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PEDORTHIC INFORMATION MODELING

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Medical footwear and foot orthoses are medical devices used in the conservative treatment of foot pathomechanics. Numerous medical evidences demonstrate their efficiency but, in the same time, highlight the problems of acceptance by the patient because of their aesthetic appearance. With a few exceptions the traditional design process is based mainly on the manual skills of the pedorthist. Even if the "hand-made" process is a landmark and a valuable quality of the pedorthic devices, it doesn't mean it offers an efficient management of the large variations of design options. More than that, some processes such as the last manufacturing, which are based on the manual skills of the pedorthist, seem to be in decline because of the master's age and lack of interest for the new generations. On the other hand, other industries like building and architecture rely on modern design processes based on the parametric thinking, which allow an optimum management of the variation in the input and output data. The parametric design is the core of the Pedorthic Information Modeling allowing the propagation of any modification of the input parameters with an instant updating of the outputs. The current work is presenting the concept of Pedorthic Information Modeling.

Keywords: medical device, pedorthics, parametric design.

INTRODUCTION

Medical footwear and foot orthoses are medical devices successfully used in the conservative treatment of the foot pathomechanics. There are different professions such as pedorthics, podiatry, physiotherapy, etc., which have the provision of medical footwear and foot orthoses included in their competences. The points of intersection between all these professions are the foot orthoses and OTC footwear. If we are considering the Unique Selling Point as one product or service that is specific to a profession and mark the difference from the competition while giving unique benefits to the consumer, then the competences of pedorthics to provide solutions for custom-made medical footwear for complex foot problems is what makes the difference when compared with the other mentioned professions[1].

According to Pedorthic Association of Australia, Pedorthics is "the professional field concerned with the provision of medical grade footwear, orthotic appliances and appropriate advice to a patient after assessment and analysis of the patient's problem(s)"[2]. Pedorthic devices are included in the World Health Organization's Priority Assistive Products List under the categories of "Orthoses, lower limb" and "Therapeutic footwear; diabetic, neuropathic, orthopaedic"[3]. Pedorthics is a much more challenging field than mass production footwear industry because, next to all the elements of shoe industry, it focuses on treating a foot health problem especially when the foot morphology is not in usual "normal" standards. If we have to assign two keywords for each industry, they could be:

– for mass production footwear industry: symmetry and normality,

– for pedorthics: asymmetry and pathomechanics

Through asymmetry we understand the significant difference existing between the feet morphology of a patient which can't be analyzed through any standard that is governing the mass production footwear industry, starting from the dimensional one (size) to those much harder to be defined as the design/fashion ones.

More than that if in the mass production footwear industry there are different branches which contribute to the final product (designers, last producers, sole producers, footwear manufacturers, etc.), the pedorthist manages all the design and manufacture chain for the custom-made footwear. Generally, the pedorthist is the designer, the last and the sole/midsole producer, the lasting operator.

Despite of the medical efficiency, the problem of the product aesthetics is often mentioned by the medical literature as a barrier in their acceptance

by the patients having as a result their rejection. In the case of diabetic foot this rejection could lead to serious consequences for the patient's health, including the increasing risk for ulceration and amputation[4]. There are plenty of scientific articles which analyze the problem of acceptance or rejection of the custom-made footwear by the patients[4,5,6,7]. It is important to remark that literature generally provides the analysis of the patient's experience without indicating what the product aesthetics is and, furthermore, which are the principles based on an aesthetic product that can be designed in the condition of the above mentioned significant asymmetry between feet. It is important to note that a chapter dedicated to aesthetically principles is missing from the well-known pedorthic books, while a distinct section regarding pedorthic devices aesthetics is not available in the Pedorthic's curricula of the pedorthic schools.

If we discuss about the problem of prevention strategies for diabetic foot another barrier mentioned in the literature, next to the issues with the custom-made footwear aesthetics, is the financial margin of this product, which is much smaller compared to wound healing products[8].

Generally the use of software solutions for footwear designing is limited in practice of manufacturing to the 2D approach which implies that the 2D flattened surface of the 3D shoe last shape is obtained through the traditional "hand-made" methods (paper of thermoplastic sheets) and then digitized into a 2D CAD system. Practically there isn't a direct link between the 3D model and the 2D process of pattern design even if theoretically the existing software solutions are containing this feature. One important fact is the shoemaker/pedorthist's lack of trust in the solution provided by software and from here the weak adherence of the shoe specialists for these 3D CAD solutions. If we take as an example the shoe last manufacturing process, we we'll have a good image of the actual state of art of the industry. The majority of traditional specialists in the shoe last manufacturing is not skilled in using software solutions and don't have trust in them, even if they are very skilled with manual "sculpting" of the last shape from a raw block of wooden. From here it comes the gap between the development of software solutions and practical reality. Additionally, in the case of molded shoe made starting from positive foot cast, the modifications of the cast are not similar with the traditional last making designing process, some elements that influence the design of the final product being hard, messy and time consuming to be achieved through the using of Plaster of Paris. This can be a source of the problems with the final design appearance and the weak patients' adherence mentioned in the literature. Because the traditional shoe last making specialists are older and new specialists seem not to be attracted by this manual process, a decline in finding professional last makers is noted. If we add the major investments in technology for biomechanical evaluation and CAD-CAM manufacturing, which are almost impossible to be achieved by the small pedorthic facilities, we have a better image of the barriers existing in the large development of the pedorthics field on a digital fabrication basis. These barriers maintain the image of a mainly hand-made based or craft industry relying on the manual skills of a craftsman. This is a valuable image with a powerful appeal to the final customers even if the medical literature is demonstrating the problems with medical footwear acceptance because of its aesthetics.

This paper is proposing an enhancing of the value of Pedorthics through adding a new dimension: the one of the pedorthic devices designing process based on "parametric thinking" more than on the manual skills. The value of 'parametric thinking' should be measured through a greater flexibility, reducing the fabrication time, increasing the designing possibilities and more importantly, improving the design/fashion appearance with increasing the patient adherence. Last but not least, is important to make Pedorthics more appealing for younger specialists as it deserves for all the aspects of its complexity, starting from last design and manufacturing to the treating of complex pathomechanics problems using modern technologies and including an enhanced aesthetic dimension of the pedothic devices.

DEFINITION OF PEDORTHIC INFORMATION MODELING

A major source of inspiration in defining Pedorthic Information Modeling comes from the AEC industry (Architecture, Engineering, Constructions) where Building Information Modeling (BIM) is becoming a standard. Firstly, we can say that the Pedorthic Information Modeling represent an adaptation of Building Information Modeling to the specific Pedorthics. Some useful basic aspects regarding the definition of Building Information Modeling should be mentioned. There are different definitions for Building Information Modeling, making references to[9,10,11,12]:

– a strategy for the application of information technology to the building industry

– a type of software for simulating and documenting a building design

– a process involving creating and using 3D models

– a process and a tool to deliver particular construction projects

– a 3D model of the building

– an information model

– a collaborative working environment using shared digital representation of an asset to facilitate design, construction and operation processes

– a digital representation of physical and functional characteristics of any build object, etc.

According to Autodesk, Building Information Modeling solutions is operating on digital databases which allows the management of changing to be coordinated throughout those databases while the information is preserved and ready to be used by other applications or processes[11]. This process can be implemented through many software solutions. In the development of the Pedorthic Information Modeling concept, computer-aided design software Rhinoceros 3D and Grasshopper visual programming language were used.

Starting from these aspects we are defining Pedorthic Information Modeling as it follows:

Pedorthic Information Modeling *is the environment for the digital representation and manipulation of the aesthetic, physical and functional characteristics of the information model of the pedorthic devices relying on the parametric design approach and leading to the efficient management of multiple variations of the designing, manufacturing and evaluation processes required to fulfill the patient needs, the objectives of foot pathomechanics' conservative treatment, economic viability and legal requirements over its life cycle.*

It was preferred to be used the term "environment" as it describes the frame in which specific activities and processes are designed and is taking place in a continuous evolution.

All BIM definitions make a reference to the collaboration and information shared between the different teams which participate in a project and the ability created to the management to take decisions in an efficient way because of an improved management of information. The specific of Pedorthics imply that a small team has to manage the entire design and manufacturing process. Somehow in opposition to the Building Information Modeling the Pedorthic Information Modeling could be seen as an environment where the collaborative principles are applied to only one small team who has to fulfill the tasks of many other teams. Like in the case of AEC industry "the power of managing variation with the capacity to store, access, manage and meaningfully recombine vast quantities of relevant knowledge on a scale that is impossible for an individual to perform"[13] is possible through parametric information technologies.

PEDORTHIC INFORMATION MODELING DESCRIPTION

In order to understand the concept of Pedorthic Information Modeling better, an explanation of the included terms is necessary. A schematic representation of the concept is represented in Figure 1.

The main notions included are:

– pedorthic devices mean custom-made medical footwear or medical grade footwear and foot orthoses,

– digital representation refers to the use of CAD systems in order to obtain a virtual representation of the pedorthic devices,

– digital manipulation represents the process of image editing. Through this process it is possible to create an image of the product close to its final real look which will help the patients to understand and see how their footwear will look like,

– "information model" consists of the 3D Model geometry, non-graphical information, documents and drawings[9].

– pathomechanics can then be defined as the mechanics of living systems in motion resulting in, or leading to, dysfunction or injury[14],

– "parametric" represents "a set of equations that express a set of quantities as explicit functions of a number of independent variables, known as "parameters"[15],

– "prescription file" represents the document through which the communication between the prescriber and manufacturer is realized[16]. It contains the prescription variables[17] which are used as input parameters of the parametric design,

– "product design principles" means all the technical principles used for designing the medical footwear. Essential information for the Pedorthic Information Modeling is the anthropometric correlations between different dimensions of the foot[18]. These correlations, expressed as a function of different foot's dimensions by its length or width, are used for the generation of an initial virtual solution which will be later modified according to the prescription file and aesthetically requirements. Tools for online customization of some parameters made by the patient could be available.

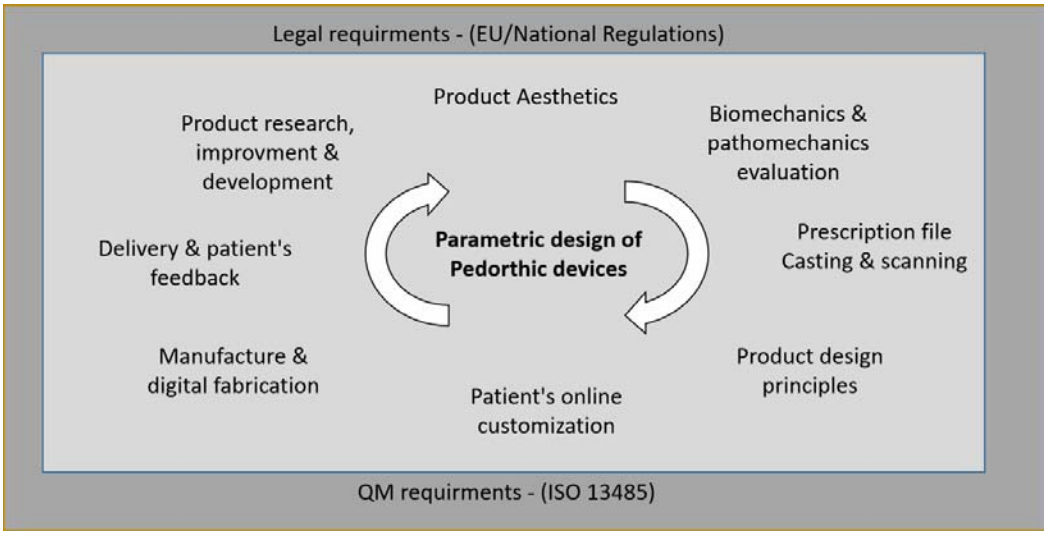


Figure 1. Schematic representation of Pedorthic Information Modeling environment.

– legal requirements, including Quality Management, refer to all the legal conditions in which a medical device is prescribed and manufactured[19,20].

The next section of the present paper will focus on explaining the core of Pedorthic Information Modeling concept which is parametric thinking and design.

PARAMETRIC DESIGN – THE CORE OF PEDORTHIC INFORMATION MODELING

In order to understand parametric modeling better we should visualize the traditional handmade process of design and manufacture of custom-made medical footwear. The design process imply operations as handmade design on 3D last, flattening of the last's surface, 2D digitization and pattern making, etc. A trial shoes made from a transparent plastic is produced and, if the fitting should be adjusted in some high pressure areas, then the last is modified through adding or subtracting material from that area of the last. If the modification is significant as magnitude then the process of making the upper's patterns should be remade. Generally the patient chooses the model according to some images from a catalogue which don't necessarily represent the final appearance of the product adapted to its feet specific morphology. It can be deducted the laborious, time consuming and difficult process of finding the most appropriate solutions in terms of aesthetics, fitting and fulfilling the medical requirements of the conservative treatment. This process is mainly a trial and error one.

In opposition with this situation, Pedorthic Information Modeling will generate a complete set of digital design manufacturing files and documentations able to manage in real time the large variation and modifications required. In this situation the hand-made process will remain only in the manufacturing process of stitching and lasting for example. It is very probable that in the near future new digital technologies, for example 3D printing, will replace the handmade process of stitching and lasting.

The economic efficiency included in the definition of Pedorthic Information Modeling could be very well explained through Boyd Paulson and MacLeamy's graphs (the later one represented in Figure 2). According to these authors, the ability to impact the costs of a project/product is greater in the first stages of development and it decreases in time in parallel with an increasing of costs imposed by a changing made towards the end of the project implementation. As a consequence the designer has to be able to generate a sustainable solution from the design process in an opposition with a traditional process where it could be significant differences between the catalogue and final product, the modifications needed requiring the manufacturing of another product[15].

In order to be able to generate such a solution the designer should entirely rely on valid parametric information technologies able to generate the digital representation of the final product.

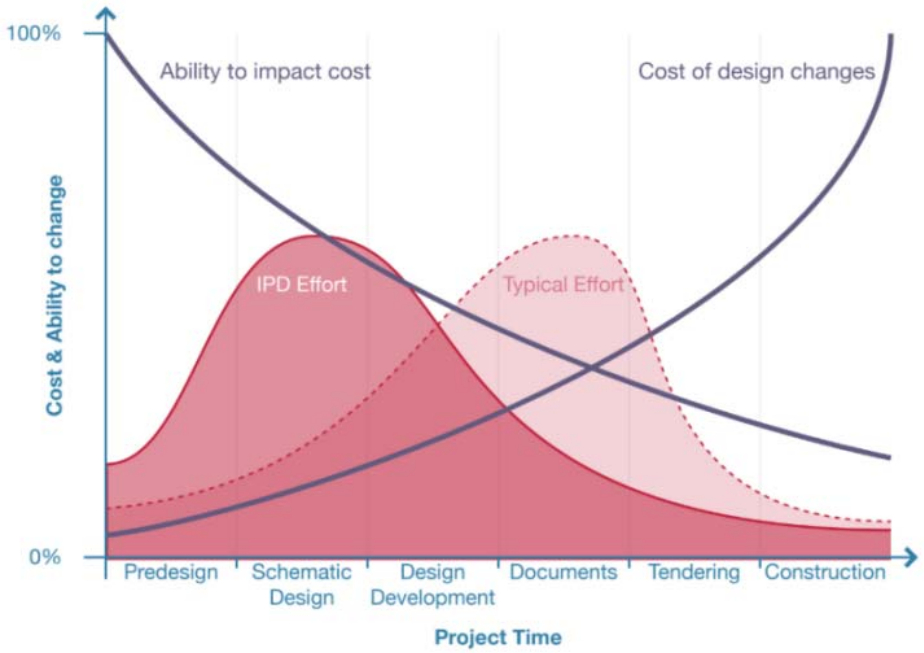


Figure 2. MacLeamy's curve (2001) from Daniel Davis reprinted with permission.[15]

PARAMETRIC THINKING

In its simplest form parametric thinking implies the understanding of the fact that in order to achieve a goal (for example designing a shoe last) through a software solution it is necessary to manipulate some input data (such as heel height, ball width, bottom last length, shape of some curves, etc). In its advanced form it implies an understanding on how a geometric model (like last surface) representing an output can be designed through a set of functions of parameters which are the independent variables or the inputs. According to Daniel Davis[15], "a parametric model is created by a designer explicitly stating how outcomes derive from a set of parameters" while "expressing design intentions with parameters and explicit functions requires a different way of thinking than most designers are accustomed to. In addition to thinking about what they are designing, architects working with parametric models must also think about the logical sequence of formulas, parameters, and relationships that explain how to create their designs". With Pedorthic Information Modeling a pedorthist has to think like an architect.

These are the fundamental characteristics which make Pedorthic Information Modeling different from the traditional approach of custom-made shoe making where the craftsman skills are mandatory. These skills are based on the native qualities and many years of practice based mainly on a trial and error process. More than that, the way in which the last shape is created, can't be very clear explained by the craftsman, making the process of learning difficult. The traditional shoe designing and manufacturing process 'can be described as an art of producing a three-dimensional, dynamic article from two-dimensional material'[21]. It can be seen that parametric design brings a total different philosophy of thinking, designing and manufacturing medical footwear. Pedorthic Information Modeling represents a logical evolution of a profession from mainly a handmade design to a data-driven design in the actual context of evolution of design concepts from other design domains.

The process of parametrical thinking could be schematically represented through a function which is modifying an input in order to obtain the desired output (Figure 3). In the easiest example: if we need a "line" as output, then we have to provide to the "draw a line" function the 2 points required. In the next step: if we want to modify the properties of the line, (as length or position) we only have to modify the positions of initial points and this modification will be propagated, modifying the final output.

Figure 3. Parametric thinking.

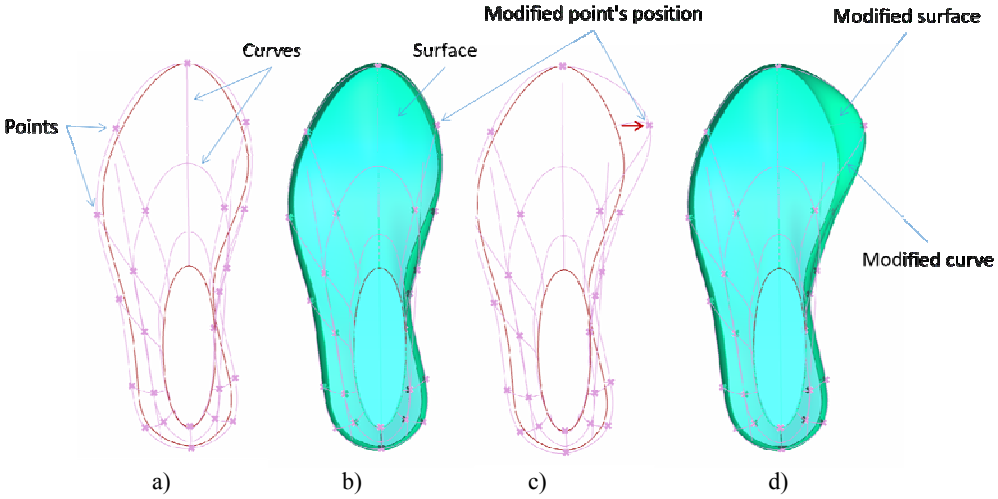


Figure 4. Thinking parmetric applied to the shoe last's design:
a) initial points (inputs) and curves, b) generated last surface (output), c) point and curves modifications, d) resulted modified surface.

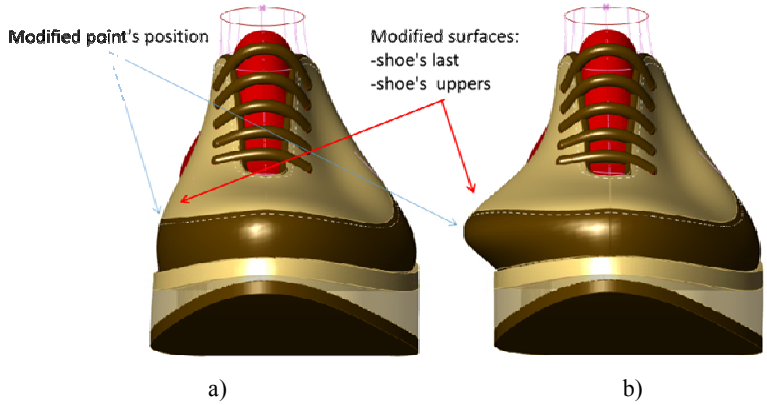


Figure 5. Input (point's position) modification effect on outputs (last and uppers' surfaces).
The modification corresponds to those exemplified in Figure 4: a) initial shapes, b) modified shapes.

An example on how this principle functions in the case of footwear is shown in Figures 4 and 5. If the last surface is defined starting from points as inputs, (Fig. 4a) which generate curves (Fig. 4a) using specific functions in order to obtain as output the lateral surface of the last, (Fig. 4b) then modifying the position of one point (an input) in medio-lateral direction (Fig. 4c) will generate a modification of the shape of the curve containing that point (Fig. 4c) and of the last surface shape (Fig. 4d).

This initial modification of an input parameter (point's position) will propagate instant in all dependent objects as shoe uppers (Fig. 5), shoe sole or foot orthoses.

In this way it is possible to manage easily a multitude of variations and changes in the input parameters and rapidly visualize their effect on the final product. A simplified representation of the parametric design process is presented in Figure 6. The inputs can be of different formats as spreadsheet, images, CAD files, sliders (for the control of numeric values), .stl files, etc. Files generates from biomechanical evaluations (force platforms, pressure platforms, sensors, etc.) could be an input through spreadsheet or .csv similar types of files. An output file could be used as an input file. For example working alternatively to the right and left foot in the same session implies that the corresponding data files for each foot are alternatively saved and loaded into application until the final design is achieved. As it can be seen, the modifications required are made in the design process prior to enter in the manufacturing process. It could be implemented an online customization tool where the patient has the possibility to modify some aesthetical parameters as colors, textures or type of design and to give his final accept for the medical footwear to enter in the manufacturing phase. Such a tool has the potential to increase the product acceptance because the patient will see, in a realistic representation, how the product will fit the morphology of his feet.

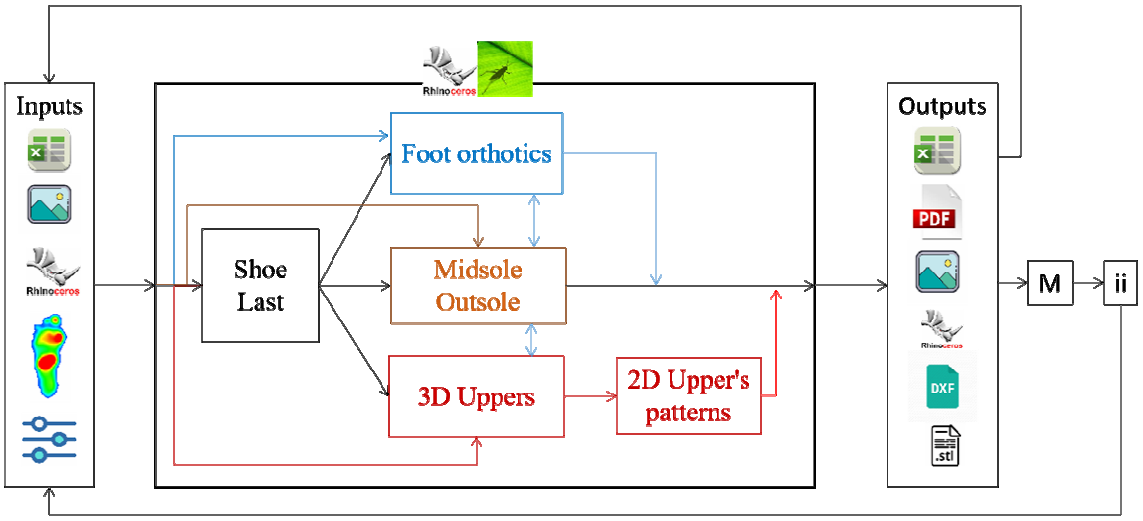


Figure 6. Simplified representation of the parametric design process
where "M" = manufacturing, "ii" = Implementation-Improvement.

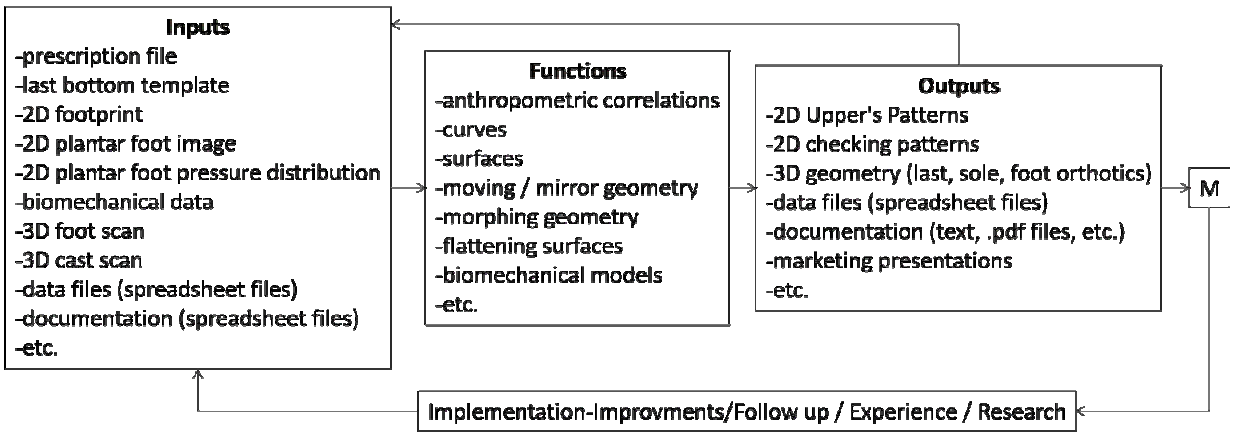


Figure 7. Examples of inputs, functions and outputs of Pedorthic Information Modeling
"M" means manufacturing process.

A more detailed list of possible inputs, functions and outputs is presented in Figure 7 followed by examples of inputs, functions and outputs.

1. Inputs:

– independent variables: initial coefficients of anthropometric correlations, 2D images, 3D scans, biomechanical data, etc.

– aesthetic – mainly introduced through feet proportions, product design principles and flexibility and rapidity of performing modifications.

Initial inputs are generating an average virtual initial solution which doesn't have any practical applicability for the requested outcomes in terms of final functionality. Through the application of functions, the initial input will be transformed in the final output which will represent a fully functional initial solution. Furthermore, following the implementation of the conservative treatment, this initial solution could be improved based on the patient's feedback and clinical evaluations.

The inputs could be introduced through different types of files as spreadsheets, text files, image files, CAD files, etc.

2. Functions:

– human foot proportions or anthropometric correlation between different dimensions of the foot are used to calculate initial values for different input parameters (such as basic points positions, which are defining a standard shoe last' shape),

– translations,

– rotations,

– scaling – for example if a last bottom template is used and its length should be modified according to patient's foot length then a scaling function will be applied,

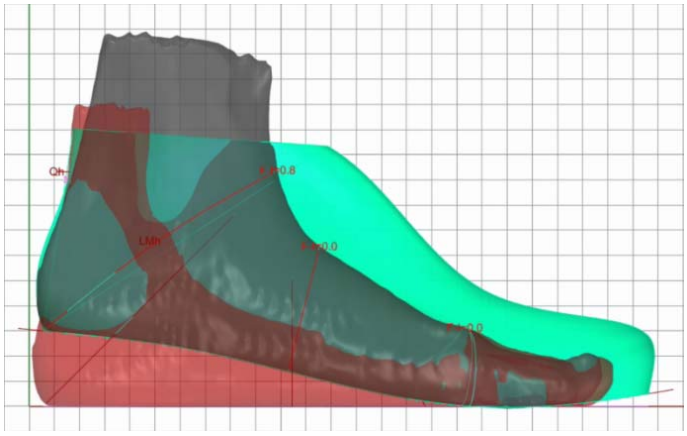
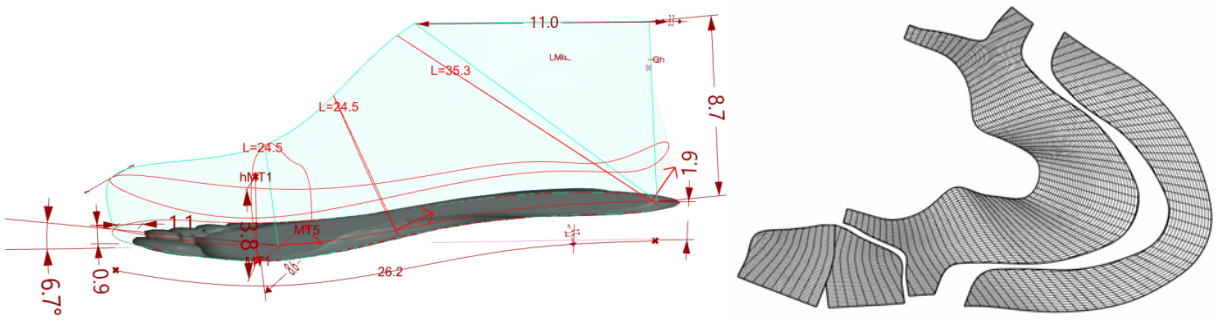


Figure 8. An example of the morphing function.



a) b)

Figure 9. An output containing: (a) the relevant shoe last's dimensions and (b) 2D upper's pattern ready for automated cutting.

– morphing – a basic morphing function is presented in Figure 8. With this function an initial input as an weight bearing foot scan is modified according to the parameters which are defining the sagittal profile of the last (for example: prescribed heel height, toe rocker angle, cuboid height, etc.). In this way using a valid morphing function which will take into account the modification of the shape of the foot in dynamics (walking or running), the final fitting is virtually checked in the design phase. This will eliminate the need for transparent/testing footwear, will decrease the costs with trial fitting and transparent footwear and will reduce the manufacturing time and the need for patient to come for fitting check.

– flattening is the function which is transforming the 3D lateral surface of the shoe last in a 2D surface used to obtain the 2D uppers' patterns. The process is allowing the automated generation of the 2D patterns leaving the possibility to perform some adjustments of the position of the specific 2D patterns.

3. Outputs:

– 3D parts like the ones in the last file (Figure 9a), the shoe's own component files (outsole, midsole, etc.),

– 2D parts as patterns: uppers (Figure 9b), lining, stiffeners or checking patterns for last surface,

– spreadsheet files with the parameters' values for one specified solution/design. These files can be used as input files when a modification or replication of a solution is required. Them will form a database of solutions useful for future analysis,

– tools for online customization – the customer can choose for example the color, type of material, textures, etc.

FUTURE DEVELOPMENTS

There is an increased interest in introducing digital fabrication method in pedorthics on a large scale. This is reflected especially into specific products and technologies focused on foot scanning and foot orthoses printing at the moment, but, also through dedicated sections as "Digitalization in Pedorthics" in the frame of pedorthics congresses[22–24] If these methods and technologies are presented for particular components of pedorthic devices, the Pedorthic Information Modeling is introducing an environment for the

design of pedorthic devices as a whole. This paper was focused especially on the parametric design of the footwear geometry, but Pedorthic Information Modeling could be improved in many directions, as for example:

– introducing subdivision surface modeling methods, morphing functions and generative design,

– improved digital image manipulation and rendering techniques,

– using the lattice structures in order to add next to the cushioning and support the possibility to influence the rotational friction of pedorthic devices[25],

– controlling the material stiffness in different regions of the same part,

– data mining on the resulted databases,

– including simple biomechanical models for the simulation of the dynamic behaviour of the foot-foot orthoses-footwear assembly[26].

A "digital pedorthics educational agenda" is desirable to be introduced as it happens in fields like AEC industry, where BIM concept is part of curricula, allowing the architects and engineers to have the knowledge and competences to build their own applications for the design of the projects[27].

CONCLUSIONS

Pedorthic Information Modeling could be seen as an application and adaptation of the Building Information Modeling from AEC industry to the specific of Pedorthics.

It is defined by:

– introducing a complex environment for the digital design and fabrication of all components of pedorthic device according to their construction interdependence,

– using parametric thinking,

– enhancing the aesthetically value of pedorthics devices based on parametric design,

– adding the dimension of data-driven design to the Pedorthic profession, making possible a new development direction next to the traditional one based on the hand-made approach.

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