FutureFeet

1.Design inputs

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1 Theoretical content

From a general point of view, the term design is defined as the action of making or drawing plans for something (Cambridge dictionary) which in this case is a FO model. When designing a FO, the pursued effect of the treatment should be considered simultaneously with the manufacturing constraints [2–4]. The manufacturing constraints are especially related to the manufacturing process itself, and to the materials usable with this manufacturing process [2–5].

With this perspective in mind, it seems logic that the emergence of new manufacturing techniques have allowed the design of products with new properties [6] and also gave birth to new ways of designing a product [7]which have then been applied into the world of orthotics [8,9]. These innovations have brought promising opportunities in particular to improve the understanding of the effect of FO geometric features on biomechanical variables. This part illustrates these opportunities and also gives a critical appraisal.

Input, as defined by the *Cambridge Dictionary*, can be an 'information that is put into a system so it can operate'. In this work we defined the term design input as data which are used to design a FO model and which can be classified into biological, psychological, social or multi-dimensional components. These input data can be collected in different ways, and their collection will probably depend on the clinician's clinical knowledge and skills and on his scientific and philosophical viewpoints[10]. Below, the design inputs used to **design a FO** are described separately, but it is important to emphasize that the FO design can also be based on a combination of several inputs [11,12]. Actually, despite the potential added value created by the combination of different design inputs[11,12], it seems that FO literature mainly analyzed FO which were designed with the unique use of a foot geometry representation. Thus, there is probably a discrepancy between the design process implemented in practice[13–25] compared to the one implemented in research and therefore, the debate on the degree of customization of FO might only apply to scientific literature. By introducing a **specific terminology**, this work aims to meet the need to better describe and embrace these design inputs and their method of acquisition and thus fill the gap between research and clinical practice[26]. In this work, a better description of FO design was identified as the first step to allow a more accurate replication of FO.

I. Biological component

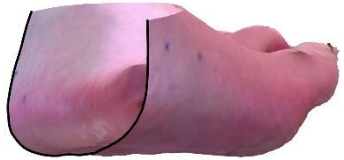
As it has been highlighted in the literature, the geometry of the foot may notably be associated with plantar pressure variables [27] and postural stability[28]. In this perspective, the foot geometry may be considered as a biomarker since it is a variable associated with disease outcome [29]. Actually, the foot geometry representations used to design FO have often been used to define the degree of customisation of FO [13,14]. The use of such representations, referred as foot model in this work, is systematic for the design of a FO since FO should at least correspond to a shoe size. Findings also suggest there are critical dimensions of the feet for footwear fitting to ensure good fit and comfort[30]. The same considerations are likely to be true when taking measurements for good fit and comfort of foot orthotics. Achieving an accurate fit of a foot orthotic is an important factor in foot orthoses design and manufacture and requires some consideration to be given to reliability and repeatability of measures for capturing foot model.

Previously, foot models have exclusively been captured in a physical way typically via the use of foam box or plaster cast techniques [13,14]. Nowadays, we are able to capture and generate foot models in a digital way via the use of technologies such as digital camera or 3D scanner[13,14]. This section illustrates these new technologies as well as their added value. In addition, a new terminology is introduced to better describe foot models.

Foot models can have different dimensions and since the geometry is considered as an attribute of an object [31], a foot model will always be represented in the spatial dimension. The spatial representation of a foot model can vary according to:

A) The number of dimensions
B) The type of geometry
C) The fact it is specific or unspecific to a patient (if its patient specific, it will be a biomarker).

Firstly, the foot model has a number of spatial dimensions which can be determined in different ways [31–33]. In this work, it will be determined by the dimension of the space that encompasses the model [33] (Figure 1). Secondly, the foot model can be a point, a line, a curve, a surface or a solid [33]. While the point, the line and solid have a consistent number of dimensions, the curve and surface can have 2 or 3 dimensions (Figure 1). Finally, the foot model can be defined as patient-specific or patient-unspecific depending on whether it comes from patient-specific data or not.

Image	Type of Geometry	Number of dimensions	Description	Illustrations
	Point	0	Point Foot Model	
	Line	1	Line Foot Model	
	Curve	2	2D Curve Foot Model	
		3	3D Curve Foot Model	

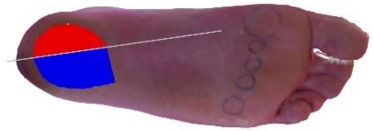
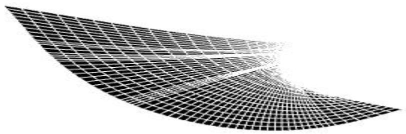
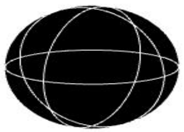
	Surface	2	2D Surface Foot Model	
		3	3D Surface Foot Model	
	Solid	3	Solid Foot Model	Foot skeleton, IRM ?

Figure 2: Type of geometry and number of dimensions of a model

Foot models are typically used to determine the 3D upper surface of a FO. In some cases, an extrapolation of data is needed in order to determine the FO's 3D upper surface[13]. This is namely the case when a point, a line, a 2D or 3D curve or a 2D surface foot model is used to design a FO since some deductions are required to obtain the 3D upper surface of the FO. [13]. A great example is the use of the navicular height (patient-specific point foot model) to determine the arch height of the FO [12]. While the point, 2D or 3D curve and 2D surface foot models can all be extrapolated to determine the FO's 3D upper surface, FO based on a patient-specific line foot model have received particular attention in the scientific literature and are regularly used in clinical practice [34–37]. These FO, which have often been referred as "prefabricated FO", are based on the foot size of the patient [34–37].

A lot of effort has also been dedicated to the analysis of FO referred as "customised FO" which are defined as FO based on a patient-specific 3D surface foot model [38]. The patient-specific 3D surface foot models have long been physical models but the development of 3D scanning techniques has also enabled the acquisition of digitized models [1,26,39,40]. While the measurements on the physical and digitized models are in general comparable, the use of the 3D scanning techniques have a time and cost advantage which can be maximized by making the acquisition directly on the patient's foot to avoid a casting procedure [26]. From an ecological point of view, avoiding the casting procedure can also be deemed advantageous since it automatically reduces the waste of material[41]. In addition, whilst use of impression boxes and plaster casting for capturing foot shape have remained unchanged for decades, they been shown to be error prone and less repeatable than 3D scanning. Some studies provide some evidence that high levels of intra and inter-rater reliability can be achieved using digital scanning methods compared to use of a manual suspension cast and foam impression boxes. Nevertheless, to promote a repeatable acquisition of a 3D surface model the method of acquisition should be well-described and in particular the positioning of the foot since it has already been suggested that it can impair the reliability of the 3D surface model acquisition [39,42–45].

The 3D scanning techniques allow the digitalization of the 3D surface of physical parts and has undergone a revolution in the past few years in terms of technology and costs [1,26,39,40]. There are numerous 3D scanning techniques [1] which can differ in their ability to capture the three-dimensional anatomy of a person's foot [4,26,40,46], their speed of processing [46] and their cost-effectiveness [46]. Price (2016) looked at the repeatability and validity of producing 3D models from an APP and a 3-D scanner to capture the 3D surface foot model to get an accurate picture of foot size[47]. The 3-d scanner demonstrated greater repeatability and the study recommended that caution be applied when using APP's to estimate foot size as there is a greater degree of observed error[47]. While it has been suggested that the laser scanning and the structured light techniques are the most used techniques to obtain a 3D surface model of a body part [48], it has also been highlighted that the laser scanning seems to be the most suitable technique [49]. The laser scanning technique uses a projected laser to measure the distance to the surface [48]. This technique is usually performed with a hand-held device which can move around the scanned part and in this way allow the capture of certain details which would be much more difficult to capture with a stationary scan [48]. In addition, it has a high performance in terms of costs, resolution, speed, accuracy and overall efficiency [48,49].

New technologies which measure objects in three spatial dimensions over time (4D scan) have enabled to describe the dynamic behaviour of a patient-specific 3D surface foot model [11,12,50]. As it has already been demonstrated before, using the dynamic behaviour of a patient's foot for the design of FO resulted in improved biomechanical effectiveness [11,12]. It can therefore be speculated that the incorporation of the dynamic behaviour of a 3D surface foot model into the design of FO could result in similar improvements in FO effectiveness, but it has never been investigated yet. This can be explained by the fact that until now the literature has especially focussed on the technological challenges associated with measurements [50–54]. On the other hand, the Finite Element Analysis which use the dynamic behaviour of a patient-unspecific solid foot model for the design of FO has also been shown to be effective from a biomechanical perspective [55–64]. However, due to its time consuming procedure and its complexity, its utilization is probably not suitable for clinical practice at the time being [56] and it might be even more the case when the data are patient-specific [64].

Previous work have demonstrated that combining the use of a foot model with another biological input for the design of FO can improve the biomechanical effectiveness of FO[11,12]. However, while foot models are systematically used to design a FO, very few studies have combined them with other biological inputs to design FO [11,12,65]. While such type of combinations has rarely been used in the scientific literature it would be hard to believe that it is also the case in clinical practice. Effectively, beside the kinematic variables used in the prominent concepts[13,14,23–25,15–22], other variables can also be used such as skin elasticity, hyperkeratotic lesions, loss of fat pad thickness, bony prominence or medical imagery.

II. Psychological component

Some research has taken into account the user's opinion in the design of an orthotic in order to change the way they will perceive and relate to the final product [66]. The integration of the user's opinion has been done without interfering with the functional characteristic of the model [66]. It has been shown that personalising a product can increase the value perceived by the user [67] and that it is a potential source of greater product usage life and hence improved sustainability [68,69]. Thus, integrating the user's opinion in the design of FO could among other things be a great strategy to improve the adherence to FO intervention which is a critical point among diabetic patients [70]. Based on previous research results, it can also be suggested that the appearance of FO affects some treatment outcomes via its influence on the expectation of the intervention[17,71–73]. Thus, it can be speculated that some visual properties related to the FO can affect the placebo effect[17].

III. Social component

To the best of our knowledge, the integration of a social variable into the design of FO has never been investigated yet. However, the reaction forces at the FO interface will always depend on the activity performed [74]. It can therefore be speculated that taking the activities of a patient into consideration when determining the biological stimulus of FO could result in improvements in FO effectiveness.

IV. Multi-dimensional component

Some information used to design FO cannot categorically be classified as biological, psychological or social since they concern by nature more than one of these components. This is namely the case for pain and perceptions which are multi-dimensionnal variables that can be used to design FO [17,71–73,75–78].

2 Task

- After having consulted the videos related to the scanning, compare the geometry of some of the 3d surface foot model provided:

    - Example 1 VS Example 2

    - Example 1 VS Example 3

    - Example 3 VS Example 5

- For each of the category below, report one design input and how it could potentially impact the geometric feature or the visual or physical properties of a FO design:

    - Biological design input:

    - Psychological design input:

    - Social design input:

    - Multidimensional design input:

3 References

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