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A collaborative web-based platform for the prescription of Custom-Made Insoles

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ABSTRACT

Many foot pathologies are prevented or treated with Custom Made Insoles (CMIs). Although a strong computerization has characterized the shoe development process during the last decade, the CMI sector still lacks a software platform integrating the design and diagnosis tools used by the stakeholders of this area. Moreover, the prescription of CMIs is only based on the experience of skilled podiatrists rather than on a common and shared knowledge (e.g. guidelines, best practices, rules, etc.).

This paper presents a multi-users and knowledge-based platform, called *Smart Prescription Platform* (*SPP*), covering the whole CMI development phases, from foot diagnosis to the production, involving clinicians, patients, manufacturers and controllers. The web-based platform is fully integrated with the technologies available in the orthopaedic sector, which are 3D/4D scanners, baropodometric platforms, footwear virtual catalogues, plantar pressure simulators, Augmented Reality devices and 3D CAD systems. The use of standard file formats (e.g. *.stl*, *.bmp*, *.xml*) allows an electronic dataflow among the tools. The main module of the platform, called *Prescription System* (PS), is used for prescribing custom-made insoles for patients with different health conditions, satisfying the needs of all actors and optimizing the data exchange. PS is a knowledge-based prescription system integrating the best practices related to the prescription of CMIs. The PS output is a *XML* file representing the electronic order, used to exchange data with the other tools of the *SPP*.

The proposed platform has been tested with a twofold aim: to validate the usability of the Prescription System and the inter-operability of the platform tools. The positive results gathered during the validation, led the experts to start using the web platform for their daily work.

1. Introduction

Many foot pathologies are prevented or treated with custom made shoes and Custom Made Insoles (CMIs), which play the most important role for the majority of the foot pathologies. Although during the last decade, the footwear sector was characterized by a strong computerization of the shoe development process (from the foot diagnosis to the manufacturing of the shoe), there is still the lack of knowledge-based software platforms supporting the whole development process of CMIs. For this reason, orthopaedic centres and manufacturing companies of insoles are forced to use handicraft procedures [22], based on the manual exchange of hard copy documents or the subjective prescription of skilled podiatrists.

The Custom-Made Insole development process entails the attendance of several stakeholders and the application of different tools. Clinicians, patients, manufacturers and controllers are all involved in the CMI development process and 3D scanners, baropodometric platforms, CAD software and NC machines are just some of the systems used by the different actors. At present, the stakeholders and the instrumentation that they use lack of an appropriate integration, and this situation leads to scarce interaction, misunderstandings and delays in the production of the insoles. The actors involved in the CMI development process have different roles and needs. Clinicians want to interact with patients, demonstrating them the importance of the product prescribed and evaluating the user's opinion. Meanwhile, the patients ask for CMIs fitting their fashionable and comfortable orthopaedic shoes. On the other hand, the controller wants to monitor the work of the clinicians in order to reduce medical malpractice. The manufacturers would like to receive electronic insole orders for their integration with design software tools (CAD and CAM) and manufacturing systems (NC

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milling machines or additive manufacturing machines). Standard and advanced tools, for the quantitative measurement of the foot parameters and for the insole modelling, produces many different and heterogeneous data, which should be collected and integrated within an only one system. Nowadays, integrated systems supporting the custom-made insole development process are not available neither in literature nor on the market.

Therefore, it is desirable to have a software platform, mainly oriented to the podiatrist needs in order to help and drive the clinicians, in a user-friendly environment, through the prescription process. Moreover, the platform has to be integrated with the existing devices and it has to involve also the patients, the manufacturers and the controllers, promoting the collaboration between stakeholders.

This paper proposes a web-based platform called *Smart Prescription Platform* (SPP), integrating all the tools and devices used during the CMI development process. In particular, the paper presents the *Prescription System* (PS), a module of *Smart Prescription Platform* used for prescribing custom-made insoles for patients with different health conditions, satisfying the needs of all actors and optimizing the data exchange.

The PS has specific functions dedicated to the four actors (podiatrist, customer, manufacturer and controller) involved in the process. It implements a user-centred methodology to connect the web application to the main important software and hardware applications currently available. In this way, the exchange of data between the various tools is safer and easier. The podiatrist collects and manages all the necessary data, coming from different systems, being able to prescribe an insole as correct as possible. In fact, the product quality will be ensured by the process itself, which controls systematically the clinician's work adherence to standard and formalized best practices of experienced personnel. Such rules are embedded into the dedicated knowledge based system.

The paper is structured as follow. Section 2 presents the state of the art related to the CMI sector, collaborative and integrated platforms to support the Product Development Process. Section 3 firstly describes the actors involved in the process and their needs. Then, this section gives a brief summary of the current practice to configure and design insoles and the main software and hardware tools available to support this process. Section 4 presents the whole Prescription Platform with an overview on the architecture (Section 4.1) and an insight on the Prescription System modules and workflow (Section 4.2). Section 4.3 presents the standard xml representing the CMI, while Section 4.4 describes the data synchronization among the databases of the platform tools. Section 4.5 presents a Custom Made Insole development process by using the Smart Prescription Platform. The proposed platform has been tested through a set of real case studies described in Section 5, which contains also the results discussion.

2. Related works

2.1. The custom-made insoles sector

Several studies (The 2009 Report on World Market Segmentation by City, The 2009–2014 World Outlook for Orthotic Insoles, The 2011–2016 World Outlook for Orthotic Insoles) found that the demand for plantar orthotics is growing. Custom-Made Insoles for the nonsurgical treatment and prevention of foot and ankle diseases can be prescribed with different aims. To off-load foot pressure in case of diabetic foot [8] or in case of loaded situations, such as for obese people [27], to avoid complications in the Charcot neuro-osteoarthropathy [13], or in rheumatic and neuropathic feet [37]. A CMI ensures postural stability in older adults [28] or in workers [33]. Moreover, a CMI can be used to guarantee comfort during running and sport activity [26,29].

In the current practice, the prescription and the development process of a custom made insole can be divided into three main steps. The first one consists in the foot analysis phase, where the podiatrist obtains all necessary foot and patient data. The second one is the insole design phase, where a technician, by using dedicated CAD systems, designs the insole and related accessories. The third one consists in the production phase, where skilled workers or NC machines are employed to manufacture the insole. Therefore, the actors involved in the CMIs development process are at least three: the patient, the clinician and the manufacturer. A fourth actor could be the controller, namely the chief of a group of orthopaedic shops or the National Health System (NHS). Although the cooperation between the participants in the process is necessary, no approaches and systems to support the prescription of CMIs, able to involve all the stakeholders working during the insole development process, are available in literature.

Furthermore, in the custom-made insole sector, the development of innovative tools made possible the transition from handcraft to digital processes. Historically, the CMIs were designed just following the foot shape [2], while nowadays also 3D foot scans and plantar pressure maps are taken into account during the insole prescription [37,8]. The instrumentation currently available in the market permits a correct and quantitative foot diagnosis. The foot shape is obtained through classic impression box while dedicated 3D or 4D scanners are used to achieve the virtual geometry of the foot respectively in a static or dynamic mode. Plantar pressure information is obtained with in-shoe pressure sensors [36,35,32], or through baropodometric platforms (e.g. F-scan System or Parotec). Simulation software tools are used to predict and visualize plantar pressure maps, curves and distributions [10]. Systems for gait analysis are also useful in the orthopaedic footwear prescription phase. Regarding the customized insole design, CAD-based solutions are available both on the market and in literature [18,17,22]. However, these tools are not interconnected in an integrated process because they are based on different databases and platforms and they do not communicate or exchange data, so the insole development process lacks of effective collaboration.

2.2. Collaborative systems

The need of integrated collaborative system is a widespread research topic addressed by the main industrial sectors. Networked collaborative design and manufacturing processes are promoted in several scientific works [12,20,11], to reduce errors and misunderstandings between stakeholders. Several collaboration technologies, which provide a consistent set of solutions to support the collaborative creation, management, dissemination, and use of information through the entire product and project lifecycle have been deployed to different application domains, including architecture, engineering, construction, and facilities management. These collaborative systems allow a more effective integration between people, processes, business systems, and information [31].

The integration of stakeholders is not sufficient to create collaborative environments. The tools and devices integration needs to be also considered. Integrated platforms are already present in several sectors. For example, in the case of Engineering, Architecture and Construction industries, a theoretical framework of technical requirements for using BIM-server as a multi-disciplinary collaboration platform has been developed [34]. Moreover, some researchers developed collaborative modelling and simulation platforms, which provide an integrated environment for multi-disciplinary teams to create, share, and integrate simulation