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RESEARCH

The Role of Additive Manufacturing in the Design Workflow of a Physical Human – Robot Interface for an Active Orthosis

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Abstract

Active orthoses are gaining increasing interest, particularly those intended for lower limbs, due to their potential to enhance independence in performing Activities of Daily Living (ADLs). Nevertheless, numerous impediments to their widespread adoption persist. Among these are the necessity for an adequate production process to ensure the quality of a custom-made product in terms of functionality, geometry, and aesthetics. Additive Manufacturing (AM) emerges as a promising technology for the production of patient-specific active orthoses intended for ADLs assistance. However, a comprehensive workflow to support the effective integration of this technology is still lacking. The present work proposes a structured methodological workflow for the design of active orthoses to be produced via AM. The workflow outlines relevant guidelines and international standards, and defines the data flows, as well as the hardware and software resources required for AM-based design implementation. The methodology is validated through a theoretical case study of an active knee orthosis. This case study highlights the importance of a detailed workflow that specifies the resources needed to carry out integrated design, in order to ensure an efficient and effective design process. This methodological approach addresses all project requirements, including user comfort, functionality, and manufacturability, to create a compliant device. The workflow developed in this manner, thus, serves as a comprehensive practical guide for those interested in exploring AM as a technology for active orthosis production.

Keywords 3D Printing · Exoskeleton · Active orthosis · Design · pHRI · Lower limb

1 Introduction

Gait, defined as the pattern of movement occurring while walking, represents a fundamental aspect of human locomotion. Disorders affecting gait have been shown to significantly impact daily life and overall well-being, leading to social discrimination, restricted access to education and employment, limitations in social participation, loss of personal autonomy, and an increased risk of secondary health complications [1, 2]. Gait disorders are frequently associated with neurological conditions, musculoskeletal problems, and aging, as stated in previous studies [3–6].

Given the estimation that by 2050 the global population of individuals aged 60 years and over will increase twofold [7] and that the population is expected to remain socially active for longer and longer, there is an increasing demand for assistive devices aimed at restoring a normal gait pattern. These devices play a crucial role in enhancing Activities of Daily Living (ADLs) and human well-being. The objective is to encourage an active lifestyle, thereby reducing the risk of secondary health complications, including, but not limited to, the occurrence of obesity [8], cardiovascular diseases [9] type 2 diabetes [10], depression [11] and anxiety [12]. In Europe, for instance, with the Active Assisted Living Program (AAS Program) first [13] and the Transforming Health and Care System (THCS) later [14], efforts are being made

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to promote active and independent living by funding more efficient, inclusive, innovative, and high-quality care systems that are people-centered and accessible to all.

The World Health Organization (WHO) has identified a range of assistive products that are recognized as effective solutions to address specific health needs [15]. Within this classification, lower limb orthoses are included as key devices for individuals with gait disorders.

According to ISO 8549:1:2020 [16], a lower limb orthosis, also referred to as a lower limb orthotic device, is defined as a device for external use that is applied to the entirety or a portion of the lower limb compensating for structural and/or functional impairments of the neuromuscular and skeletal systems.

In particular, orthotic treatment has clinical objectives that principally include the alleviation of pain, the promotion of activity, the management of deformities, the prevention or limitation of excessive range of motion of joints, and the management of impaired neuromuscular functions such as weak muscle activity or excessive muscle activity [17].

The classification of orthoses depends on the specific anatomical region involved and on the degree of mobility afforded to the corresponding joints. In the first case, lower limb orthoses can be classified into [18]: toe orthosis (TO), foot orthosis (FO), ankle-foot orthosis (AFO), knee orthosis (KO), knee-ankle-foot orthosis (KAFO), hip orthosis (HO), hip-knee orthosis (HKO), hip-knee-ankle-foot orthosis (HKAFO). In the second case static and dynamic orthoses are identified [19]. Static orthoses do not permit joints movements; in contrast, dynamic orthoses allow for movement through the utilization of moving components that can be automated. If the moving parts are free of actuation sources, they are referred to as passive orthoses; conversely, if actuation systems are present, orthoses are categorized as active.

Dynamic active orthoses are designed to assist, facilitate, and potentially integrate the functions of the musculoskeletal system by optimizing the utilization of residual skills, thereby facilitating partial or complete recovery of limb function. It is important to note the distinction between active orthoses and exoskeletons [20], as the two terms are often used interchangeably in the literature.

According to ISO 13482:2014 [21], exoskeletons fall within the general category of physical assistant robots. ASTM F3323-24 [22] provides a more specific definition describing an exoskeleton as "a wearable device that augments, enables, assists, and/or enhances physical activity through mechanical interaction with the body". The ASTM International Committee F48 on Exoskeletons and Exosuits further outlines their general use cases across medical, industrial, military, public safety and recreational domains [23].

Within this context, dynamic active orthoses can be considered a specific subcategory of medical exoskeletons. The distinction is therefore not primarily technological but regulatory and contextual.

This study identifies the primary impediments to the diffusion of these assistive devices and defines principal design criteria, highlighting Additive Manufacturing (AM) as a promising production technology.

It then focuses on the development of a comprehensive methodological framework for the design and production of dynamic active orthoses through AM.

To validate the proposed workflow, a theoretical case study is presented involving the design of a dynamic active knee orthosis. No claims of clinical validation or functional efficacy are made. The case study demonstrates the applicability and coherence of the proposed framework, with the objective of supporting evaluation of AM-based design processes by medical figures, orthotists, and industry professionals without a strong AM background.

2 Active Orthoses for Locomotion Assistance

Active orthoses have been investigated in different medical and ADLs scenarios. In their study, in the context of senile gait disorders, Giovacchini et al. [24] presented the mechatronic design of a lightweight active pelvic orthosis intended to assist with hip flexion and extension. They conducted a series of experimental tests to assess the performance of the orthosis. They concluded that orthotic shells provided a satisfactory level of comfort, and the hardware of the orthosis is capable of transmitting relatively high assistive torque, without hindering the user. Biao et al. [25] proposed and tested a lower limb orthosis for gait rehabilitation of individuals who had suffered a stroke. Laboratory tests demonstrated that the orthosis is capable of achieving natural full gait motion; however, further adjustments are required to the forces and torques delivered by the actuation system. While Cardona et al. [26], within the ALICE platform project, focused on the development of a active lower limb orthosis with a dual purpose: rehabilitation of the pathological gait and performance augmentation function for patients with permanent disabilities such as multiple sclerosis. The EXOATLET [27] has been proposed as effective for the rehabilitation of patients affected by a range of conditions, including but not limited to stroke, multiple sclerosis and cerebral palsy. The E-MAG Active [28], developed and marketed by Ottobock, is designed to support individuals with partial paralysis or a complete deficiency of the knee extensor muscles, who are unable to stabilize the knee joint independently, in performing ADLs. Kalita et al. [29] proposed a systematic review on active orthoses, providing an in-depth analysis of the state of the art regarding devices designed to assist healthy individuals and support users ranging from those with single-joint impair-

ments and muscle weakness to paraplegic and fully disabled patients.

Despite the fact that dynamic active orthoses for lower limbs are the most indicated for the restoration of locomotion function [30], the use of static and dynamic passive orthoses is still most documented for both rehabilitative and assistive use in the ADLs, especially when applied to the ankle and foot. Conversely, information regarding dynamic active orthoses is limited. The challenges hindering the adoption of dynamic active orthoses as assistive devices for ADLs are manifold. In addition to the high cost of the limited number of devices available on the market, the main challenges concern the interaction between the orthosis and the patient, which occurs at two levels: a cognitive level and a physical one.

The first level, defined as the cognitive Human–Robot Interface (cHRI), concerns the information flow between the user and the orthosis. It is closely related to the hardware of the control system, namely the orthosis sensors, as well as to the software governing actuation and control. Once the user's intention is generated, it must be correctly recognized and processed by the orthotic device so that it can respond with congruent actions. The main challenges include the complexity of predicting the user's movement intentions and adopting a real-time control strategy for the orthosis [31].

The second level of interaction, referred to as the physical Human–Robot Interface (pHRI), concerns the transfer of forces and torques between the orthosis and the patient. It primarily consists of the load-bearing shells and the hardware of the actuation system, namely the actuators of the orthosis, and has been identified as a problematic aspect too. The weight, size and position of actuators and energy sources exert a significant influence on the usability and ergonomics of active orthoses. Reliance on electric motors, utilized in 73% of the case studies reported in literature [32], introduces significant limitations in terms of weight, motor and battery size. Moreover, evaluating the maximum normal and tangential contact forces and the maximum exchangeable torques between orthosis and user is essential to ensure proper function of the orthosis, to avoid damage to the user, and to guarantee comfort of use. These aspects are particularly critical. As wearable devices intended for clinical use, orthoses must ensure user comfort while simultaneously ensuring proper functional performance. In spite of this, there is a lack of interest in the literature in this regard [33], and this implies a lack of standardized clinical threshold values that can be used in the design phase. It is also extremely complex to identify when these become individual parameters that cannot be generalized to a group of people.

A further obstacle, associated to pHRI issues, is the adaptability of the active orthosis to the human anatomy [34]. Achieving proper alignment between orthotic joints and corresponding anatomical joints is a critical aspect of orthotic fabrication and fitting. The rigidity required to ensure joints alignment may cause discomfort and reduce the user's mobility. The challenge of achieving optimal alignment in joints and articulations gives rise to uncontrolled forces that, in addition to increasing energy expenditure, have the potential to inflict harm upon the user. In literature, problems linked to the reduction of weight and size of orthotic devices structure are highlighted too. Excessive structures prevent natural movement and may instigate erroneous locomotion patterns, potentially resulting in long-term joint, muscle, or tendon complications. Furthermore, it has been demonstrated that lower limb mass and moment of inertia alterations to respect the hip have a negative effect on the metabolic cost of walking [35]. For instance, Böhme et al. [36] examined an orthosis designed to facilitate stair climbing and descending activities. They concluded that, while the orthosis has the potential to assist with these activities, its current limitations include an excessive weight and non-optimal adherence to the human anatomy. Additionally, the different locomotion behavior exhibited by the patient when wearing the orthosis necessitates further assessment to ascertain its safety. These issues are further exacerbated by the difficulty in categorizing orthoses for ADLs as either medical or non-medical devices. As highlighted by Rupal et al. [37], this leads to a lack of clarity regarding the regulations governing device design and verification. Furthermore, it creates confusion concerning the nomenclature used to refer to the individual wearing the device. For instance, the beneficiary of a non-medical device is generally referred to as a user, while the individual wearing a medical device is often referred to as a patient. In this article, the terms "user" and "patient" will be used interchangeably to refer to those who benefit from orthotic intervention.

2.1 Certification Criteria

The issue of certification is a highly intricate matter.

When intended as medical devices, dynamic active orthoses specifically designed to meet individual patient needs fall under the definition of custom-made devices as outlined in Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices (Medical Device Regulation - MDR) [38]. Consequently, these devices do not require CE marking. Nevertheless, to be placed on the market, custom-made active orthoses must be accompanied by, among other documents, a declaration of conformity. This declaration attests that the device complies with the MDR's general safety and performance requirements. Furthermore, despite being custom-made, these devices still necessitate risk classification. Assigning a device to a specific risk class is a complex process, requiring consideration of numerous factors. Dynamic active orthoses, by definition, rely on an energy source other than that directly generated by the human body.

Under EU regulations, they are classified as active devices, which inherently places them in one of the two highest risk classes: Class IIb or Class III. With regard to compliance with general safety and performance requirements, numerous standards can be taken into consideration. The ISO 22523 standard [39] specifies requirements and test methods for external orthoses and external limb prostheses. While, for instance, the ISO 10993 series of standards [40] and the IEC 60601 series [41] respectively assess the biocompatibility of devices intended for direct or indirect physical contact with body tissues, and the general requirements for the basic safety and essential performance of medical electrical equipment.

If, on the other hand, dynamic active orthoses are not seen as medical devices but as personal care robots in non-medical applications, reference can be made to ISO 13482: Robots and robotic devices - Safety requirements for personal care robots [42]. This was developed specifically to address emerging robots and robotic devices for new applications in non-industrial and non-medical environments that can improve the quality of life of intended users. Developed as applications of the latter, there are also ISO/TR 23482-1 [43] and ISO/TR 23482-2 [44], which deal with safety-related test methods and application guidelines, respectively.

2.2 Traditional Fabrication

The fabrication of active orthoses also present significant challenges. The use of prefabricated devices has the advantage of extending the potential range of users, with different weights and heights. However, in terms of ergonomics, comfort, lightness and compactness, these devices do not reach optimal performance. These devices are composed of preformed structural shells and adjustable orthosis-user interfaces such as straps, bands, and guides, which serve to adapt the orthosis to the person and ensure its firm adherence to the limb. This results in a bulky and aesthetically unappealing device, a crucial factor to consider if the objective is to encourage the use of active orthoses as devices for supporting daily activities and not exclusively for rehabilitation purposes. As a matter of fact, the majority of prefabricated dynamic active orthoses, that concern hip-knee-ankle-foot joints, are used for rehabilitation activities, excluding the function of assisting ADLs. For instance, Indego by Ekso Bionics [45] and REX by Rex Bionics [46] are designed with a modular prefabricated architecture, allowing them to adapt to multiple users with sever impairments in rehabilitation settings. These are used on people with paralyzed lower limbs or extremely reduced mobility, where the primary design drivers are the total compensation of joint torque and the need to implement several actuated joints simultaneously. In the domain of dynamic active orthoses for assistive use, there is potential for the production process to be inspired by that employed for passive orthoses. This is due to the fact that the design requirements are less stringent, the joint torque does not have to be fully compensated, and hip, knee and ankle joints do not have to be implemented simultaneously.

Conventional custom manufacturing techniques, on the other hand, involve the physical acquisition of the limb. According to ISO 13404-1:2024 [19], a custom-made orthosis, intended for the sole use of a particular individual, must satisfy specific anatomical requirements. Historically, the structural shells of custom-made orthoses, as for prosthetic sockets, have been manufactured using plaster casting and thermoplastic molding [47, 48]. A negative cast mold is created by hand wrapping plaster bandages around the anatomical part. A positive mold is subsequently obtained by filling the negative cast with plaster. Once the positive mold has solidified, thermoplastic sheets can be formed over it. After this stage, the thermoplastic shell can be trimmed to achieve the desired geometry, and further manual adjustments may be made to enhance the comfort and functionality of the final product. To date, manual carbon fiber lamination from molds obtained from the negative cast of the limb is also utilized [24, 49, 50]. This process too remains highly reliant on artisanal techniques [51–53] and does not involve the creation of a virtual model of the orthosis. As a consequence, there is an absence of virtual verification phases, and some aspects of the design phase are replaced by the operator's experience. The operational effectiveness of these devices is thus strongly operator dependent. Furthermore, the acquisition of morphology is conducted in static patient conditions. This may result in an erroneous evaluation of the orthosis-user interface areas, which could potentially lead to discomfort and soft tissue injury dur-

Table 1 Pros and Cons of traditional fabrication

Pros	Cons
Wide range of potential users.	Not ergonomics, comfort, lightness, and compactness optimal performance.
Suitability for rehabilitation activities.	Absence of virtual verification phases.
Less hardware and software resources required.	Operational effectiveness of devices strongly operator dependent.
Greater chance of being able to carry out the entire process within the healthcare facility.	Acquisition of morphology conducted in static patient conditions.

ing utilization. Table 1 offers a summary of the advantages and disadvantages associated with conventional fabrication methods for both prefabricated and custom-manufactured devices.

2.3 Additive Manufacturing for Wearable Orthoses

With regard to advanced manufacturing techniques, AM has been recognized as a viable technology for the fabrication of custom-made devices (CMDs) [54]. It is extensively investigated for polymeric static and dynamic passive orthoses, as well as for prosthetic sockets. While to date, to the best of the author knowledge, extant literature contains only few evidence for the production of dynamic active orthoses, and they mainly focus on hand or ankle foot orthoses [55–57].

AM is a manufacturing technique that was developed in the context of rapid prototyping [58]. It rapidly evolved into a production technology in the biomedical [59, 60] and industrial sectors [61]. AM is a production process that enables the manufacture of a component through the sequential deposition of material, layer by layer, starting from the virtual model of the object. This approach enables extensive design freedom, allowing for the creation of complex geometric shapes without an increase in time and labor costs [62]. In comparison to the conventional procedure for the fabrication of a custom-made device, the utilization of AM enables the acquisition of the morphology of the limb [63] through the employment of Reverse Engineering (RE) techniques [64]. In the context of industrial manufacturing, RE can be defined as the set of techniques that allow the geometry of a physical element to be acquired and digitized to obtain the corresponding virtual model. Thus, these methodologies facilitate the acquisition of limb morphology to create a virtual model of the body region under examination. The limb virtual model is then employed as a starting point for the customized design of the orthosis, ensuring optimal adaptability to the user's anatomy. This is a crucial step in the design phase since it allows for optimal alignment between the orthosis and limb articulation. Following the design phase, virtual simulations can be conducted in order to assess the structural integrity and functional performance. Furthermore, the virtual model can be readily archived for future use in the event of component replacement. Due to the absence of geometric constraints in the design process, AM frequently employs Topology Optimization (TO) techniques [65] to maximize material efficiency and produce the lightest possible components while preserving their functionality. TO thus makes it possible to reduce the mass and therefore the inertia of the orthosis in favor of the metabolic cost of walking. AM also enables design not only based on the functional requirements of the component but also on its appearance to align with user preferences and expectations, ensuring both functional reliability and aesthetic appeal.

Table 2 highlights the potential advantages of AM-based active orthoses compared with conventional solutions. The comparison is performed assuming comparable functionality, intended as the quality of being useful and suitable for the purpose for which something was created.

The criteria reported in Table 2 refer to key aspects influencing the functional performance and usability of active orthoses. *Compactness* and *lightness* are directly related to the inertia of the orthosis and, consequently, to the metabolic cost of walking and the overall comfort during use. *Customization* refers both to the capability of the device to accurately conform to the anatomical geometry of the individual for whom it is designed, while also accounting for the user's aesthetic preferences, and to the ability of the device to address the specific functional needs of the patient without requiring further adaptation. *Design freedom* describes the extent to which the manufacturing approach allows the designer to satisfy customization requirements and to optimize the structural layout, enabling material to be placed only where it is required. This aspect is closely related to *mass efficiency*, which refers to the ability to achieve the desired mechanical performance while minimizing material usage. *Load capacity* indicates the maximum load that the orthotic structure can withstand while maintaining its functional integrity. Finally, *market readiness* refers to the readiness of the device for commercialization. It is closely related to the concept of time-to-market, *i.e.*, the elapsed time between the design of the device and its availability for end users.

Compared with prefabricated and conventionally manufactured custom devices, AM enables higher levels of customization, design freedom, and mass efficiency.

Despite these favorable conditions for AM to become a well-established production process in the field of active orthoses, various challenges are still to be faced.

The adoption of AM requires a highly detailed virtual design phase, as the final component directly derives from

Table 2 Qualitative comparison between different orthotic manufacturing approaches assuming comparable functionality

Criterion	Prefabricated device	Conventional manufactured custom device	Additive manufactured custom device
Compactness	+	+++	+++
Customization	+	++	+++
Design freedom	+	++	+++
Lightness	+	++	++
Load capacity	+++	+++	++
Market readiness	++	+	+
Mass efficiency	+	++	+++

Note: + limited, ++ moderate, +++ high

its virtual model. This implies that all relevant information must be available and validated before the production phase. In addition, the adoption of new technologies, machines and dedicated software, enhanced computational resources, the involvement of specialized professional roles, the definition of new protocols, and the understanding and management of the legal implications associated are a prerequisite for the adoption of AM techniques.

Introducing a complete workflow is therefore essential to contextualize the AM-based design phase within the broader development process to clarify how information flows between the different stages, and to identify the required resources, including technological, material, and human aspects.

In their critical review, Alrasheedi et al. [47] pointed out the new, different workflows that have emerged for orthoses production. The authors considered the conventional fabrication process, as well as various workflows in which AM can be utilized. Wang et al. [66] proposed a systematic framework for the design of orthoses and prostheses to be produced in AM. In particular, they focused on the importance of physical interaction between patient and orthosis/prosthesis. In their flowchart, the production of a 3D-printed initial design allows for validation of the device design based on several factors, including the shear forces exchanged at the interface and tissue stress. To complete the study of Wang et al., Kumar and Chhabra [67] provided a highly detailed and comprehensive description of each stage in the design of the physical interface between human and device, highlighting the intricate system of relationships in an integrated design process. In [68], the authors presented the general workflow followed for the design of an active ankle-foot orthosis, also including the phases related to the development of actuation and control.

Even though a lot of work has been done, to the best of the author's knowledge, there is no evidence in the literature of comprehensive frameworks detailing the entire development process of a dynamic active orthosis intended for AM production. Such frameworks should encompass the entire workflow, from the initial medical assessment to production. They should precisely specify when and how different guidelines and certification criteria are integrated. Furthermore, it is crucial that these approaches consider the orthosis design in its entirety: from structural elements to the control system software, extending through the orthotic joint and culminating in the definition of the control system, including actuators, sensors, ancillary components. The absence of such systematic methodologies represents a significant impediment for practitioners seeking to adopt AM for dynamic active orthosis fabrication. Given the substantial initial investment required to establish an AM-based design and production, combined with the still limited clinical evidence validating the functional superiority of AM-produced orthoses, practitioners face insufficient incentives to overcome initial challenges and embrace this technology.

This work aims to define a comprehensive workflow for the design and production of AM-based dynamic active orthoses, in order to address the challenges associated with the adoption of AM as a viable production process.

The workflow highlights patient clinical assessment, device structural design, actuation and control system development interdependence in enabling a coherent and effective virtual design process. Specific attention is dedicated to AM design phases, from the acquisition of anatomical morphology to the detailed design of orthosis, to specify where, how, and when orthotic design criteria, certification requirements, hardware and software resources, and AM-specific design principles are introduced.

3 Methods

Starting from a patient suffering from neuromuscular or skeletal disorder, through the translation of her/his needs into engineering criteria, the proposed workflow provides the design pathway for a dynamic active orthosis to be manufactured via AM.

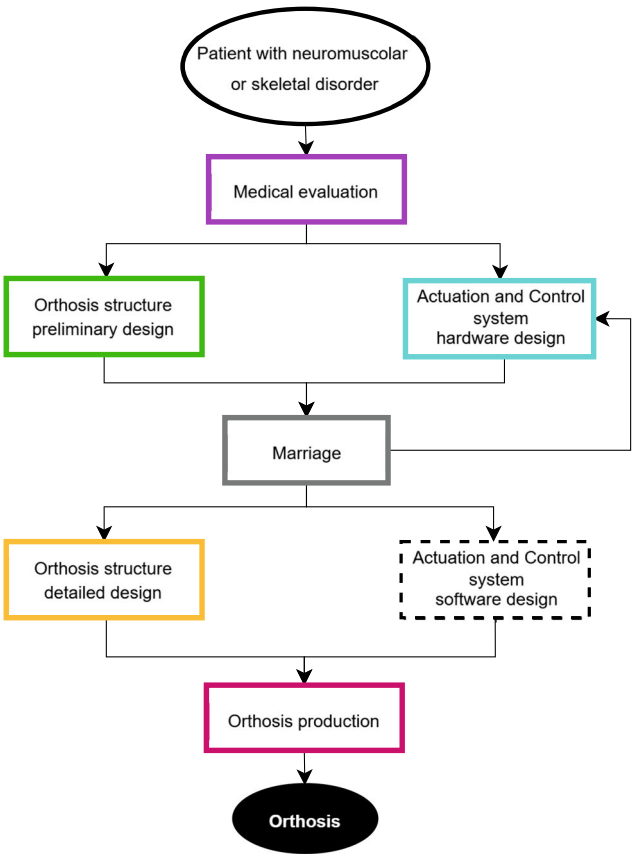


Fig. 1 Workflow overview

Within this framework, step by step, technical requirements, relevant guidelines, software, and hardware resources are detailed. Attention is given to the specific stages at which AM requirements become design-driving factors.

A summarized representation of the theoretical framework is shown in Fig. 1. Five successive steps are identified: (i) the medical evaluation of the patient enables the definition of (ii) the preliminary design of the orthosis in its pHRI components and the selection of the control system. The integration of pHRI and cHRI (iii) leads to (iv) the detailed design of the active orthosis, and (v) the orthosis production.

In the following sections, each phase is discussed individually, highlighting, if applicable, the process steps that involve dedicated RE and AM hardware and software resources. In particular, a detailed representation of the relevant flowchart is provided for each section. In these representations, steps requiring hardware resources are delineated by orange boxes, while those involving software resources are indicated by blue outlines.

However, the aim of this work is not to provide an exhaustive description of each step of the workflow, but rather to focus on the AM-based methodology for orthosis design and to identify the information exchanged at the interface between AM-based stages and the other phases. For this reason, in Section 3.2, the actuation and control system is analyzed mainly from the point of view of the requirements of the actuators that act directly on the structure of the orthosis, leaving aside the specifications related to sensors and ancillary devices. As regards the ***actuation and control system software design*** phase, focused on developing the software of the orthosis, it will not be investigated in this article since it does not directly influence the AM design and fabrication steps.

3.1 Medical Evaluation

The ***medical evaluation*** marks the beginning of the workflow. It aims at evaluating the patient, identifying the anatomical joint(s) requiring active assistance, and defining the appropriate dynamic active compensatory strategy, i.e., the set of methods for deficit compensation that integrate the forces and torques the user can exert. This phase of the workflow allows to translate medical information into engineering criteria useful for orthosis design. As illustrated in Fig. 2, this phase begins with a comprehensive medical evaluation aimed at establishing the actual capacity of the patient and the specific functional goals to be achieved. The assessment considers the patient's general health condition, including factors as gender, age, height, weight, psychological and social well-being, level of physical activity they participate in (i.e., sedentary or active lifestyle), among others. Concurrently, as prescribed by ISO 8551:2020 [17], the evaluation assesses impairments of body structures and functions, alongside activity limitations. A comprehensive evaluation of neuromuscular and skeletal impairments is essential to identify which activities the patient can no longer perform due to these limitations, and thus to define the patient's actual capacity. This information, in conjunction with the overall health profile, supports the formulation of one or more Functional Goals FGs ($FGs, 1 \leq i \leq n$). Each i-th FG is defined as the restoration of a specific function, such as walking, jumping, or running.

Dynamic active orthoses compensate for the neuromuscular and/or skeletal deficiencies by transmitting forces and torques to the anatomical joints. Thus, to evaluate the most suitable compensatory strategy, for each i-th FG it is necessary to identify the involved Anatomical Joints ($AJs, 1 \leq j \leq m$). For each j-th AJ involved in each i-th FG, a functional target should be defined in terms of Range of Motion (ROM), angular velocity, torque, and power, according to the phases of the motor task under consideration. In the context of walking, for instance, it is necessary to determine joint parameters as a function of the gait cycle percentage. These data can be obtained either through direct measurements of the unaffected limb or from existing literature. In the former case, it is necessary to account for potential compensatory strategies employed by the unaffected limb to counterbalance the limitations of the impaired limb. In the latter, consideration must be given to the fact that published data are derived from population studies and may not be entirely specific to the individual patient.

Once the FG target has been taken into account, the patient's locomotor deficit can be quantified as the difference between the FG target and the actual capacity. Not all AJs necessitate orthotic support: if no disparity is observed, no compensatory measure is required for the j-th AJ, and this is excluded from the design process. Conversely, when a deficit is present, a clinical evaluation is conducted to determine whether orthotic support is suggested. If the clinical criteria that determine which deficiencies can be disregarded and which require compensation, that are beyond the scope of this article, do not justify orthotic support, other compensatory strategies (e.g., physiotherapy or kinesiotherapy) may be prescribed. However, if orthotic compensation is deemed appropriate, the specific type of orthosis (static, dynamic passive, or dynamic active) is selected. This evaluation is reiterated for all m AJs across all n FGs.

At the conclusion of this phase, a synthesis of all prescriptions related to AJs requiring actuation, from hereinafter referred to as Prescribed Anatomical Joints ($PAJs, 1 \leq k \leq l$), is produced. This synthesis constitutes the engineering translation of patient needs into patient-specific design requirements. In case a joint is included in multiple FGs, a single unified prescription is formulated in accordance with medical guidance.

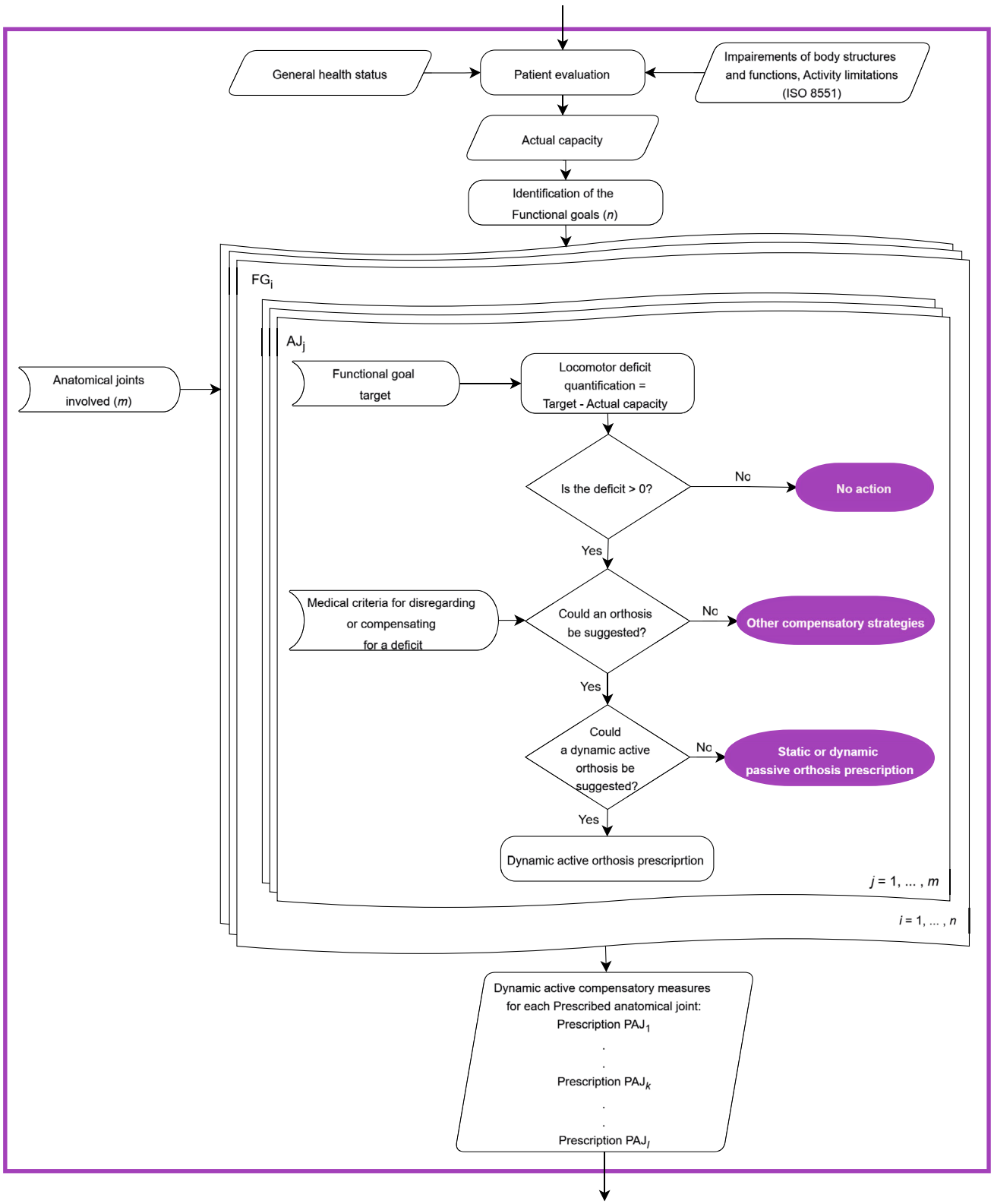


Fig. 2 Detailed flowchart of the Medical evaluation phase

The anatomical regions of the PAJs will guide the acquisition of the morphology of the anatomical segment(s) affected by the dynamic active orthosis. Concurrently, the prescribed dynamic active compensatory measures will guide the selection of the actuation and control system and its ancillary components.

3.2 Orthosis Structure Preliminary Design and Actuation and Control System Hardware Design

The patient-specific design requirements enable the ***orthosis structure preliminary design*** and ***actuation and control system hardware design*** phases. Based on the virtual acquisition of anatomical segments, the preliminary 3D computer aided design (CAD) model of the orthosis is realized looking at the patient's wearing comfort. Concurrently, taking into account all the anatomical joints that require an active orthosis, the actuation and control system is dimensioned and selected, including actuators, sensors, and ancillaries.

As shown in Fig. 3, the acquisition of the anatomical region through RE methodologies represents the first step in the personalized design of an orthosis manufactured via AM. This phase is crucial, as it directly affects the accuracy of the virtual model used to design the orthosis structure.

The acquisition of limb morphology can be performed under static or dynamic conditions. In the first case, the anatomical region is acquired in a single static posture. However, a single configuration cannot fully represent the morphological variations occurring during the different phases of the FG [69]. Alternatively, multiple static acquisitions can be performed under load and in different postures in order to approximate morphological variability. Therefore, it is necessary to evaluate whether one or more static acquisitions are sufficient to obtain a satisfactory virtual model for defining the geometry of the orthosis structure, or whether compensatory strategies are required. In the proposed workflow, potential compensations are implemented during the preliminary structural CAD design phase. These may include geometric orthosis adaptations or local modifications of the interface. Concerning dynamic acquisition, limb morphology may be captured using 4D Body Scanning techniques, which enable reconstruction of the anatomical geometry over time during a given FG. While this approach provides a more comprehensive representation of morphological changes, it presents several limitations, including reduced anatomical resolution compared to static scans, high equipment costs, complex experimental setups, and significant computational demands for accurate reconstruction [70].

This article does not delve into the choice of the most suitable RE strategy, as it depends on design constraints and resource availability. An overview of commonly adopted RE technologies in medical applications, along with a brief description of the RE process and the factors affecting its quality, is provided in Appendix A.

After the acquisition of the anatomical region, appropriate software allows to elaborate the point cloud and create the STL model of the acquired geometry. At this stage, if the acquired geometry is intended to be used without modification, the preliminary design of the orthosis can be carried

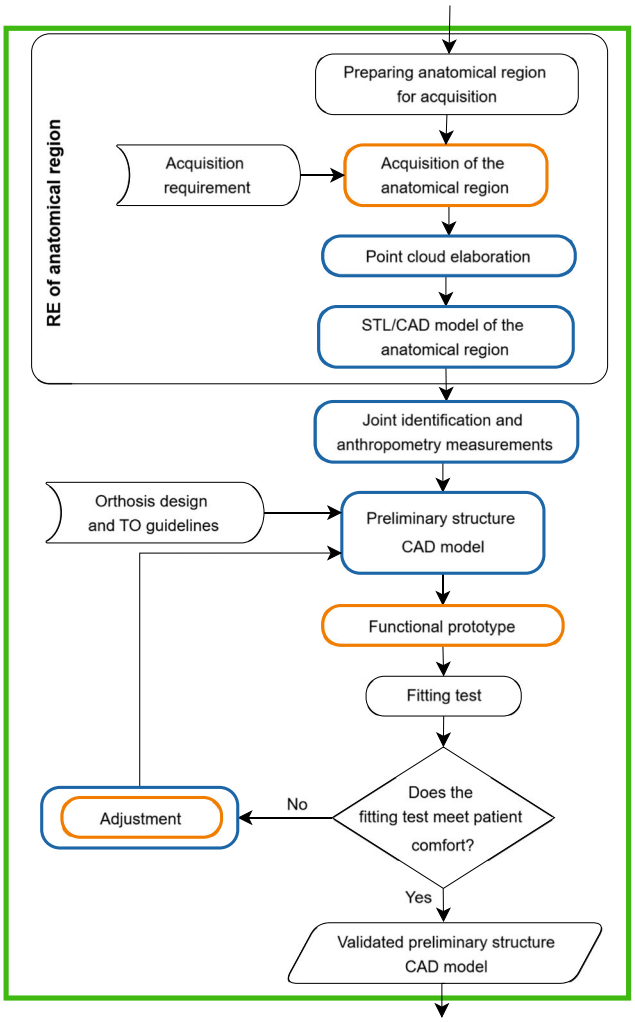


Fig. 3 Detailed flowchart of the Orthosis structure preliminary design phase

out directly from the STL file. Conversely, if design-related adjustments are required, it may be advisable to proceed with the reconstruction of a CAD model to enable appropriate modifications. In this case a CAD software is required. At this stage, orthosis design guidelines must be introduced. The STL\CAD model is utilized as a reference for anthropometric measurements and identification of anatomical joints, in order to ensure proper fitting of the orthosis and correct alignment between the anatomical joints and the orthotic joints, which represent key constraints in orthosis design. If a static RE acquisition is performed, it is necessary to decide whether compensations should be applied to the orthosis geometry. If so, adjustments can be applied to the orthosis structure, modifying the geometry based on multiple static acquisitions in different postures. Alternatively, compensations can be applied at the interface level, for example by introducing padding with variable thickness and density distributions to accommodate soft tissue deformation during movement, depending on the specific region of the ortho-

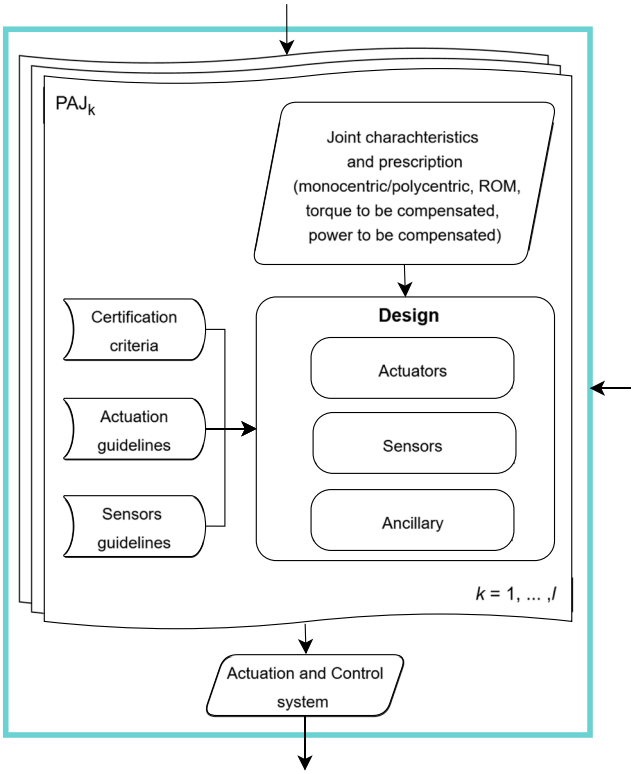


Fig. 4 Detailed flowchart of the Actuation and Control system hardware design phase

sis. Comfort and joint alignment guidelines must also be considered to ensure proper functionality. Moreover, TO requirements should already be taken into account at this stage of the design process. In particular, the material of the orthotic shells and their thickness must be defined so as not to impose unnecessary constraints on the TO performed in the subsequent design phase. All these data are used to design a preliminary, simplified, three-dimensional virtual model of the orthosis structure. This model is then prototyped using AM, usually, to conduct patient comfort and fitting tests. This preliminary model only includes load-bearing elements of the orthosis. In detail, load-bearing elements provide the functional role of the orthosis and connect the interface components [19]. They consist of shells that provide support to the anatomical segment(s) and bars that serve to correctly connect and stabilize the shells, maintaining their relative alignment.

If the fitting test is unsuccessful and the patient experiences discomfort, adjustments are required. These can be only virtual or both physical and virtual. In the former scenario, changes are applied directly to the preliminary structure CAD model. In the latter, adjustments are made to the physical prototype that is then acquired by RE, to update the CAD model of the structure. Once the fitting test meets the patient's comfort requirements, the orthosis structure preliminary design stage concludes, resulting in a validated preliminary structure CAD model.

Concurrent with the orthosis structure preliminary design, the dimensioning and selection of the actuation and control system, encompassing actuators, sensors, and ancillaries, is performed for each k-th PAJ, Fig. 4.

The selection of the actuation system is guided by the prescribed dynamic active compensatory measures derived from the medical evaluation. The term 'actuation system' refers to the combination of actuators, transmission chain, and power source. A brief description of each component is provided in Table 3.

In dynamic active orthoses, the actuation system plays a key role in determining the performance of the device. In order to proceed with its selection, it is essential to know:

- The FGs that involve the use of orthosis.
- The joints configuration, whether monocentric or polycentric.
- The ROM that must be guaranteed.
- The torque to be compensated, along with the corresponding angular velocity at each phase of the motor action. These data facilitate comparison with the torque-angular velocity characteristics of the actuation system.
- The maximum required power, ensuring the selection of an actuator capable of delivering it.

In accordance with the aforementioned actuation system specification, the designer is responsible for providing the following output, which are necessary for dimensioning and selecting all the elements constituting the control system:

- The most suitable actuator energy source (e.g., electric, pneumatic, or hydraulic).
- The reduction ratio that is required for the actuator to fully compensate for the prescribed torque.
- The transmission chain components.
- The modality of orthotic device activation (e.g., manual, sensor-based).

Table 3 Description of the constituent elements of the actuation system

Components	Description
Actuators	They generate the required mechanical power.
Transmission chain	It represents the mechanism that transfers power from actuator to the orthotic joint.
Power source	It supplies power to the entire system.

- The type of control system to be implemented and the involved mechanical properties.
- The most appropriate sensors for the functional goal to be achieved and for the chosen control strategy.

Sensors constitute the primary components of the control system and represent a fundamental part of dynamic active orthoses. They allow to collect data coming from the interaction between the orthosis and the human, and between the orthosis and the external environment [32]. These data are fundamental for correct and effective orthosis control. Sensor-based control systems are categorized into those that detect the movement via its mechanical manifestation and those that detect the user's intention through neural signals. The former, for instance, include sensors that measure forces and torques exchanged between the orthosis and the user or between the orthosis and the external environment; sensors that measure the kinematics of the joint: angle, speed, etc.; pressure sensors; force sensors and IMU sensors. The latter category comprises sensors that measure cHRI through electroencephalogram (EEG) or electromyography (EMG).

Additional general selection criteria, that concern common aspects of comfort, safety, and usability and that are independent of the specific joint, include:

- Weight and dimensions, following the principle that a smaller and lighter device is preferable.
- Preventing vibrations that could cause discomfort.
- Avoid noisy devices that may interfere with the person's comfort.
- Ensuring adequate ventilation for actuation systems susceptible to overheating.
- Protecting mechanical components in relative motion to prevent user injuries or system malfunctions due to external interferences.
- Ensuring that the actuation system does not leak fluids that may be hazardous to the user or the environment.
- Sensors capability to guarantee a signal consistent with the timing of the functional goal.

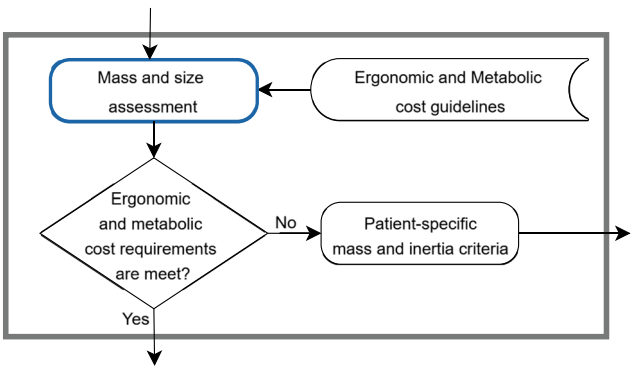


Fig. 5 Detailed flowchart of the Marriage phase

In parallel with the actuation and control system selection, ancillary components are also defined. These components include manual safety locks, switches for power management, cables, etc.

The result of all these considerations is the dimensioning and selection of the actuation and control system hardware.

3.3 Marriage

Following the identification of the actuation and control system hardware, the subsequent stage involves the spatial arrangement of all the elements on the validated preliminary structure CAD model. This virtual marriage, Fig. 5, is guided by two fundamental criteria:

- Ergonomics. The actuation and control system must not induce unintended alteration to the movements of the user, allowing only those directly related to the targeted body segment.
- Metabolic cost. Any increase in weight and inertia of body segments results in a higher metabolic cost for segment mobility, which should be minimized.

If the selected actuation and control system configuration meets these criteria, the orthosis detailed design process can proceed. Otherwise, a reconfiguration of the actuation and control system or a reconsideration of its components and ancillaries, based on patient-specific mass and inertia criteria, becomes necessary to identify a more suitable alternative. These verifications may be conducted either within the CAD environment or through more advanced modeling, simulation, and analysis platforms for dynamic systems, depending on the desired level of detail.

3.4 Orthosis Structure Detailed Design

Once assessed that ergonomic and metabolic cost criteria are met, the detailed design process of the orthosis begins, as detailed in Fig. 6.

The detailed design of load-bearing and interface elements of the orthosis structure, as well as orthotic joints, is conducted.

The detailed orthosis design is aimed at ensuring the functionality of the device while adhering to regulations and standards introduced in Section 2.1 Certification Criteria, and orthosis design principles, including:

- Ergonomics (e.g., adaptability to human anatomy, adequate ventilation, adequate contact pressures, and ease of wearing).
- Minimization of weight and size.
- Reduction of metabolic cost.

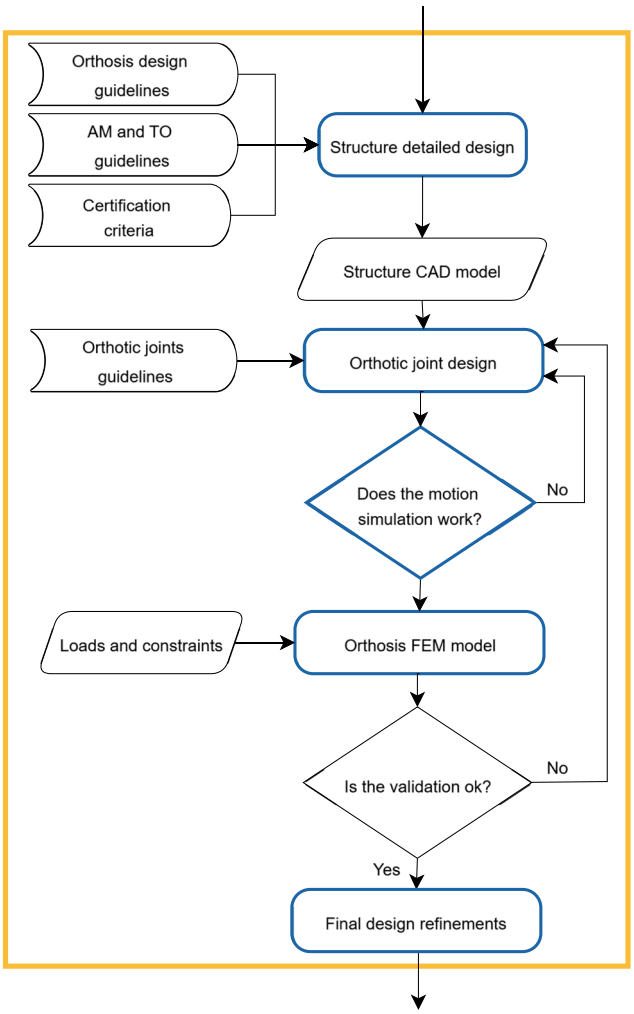


Fig. 6 Detailed flowchart of the Orthosis structure detailed design phase

When AM is considered as the production process, general and technology-specific AM design criteria are also applied. These principles are collected under the umbrella expression Design for Additive Manufacturing (DfAM), which refers to the comprehensive set of design guidelines to be considered when developing components intended for AM processes [71]. The most suitable technologies for orthotic applications include Multi Jet Fusion (MJF), Selective Laser Sintering (SLS), and Fused Deposition Modeling (FDM). A brief overview of these technologies is provided in Appendix B.

TO software tools are used to design AM components that are lightened and optimized for functionality. TO is a computational process that efficiently distributes material to solve a specific problem, such as maximizing component stiffness or minimizing component mass. These problems are solved based on selected design space, predefined loading conditions, material properties, and boundary constraints [72]. The preliminary structure CAD model, already validated on the patient and integrated with the actuation and control system, is used as the starting point. The resulting geometry is usually not immediately suitable for direct manufacturing [73] and requires further redesign for AM. At this stage of the process, TO, structural simulation and CAD modeling software packages are needed.

Subsequently, orthotic joints are designed to ensure optimal alignment with the anatomical joints, while fulfilling functional requirements identified in Section 3.1 Medical Evaluation and the constraints imposed by the selected actuation and control system. At this stage, it is established whether the orthotic joint can be produced via AM or via conventional manufacturing.

Before proceeding with the orthosis FE validation, a motion analysis is conducted to confirm that the designed model aligns with the initially established FGs requirements. If the motion analysis fails, the joint design is modified to correct possible interferences. Otherwise, once the orthosis is verified, structural analysis is performed, considering the loads exerted by the actuators, and constraints deriving from the FGs. The orthosis design is finalized with last refinements, including the virtual assembly of Velcro closures, cables, etc., and the production phase can proceed.

3.5 Orthosis Production

The production of the orthosis, in Fig. 7, is the last step in obtaining the finished device. This mainly consists of two phases: one dedicated to hardware production and orders, and one dedicated to the software integration.

Orders are placed for off-the-shelf parts such as components of the actuation and control system (actuators, sensors, and ancillaries), small mechanical parts for assembling the orthosis (screw, nuts, seals, etc.), and fastening systems for the orthosis such as straps.

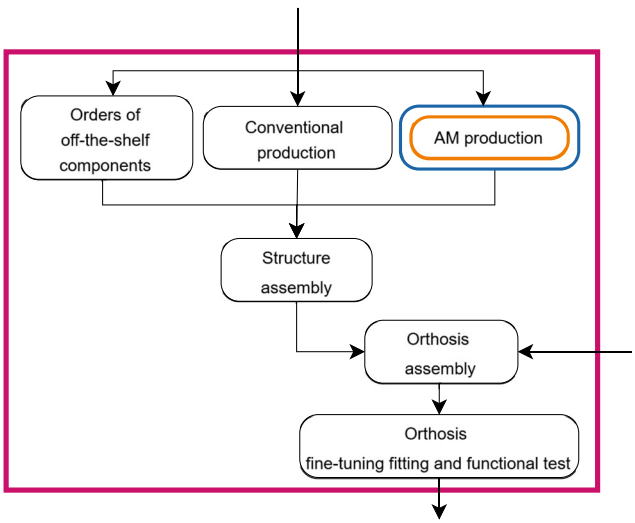


Fig. 7 Detailed flowchart of the Orthosis production phase

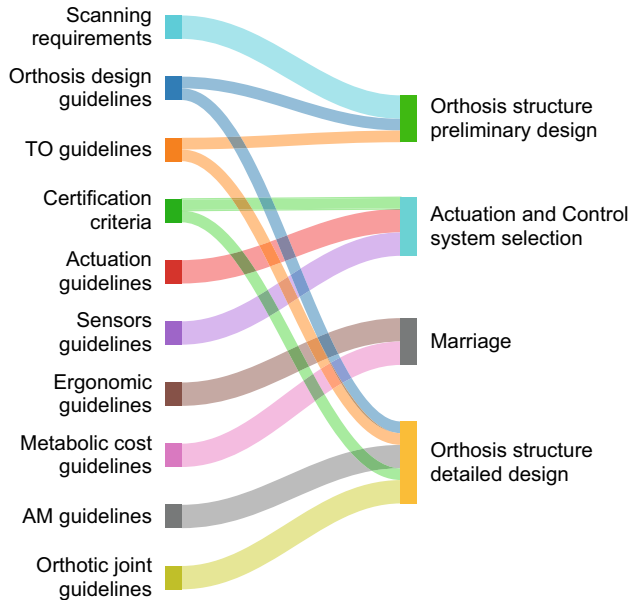


Fig. 8 Qualitative Sankey Diagram of the distribution of guidelines and criteria in the distinct phases of the flowchart. Made at SankeyMATIC.com

Conventional production may involve the orthotic joint(s) in parts or in its entirety. This can be carried out within the healthcare facility, if a mechanical workshop is available, or it can be outsourced.

AM process is preferred for the fabrication of customized parts such as the orthotic shells, the interface components between the orthosis and the actuation and control system, the orthotic joint, either partially or entirely, as well as any ancillary elements such as attachment and fastening systems for the orthotic straps. In this case too, AM production can take place in appropriate laboratories within the healthcare facility or can be delegated to external parties.

A subsequent assembly phase is required to integrate off-the-shelf components, parts produced using conventional manufacturing techniques, and those fabricated through AM.

Once the orthosis has been fully assembled and the control software implemented, a testing phase follows, including both comfort and functional assessments. This phase is aimed at fine-tuning the device based on patient feedback, in order to ensure optimal performance and usability.

A qualitative Sankey Diagram is presented (Fig. 8) to provide a comprehensive overview of the information flows between the key guidelines and criteria that influence the design process of a dynamic active orthosis based on AM, and the specific flowchart stages where these information are applied in.

Table 4 provides a summary of the specific hardware and software resources required for each phase of the workflow to implement a design based on RE and AM.

4 Case Study

The proposed methodology was applied to a theoretical case study regarding a dynamic active KO intended to assist users in performing ADLs, a context in which AM-based orthoses

Table 4 RE and AM required hardware and software resources

Phase of the workflow		Hardware	Software
Orthosis structure preliminary design	RE of anatomical region	Scanner/High resolution camera	Filtering and sampling software, CAD software
	Joint identification and anthropometry measurements	-	CAD software
	Preliminary structure CAD model	-	CAD software
	Functional prototype	AM facilities[1]	AM software[1]
	Adjustment	Scanner[1]/High resolution Camera[1]	Filtering and sampling software[1], CAD software
Marriage	Mass and size assessment	-	CAD software/Modeling and analysis environment for dynamic systems
Orthosis structure detailed design	structure detailed design	-	CAE software, TO software
	Orthotic joint design	-	CAE software, TO software
	Does the motion simulation work?	-	CAE software
	Orthosis FEM model	-	CAE software
	Final design refinements	-	CAD software
Orthosis production	AM production	AM facilities[1]	AM software[1]

[1]Non-essential resource

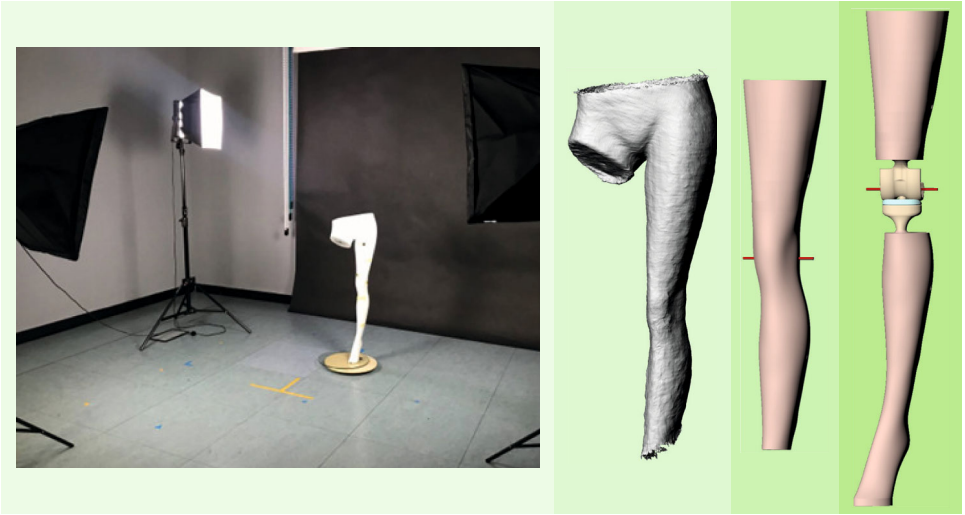


Fig. 9 RE of the mannequin leg. (**a**) Laboratory acquisition setup of the mannequin leg with three softboxes arranged at 120° to minimize shadowed areas. (**b**) Elaborated point cloud of the mannequin leg, preserving details of the adjacent leg and pelvis. (**c**) CAD model of the extracted leg involved in the case study, with the assumed axis of rotation highlighted in red. (**d**) CAD model of the leg involved in the case study, modified by adding a schematic model of the knee joint

may offer potential advantages according to the literature. The design process was carried out considering that the shells and joints of the orthosis will be AMed in polyamide 12 (PA12) using SLS technology. The fastening will be secured by Velcro straps, and the orthosis, being active, will feature external actuation.

4.1 Medical Evaluation

The presented case study concerns a hypothetical female patient, 50 years of age, approximately 175 cm in height and 70 kg in body weight, in overall good general health. No signs of cognitive impairment are supposed; the patient leads a predominantly sedentary lifestyle, though she actively participates in social activities. In the context of this study, a permanent deficit of the flexor and extensor muscles of the left knee is hypothesized (for example, due to a stroke [74] or significant unilateral injury [75]), with all other types of impairments being excluded. The patient is assumed to experience significant difficulty walking independently.

Based on these conditions, a single FG ($n = 1$), restoration of walking ability, was identified. In accordance with the proposed methodology, the anatomical joints involved in locomotion were determined, along with the corresponding FG target. Walking involves activation of the hip, knee, ankle, and foot ($m = 4$). Since the hypothesized deficit is restricted to the musculature of the left knee, deficit quantification for the hip, ankle, and foot led to the exclusion of any compen-

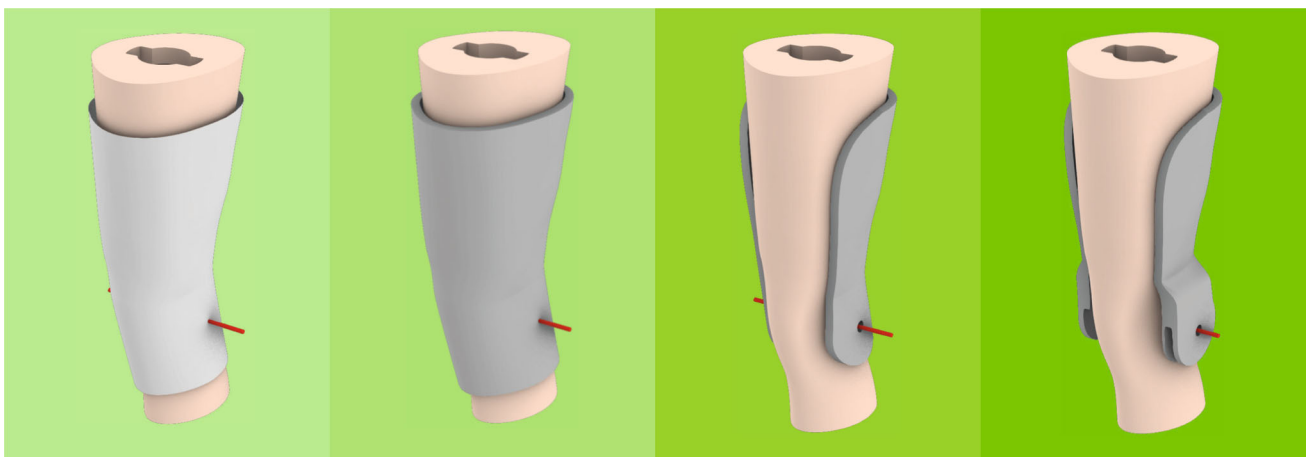


Fig. 10 Preliminary CAD model of the upper shell of the orthosis structure. (**a**) Internal shell surface generated by offsetting the anatomical leg geometry. (**b**) Solid shell obtained by thickening the internal shell surface. (**c**) CAD model resulting from the split function. (**d**) Preliminary CAD model of the joint for the upper shell

satory measure (deficit = 0). Consequently, no further design actions were required for these joints, and they were excluded from the orthosis design process.

With regard to the knee, the FG target was characterized using biomechanical parameters derived from the scientific literature for a person with weight and height characteristics similar to those of the hypothetical subject [76]. It was hypothesized that a deficit of 50% was present with respect to the first positive peak of the knee moment-time curve, which characterizes the gait cycle. Thus, the patient was capable of producing a maximum torque of approximately 20 Nm at the knee joint. Based on this analysis, the use of a dynamic active orthosis, with a monocentric knee joint, was supposed to be appropriate to compensate for the deficit and enable the patient to achieve the defined FG. From this point onward, the knee is to be regarded as the PAJ ($l = 1$).

4.2 Orthosis Structure Preliminary Design and Actuation and Control System Hardware Design

To proceed, the morphology of the left leg of a female mannequin was acquired utilizing the TrueDepth camera system of an Apple iPad Pro (11",4th generation). The anatomical geometry of a mannequin leg was chosen as a reference, as this provides a safe and realistic alternative to using actual patient data. Due to the opacity of the mannequin's leg, no surface preparation was required to prevent light reflection during the scanning procedure. Optimal lighting and minimal shadow areas were ensured by employing three lighting Softboxes arranged at 120° around the mannequin (Fig. 9a). The ScandyPro application, compatible with the Apple iPad Pro TrueDepth camera, was utilized to elaborate the acquired point cloud and to generate the STL file (Fig. 9b). Given the initial geometry of the mannequin, the STL file was converted into a CAD model to allow the necessary design modifications.

The CAD model of the leg was obtained using Rhino 8 by Robert McNeel&Associates. The QuadRemesh, SubD and ToNURBS functions were applied to convert the STL file into a editable CAD model. Given the inherent lack of anatomical detail in the mannequin and the inability to articulate the leg to determine the axis of rotation of the knee, this was assumed for design purposes (Fig. 9c). Based on this assumption, a further step involved the schematic modeling of a knee joint, enabling the creation of an articulated leg model suitable for the subsequent orthosis design (Fig. 9d).

Following the proposed workflow, a preliminary CAD model of the orthosis was developed.

Starting from the CAD model of the leg, the design constraints for modeling the preliminary CAD of the structure of the orthosis were:



Fig. 11 Functional 1:5 scale orthosis prototype AMed in PA12 using SLS technology

- The center of rotation of the knee, which was theoretically determined during the joint identification and anthropometry measurements phase.
- The gap between the surface of the leg and the inner surface of the orthosis to comply with orthosis design comfort guidelines [54]. A uniform gap of 3 mm was chosen to accommodate daily fluctuations in limb circumference and the thickness of trousers.
- The overall structure configuration, derived to comply with the functionality requirements from orthosis design guidelines [54]. The configuration comprised a rigid upper shell that provide support to the posterior region of the thigh, and a rigid lower shell that covers the anterior lower leg.
- The thickness of the preliminary structure , which was set at 10 mm to ensure sufficient material volume on which to perform effective TO in the subsequent orthosis structure detailed design phase.

SOLIDWORKS by Dassault Systèmes was employed to create the preliminary structure CAD model of the orthosis. The Offset Surface, Thicken, and Split functions were used to model the orthosis shells, followed by the creation of a simplified joint. Figure 10 illustrates the sequence of steps derived from CAD modeling in order to achieve the preliminary design of the upper shell of the orthosis. The same steps were also followed for the preliminary design of the lower shell of the orthosis.

A functional 1:5 scale prototype, shown in Fig. 11, was subsequently manufactured in PA12 using SLS technology to evaluate the fit of the orthosis, the correct alignment between the anatomical joint axis and the corresponding orthotic joint axis, and the geometry of the strap attachment features.

Accordingly, the functional prototype was used to validate the preliminary structure CAD model.

In parallel, actuation and control system selection was performed. The medical assessment revealed the following design constraints:

- The chosen actuation system must comply with the constraints dictated by the gait cycle characteristic diagrams. An example of such diagrams is provided in Fig. 12 for reference.
- The actuation system must be compatible with a monocentric orthosis knee joint.
- The actuation system must be capable of deliver 20 Nm of required torque.

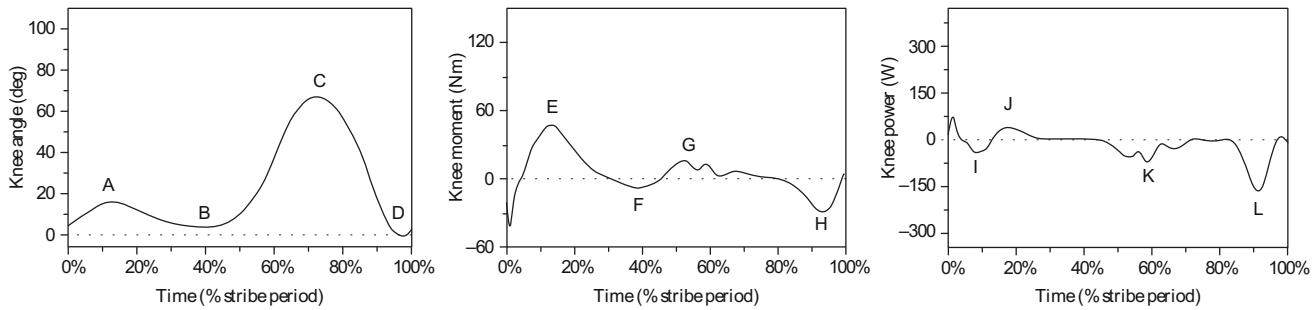
Based on this information, an electric actuator energy source was selected. The following factors were mainly taken into consideration when choosing the type of actuator and transmission chain:

- The pull out torque curve of the actuator must allow all phases of walking to be covered.
- The system should be dimensionally contained and lightweight.
- The correct reduction ratio to reach the FG target must be ensured.
- The axis of rotation of the motor shaft is not necessarily aligned with the axis of rotation of the PAJ.

The first two points were solved choosing a NEMA 23 Stepper Motor (57 mm x 57 mm x 77.3 mm, 0.72 kg, 1.1 Nm maximum torque output at 50 rpm [77]) to be positioned with the shaft rotation axis perpendicular to the knee rotation axis. In order to ensure that the performance required for walking could be achieved with the selected motor, the most critical phase of the gait cycle was compared with the motor's pull out torque curve. The coordinates of the critical point were determined through the torque and power that had previously been adopted in Section 4.1 Medical Evaluation to characterize the FG target, taking into account that the patient is capable of delivering 20 Nm and that the minimum gear ratio required to achieve the FG target is 20:1. The most critical point was identified at approximately 10% of the gait cycle where 90% of the available torque (1 Nm) is required from the motor to compensate for the muscle deficit. The remaining phases of the gait cycle were identified as non-critical, as the patient's muscular capacity primarily satisfied the requested torque. To reach the correct maximum output required torque while keeping the overall dimensions contained, the Framo Morat A40U20 worm gearbox was selected: it is capable of 20:1 gear ratio and in the worst lubricant case, it guarantees a 28.9 Nm maximum output torque. Furthermore, the worm gearbox enables a 90° redirection of the motion transmission axis. This configuration facilitates the rotational axis, initially defined by the motor's mounting orientation, to be reoriented coaxial with the axis of rotation of the PAJ, which is necessary to achieve proper alignment. In order to be able to control the motor in closed loop, this was chosen with an encoder and a specific driver. For signal processing and control of the entire system, Mega 2560 microcontroller by Arduino was chosen.

4.3 Marriage

To perform the mass and size assessment, SOLIDWORKS by Dassault Systèmes was utilized. A simplified motor support was modeled on the upper shell of the preliminary structure CAD model to evaluate its positioning. This was done taking into account the chosen transmission chain, to allow for a more compact design, as close as possible to the knee and leg. Figure 13 shows the 1:1 scale test bench



(a) (b) (c)

Fig. 12 Generic gait cycle characteristic diagrams adapted from [76]. (**a**) Knee angle-time curve. (**b**) Knee moment-time curve. (**c**) Knee power-time curve

prototype developed to evaluate the marriage between the actuator, the transmission chain, and the portion of the orthosis structure directly involved. The microcontroller, driver, and power supply, on the other hand, were placed in a belt or backpack to be worn by the patient in order to reduce the increase in mass and inertia of the limb as much as possible.

4.4 Orthosis Structure Detailed Design

The first step was to identify the information needed for the structure detailed design phase, which is developed according to a TO-based design approach. Based on these information related to material, design space, loads, and constraints, finite element method (FEM) analysis, TO, CAD reconstruction, and FEM control analysis were performed. With the exception of the CAD reconstruction, all these steps were conducted on the computer aided engineering (CAE) platform Inspire by Altair. Table 5 illustrates the dependencies between TO variables and previous stages of the design process, as well as the guidelines indicated in the flowchart.

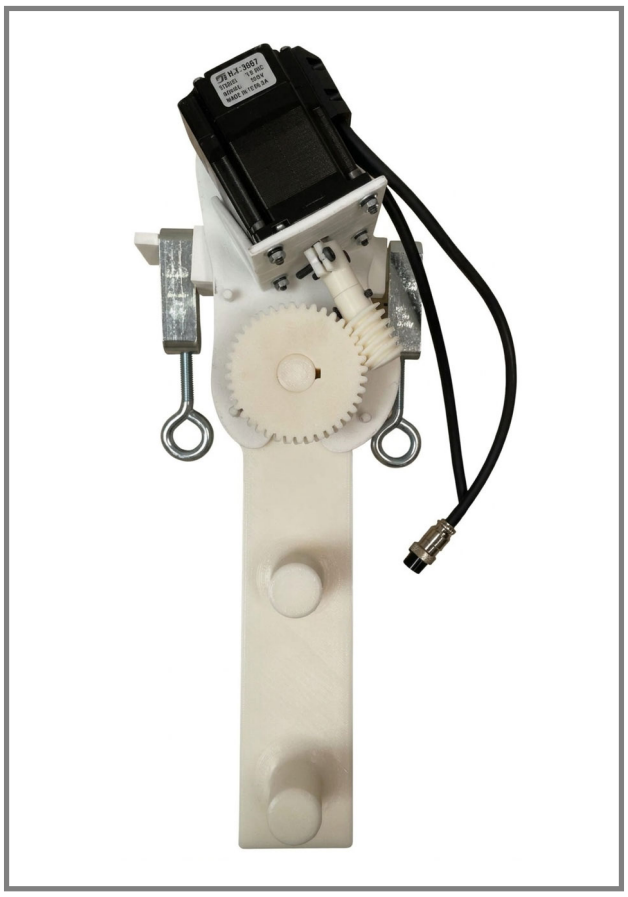


Fig. 13 1:1 scale test bench prototyped to evaluate the integration between the orthosis structure and the actuation system

For the material, PA12 was chosen, a semi-crystalline thermoplastic polymer commonly used in MJF and SLS AM processes for biomedical applications [78, 79].

The design space is defined by the region of the component on which the software can operate to find the optimal material layout that meets the imposed load conditions and TO goal, in this case maximizing stiffness. Starting from the preliminary structure CAD model of the orthosis, the following areas were excluded (Fig. 14a):

- The edge of the orthotic shells, so that the validated preliminary structure CAD model is not compromised.
- The preliminary motor support, where the motor constraints will be applied.
- The areas of the preliminary orthotic joint, directly affected by the transmission chain of the actuation system, where the torques for the simulation will be applied.
- The areas assumed to have the greatest exchange of forces between the orthosis and the leg.

The definition of loads refers to the identification of external forces and torques acting on the system to be analyzed, the orthosis. The orthosis was dimensioned, taking into account a safety factor of 2, for the maximum torque expected to be exchanged between the motor and the orthosis, equal to 20 Nm as previously determined. Two load cases were evaluated: with the same torque applied, the orthosis was evaluated in opening and closing modality (leg extension and leg flexion). The definition of loads also involves defining their points of application, which are determined based on the type of transmission chain specified in the control system selection and the layout of the orthosis actuation system defined in Section 4.3 Virtual Marriage.

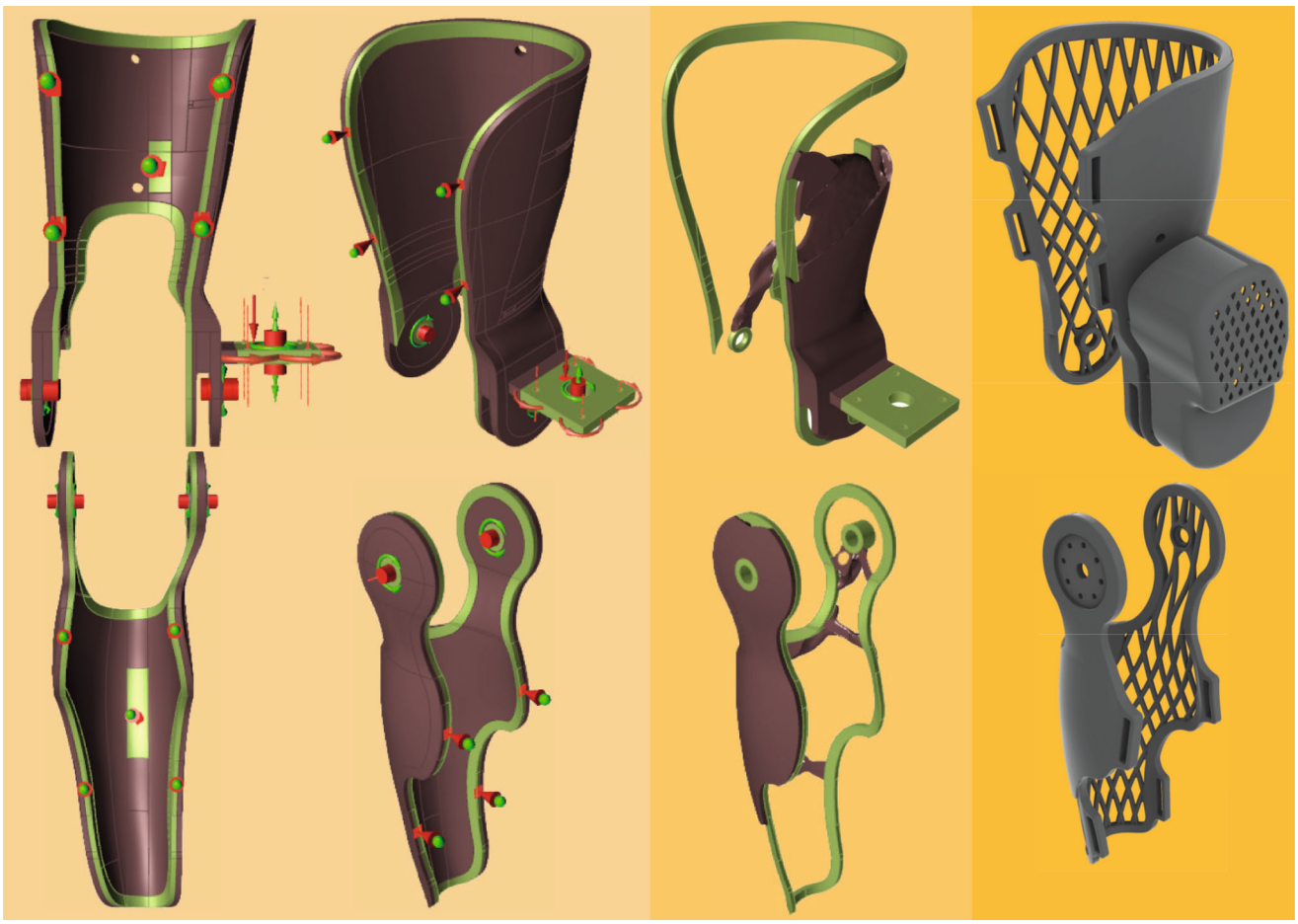
In order to proceed with the finite element analysis (FEA), for each load case it is necessary to know the constraints of the system, i.e., how the orthosis is anchored to the surrounding environment, the leg, and the areas where the applied forces and torques are discharged. Based on the chosen actuation system, the structure CAD model of the orthosis made it possible to assess the areas of the orthotic shells most affected by the exchange of forces with the leg, along with the methods of anchoring the orthosis to the leg. At this stage, therefore, the position of the holes for the passage of the Velcro fasteners must be defined in order to set the system's constraints.

TO was carried out according to optimization goal of maximum stiffness: the objective was to obtain the lightest possible structure compatible with the resistance of the structure to the loads exerted by the motor and with the least possible deformation so as not to compromise its functionality dictated by the design criteria of the orthoses. Figure 14a and b illustrate the loads and constraints applied in both the opening and closing scenarios, together with the result of the relative TO.

Table 5 Factors influencing TO variables

TO variables	TO dependencies
Material	Orthosis design guidelines
	AM guidelines
	Certification criteria
Design space	Orthosis structure preliminary design
	Orthosis design guidelines
	Virtual marriage
Loads	Actuation and Control system hardware design
	Virtual marriage
Constraints	Orthosis structure preliminary design
	Actuation and Control system hardware design

The CAD reconstruction was performed using SOLIDWORKS software by Dassault Systèmes. The results obtained from the optimization of both load histories, leg flexion and extension, were combined and reconstructed. Starting from the optimized models, where the optimization process left material, this was remodeled to avoid sudden changes in thickness, ensure minimum wall thicknesses suitable for the SLS chosen AM process, and eliminate geometries that were insignificant for the functionality of the orthosis or unappealing. Instead, where topological optimization removed material, in accordance with the constraints of the chosen AM technology, a rhomboidal filling lattice was created to



(a) (b) (c)

Fig. 14 Orthosis detailed design. (**a**) Loads and constraints applied to the defined design space in brown color. In green color the listed areas that were excluded from the design space. (**b**) TO results of the upper and lower shells of the orthosis. (**c**) Final design

Table 6 Bill of materials of knee orthosis case study

Part description	Technical specification	Quantity	Production
Mold-in insert for plastic	M4 x 6 mm	8	Off-the-shelf component
Hex drive flat head screw	M4 x 15 mm	8	Off-the-shelf component
External retaining rings	13 mm shaft	2	Off-the-shelf component
External retaining rings	10 mm shaft	1	Off-the-shelf component
Flat-tip set screw	M5 x 5 mm	1	Off-the-shelf component
Socket head screw	m4 x 18 mm	4	Off-the-shelf component
Locknuts	M4	4	Off-the-shelf component
Split lock washers	M4	4	Off-the-shelf component
Slotted spring pin	d6 x 40 mm	1	Off-the-shelf component
Slotted spring pin	d6 x 25 mm	1	Off-the-shelf component
Flanged sleeve bearings left joint	Mechanical drawing	1	Conventional production
Flanged sleeve bearings right joint	Mechanical drawing	1	Conventional production
Socket welded flange	Mechanical drawing	1	Conventional production
Drive shaft	Mechanical drawing	1	Conventional production
Driven shaft	Mechanical drawing	1	Conventional production
Gear	Framo Morat A40U20	1	Off-the-shelf component
Worm	Framo Morat A40U20	1	Off-the-shelf component
Higher orthosis: shell + orthotic joint	STL file	1	AM production
Lower orthosis: shell + orthotic joint	STL file	1	AM production
Motor case	STL file	1	AM production
Stepper motor	23E1K-12 NEMA23 Closed loop	1	Off-the-shelf component
Driver closed loop	CL57T-V41	1	Off-the-shelf component
Power supply	S-250-24	1	Off-the-shelf component
Microcontroller	Arduino MEGA 2560	1	Off-the-shelf component
Other ancillaries	-	-	Off-the-shelf component

improve the comfort of the orthosis, ensuring good contact with the leg. Following CAD reconstruction, FEA was performed to verify that the orthosis met the required safety coefficient.

Subsequently, the detailed design of the orthotic joint was carried out. The design of the orthotic joint involves its mechanical design and modeling, together with the design and modeling of the interface between the joint and the transmission chain (bushings, flanges, etc.). The joint in its entirety was modeled according to what was defined in Section 4.2 Orthosis Structure Preliminary Design and Actuation and Control System Selection and Section 4.3 Virtual Marriage: seats for bushings, snap rings, shafts, etc., were prepared. Once the orthosis CAD had been virtually assembled in its main components: shells, joint, control system and transmission chain, a motion simulation was performed using the SOLIDWORKS Motion simulation package by Dassault Systèmes. To evaluate the correct functionality of the orthosis, the angular velocity trend at the knee over time of gait cycle was implemented in the simulation. This verified that there was no interference within the final CAD during the entire gait cycle.

The design phase of the joint did not involve any major changes to the preliminary design. The structural validation obtained during the TO was deemed sufficient to verify the orthosis. Therefore, once the TO and movement analysis were completed, the CAD of the orthosis structure was finalized (Fig. 14c). The Velcro attachments were modeled, and the motor support and its case were defined in detail.

4.5 Orthosis Production

The production phase is introduced by the bill of materials shown in Table 6, which also marks the conclusion of the proposed case study. Components intended for conventional production were accompanied by mechanical drawings and CAD models, while components to be produced using AM technology were accompanied by STL files. Finally, a 1:5 scale prototype was AMed in PA12 using SLS technology, as shown in Fig. 15. This prototype served to evaluate the overall consistency of the design.

5 Conclusion

The present article began with an overview of the many open questions in the literature about the use of dynamic active orthoses to assist ADLs. Given the increasing interest from

both scientific communities and institutions in active orthoses as assistive devices for ADLs, this study moved from analyzing the potential of these devices to addressing several critical issues. These issues range from the high cost of commercially available devices to the lack of clarity in current regulations, to the difficulty of identifying the most appropriate design methodology and production process for obtaining functional, comfortable, and highly customized orthotic devices. Orthoses, being wearable devices, are more effective when they firmly adhere to the surface of the human body. Consequently, the efficacy of the offered service is contingent upon the effectiveness of the manufacturing process. While numerous aspects necessitate further discussion, the research has led to a discussion on the potential of AM as a viable production process. The establishment of a detailed design workflow was emphasized as a pivotal factor in enabling the successful adoption of AM for producing compliant dynamic active orthoses.



Fig. 15 1:5 scale prototype of the orthosis, with all structural components to be produced via AM

Based on the shortcomings identified in the existing literature, the proposed methodology is intended to be a practical guide for industry professionals interested in designing active orthoses to be produced by AM. The methodology was validated through a theoretical case study involving a dynamic active knee orthosis intended for use as an assistive device during ADLs. Based on the study conducted, the conclusions can be summarized as follows:

- The definition of a detailed workflow, which specifies the integration points of design criteria and guidelines throughout the active orthosis design process, is fundamental for accurate virtual orthosis design.
- The interconnection of the various process phases, in conjunction with an effective exchange of information between them, is crucial for the successful design of custom orthoses produced via AM.
- While developed in the context of active lower limb orthoses for ADLs assistance, the proposed methodology is suitable for a wider range of dynamic active orthoses, not exclusively for those intended for the lower limbs.
- The proposed workflow, by highlighting the necessary hardware and software resources for implementing an AM-based design process, can be readily adopted by professionals even without extensive AM expertise.
- Within the context of designing active orthoses for AM, TO emerges as a critical phase. It consolidates the outcomes from preceding stages and integrates numerous, context-specific design guidelines.

While the proposed workflow provides a comprehensive methodological framework for AM-based dynamic active orthoses, some limitations must be acknowledged. The framework has been illustrated through a theoretical case study and does not include experimental testing or clinical validation. Furthermore, since this study focuses on defining the phases of the design process and the exchange of information between them, intermediate results are not discussed in detail.

While comprehensive, the proposed framework primarily focuses on the technological aspects related to the implementation of AM. Issues related to large-scale adoption in real-world clinical contexts are not addressed. In particular, the introduction of a new design paradigm in healthcare environments may involve organizational challenges, including the integration of new professional roles in interdisciplinary working groups, the definition of new procedures, and compliance with regulatory requirements for the use of AM in medical settings. Additionally, the initial implementation of the workflow may require non-negligible design time before process standardization is achieved.

Nevertheless, the modular structure of the proposed workflow facilitates the progressive investigation of each indi-

vidual phase. This enables the gradual consolidation of the required knowledge and the subsequent integration of the different stages, ultimately supporting the scalability of the proposed framework.

In conclusion, the proposed workflow details all factors involved in the design process of a dynamic active orthosis and highlights the interdependencies between phases, providing a framework for exploring a novel design and production approach based on AM.

Future research will focus on the experimental validation of the proposed workflow through the production and testing of the 1:1 scale physical prototype designed within the theoretical case study. Collaboration with professionals in the biomedical sector will support a more detailed characterization of the individual phases of the workflow, with the objective of extending the methodology from prototype development to devices suitable for patient testing. In this context, a thorough analysis of certification and regulatory requirements will be necessary to understand how AM-produced components can be integrated into active orthosis, thereby supporting the transition from a methodological framework to scalable clinical practice. Furthermore, efforts will be directed toward the development of dedicated software tools capable of supporting the entire design process within a single integrated platform.

Appendix A Reverse Engineering Techniques

This first appendix provides an overview of the most commonly used technologies for small and medium-sized objects that are also suitable for medical applications [80–84], and briefly describes the different steps that constitute RE phase.

Whether anatomical geometry is acquired under static conditions (i.e., 3-Dimensions) or under dynamic conditions (i.e., 4-Dimensions, including the time variable), the acquisition technology and the principles governing geometric reconstruction from the point cloud remain consistent. The main differences concern the acquisition setup and the hardware configuration. In dynamic acquisition, multiple cameras or optical sensors must operate simultaneously in a synchronized configuration to capture the evolution of the geometry over time.

Given that orthoses are external devices requiring only surface anatomical data, Magnetic Resonance Imaging (MRI), Computed Tomography (CT), X-rays, or ultrasound are not necessary [85]. The following techniques are primarily recommended:

- Structured light is an active acquisition system based on the interaction between an object and a projected light pattern [86]. This pattern typically consists of a grid of bright and dark stripes emitted from a high-resolution projector. The curvature of the object surface deforms the projected grid, and the resulting reflection is recorded by one or more optical sensors. By comparing the deformed pattern with the same pattern projected onto a flat surface, the shape and dimensions of the object are obtained. The deformation of the pattern also depends on the position of the device with respect to the object. In order to have an accurate acquisition, a system calibration is required. The precision and density of the acquired point cloud are dependent on the projector's resolution, camera quality, and the distance between the projector and the object. This technique facilitates rapid and precise acquisitions; however, it is susceptible to variations in lighting conditions and the reflectivity of the scanned surfaces.
- 3D Photogrammetry is the most cost-effective method; however, it is also the least time-efficient. No specialized equipment is needed, only one or more high-resolution cameras. The method relies on the principles of stereoscopic vision [87]: by capturing multiple high-resolution images of the target surface from multiple viewpoints, it is possible to recognize the scene depth and to reconstruct the 3D model of the captured geometry. To ensure high accuracy, it is necessary that the same details are visible in a minimum of three distinct images. Subsequently, the frames are processed using specialized software that identifies common points across images and reconstructs their spatial positions, thereby producing a three-dimensional model of the scanned object. The resolution of the acquisitions strongly depends on image quality, lighting conditions, and the strategy employed for capturing photographs.

Regardless of the specific acquisition technology employed, the acquisition system software generates a point cloud at the end of the scanning process. A point cloud is a set of points in space belonging to the captured surfaces. In static acquisition, each point is defined by three spatial coordinates (X, Y, Z), whereas in dynamic acquisition an additional temporal coordinate (t) is included, resulting in four-dimensional data (X, Y, Z, t).

At this stage, dedicated software is required to elaborate the point cloud. This processing phase typically involves noise filtering and sampling procedures aimed at removing redundant or erroneous data. Upon completion of this step, only the points necessary for surface reconstruction are retained.

Starting from the processed point cloud, a mesh can be generated either manually or automatically using dedicated software, which in some cases may be a part of the acquisition system software. The mesh consists of a set of triangles, each defined by three vertices corresponding to points of the cloud, and represents an approximation of the acquired surface. The accuracy of the reconstructed geometry depends

on the size of the triangles and the density of the mesh. If required by the design workflow, the mesh can subsequently be converted into a CAD model. This step is typically necessary when geometric adjustments, or integration with other design components are needed.

The success of the acquisition process depends not only on the technical characteristics of the employed technology and software, but also on several factors that influence acquisition accuracy. Following the selection of appropriate RE technology, the anatomical region must be prepared. The patient must remain still throughout the procedure; any movement could compromise accuracy. Additionally, the anatomical segment to be acquired must be positioned correctly to allow for complete acquisition. To determine the most suitable strategies and parameters for acquiring the geometry of the relevant anatomical segments, acquisition requirements must be considered. They are primarily influenced by the chosen RE technology (e.g., scanning speed), the anatomical region to be acquired, and the environmental conditions in which the process occurs. Lighting and shadows can interfere with the accuracy, and a lack of sufficient chromatic contrast between the object and the background may generate noise in the acquired data.

To the best of the authors' knowledge, current literature does not provide explicit references regarding the required accuracy for anatomical morphology acquisition in the context of dynamic active orthosis design. However, considering that conventional design methodologies rely on plaster casting, and taking inspiration from literature regarding the acquisition of anatomical geometry via 3D scanning [88–90], it is reasonable to conclude that an accuracy below 1 mm is adequate to ensure a proper scan. Accuracy exceeding 1 mm may results in discomfort due to misalignment between the orthotic joint and the anatomical joint. Furthermore, in relation to accuracy, it is also important to evaluate resolution. A resolution below 0,1 mm would capture details that are unnecessary to the orthosis design and functionality, while a resolution over 1 mm does not guarantee the required accuracy. This approach ensures the development of patient-specific orthosis that meets both comfort and functional criteria.

Appendix B Additive Manufacturing Technologies

This appendix presents a brief overview of the AM technologies most suitable for the production of orthoses.

For each of these methods, different design considerations must be addressed, such as:

- Minimum wall thickness.
- Optimal build orientation to minimize support structures.
- Clearance tolerances to ensure proper device functionality.

Multi Jet Fusion (MJF) is the most suitable AM technology for surface aesthetics, dimensional tolerances, productivity and print volume. In MJF, the process is carried out using a bed of polymer powder, which also functions as a support material for the component during printing. Powder consolidation to form each layer is achieved through the combined action of a detailing agent, a fusing agent, and an infrared lamp. The liquid fusing agent is deposited in areas where polymer fusion is desired, as it lowers the melting point, whereas the detailing agent increases the melting point and is applied along the edges of the part to ensure high-definition contours. The infrared lamp then supplies the energy required to melt the polymer selectively in the designated areas. This process is repeated layer by layer. MJF technology enables the production of components with excellent surface finish and dimensional accuracy. It also ensures high productivity, owing to the availability of large-format industrial machines and the absence of dedicated support structures, since the surrounding polymer powder inherently supports the part during printing. This characteristic allows for optimal utilization of the build volume and significantly reduces post-processing time, as no support removal is required.

Selective Laser Sintering (SLS) and Fused Deposition Modelling (FDM) technologies also represent viable alternatives [91–93].

The SLS process shares similarities with MJF, as it likewise utilizes a bed of thermoplastic polymer powder as the starting material. However, in this case, the powder is selectively fused, section by section, through a precisely directed laser beam, with the process repeated layer by layer. As with MJF, the powder bed itself provides support for the component, eliminating the need for additional support structures. Nonetheless, the SLS process is generally slower than MJF and yields a slightly lower surface finish quality, which necessitates extended post-processing. Furthermore, for large-scale production volumes, SLS tends to be more costly.

As for FDM, it is the most commonly known technique. It involves the extrusion of a solid thermoplastic filament through a heated nozzle, which deposits the material layer by layer onto a build platform to form the cross-sections of the component. This technology is widely adopted for hobbyist and prototyping purposes. In comparison to MJF and SLS, FDM requires support structures to anchor the part to the platform, prevent thermal deformation, and provide structural stability during fabrication. This requirement limits the ability to fully saturate the build volume, and it results in a slower process with increased material waste, and longer post-processing due to the need for support removal. Moreover, due to the filament-based material feed and the presence of support structures, FDM typically yields the poorest sur-

face finish and the highest surface roughness among the three technologies discussed. Additionally, it offers smaller build volumes when compared to MJF.

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