toes) 2 - (Flat foot)	1 - (Hammer toes) 1 - (Hallux valgus)	1 - (Pes cavous) 1 - (Diabetic foot)	1 - (Pes cavous) 1 - (Diabetic foot) 1 - (Flat foot)
Sensations of the patients	The insole made by the new method result more comfortable.	Both patients complain that new insoles are a little bit harder than the others.	Both patients said that the insoles made by the new method fit better the foot arch	The three patients are really satisfied of the new insole. No differences felt with the others.

Tab. 1: Details on the group of patients involved in the tests.

After the distribution of the insoles to the patients, they were asked to daily wear the orthotics, alternating the traditional and the digital types after two weeks. The orthopaedic technicians also gave some instructions for a correct use and care of the orthotics. After the first month, the patients were recalled in orthopaedic centers and questioned on the perceived comfort, the presence of skin abrasions or even pain, comparing the two types of orthotics. In addition, the orthopaedic technician has personally inspected the insole to assess the state of the materials, degradation and capacity of still performing the desired supporting function. The testing procedure was repeated for another month and then again after 6 months.

### 3.2. Results and Discussion

The testing phase has highlighted significant advantages in the introduction of the virtual design approach. The first one consists in a considerable reduction of the production time of the plantar, which passes from an average of 55 minutes for a couple of orthotics, to 33 minutes, with a time savings of approximately 40 percent as shown in Tab. 2. In the virtual process the time for realizing the virtual model using the *InsoleDesigner* is approximately of 10 minutes. The rest of the time is necessary for the milling phase, which strongly depends by the complexity of the insole. The advantage is that the operator time is limited to a couple of minutes to load and unload the machine while the rest of the process is unsupervised.



	Traditional process (minutes)	Proposed process (minutes)	Improvement (minutes)
Acquisition of foot data	3	3	-
Vacuum thermoforming of the the row insole	20	-	- 20
Virtual prototyping of the insoles	-	10	+ 10
Manual realization of the insoles	22	-	- 22
Automatic milling of the insoles	-	17	+ 17
Finishing of the insole	10	3	- 7
Total time	55	33	- 22

Tab. 2: Comparison of realization times of the different phases of the traditional approach against the proposed one.

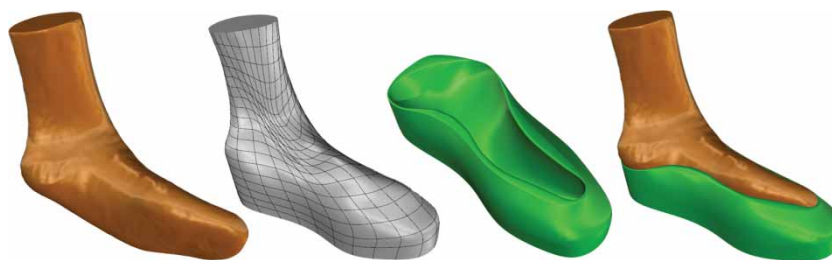


Fig. 7: The virtual realization of the plantar presented in Fig. 1. From the left: the foot scan (a), the virtual last (b), the digital model of the insole (c) and the assembly of the foot with the insole (d).

Therefore, during the process of creating the insole, the CAD operator can perform other tasks.

Another benefit derives from the formalization and the consequent automation of the design and manufacturing process of the insoles. Nowadays, procedures are manual, requiring skills and experience from the operators. The proposed CAD tool embeds knowledge on the steps and necessary geometric conditions to obtain valid plantar shapes. Moreover, it starts from a complete representation of the geometry of the foot shape giving to the designer more data to pursuit a better functionality of the orthotics. The standardized procedure also guarantees the repeatability of the result.

CAD-based tools represent attractiveness for inexperienced young orthotic makers. Young workers generally find more appealing and stimulating to work in an office environment using innovative tools. This leads to many advantages for the company: reduced costs for the training of the personnel, better attitude of the operators, and possibility of finding more resources as the business expands. Nevertheless, the software tool has demonstrated to be flexible and easy to use also by the senior technicians already in the company.

From the point of view of the patients, tests have shown that orthotics made in the traditional way have similar performances compared with the one digitally created. Fig. 7 reports the results for a difficult test case, such as the one reported at the beginning of the paper (Fig. 1). Orthopaedic technicians have sometimes highlighted defects in the shape of the insole, caused by lack of confidence and the



Fig. 8: The physical realization of the plantar presented in Fig. 7.

substantial inexperience with the tool. The majority of these problems can be eliminated through an extended usage of the system. Fig. 8

#### 4. CONCLUSIONS

The paper has presented a method and the related CAD tool to design bespoke footwear orthotics for

patients with serious pathologies. For such a kind of clinic conditions, no commercial software tools or academic prototypes are available. The paper has described also the nowadays insole development process, mainly based on manual operations, and it proposed an innovative procedure, supported by a specific 3D scanner, CAD (*LastDesigner*<sup>®</sup>) and CAM software tools and a CNC milling machine. The proposed CAD tool (*InsoleDesigner*), fully integrated with the other tools used during the process, has allowed the changeover from the traditional to the innovative production process. The algorithms used to model the insole have been described step by step with the aim to demonstrate how the shoe last and the foot geometry influence the insole.

The CAD tool has been tested within an Italian orthopaedic footwear company. Both the development processes have been carried out during this phase (traditional and innovative), with the aim to evaluate the feasibility, time saving and quality of the orthotics achieved with the proposed process. Twenty patients have been involved during the testing activities. The experimentation has demonstrated an average time saving, for the overall insole production process, of around 40%. The patients have not recognized any particular differences between the insoles obtained with the traditional and innovative processes. It is possible to conclude that the proposed CAD tool and the related process are feasible.

Future works aim to introduce a set of commands to model the “additions” on the insole top surface, required to offload the foot plantar pressure. The podiatrists involved during the tests, have also raised the necessity to include parametric commands to locally modify the insole geometry (i.e. change the height of the arch area and the insole heel).

#### ACKNOWLEDGEMENTS

The authors are grateful to *Duna srl*, an Italian company producing orthopaedic shoes and orthotics, for supporting the research activities presented in this paper. A special thanks goes to Eng. Paolo Bellelli (*R&D Manager at Duna srl*) and Eng. Raffaele Ieluzzi (*Researcher at Duna srl*), for their support during the definition of the software tool technical requirements and validation phase.

#### REFERENCES

- [1] Actis, R.-L.; Ventura, L.-B.; Lott, D.-J.; Smith, K.-E.; Commean, P.-K.; Hastings, M.-K.; Mueller, M.-J.: Multi-plug insole design to reduce peak plantar pressure on the diabetic foot during walking, *Medical & Biological Engineering & Computing*, 46, 2008, 363–371. <http://dx.doi.org/10.1007/s11517-008-0311-5>
- [2] Bernab e, J.-A.; Germani, M.; Mandolini, M.; Mengoni, M.; Nester, C; Preece, S; Raffaelli, R.: CAD tools for designing shoe lasts for people with diabetes, *Computer-Aided Design*, 45(6), 2013, 977–990. <http://dx.doi.org/10.1016/j.cad.2012.12.005>
- [3] Canfit™ Insole Design, <http://www.vorum.com/english/footware/insoledesign.php>, Vorum.
- [4] Cheung, J. T.-M.; Zhang, M.: Parametric design of pressure-relieving foot orthosis using statistics-based finite element method, *Medical Engineering & Physics*, 30(3), 2008, 269–77. <http://dx.doi.org/10.1016/j.medengphy.2007.05.002>
- [5] Chung, N.-H.; Ming, Y.-L.; Chong; C.-C.: Computer-Aided Design and Manufacturing of Customized Insoles, *IEEE Computer Graphics and Applications*, March/April 2011, 74–79. <http://dx.doi.org/10.1109/MCG.2011.19>
- [6] Correct and Confirm, <http://www.amfit.com/products/correct-confirm>, Amfit Inc.
- [7] Davia, M.; Germani, M.; Mandolini, M.; Mengoni, M.; Montiel, E.; Raffaelli, R.: Shoes Customization Design Tools for the Diabetic Foot, *Computer-Aided Design & Applications*, 8(5), 2011, 693–711. <http://dx.doi.org/10.3722/cadaps.2010.693-711>.
- [8] Fangyu L.; Yefei L.; Meiqiong W.; Jianfeng W.: Research on Computer Aided Design of Customized Insoles, *Computer-Aided Industrial Design & Conceptual Design*, 2009, 1430–1433. <http://dx.doi.org/10.1109/CAIDCD.2009.5375270>
- [9] Insole-Designer, <http://www.pedcad.de/en/inhalt/konstruktion/konstruktion.php>, Pedcad.
- [10] Lochner, S.-J.; Huissoon, J.-P.; Bedi, S.-S.: Parametric Design of Custom Foot Orthotic Model, *Computer-Aided Design and Applications*, 9(1), 2012, 1–11. <http://dx.doi.org/10.3722/cadaps.2012.1-11>
- [11] Luximon, A., Luximon, Y.: Shoe-last design innovation for better shoe fitting, *Computers in Industry*, 60(8), 2009, 621–628. <http://dx.doi.org/10.1016/j.compind.2009.05.015>
- [12] OrthoModel, <https://www.delcam.com>, Delcam.
- [13] ParoContour®-System, <http://www.paromed.de/medien/medienpool/paroContour-System-4S-EN2.pdf>, Paromed.
- [14] Sambhav, K.; Tandon, P.; Dhande, S.-G.: Computer Aided Design and Development of Customized Shoe Last, *Computer-Aided Design & Applications*, 8(6), 2011, 819–826. <http://dx.doi.org/10.3722/cadaps.2011.819-826>
- [15] Yu-Chun, H.; Yih-Wen, G.; Shih-Liang, S.; Chi-Kuang, F.; Shun-Hwa, W.; Chung-Huang, Y.; Chen-Sheng, C.: Using an Optimization Approach to Design an Insole for Lowering Plantar Fascia Stress—A Finite Element Study, *Annals of Biomedical Engineering*, 36(8), 2008, 1345–1352. <http://dx.doi.org/10.1007/s10439-008-9516-x>