COMPOSITE MATERIALS FOR LIMB PROSTHETICS LINERS

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ABSTRACT. Managing the soft tissues of residual limbs in individuals with lower limb amputations presents a significant challenge. Unlike the plantar tissues of an intact foot, the soft tissues of the residual limb are unaccustomed to mechanical loading. Consequently, the loads transferred to the residual limb by the prosthetic socket can frequently lead to the development of ulcers and other skin issues including infection. This review aimed to comprehensively analyze current research about perspective materials used for prosthetic liners. The most promising materials used for liners includes composite materials, leather and combining phase change materials. Optimizing the material composition of prosthetic liners requires a comprehensive approach that considers both mechanical and surface properties.
KEY WORDS: prosthetic liners, composite materials, limb

MATERIALE COMPOZITE PENTRU CĂPTUȘELI DE PROTEZE PENTRU MEMBRELE INFERIOARE

REZUMAT. Gestionarea țesuturilor moi ale membrelor reziduale la persoanele cu amputații ale membrelor inferioare prezintă o provocare semnificativă. Spre deosebire de țesuturile plantare ale unui picior intact, țesuturile moi ale membrului rezidual nu sunt obișnuite cu sarcina mecanică. În consecință, sarcinile transferate de manșonul protezei către membrul rezidual pot duce frecvent la dezvoltarea de ulcere și alte probleme ale pielii, inclusiv infecții. Această trecere în revistă și-a propus să analizeze într-o manieră cuprinzătoare cercetările actuale despre materialele de perspectivă utilizate pentru căptușelile protetice. Cele mai promițătoare materiale utilizate pentru căptușeli includ materiale compozite, piele și materiale combinate cu schimbare de fază. Optimizarea compoziției materialelor căptușelilor protetice necesită o abordare cuprinzătoare care să ia în considerare atât proprietățile mecanice, cât și cele de suprafață.
CUVINTE CHEIE: căptușeli proteze, materiale compozite, membru inferior

MATÉRIAUX COMPOSITES POUR LES REVÊTEMENTS PROTHÉTIQUES DES MEMBRES INFÉRIEURS

RÉSUMÉ. La gestion des tissus mous des membres résiduels chez les personnes amputées des membres inférieurs présente un défi important. Contrairement aux tissus plantaires d'un pied intact, les tissus mous du membre résiduel ne sont pas habitués aux charges mécaniques. Par conséquent, les charges transférées au membre résiduel par le manchon de prothèse peuvent fréquemment conduire au développement d'ulcères et d'autres problèmes cutanés, y compris l'infection. Cette revue visait à analyser de manière approfondie les recherches actuelles sur les matériaux potentiels utilisés pour les revêtements prothétiques. Les matériaux les plus prometteurs utilisés pour les revêtements comprennent les matériaux composites, le cuir et la combinaison de matériaux à changement de phase. L'optimisation de la composition des matériaux des revêtements prothétiques nécessite une approche globale qui prend en compte à la fois les propriétés mécaniques et de surface.
MOTS CLÉS : revêtements prothétiques, matériaux composites, membre inférieur

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INTRODUCTION

Prosthetic limbs have become an integral part of modern healthcare, providing individuals who have experienced limb loss with the opportunity to regain mobility and improve their quality of life. Traditionally, these prosthetic limbs have been constructed using a variety of materials, including metal, plastic, and rubber. However, the development of composite materials has opened up new possibilities for the design and fabrication of prosthetic limbs, particularly in the area of limb prosthetic liners. Prosthetic liners play a crucial role in the comfort and functionality of prosthetic devices, serving as the interface between the residual limb and the prosthetic socket. Their significance is further accentuated by the global shortage of trained prosthetists, which highlights the need for well-designed and easily adjustable prosthetic components.

Recent advancements in materials and manufacturing techniques, such as 3D printing, have enabled the fabrication of customized prosthetic liners that can better accommodate individual anatomical variations and user preferences [1]. However, the functionality of these 3D-printed liners is still a concern, and more robust research is required to fully understand their impact on end-user outcomes [2]. Materials like silicone and thermoplastics have been widely used in prosthetic liners, offering improved comfort and reduced skin irritation [3].

Incorporating innovative technologies, such as osseointegration and implanted interfaces, into prosthetic liners has the potential to enhance prosthetic function and user acceptance, ultimately improving the quality of life for individuals with limb amputations [3].

Composite materials, which are made up of two or more constituent materials with different physical or chemical properties, offer a number of advantages over traditional materials. These materials can be engineered to have high strength-to-weight ratios, which is particularly important for the design of prosthetic limbs that must be both durable and lightweight. Additionally, the ability to manipulate the properties of individual materials within a composite can allow for the creation of complex designs that take advantage of the unique properties of each component.

Skin nanomaterials are mainly composite materials, generally containing metal- and carbon-based materials. Ionic gels, ionic liquids, hydrogels, and elastomers have become the focus of attention due to the sensitivity, multimodal, and memory properties of their materials [4].

The prosthetic socket, which interfaces directly with the residual limb, plays a vital role in user comfort and skin health. An ideal socket material should provide a snug fit, minimize skin irritation, and manage perspiration effectively. Sakthivel Sankaran *et al.* [5] highlight the importance of reducing allergic reactions, friction, and ensuring proper pressure distribution. Recent advancements in socket materials have yielded promising results in creating a more comfortable and skin-friendly environment for users.

MATERIALS AND METHODS

Over 60 literature sources from Google Scholar and PubMed databases were checked. The search terms included combinations of «lower limb prosthetic liners», «prosthetic liners», «liners materials», «prosthetic materials». The search was limited to papers published in English between 2019 and 2024 except searching for clinical cases (1999-2024). In order to select relevant publications, the following search strategies were utilized:

1) Phrase searching – keywords were enclosed in quotation marks to search for exact matches;
2) Use of Boolean operators AND, OR, and NOT to combine keywords and refine the search;
3) Use of the wildcard character (*) to substitute for one or more unknown characters within a keyword.

RESULTS

Research and clinical trials have consistently demonstrated the significant impact of prosthetic liner design and material properties on user comfort and functional outcomes. Studies have investigated the relationship between liner elasticity, conductivity, and coefficient of friction, finding that these factors can influence residual limb comfort and satisfaction. For example, Lee *et al*. [6] found that liners with higher elasticity and lower conductivity were associated with improved user comfort. Additionally, clinical trials have compared various liner types, such as silicone vs. polyethylene foam, and observed benefits like reduced pistoning and improved suspension with specific designs. MacLean *et al*. [7] demonstrated that liners with a higher coefficient of friction can improve suspension and reduce in-socket movement. Furthermore, research into temperature regulation within the prosthetic socket has shown promising results for liners containing phase-change materials. Ferris *et al*. [8] found that liners with phase-change materials can help regulate temperature and reduce discomfort for amputees.

Overall, these findings contribute to the ongoing development of prosthetic liners that are more comfortable, effective, and tailored to individual user needs. Future research is needed to further explore the long-term benefits of specific liner designs and their impact on functional outcomes for prosthesis users.

The principle of liner evaluation is to evaluate whether amputees have a positive experience after donning the liner [9].

Choice of materials employed in the construction of prosthetic liners is of paramount importance within the realm of prosthetic design and engineering, as these components serve as the critical interface between the user's residual limb and the prosthetic liners.

Material Types and Properties

Liners can be made of elastomeric materials (gels or silicones) or of open/closed cell foam materials. The selection of appropriate materials for prosthetic liners is crucial to ensure optimal comfort, function, and durability for amputees. Important material key properties must include elasticity, breathability, moisture management, biocompatibility and overall comfort as well as durability. The last one is also considered for economic reasons.

Table 1: Comparison of the most popular material types for lower limb prosthetic liners

Key Properties of Prosthetic Liner Materials							
Material	Elasticity	Breathability	Moisture Management	Durability	Comfort	Biocompatibility	References
Silicone	High	Moderate	Good	High	Excellent	Generally good	[10]
Polyethylene Foam	Moderate	High	Good	Moderate	Good	Generally good	[11, 12]
Gel liners	High	Moderate	Excellent	Moderate	Excellent	Generally good	[13]
Aerogels	High	Excellent	Excellent	Moderate	Excellent	Generally good	[14]
Hydrogels	High	Excellent	Excellent	Moderate	Excellent	Generally good	[15]
Hybrid Liners	Varies	Varies	Varies	Varies	Varies	Varies	[16]
PCM liners	Moderate	Good	Varies	Generally good	Excellent	Generally good	[17]

Recent research has further emphasized the importance of these material properties. For example, Ali *et al*. [10] investigated the mechanical properties of different prosthetic liner materials and found that silicone liners generally exhibited higher elasticity and shear strength, which can contribute to improved comfort and suspension. These liners are made from a soft, rubbery material that can conform to the shape of the residual limb, providing a custom fit and reducing the risk of skin irritation. Silicone liners are often used in combination with other materials, such as gel or fabric, to enhance their properties and performance. More recent studies have also explored the use of innovative materials, such as hydrogels and aerogels, for prosthetic liners. These liners contain a gel-like material that can provide cushioning and pressure relief, particularly for individuals with sensitive skin or pressure sores. Gel liners can be used alone or in combination with other materials, such as silicone or fabric. These materials offer potential benefits in terms of comfort, moisture management, and pressure distribution.

For example, Cagle *et al*. [18] investigated the properties of hydrogel liners and found that they have good breathability and load-bearing capabilities. Zhang *et al*. [19] explored the use of aerogel-based liners for improved temperature regulation and moisture management.

Based on the general description both types of gel liners – aero-based and hydrogels – could be a good choice. In fact, aero-gel and hydrogel liners are both innovative materials used in prosthetic applications, but they offer distinct properties and benefits (Table 2).

Table 2: The distinct properties of gel liners types

Feature	Aero-Gel Liners	Hydrogel Liners
Structure	Highly porous, lightweight material	Gel-like, hydrophilic material
Moisture Management	Excellent, due to high porosity	Excellent, due to hydrophilic nature
Temperature Regulation	Can incorporate phase-change materials	Can help maintain a cool environment
Pressure Distribution	Even distribution	Cushioning and pressure relief
Durability	Moderate	Moderate
Comfort	Generally comfortable	Generally comfortable

Aerogel-based Materials

Aerogel-based materials first were developed as thermal insulation in lightweight protective clothing and footwear for extreme temperatures, shelters for military personnel in the field, military and aerospace vehicles, protection for electronic equipment, tank engine, etc. [20]. Aero-gels excel hydrogels in breathability and temperature regulation, while hydrogels provide excellent moisture management and cushioning. The optimal choice for a specific amputee may depend on individual needs and preferences. The study by Lee *et al*. [21] highlights the potential of silica aerogels for prosthetic liners. These ultralight materials boast excellent breathability and moisture management, addressing common issues associated with traditional liners. Additionally, their hydrophobic nature could potentially reduce perspiration build-up within the socket, promoting skin health.

Phase Change Materials (PCMs)

Phase change materials (PCMs) are a class of thermo-responsive materials that can be utilized to trigger a phase transition which gives them thermal energy storage capacity [17]. When incorporated into prosthetic liners, PCMs can help regulate temperature and improve comfort for amputees. Maintaining a consistent temperature can help prevent skin irritation, blistering, and other skin problems associated with prosthetic use. This is especially important for individuals with sensitive skin or underlying medical conditions. A comfortable and well-regulated temperature can improve the overall function and performance of the prosthetic limb. By reducing discomfort and distractions, PCMs can help amputees engage in more physical activities and maintain a higher quality of life. However, PCMs could not function by itself, they should be encapsulated within a suitable material to prevent leakage and ensure proper functioning.

Composite Materials: Strength Meets Lightweight Design

Composite materials, which are formed by combining two or more different materials with distinct properties, have gained increasing attention in the field of prosthetic liner development. These materials offer the potential to enhance the performance and comfort of prosthetic liners by combining the advantages of various components. For example, composite liners incorporating carbon fiber or Kevlar can provide increased strength and durability, while other components can contribute to factors such as elasticity, breathability, and moisture management.

Recent advancements in materials have significantly improved the functionality, comfort, and affordability of these devices. Traditional metallic prosthetics, while strong, can be bulky and heavy. Composite materials, particularly carbon fiber-reinforced polymers, offer a compelling alternative. These materials boast an excellent strength-to-weight ratio and biocompatibility**,** making them ideal for prosthetic applications. Researchers like Timoshkov *et al*. [22] have explored the use of various composite materials like carbon fiber, Kevlar, and glass fiber, each with unique mechanical properties that cater to specific prosthetic limb requirements. Results showed that formulations grouped into three categories based on mechanical strengths: the weakest were laminates with fibers of perlon or nyglass stockinette, spectralon, nylon, and cotton, ranging between 18 and 42 megapascals (MPa); the midrange was fiberglass, ranging between 67 and 109 MPa; the highest strengths were found in carbon fiber laminates, ranging between 236 and 249 MPa.

Perlon, a type of nylon, has historically been a common material used in the construction of prosthetic sockets. Known for their durability and formability, perlon sockets have been a staple in the prosthetics industry for many years. Due to the limitations of perlon and advancements in materials science, the prosthetics industry has seen a shift towards more advanced materials. Carbon fiber-reinforced polymer (CFRP) composites are increasingly used in prosthetic applications due to their excellent strength-to-weight ratio and biocompatibility [22, 23]. These materials offer advantages over traditional metallic components, particularly in addressing stress shielding issues in joint replacements [23]. For prosthetic sockets, CFRP composites demonstrate superior mechanical properties compared to other materials. A study found that carbon fiber layers exhibited higher flexural strength, shear stress resistance, and impact strength than jute or glass fibers [24]. Another investigation revealed that carbon fiber sockets outperformed perlon sockets in tensile strength and fatigue resistance, with carbon fiber sockets showing a safety factor of 1.35 compared to 0.22 for perlon [25].

One innovative approach to the use of composite materials in prosthetic limb design involves the use of additive manufacturing-based molding techniques. These techniques allow for the fabrication of prosthetic components, such as fingers, using the same materials and techniques employed in high-grade aerospace components. This method involves the creation of a three-layer composite structure, with a carbon-fiber structural shell, a lightweight foam filler, and a soft urethane grip surface. In the study conducted by Bhatt *et al*. [26], this approach was shown to be a viable alternative to current methods of prosthetic hand production. Other composite materials are also being explored for use in prosthetic limb liners. Among these are not only carbon fiber composites, but also advanced materials such as graphene and carbon nanotubes. Graphene and carbon nanotubes have been shown to offer superior mechanical properties and relatively low densities, making them attractive options for the development of lightweight, high-performance prosthetic limbs. Overall, the use of composite materials in the design and fabrication of prosthetic limb liners represents a promising area of research and development.

Polymeric Composites

The design of prosthetic devices has become increasingly sophisticated in recent years, driven by the imperative to improve the overall quality of life for individuals with limb differences. Polymeric composites have emerged as a promising class of materials for the fabrication of prosthetic liners, offering a unique combination of strength, flexibility, and biocompatibility. Traditionally, prosthetic liners have been constructed from a variety of synthetic polymers, such as polyethylene and polyurethane. However, the mechanical properties of these materials have often been limited, leading to issues with durability and comfort. The incorporation of reinforcing fibers, such as carbon or glass, into polymeric matrices has shown great potential in enhancing the mechanical properties of prosthetic liners, while maintaining the desired flexibility and biocompatibility.

One of the key advantages of using fiber-reinforced composite materials for prosthetic liners is the ability to tailor the mechanical properties to the specific needs of the user. By varying the type, orientation, and volume fraction of the reinforcing fibers, as well as the matrix material, the stiffness, strength, and anisotropic behavior of the composite can be customized to provide a precise fit and optimal performance [27]. Furthermore, the use of additive manufacturing techniques, such as 3D printing, has enabled the fabrication of complex, patient-specific prosthetic liners with intricate internal geometries and surface textures [28]. Polymer composites have revolutionized the prosthetics industry, offering a range of benefits over traditional materials like perlon. These materials are engineered to provide optimal performance, comfort, and durability for prosthetic liner users.

Silicon-based materials have long been utilized in the realm of prosthetic liners, providing a versatile and dynamic solution for individuals seeking comfort, durability, and enhanced functionality in their prosthetic devices. The inherent properties of silicon, including its biocompatibility, flexibility, and resistance to wear and tear, have made it a prime choice for medical applications, particularly in the context of prosthetic limb design and fabrication. Silicone has become a staple in the production of prosthetic liners due to its ability to conform to the unique contours of the residual limb, distributing pressure evenly and minimizing the risk of skin irritation or breakdown [9].

Natural Fiber-Reinforced Composites (NFRCs)

The examples of NFRCs for prosthetic liners [29] demonstrate the continued efforts to explore sustainable and environmentally-friendly materials for this application. Such composites include natural fibers, such as *Boehmeria nivea* (ramie), embedded within an epoxy matrix, offering a potentially more durable and customizable prosthetic liner solution that leverages the inherent properties of naturally-derived materials. The case study of *Boehmeria nivea* natural fabric reinforced epoxy matrix composite [30] further demonstrates the feasibility of incorporating natural materials into advanced prosthetic designs while maintaining desirable mechanical properties. In this study, the authors report on the successful fabrication and testing of a hybrid laminate reinforced with natural fibers, indicating the potential for natural fiber-based materials to be utilized in prosthetic applications. The other case study on the fabrication and testing of hybrid laminates reinforced with natural fibers [31] also underscores the growing interest and viability of natural materials in advanced composite applications.

Natural Leather for Prosthetic Liners

While conventional synthetic polymers and advanced materials have been the predominant focus of research and development in the field of prosthetic technology, the ancient origins of prosthetic medicine suggest that natural materials, such as leather, have played a significant role throughout the evolution of prosthetic solutions [32]. Historically, the utilization of natural leather has been explored as a potential solution for addressing the unique challenges associated with prosthetic suspension and comfort in veterinary patients [33]. The inherent properties of leather, including its conformability, breathability, and ability to mold to the contours of the residual limb, make it a potentially viable option for improving the overall comfort and suspension of prosthetic liners, particularly in populations where the use of vacuum or suction-based systems may be limited, such as in veterinary patients [33].

However, the adoption of leather as a prosthetic liner material is not without its own set of challenges. Leather, like other natural materials, is subject to degradation and wear over time, potentially compromising the long-term durability and performance of the prosthetic device. Furthermore, the availability and cost-effectiveness of leather as a prosthetic material may vary significantly depending on geographic location, market conditions, and the specific requirements of the prosthetic application, potentially presenting logistical barriers to its widespread implementation in liners manufacturing. Nowadays, perspectives of leather use in prosthetic liners have shifted, with the development of advanced synthetic materials and manufacturing techniques that can potentially offer improved performance, customization, and cost-effectiveness compared to traditional leather-based solutions.

Ultimately, the selection of the most appropriate prosthetic liner material, whether it be natural leather or a synthetic alternative, must be carefully evaluated based on the specific needs and requirements of the patient, the intended use case, and the available resources and expertise within the prosthetic design and fabrication ecosystem [34].

Natural Plant-Derived Fibers for Prosthetic Liners

Natural plant-derived fibers for prosthetic liners have been investigated as a potential solution to address the limitations of traditional leather, as they offer a more sustainable and potentially more customizable approach to prosthetic liner design. Natural fibers, derived from plants or animal tissues, offer several potential advantages for prosthetic liner applications. Natural fiber-reinforced composites show promise for lower-limb prosthetic designs. Among these fibers a number of materials are used, including flax (linen), hemp, bamboo, sisal, cotton and jute [34]. The continued exploration of natural and synthetic materials, as well as the ongoing advancements in material science and prosthetic manufacturing techniques, will undoubtedly shape the future of prosthetic liner design and the utilization of natural leather within this critical domain [30]. Studies have explored materials like rattan fiber and alfa fiber [35] for prosthetic sockets, demonstrating good mechanical properties and potential for affordability. These composites offer benefits such as sustainability, comfort, and safety in prosthetic applications. Research has also focused on evaluating the mechanical properties of natural fiber-reinforced prosthetic sockets [36] and incorporating computational biomechanical models to assess prosthetic effectiveness [37]. While synthetic fiber-reinforced composites offer superior strength and durability, they can be expensive, stiff, and uncomfortable. Natural fiber-reinforced composites**,** such as those made from Ramie, kenaf, pineapple, and banana fibers, present a promising alternative. These materials offer a low-cost, comfortable, and sustainable option for prosthetic sockets, as evidenced by research by Endalkachew Gashawtena *et al*. [38]. However, natural fibers may not possess the same strength and durability as synthetic counterparts, requiring careful material selection and composite development [37].

Smart/Personalized Prosthetic Liners

Despite the existence of literature reporting the experience of individuals with amputation with different liners, confounding factors, methodological rigour and issues with validity and reliability of outcomes preclude meaningful clinical decision-making. The findings of *ex vivo* tests need to be confirmed by human subject experiments to establish liner prescription clinical guidelines [39]. Prosthetic liners are currently designed to fit individuals generically rather than specifically. A more adaptive, «smart» liner that could conform to the residual limb more precisely might enhance skin health at the stump-socket interface and improve the accuracy of topological tracking [40]. This diagnostic tool could track changes throughout the day, considering factors like activity level, body position, and the forces exerted on the limb by the prosthetic socket. To maintain the comfort and functionality of the liner, the embedded sensors should possess similar mechanical properties as the liner itself, being flexible, pliable, and thin. This would ensure that the sensors do not interfere with the liner's performance or cause discomfort [41].

Personalized prosthetic liners require innovative design and manufacturing methods to seamlessly integrate sensor technologies. This integration will facilitate biomechanical and physiological characterization of the prosthesis-limb interface, enabling objective comparisons and assessments of socket system quality. For example, Brothers *et al*. [42] created a transtibial impact-reducing liner combined with integrated haptic feedback to enhance comfort and restore proprioceptive senses. The impact-reducing liner includes impact reduction over pressure-intolerant regions, impact redistribution over pressure-tolerant regions, and a variable volume system that dynamically adjusts to changes in the residual limb's volume throughout the day. The haptic feedback system employs force-sensitive resistors located on various regions of the prosthetic foot. These sensors transmit via Bluetooth to vibrational nodes embedded in the liner to provide the user with real-time feedback. Prototype testing has shown positive results in reducing pressure similar to the field's gold standard.

While 3D printing offers potential benefits, its current limitations for soft materials, including high costs, lengthy manufacturing times, and suboptimal material properties, hinder its widespread adoption in prosthetic liner production. Cryogenic Computer Numeric Control (CNC) machining presents a promising alternative for rapidly manufacturing soft polymer products [43]. This technique involves freezing elastomeric material below its glass transition temperature (Tg) and then machining it using traditional CNC tools. This approach offers a fast and cost-effective solution for creating prototypes with high accuracy and conformity. Thus, in the study [43] the liner machining process took 4 hours approximately with use of CNC tools and resulted in better thermal properties with respect to the current liner solution.

CONCLUSIONS

Optimizing the material composition of prosthetic liners requires a comprehensive approach that considers both mechanical and surface properties. Composite materials hold great promise for the development of advanced prosthetic limb liners with improved performance, antimicrobial properties, and biocompatibility. The integration of materials such as graphene, carbon nanotubes, and silver nanoparticles into composite structures offers opportunities to create highly customized and functional prosthetic liners that can enhance the comfort, mobility, and overall quality of life for individuals with limb loss or amputation. Careful selection and design of prosthetic liners are crucial in ensuring the comfort, functionality, and long-term success of prosthetic devices, making them an essential component of modern prosthetic care.

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