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DEVELOPMENT OF NEW PRODUCTS - CONSIDERATIONS FOR REHABILITATION TECHNOLOGIES

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Abstract: *Oxford's English Dictionary defines technology as the application of scientific principles and knowledge for practical purposes, like building and designing specialized equipment. In the last 50 years we can observe an increase in usage of assistive and rehabilitation technology in the personal and professional life of human beings, including technology used for everyday life assistance and rehabilitation. Developing new technology for rehabilitation requires defining precisely the beneficiary and the user, pathological aspects and physiological function of the target segment that needs to be treated, and general organizational aspects of a physical therapy clinic or department, while taking into careful consideration medical device regulation.*

In this study we intend to analyze and propose practical recommendations for developing new rehabilitation devices and technologies applied on an ankle foot orthosis.

Keywords: *rehabilitation technologies, safety, new product development, innovation*

1. INTRODUCTION

In 1986, the United States Congress defined rehabilitation technology as "the systematic application of technologies, engineering methodologies, or scientific principles to meet the needs of and address barriers confronted by individuals with disabilities in areas which include education, rehabilitation, employment, transportation, independent living and recreation" [1] which is a very broad and comprehensive definition. At the same time, as knowledge and technology advanced in development, so did the opportunities to assist people with disabilities, but also the risks. Regulations need to catch up without hindering development, as well as considering all the stakeholders' interests. With different end-users, with complex goals, the development of rehabilitation technologies can be a very difficult challenge with a high risk of failure. A complex and multidisciplinary team is required, as well as not skipping any step of product development. To demonstrate this, we propose a model of development for a simple ankle-foot orthosis (AFO) with gel cushions in order to overcome present shortcomings of traditional AFOs identified

2. ASSITIVE DEVICES VERSUS REHABILITATION TECHNOLOGIES

While the terms are usually used as synonyms, lately, a significant differentiation can be observed on the market, with assistive devices being seen as "any item, piece of equipment or product, whether it is acquired commercially, modified or customized, that is used to increase, maintain or improve the functional capabilities of individuals with disabilities" [2], but highly focused on personal daily use, to assist in communication, mobility, accessibility and sensorial impairments. Examples could be wheelchairs, magnifying glasses and others.

Rehabilitation technology is used to describe technology that assists in recovering and restoring function, that is mostly designed for hospital use, by trained medical personnel, with different patients. They are complex systems that could include inertial sensors, robotics, virtual reality and so on. This does not imply

that rehabilitation technologies do not exist for home use, or that different types of assistive devices are not used in hospitals.

3. EUROPEAN AND INTERANTIONAL MEDICAL DEVICE REGULATIONS [3,4]

The European Medical Device Regulation (EU – MDR) is the legal guidance standard for introducing and using medical devices, including rehabilitation equipment in Europe, with Food & Drug Administration in the United States of America. The EU-MDR was introduced in 2021, replacing the previous European Medical Device Directive. The purpose of this is to ensure technology quality and safety, and to respond to the ever-changing market and trends. It includes even software as a medical device, requiring careful regulation.

To develop, certify, distribute and implement a medical device, the manufacturer needs to consider its classification in the legal domain. There are at least 4 domains that need to be considered when developing a new product (from a legal point of view):

- **Design Control** – absolutely every aspect of the development process must be documented considering: device description and specification, design and manufacturing process (any changes in this process needs to be documented) and risk management throughout the life cycle of the device, and solutions to manage those risks.
- **Risk Management and Clinical Performance pre- and post- market**. For the manufacturer, it is mandatory to gather information regarding its product, if it cannot offer enough scientific information, it must invest into its own clinical studies, which will add costs and underline the need to find medical facilities willing to partner on a long period of time.
- **Document Control and Record Management**. Besides all the documentation during development, stated clinical benefits and impact, the manufacturer needs to implement a post market surveillance system that includes regular device monitoring, product performance evaluation, incidents, safety updates report, device modifications, removal/recalls of devices and device traceability.
- **Supplier Management**

4. IDENTIFICATION AND IMPORTANCE OF STAKEHOLDERS IN PRODUCT DEVELOPMENT [5, 6]

Any new products should take into consideration the final user and all the parts that have an interest in purchasing and using a certain system/device. While a sports car will be focused on the driver's satisfaction and safety, a rehabilitation technology manufacturer should take into consideration the following groups:

Healthcare professionals - one of the most important groups, having the responsibility of deciding if and which group of people will benefit from a certain type of therapy and technology. They should contribute from the beginning of product development in identifying needs and goals.

Most health care professionals divide their goals into the following categories:

- **Patient** – what is the extra benefit for therapy and patient?
- **Safety** – patient's safety and their own safety.
- **Organizational and administrative** – how difficult it is to operate and use a certain device? How much time does it take? How many people need to be involved in using the device?

1. Patients. They have been considered the main beneficiaries of rehabilitation technologies, with devices built around pathologies and biomechanical particularities, patient satisfaction and safety. If patients' needs are not fulfilled, they will most likely refuse to participate during therapy or refuse this type of approach for their therapeutic plan. Patients' interests revolve around the following:

- **Therapy** – efficiency and success – previous failures are always a barrier in trying something new.
- **Safety and comfort.**
- **Pricing and payment requirements** – considering trying a new product/therapy, most patients will be skeptical.

2. Investors and administrative decision makers (managers, administrators) – this group of people will focus their attention on costs/benefits balance and return of their investment.

3. Payment agencies and insurance are a key part of the investors' group and will significantly

influence any technological acquisition, as in most industries, the ability to produce revenue is what keeps business alive.

4. Industry partners – from spreading the news (marketing), to sales and to post-sales services (training, service and maintenance), the ability to provide all of these is a key component in developing and reaching the main goal of any new product.

While all the stakeholders might appear as if they have different objectives and goals, there is common ground amongst them: patient satisfaction and treatment success in as little time as possible, with minimum amount of effort (physical and/or financial).

We think that while motivation and goals are highly important in developing and using different products, lack of knowledge is one of the biggest hinderers of introducing technology in any field. Knowing and understanding the physiological way of functioning, biomechanics and the latest research in treatment by all the stakeholders can significantly influence the development of a high-quality device, acquisition and successful implementation.

5. GENERAL PRINCIPLES OF DEVELOPMENT OF A NEW PRODUCT [7,8]

The science behind product development has evolved as fast as product development itself. From 3 steps developing process to 13 steps, we recognize that there are certain criteria that are absolutely mandatory in new product development: identifying a need/gap in the market, clearly defining the target population, identifying and calculating the financial demands for design and production, testing in-house and customer testing, making the necessary adjustments, retesting and, of course, planning the launch and marketing strategy

- **Initial process** – or identify the idea, whether is in house, market suggestion, or brainstorming with a friend, identifying a need is always the first step in product development. This is followed by in-depth analysis of the idea and the decision to follow or not following through.
- **First market analysis** – could be merged with the previous step; there is a quick analysis of the market – is this idea really fulfilling a need?
- **Technical Analysis** – what are, at first sight, the technical implications and needs to build and design a product that will fulfill the market's needs.
- **Financial and costs analysis planning and funding** – is the manufacturer able to cover the costs, and are the possible gains worth the investment and the time?
- **The core product development** – this is the most practical part in product development – the actual building of the product, with prototypes and samples.
- **First testing in a controlled environment** - does the product provide real health benefits, functionality and safety.
- **Customer testing** – testing the product with real users, in real life conditions, followed by clearly and structured feedback from the potential users. Adjustments and changes require a new customer testing with confirmation that the adjustments are successful.
- **Trial production and sale with business analysis** – after observing all the technical and financial aspects from all the previous steps, the final analysis is done.
- **Starting the production and marketing launch.**
- **Full scale market launch of the product**.

6. SPECIFIC RECOMANDATIONS AND ADAPTATIONS FOR REHABILITATION TECHNOLOGY

Regarding developing rehabilitation technology, we recommend adding a few steps:

- **Problem defining**. Depending on who initiated the idea, the analysis should be different: is this an individual with or without medical expertise and experience? Is this a gap that is identified on a small or large scale? It always requires analyzing not only the problem, but also the generating cause and occupational environment in which the problem appears, as well as behaviors around the specific problem. Another aspect is fully

knowing the physiological and pathological implications of the disease for which the design of the device is made, including mechanical and neurophysiological issues. We cannot offer a solution for gait training if we do not know what gait implies.

- **The first marketing analysis** will automatically include a scientific analysis answering the question if the solution is aligned with evidence-based principles, already existing, needs improvement or is it a need for a new product?
- **Technical Analysis** – to manage a technical analysis, a multidisciplinary team is required. In his book, Hacking Health, David Putrino suggests recruiting: a health professional, a good software developer and user interface expert (in case the technology requires software operations – in most cases it does), a regulatory expert, a clinical researcher, engineers specialized in mechanics, robotics and electronics, depending on the type of technology and a patient representative. The process concerning also a systemic analysis of all problems needs to be solved.
- **Financial cost analysis** and funding should absolutely take into consideration the medical certification process.
- **Design and product development** – a dynamic process taking in account the design and development of a safety, friendly to use and not expensive assistive device.
- **Prototype and Customer Testing** in accordance with the specific medical regulations and technical requirements, considering the documentation and patient screening.
- **Trial production and business analysis.**
- **Medical Certification** according to applied legal regulations.
- **Product manufacturing.**
- **Product Launching and Post Sales Services**. Integrating new devices and successful sales are done when the products fulfill their purpose and are used to help in the rehabilitation process. This requires the training of the medical personnel for maximum use. There is an increase in post-sales feedback demand, with companies adjusting products based on clients' feedback long term [7,8].

7. EXAMPLE OF DEVELOPMENT OF A INNOVATIVE ANKLE FOOT ORTHOSIS FOR STROKE PATIENTS

The World Health Organization defines stroke as "rapidly developing clinical signs of focal (or global) disturbance of cerebral function, with symptoms lasting 24 hours or longer or leading to death, with no apparent cause other than of vascular origin" [9].

Stroke patients usually face alteration of movement patterns, asymmetric increased muscle tone on certain muscle groups with altered muscle activation and modified spatiotemporal gait parameters, with an increased in energy costs during walking. Stroke patients usually show an increase in muscle groups that are responsible for the extension of the lower limb's joints, with the inhibition of the flexor muscles, which prevents the shortening of the lower limb during walking, especially during the swing phase.

To compensate for this deficit, the patient will increase their trunk lateral flexion, and hip abduction. Rolling of the foot during the stance phase will be altered or nonexistent, disturbing the physiological gait pattern and facilitating abnormal movement [10].

One of the easiest ways of prevention is the use and prescription of the ankle-foot orthosis (AFO). The ankle-foot orthosis is a simple assistive device, made of thermoformable materials. Fixed AFOs do not present any joints and fix the ankle in a neutral position. The main goals of this device are protection of muscles, ligaments and the ankle joint during walking, prevention of joint deformations, facilitation and inhibition of certain muscle groups, assisting during walking. Because of the fixed position of the ankle, while it does improve gait parameters, the fixed AFOs does not facilitate natural foot and ankle movement. Following the steps outlined in points 4 and 5, we present the proposed roadmap for the development of our new AFO:

- **The initial idea and process**. Most scientific publications agree on the benefits of simple fixed AFOs. To add to the body of knowledge we recruited 5 stroke patients (age between 56

and 69), already used with their prescribed AFO. We measured the number of steps during treadmill walking on a 100m distance for all patients, the only exception was patient number one, that completed only 50m (Fig. 1).

Afterwards, the patients were asked what the main complaint about their AFO was. While we observed a significant decrease in the number of steps for the same distance, associated with an increase in step length and overall stability, the main complaint was comfort, all patients describing the orthosis as too rigid.

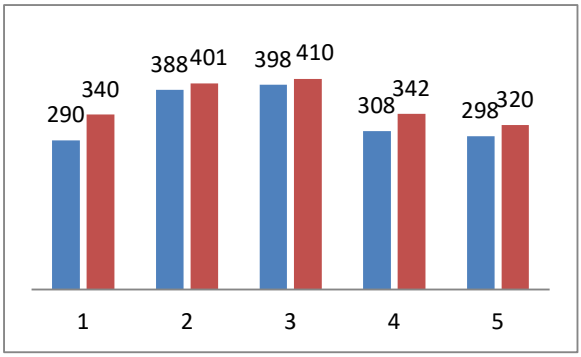

Fig. 1. Number of steps measured with orthosis

This is consistent with previous studies reporting patient concerns regarding the weight of the orthosis, its impact on mobility, ease of use, and even cosmetic appearance [11, 12, 13].

To increase comfort and assist mobility our initial idea is to add inbuild gel cushions in the orthosis sole of a simple AFO. This will present two communication chambers, corresponding with the metatarsal joints and the calcaneus – two main pressure points during walking and standing. The purpose of the two gel chambers would be to increase comfort and allow slight controlled movement between the foot joints, as well as better foot rolling. All these are highly important aspects of gait biomechanics [14].

- **Marketing Analysis and Scientific Research**. It has already been proven that off the shelf, as well as customized AFOs, improve gait parameters (spatial as well as temporal parameters) and gait kinematics. [15,16].

The present research studies regarding patient experience demonstrate that comfort and mobility, ease of use and aesthetics are very important aspects. Finally, the end-user's opinion is the most important aspect that must be taken into account. Long term use and acceptance of any device are highly connected with perceived usefulness, as well as ease of use. These two components influence attitudes and behaviors, as well as actual use of the device/technology [17].

- **Technical analysis**. In order to build a specific orthosis, adjusted to each patient category, we propose a three-step patient analysis. First, a 3D scanning of the foot, ankle and calf, followed by a sole pressure distribution analysis during standing and walking – to identify the main force trajectories. 3D scanning, while being a new approach, has been proven to be a faster and more efficient method to manufacture individualized assistive devices, specifically AFOs.

Photogrammetric and Structured Light Scanners represent the most promising solutions for assessing practical applicability, although they still present certain challenges. Photogrammetric Scanners capture multiple photographs to reconstruct a 3D model. While this approach addresses patient movement, it lacks the accuracy of Structured Light Scanners. In contrast, Structured Light Scanners offer higher detail by projecting pattern lines and capturing precise coordinates of the scanned model. However, due to their continuous scanning process, any patient movement can introduce errors [18, 19].

Pressure analysis will be done with a method called baropodometry. Baropodometry is defined as the study of the pressure between the plantar surface of the foot and the support surface. It allows an objective assessment of plantar pressure distribution while still standing and walking. Pressure platforms are commercially available and are associated with specific software that allows information acquisition and processing in a manner that can be useful for AFO designing [20].

The next steps will involve identifying the most suitable manufacturing methods and investigating appropriate materials for the orthosis, including the membrane and gel types. Given the use of 3D scanning, 3D printing stands out as one of the most accessible, faster, and more user-friendly alternatives compared to traditional methods such as molding.

Fig. 2. 3D Patient foot model

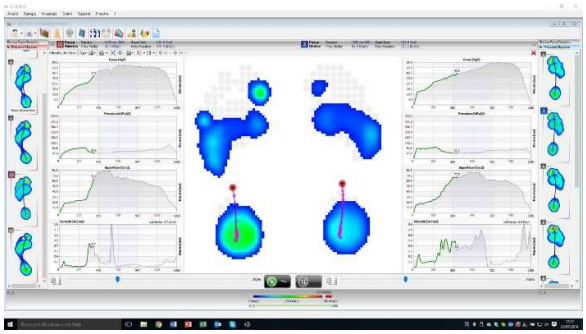

Fig. 3. Exemple of dynamic baropodometric analysis with P-Walk System, BTS Bioengineering, Italy

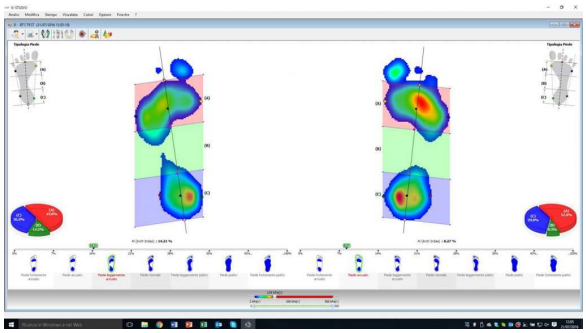

Fig. 4. Example of dynamic baropodometric analysis, with pressure analysis and foot type classification, with P-Walk System, BTS Bioengineering, Italy

Regarding materials, the main characteristics of the ideal materials would be durability and the ability to maintain the same material consistency, as well as contact compatibility with human skin.

- **Financial analysis.** Costs will be based on material choices, production goals and personnel.
- **Product testing.** We proposed that the first testing will be in-house testing and followed by patient testing – we propose the first testing to be done on the same group of patients we used for our test.

A full gait analysis is recommended, to understand full body biomechanics and posture during walking, as well as spatial-temporal parameters. Gait labs are complex motion analysis labs that combine force platforms, optoelectronic cameras, EMGs, video cameras, markers for specific points on the human body and specialized software for gathering and processing. Operating the different components requires trained personnel. The orthosis is required to improve walking, without causing any further joint damage that can lead to complications [14, 21, 22], identifying gait perturbations is key in ensuring that patient's biomechanics respect the physiological parameters.

- **Medical Regulations**. AFOs are considered Class I devices that do not require mandatory involvement of a Notified Body. Clinical Research will use the already existing body of knowledge regarding fixed AFOs.
- **Product manufacturing.**
- **Post sales/Post market services and requirements**. Considering that the devices will be individual, we propose a user check-up in the first week, month, after three months and six months. The first two checkups we recommend being done in person, the next checkups could be done via questionnaires.

8. CONCLUSIONS

The Rehabilitation Technology development imposes medical and technical legal regulations, especially on personalized assistive devices, based on patient impact and risks. Devices require strict rules in development.

The designing and developing of rehabilitation technologies or assistive devices is a highly demanding process, depending on technical, clinical and psychological factors. The development of simple assistive devices, like ankle-foot-orthosis can become challenging when we consider all biomechanical factors and it requires a true dynamic in the development process. Focusing on developing a more malleable assistive technology and taking into consideration patient perspectives and opinions

we proposed a guide for development of an orthosis with a dual chamber sole, that could assist patients with stroke in gait.

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Dezvoltarea de noi produse – considerente pentru tehnologiile de recuperare

Dicționarul englez Oxford definește tehnologia ca fiind aplicarea principiilor și cunoștințelor științifice în scopuri practice, cum ar fi construirea și proiectarea de echipamente specializate. În ultimii 50 de ani putem observa o creștere a utilizării tehnologiei asistive și de reabilitare în viața personală și profesională a ființelor umane, inclusiv a tehnologiei utilizate pentru asistență și reabilitare în viața de zi cu zi. Dezvoltarea unei noi tehnologii pentru reabilitare necesită definirea precisă a beneficiarului și utilizatorului, a aspectelor patologice și fiziologice a segmentului țintă care trebuie tratat și a aspectelor organizatorice generale ale unei clinici sau secții de recuperare medicala, luând în considerare cu atenție legislația privind dispozitivele medicale. În acest studiu ne propunem să analizăm și să propunem recomandări practice pentru dezvoltarea de noi dispozitive și tehnologii de reabilitare aplicate pe o orteza glezna picior.

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