Advancements and challenges in the development of robotic lower limb prostheses: a systematic review

Ilaria Fagioli*, Alessandro Mazzarini*, Chiara Livolsi, Emanuele Gruppioni, *Member, IEEE*, Nicola Vitiello, *Member, IEEE*, Simona Crea *Member, IEEE*, Emilio Trigili, *Member, IEEE*

Abstract—Lower limb prosthetics, essential for restoring mobility in individuals with limb loss, have witnessed significant advancements in recent years. This systematic review reports the recent research advancements in the field of semi-active and active lower-limb prostheses. The review focuses on the mechatronic features of the devices, the sensing and control strategies, and the performance verification with end-users. A total of 53 prosthetic prototypes were identified and analyzed, including 16 knee-ankle prostheses, 18 knee prostheses, and 19 ankle prostheses. The review highlights some of the open challenges in the field of prosthetic research.

Index Terms—Prosthetics, mechatronics, control, robotic rehabilitation.

I. INTRODUCTION

A lower limb amputation (LLA) occurs worldwide every 30 seconds due to diabetes alone [1]. The leading causes of LLAs are dysvascular diseases, such as diabetes, which accounts for more than 93% of the total LLA cases, followed by trauma (more than 5%) and cancer (around 1%) [2]. Transtibial and transfemoral amputations (respectively 28% and 26% of all LLAs) pose significant challenges to the affected individuals, impacting their mobility, independence, and overall quality of life [3]. The World Health Organization has identified physical inactivity as the fourth leading global risk factor for mortality, affecting countries across all income groups [4]. Consequently, the restoration of ambulatory capabilities in individuals with LLA is of paramount importance for prosthetic technologies.

Currently, the vast majority of commercially available solutions for prosthetic limbs are passive, hence they cannot introduce net positive energy into the locomotion [5]. While passive prosthetic knees can enable swing during level ground walking, they cannot assist with high-energy demanding activities, such as stair ascending and sit-to-stand transitions [6], [7]. Passive prosthetic ankles can effectively provide stability and support, but their intrinsic elasticity only allows them to reach up to 45% of the physiological push-off peak

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I. Fagioli, A. Mazzarini, C. Livolsi, N. Vitiello, E. Trigili and S. Crea and are with The BioRobotics Institute, Scuola Superiore Sant'Anna, Pontedera,

power [8]. These limitations result in a less efficient, slower, and asymmetric gait [5], and alterations that may lead to comorbidities such as chronic back pain and osteoporosis [9]. Conversely, robotic prostheses (i.e., active, and semi-active) can mimic a wider variety of physiological limb behaviors, offering greater control and adaptability [10]. Semi-active prostheses (also referred to as microprocessor-controlled prostheses) combine passive mechanical elements with adjustable damping or stiffness mechanisms to offer improved stability, or incorporate low-power actuators to adapt to changing walking conditions or power-specific gait phases [11], [12], [13], [14]. Active prostheses integrate actuators that provide powered assistance throughout the whole gait. These prostheses incorporate motors, sensors, and control algorithms, that enable the device to mimic the biomechanical behavior of the lost limb, facilitating a more natural and efficient gait pattern [15], [16], [17], [18], [19], [20], [21].

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Given the considerable advancements in active and semiactive lower limb prostheses, a comprehensive understanding of the current state of the field is necessary to identify the key challenges, technological trends, and potential clinical benefits associated with these devices. In fact, in 2021, the World Intellectual Property Organization identified prosthetics as one of the most rapidly advancing technologies within the category of mobility assistive devices [22].

Previous reviews have focused on only knee or ankle prostheses [23], [24], [25], or on specific aspects of lower limb prostheses, such as control methods [26], [27], [28], [29], user needs [30], [31], [32], [33], or outcome measures [34], [35]. This systematic review focuses on both the mechatronic design of semi-active and active knee and ankle prostheses, their sensing and control strategy, as well as their assessment through experiments involving end-users. A prior systematic review of active lower limb prostheses was conducted in 2016 [36]. Although this previous review provided valuable insights into the design solutions for active devices, it did not include semiactive prostheses. Furthermore, significant advancements have been made in the field of lower limb prosthetics in the last few

Italy, and with the Department of Excellence in Robotics & AI, Scuola Superiore Sant'Anna, Pisa, Italy (correspondance e-mail: ilaria.fagioli@santannapisa.it). E. Gruppioni is with Centro Protesi Inail di Vigorso di Budrio, Bologna, Italy.

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Fig. 1. PRISMA flowchart illustrating the systematic review process.

years, leading to the design and testing of numerous prototypes on end-users.

The primary objectives of this systematic review are to report the: (i) mechatronic design, (ii) sensing and control strategies, and (iii) methods for the functional verification associated with the semi-active and active lower limb prostheses from 2016 to the present. The review examines only research prototypes because detailed technical information about commercial prostheses is limited. Nonetheless, the recent introduction of a few active prostheses to the market indicates an increasing interest in powered solutions [37], [38], [39], [40]. This review will contribute to the existing knowledge by providing an updated and comprehensive overview of the technical advancements and potential benefits of robotic lower limb prostheses.

II. METHODS

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We performed a systematic review following the Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) guidelines [41].

A. Eligibility Criteria

We included studies that involved physical prototypes of active and semi-active lower limb prostheses tested on at least one person with LLA. Given the last systematic review published in 2016 [36], the search was limited to journal papers and conference proceedings published from that year onward. Articles were excluded if they involved a prototype developed before 2016 or a commercial prosthesis. Only studies published in English were considered.

B. Search Strategy and Data Collection Process

The following search string was used to search the Scopus, PubMed, IEEE Xplore, and Web of Science databases:

Prosth* OR Artificial limb) AND

(Knee OR Transfemoral OR Foot OR Ankle OR Transtibial OR Leg OR lower-limb OR Lower-extremity OR Lower-leg OR lower limb OR Lower extremity) AND (Active OR Robotic OR Adaptive OR Artificial OR Intelligent OR Powered OR Bionic OR Microprocessor OR Power OR Semiactive OR Semi-active) AND NOT (Replacement OR arthroplast*).

The search was performed on March 14, 2023, by the primary researchers. The search string was obtained by grouping keywords in a logical structure. As in [36], an exclusion criterion was inserted to exclude publications regarding arthroplasty and limb replacement. All publications regarding devices or medical topics different from active or semi-active knee and ankle prostheses were excluded.

The results exported were screened by title and abstract by two reviewers (namely the first and second authors of this manuscript) to determine their relevance. Articles that met the



Fig. 2. Timeline depicting the publication years of the robotic prosthetic prototypes reviewed in this paper.

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Actuation

Fig. 3. Diagram illustrating the key characteristics of the robotic prosthetic prototypes reviewed in this paper.

inclusion criteria during the title and abstract screening were selected for full-text review. Any discrepancies between the reviewers were resolved by a third reviewer, namely the third author. Moreover, relevant studies published after the search were analyzed, and 13 additional papers were included. The search retrieved a total of 6210 publications across the selected databases. Results were imported in Zotero, and 1787 duplicates were removed. A total of 4421 publications underwent screening by title and abstract, and 294 records were assessed for full-text analysis. In the end, a total of 109 studies were included in the analysis (see Fig. 1).

III. RESULTS

The identified studies included tests with 53 different lower limb prostheses, comprising 19 ankle prostheses, 18 knee prostheses, and 16 knee-ankle prostheses (as summarized in Figure 2 and Table I). The following sections report the main findings in terms of mechatronic design, employed sensors and control systems, and verification reported with the end-users.

A. Mechatronic Design

Actuation stands at the core of robotic lower limb prostheses, providing the means to emulate the biomechanics of natural human gait. The choice of the actuation architecture and components is critical to match the requirements of the biological missing limb while avoiding oversizing the overall assembly [42], [43]. Among the identified prototypes, all kneeankle prostheses are fully active. The highest percentage of knee prostheses are semi-active while the highest percentage of ankle prostheses are fully active (Figure 3). Electric motors emerged as the most prevalent type of actuators, being utilized in 40 out of the 53 prostheses analyzed, surpassing pneumatic and hydraulic solutions. In the case of multi-joint active prostheses, the typical approach involves actuating each degree of freedom in the sagittal plane with a dedicated electric motor.

Active multi-joint prostheses have been mostly developed for the knee and ankle joints, enabling flexion-extension and plantar-dorsiflexion movements, respectively. Some ankle prostheses have been designed to feature two degrees of freedom [44], [45], [46]. Among these, the MIT prosthesis designed for rock climbing stands out as is the only prototype with two degrees of freedom for the ankle joint that has been tested on at least one subject with a lower limb amputation. This design allows for dorsiflexion\plantarflexion and inversion/eversion movements by means of two linear actuators [46]. Another approach for multi-joint active prostheses is the incorporation of underactuated mechanisms [20], [47], which allow to actuate multiple joints using a single power actuator. Tran et al. proposed an underactuated ankle-toe mechanism comprising a five-bar mechanism coupled with a linear series elastic actuator, resulting in a lightweight and energy efficient assembly [20]. The prosthesis presented in [47] uses a differential mechanism to convey the power of one actuator to both the knee and the ankle joints. Of the remaining prostheses, 11 prototypes incorporate hydraulic actuation units [48], [49], [50], [51], [52], [53], [54], [55], [56], [57], [58], while only one ankle prototype features pneumatic actuation [59]. This prosthesis modulates the stiffness of the ankle thanks to a pneumatic cylinder and a solenoid valve. By opening and closing the valve, the prosthesis has two operating modalities: (i) a free-swinging mode to achieve toe clearance during walking, and (ii) a high stiffness mode for controlled dorsiflexion and energy storage purposes.

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For knee-ankle prostheses, the average power to actuate the joints – considered as the sum of the electrical powers of each motor – is over 400 W. Active knee prostheses have an average motor power of 110 W, while ankle prototypes require around 140 W. Semi-active knee prostheses maintain an average power of over 100 W, while for semi-active ankle prostheses, it decreases to just over 25 W.

 Table I Overview of the reviewed prosthetic prototypes

 Joint: (A) Ankle; (K) Knee; (AK) Knee + Ankle. Actuation: (E) Electric; (H) Hydraulic; (P) Pneumatic. Sensors: (P) Position sensors; (F) Force sensors; (I)

 Inertial sensors; (E) EMG sensors; (O) Other. Battery: (I) Internal battery; (E) External battery. Weight is reported in kg, height is reported in cm.

 a: devices with toe joint; b: weight reported without battery.

Device name, research institution	Joint	Actuation	Weight	Height	Sensors	Battery
Fully active						
AMPRO, Georgia Institute of Technology ^[64]	AK	Е	8.1	56.3	P,F,I	Ι
AMP-Foot 3, Vrije Universiteit Brussel ^[67]	А	Е	3 ^b	26	P,F,I	Ι
AMPRO II, Texas A&M University ^{[60][121]}	AK	Е	5		P,F,I	Е
Cleveland State University ^[75]	Κ	Е	4.23		0	
CMU prosthesis, Carnegie Mellon University ^{[61][115][123]}	AK	Е	6		P,I,O	Е
CYBERLEGs beta, Vrije Universiteit Brussel ^{[79][122][128]}	AK	Е	5	50	P,F,I	Е
<i>CYBERLEGsPlusPlus gamma</i> , Université catholique de Louvain, Vrije Universiteit Brussel ^[86]	AK	Е			F,I	Е
Georgia Institute of Technology ^{[62][108][109][135]}	AK	E	8	49	PFI	E
LDKP Peking University ^[69]	K	E	2 7 ^b	20.8	PFO	E
MIT prosthesis for rock climbing, Massachusetts Institute of	A	E	1.29	25	F,E	I
Open Source Leg University of Michigan ^{[19][151]}	AK	E	4	453	PFIEO	I
PANTOF II Beijing Institute of Technology ^{[81][141]}	Aa	E	1.95	19.5	P O	Ē
<i>PKP-SEA</i> . Sony Computer Science Laboratories ^{[18][127]}	K	E	1.2 ^b	8.6	г,0 Р	Ľ
PKU RoboTPro II. Peking University ^{[72][104][105][106][107][118][119]}	A	E	1.75 ^b	0.0	P.F.I	I
PKU RoboTPro II ProVersion Peking University ^{[16][134][140]}	A	E	1.75		PF	I
Powered polycentric ankle. University of Utah ^[83]	A	E	1.32	12	P.F.I	I
<i>PR leg</i> , The University of Texas at Dallas, University of Michigan ^{[21][102][112][116][124][125][137]}	AK	E	6.61	49.2	P,F,I	I
Retractor type knee. Mie University ^[85]	Κ	Е			P.I	Е
<i>RTFP</i> . Peking University ^[53]	AK	Н	3.8	47.3	P.I	Ι
Shenzhen Institute of Advanced Technology, The Chinese University of Hong Kong ^[63]	K	Е	2 ^b		I,O	Ι
SuKnee. The University of Tokyo ^[17]	К	Е	2.6	28.7	P.F.I	Ι
SynPro, Scuola Superiore Sant'Anna ^[47]	AK	Е	6.2		P.F.I	Ι
<i>TF8.</i> Massachusetts Institute of Technology ^[77]	AK	E	3.7	44.3	P.F.I	I
The Chinese University of Hong Kong ^{[73][88][129]}	A	E	23	21	PF	I
The University of Tokyo ^[65]	AK	F	5.62	48.4	PFI	I
The University of Tokyo ^[66]	A	E	27	23	PFI	I
University of Science and Technology of China ^[101]	AK	F	4.8	23	FIF	F
UT Dallas powered prosthesis, University of Texas at	AK	E	4.8		P,F,I	E
$U_{tab} Rionic Leg University of Utab[20][91][111][113][143]$	ΔKa	F	32		PFIF	I
Utah knog University of Utah ^[71]	K	F	1.59	29.8	PFI	I
Utah lightweight leg University of Utah [91][100][114]		E	2.7	27.0	DELE	I
Vandauhilt neuronad prosthosis Vandarhilt University [15][103][110][142]		E	2.7			I
Warrier ankla, Walter Beed National Military Medical Center ^[136]	A	E	3		F,I,E DF	I
Semi active						
BP ankle University of Washington ^[138]	Δ	F			F	
DSR Vanderbilt University ^[58]	Δ	H	1 35	163	PFI	I
$E_{\rm r}K_{\rm reg}$ The University of Texas at El Paso ^[48]	K	н	1.55	10.5	0	I
ECT knee Vanderbilt University ^[80]	K	F	1.97	36	PEI	I
EH4 University of Bath ^{[56][92]}	Δ	H	4.5	50	FIO	F
Hybrid knee [Iniversity of I]tab[68][139]	K	F	1.68	29	PFI	I
HSAK Jilin University ^[49]	K	H	2.68	25.8	DEI	I
IPK University of Shanghai for Science and Technology ^[50]	K	н	2.00	25.0	DE I	I
IPK University of Leeds ^[82]	K	E			DEI	F
Rehabilitation Institute of Chicago ^[59]		P	1		PF	L
Peking University ^[51]	K	H	1	24.8	PFI	F
PHKP Jilin University ^[52]	K	н	1 88	25.8	PFI	I
SCS4 Vanderhilt University ^[54] [130] ^[131]	K	Н	2.00	23.0	PFI	I
Swing assist knee Vanderhilt University ^[55]	K	H	1.68	28	P I	I
Ultracanacitor hased knee Cleveland State University ^[93]	K	F	1.00	20	P O	F
Utah ankla University of Utah ^[76]	Γ <u></u>	E	1.165	5	T,O DEI	E
USE University of Wisconsin Medison ^{[74][133]}	A	E	0.640	87	Г,Г,І РЕІ	I
VAEP Tarbiat Modares University ^[57]	A	Ц	2.049	0.7	1,1,1	1
VSP4 foot Northwestern University ^[12]	A	E	1.1		D	I
WRL TTP Scuola Superiore Sant'Anna[11][144]	A	F	2.7		FI	I
The first source of the same find and the same second seco	11	L	2.1		1,1	1

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commonly employed transmission stages are harmonic drives [11], [18], [47], [60], [61], [62], [63], [64], slider-crank mechanisms [54], [55], [65], [66], [67], pulley belts [15], [16], [17], [19], [47], [51], [52], [53], [62], [68], [69], [70], [71], [72], [73], [74], and screw mechanisms [12], [20], [46], [52], [53], [55], [66], [67], [70], [71], [72], [73], [75], [76], [77], [78], [79], [80], [81], [82], [83]. High-speed, low-torque electric motors are typically coupled with transmission ratios greater than 100:1, enabling high output torques and precise position control. At the same time, this architecture decreases the maximum possible speed and increases output impedance and reflected inertia [84]. In order to exploit the passive dynamics of human locomotion, recent prototypes have been developed featuring either low transmission ratios [21] or variable transmission ratios [17], [20] at the knee joint. Since lower transmission ratios enhance backdrivability, these mechanisms provide the possibility of passive walking if the prosthesis runs out of battery.

Elastic elements are often embedded in prosthetic devices to provide mechanical compliance and shock-absorption, and to modulate the output impedance, enabling different control techniques. Several prototypes embed springs in series to the motor [20], [68], [85], using the so-called Series Elastic Actuator (SEA) architecture [18], [19], [47], [61], [62], [65], [67], [77], [79], [81], [86], which enables precise torque measurement and compliant interaction with the environment, at the cost of a reduced control bandwidth [87]. This configuration allows to mimic knee damping during weight acceptance or the shock absorption of the ankle at heel strike. Springs have also been embedded in parallel [15], [17], [73], [79], [81], [86], [88] to reduce the requirements of the motor by additionally contributing to the total joint torque. This configuration is mainly used in ankle prototypes, in order to mimic the Achille's tendon capability to store energy during stance and effectively releases it during the push-off phase [89].

The choice of the mechatronic components is among the main determinants of the size and weight of the prosthesis. In fact, robotic prostheses should be significantly lighter than a natural limb, as users may perceive them as uncomfortably heavy due to a combination of cognitive and sensorimotor factors [90]. Furthermore, a lightweight and compact prosthesis increases the variety of subjects that can wear it. Figure 4 represents the distribution of actuation power and minimum heights against the weights of the analyzed prototypes. Only prototypes with available weight information have been included in the figure. However, it should be noted that some works provided information regarding the weight of the mechatronic system including batteries, such as the EHA prosthesis, which includes the weight of the backpack for the electronics and the battery pack (approximately 2.3 kg) [56], while others did not report the weight of the battery pack. The latter case include for example the AMP-Foot 3 [67], the CYBERLEGS Beta-Prosthesis [79], the LDKP [69], the PKP-SEA [18], and the Shenzhen Institute Knee [63]. For knee prostheses, the median (IQR) weight is 1.97 (0.94) kg. The lightest semi-active device is the Hybrid knee with a weight of 1.68 kg [68], while the lightest fully active device is the PKP-SEA with a weight of 1.2 kg (not including the battery) [18]. The Utah Knee is the lightest fully active knee including the battery pack, weighting 1.595 kg [71]. Ankle prototypes

showed a median (IQR) weight of 1.75 (1.44) kg. In this case, the lightest fully active device including the battery pack is the MIT prosthesis with a weight of 1.292 kg [46], while the lightest semi-active device is the VSF, weighting only 0.65 kg including the battery [74]. The median (IQR) weight of knee-ankle prostheses is 5 (2.3) kg. The lightest fully active transfemoral prosthesis is the Utah Lightweight Leg, weighting 2.7 kg including the battery [91].

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Among the ankle prostheses, the median height at its lowest setting (IQR) is 20.3 (9.9) cm, with the shortest prototypes being the VSF with a minimum height of 8.7 cm [74]. Among the knee prostheses, the minimum height has a median value (IQR) of 28 (3.9) cm. The shortest prototype is the PKP-SEA, with a reported height of 8.6 cm without considering the battery [18]. Considering the battery, the shortest prototype is the LDKP, with a height of 20.8 cm [69]. The median height (IQR) for knee-ankle prostheses is 47.9 (4.8) cm, with the shortest prototype being the Georgia Institute prosthesis [62].

Lithium-ion or lithium-polymer batteries are typically employed to power the actuators and the electronic components of a prosthesis. Out of the 53 prototypes identified, 34 are powered by batteries integrated within the prosthetic assembly or secured to either the socket or pylon, aiming to reduce the distal weight of the prosthesis. In some cases, batteries are placed in backpacks alongside with other electronic components, or external power sources are employed. For 19 out of the 53 prototypes the indication regarding the batteries' duration is available in terms of estimated time or number of steps before discharge. A few studies mention the possibility of using the device in passive mode after battery discharge: in this way the user can continue to walk with the prosthesis not injecting active power into the gait [11], [17], [20], [67], [92]. Notably, energy regeneration has been demonstrated in three prototypes. In the Ultracapacitor based knee, power is regenerated and stored in the ultracapacitor during swing, when the controller injects negative damping into the system [93]. The PR leg employs low-impedance actuators that allow for the regeneration of energy during phases of negative joint work, thereby reducing power consumption and increasing the efficiency of the device [21]. The Utah Bionic Leg features an underactuated mechanism that transfers mechanical energy from the toe to the ankle joint during ambulation, regenerating 4.5 J per stride [20].

With the aim of optimizing the performance of actuators typically used in robotic prostheses, Azocar and Rouse [94] presented a characterization procedure to analyze and improve energetic efficiency.

B. Sensing and Control

The ability of a robotic prosthesis to mimic the biological behavior of an nonimpaired human joint is highly dependent on the ability of its control and sensing to coordinate the actuation with the user's central nervous system [10], [28], [95].

1) Sensory system

To enhance their sensing capabilities, most robotic lower limb prostheses incorporate a combination of position (81.1%), inertial (75.5%), and force (73.5%) sensors. Position sensors are primarily employed for joint angle monitoring. Thanks to their high resolution and update rate, these sensors play a





Fig. 4. Distribution of the motor power and minimum height against weight for the prosthetic prototypes reviewed in this paper. For knee-ankle prostheses, motor power is calculated as the cumulative power of the embedded motors. Shapes outlined in black represent semi-active devices, whereas those without outline denote fully active prototypes. Prostheses marked with an asterisk in the legend were originally reported in the articles without accounting for battery weight and height.

fundamental role in tracking the movement and position of the prosthetic joints, enabling precise and responsive control mechanisms. Inertial Measurement Units (IMUs) are used in most prototypes to estimate the pose and orientation of body segments in the three-dimensional space, enabling a more accurate motion detection and control. Custom force-sensing technologies have been developed and embedded in prosthetic devices to measure the interaction between the user and the robot/environment. Instrumented pyramid adapters and custom load cells have been designed to encompass force and torque sensing while minimizing weight and height [55], [71], [83], [96], [97]. Custom pressure-sensing insoles have been developed to estimate the vertical ground reaction force [16], [98] and the center of pressure along the antero-posterior direction of the foot [11], [47], [86], [99].

Some prototypes embed other types of sensors (24.5%), such as electromyography (EMG) to implement myoelectric control [46], [100] or to perform intention detection [101], and strain gauges used either to detect gait events [56], [92] or to estimate the force transmitted between the foot and the knee through the prosthetic shank [75]. The integration of accurate sensory data into the control system is essential to achieve precise and seamless control of the prosthesis.

2) Control system

The control system of a robotic prosthesis is commonly described as a hierarchical, three-layered structure [95]. The high-level control layer is devoted to intercept the user's movement intent through intention decoding algorithms capable of recognizing various locomotion modes. The midlevel control layer is devoted to translating the user's motor intention into a reference trajectory for one of the device joint and state variable (e.g., joint torque, position, velocity, or impedance). These desired trajectories are subsequently sent to the low-level control layer, responsible of driving the actuator depending on the error between measured and desired device state. Most of the retrieved prototypes still lack real-time intention detection, relying on manual selection of the locomotion mode. Among the tested prototypes implementing intention decoding strategies, a common real-time approach is based on threshold-based algorithms to discriminate between

standing and walking [15], [69], [79], swing or support phases [101], or to recognize multiple locomotion modes, such as sitto-stand transitions [102] and stair negotiation [103]. Some studies present intention detection algorithms for locomotion mode recognition based on machine learning techniques, such as quadratic discriminant analysis [104], [105], support vector machines [106], and neural networks [107], [108], [109].

A possible approach is to overcome the intention detection layer using a unified controller. This approach consists of applying the same control strategy regardless of the task, thus not requiring an explicit classification of the locomotion activity. For example, unified walking controllers were developed by exploiting the idea that the quasi-stiffness of the shank is consistent across different tasks [58] and different terrains [110]. Recent studies used inertial sensors to indirectly detect the volitional movement of the user's residual limb, achieving adaptation to variable speeds, inclines, and uneven terrains [111], [112]. In particular, Best et al. [112] recently introduced a data-driven hybrid controller for continuously walking at different speeds and inclines, combining variable impedance control during stance and kinematic control during swing.

Cowan et al. [113] proposed an EMG-based controller for powered knee prostheses which allowed for walking and stair negotiation tasks without explicit classification of the activity and enabling seamless transitions both with sound and prosthetic sides. Another example is from Hunt et al. [100], where EMG signals are used to control the prosthesis in various locomotion tasks through shared neural control: by detecting the activation of flexor and extensor muscles in the residual limb of subjects, the controller facilitates tasks such as standing up and sitting down, lunge, squat and walk. It also allowed seamless transitions between these tasks without any explicit classification or detection.

For what concerns the middle-level control, the specific phase of each locomotion task can be determined either discretely through segmentation algorithms or through continuous phase estimation approaches. Most of the identified prototypes employ finite state machines (FSMs), dividing each task into different subphases where a specific control law is applied. Transitions between subphases and/or states are typically determined by a set of threshold-based transition conditions. This approach is adopted for its intuitiveness and ease of development, allowing the easy addition of new subphases. However, it can lack in robustness and the number of tuning parameters can considerably increase with the growing number of locomotion tasks and subphases in each task [26]. To simplify the control architecture, a unified FSM can be shared across tasks. For example, Culver et al. [80], [96] implemented a FSM with six states, and defined a different sequence of states for each task. Another example was presented by Tran et al. in [71], where different tasks were segmented into the same states. Other studies implemented security states within the FSM to rapidly extend the knee in case of knee buckling or stumbling [17], [65]. Some prototypes implemented either adaptive FSM with varying thresholds to adapt to gait characteristics [85] or adaptive control laws to make the prosthesis compliant to different stair heights, cadences and gait patterns [91] or to enable obstacle avoidance [114], [115], [116].

As an alternative to the discrete detection of gait events, one can track the progression of periodic tasks through continuous phase estimation. This approach is generally subjectindependent, it may require a lower number of parameters to be tuned with respect to FSMs, and it can naturally adapt to changes in the walking speed [117]. A common approach involves the use of Adaptive Oscillators (AOs) [11], [86], [118], [119], dynamical systems that can change their parameters to learn a quasi-periodic signal [120]. While this approach has been proved to precisely estimate the phase in steady-state conditions, it still cannot provide an exact estimate during transitory movements or initial and terminal steps. Another approach is to use phase variables based on the position and velocity of the residual limb's segments [55], [70], [102], [117], [121], [122]. This strategy may also work in nonsteady state conditions, given that the defined monotonic phase variable can capture the volitional intent of the user during a locomotion task. For example, Thatte et al. [123] used the information from hip, knee, and ankle joints in an extended Kalman filter to estimate the gait phase and phase velocity. Alternatively, phase variables based on the thigh angle have been used to estimate gait phase during rhythmic and nonrhythmic tasks [117], walking [112], stair negotiation [124], and sit-to-stand [125].

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The information on the gait phase estimation (either discrete or continuous) is then translated into a desired joint position or torque. These desired references aim to replicate the physiological behavior of the missing joint, and can be implemented using handcrafted trajectories, lookup tables, or polynomial fitting. The desired position or torque references are then translated by the low-level controller (typically using PID controllers) into a signal to drive the mechatronic assembly [26], [95].

C. Verification with End-Users

The stage of development of a device determines the goals of the tests conducted with end-users. Pilot (or feasibility) studies typically focus on assessing the functionalities of newly developed prototypes, while validation studies involve mature prototypes that have undergone extensive verification with healthy individuals and early tests with end-users. Pilot studies usually involve only one or two participants. Given that the present review takes into consideration recently developed prototypes, most of the reviewed studies were pilot studies aimed at verifying that the prototypes' functionalities met the requirements. To do so, these prosthetic prototypes were typically tested with high-mobility individuals with amputations (i.e., K3-K4 on the Medicare Functional Classification Level [126]), except for one device tested with a K1-level participant [79]. Two prototypes were tested on bilateral lower limb amputees [91], [127]. For the reviewed prototypes, the median (IQR) age of the tested population is 41 (22) years, with a strong prevalence of male participants (94.8%). The most common cause of amputation among those reported was trauma (25 out of 50), followed by congenital diseases (10 out of 50), tumors (8 out of 50), dysvascular disease (5 out of 50), and infections (2 out of 50). Most of the studies were conducted in a single session or over a few sessions lasting no more than 4 hours. In most cases, participants underwent up to 3 hours of familiarization with the

device, although there were a few instances where participants had the opportunity to become acclimated to the new device for an extended duration [20], [46], [60], [61], [69], [91], [103], [128], [129].

The first objective when assessing the functionality of a new prototype typically involves testing it with a single individual with amputation performing level-ground walking, as can be seen in Figure 5. Across all the selected studies, prosthetic devices were tested in level-ground walking and in some cases other 1 or 2 tasks. Common tasks include stair and ramp negotiation [49], [112], [124], [130], [131], [132], [133], [134], [135], and less frequently, sit-to-stand transitions [7], [17], [47], [100], [102], [125]. In addition to these tasks, other studies have included activities such as backward walking [80], [117], simulated hikes [136], navigating uneven terrains [110], squatting and lunging [100], performing turning motions [102], [105], and rock climbing activities [46].

To verify the functionality of newly developed prototypes, the most reported metrics include a comparison with healthysubject kinematic and kinetic data (49 out of 53 prototypes), such as joint angles and torque profiles. Among these, some studies defined clinically relevant goals and compared them with the prosthesis' performance [19], [91] or verified reductions of compensatory movements at the hip [117], [137]. Only 6 prototypes reported the users' subjective feedback [11], [37], [61], [76], [106], [107], utilizing questionnaires such as the Visual Analog Scale or the full-body pain diagram.

Depending on the specific design of the prototype, other metrics can be taken into consideration during the preliminary verification. For example, some studies evaluated device performance in terms of mechanical and electrical energy exertion. Some of these studies focused on energy regeneration [11], [21], [74], [75], [93], [138], while others investigated energy consumption in relation to current consumption [17], [65], [76]. Studies dedicated at evaluating the performances of control algorithms also consider metrics such as classification accuracy [139] or classification errors [74].

Some of the analyzed studies preliminarily verified outcomes of clinical relevance, such as symmetry, metabolic consumption, and compensatory movements. Spatiotemporal parameters were examined in 5 ankle prototypes [11], [129], [140], [141], [142] and 3 knee-ankle prostheses [53], [125], [143]. For example, powered prostheses have demonstrated the ability to enhance the symmetry of ground reaction forces [53], [129], [141], [142], and weight-bearing symmetry in sit-tostand tasks [143]. Among the 53 prototypes analyzed in this review, 6 assessed metabolic effort using a respirometer to measure oxygen consumption and gas exchange or indirectly via heart rate monitoring. Of these, 4 ankle prostheses exhibited a reduction in energy consumption of over 10% compared to passive prosthesis [72], [129], [140], [144]. Notably, [140] utilized gait symmetry as a cost function in human-in-the-loop optimization control, revealing a correlation between gait symmetry and metabolic cost. In one knee prototype, different control strategies were evaluated based on metabolic cost, with no significant differences observed between them [50].

8

IV. OPEN CHALLENGES

As the field of robotic lower limb prostheses evolves, there are several open challenges that must be considered to make the user-prothesis interaction seamless and intuitive.

A. Mechatronic Design

The following are key design challenges in the mechatronic design of lower limb prostheses, which the authors think deserve attention for a widespread adoption of powered prostheses.

1) Miniaturization and weight reduction

To be acceptable from the end-users' perspective, prostheses should be compact and lightweight. While the human leg and foot weight approximately 6% of the total body mass [145], a general design rule for prosthetic devices is to keep the device weight close to the half of the weight of the human limb counterpart. When this requirement is not met, prosthetic legs are not well tolerated by end-users [11], [48], [75], as the human-device interface may become unstable and lead to discomfort [146]. Also, people with amputations are accustomed to the weight of passive prosthesis, and when testing powered prostheses, they may perceive that the functional advantage of using a powered device is not sufficient to overcome the cost of the additional burden they have to carry



Fig. 5. (a) Bar plot illustrating the distribution of prostheses tested across various tasks and sample sizes. (b) Summary of outcome measures employed to evaluate the prototypes.

[144]. Advancements in materials and manufacturing techniques are required to achieve miniaturization without compromising dependability and performance [147]. Simultaneously, a smaller and lighter prosthesis often lends itself to a more visually appealing design, contributing to enhance the overall satisfaction with the prosthetic device.

2) Energy efficiency and autonomy

To compete with passive commercial prostheses, robotic devices should be self-standing and capable of providing at least a full day of autonomous operation. Only few studies investigated the effect of different control strategies on power consumption [64], [75]. Moreover, electrical energy regeneration is a promising strategy for enhancing energy efficiency converting the otherwise bv dissipated biomechanical energy during human locomotion into electrical energy for recharging the onboard batteries. For example, the knee joint exhibits net negative power during the gait cycle, making it a source of energy regeneration for transfemoral prostheses [145].

3) Cost reduction

Making advanced mechatronic prostheses more affordable and accessible is an ongoing challenge in the field. Currently, the cost of robotic prostheses typically ranges between 20,000 USD and 100,000 USD, depending on the model and functionalities [148]. This would not only benefit individuals who require prostheses but also contribute to enhancing the overall accessibility of advanced healthcare solutions [30]. Additive manufacturing and 3D printing have shown potential benefits in terms of reducing fabrication costs, time, and material waste [147], [149]. Nonetheless, these techniques may introduce new challenges in the mechanical design of the prostheses related to the compliance of the materials used, such as precise alignment and critical tolerances.

B. Sensing and Control

Commercially available microprocessor-controlled prostheses employ control strategies based on key-fob mechanisms, switches, or predefined sequences of movements. Requiring the subject's input, these controllers are reliable and grant safe intention decoding, but cause an increased cognitive burden and unnatural transitions between tasks. The following are key open challenges to enable a more natural and intuitive locomotion of robotic lower limb prostheses, while maintaining their safety and reliability.

1) Volitional control and user adaptability

EMG-based algorithms have the potential to restore volitional control by directly decoding the neural activity of the muscles in the residual limb of the users, potentially improving prosthetic embodiment. For instance, this control strategy has demonstrated effectiveness in restoring normative postural control during standing perturbations [150], or enabled users to perform activities such as standing on tip-toes, foot tapping, side-stepping, and backward walking [151]. Nonetheless, EMG-control is highly dependent on the quality and availability of residual muscles and is vulnerable to motion artifacts and noise. Adaptive Dynamic Movement Primitives (aDMP), dynamic systems that can encode the kinematic patterns of rhythmic and non-rhythmic movements [152], have recently shown potential for accurate locomotion mode recognition and continuous gait phase estimation [153], [154].

In addition, prosthetic devices should be tailored to the user to enhance their comfort and usability. To this end, machine learning algorithms and artificial intelligence hold promise in enabling prosthetic devices to learn from user behavior and preferences [26]. These technologies can empower the development of control systems that self-optimize based on real-time user feedback and usage patterns (frequency of use, most performed tasks, preferred movement patterns), ultimately offering a more personalized and comfortable user experience. For example, Human-In-the-Loop Optimization is a way to customize control parameters in real-time by iteratively minimizing a cost function. This approach gave promising results in reducing metabolic cost in exoskeletons [155], [156] and is recently being explored to tailor the behavior of lower limb prostheses on the users [140], [157].

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2) Sensory feedback integration

Neural sensory feedback systems have shown the potential to revolutionize prosthetic technology, improving symmetry [158], [159], mitigating phantom pain and improving walking speed and metabolic cost [160]. Moreover, this approach has demonstrated to positively affect the embodiment of the device, decreasing the subjective perception of the prosthesis' weight [90].

3) Safety and real-time environmental awareness

Prosthetic limbs should have the ability to sense and adapt to different environments and terrains. Challenges include exploiting sensors and control algorithms that can detect obstacles or changes in terrain, adjust joint stiffness, and optimize gait patterns accordingly. Recently, sensing modalities such as vision and pressure were integrated into the prosthesis' control system to recognize the surrounding environmental features [116], [161], [162], [163].

C. From Verification to Validation

This review focused on the development and preliminary verification of the analyzed prototypes. Nonetheless, the subsequent validation phase plays a pivotal role in bringing powered lower limb prostheses to market. The following are key open challenges to foster the real-world adoption of this technology.

1) Ecological assessment

Verification studies, typically conducted in controlled laboratory settings, are an essential initial assessment for prosthetic prototypes, offering valuable insights into their functionality under controlled conditions. However, to simulate real-world use and progress towards market readiness, validation studies should transition to ecological settings. According to the World Health Organization, it is paramount to assess the functionality of a prosthesis both in indoor and outdoor settings, and considering dynamic activities typical of daily life, such as stand-to-sit, stair ascending, and obstacle avoidance [164]. This approach ensures that prosthetic devices can address the diverse needs of users across various contexts, ultimately improving their marketability.

2) User training and study population

While the functionality of robotic prostheses is typically verified on small sample sizes consisting of high-mobility amputees, an adaptation phase involving effective user training is essential [165]. After the preliminary verification of a prototype, validating the device requires larger sample sizes and

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a broader spectrum of users, including individuals with limb loss due to dysvascular diseases. Such individuals are typically low-mobility and represent the majority of people with lower limb amputations. This step is crucial for bridging the gap between research-driven applications and market-ready devices [35].

3) Standardization of assessment

While research prototypes explore different design principles, the main outcome for their preliminary assessment is comparing them with the natural kinematic and kinetic profiles of human locomotion. This comparison enables meaningful performance evaluation across different prototypes. For the same reason, validation studies should include common clinical outcomes to demonstrate advantages over existing prostheses in the market [34].

4) Healthcare technology assessment

Integrating robotic lower limb prostheses into clinical practice requires convincing decision-makers of their value for the society. This necessitates not only demonstrating the clinical benefits and improved quality of life they offer but also proving their cost-effectiveness. To this aim, healthcare technology assessment activities may be a pivotal tool to evaluate the clinical, social, and economic impact of these devices, paving the way for broader acceptance and integration into clinical practice [166]. Particularly noteworthy – and yet to be demonstrated – is the potential for significant economic and social benefits associated with low-mobility amputees achieving functional recovery through robotic prostheses.

V. CONCLUSION

This systematic review provides an overview of the current state-of-the-art and recent advancements in active and semiactive lower limb prostheses. Since the previous systematic review in 2016 [36], we have identified and analyzed 53 new prototypes of semi-active and active lower limb prostheses. This review covers key aspects including (i) the actuation principles and mechatronic designs, (ii) the sensory apparatus and control architecture, and (iii) the methods used to verify the prototypes' functionality with end-users.

Our findings highlight important challenges that warrant attention. The mechanical design should aim at reducing the weight and encumbrance of prosthetic devices. Moreover, robotic prostheses should be equipped with embedded batteries, and both their mechatronic embodiment and control system should prioritize energy efficiency. To enhance usability and acceptance, the control system should be perceived as seamless, capable of adapting to different tasks and environmental conditions. Furthermore, the integration of sensory feedback holds promise for enhancing user-environment interaction. Lastly, extensive user training and clinical trials are needed to gain meaningful insights into the widespread adoption of robotic solutions in prosthetics.

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