Beyond Boundaries: PICO-Driven Design Criteria for Robotic Rehabilitation Medical Devices

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Abstract. The inter- and intra-fields translation of knowledge related to research methods, procedures and best-practice strategies developed within the constraints of a given sector may represent a fundamental source of virtuous cross-contamination, enhancing the innovative spin of effective approaches and promoting the optimization of resources and of their use. The PICO framework is a well-known and widely adopted model, primarily used in evidence-based practice to formulate clinical questions and guide research in healthcare. In this paper, the PICO framework is evaluated from a new perspective, specifically as a valuable tool for identifying the necessary criteria in the design of medical devices intended for robotic rehabilitation, particularly but not exclusively for hand rehabilitation. This new application of the model can help ensure that devices are developed with consideration for the specific needs of patients and the characteristics of their rehabilitation. The proposed study concurs to address the SDG3 (Ensure healthy lives and promote well-being for all at all ages). Finally, a practical application of the framework is presented, highlighting the strengths and limitations of this approach. This analysis is intended to provide meaningful insights for the design of more effective devices and to improve the outcomes of robotic rehabilitation.

Keywords: SDG 3, device for robotics, PICO, exoskeleton, medical device.

1 Introduction

In recent years, the field of design has increasingly emphasized the importance of the user, with a notable shift toward user-centered and user-oriented methodologies [1-4]. This is particularly evident in the growing focus on usability, which has become a central concern in the development of products and systems across various industries. A similar trend is already well-established in healthcare, where personalized medicine and tailored treatments have gained paramount importance, underscoring the need to consider individual patient characteristics in clinical decision-making [4,5]. Accordingly, the optimal devices today can be customizable to fit the patient's body dimensions, using adjustable geometric parameters and 3D scanning technologies for better adaptability [6,7]. They are equipped with sensors, lightweight materials, ergonomic designs, and control systems to ensure safety and functionality [8,9].

According to the open innovation framework, innovation can be particularly stimulated when solutions are sought outside the conventional boundaries of a problem [10], and at present, it is also widely accepted that tools and frameworks developed within one sector often hold valuable insights that could benefit other fields. One such example is the PICO (Population/Problem, Intervention, Comparison, Outcome) framework, broadly used in Evidence-Based Medicine (EBM) to structure clinical questions. While PICO is not typically associated with design processes, its structured approach offers potential for application in the design of medical devices, particularly in the realm of robotic rehabilitation. For instance, PICO may be utilized as an effective tool in user-centered design (UCD), to both systematically and traditionally organize information focusing on structural and functional impairments related to specific health conditions [11].

Strategic objectives such as resource sustainability, the elimination of information redundancy, and the optimization of expertise call for cross-disciplinary collaboration and knowledge transfer. In this light, we propose the use of the PICO framework as a tool to inform the design of robotic rehabilitation medical devices, and particularly as a guiding design criterion [12]. With a view to investigating new and broader protocols aimed at design, the oriented design methodology supports actions focused on improving functional design, aligning with the Sustainable Development Goal (SDG3) to ensure healthy lives and promote well-being for all ages. Thus, the analysis presented enables the optimization of skills, leading to cross-contamination among physiotherapists, experienced users, healthcare professionals, and engineers. We also recognize the current limitations of PICO for design, as it was not originally intended for this purpose. Therefore, we here highlight the growing need for a new research line to develop a novel framework, inspired by PICO, but more appropriately tailored to guide the design of such medical devices. This paper explores the potential of PICO in this new context while outlining the necessary future steps to develop a more suitable framework for robotic rehabilitation design.

2 The PICO framework

The PICO model serves as a method for formulating research questions and is widely used to properly conduct meta-analyses and clinical studies [13], but in the context of rehabilitation, where the goal is to improve functional outcomes for patients recovering from injury or managing chronic conditions, the use of PICO can help designers and researchers structure and clarify key components of the design process.

The foundation of PICO is based on four key elements that define the potential components of a clinical question: population/problem (P), intervention (I), comparison (C), and outcome (O).

The first element (P) identifies the characteristics of the population or the problem under investigation. In the context of this paper, the problem under consideration is the impairment experienced by the end-user of a robotic device. These impairments may stem from a wide range of underlying pathologies (see Table 1 in Achilli et al 2023 [12]). For the designer, it's crucial to identify actual users (e.g., patients recovering from surgery, stroke survivors, individuals with mobility limitations, or those with neurological disorders) and the functional challenges they experience.

The second component (I) refers to the intervention (e.g., physical therapy, pharmacological treatment, exercise) being evaluated for the specific population. The analysis of the intervention may reveal additional unexpected but relevant requirements for the design of new devices [14]. As a matter of fact, the designer may face a wide variability in the technical constraints, as the rehabilitation device or technology may include physical devices like prosthetics or exoskeletons, as well as digital interventions like virtual rehabilitation platforms. Moreover, the central goal is to help users improve their function within the boundaries of their limitations and to enhance their physical, cognitive, or emotional abilities to restore or maximize their independence and quality of life. All these aspects describe a context which is specifically referred to the intervention (I).

The third element (C) involves comparing the proposed intervention with alternative options (e.g., placebo, sham, pharmacological treatment, surgery), to assess the effectiveness of the intervention on the specific population. On the other hand, comparing interventions and evaluating the new device against existing alternatives with other rehabilitation options or existing products can indeed provide valuable insights for the development of a new device, particularly when evaluating its performance, features, and potential advantages over existing products. Besides, in the context of medical device development, especially for rehabilitation technologies, a key aspect of this comparison is the demonstration of equivalence. This is an essential step in the clinical evaluation of a medical device, particularly in Europe, where the device must meet regulatory standards before it can be marketed. The comparison with competitors can provide the designer with crucial guidance for device development also for this purpose [15].

The fourth element (O) defines the outcomes deemed relevant to assess the effectiveness of the intervention. Determining measurable outcomes of the designed device like functional improvement, user satisfaction, usability and portability, allows evaluating how the device impacts the user's rehabilitation process, such as how and how much it improves functional abilities, promotes recovery, and in the long run enhances the quality of life for patients. As outlined by Achilli et al (2023) [13], in the context of device design, outcomes are especially important and there is a strict connection between outcomes and the core features of the exoskeleton. For instance, the recovery of specific functions can guide decisions about integrating sensors or tracking systems into the device. In other words, the outcomes used to assess the effectiveness of treatment correspond to the device's features, and the degree to which a device aligns with those features determines its suitability for addressing a specific impairment.

In summary, the PICO model may facilitate the systematic identification of both functional and structural impairments that are likely to affect the end-user of a robotic device and, therefore, it offers valuable insights for researchers and developers.

3 Design Guided by the PICO Framework

When designing medical devices, making the patient the key focus of the design process is nowadays considered a good practice. In fact, the specific characteristics of the end user determine the functional and technical specifications required of devices.

Several of those elements are also depicted by PICO, although from a clinical perspective. In the following, a case study is presented, which implements the proposed approach of collecting design constraints from the application of the PICO framework on a new device, and their direct use in the design process of a new prototype.

The design of an actuated glove for hand rehabilitation following an impairment-guided approach is presented in Dragusanu et al. 2024 [17] (Fig. 1). The device consists of a tendon-guided soft glove based on twisted string actuators (TSA). The design followed a parametric and modular approach, allowing easy adaptation to different users' needs and characteristics. Each finger module can be employed independently. The modules are flexible and tendon-actuated, with up to two tendons for each finger. In the configuration reported in Fig. 1, the thumb and index modules are worn by the user. Both modules employ two tendons arranged to actuate flexion, adduction, and abduction motions. Finger extension is passively recovered by the elastic structure on the back of the finger. Employing a suitably designed routing system, passing through a series of adaptable anchor points on the glove part in contact with the palm, tendons are connected to the actuation unit, located in the forearm. The role of tendon routing and anchor point position for finger motion control has been investigated in [18], where two versions of finger modules, with one and two tendons, are analyzed. TSA actuators can be realized with small motors that can be comfortably embedded in a bracelet.

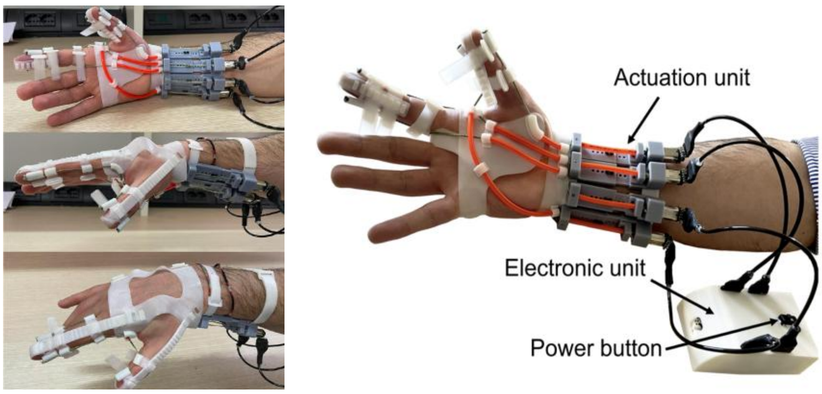

Fig.1 Prototype of the actuated glove for hand rehabilitation designed according to an impairment-guided approach.

Concerning the (P) element of the PICO approach, the system has been conceived as a rehabilitation and training tool for patients with low active control of the hand, a low residual force, low muscle tone, and low spasticity. According to the impairment/pathology mapping proposed in [13], it's worth noticing that this type could be caused by different neurologic conditions (e.g. stroke, Parkinson's disease, Limb-Girdle Muscular Dystrophy, etc.). According to the results of the analysis and comparison proposed in [13], for this type of disease, a soft implementation was considered more convenient with respect to rigid or hybrid ones, since it allows much higher adaptability and flexibility properties, while the level of forces and precision required for this specific application was not very demanding. The intervention (I) provided by the exoskeleton is the assistance in grasping and releasing objects by supporting the user's finger movements and force, and in realizing rehabilitation exercises. To realize the hand movements needed in grasping tasks, for each finger, the flexion, adduction, and adduction motions need to be actuated. The 2-DoF version of finger modules described in [17] is then the more suitable. A direct comparison (C) with other therapies has not been exploited in a quantitative manner. A comparative analysis of the device with various robotic gloves for hand rehabilitation and assistance that have emerged over the past decade in terms of actuation, transmission, mechanical structure, number of fingers actuated, tip force, system weight, portability, type of motion, modularity, and intrinsic safety is proposed in [17].

Notwithstanding the device is still in the laboratory test phase, some preliminary tests involving a potential user demonstrated its potential outcomes (O) in terms of hand joint ROM recovery; for instance, the ROM of index adduction/abduction motion passed from 8° without assistance to 15° wearing the glove. To assess and monitor system outcomes, the device is equipped with sensors to detect the user's hand movements and provide their feedback. In particular, IMU based tracking system already developed for other wearable applications, as the one described in [19] for the wrist, can be adapted and integrated for exoskeleton motion tracking, monitoring and control. The feedback to the user can include visual or auditory cues to guide the exercise movement. The device has a modular structure allowing different combinations so that the user can decide to use partial configurations, as for instance the thumb and index module only, or all finger modules. The design is parametric, and the structural parts can be manufactured with standard FDM (Fused Deposition Modelling) technologies; the solution is then adaptable to different subjects and different needs.

The ROM actuated by the glove considered in the design phase has been chosen as wide as possible to support the hand in all its possible tasks and rehabilitation exercises, but absolutely not wider than the physiological values, to avoid unsafe and painful situations. The glove has been designed to fit comfortably and securely on the user's hand with minimal interference to natural hand movements, is lightweight and flexible to avoid restricting the user's hand movement. It is equipped with a power source that can provide sufficient power for the actuation mechanism and sensors, that is lightweight and portable to allow for use in daily living activities. An aspect that needs to be carefully considered in the design of this type of devices, especially when they can be autonomously managed by the user, is the safety. In the presented example, the design considered user's safety and in particular the system's back-drivability. In case of motor failures, blockage, or other types of issues that could block the glove in a flexed configuration, the interruption TSA pins and the DC motor are easily removable.

4 Discussion

As a structured method, the PICO framework collects and presents information according to a standardized scheme. This structure is intended to guide the clinician involved in formulating research questions or conducting meta-analyses, but it also facilitates the designer looking for the essential characteristics of a device in a given scenario.

Encouraging the use of potentially useful tools across traditional disciplinary boundaries is certainly an innovative approach to optimizing resources, increasing the efficiency of applied efforts toward new breakthroughs, stimulating the creativity of scientists, and enhancing the impact of discoveries. This rationale is also in line with the indications provided by the United Nations for the development of the SDGs and may represent an interesting approach for radical innovations in SDG3, “Ensure healthy lives and promote well-being for all at all ages”.

Nonetheless, the information embedded in the PICO framework may not be considered exhaustive for defining the technical requirements needed to design medical devices, both in terms of quantity and quality of the data provided. For instance, the need for home use may suggest the necessity for lightweight, portable solutions, as well as constraints on the electronics due to the need to use batteries or the home power grid, but these and analogous considerations are still left to the interpretation of the designer, and may or may not be captured depending on their awareness or experience in the field. For this reason, we believe that the PICO framework could prove to be an even more effective design tool if properly adapted to better serve this alternative purpose.

Examples of improvements include making explicit the key technical requirements expected from the device, as well as the constraints related to the intended operational environment. As a direct result of this adaptation process, the development of a new PICO-based model, optimized for the specific application context, is envisaged in the near future, but further evaluation in this sense should be properly carried out, as any modification should be carefully balanced to ensure that the final model is as complete as possible and actually effective in practical use. Some preliminary analyses are currently underway to evaluate these aspects in particular, and future research may include the generalization of this approach or its extension to different application areas.

In fact, special attention should be paid to the context, as medical devices represent a very specific type of application: these systems are expected not only to interact with humans, sharing workspaces as industrial cobots, but also to work in direct contact, exchanging forces and information with the user. Moreover, this interaction is expected to produce precise, clinically relevant results. Accordingly, the complexity of this scenario is also reflected in the normative framework. Ideally, an adapted version of the PICO framework should be able to take these aspects into account.

5 Conclusions

The PICO framework (Population, Intervention, Comparison, Outcome) is a well-established method that can offer valuable insights for the design of new medical devices, as it helps to structure questions and clarify the key elements to consider in clinical and practical contexts. However, while it provides a solid starting point, there are certain limitations that suggest some degree of adaptation is necessary in order to enhance its effectiveness and applicability in the field of medical device development. Specifically, the framework may require modifications to account for the unique complexities and varied requirements that come with designing and assessing medical technologies, which often involve multiple stakeholders and regulatory considerations.

Current preliminary evaluations of the PICO framework are revealing opportunities to refine and evolve the structure into a more comprehensive and flexible proposal. This evolution could enable the framework to better address the specific needs of device designers, while also making it more directly usable in real-world settings. In our approach, we envision this revised framework not only as a tool for guiding the development of novel medical devices but also as a means to map the key characteristics of off-the-shelf devices—those already available on the market. This extension could help bridge the gap between new innovations and existing solutions, providing a more holistic and user-friendly approach for professionals seeking to evaluate or integrate various medical technologies into clinical practice.

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