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A KNOWLEDGE-BASED DESIGN PROCESS FOR CUSTOM MADE INSOLES

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Abstract

The Custom Made Insoles (CMI) context is characterized by a lot of software tools mainly used by skilled technicians of manufacturing companies. It is missing a tool to support the prescription of a CMI, mainly oriented to the podiatrists, but that could be used, at the same time, by customers, for self-monitoring activities, and by controllers to monitor the work of podiatrists.

The paper aims to illustrate an innovative design process to prescribe a CMI, by using a knowledge-based web application: the prescription is based on configuration rules and templates, that provides to the clinicians a set of insole geometries and materials (knowledge-based approach).

The proposed web platform Insole Designer is fully integrated with the most common monitoring devices (3D scanners and baropodometric platforms), 3D modelling software, and interactive shoes catalogues. The main output is the order (XML file) of the customised insole, used by an insole manufacturing company to produce the CMI.

The validation is an ongoing activity, even if preliminary results are available. Italian podiatrists have been involved to evaluate each software module giving a score in a 3-point scale.

Keywords: Biomedical design, Design process, Insole Design, Custom Made Insole

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1 INTRODUCTION

Insoles provide the most important interface between the foot and the shoe. The right insole/outsole combination offers the best approach to the reduction of potentially damaging tissue stresses on the foot sole. Many studies have found a growing demand for plantar orthotics, suitable and configured for each patient (The 2009-2014 World Outlook for Orthotic Insoles, The 2011-2016 World Outlook for Orthotic Insoles, The 2009 Report on: World Market Segmentation by City). A lot of scientific papers demonstrated the importance of the use of Custom Made Insoles (CMIs) for the nonsurgical treatment or prevention of foot and ankle disease. Insoles are mainly used to ensure postural stability in older adults (Qu 2015), to avoid complications in the Charcot neuro-osteoarthropathy (Fernández et al. 2014) or in rheumatic and neuropathic feet (Ulbrecht et al. 2004), to perceived comfort during running (Lucas-Cuevas et al. 2014) or as a means of proper off-loading in case of diabetic foot ulcers (Chand et al. 2012).

The orthopaedic sector, including the orthotics one, is complex and involves different actors with specific needs. The first actor is the *final customer* who requires a custom made insole. If it is properly designed for the patient specific pathology, the insole will have good effects on patient's health, providing a total improvement of his/her quality of life and the recovery of all normal daily activities (Amer et al. 2013). Moreover, patients desire an higher involvement during and after the design phase in order to have more and more fashionable and comfortable products. On the other hand, the second actor is the *clinician* who has to interact with users, increasingly curious and skilled. The clinician wants to work with user-friendly tools with the aim to guarantee and demonstrate to the end user the importance of the product that they are prescribing. The third actor in the orthopaedic sector is the *controller*, which could be, for instance, the chief of a group of orthopaedic shops or the National Health System (NHS). Due to the economic crisis, they are looking for new methods and tools in order to reduce costs for the treatment of chronic conditions, such as those related to the feet. These objectives can only be achieved by focusing more on prevention than on cure of these diseases, trying to take care of patients remotely, avoiding hospitalization, and training them to a healthy lifestyle, appropriate for the disease they have. On the other hand, it is also important for any chief of a medical facility to monitor the work of the clinicians themselves, in order to reduce medical malpractice. The fourth actor of the orthopaedic sector is represented by the footwear and related components *manufacturer*. Moving from the traditional design systems (with a high manual contribution) towards innovative ones, it is important to make the insole design process oriented to innovative manufacturing systems, based, for instance, on the additive manufacturing technologies, which allow to realize highly personalised products.

In this articulated context, this paper proposes a method and the relative software tool for prescribing custom made insoles for patients with different health conditions, satisfying all needs of all actors.

After a brief summary of the current practice to configure and design insoles and of the main software and hardware tools available to support this process (section 2), there is the description of the proposed approach (section 3) and of the web application, called *Insole Designer* (ID), developed to implement the new workflow (section 4). The tool has specific functions dedicated to the three actors (podiatrist, customer, controller) involved in the process and it implements a user centred methodology to connect the web application to the main important software and hardware applications currently available and to allow the exchange of data between them. In this way, the podiatrist collects and manages all the necessary data, coming from different systems, and he/she is able to prescribe an insole as correct as possible. In fact the product's quality will be ensured by the process itself, which controls step by step the clinician's work adherence to standards and formalised best-practices of experienced personnel. Such rules are embedded into the dedicated knowledge based system (section 3). In section 5 the proposed workflow is tested through a set of real case studies. At last, section 6 proposes an insight on how to improve and extend the approach and the software tool, in order to fulfil all requests arising from the end-users.

2 STATE OF ART OF THE INSOLE DESIGN PHASE

In the current practice, the configuration and prescription of a custom made insole is carried out by following three main steps:

- step 1: the foot analysis phase, during which the podiatrist obtains all necessary foot and patient data;

- step 2: the insole design phase, where the insole and related accessories are designed by a technician through a CAD system;
- step 3: the production phase, where skilled workers or CNC machines are employed to manufacture the insole.

The clinical practice has changed over the years. After decades where the custom made insoles were designed just following the foot shape (Ball and Afheldt 2002), different research approaches evaluated the effectiveness of custom foot orthoses based also on plantar pressure (Mayfield et al. 1998), (Ulbrecht et al. 2004), (Chand et al. 2012). The value of pressure reduction, necessary for footwear and insoles for patients at risk for ulceration or re-ulceration, is proposed in Owings et al. (2009). The advice is to maintain the plantar pressure below 200kPa. Nowadays, a lot of tools for a correct and quantitative foot diagnosis (step 1) are available in the market: classic impression box to obtain the foot shape, dedicated 3D or 4D scanners to achieve the virtual geometry of the foot respectively in a static or dynamic mode, pressure platforms to obtain barefoot plantar pressure maps, simulation software tools to predict and visualize the plantar pressure distribution, in-shoe pressure sensors to obtain pressure information with a patient wearing footwear, systems for gait analysis.
The insole design phase (step 2) consists both in the determination of its geometry and the set of materials to be used. The literature of the last years presents CAD/CAM systems for customized insoles (Li et al. 2009), (Chung-Neng Huang et al. 2011), (Mandolini et al. 2014). Whereas, for the material selection phase there are few contributions in literature (Mandolini et al. 2013).
From an industrial point of view, several CAD-based solutions are available on the market. They consist of systems to digitize the foot (3D scanners), CAD tools to design custom made insoles, aiming at replacing as much as possible the manual manufacturing processes, and dedicated CNC milling machines used to produce individual insoles (i.e. AMFIT, DELCAM, VORUM, PEDCAD, PAROMED and TECNO INSOLE).
Therefore, during the last decades, the insole sector has been characterized by a strong effort towards the digitalization of the product development process, from the foot diagnosis to the manufacturing of the insole. Despite this, these tools are not interconnected in an integrated process, they are based on different databases and platforms that scarcely meet all the whole actors' needs. The product development process lacks of effective collaboration. The different actors exchange information and data in a "over the wall" way that can generate errors and iterations. Moreover, the work managed by the podiatrist is supported only during the foot analysis (step 1), then it is assumed that he/she does the insole prescription on the basis of experience and tacit knowledge.
In this scenario, it is desirable to have a software tool oriented to the podiatrist needs where the cultural barriers between the geometrical modelling field and the medical experience are broken down. The tool has to help and drive the clinician, in an easy way, during the phases of the insole configuration process, from the foot analysis until the insole geometrical and material features setting. At last, it has to be integrated with the existing devices and it has to facilitate the involvement of the other actors (patient and controller) in order to fulfil all needs.

3 METHODS

3.1 Proposed design workflow of a customised insole

As stated above, this paper proposes a new process to configure and prescribe a custom made insole, thanks to the use of an innovative web tool, the *Insole Designer*.
The proposed workflow is illustrated in Figure 1. The process starts with the analysis of the patient clinical condition, including the measurement of the height and weight, the analysis of the foot conditions and shape, clinical history and evaluation of neuropathy. This phase can be supported by numerical data through the use of the tools currently available for foot diagnosis (step 1), as described in section 2. After the diagnosis phase, the podiatrist uploads the files coming from external tools into the *Insole Designer* tool (ID), used as a gateway of all the necessary information required to design and manufacture a CMI. Then, he/she configures a new insole taking into consideration all the data just acquired, his experience and the knowledge inside the software system.
This knowledge consists of all the possible insole features (i.e the insole thickness in the forefoot) with the appropriate values (i.e. the list in mm of all possible values for the insole thickness in the forefoot) and some prescriptions rules. Combining these data, insole templates are saved into the ID: the

templates are pre-configured insoles for different common foot conditions, with specific values for each insole feature.
The podiatrist chooses the most appropriate template for that patient and, then, he/she can adjust geometrical dimensions, materials and additions, ensuring the respect of the prescriptions rules to meet the patient needs. The user is actively participating in the prescription, with the possibility to see the changes done in the insole template thanks to a viewer 3D, with a photo-realistic rendering, where he/she can visualize, move and zoom a 3D model. He/she can also create new templates or save a prescribed insole as a new template. At the end of the configuration process, the podiatrist adds some instructions for the patient (advice about lifestyle, diet and physical activity) and links to web sites to train the customer about his/her clinical condition and how to improve it, to support the patient everyday life and promote his self-monitoring. The podiatrists can also setup a custom questionnaire suitable to that specific patient in order to collect opinions about the prescriptions, in terms of how much the insole fits with his/her feet and related pathologies. In this way, the podiatrist knows the patient condition and he/she can remotely plan future examinations. At the end, the insole order (an XML file) is automatically sent to the manufacturing company where a CAD-based software reads the XML file and automatically produces the CAD insole model to realize the final product with the most suitable technology (i.e. rapid manufacturing machines).
The customer can give feedback about the custom made insole more times, as decided by the clinician, i.e. after two weeks from the first prescription. Thanks to this feedback, the controller can elaborate different statistics, to evaluate, for instance, the clinicians work in the health facility, the effectiveness of the prescribed insole, the satisfaction of customer.

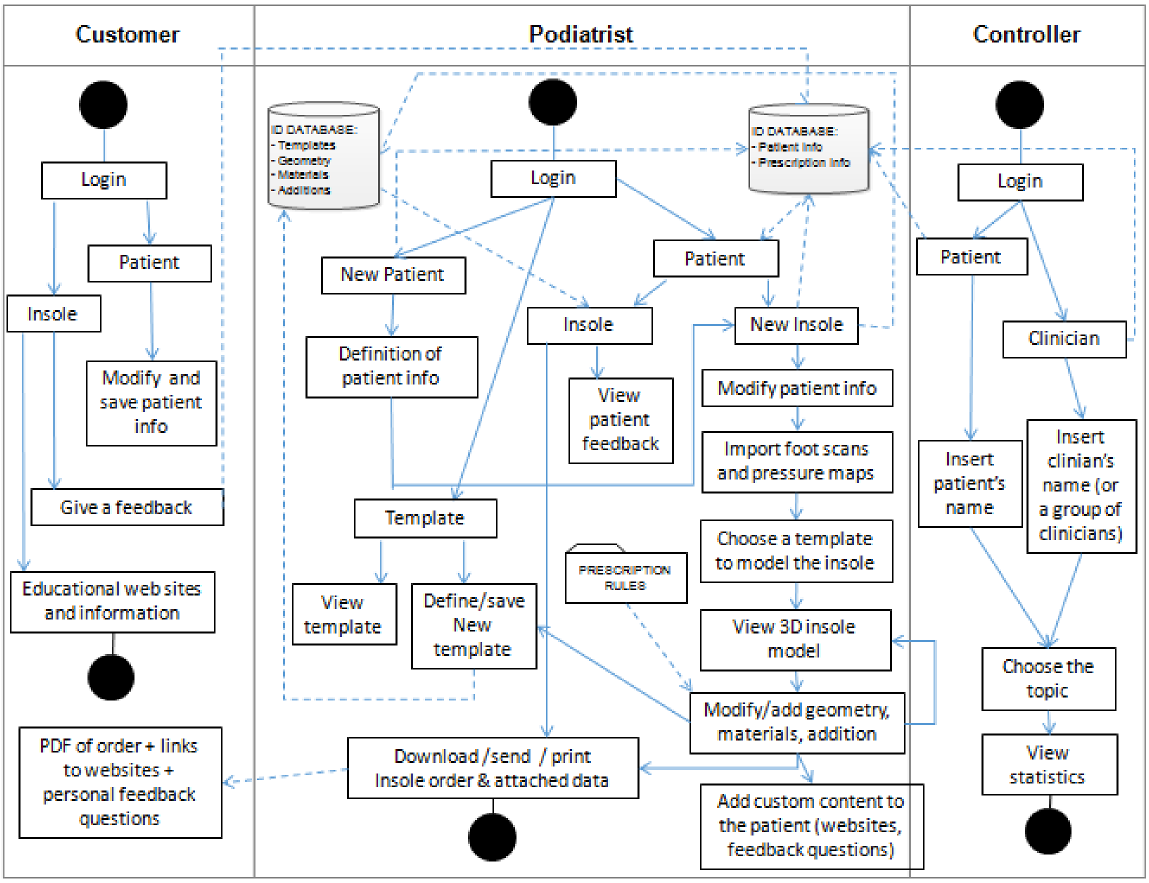

Figure 1. The proposed workflow to configure a new custom made insole

3.2 Insole design features and prescription guidelines

The knowledge behind the *Insole Designer* is represented by a set of rules that combine the insole features and related values, into a pre-built templates, though to satisfy specific patient's needs. According to the literature, the insole features are divided in two groups: insole's main features, that are geometry's and material's features (Healy et al. 2010), and the forefoot additions.

The insole features taken into account by the *Insole Designer* are:

- *Insole model type*: "full", if the insole covers the entire foot, "¾ long", if the insole does not cover the forefoot.
- *Main shell thickness and its material*: the main shell is the bearing structure of an insole that gives the right support to the patient's foot, thanks to the suitable thickness of a specific material. It may be a soft material like a low density EVA, or a more rigid one like the Polypropylene. The shape of the insole will depend on this parameter: rigid insoles can be only ¾ long. The insole density, useful for milling purposes and also for the patients need, can be defined only for soft insoles. The insole shape is not affected by the value of the density.
- *Top cover thickness and its material*: the top cover is a thin layer (generally from 1 to 3 mm) in contact with the foot, commonly made of breathable, antibacterial and antimicrobial material in order to avoid the proliferation of infections that, for example, in cases of ulcers, could be very dangerous.
- *Total thickness in the forefoot*: this feature, for a full insole type, is calculated by summing the thickness of the main shell material, of the top cover and of the forefoot cushion.
- *Heel wedge*: this feature allows the addition of a heel wedge to the rearfoot. The value entered corresponds to the angle of the wedge, with also the option to choose between a lateral and a medial heel wedge.
- *Arch height*: this feature is the height of the foot arch (from the central point on the ground - under the arch - to the Navicular midpoint on the medial aspect of the foot).
- *Heel raise*: this feature is the lifting of the heel, therefore affecting the heel to toe position (toe spring).

The forefoot additions are: metatarsal bar, metatarsal dome, metatarsal cavity, metatarsal cut out and forefoot cushion (Deshaies et al. 2011), (Hayda et al. 1994). Each one is defined by its height, in case of addition of material, or depth, in case of removing of material, and its position on the foot (i.e. for the metatarsal dome, the position is defined as the metatarsal bones between which the addition is placed).
The most important rules that control the podiatrist's work are illustrated in Table 1.

Table 1. Insole prescription guidelines

# RULE	FEATURES/ ADDITIONS	PRESCRIPTION RULES
1	arch height	It must be between -6mm and 6 mm.
2	top cover	Its thickness must be less than or equal to total thickness forefoot.
3	total thickness forefoot	For any selection of total thickness forefoot ≥ 5mm, an alert is used to warn that not all shoes might be suited to that insole.
4	total thickness forefoot	If model is set as "full", the podiatrist has to choose also the value for the total thickness forefoot; if insole is "3/4" long, this feature has not to be specified.
5	Main shell (thickness and material)	A rigid insoles (so in polypropylene) can be only ¾ long; in this case the user has to choose also the value for the thickness of the main shell (2 or 3 mm). For soft insole (so in EVA), the user has to be specify also its density; its thickness has to be bigger than 1 mm but it is automatically determined as the difference between the total thickness of forefoot and the sum of top cover layers thickness and forefoot cushion height.
6	forefoot cushion	If the addition "forefoot cushion" is selected, forefoot cushion height plus the top cover thickness must be no more than the total thickness forefoot.
7	metatarsal cavity, metatarsal cut out	it is not possible to have metatarsal cavity and metatarsal cut out in the same metatarsal.
8	metatarsal bar, metatarsal dome	if podiatrist selects the metatarsal bar, he can not select also the metatarsal dome and viceversa.

9	all forefoot additions	If insole is “3/4” long, it can not have a forefoot addition.

4 SOFTWARE TOOL FOR THE INSOLE DESIGN PROCESS

The *Insole Designer* tool (ID) is a web application. It has been developed in *Visual Studio 2010* (by *Microsoft*), a well-structured Integrated Development Environment (IDE). For back end, the *.NET framework* v. 4.0 has been used, while the front end was implemented by using *html*, *CSS,* and *Java Scripts*.

The database of the application consists of 32 tables containing insole templates with the relative features values (additions, geometry and materials, already described in section 3.2). Moreover, the database contains the prescriptions generated by the podiatrists, each one characterized by the patient information, the feedbacks from the patients and the instructions, advices and web sites chosen by the clinician for that patient and that prescription.

The web application is thought to have three different users, with three different authentication levels:

- *patient* log-in and interface for the final user of the prescribed insole;
- *clinician/podiatrist* log-in and interface for the prescriber of a new custom made insole;
- *controller* log-in and interface for members of the NHS or chief of the orthopaedic shops to supervise the work of his employees.

The web application is structured in modules, as illustrated in the Figure 2.

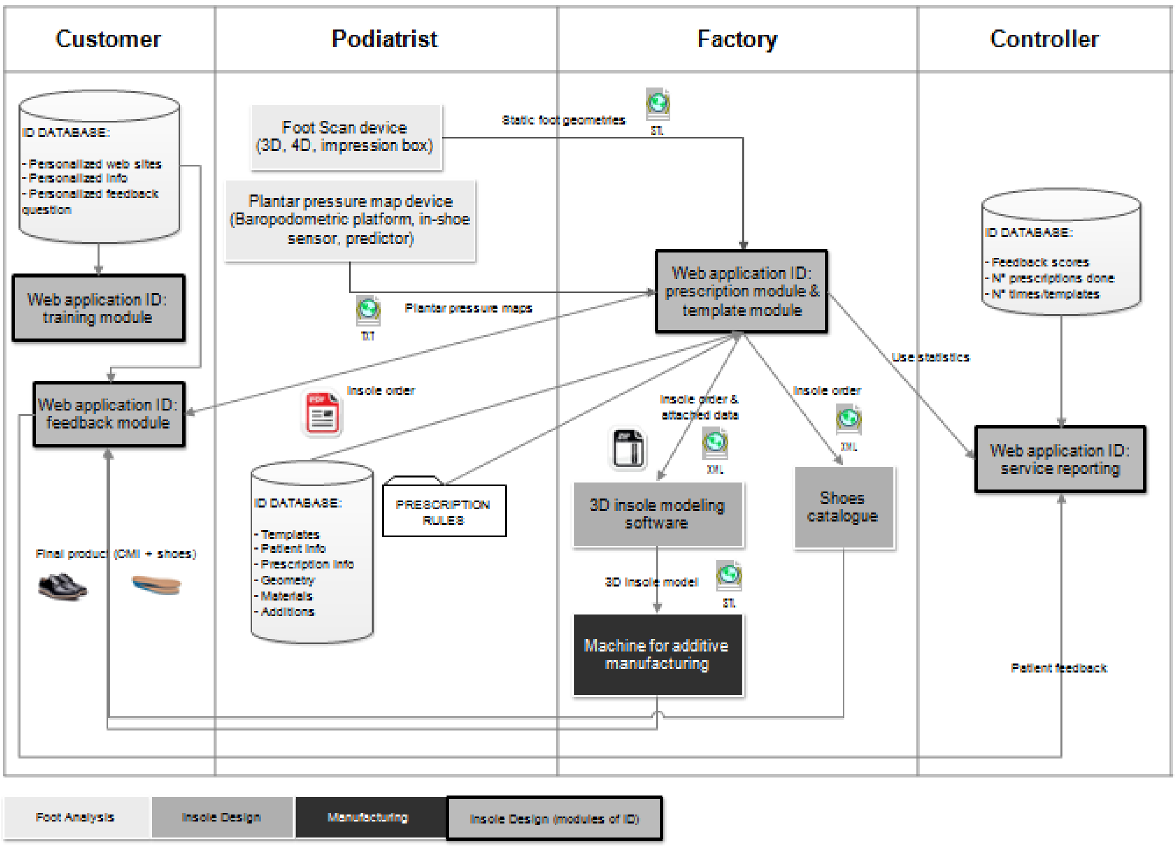

Figure 2.The software modules

The modules of the web applications are: template module, training module, feedback module and service reporting. The output of ID, an order in XML file format, contains all the insole features, patient data and additional data uploaded during the prescription process. This file will be used by the insole manufacturing company, to produce the insole, and by any footwear configurator tools, where the customer can personalize the shoes, suitable for the prescribed insole, according to the fashion trends and his/her preferences.

The prescription module, when the user is a podiatrist, is the core of the system and it is divided into different portions to simplify and speed up the podiatrist’s work:

- *patient data*: to insert patient information and upload files from external tools;
- *design template*: to choose the insole template suitable for the specific patient condition. There are templates for different situations such as flat foot, early diabetic, neuropathic foot, sports support;
- *customize*: to personalize the template for that patient, changing geometry and materials and adding feedback questions, educational web sites, advices and instructions for that patient;
- *additions*: to add eventually forefoot additions;
- *confirm*: to review, save and confirm the order and eventually save the final insole as a new user defined template, in order to use it for future prescriptions.

The functions of each module, differentiated according to the user log-in, are listed in the Table 2.

Table 2. Functions per software module available for different users

	CLINICIAN	CUSTOMER	CONTROLLER
PRESCRIPTION MODULE	view details of a patient; insert new patient; view details (including feedbacks) of an insole already prescribed; configure a new insole; use the 3D viewer to view the insole 3D model;	view, modify and save personal data; view personal prescriptions;	-
TEMPLATE MODULE	view details of an insole template; configure and save a new user defined insole template;	-	-
TRAINING MODULE	direct links to institutional web sites and medical news (page “Community”);	personalized direct links to institutional web sites and medical news (page “Community”); personalized instructions and advice for the daily life; educational part about their foot conditions and insole features;	-
FEEDBACK MODULE	-	give personal feedbacks to a prescription, after receiving an automatic reminder by email/sms;	-
SERVICE REPORTING	-	-	templates use statistics; prescriptions score; customer satisfaction;

5 EXPERIMENTATION

5.1 Case studies

The proposed approach and related software tool have been tested within an orthopaedic department of an Italian Health Facility, that aims at changing the traditional insole configuration and prescription processes with more innovative ones. Indeed, it has been possible to evaluate, on real test cases, the results achieved with the developed software tool. The main purpose of the validation phase was the evaluation of the proposed workflow and the usability and effectiveness of each software module, by using a specific questionnaire.

Four podiatrists of the department have been selected (3 males and 1 female) and trained to use the proposed web application, following the proposed workflow. They used the system for about one month for the insole prescriptions of 20 patients (five patients for each podiatrist). Patients have been chosen to have heterogeneous distribution of sex, age and pathology as reported in the Table 3. This reference group provided a wide base of different design situations, which allowed the ID to be deeply tested. To implement the proposed workflow, the following technologies available at the department have been used together with the ID: a 3D foot scanner, to obtain the foot shapes, and a baropodometric platform to have the real plantar pressure maps. To simulate the entire workflow, a local manufacturing company was involved. It currently uses a CAD modelling software (plug-in of Rhinoceros v.5 by *McNeel*), that accepts and reads the XML file (output of ID) to automatically model the prescribed insole. After the distribution of the insoles to the patients, they were asked to daily wear the orthotics for a period agreed with the podiatrist. This period is still going on, so at this time only preliminary results, from the clinical operators, are available.

Table 3. Details of the group of patients involved in tests

range of age	under 30	31-45	46-60	over 60
N° patients – sex	2 - M 3 - F	2 - M 2 - F	3 - M 2 - F	3 - M 3 - F
N° patients – (range of BMI)	4 - (19-24,99) 1 - (25-29,99)	4 - (19-24,99)	2 - (19-24,99) 3 - (25-29,99)	3 - (19-24,99) 3 - (25-29,99)
N° patients - level of activity	3 - active 2 - low	3 - active 1 - normal	2 - normal 3 - low	3 - normal 3 - low
N° patients – disease	1- hammer toes 3- flat foot 1-clubfoot	2- hammer toes 1- pes cavous 1- hallux valgus	2- early diabetic foot 2- pes cavous 1- hallux valgus	1- early diabetic foot 2- neuropathic foot 1- pes cavous 2- flat foot

5.2 Results and discussion

The questionnaire distributed to podiatrists is structured in different sections to evaluate six macro aspects: ease of use of the tool, the functionalities of the software modules dedicated to podiatrists and their importance to achieve the purpose of configuring a new insole (prescription module, template module, training module), the navigation and the organization of the tool, the language, the manual as a support to know and learn the tool, error prevention during the phase of doing a new prescription thanks to the implementation of the insole templates and prescription rules. Each question had to be answered giving a score in a 3-point scale: score 3 if the tool does not meet minimal requirements, score 6 if the tool meets the minimal requirements, score 9 if the tool fully satisfies the requirements indicated in the question.

The results of the testing phase, collected within the Table 4, have highlighted several advantages in the introduction of the proposed design approach, implemented in the software. The first one consists in the use of insole templates: their definition simplifies significantly the prescription of a new insole. All podiatrists used the insole templates during the test phase with small modifications. In particular, among the 20 insoles prescribed, 15 of them correspond to the pre-built templates: for these cases, the starting templates have not been changed. Moreover the prescription rules have supported the podiatrist during the definition of the insoles. However the podiatrists themselves pointed up that the changes to the pre-built insole templates available in the software strongly depends by the complexity of the insole and the patient disease. Another benefit derives from the formalization and the consequent automation of the design and manufacturing process: by using an electronic order, the insole is designed by using a 3D CAD system, whose result will feed the CNC machines (additive or subtractive manufacturing). The secondary benefits is related to the reduction of the required skilled and experienced operators, more and more difficult to find in the job market. The standardized procedure also guarantees the repeatability of the result and the quality of the final product for the customer.

Clinicians involved during tests appreciated the innovative module to collect feedbacks from patients, as assessment and validation of effectiveness of customized insole (and orthoses in general) is fundamental to continuously improve the knowledge and the best practices used by the clinician to design a product.
The proposed ID represents attractiveness for inexperienced young clinicians because their work is supported by the system knowledge, that allow to avoid mistakes due to inexperience or oversights. Moreover, young workers generally find more appealing and stimulating to work using innovative tools. Nevertheless, the software tool has demonstrated to be flexible and easy to use also by the senior technicians already in the department.

Table 4. Results of the tests during the validation: scores for each podiatrist in each macro aspect

Sections	podiatrist A	podiatrist B	podiatrist C	podiatrist D	average (for each section)
Ease of use	8,2	8,7	8,1	8,3	8,3
Functionality: prescription module	6,5	8,3	8,1	7,2	7,5
Functionality: template module	8,5	8,6	8,3	8,3	8,4
Functionality: training module	8,5	8,2	8,6	8,7	8,5
Navigation	7,0	8,2	8,8	7,6	7,9
Language	9,0	8,8	9,0	8,2	8,8
Manual	8,7	9,0	9,0	8,8	8,9
Error prevention	7,5	8,7	8,2	7,2	7,9
Average (for each podiatrist)	8,0	8,6	8,5	8,0	8,3

6 CONCLUSIONS

The custom made insole sector lacks a software tool able to integrate the stakeholders working on this area (podiatrist, controller, manufacturer, including also the patient), in order to implement a fully electronic insole development process.
The paper presented a method and the related web application to prescribe custom made insoles for patients with different pathologies in a user-friendly environment. The tool, even if it is mainly oriented to podiatrists, has also interfaces and functions for involving the final customers and controllers, with connections toward the systems used by the manufacturing companies. In particular, *Insole Designer* is integrated with existing external devices (3D scanner, baropodometric platform, shoes configurator, 3D modelling software, rapid manufacturing machines). The approach has allowed the changeover from the traditional (handmade) to the innovative (electronic based) configuration process, thanks to a knowledge base used to help and guide the podiatrist, speeding up and standardizing his/her work.
The web application has been properly tested. Twenty patients and four podiatrists have been involved during the validation. Preliminary experimentations were carried out to evaluate the software sections oriented to the clinicians. The results have demonstrated high average scores in each aspect and an overall good satisfaction of all users involved. It is possible to conclude that the proposed process for the prescription of a custom made insole and the related web application represent an achievement that can be used by a wide range of podiatrists during their daily work. The podiatrists involved during the tests have raised the necessity to improve the feedback module with a self-learning system able to analyse the customer feedbacks and take decisions (i.e. give an alert or an advice), in order to decrease the workload on medical staff, decreasing the enclosed costs.
Future experimentations will be carried out with the aim to extend the questionnaires to all the patients and controllers of the structure involved. A questionnaire with a structure similar to that one distributed to the clinicians, but with specific questions, will be realized and used to gather the final results.

The strengths of the proposed approach are twofold. On one hand, the knowledge behind the tool lets the clinical personnel to use pre-established insole templates to configure custom made products. On the other hand, there is the full integration between the proposed tool with the most used and modern systems available in the market, that provide to the podiatrists important quantitative data. For both these aspects, future developments need to be faced in order to automate as much as possible the data exchange with the external tools integrated with the ID. Furthermore, more rules and logics have to be defined to support the selection of the most suitable insole template, the choice of the parameters to be changed and how to change them. On the other side, future works concern the possibility to connect the proposed web application ID to other external tools with clinical interest, for example a material simulator for the different layers of a custom made insole.

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