Final Report Summary - SMARTPIF (Smart tools for the Prescription of orthopaedic Insoles and Footwear)

Executive Summary:
In order to help and support practitioners to prescribe orthotic footwear and insoles, SMARTPIF project has developed a set of technological devices and computer tools that will assist them in achieving the best therapeutic prescription for their patients.

This set of tools can, on the one hand, allow podiatrists to scan the patient’s foot in dynamic conditions and provide a prediction of the pressures to be exerted in whatever point of the foot during a gait cycle for a combination of shoe and insole chosen from a catalogue or from previously designed models, and a pressure visualisation in real time in the format of a 3D image of the patient’s foot with a superimposition of the pressure map.

On the other hand, we also address the problem of the patient having to choose a shoe model that has not yet been manufactured or is not available in the podiatric clinic (which often lacks of footwear store stocking facilities). The software tool makes it possible to offer to their patients the possibility to virtually try-on the selected shoes by means of augmented reality techniques through a virtual mirror, without having footwear stocks available at the podiatrist’s consulting office.

PROJECT CONSORTIUM:

SMARTPIF is an industry-driven project, where SMEs participating in the Consortium have shown close cooperation from the beginning and throughout the project lifetime to achieve the project objectives, ensuring that the industry needs are always being considered as a priority goal: Biomech Technologies International Ltd. (United Kingdom); Alu Group, S.L. (Spain); Lion Systems SA (Luxembourg), and EUROSUOLE SpA (Italy).

SMARTPIF project is managed by Instituto Tecnológico del Calzado y Conexas (INESCOP), who has also been Technical Coordinator and responsible for the research team. Said team was comprised of four well-known RTD performers leading the research work, from the point of view of the user and/or market needs and application possibilities of 4 SMEs, who ensured that final results are feasible and meet the market expectations: Instituto Tecnológico del Calzado y Conexas, INESCOP (Spain), University of Salford, USAL (UK); Università Politecnica delle Marche, UNIVPM (Italy) and Universitat de Valencia, UVEG (Spain).

Project website: www.smartpif.eu
sole during a gait cycle by means of a particular shoe-insole combination and a specific set of materials. Furthermore, patients are not left out but they are involved in this process thanks to the use of advanced augmented based tools that allow them to virtually try-on the co-designed shoes (not yet manufactured/not available at the podiatric clinic).

Hard research work has resulted in a set of technological advanced products and devices that have been validated and tested by health care professionals to deliver an integrated system comprised of: two versions of a 4D scanning device able to scan the patient’s foot in dynamic conditions during gait; software allowing for the 3D visualisation of pressure (over patient’s scanned foot or over the insole), and able to predict foot plantar pressures on foot sole key areas; specialised insole prescription software connected to CAD/CAM software to automate the design and manufacture of the prescribed insole; and a footwear co-design tool (interactive catalogue) connected with a virtual mirror, able to display the selected footwear articles customised by the client, superimposed onto the real image of the patient.

Taking full account of the current market needs and expectations, four SMEs close to the market have used their expert knowledge to guide research, in order to ensure that final results are feasible and meet the market demand. Project beneficiaries bring together expertise in all required areas: biomechanics, clinical health care treatment, footwear and insoles design and customisation, software development, 3D imaging and geometry reconstruction, geometry scanning, neural networks, advanced decision trees, and augmented reality. The main challenge has been to provide podiatrists with tools that will allow them to create a footwear-insole prescription suitable for the specific foot condition of patients, in a user-friendly environment, without requiring complex technical operations.

Project Results:
SMARTPIF provides a set of results related to three fields of activity: podiatrists, patients and manufacturers.

The description of single components making up the whole SMARTPIF system is provided below:

- SMART PRESCRIPTION SYSTEM (Insole Designer): The Smart Prescription System (SPS) is a software tool for assisting the therapeutic prescription of insoles. When used by clinicians, it guides them through the definition of a customised insole prescription, by means of a complete set of pre-built insole templates, related to the most frequent foot health diseases, which can be customised to adapt them to the specific needs of each patient.

The SPS is the pivotal application of the SMARTPIF system, this being connected to external data acquisition devices, like baropodometric platforms and foot scanners, and to other software utilities like the 3D Plantar Pressure Viewer and Predictor, and the Interactive Catalogue and Virtual Mirror.

When used by patients, the SPS allows them to provide clinicians with feedback related to the prescription, as well as to gain information about their treatment. This feedback from patients helps clinicians to adjust their prescriptions and to better fit them to the patients’ expectations and feelings.

After defining and customising the insole, the tool generates a standard data file (XML format) that collects the main features of the prescription. This file is used to connect with other SMARTPIF software apps. The SPS main functions are:
- to support and assist the podiatrist’s work during the phase of making an insole prescription, thanks to the use of clinical and geometrical design rules applied to the template selection and customisation;
- to create new user-defined templates;
- to make available data from external devices, to be used during the prescription: foot scans and plantar pressure data;
- to exchange information related to the prescription with other software tools (Plantar Pressure Viewer, Pressure Predictor,
Interactive Catalogue, Virtual Mirror, Insole CAD/CAM), that predict plantar pressure;
- to view the 3D model of the prescribed insole;
- to manage patient personal data;
- to inform and educate patients by means of access to medical web sites and information about the prescription’s main features;
- to provide patients with the possibility of evaluating their prescriptions, by means of standard and personalised feedback questionnaires;
- to provide clinicians with patients’ feedback related to each prescription.

▪ 4D SCANNER- Version A: The 4D Foot Scanner, ToF version, is a dynamic foot scanner based on three time-of-flight cameras able to record the whole foot geometry during the gait cycle, obtaining the digitisation of anatomic foot changes while walking.

The 4D Foot Scanner is comprised of a capture device, a single scanning module with two additional walkways, and the scanning software, which is used to capture, reconstruct, and even measure the 3D foot geometry.

The 4D Foot Scanner, ToF version, provides practitioners with a sophisticated tool able to capture their patients’ whole foot geometry during a whole gait cycle, offering the opportunity to detect the anatomic modifications and foot real behaviour that take place during the different gait phases.

The captured geometry can be viewed in motion, as an animation of the different samples captured while walking, and can be exported to standard STL file format. It can also be measured using the same software tool, without requiring external software applications.

Providing the podiatrist with a sequence of the complete gait cycle, the 4D Foot Scanner offers a unique opportunity for the clinician to analyse the structural changes that different anatomical structures of the foot undergo, in contrast with the classical approach of static 3D scanners, which only capture a single stance of the foot in a static condition, and not under load during the gait cycle.

The observation, by the practitioners, of the time related changes on the whole foot, allows them to better design and adapt their therapeutic prescriptions (for both, insoles and footwear) to the dynamic changes of the foot during the gait cycle.

▪ 4D SCANNER- Version B: The 4D Foot Scanner, single 3DCam, is a dynamic foot scanner based on a single 3D camera able to record the foot plantar geometry during a gait cycle, obtaining the digitisation of anatomic sole changes while walking.

The 4D Foot Scanner is comprised of a capture device, a single 3D camera sensor and up to two optional IR illuminators, a walkway, and capture and reconstruction software.

At the walkway, a gait sensor is able to automatically start the recording process and the foot digitisation as soon as the patient walks through the recording area.

The 4D Foot Scanner, single 3DCam, provide practitioners with an easy-to-use, low-cost tool able to capture their patients’ foot plantar geometry during a whole gait cycle, offering them the opportunity to detect the anatomic modifications that take place during the different gait phases, in contrast with the static capture offered by traditional 3D scanners.

The scanner captures up to 10 seconds of foot movement, and can export the captured geometry in standard STL file format, making it possible to use these geometries not only for examining the anatomical changes of the patient’s foot, but also to help to better adapt the insole, and eventually the footwear prescription to the particular geometric characteristics of the patient.

The reconstructed 3D foot sole files can also be used to obtain precise sole measures, and to analyse these changes in the different gait phases, using these data to improve the insole prescription.

▪ PRESSURE VIEWER & PRESSURE PREDICTOR: The 3D Plantar Pressure Viewer is an easy to use viewing tool that supports the podiatrist during the generation of an insole prescription, allowing plantar pressure maps to be viewed onto the foot 3D geometry, or the insole 3D geometry.

This Rhinoceros plug-in allows pressure maps (from baropodometric or in-shoe systems) and foot scans (from 3D or 4D
scanners) to be overlapped, automatically aligned and analysed, both in a static and in a dynamic way. In the dynamic analysis, the tool is also able to select and display foot shapes and plantar pressure maps related to the main phases of the human gait cycle: heel strike, foot flat, heel off and toe off.

A specific module of this tool is the Pressure Predictor, a system developed to predict plantar pressures associated with a specific insole design (geometry and materials). It is internally implemented by means of sound mathematical models that are completely transparent for the final user, who needs no knowledge about them to understand and run the application. It makes use of the data acquired in the first visit of a diabetic foot patient to a podiatry clinic to assess the plantar pressures that the patient himself/herself will exert while walking with a specific insole. The 3D Plantar Pressure Viewer is useful for clinicians to know exactly the plantar pressure values in the foot sole, both in a static condition and while the patient is walking: the tool is able to select and display foot shapes and plantar pressure maps related to the main phases of the human gait cycle, even if the input is made up from several files of foot and pressure information. Moreover it offers a set of functions to analyse the foot condition, such as the possibility of aligning foot and pressure data, viewing the projection of pressure maps and calculating the relative isobar curves.

The Pressure Predictor module is also useful for clinicians in the framework of the project, since plantar pressures are a good indicator of how likely a diabetic patient is to undergo foot ulcers, and this module is able to provide a pressure prediction given the characteristics of the prescribed insole. Therefore, if podiatrists know the relationship between a given insole and the corresponding plantar pressures, they will be able to prescribe the most adequate insole for each individual patient. Five key areas were selected as the most probable to develop ulcers; hence, models were focused on predicting pressures in each one of those areas.

Furthermore, the 3D Pressure Map Visualization Tool is a Rhinoceros plug-in, compatible with Rhino 5.3 and with the Windows OS 7 and 8.

For the static analysis, as input it accepts one foot geometry (from a 3D or 4D scanner, STL format) or one insole model (IGS format), and one pressure map (real or predicted, TXT or ASC format). For the dynamic analysis, as input it accepts n foot scans (from a 4D scanner, list of STL files) and n pressure maps (real or predicted, TXT or ASC format), n being a variable number of scans and maps (from 1 to 100).

The system is able to export four different types of data: pressure map (PNG), projections (VRML), isobar curves (IGS), or a combination of previous data.

The Pressure Predictor is an executable file, called directly from the 3D Pressure Viewer, which uses universal function approximators as mathematical models for pressure prediction. This module needs to be fed with data acquired during the first patient visit and provided by the Smart Prescription System (as an XML file): plantar pressures using a standard foot and insole (measured by means of sensors spread over the foot sole), as well as some patient characteristics (height, weight, age, shoe size, of first and fifth metatarsal length, toe length and arch height while standing). Based on those data, the tool will be able to provide a pressure prediction given the characteristics of the insole (density, thickness, hardness, resilience, compression fatigue and Young’s modulus) and the position of the metatarsal bar.

INTERACTIVE CATALOGUE & VIRTUAL MIRROR: The Interactive Catalogue is a software tool that allows the patient to co-design and customise the footwear preselected by the Smart Prescription System as the most suitable for the prescription made by the podiatrist.

This software app is available for iPad tablets, and uses a very simple and intuitive interface for changing colours, materials and textures of the different parts of the shoe, working directly on a 3D virtual model.
The Interactive Catalogue has an additional module, the Virtual Mirror. This software app allows the patient to visually check the co-designed and customised shoes: when used in conjunction with a real mirror, it shows the co-designed shoe superimposed on the patient’s own foot in real time.

The Interactive Catalogue receives information from the Smart Prescription System, preselecting the most suitable footwear for the prescription made by the clinician. Using a graphical touch interface, the user can:
- select pieces of the footwear and apply different materials, colours and textures;
- select accessories and embellishments for the co-designed shoes;
- save shoe models to a Favourites library;
- place an order and buy the model, starting the manufacturing process.

The Virtual Mirror is an additional module, connected to the Interactive Catalogue, which allows the patient to try on the co-designed shoe, viewing the virtual model over an image of the patient reflected by a real mirror. The available functions are:
- to view a virtual model of the shoe over his/her foot;
- to view a previously co-designed shoe, stored in the Favourites library;
- to modify the basic dimensions of the virtual model of the shoe, in order to make it fit for the patient, by grading width and height;
- to modify the spatial location of the virtual model, in reference to the patient’s foot, in order to enhance the visualisation and offer a better fit: translation of the model in three axes, rotation of the model, mirroring of the model (selecting left or right foot).

Potential Impact:
The expected impacts derived from the application of the above-mentioned project results are:
- Direct increase of productivity, by means of reduction of fitting time of insoles. The system will reduce the number of times that the patient must return to the practitioner due to wrong adjustment/fitting of the insoles.
- More accurate prescription, based on pressure prediction, offering to the patient a higher degree of excellence in the treatment, subsequently enhancing the practitioner’s image.
- Reduced stock of models and sizes at the clinic, as the Interactive Catalogue will incorporate and show all footwear models in a realistic way. The patient also has the Virtual Mirror to see how different models look like in their feet.
- Increased adherence of the patient to the prescription, allowing him to participate in the shoe design/election, by means of using the Interactive Catalogue to co-design the aesthetic of the prescribed footwear.
- Increased added value by means of the technologically advanced set of tools, which meet the patients’ demand of hi-tech elements in the most up-to-date practitioners’ clinic (the technological fashion factor as a marketing argument): 4D Dynamic Foot Scanner, pressure maps over 3D model of patient’s foot, Pressure Prediction, Interactive Catalogue, and Virtual Mirror.

On a longer time horizon, i.e. 7-10 years, the whole European podiatrist sector has the opportunity to grow by more than 50% by exploiting the project results on the worldwide global market. As a consequence of the above mentioned direct strategic impact on podiatrist, there is also a corresponding direct impact for all their suppliers and retailers, starting from the companies involved in the project. Therefore, a significant impact is expected for European suppliers and retailers in the mentioned market segments, which have the opportunity to grow by more than 25% by exploiting the final project results.

List of Websites:
The project website [www.smartpif.eu](http://www.smartpif.eu) was developed during the first months of the project and it has been considered as one of the most important dissemination tools, being regularly updated to present the latest advancement in project results.
The SMARTPIF project website was conceived with a two-fold objective:
- Having a project website as a window to the world, through which organizations/companies within the podiatry and health related sector, interested in the project outcomes, could be aware of progress and project outcomes;
- Ensuring a communication platform for the project beneficiaries and a document repository supporting collaborative work (in the private section).

Following the initial tasks related to the domain registration, selection of the web deployment technology and the creation of the website, during the second period the project Website was continuously updated with news and documents.

To sum up, the website includes the following sections:

- Home, including the project overview, SMARTPIF focus, challenge, objectives and results.
- Consortium: providing information about the project beneficiaries.
- Management: Organisation chart, contacts, WP relationships and descriptions and Work Plan.
- Results: including information of all project results achieved and explained through the project Handbook and video.
- Publications: repository of public documents generated during the project.
- Events: Information and press-releases on the project dissemination events, meetings, etc.
- Media Centre: a public repository of project logos, images and videos.
- Private login: giving access to the private section of the website (for project beneficiaries, EU Project Officer and Reviewer only).

SMARTPIF project website has been updated regularly to provide information on dissemination/validation events, project outcomes and even changes taking place throughout the project lifetime (such as the removal of the FP7 logo following the EU Commission recommendations on logo policy and the changes derived from the change of coordinator).

Furthermore, it is worth mentioning that a publishable executive summary of all project deliverables (even of confidential documents) are available in the public section of the website for downloading (publications/deliverables).

SMARTPIF project website includes Google Analytics, a free Google service (the most widely used) that generates detailed statistics about the website’s traffic. This tool allowed us to get information on the most visited sections of the website, as well as to know those documents in the website with increased number of downloads.

In fact, the website received 52,507 hits and as regards downloads, it is worth mentioning that in total 1,209 downloads of publishable summaries of project public reports.

For further information: [www.smartpif.eu](http://www.smartpif.eu)
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### Related information

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