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ORTHESIS DESIGN: DEFINITION OF REQUIREMENTS BASED ON THE USER, PRODUCT AND CONTEXT OF USE

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Abstract The definition of design requirements is necessary for the generation of alternatives in the product development process. In this case, the Guidance for Project Development (GODP) was used, which is based on information related to the blocks of information associated to the user, product and context. The specific case of this research is the development of a knee joint orthosis of a patient with walking difficulties associated with mental disorders. The requirements defined for each block were divided into health, safety and comfort. The user block refers to the stabilization of the gait and consequently the improvement of the body posture. The product block contextualizes the joint with locking and adjustment of the angle of flexion and extension of the knee. Finally, the context block, which is related to the use of the orthosis during gait in the parallel bars

Keywords: Orthotic Project, Ergonomics, Guide to Guidance for Project Development, Knee Joint

1. INTRODUCTION

Segundo dados do Censo de 2010, o Brasil apresenta 23,9% da população, ou seja, 45,6 milhões de Pessoas com Deficiência (PD). O estado de Santa Catarina apresenta 21,3% ou 1,3 milhões de PD, dos quais 31,58% ou 420,5 mil apresentam deficiência motora (IBGE, 2011). Com base nestes dados, o Governo Federal lançou por meio do Decreto nº 7.612, de 2011, o Plano Nacional dos Direitos da Pessoa com Deficiência – Viver sem Limite, para que todas as PD alcancem equiparação de oportunidades e não sejam impossibilitadas de realizar sonhos, desejos e projetos de vidas. Nesse sentido, as pessoas com deficiência necessitam de recurso tecnológico que auxilie na execução de suas tarefas ou locomoção da melhor forma possível.

Diante desse contexto, verifica-se que a mobilidade é considerada um aspecto essencial da vida humana e desempenha papel determinante no estado de saúde, na realização das atividades de vida diária, na participação social e laboral e, conseqüentemente, na qualidade de vida. No entanto, as pessoas com redução da mobilidade podem ter o estado de saúde comprometido (JOHNSON et al., 2008). Dentre os distúrbios que alteram a mobilidade de um indivíduo, as patologias neurológicas apresentam importância, pois segundo Adams e Perry (2007) com a perda parcial do controle motor, ocorre comprometimento muscular, equilíbrio e sensorial.

Dessa forma, os estudos dos dispositivos de auxílio à mobilidade têm sido conduzidos, no sentido de identificar quais os aspectos do produto estão relacionados ao uso seguro, eficiente, satisfatório e a usabilidade. No entanto, a interação entre design e saúde, no âmbito projetual é carente, uma vez que a intervenção do design nos dispositivos de Tecnologia Assistiva (TA) disponíveis no mercado ainda é limitada. Além disso, as tecnologias atuais para desenvolvimento

de órteses customizadas são bastante artesanais, implicando em desconforto, imprecisão, longo tempo para sua confecção e processos

tradicionais de manufatura com limitações em relação ao custo e tempo para a sua obtenção.

Diante do exposto, verificando a necessidade do desenvolvimento de órteses de baixo custo para auxílio e mobilidade das PD, o objetivo da pesquisa foi definir requisitos de projeto para a órtese, com base em informações do usuário, do produto e do contexto de uso em um paciente com dificuldades de marcha (necessitando estabilizar as articulações dos joelhos) associados a distúrbios mentais.

2. METHODOLOGY

THEORETICAL REFERENCE

In the context of PD, ergonomics helps in the development of products that can increase the independence and quality of life of these people, such as Assistive Technology equipment. AT covers products, equipment, devices, resources, methodologies, strategies, practices and services that aim to promote functionality, related to the activity and participation of PD or those with reduced mobility, aiming at their autonomy, independence, quality of life and social inclusion (BRAZIL, 2015). AT encompasses knowledge from different professions, such as physiotherapists, occupational therapists, doctors, engineers, designers, among others (GUIMARÃES, 2015).

In this sense, the different approaches in Assistive Technology must seek to intervene efficiently in the disability-disability-disadvantage process, in order to guarantee conditions for the full social inclusion of PD or reduced mobility. Engineering and Design can, through their scientific knowledge and design practice, contribute both to the humanization of user interactions, such as MT in the use process, and to the development of products and systems that aim to promote autonomy, quality of life and social inclusion.

In this context, orthoses, which are examples of AT, are any support or external device applied to the body to

modify the functional or structural aspects of the musculoskeletal system, to obtain some mechanical or orthopedic advantage (LEVY and CORTÉS BARRAGÁN, 2003). Furthermore, according to Kakkad (2011), lower limb orthoses have the functions of providing stability, reducing load, relieving pain, controlling deformities and limiting joint movement, helping the user to walk.

In the market for orthoses for the lower limbs, the most common are orthoses for the post-operative period, fractures and ligament injuries, in which the knee joint is fixed at a certain angle or completely free, allowing significant variations in amplitude of movement. movement (MOREIRA, SEABRA and FLORES, 2007). In addition, there are several orthoses that are used for patients with neuromuscular disorders that also aim to stabilize the knee. In this sense, KAFO orthoses (Knee Ankle Foot Orthosis - knee-ankle-foot orthosis) have been widely used, which are dynamic, that is, they allow fixation of the knee during the support phase and flexion of the knee during the swing phase of gait (MOREIRA, SEABRA and FLORES, 2007). Furthermore, the

Orthoses can be used to assist physiotherapeutic treatment, for example, generating stabilization in the lower limbs and facilitating the patient's gait. However, currently, many of these orthoses are expensive and are not yet available to the majority of the population.

The process of making custom-made orthoses and prosthetics is complex and must always be prescribed by a doctor or, when non-surgical, by a physiotherapist. The simple distortion in this type of product is capable of causing bad consequences for users. Therefore, it is important that companies provide assistive products within the concepts of ergonomics (SILVA et al. 2014). In this sense, according to Silva (2005), the elaboration of a project needs to be based on careful planning, solid conceptual reflections and based on existing knowledge, so that the results are satisfactory.

METHODOLOGICAL PROCEDURES

This research is characterized as applied in nature, with a qualitative, descriptive and exploratory approach. It took place at the Institute of Psychiatry of Santa Catarina (IPq-SC), which is the only public hospital in the State that provides Psychiatric care maintained by the State Department of Health of Santa Catarina and contracted with the Ministry of Health, during the year 2015. The institute mainly serves a low-income population, coming from the municipalities of Greater Florianópolis and the interior of the State.

The research was carried out in two stages, one theoretical and the other practical. In the first stage, data collection was carried out through bibliographical research (books, scientific articles, theses and dissertations) and in the databases of the CAPES Periodicals Portal (Coordination for the Improvement of Higher Education Personnel). In the second stage, visits were made to IPq-SC, specifically to the physiotherapy sector and with the patient, using information collection techniques and tools (interviews, records, document analysis) as well as the use of equipment (motion capture, electromyography, thermography and dynamometry). The Guidance Guide for Project Development (GODP) was used to generate the information blocks (user, product and context) and consequent definition of the orthosis design requirements (MERINO, 2014).

DEVELOPMENT

GODP aims to organize and offer a sequence of actions that enable design to be developed consciously, taking into account the greatest number of aspects and responding in a more assertive and consistent way to the objectives established for design practice (MERINO, 2014). The GODP is divided into eight stages, separated into three moments: Inspiration (-1/0/1), Ideation (2/3) and Implementation (4/5/6). This study covered steps -1, 0, 1 and 2. Below is a summary of the steps performed.

In stage -1, the project opportunity arose with the visit to IPq-SC, where patient A's insecurity and postural

instability were verified when walking without support or assistance. Therefore, depending on the circumstances, it was decided that an orthosis would be developed to stabilize the knees to assist the patient's gait. From stage 0, prospecting, a preliminary study was carried out defining the central problem of the project. In addition to research at the National Institute of Industrial Property and Google Patents. Research was carried out on the musculoskeletal system of the lower limbs, to gain greater understanding of the topics involving the development of the orthosis. Stage 1, referring to data collection, in addition to understanding information about context, product and user, covers ergonomic, anthropometric, usability, biomechanics and other issues related to legislation and technical standards. This data was collected mainly in books, theses, articles and research websites, such as the CAPES journal database. In stage 2, organization and analysis, synchronic and diachronic analyzes of knee orthoses were carried out. This stage allowed the elaboration of information blocks (user, product and context) and the consequent definition of project requirements.

Studies on orthoses were deepened in new visits to IPq-SC, where data about the patient was collected, through interviews (physiotherapist), observations, photos and filming of the march on the parallel bar, as well as surveys with equipment, previously mentioned. .

Thus, the data collected made it possible to generate three blocks of information centered on the user, product and context that made it possible to define the orthosis design requirements.

Regarding the user, patient A, who participated in this research, is male, is 57 years old, 1.62 meters tall, weighs 60 kg, has gait problems and mental disorders. Figure 1 represents the patient's current situation.

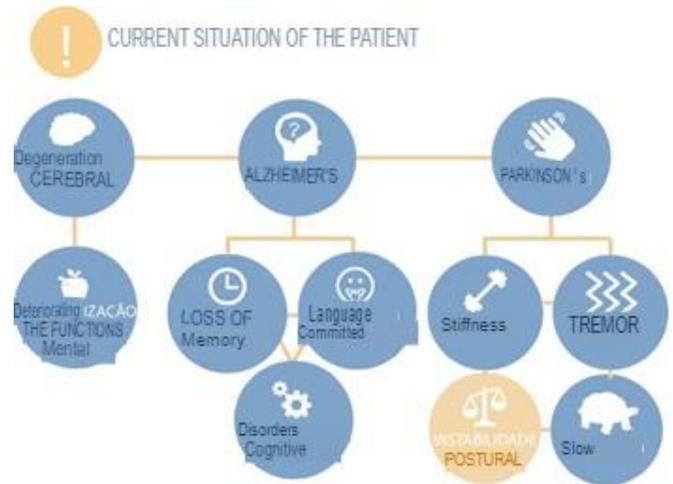


Figure 1 - Current situation of the patient

As for the product, the orthosis must fulfill the function of supporting the user, stimulating flexion and extension of the lower limb, and consequently assisting in gait rehabilitation. This product must provide at least one support point in the gluteal fold and one below the knee. In order to guarantee better gait performance, the need to use materials such as plastic or carbon fiber was felt, as the orthoses would be lighter and offer greater comfort to the user.

For the orthosis to function effectively, it must include several materials, each with its own purpose. Velcro must be used on the opening/closing straps of the orthosis; There will be specific locks in the joint, depending on the patient's problem. Regarding support points, they should be positioned on the back of the thigh and on the front of the leg, just below the knee. After collecting data, it was verified that polymer is one of the most used materials in the manufacture of orthoses, both as the main structure and for support straps and internal padding, due to the cost-benefit of the material (CAMERON and MONROE, 2011). Neoprene should be used for internal lining, as it is resistant to fungi and bacteria, has anti-inflammatory properties. degenerative, it is waterproof and promotes perspiration. In addition to surveying the properties of each material mentioned, market research into the costs of each material was also carried out.

In the information block that refers to the context, data was collected regarding the patient in the physiotherapy sector. Measurements were taken of the stretcher, the parallel bar and the patient's lower limbs. Furthermore, before the patient performed the march on the parallel bar, the

maximum handgrip strength was measured with a dynamometer (Saehan, model DIGI II). Using a thermal imager (FLIR E40), thermographic images of the lumbar region were obtained. During the march on the parallel bars, equipment was used to capture body movements, using inertial sensors (Xsens MVN Biomech Link) and surface electromyography (Miotec and Miotool 400@ software) to measure the activity of the paravertebral muscles of the lumbar region. and bilateral semitendinosus muscles. After the walking activity on the parallel bars, a new thermographic image was acquired of the patient's lumbar region (figure 2).

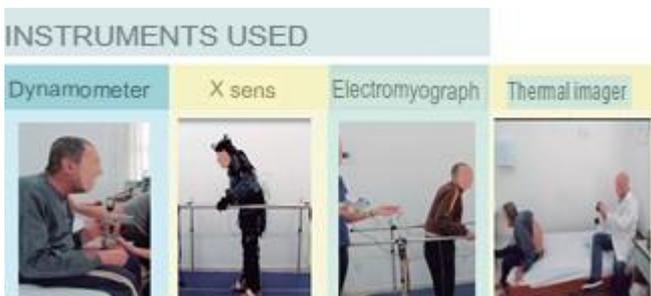


Figure 2 - Equipment used to collect data about the patient

Thus, based on the data and analyzes carried out, the Information blocks were created and the basic requirements of the project were defined (Figure 3).

	USUÁRIO	PRODUTO	CONTEXTO
Saúde	Manter joelho estendido e flexionado com angulação entre 0 e 90	Articulação com trava para regular as angulações de flexão e extensão do joelho	Materiais da órtese devem ser de fácil limpeza
	Melhorar postura corporal	Reduzir a carga no joelho	
Segurança	Estabilizar a marcha	Prevenir quedas	Utilização durante a marcha nas barras paralelas
	Sistema de fechamento e abertura fácil e seguro	Oferecer firmeza/material rígido	
Conforto	Possuir tamanho adequado ao paciente	Articulação que permita regulagem em graus de flexão e extensão do joelho	Colocação da órtese com o paciente deitado
	Não possuir saliências que entrem em contato com o paciente	Tiras de sustentação firmes de velcro	
		Pontos de apoio na coxa e na canela sob medida	Não impedir o uso da cadeira de rodas com a órtese (tamanho)
		Acolchoamento interno	

Figure 3 – Project requirements

3. CONCLUSION

The procedures adopted allowed the large amount of information collected to be synthesized into the

requirements, through information blocks and thus assist in the next stages of the project that deal with the generation of alternatives (Figure 4), elaboration of volumetric models and functional prototypes, which will be tested with the patient and refined with the help of the (rehabilitation) team.

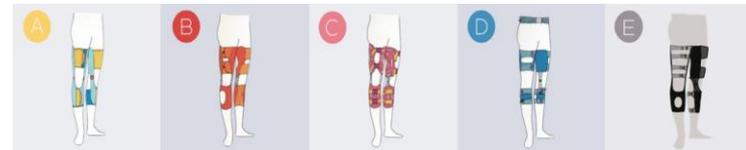


Figure 4 – Final alternatives selected

Therefore, it is believed that the role of ergonomics is of fundamental importance for AT, helping design to design quality products that will assist in rehabilitation and consequently, increase autonomy and improve the patient's quality of life.

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