Journal of Disability Research

2023 | Volume 2 | Issue 3 | Pages: 10–23
DOI: 10.57197/JDR-2023-0031

Functionality and Comfort Design of Lower-Limb Prosthetics: A Review

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Received: June 26 2023; Revised: August 17 2023; Accepted: August 17 2023; Published Online: September 15 2023

ABSTRACT

This literature review on the design of amputated lower limbs has covered various aspects related to prosthetic limb design. It has highlighted the need for continuous improvement and innovation in order to enhance user satisfaction, mobility, and overall quality of life. Biomechanical factors such as gait analysis, joint range of motion, force distribution, and energy efficiency were identified as crucial considerations in amputated lower-limb design. Socket design principles, focusing on comfort and proper load distribution, were found to be essential for achieving a well-fitting and functional prosthetic limb. Emerging technologies, including advanced materials, robotics, neural interfaces, and sensor technology, were explored as potential avenues for improvement. These technologies showed promise in enhancing functionality, control, and sensory feedback in prosthetic limbs. A user-centric approach was emphasized, involving users in the design process and incorporating their feedback and preferences. Affordability and accessibility were highlighted as significant concerns, calling for the development of cost-effective solutions. Long-term performance and durability were also emphasized, stressing the need for robust materials and quality control processes. The integration of neural interfaces and sensory feedback posed opportunities and challenges for achieving more natural limb control and sensation. To sum up, this literature review has furnished valuable perspectives on amputated lower-limb design, underscoring the significance of refining design principles, accounting for biomechanical variables, embracing emerging technologies, and integrating user input. Future directions include addressing affordability, long-term performance, and neural integration while leveraging advancements in materials, technology, and user-centered design.

KEYWORDS

lower limb, prosthetic, biomechanics, design, functionality, comfort

INTRODUCTION

Background and significance of designing amputated lower limbs

The loss of a lower limb has a profound impact on an individual's mobility and quality of life. Whether resulting from trauma, disease, or congenital conditions, lower-limb amputations necessitate the development of effective prosthetic limbs to restore functionality and improve the overall well-being of individuals (Legro et al., 1998; Livneh et al., 1999; Behel et al., 2002; Horgan and MacLachlan, 2004; Kauzlarić et al., 2007). The design of amputated lower limbs plays a crucial role in facilitating mobility, enabling activities of daily living, and promoting psychological and social integration. This review provides an in-depth analysis of the background and significance of designing prosthetic limbs for amputated lower limbs, emphasizing the biomechanical considerations and psychosocial impact on individuals. The foundation of lower-limb amputation design lies in a thorough comprehension of the biomechanics of the human body. Essential for superior performance and comfort of prosthetic limbs, proper distribution of loads and weight-bearing capabilities are of paramount importance. Designers must consider factors such as the alignment of the prosthetic limb, joint biomechanics, and gait patterns (Dipl-Ing et al., 2012; Simon et al., 2016; Edelstein and Chui, 2019; Mohamed and Appling, 2019; Zhang et al., 2019, 2020; Kobayashi et al., 2020; Siddikali and Sreekanth, 2020; Butowicz et al., 2021; Jarvis et al., 2021; Köhler et al., 2021; Pinhey et al., 2022). Load distribution plays a pivotal role in prosthetic limb design. Prostheses must be engineered to mimic the natural load distribution of the lower limb, ensuring that forces are appropriately distributed across the residual limb and the

prosthetic limb. This helps prevent pressure points and discomfort while maintaining stability and balance during various activities. Joint biomechanics, including the ankle, knee, and hip, are essential considerations for designing prosthetic limbs. Mimicking the natural range of motion and providing appropriate joint stiffness enable users to engage in a wide range of functional activities. Moreover, proper alignment of the prosthetic limb is crucial to achieve optimal biomechanical efficiency, facilitating an efficient gait pattern and reducing the risk of secondary health issues such as back pain and joint degeneration. Gait analysis is another critical component of amputated lower-limb design (McFadyen and Winter, 1988; Schmalz et al., 2007). Understanding the dynamics of walking and the forces exerted during different phases of the gait cycle enables designers to develop prosthetic limbs that closely mimic the natural movement patterns of the lower limb. This enhances mobility and minimizes energy expenditure, ultimately improving overall functional outcomes for amputees (Burger et al., 1997; Deathe and Miller, 2005).

In addition to the biomechanical considerations, the design of amputated lower limbs has a significant psychosocial impact on individuals. Prosthetic limb design can greatly influence an individual's psychological well-being, self-esteem, and social integration (Jackson et al., 2001). The appearance and aesthetics of prosthetic limbs play a crucial role in user acceptance and confidence. Designing prostheses that closely resemble the natural limb can help amputees regain a sense of normalcy and promote positive body image. Additionally, advances in prosthetic limb aesthetics, such as the use of realistic skin-like coverings and customizable designs, contribute to the overall acceptance and integration of prostheses into the individual's self-identity. User-centered design approaches are vital in ensuring user satisfaction and quality of life outcomes. Engaging amputees in the design process, considering their unique needs, preferences, and functional requirements, allows for personalized and tailored prosthetic limb solutions. User involvement empowers individuals, fosters a sense of ownership, and promotes a more positive experience with the prosthetic limb. Psychosocial integration is another significant aspect influenced by prosthetic limb design. A well-designed prosthetic limb can enable individuals to participate in social activities, enhance their self-confidence, and reduce stigmatization. Providing individuals with functional and aesthetically pleasing prostheses contributes to their overall well-being, allowing them to engage in various activities and roles within their communities (Datta et al., 1992; Pezzin et al., 2004; Johannes et al., 2019; Safari, 2020; Yu et al., 2021).

Definition and classification of lower-limb amputation

Lower-limb amputation involves the removal of a part or the entire lower extremity, including bones, muscles, and soft tissues. The extent of the amputation can vary depending on the underlying conditions, the extent of tissue damage, and the goals of the procedure. Amputations can be categorized into different levels based on the location of the amputation relative to anatomical landmarks (Wong et al., 2016). Figure 1 shows the major classification of lower-limb amputation. Following are the classification of lower-limb amputation:

Toe or partial foot amputation type of amputation involves the removal of one or more toes or a portion of the forefoot. It is commonly performed for conditions such as gangrene, infections, or deformities that affect a localized area of the foot. Transmetatarsal amputation involves the removal of the forefoot up to the metatarsal bones. It is performed when there is a need to remove a larger portion of the foot, while preserving the ankle joint and the ability to bear weight on the residual limb. Lisfranc or Chopart amputation involves the removal of the midfoot, including the metatarsal bones, tarsal bones, and the corresponding articulations. This type of amputation is typically performed in cases of severe trauma or deformities affecting the midfoot. Syme amputation is a surgical procedure that involves the removal of the foot and ankle joint while preserving the heel pad. This procedure aims to provide a weight-bearing surface for better prosthetic fitting and improved functional outcomes. Transtibial amputation refers to the removal of the lower leg, including the tibia and fibula bones, while preserving the knee joint. It is one of the most common types of lower-limb amputations and is performed for various reasons, including trauma, vascular diseases, or complications of diabetes. Knee disarticulation involves the removal of the lower-limb at the knee joint level, preserving the femur bone. This type of

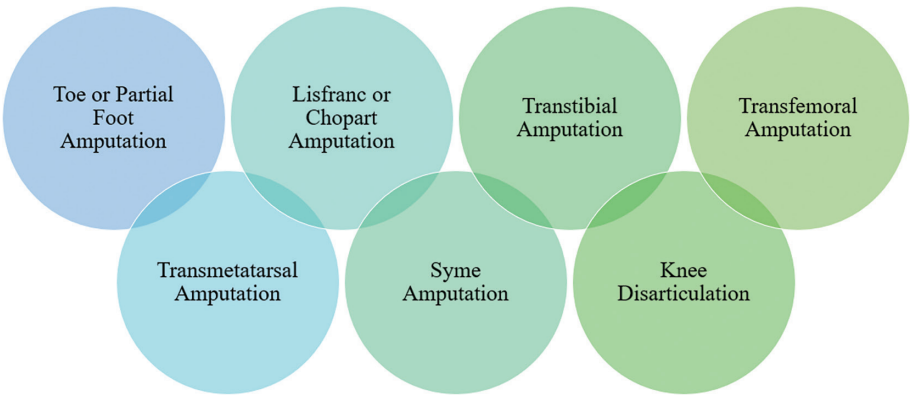

Figure 1: Major classification of lower limb amputation.

amputation is typically performed when preserving the knee joint is beneficial for maintaining stability, allowing for better prosthetic fitting and functional outcomes. Transfemoral amputation, also known as above-knee amputation, involves the removal of the entire lower limb, including the femur bone. This is a more complex procedure that requires the use of a prosthetic knee joint for functional mobility. Hip disarticulation is the most extensive form of lower-limb amputation, involving the removal of the entire lower limb along with the hip joint. This procedure is performed in rare cases where there is extensive disease or trauma involving the hip joint.

Importance of optimal design for prosthetic limbs

The pivotal role of optimal design in crafting prosthetic limbs cannot be overstated, directly influencing functionality, comfort, and the well-being of those with limb loss. Prosthetic limb design surpasses aesthetics, encompassing a holistic grasp of biomechanics, user requirements, and technological progress. This work highlights the importance of optimal design for prosthetic limbs and its significant impact on enhancing mobility, promoting independence, and improving the overall well-being of individuals. One of the primary goals of prosthetic limb design is to restore and enhance mobility for individuals with limb loss. Optimal design takes into account the biomechanical principles of human locomotion, ensuring that the prosthesis closely mimics the natural movement of the missing limb (Jönsson et al., 2011). By providing appropriate joint dynamics, alignment, and weight distribution, prosthetic limbs enable users to engage in various activities, such as walking, running, and climbing stairs. An optimal design ensures a seamless integration between the residual limb and the prosthetic component, allowing for efficient energy transfer and reducing the effort required during locomotion. This results in improved walking efficiency, reduced fatigue, and enhanced overall functionality, enabling individuals to regain their independence and actively participate in daily activities (Taylor et al., 1996). Chen et al. (2022) studied a robust gait phase estimation method using thigh angle models to avoid measurement errors. A Kalman filter-based smoother is designed to further enhance the estimation. The proposed method is evaluated through offline analysis and validated in real-time experiments.

Comfort is a vital aspect of prosthetic limb design. A well-designed prosthesis considers factors such as socket fit, cushioning, and interface pressure management to minimize discomfort and skin-related issues. Proper weight distribution and alignment of the prosthetic limb alleviate excessive pressure on the residual limb, reducing the risk of pain, skin breakdown, and long-term complications. Customization is another critical component of optimal design. Each individual's residual limb is unique in terms of size, shape, and sensitivity. A customized prosthetic limb ensures a precise fit and accommodates the specific needs and functional requirements of the user. Customization also extends to aesthetic considerations, allowing individuals to personalize their prosthetic limbs, contributing to their self-esteem and body image (Ma et al., 2019; Pei et al., 2021). Prosthetic limb design significantly impacts an individual's psychological and social well-being. Aesthetics and cosmesis play a vital role in promoting body image, self-confidence, and social acceptance. Advancements in design techniques, materials, and coverings allow for the creation of realistic-looking prosthetic limbs that closely resemble natural limbs, reducing the stigma associated with limb loss. User-centered design approaches empower individuals by involving them in the design process, considering their preferences and addressing their psychosocial needs. This collaboration fosters a sense of ownership and promotes a positive user experience, enhancing user satisfaction and overall well-being. By providing functional and aesthetically pleasing prosthetic limbs, individuals can feel more confident, actively engage in social interactions, and regain a sense of normalcy in their lives (Cohen and Hoberman, 1983; Dunn, 1996; Gallagher and MacLachlan, 2001; Behel et al., 2002).

The significance of ideal design is magnified by ongoing technological progress. Prosthetic limb design stands to gain from breakthroughs like microprocessors, sensors, and robotics, allowing for intelligent prosthetic systems that dynamically adjust to users' motions, enhancing control, stability, and responsiveness. Technological advancements also facilitate the integration of wearable devices and smart interfaces, allowing users to monitor their activity levels, adjust settings, and receive real-time feedback. These features enhance the functionality and usability of prosthetic limbs, promoting a seamless interaction between the user and the device (Siddiqui et al., 2023b; Deathe and Miller, 2005).

Objectives and scope of the review

The objective of conducting a systematic literature review on the design of amputated lower limbs is to provide a comprehensive and evidence-based analysis of the existing knowledge in this field. The review aims to identify and evaluate relevant research studies, articles, and publications that address various aspects of prosthetic limb design for individuals with lower-limb amputations. The review aims to identify and analyze the key design factors that influence the development of prosthetic limbs for amputated lower limbs. This includes examining aspects such as biomechanical considerations, material selection, alignment techniques, socket design, interface technology, and customization options. The present work seeks to assess the impact of different design approaches on functional outcomes for individuals with lower-limb amputations. This includes analyzing gait analysis, energy expenditure, mobility, stability, balance, and performance in various activities of daily living. This involves examining factors such as comfort, fit, aesthetics, cosmesis, psychosocial integration, and overall user experience. The review aims to identify design features that contribute to higher user satisfaction and improved psychosocial well-being. The review seeks to explore and discuss emerging technologies and innovations in prosthetic limb design for amputated lower limbs. This includes examining the potential applications of robotics, sensor technology, artificial intelligence (AI), and wearable

devices in enhancing the functionality and usability of prosthetic limbs.

This systematic literature review concentrates on the design elements of prosthetic limbs intended for individuals with lower-limb amputations. The review's coverage encompasses peer-reviewed journal articles, conference proceedings, and pertinent materials from the gray literature. The review encompasses research conducted in various disciplines, such as biomechanics, engineering, rehabilitation, and clinical practice. The inclusion criteria for this review involve studies that address the design of prosthetic limbs, including but not limited to socket design, alignment techniques, material selection, control systems, and user-centered design approaches. Studies evaluating functional outcomes, user satisfaction, and quality of life measures related to prosthetic limb design are also included. This review excludes studies that focus solely on surgical techniques, rehabilitation protocols, or clinical outcomes unrelated to prosthetic limb design. Additionally, studies that do not provide sufficient information on the design aspects or lack empirical data are excluded from the review.

METHODOLOGY

Research question(s) and objectives

Identify the key design factors and considerations involved in the development of prosthetic limbs for individuals with lower-limb amputations, including biomechanical considerations, material selection, alignment techniques, socket design, interface technology, and customization options. Evaluate the impact of different design approaches on functional outcomes, including gait analysis, energy expenditure, mobility, stability, balance, and performance in various activities of daily living for individuals with lower-limb amputations. Assess user satisfaction and quality of life outcomes associated with different prosthetic limb designs, including factors such as comfort, fit, aesthetics, cosmesis, psychosocial integration, and overall user experience. Explore emerging technologies and innovations in prosthetic limb design for amputated lower limbs, including robotics, sensor technology, AI, and wearable devices, and their potential applications in enhancing functionality and usability. Identify gaps in the existing literature and provide recommendations for future research and development in the design of prosthetic limbs for individuals with lower-limb amputations. By addressing these research objectives, this study aims to provide valuable insights into the design factors and considerations that contribute to optimal prosthetic limb designs. The findings can inform clinical practice and prosthetic limb development, and ultimately improve the functional outcomes, user satisfaction, and quality of life for individuals with lower-limb amputations.

Search strategy and inclusion criteria

A systematic literature review was conducted on the design of amputated lower limbs. A comprehensive search strategy was implemented to identify relevant studies. The search involved electronic databases, including PubMed and Scopus. Figure 2 shows the search terms and their variations used in conducting the literature review.

The inclusion criteria for selecting relevant literature were as follows:

- Studies published in peer-reviewed journals, conference proceedings, and relevant gray literature.
- Studies conducted on individuals with lower-limb amputations.
- Studies that focus on the design aspects of prosthetic limbs, including socket design, alignment techniques, material selection, control systems, and user-centered design approaches.
- Studies that evaluate functional outcomes, such as gait analysis, energy expenditure, mobility, stability, balance, and performance in various activities of daily living.
- Studies that assess user satisfaction and quality of life measures related to prosthetic limb design, including factors like comfort, fit, aesthetics, cosmesis, psychosocial integration, and overall user experience.

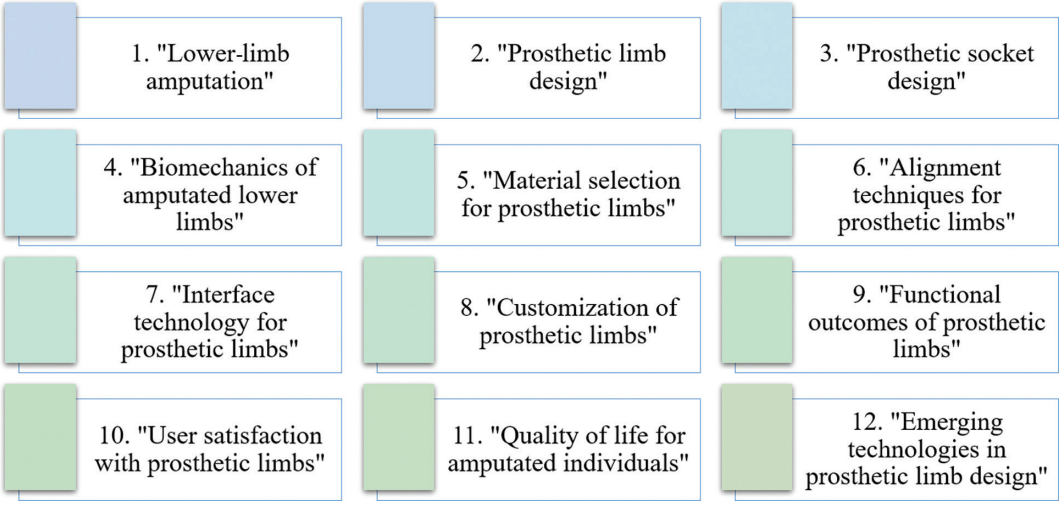

Figure 2: Search terms used in conducting literature survey.

- Studies that explore emerging technologies and innovations in prosthetic limb design for amputated lower limbs, including robotics, sensor technology, AI, and wearable devices.
- Studies published in English.

The following criteria were used to exclude irrelevant literature:

- Studies that focus solely on surgical techniques, rehabilitation protocols, or clinical outcomes unrelated to prosthetic limb design.
- Studies that lack sufficient information on the design aspects or lack empirical data.
- Studies not published in English, unless they provide a comprehensive abstract or English translation.

By applying these inclusion and exclusion criteria, this review will ensure the selection of relevant literature that addresses the research question and objectives effectively.

Study selection process

The study selection process for the systematic literature review on the design of amputated lower limbs was as follows. The titles and abstracts of the identified studies were screened to determine their relevance to the research question and inclusion criteria. Studies that clearly did not meet the inclusion criteria or were irrelevant to the topic were excluded at this stage. The remaining studies from the initial screening underwent a full-text assessment. The full-text articles were carefully reviewed to determine if they met all the inclusion criteria and provided relevant information on the design aspects of prosthetic limbs for amputated lower limbs. Studies that did not meet the inclusion criteria or lacked the required information were excluded. The included studies underwent data extraction, where relevant information such as study characteristics (author, year of publication), study design, sample size, methodology, key findings, and outcomes were extracted and organized in a standardized format. This process ensured that important information from each study was captured for analysis. The quality and risk of bias of the included studies were assessed using appropriate tools or checklists. This assessment helped evaluate the strength and reliability of the evidence provided by each study and considered potential sources of bias that may have affected the validity of the findings. The extracted data were synthesized and analyzed to identify common themes, patterns, and trends in the design of prosthetic limbs for amputated lower limbs. This synthesis may have included a narrative synthesis or, if appropriate, a meta-analysis of the quantitative data.

BIOMECHANICAL CONSIDERATIONS IN DESIGN

The design of prosthetic limbs for individuals with lower-limb amputations is a complex process that requires a comprehensive understanding of biomechanical principles. Biomechanics plays a crucial role in determining the functionality, comfort, and overall performance of these devices. Present review provides an overview of the biomechanical factors that influence the design of amputated lower-limb prosthetics, including socket design, alignment, joint mechanics, and gait analysis (Horgan and MacLachlan, 2004; Deathe and Miller, 2005; Kahle et al., 2008; Highsmith et al., 2010; Siddikali and Sreekanth, 2020; Pinhey et al., 2022). The socket is a critical component of the prosthetic limb that interfaces with the residual limb. Its design significantly affects the fit, stability, and weight-bearing distribution (Köhler et al., 2021). The socket must be customized to the shape of an individual's residual limb to ensure a precise fit, maximize contact area, and distribute forces evenly. It should also provide adequate support and promote efficient energy transfer during walking and other activities. Proper socket design reduces pressure points, enhances comfort, and minimizes the risk of skin breakdown and discomfort. Alignment refers to the correct positioning of the prosthetic limb in relation to the user's anatomy. Proper alignment is crucial to achieve optimal biomechanical function and gait symmetry. Alignment factors include the angular positioning of the knee, ankle, and foot, as well as the sagittal, coronal, and transverse planes. Precise alignment helps maintain proper joint mechanics, reduces stress on the residual limb, and improves stability and balance during walking and other movements (Schmalz et al., 2002; Zhang et al., 2019, 2020).

Prosthetic limbs must replicate the natural joint mechanics of the lower limb to ensure smooth and efficient movement. The mechanical behavior of prosthetic joints, such as the knee and ankle, should closely mimic the natural range of motion, joint axes, and kinematics. This allows users to perform activities such as walking, running, and climbing stairs with minimal deviations from normal biomechanics. Proper joint mechanics facilitates a more natural gait pattern, reduces energy expenditure, and enhances overall functionality and user satisfaction (Schmalz et al., 2002; Orendurff et al., 2006; Bae et al., 2009). Gait analysis is a valuable tool for evaluating the biomechanical performance of prosthetic limbs (Ferrari et al., 2008; Peters et al., 2010; El Habachi et al., 2015; Leardini et al., 2017). It involves the measurement and assessment of various parameters during walking, such as step length, stride length, cadence, ground reaction forces, and joint angles. By analyzing gait patterns, clinicians and researchers can identify biomechanical deviations and assess the effectiveness of prosthetic limb designs. Gait analysis helps optimize alignment, socket fit, and component selection, leading to improved walking efficiency, reduced fatigue, and enhanced functional outcomes (Stagni et al., 2005, 2009; Koh et al., 2009; Li et al., 2012; Gasparutto et al., 2015).

Optimal weight distribution is crucial for comfortable and efficient use of prosthetic limbs. Uneven weight distribution can lead to discomfort, pressure points, and skin irritation. Prosthetic limb designs should distribute weight evenly across the residual limb and the prosthetic components to minimize excessive loading and prevent overuse injuries (Simon et al., 2016). A balanced weight distribution also helps users maintain stability, balance, and control during

activities, contributing to enhanced mobility and overall functionality. To ensure the prolonged durability of prosthetic limbs, specific recommendations and best practices can be implemented. Regular maintenance routines, including thorough cleaning and lubrication of components, can prevent premature wear and damage. Proper usage techniques and weight management are essential to avoid excessive strain on the prosthetic. Consideration of these biomechanical factors is essential in the design of amputated lower-limb prosthetics. An integrated approach that combines socket design, alignment, joint mechanics, and gait analysis results in optimal prosthetic limb functionality and improved user outcomes. By understanding the biomechanical principles and their impact on design, prosthetists and engineers can create personalized and efficient prosthetic limb solutions that maximize mobility, comfort, and overall quality of life for individuals with lower-limb amputations (Duprey et al., 2017). Table 1 summarizes some recent studies carried out in prosthetic design.

Socket design

Socket design is a critical aspect of prosthetic limb development, as it serves as the interface between the residual limb and the prosthesis (Gerschutz et al., 2012; Gariboldi et al., 2022). The socket plays a crucial role in distributing forces, providing stability, and ensuring user comfort. This text provides an overview of the key principles and considerations involved in socket design for individuals with lower-limb amputations. One of the primary objectives of socket design is to achieve an individualized fit for each user. Residual limbs come in various shapes, sizes, and contours, requiring custom-made sockets to ensure proper contact and load distribution. Individualized fit minimizes pressure points, reduces shear forces, and enhances overall comfort. To achieve this, prosthetists employ techniques such as plaster casting, 3D scanning, and digital modeling to capture the unique anatomy of the residual limb (Rai et al., 2022). Efficient load distribution is crucial for optimal functionality and comfort. The socket must evenly distribute forces across the residual limb to prevent localized pressure and potential skin breakdown. Various strategies are employed to achieve proper load distribution, such as the use of pressure-relief areas, padding, and flexible materials. Pressure mapping technologies and computer simulations help evaluate the load distribution characteristics of different socket designs (Lenhart et al., 2015; Siddikali and Sreekanth, 2020). Socket design must provide adequate stability and suspension to ensure secure attachment of the prosthetic limb to the residual limb. Stability refers to the control of rotational and translational movements, while suspension involves maintaining the prosthesis in position during various activities. Various suspension methods, including suction, vacuum-assisted, and strap-based systems, are utilized to achieve secure and comfortable suspension. The socket design should accommodate the necessary suspension mechanism while ensuring stability and minimizing unwanted movements (Quinlan et al., 2020a, 2020b).

The choice of materials and construction techniques significantly impact the performance of the socket. Materials should be lightweight, durable, and compatible with the user's skin. Commonly used materials include thermoplastics, carbon composites, and silicone liners. Advanced manufacturing methods, such as 3D printing, allow for complex socket designs and customization. Proper fabrication techniques, including lamination, molding, and thermoforming, ensure the desired shape, strength, and durability of the socket (Gerschutz et al., 2011, 2012). User comfort is a critical consideration in socket design. Discomfort or pain can significantly affect the user's adherence and satisfaction with the prosthetic limb. Socket design should consider factors such as cushioning, pressure distribution, breathability, and temperature control (Gariboldi et al., 2023). Innovative technologies, including gel liners, adjustable interfaces, and modular components, help enhance comfort by reducing pressure points and improving socket fit and adjustability. Proper alignment of the socket is essential for optimal biomechanical function and gait symmetry (Marinopoulos et al., 2022). The alignment ensures that the prosthesis replicates the natural anatomical position and joint axes of the lower limb. Precise alignment contributes to improved stability, reduced energy expenditure, and more efficient gait patterns. Alignment adjustments may be necessary during the fitting process to fine-tune the socket's orientation and optimize user performance. Socket design should allow for adjustability and adaptability to accommodate changes in the residual limb, such as volume fluctuations, muscle atrophy, or bony prominences. Adjustable components, modular systems, and interchangeable interfaces enable prosthetists to make necessary modifications without requiring a complete socket replacement (Dickinson et al., 2023). This adaptability extends the lifespan of the socket and ensures an optimal fit and function over time. The interface between the residual limb and the socket, along with the suspension system, significantly influences socket performance (Quinlan et al., 2020a). Soft interfaces, such as silicone liners, help improve comfort, cushioning, and moisture management. Suspension systems, including suction, vacuum, or strap-based systems, provide secured attachment and control of the prosthetic limb.

Prosthetic components and technologies

Prosthetic limbs have significantly evolved over the years, thanks to advancements in technology and the development of innovative components. These components and technologies play a crucial role in enhancing the functionality, comfort, and overall performance of prosthetic limbs. Present work provides an overview of various prosthetic components and technologies used in lower-limb prosthetics, including sockets, feet, knees, power systems, and emerging advancements. The socket is the interface between the residual limb and the prosthetic limb. It is custom-made to fit the individual's residual limb and plays a vital role in distributing forces and providing stability. Socket components include liners, suspension systems, and adjustable interfaces. Liners, made of materials like silicone or gel, improve comfort

Table 1: Summary of some recent work in prosthetic design.

No.	Authors	Objective	Methodology	Outcome
1	Wang et al. (2023)	Design an adjustable frame-type prosthetic socket with constant force to adapt to stump volume fluctuations.	Design a constant force device based on shape memory alloy for maintaining constant stump–socket interface stress.	An adjustable prosthetic socket that allows users to adjust the socket volume, maintains constant interface stress, and adapts to stump volume fluctuations.
2	Fidelis and Arowolo (2023)	Design and implement a mechanical, body-powered, transfemoral prosthetic device for affordable functional ambulation.	Utilize anthropometric measurements to design an ergonomic prosthetic device using AutoCAD rendering and engineering methods like casting and welding.	Successful fabrication of a transfemoral prosthetic limb consisting of a polypropylene socket, galvanized iron knee joint, and perlite foot, restoring ambulatory function for the amputee.
3	Van Der Stelt et al. (2023)	Develop a workflow for producing low-cost 3D-printed transtibial prosthetic sockets in LMICs.	Use CAD and CAM to scan and 3D-print prosthetic sockets, with locally sourced foot and imported prosthetic parts.	Cost-effective production of transtibial prosthetic sockets, with a 3D-printed socket costing $20 and total material cost of the prosthesis amounting to approximately $100. Potential to sell a 3D-printed prosthesis for $170, benefiting individuals in LMICs.
4	Tang et al. (2023)	Optimize socket design to reduce local load on residual limb.	Divide residual limb into load-bearing regions and apply modifications to socket design based on carrying capacity.	Reduced contact interface pressures in specific regions, increased walking distance, and improved pressure distribution.
5	Dickinson et al. (2022)	Assess the repeatability of plaster casting and 3D scanning for prosthetic socket design.	Conduct a comparative reliability assessment in participants with transtibial amputation.	Deviation analysis shows high repeatability for plaster casting and varying reliability for different 3D scanners.
6	Vásquez and Pérez (2022)	Design a low-cost alignment device for lower transfemoral prostheses.	Implement conceptual design methodology, model the device in SolidWorks, and analyze its mechanical resistance using finite element analysis in ANSYS.	Carbon film material shows promising results for a 3D printed alignment device prototype, with potential for mass production and implementation in prosthetic centers worldwide.
7	Sturma et al. (2022)	Develop a structured rehabilitation protocol after TMR surgery.	Conduct a Delphi study involving European clinicians and researchers in upper limb prosthetic rehabilitation, utilizing a web-based survey to gather expert consensus on rehabilitation steps and their importance.	A 16-step rehabilitation protocol for TMR patients was established, emphasizing the need for multiprofessional teamwork and patient selection and education.
8	Ratnakar and Ramu (2021)	Utilize CT scan-based technology and finite element analysis to develop and evaluate 3D models of prosthetic sockets for lower-limb amputations.	Develop 3D models from CT images using image-processing software, modify them in CAD, and convert them to the STL format. Analyze the models in ANSYS under static and dynamic conditions to evaluate stress distribution. Prepare a 3D model with a 3D printer based on simulation results.	Enhanced evolution and prefabrication of prosthetic sockets, providing a development method for healthcare providers. Positive patient satisfaction with transtibial prosthetics made using 3D printers.
9	Gubbala and Inala (2021)	Design and develop a prosthetic socket for lower-limb amputation using 3D printing technology.	Utilize CT-based 3D models and perform finite element-based simulation and analysis. Extract models from CT images using image-processing software, modify them in CAD software, and convert them to STL format. Conduct static and dynamic analyses of the prosthetic stump and socket using ANSYS. Prepare a 3D model with a 3D printer based on simulation results.	Estimation of pressure distribution, evaluation of below-knee prosthesis function under static and dynamic conditions. Advancement in prosthetic socket evolution and prefabrication using finite element approach. Contribution to an overall prefabrication evaluation system for healthcare providers. Positive patient satisfaction with transtibial prosthetics made using 3D printers and simulation process.
10	Cabibihan et al. (2021)	Evaluate the functionality, durability, and cost of popular designs of body-powered, 3D printed prosthetic hands for long-term usage.	Selected representative sample of 3D printed prosthetic hands and assessed their suitability for grasping postures, durability, and cost. Tested the prosthetic hand's ability to perform 3 out of 33 grasping postures. Evaluated the material and cables used in the hand for their ability to withstand a 22 N normal grasping force. Analyzed the cost model to determine the production cost of a 3D printed hand.	The selected 3D printed prosthetic hand design demonstrated the ability to perform functional grasping postures for everyday objects. The material and cables used were able to withstand the required grasping force. The cost model indicated that a 3D printed hand could be produced at a low cost, as low as $19. These findings provide a baseline for the development of functional and affordable prosthetic hands, benefiting children with congenital missing limbs and war-wounded individuals.

Table 1: Continued.

No.	Authors	Objective	Methodology	Outcome
11	Siddiqui et al. (2023a)	Investigate the effect of different materials on the functionality of prosthetic running blades.	Conduct finite element modeling and numerical simulations to study the static behavior of a prosthetic running blade under various load conditions. Evaluate the performance based on total deformation, equivalent stress, and strain energy. Compare the use of titanium alloy (grade 5), carbon fiber, stainless steel (AISI 316), and aluminum alloy (2024 T4) as materials for running blades.	Titanium alloy exhibits high durability and tensile strength but is costly for manufacturing running blades. Aluminum alloy (2024 T4) blades experience more deformation compared to titanium and carbon fiber blades. Carbon fiber offers excellent mechanical properties and has outstanding tensile properties, making it suitable for creating running blades.

Abbreviations: CAD, computer-aided design; CAM, computer-aided manufacturing; LMICs, low- and middle-income countries; TMR, targeted muscle reinnervation.

and cushioning. Suspension systems, such as suction or vacuum-assisted systems, help secure the prosthesis to the residual limb. Adjustable interfaces allow for modifications to accommodate changes in residual limb volume or shape (Graebner and Current, 2007; Gerschutz et al., 2011, 2012; Steer et al., 2020; Gariboldi et al., 2023).

Prosthetic feet are designed to replicate the function of the natural foot and provide stability, shock absorption, and propulsion. Various foot components are available, including carbon fiber composites, energy-storing materials, and dynamic response feet. Carbon fiber composites offer lightweight and flexible properties, allowing for natural movement. Energy-storing feet absorb and release energy during gait, enhancing walking efficiency. Dynamic response feet adapt to varying terrains and provide improved stability and balance (Noroozi et al., 2013; Talla et al., 2021). Prosthetic knees are essential for providing stability, mobility, and control during walking and other activities. Knee components range from mechanical hinges to advanced microprocessor-controlled knees. Mechanical knees offer simplicity and reliability, providing basic stability and swing control. Hydraulic and pneumatic knees utilize fluid systems to adjust resistance and improve gait dynamics. Microprocessor-controlled knees use sensors and algorithms to adapt knee function in real time, allowing for more natural and dynamic movement (Lucchetti et al., 1998; Seymour et al., 2007; Simon et al., 2016). Power systems, such as microprocessor-controlled ankles and bionic systems, provide additional functionality and power for individuals with higher activity levels. Microprocessor-controlled ankles utilize sensors and advanced algorithms to adjust ankle movement and provide stability on an uneven terrain. Bionic systems use motorized components and sensors to replicate muscle function and offer powered propulsion, allowing users to walk with increased speed and efficiency (Seymour et al., 2007).

The progress of technology consistently expands the horizons of prosthetic limb design. Ongoing innovations encompass robotics, AI, sensor technology, and wearable devices. Robotics entails the incorporation of robotic elements within prosthetic limbs, enabling enhanced precision and movement control. AI enables the prosthesis to adapt and learn user preferences and gait patterns. Sensor technology provides real-time feedback on gait mechanics, weight distribution, and balance. Wearable devices, such as exoskeletons, assistive braces, and smart textiles, offer additional support and functionality (Caviedes et al., 2022; Gomez-Correa and Cruz-Ortiz, 2022). The use of advanced prosthetic components and technologies offers several advantages. Improved functionality, increased comfort, enhanced stability, and better cosmesis contribute to improved quality of life for prosthetic limb users. These advancements also enable individuals to engage in various activities and sports, promoting an active and fulfilling lifestyle. However, challenges exist, such as the high cost of advanced technologies, the need for specialized training, and the ongoing development and customization required to meet individual needs. Prosthetic components and technologies continue to advance, revolutionizing the field of lower-limb prosthetics. Socket components, foot designs, knee systems, power systems, and emerging advancements all contribute to improved

functionality, comfort, and user satisfaction. These advancements empower individuals with lower-limb amputations to lead active and fulfilling lives, bridging the gap between disability and ability. Continued research, development, and accessibility of these components and technologies are vital to further improve prosthetic limb design.

Patient-centric design considerations

In recent years, there has been a paradigm shift toward patient-centric design in the field of prosthetics. Recognizing the importance of meeting the unique needs and preferences of individual users, prosthetic design has evolved to prioritize the patient's comfort, functionality, and overall satisfaction. Here we explore the key considerations in patient-centric design, including customization, user involvement, comfort, functionality, aesthetics, and psychosocial factors. One of the fundamental aspects of patient-centric design is customization. Every individual has unique anatomical characteristics, functional requirements, and personal preferences. Customization allows prosthetists to tailor the design, fit, and functionality of prosthetic limbs to meet the specific needs of each patient. This includes considerations such as residual limb shape, size, and volume, as well as the alignment, components, and interface materials used in the prosthesis. Customization ensures a better fit, improved comfort, and enhanced overall functionality for the individual user (Beekman and Axtell, 1987; Reinbolt et al., 2005; Akarsu et al., 2013). Involving the patient in the design process is crucial for achieving patient-centric outcomes. By actively engaging individuals with amputations in decision-making, prosthetists can gain valuable insights into their unique needs, goals, and expectations. Patient involvement allows for open communication, shared decision-making, and a collaborative approach to design. Prosthetists can gain a better understanding of the user's lifestyle, preferences, and activities, enabling them to create prosthetic solutions that align with the user's specific requirements and optimize their functional outcomes.

Comfort is a paramount consideration in patient-centric design. Prosthetic limbs should be comfortable to wear for extended periods, minimizing discomfort, pressure points, and skin irritation. Factors such as socket design, padding, suspension systems, and interface materials play a crucial role in enhancing comfort. Customized socket design ensures a proper fit and weight distribution, reducing pressure on the residual limb. The use of cushioning materials, such as silicone liners or gel interfaces, improves comfort and reduces friction. Attention to detail in design and fabrication helps minimize discomfort and maximize overall satisfaction for the user. Patient-centric design places a strong emphasis on improving the functionality of prosthetic limbs. The aim is to enable users to perform a wide range of activities, including walking, running, climbing stairs, and engaging in sports or recreational activities. Prosthetic components, such as knees, feet, and power systems, are chosen based on the user's functional requirements and activity level. The alignment, joint mechanics, and range of motion should closely mimic the natural limb to facilitate more natural movement and gait patterns (Adouni et al., 2012). By focusing on functionality, patient-centric design empowers individuals to regain their independence and participate fully in daily activities. The visual appearance of prosthetic limbs is an essential consideration in patient-centric design (Hall and Dornan, 1990). Aesthetics can have a significant impact on an individual's self-esteem, body image, and social acceptance. Prosthetists work closely with patients to create prosthetic limbs that match their skin tone, incorporate realistic features, and align with their personal preferences. Advances in cosmetic covers, realistic silicone skin, and patterned socket designs allow for greater customization and aesthetic appeal. By considering the aesthetics, patient-centric design seeks to address not only the physical but also the psychological well-being of individuals with amputations. Patient-centric design acknowledges the psychosocial impact of prosthetic limbs on individuals' lives. It recognizes the importance of addressing psychological, emotional, and social aspects alongside physical considerations. Prosthetic limbs should enhance self-confidence, body image, and quality of life for the user. Factors such as ease of use, reliability, and social acceptance are crucial. Peer support, counseling, and psychological interventions are also integrated into patient-centricity.

DESIGN EVALUATION AND VALIDATION

The design of prosthetic limbs for individuals with lower-limb amputations requires a thorough evaluation and validation process to ensure their safety, effectiveness, and user satisfaction. We explore the key aspects of design evaluation and validation, including biomechanical testing, clinical trials, user feedback, and regulatory compliance. Biomechanical testing plays a vital role in evaluating the performance and functionality of prosthetic limb designs. Various biomechanical parameters, such as joint range of motion, force distribution, and gait analysis, are measured and analyzed (McFadyen and Winter, 1988; Schmalz et al., 2007; Bellmann et al., 2010). Biomechanical testing helps assess the alignment, joint mechanics, energy efficiency, and overall biomechanical behavior of the prosthetic limb. By comparing the performance of different designs, prosthetists can make informed decisions about the optimal design features and adjustments required for optimal user outcomes. Clinical trials are conducted to assess the safety and effectiveness of prosthetic limb designs in real-world settings. These trials involve a group of individuals with lower-limb amputations who use the prosthetic limb under monitored conditions. Clinical trials evaluate various aspects, including fit, function, comfort, durability, and user satisfaction. Objective measurements, such as walking speed, energy expenditure, and balance, are collected, along with subjective feedback from the participants. The data collected during clinical trials provide valuable insights into the performance of the prosthetic limb and help identify areas for improvement (Leach et al., 1999; Mohamed and Appling, 2019).

User feedback is a crucial component of design evaluation and validation. The experiences, preferences, and perspectives of individuals using prosthetic limbs offer valuable insights into the usability, comfort, and functionality of the design. Feedback can be obtained through surveys, interviews, focus groups, or user experience testing. Prosthetists actively seek user feedback at various stages of the design process, including initial fittings, follow-up appointments, and long-term use (Legro et al., 1998). User feedback helps identify issues, such as discomfort, fit problems, or functional limitations, which can then be addressed through design modifications or adjustments. Prosthetic limb designs must adhere to regulatory standards and requirements to ensure their safety and effectiveness. Regulatory bodies, such as the Food and Drug Administration in the United States or the European Medicines Agency in Europe, have specific guidelines and regulations for medical devices, including prosthetic limbs. These regulations cover aspects such as design specifications, manufacturing processes, labeling, and risk management. Compliance with regulatory requirements ensures that the prosthetic limb meets established safety and performance standards, providing reassurance to users and healthcare professionals. Design evaluation and validation are part of an iterative process in prosthetic limb development. Feedback from biomechanical testing, clinical trials, and user input is used to refine and improve the design. This iterative approach allows for continuous optimization and fine-tuning of the prosthetic limb's performance, comfort, and functionality. Prosthetists collaborate with engineers, researchers, and users to implement design modifications based on the evaluation results. The iterative design process ensures that prosthetic limb designs evolve and adapt to meet the diverse needs of individuals with lower-limb amputations.

The design evaluation and validation of amputated lower limbs are critical steps in ensuring the safety, effectiveness, and user satisfaction of prosthetic limb designs. Biomechanical testing, clinical trials, user feedback, and regulatory compliance all contribute to the evaluation process. By combining objective measurements with subjective user experiences, prosthetists can refine and optimize prosthetic limb designs to meet the unique needs and preferences of individuals with lower-limb amputations. The iterative design process ensures continuous improvement and innovation in prosthetic limb technology, ultimately enhancing the quality of life for prosthetic limb users (Gallagher and MacLachlan, 2002; Chen et al., 2006).

EMERGING TRENDS

The field of prosthetics is constantly evolving, driven by advancements in technology, research, and the evolving needs of individuals with limb loss. Several emerging trends and future directions are shaping the landscape of prosthetics, offering new possibilities and improved outcomes for prosthetic limb users as shown in Figure 3 (Peters et al., 2010; Gariboldi et al., 2022; Abubakre et al., 2023).

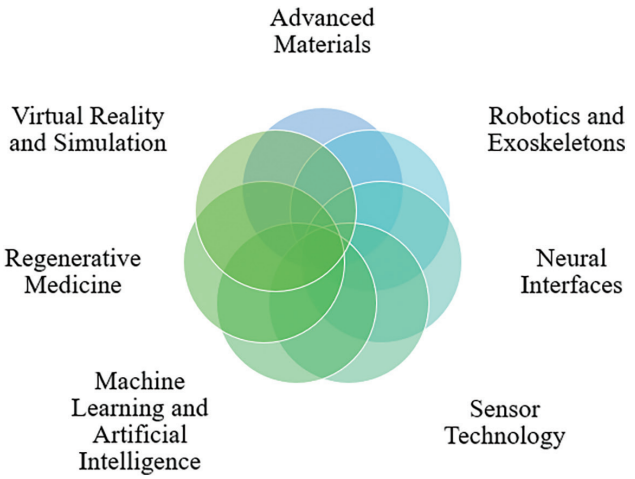

Figure 3: Emerging trends and future directions of prosthetic technologies.

- The use of advanced materials, such as carbon fiber composites, titanium alloys, and 3D-printed prosthetics, is gaining momentum. These materials offer improved strength, durability, and customization options. Carbon fiber composites provide lightweight and flexible properties, allowing for more natural movement. Titanium alloys offer strength and corrosion resistance, making them suitable for active individuals. 3D printing enables personalized and cost-effective prosthetic limb production, with the ability to create complex geometries and customized designs.
- Robotics and exoskeleton technologies are transforming the field of prosthetics. Robotic prosthetic limbs, controlled by sophisticated algorithms and sensors, offer enhanced functionality, dexterity, and natural movement. They enable users to perform intricate tasks and fine motor control. Exoskeletons provide external support and augmentation, assisting individuals with impaired mobility in walking and other activities. These technologies are continuously improving, with advancements in power sources, control systems, and sensor integration.
- Neural interfaces hold great promise for improving the integration between prosthetic limbs and the user's nervous system. Brain–computer interfaces (BCIs) and peripheral nerve interfaces (PNIs) allow for direct communication and control between the prosthetic limb and the user's neural signals. BCIs enable users to control their prosthetic limbs through their thoughts, while PNIs facilitate sensory feedback, allowing users to feel and perceive their prosthetic limb as an extension of their body. Research in neural interfaces aims to enhance the natural control and embodiment of prosthetic limbs.
- Sensors play a crucial role in prosthetic limb design, providing feedback on movement, force distribution, and balance. Advancements in sensor technology, such as inertial measurement units, force sensors, and pressure sensors, offer greater accuracy and reliability in capturing data. These sensors provide real-time feedback to users and clinicians, enabling adjustments and optimization of prosthetic limb function. Sensor technology also contributes to

the development of intelligent prosthetics that can adapt to the user's movements and the environment.

- Machine learning and AI have the potential to revolutionize prosthetic limb design and functionality. These technologies can analyze vast amounts of data, learn from user patterns, and adapt prosthetic limb control algorithms accordingly. AI algorithms can optimize prosthetic limb performance, improve energy efficiency, and enhance user experience. Machine learning and AI also enable personalized prosthetic limb solutions based on individual user characteristics and preferences.
- Regenerative medicine holds promise for the development of biological solutions in prosthetics. Tissue engineering, stem cell research, and regenerative therapies aim to promote tissue regeneration and enhance the integration of prosthetic limbs with the user's body. The development of biocompatible materials, scaffolds, and bioactive substances can stimulate tissue growth and repair, leading to improved prosthetic limb integration and long-term outcomes.
- Virtual reality (VR) and simulation technologies offer valuable tools for prosthetic limb design and training. VR simulations provide realistic and immersive environments for users to practice and adapt to their prosthetic limbs. They also enable prosthetists to assess the fit and function of prosthetic limbs virtually before physical fabrication. VR and simulation technologies aid in improving user training, prosthetic limb adjustments, and overall user experience.

FUTURE DIRECTIONS AND OPPORTUNITIES

As the field of prosthetics continues to advance, several challenges and opportunities lie ahead. Addressing these challenges and leveraging the opportunities will shape the future of prosthetic limb design and improve outcomes for individuals with limb loss. One of the key challenges is making prosthetic limbs more affordable and accessible to a wider population. The cost of advanced prosthetic technologies can be prohibitive, limiting access for many individuals. Future efforts should focus on developing cost-effective solutions without compromising on quality and functionality. This includes exploring new manufacturing processes, materials, and distribution models to increase affordability and availability. Ensuring the long-term performance and durability of prosthetic limbs is crucial. Prosthetic components and materials should withstand the demands of daily use and maintain functionality over time. Enhancements in materials science, durability testing, and quality control processes can address this challenge and extend the lifespan of prosthetic limbs.

Improving the overall user experience and satisfaction with prosthetic limbs is an ongoing goal. This includes enhancing comfort, fit, and aesthetics, as well as minimizing issues such as socket discomfort and skin irritation. User-centered design approaches, involving users in the design process, and integrating user feedback are essential for meeting individual needs and preferences. Achieving seamless neural integration and providing sensory feedback remain significant challenges. Advancements in neural interfaces and sensory feedback systems are crucial for creating prosthetic limbs that closely mimic natural limb function and provide a sense of embodiment for users. Further research and development in this area will open new opportunities for enhancing motor control and sensory perception. Effective rehabilitation and training programs are essential for maximizing the benefits of prosthetic limb use. Future efforts should focus on developing innovative training methods, VR simulations, and personalized rehabilitation programs to optimize user adaptation, functional outcomes, and long-term usage of prosthetic limbs.

CONCLUSION

This review has examined various aspects, including prosthetic limb designs, biomechanical factors, socket design principles, emerging technologies, user-centric design, and future directions. The findings highlighted the importance of optimizing prosthetic limb design to enhance user satisfaction, mobility, and overall quality of life. The evaluation of existing prosthetic limb designs revealed the need for continuous improvement and innovation. Different designs were assessed based on their performance, functionality, and user satisfaction. This evaluation helped identify the strengths and weaknesses of current designs and provided insights for further enhancements. Biomechanical factors emerged as crucial considerations in amputated lower-limb design. Gait analysis, joint range of motion, force distribution, and energy efficiency were examined to understand their impact on prosthetic limb performance. These factors play a significant role in ensuring a natural gait pattern, stability, and energy conservation for users. Socket design principles were found to be essential for achieving a comfortable and well-fitting prosthetic limb. This review has emphasized the significance of individualized socket design to enhance user comfort, minimize pressure points, and distribute loads appropriately. A well-designed socket is crucial for optimal function and user satisfaction. Emerging technologies in prosthetic limb design were explored as potential avenues for improvement. Advanced materials, such as carbon fiber composites and 3D-printed prosthetics, offered benefits like lightweight construction and customizable designs. Robotics, exoskeletons, neural interfaces, and sensor technology showed promise in enhancing functionality, control, and sensory feedback in prosthetic limbs. This review has highlighted the importance of a user-centric approach in prosthetic limb design. User feedback, preferences, and experiences were considered integral to the design process. Involving users in decision-making and design iterations led to better outcomes and higher satisfaction rates. Ensuring a patient-centric design approach is crucial for meeting the diverse needs and preferences of individuals with amputated lower limbs. Several challenges and future directions were identified. Affordability and accessibility of prosthetic limbs emerged as significant concerns, necessitating the

development of cost-effective solutions. Long-term performance and durability were emphasized, highlighting the need for robust materials and quality control processes. The integration of neural interfaces and sensory feedback posed both opportunities and challenges for achieving more natural limb control and sensation. In conclusion, this review has provided insights into the design of amputated lower limbs, emphasizing the importance of optimizing design principles, considering biomechanical factors, adopting emerging technologies, and incorporating user feedback. Future directions include addressing challenges related to affordability, long-term performance, and neural integration, while leveraging opportunities for advancements in materials, technology, and user-centered design. By addressing these key findings, the field of prosthetic limb design can continue to improve the quality of life for individuals with amputated lower limbs.

ACKNOWLEDGMENTS

The authors extend their appreciation to the King Salman Center for Disability Research for funding this work through Research Group no KSRG-2022-049.

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