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An exhaustive method for researching articular orthosis mechanisms at the conceptual design stage.

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Abstract

Population aging in recent years has increased the number of people needing orthoses to assist or rehabilitate a failing joint or limb. However, as these are a class 1 medical device, orthosis development is mainly based on companies' empirical knowledge and this can often result in usage problems and consequently, in the most extreme cases, in the devices being abandoned. Additionally, since articular orthoses may enable a movement to be performed, this imposes additional development restrictions which should be considered during the conceptual design stage of product development. As there are limited design tools available for the conceptual design stage and existing design methods are not well adapted to the development of these demanding medical devices, the development of articular orthoses may lead to inaccurate and maladjusted concepts, ill-adapted to the user's needs, and consequently, a source of discomfort. The aim of the design method proposed here is to help the mechanical designer during the conceptual design stage by taking into account from the beginning of the development process the way articular orthoses are used in life situations and at significant moments. Additionally, based on the theory of mechanisms, concepts such as the number of components, degrees of freedom and degrees of hyperstatism can be considered. This provides an exhaustive list of possible concepts for the articular mechanism which are subsequently screened according to different criteria related to the specific limb anatomy and specific medical conditions of the user in order to optimize concept choice. On this basis, this study develops an exhaustive research method to reach a large number of possible articular mechanisms to perform the desired articular movement for a specific orthosis, also taking into account the specific human body part.

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Keywords: conceptual design, design method, theory of mechanisms, orthoses

1. Introduction

The demand for medical devices in general and orthoses in particular has increased in recent years especially because of the aging of the world population, which is estimated to reach 7.3 million in 2020 [1]. Despite the evident increase in this market, the development of these devices mainly rests on the empirical knowledge of the enterprises, mainly SMEs (small and medium enterprises).

Presently there are no design methods specifically focused on orthosis design, which consequently may lead to maladjusted and inefficient devices. However, it is understandable that user needs depend on the patients' medical conditions, the human body segment to be treated, the kinematic behavior of the orthosis, the forces involved and the way to control these forces, and these are important criteria that should be taken into account during the conceptual design stage of orthosis development [1], [2].

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Additionally, orthoses are orthopedic medical devices that support or correct human body segments with the purpose of improving the users' quality of life. Based on the functions / functionalities that each orthosis needs to perform, they can be divided into two main families: the non-articular and the articular. The difference between these two groups lies in the fact that the articular orthosis is allowed a certain controlled amplitude of movement, while the non-articular is not. In other words, the articular orthosis lets the user adjust his positions according to his needs, while the non-articular ones have only one predetermined position.

Fig. 1. Examples of articular orthoses
(knee, trunk and hip orthoses from left to right)

In addition to the differences between these two kinds of orthosis, the design process associated to each one may present some particularities since it should be based on the main role that they should perform. While the non-articular orthosis should only respect the corresponding body segment in its shape, the articular orthosis should also consider the movements of the members. Thus the articular orthosis also entails problems linked with the mechanism that regulates the device (the articular part). As orthosis development especially includes the enterprises' empirical knowledge (due to a class 1 medical device classification) there are no methodologies adapted to the planning and development of such mechanisms. However in articular orthoses, the mechanism that provides the articulation between the different parts of the device may have an important impact on its performance. Planning the articular solutions that can fulfil the demands of articular orthoses therefore represents one of the main problems in its design process and is consequently a product differentiation parameter [1]-[5].

For these reasons, the development of the articular mechanism should be considered from the early stages of device development. Although several design methodologies may divide the design stages into different phases, the conceptual design stage is considered as one of the most relevant ones and one where the main decisions about the final product are made [6], [7]. This factor also indicates that the conceptual design stage may have an important impact on the final product performance and acceptance [6]-[9]. Additionally, it is during the conceptual design stage that ideas should be generated as concrete and approximate representations through an abstraction process. This abstraction process will enable the designer to empty his mind of concepts known previously, based on his experience, and search for a solution in several different fields and domains [6]-[8], [10]. Despite the relevance of this design stage and the impact that it may have on the final product (Fig.2) few tools are available to the designer to develop a concept [10]. This entails additional problems and restrictions for concept definition which will consequently be reflected in the final product. This design problem is transversal to all design domains, however, it is very relevant in the orthosis design process due to the device specificities.

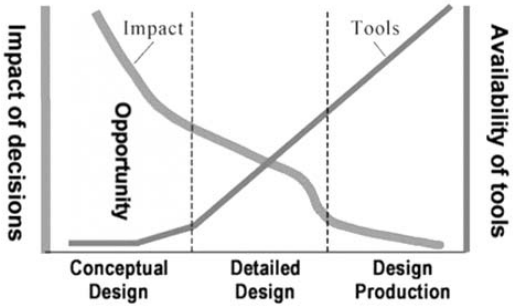

Fig. 2. Opportunity in the early design stages (adapted from [10])

Additionally, there are many uncertainties due to the lack of available knowledge or the vague information at this stage which may make design process management difficult [7], [10]. On this basis, the main purpose of design research is the search for and development of new methods and systems, moving away from the determinisms of the past and taking into account different scientific domains [6], [11], [12].

Additionally, this lack of tools leads to a lack of methods capable of being used to improve creativity during the conceptual design stage. Creativity is a complex human competence which depends largely on designer's experience. This may lead in many cases to undated products as designers may have a tendency to develop a new product based on their previous experiences. Thus it can happen that the designer may miss an optimal concept. Creativity can be described as an ensemble of knowledge that can help to solve a specific problem [8], [13]. It can open a window onto the development of research methods during the conceptual design stage [6]-[8]. Methods such as QFD (Quality Function Deployment), TRIZ (theory of the resolution of invention-related tasks) and Heuristic trees have all been used to help in creativity during the conceptual design stage [14], [15]. However, the medical domain, and more specifically the orthosis domain, has its particularities and consequently these methods alone may not provide sufficient help during the conceptual design stage.

Due to the particularity of the orthoses domain and as there is no method specifically related to orthosis development, the purpose of this work was to develop an exhaustive research method to produce technological orthosis solutions during the conceptual design stage. The proposed method takes into account concepts such as references, supports, components, degrees of freedom (DoF) and hyperstatism according to the life situation and significant moments.

2. Materials and methods

The proposed method needs some initial clarification in terms of certain concepts used later such as *references*, *supports* and *components*. Next, the definition of life situations and significant moments will be presented. Then an exhaustive research method will be used to develop articular systems during one of the defined life situations.