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Shape-Memory Polymer Systems in Custom-Fit Prosthetic and Orthotic Design

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Abstract

SMP systems have now become important materials in constructions of custom-made prosthetic and orthotic devices. They can back and forth change shape based on heat, humidity or light. The capability allows physicians and patients to shape the devices quickly and change them in real time which is not possible with ordinary plastics. Antinomy, comfort is vital and distribution of forces changes continuously in the rehabilitation engineering. The solution to these challenges is the use of SMP-based devices that are characterized by extreme personalization, easily adjustable, and enhanced functionality. They provided every user with a really personalized fit. This has been enhanced by recent advances in polymer chemistry, 3D printing, computer modeling, and integration of sensors to expand the capabilities of SMPs. They are now harder, more adjustable in mechanics and more managed using computerized drawing instruments. Such advantages have propelled them to entertainment items in labs to clinician-confidence products. New SMP compounds incorporate fibers, nanoparticles and conductive networks. It has the outcome of enhanced actuation accuracy, increased thermal capacity, and smooth integration with feedback systems applied in contemporary rehab applications. All this progress notwithstanding, there are still obstacles on the way to universal clinical implementation. It must be proven in the case of long-term durability, fatigue-resistance, complete biocompatibility, standardization of testing protocols. The partnership between material scientists, physicians, bio-mechanists, and specialists in digital fabrication is the key to unlocking the potential of SMP and providing lightweight, responsive and constantly adaptable prosthetics and orthotics. Finally, SMP-facilitated customization is an indication of a significant change to patient-friendly, more efficient, and patient-centered care.

Keywords: Shape-memory polymers, smart materials, prosthetics, orthotics, custom-fit devices, thermal actuation, 4D printing, adaptive rehabilitation, polymer composites, personalized medicine

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INTRODUCTION

Shape-memory polymers (SMP) are intelligent materials, which can be altered in shape under the influence of heat, radiation, pH or water. Such a shape-memory effect allows one to deform the material temporarily and lock it into place and then restore it to its initial form. It is due to this fact that SMPs provide improved suitability, simplified adjustability and adaptive forms of prosthetic and orthotic supplies. The SMPs will enable the device to adjust to individual variations of the anatomy, meaning that the balance of pressure in rehabilitation cases will be adjusted and optimize comfort and functionality in patient-centered unbiased data-driven rehabilitation programs [1].

Conventionally, prosthetics sockets and orthotic braces are available and are usually plaster molded or laminated in rigid polymer. They are tedious, time consuming, and painful at times when the body of a patient alters because of swelling, muscle erosion or development. SMPs can be remodeled, thus the same device can be reconfigured with ease, without making it. SMPs in personalized medical devices have become more convenient with the modern design processes that have been facilitated by 3-D scanning, simulation and additive manufacturing. Consequently, SMP systems are being necessitated to make light and adaptive prostheses and orthoses which are simple to process and prompt acting.

This review examines the recent SMP materials, their operation, manufacture and their capability in custom-fitting prosthetics and orthotics. It, also, addresses the latest advances in SMP composites, 4-D printing, multi material integration and digital adaptive systems that can facilitate continuous customization and improved rehabilitation results.

FUNDAMENTAL CONCEPTS AND MECHANISMS OF SMP SYSTEMS

Shape-Memory Effect

SMA Shape-memory effect (SME) is an effect in polymers on thermomechanical programming. An SMP is heated to a higher temperature than the distance to transition (T trans) and made into a temporary shape leveraged by the cooling of the temporary shape. Upon re-warming the material, it goes back to its permanent arrangement. Depending on the morphology of the polymer the transition temperature may be the marrow points temperature (T g) or the melting point (T m) [2].

The SME consists of three integral components:

- Switching segments, which respond to thermal or chemical stimuli.
- Netpoints, which define the permanent structure.
- External trigger, which activates the recovery.

This architecture allows for high deformation ratios, controlled stiffness changes, and rapid or delayed recovery profiles, making SMPs ideal for anatomically conforming devices.

Stimuli-Responsive Behavior

The most widespread is thermal activation and newer SMP systems utilize various stimuli. They can be moist and heated by light through built-in nanoparticles fetched, change form with pH or behave as electrically when conductive fillers are incorporated [3]. Such multi-stimulus SMPs are particularly applicable in adjustable orthoses that require localized heating which is gentle and without external devices that are bulky.

Mechanical Properties and Functional Tunability

In load bearing prosthetic sockets and orthotic braces, mechanical performance is important. SMPs tend to be less stiff than metallic or high-performance thermoplastics but modulus can be optimized by making copolymer, using crosslinks, and fillers. Recent advancements of SMP composites offer tremendous enhancement in terms of fatigue resistance properties, micro-crack management, and cyclic loading properties used in lower-limb prostheses [4].

SHAPE-MEMORY POLYMERS FOR PERSONALIZED FIT

Anatomical Customization

Custom sockets are quite compatible with SMPs since they can shape themselves to fit the structures of each limb. In the process of fitting, SMP sheets or printed components are placed into the residual limb and are heated to shape under equal pressure, which reduces the skin irritation. They are also flexible and allow changing to the compliance of the tissue, which is more comfortable than rigid sockets [5].

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Dynamic Adaptation to Anatomical Changes

One of the primary problems with prosthetics is volume changes of limbs, which usually require the frequent replacement of sockets. The SMP sockets can be easily remodeled back to an appropriate fit thus avoiding replacement sockets. Pediatric orthoses may be remodeled along with the growing of children, reducing costs and prolonging their usefulness of the devices [6].

Enhanced Comfort and Pressure Management

SMP foams and elastomers have variable compression – local flexibility or stiffness – can be adjusted. This assists in preventing pressure ulcers, distributions of force become more uniform, as well as enhancing the skin device interface particularly in braces which hold the parts of the body in immobility [7].

MATERIAL AND MATERIAL DEVELOPMENT

Thermoset SMPs

Thermoset SMPs, including epoxy based and polyurethane based systems, provide high shrinkage resistance and stress level, and stability at a long period. They are often used in high strength operations that involve repetitive reshaping or thermoforming. Thermosets are, however, less recyclable and should be handled with care [6].

Thermoplastic SMPs

Popular SMPs in thermoplastic materials are polyurethane, PLA based PLAs and polyether-based block copolymer, which are used in prosthetic and orthotic applications. They are reprocessable, bio-compatible and simple to 3D print. The activation temperature is adjustable to be below 65°C and, as such, is safe to fit into patients [8].

SMP Composites

Fiber reinforced SMP works with carbon fibers, glass fibers or nanofillers as the aids in enhancing stiffness and heat conductivity. Carbon-fiber SMP laminates form powerful and reconfigurable designs that are suitable to dynamic orthoses with a specified adjustment of curvature. The Graphene filled SMPs offer a high photo-thermal response and allow contactless restructuring [9, 10].

Biocompatibility and Safety Considerations

SMPs of medical grade should comply with the biocompatibility and skin-contact safety criteria. The emerging formulations of SMP contain low amounts of residual monomers, are thermally stable, and exhibit pH neutral degradation behaviors, which increases their clinical acceptability [11].

Comparative Thermomechanical Performance of Shape-Memory Polymer Systems

Different shape-memory polymer (SMP) systems exhibit distinct thermomechanical characteristics that influence their suitability for prosthetic and orthotic applications. Thermoset SMPs generally provide high shape-fixity ratios (95–99%), greater recovery stress (2–5 MPa), and excellent dimensional stability, making them suitable for load-bearing devices. Thermoplastic SMPs offer shape-fixity and recovery ratios of approximately 90–98%, together with lower activation temperatures (40–60°C), good processability, and compatibility with 3D/4D printing. In comparison, fiber- and nanoparticle-reinforced SMP composites combine high shape-fixity (>98%), improved recovery stress (3–6 MPa), enhanced cyclic durability, and superior fatigue resistance. Activation temperature remains a critical consideration to ensure safe clinical reshaping, while medical-grade polyurethane- and epoxy-based SMPs demonstrate good biocompatibility for prolonged skin contact. Overall, composite SMP systems provide the most balanced combination of mechanical performance, durability, recovery efficiency, and clinical safety, making them the most promising materials for advanced customized prosthetic and orthotic devices.

Table 1 compares the key thermomechanical and biological properties of thermoset, thermoplastic, and composite shape-memory polymer systems. The quantitative comparison highlights differences in shape-memory performance, recovery stress, durability, activation temperature, fatigue resistance, and biocompatibility, facilitating the selection of suitable SMP materials for customized prosthetic and orthotic applications.

Table 1. Comparative thermomechanical performance of shape-memory polymer systems.

Property	Thermoset SMPs	Thermoplastic SMPs	SMP composites
Shape-fixity ratio (%)	95–99	90–97	>98.
Shape-recovery ratio (%)	95–98	90–98	97–99.
Recovery stress (MPa)	2–5	1–3	3–6.
Activation temperature (°C)	50–80	40–60	40–70.
Cyclic durability	High	Moderate	Excellent.
Fatigue life	Good	Moderate	Excellent.
Biocompatibility	Good	Good–Excellent	Good–Excellent.
Typical application	Load-bearing prostheses	3D/4D-printed orthoses	Advanced adaptive prosthetic and orthotic devices.

FABRICATION TECHNIQUES FOR SMP-BASED DEVICES

Additive Manufacturing (3D/4D Printing)

The 4D printing is an extension of 3D printing, in which the shape-memory polymers (SMPs), capable of changing shape post-fabrication, are added. In this method, flat components printed initially will be formed in complex shapes that fit into a limb, which saves the amount of time it takes to shape them manually. Components Writing High-resolution SMP components are frequently created by fused filament fabrication (FFF), stereolithography (SLA), or digital light processing (DLP) [12].

Thermoforming and Manual Shaping

Still in rampant use is traditional thermoforming. Portable devices are used to heat SMP sheets or foams, apply them to the patient and cool them to preserve the required shape. This is an easy procedure that can be applied in the low-resource clinical setting where complex printing facilities are not accessible [13].

Hybrid Digital-Physical Manufacturing

Many clinics are now incorporating computerized scanning of limbs along with SMP thermoforming. Simulation of pressure point and socket fit can happen with the use of digital models whereas the final manual adjustments are possible with SMPs. The overall workflow reduces the amount of prototype iterations, and it increases consistency [14].

APPLICATIONS IN PROSTHETICS

SMP systems have led to dramatic innovation in the field of prosthetic technology, by permitting devices to be repeatedly modified and shaped in accordance with changes in the physiology, degree of activity and comfort of the user. The development of adjustable sockets of prosthetics is one of the most essential applications. The conventional making of socks can usually be permeated with a great deal of manual labor, several separate attracting procedures, and several redoes since the anatomy is not always the same. SMPs are used in creating sockets to eliminate these issues because the material can easily be remodeled by clinicians in response to heat or electricity. Clinicians will be able to focus the position where the user experiences pressure or pain to warm the SMP locally so that it shapes itself again and forms a perfect fit with no need to change the entire socket [15]. This is especially handy during the early post-acquired amputation time when limbs volume may change rapidly.

Advanced prosthetic liners offering a more dynamic interface between the socket and the residual limb are also made using SMPs. SMP foams and elastomers can be softened when a limb is inserted into the

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socket reducing shear forces and hardened during walk stance phase to provide better support. Liners may also be customized to provide personalized compression profiles, which will be needed to prevent skin breakdown and irritation because they can be tuned regarding their density and pore structure [16].

Besides that, SMP-enabling actuation technologies allow self-adjusting prosthetic components design. SMP composites that contain conductive or magnetic fillers are known as electroactive in electronically responding to shape or stiffness change by small electron electric stimulations. The abilities are promising semi-active ankle positioning systems or socket volume-adjustment modules which programmatically react to gait variations, changes in temperature or sensor-data [17].

With prosthetic systems that incorporate SMPs, we open a new frontier of intelligent, lifestyle, patient-inspired devices that have high functionality and response capabilities as compared to the traditional rigid material.

Engineering Considerations for Clinical Performance

The clinical performance of shape-memory polymer (SMP)-based prosthetic and orthotic devices depends not only on material selection but also on engineering design parameters that govern shape-memory behaviour under physiological loading. Thermo-mechanical programming conditions, including programming temperature, applied strain, and cooling rate, significantly influence shape-fixity and shape-recovery performance. Activation temperatures should remain within a clinically safe range (approximately 40–60°C) to enable efficient reshaping while minimizing the risk of thermal injury. Recovery kinetics are equally important, as controlled recovery ensures gradual adjustment without generating excessive interface pressure at the residual limb or body surface. Repeated loading during daily activities may reduce recovery efficiency because of polymer fatigue; therefore, cyclic durability and long-term mechanical stability should be considered during material selection. In addition, effective interface mechanics and uniform load-transfer are essential for minimizing stress concentrations, improving pressure distribution, and enhancing patient comfort. Engineering evaluation using parameters – such as recovery stress, fatigue life, dimensional stability, and cyclic shape-memory performance – provides a more reliable assessment of long-term clinical performance. Integrating these design considerations with patient-specific digital manufacturing strategies can further improve the safety, durability, and functional effectiveness of SMP-based prosthetic and orthotic devices.

APPLICATIONS IN ORTHOTICS

SMP systems will benefit orthotic devices as they will allow balancing the structural support and patient comfort. One of the innovations, in this area, is the spinal orthoses that are based on SMP. Conventional spinal braces are hard, thick, and might be uncomfortable to the patients and hence poor rivalry. Using SMP material means that the brace could be shaped accurately to fit the torso of the patient and redesigned whenever the treatment requires it. An example is that during therapy, corrections on the curvature on the spine in scoliosis can be corrected without necessarily rebuilding the brace. SMP composites are lightweight as well making them more comfortable and mobile [18].

SMP variable rigidity is beneficial to lower-limb orthoses. These devices operate on heat-activated segments that change the state of a flexible or a rigid device. Elasticity is useful as individuals put them on and stiffness is useful as they walk. New designs incorporate SMP struts or hinges with provide it with excellent stiffness control, aid gait training, and repair a musculoskeletal injury (post-musculoskeletal injury) [19].

There are adjustable orthoses of the upper limbs such as wrist, hand, and elbow support. SMP composite may be programmed to maintain certain joint angles, which is helpful in neurological rehab where limb position must be modified frequently due to changes in muscle tone. Lightweight peripheral allows the device to take a load off of upper body, and repetitive deformation allows clinicians to adjust the device as recovery advances [20].

SMPs similarly aid orthoses which need to increase with children or accommodate swelling. Since they may be remodeled, there is no longer a need to resize too often. This saves on the early replacement expenses and increases clinical efficiency. Overall, SMP integration introduce individualization, comfort and in the long term, flexibility to orthotics.

Figure 1 presents a comprehensive overview of shape-memory polymer (SMP) systems used in custom-fit prosthetic and orthotic devices. Panel A classifies SMPs into thermoset, thermoplastic, and composite systems, highlighting their structural characteristics, representative materials, and common activation stimuli. Panel B illustrates the clinical fabrication workflow, beginning with patient assessment and digital design, followed by additive manufacturing or thermoforming, shape programming, clinical fitting, and long-term adjustment.

Panel C depicts the structure–property–performance relationship, demonstrating how molecular architecture and reinforcement influence thermomechanical properties, including shape-fixity ratio, shape-recovery ratio, recovery stress, activation temperature, cyclic durability, and fatigue resistance, ultimately determining device performance, patient comfort, durability, and rehabilitation outcomes. Collectively, the figure integrates material selection, fabrication strategies, and functional performance into a single graphical framework, providing a concise visual summary of the current state of SMP-based prosthetic and orthotic technologies.

INTEGRATION WITH SMART TECHNOLOGIES

The state of SMP-based prosthetic and orthotic systems grows in smart technologies which enhance their performance and enable customization based on data. One among them is the incorporation of flexible sensors, such as pressure, temperature and strain, into the SMP structure. The sensors provide real-time information on Interface between the user and devices.

Clinicians will be able to view performance remotely and identify areas that require changes [21]. The feedback helps with the proactive maintenance and ability to observe issues early, like hotspots in pressure or impropriety, which lowers the risk of skin damage and discomfort.

Another important improvement is the digital fitting systems. Gait, AI-based optimization, force mapping, and 3D scanning of patient anatomy at a high resolution are used to design SMP devices. These computer programs allow clinicians to model the behavior of SMP materials in the process of actuation or reshaping. The outcome is a fit and functioning prediction prior to the fabrication prior to its accuracy. Machine-learning algorithms are used to identify optimal material formulations and activation parameters of every user based on historical data of the patients, and highly personalized interventions are implemented [22].

SMPs are used to develop lightweight and compliant actuators, which react to motion and are used in wearable robotics and soft exosuits. The non-emerging robotic actuators, SMP, can vary stiffness or shape, whereas in reaction to the heat or electric signals, which makes driving more natural and smoother than the movement of rigorous robots [23].

This is particularly applicable in soft type exosuits during gait rehabilitation when natural movement patterns are very important. SMP might improve as safety factors too, absorbing force or dissipating the strain within the event of abnormal movements.

Combined, the use of SMPs with sensors, AI-based fitting tools and soft robotics will advance intelligent assistive devices that are constantly updated to the needs of users, environmental factors, and therapeutic objectives. Table 2 shows the Shape-Memory Polymer (SMP) Systems for Custom-Fit Prosthetic and Orthotic Applications.

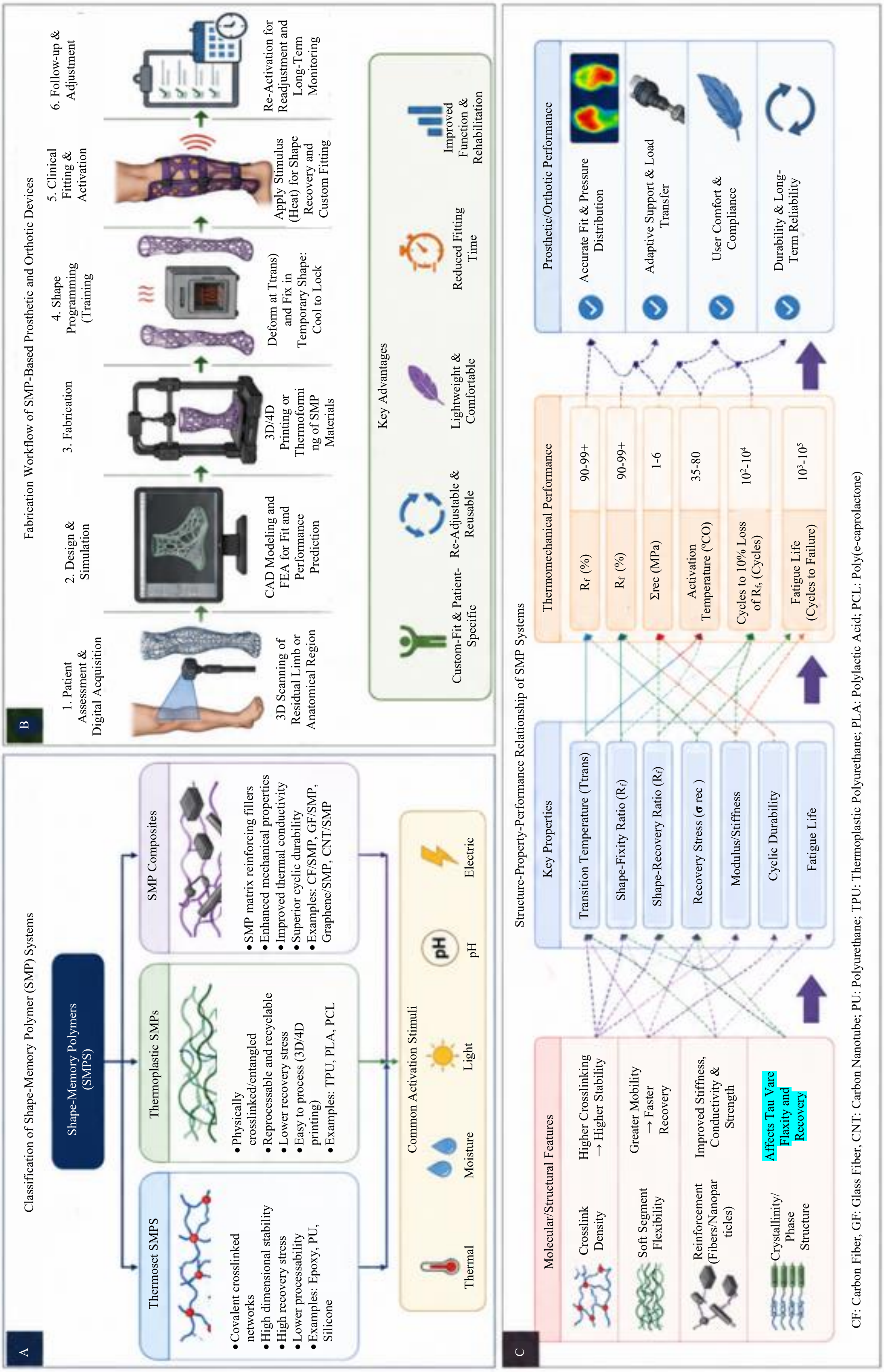

Figure 1. Comprehensive overview of shape-memory polymer systems for custom-fit prosthetic and orthotic applications.

Table 2. Shape-memory polymer (SMP) systems for custom-fit prosthetic and orthotic applications.

SMP aspect	Key details from CH-16	Functional role in devices	Representative prosthetic orthotic applications
Shape-Memory Mechanism	Thermally activated SME (Tg or Tm); programming–fixing–recovery cycle	Enables reversible reshaping and refitting	Adjustable prosthetic sockets, demoldable orthoses.
Stimuli-Responsive Triggers	Heat (primary), moisture, light, pH, electro-thermal actuation	Localized, controlled activation and reshaping	Pediatric orthoses, localized socket adjustment.
Thermoset SMPs	Epoxy-based, PU-based SMPs	High shape fixity, recovery stress, durability	High-load prosthetic sockets, spinal orthoses.
Thermoplastic SMPs	PU, PLA-based systems, block copolymers	Reprocessability, biocompatibility, 3D/4D printability	Custom sockets, AFOs, KAFOs.
SMP Composites	Fiber-reinforced (carbon, glass), graphene-filled SMPs	Improved stiffness, fatigue resistance, thermal conductivity	Dynamic orthoses, curvature-adaptive braces.
Comfort & Pressure Management	SMP foams and elastomers with tunable modulus	Pressure redistribution, skin protection	Liners, torso braces, immobilization supports.
Fabrication Techniques	Thermoforming, 3D/4D printing, hybrid digital–manual workflows	Patient-specific geometry and rapid customization	Custom prosthetics and orthotics.
Smart Integration	Embedded sensors, AI-guided fitting, soft-robotic actuation	Real-time monitoring and adaptive response	Smart sockets, adaptive exosuits.
Key Challenges	Fatigue, cyclic durability, regulatory standardization	Limits long-term deployment	Load-bearing lower-limb devices.

CHALLENGES AND FUTURE DIRECTIONS

Despite the enormous potential of shape-memory polymer (SMP) systems, there are several issues that restrict their application to other clinical areas. The biggest problem is after-effectiveness. The shape-memory cycles impose stress upon the microstructure of the material thus results in fatigue, reduced recovery ratio, and reduced overall performance. This issue is severe in mechanical support devices, such as prosthetic sockets and ankle foot orthoses, where mechanical stability cannot be done without. The work done in recent years in nano-reinforcement, dynamic covalent networks and hybrid composite indicates potential improvements in fatigue life and structural reliability [24].

The second obstacle is that there are no standardized testing and regulatory systems of SMP medical devices. Mechanical performance standards, thermal activation safety standards, and reliability requirements vary with those that apply to the orthotics and prosthetics that are conventional. There should be clear guidelines for safety, market permits, and clinical decision making. Clinicians too require intensive training pertaining to shaping, setting up and servicing of SMP devices.

More barricades are cost and workflow integration. Although SMPs enable saving money in the long-term perspective, due to the reusability and customizability of the technology, the initial expenses of SMP-compatible equipment, such as localized heating devices and 4D printers, are rather expensive. Simple thermoforming can be used to decrease barriers in low resources, although more accessible ease of activation mechanisms is still needed.

The future SMP studies will aim at finding materials that are responsive to multi-stimuli and can be stimulated with non-hazardous, low intensity stimuli like body heat, electromagnetic fields, or light. Digitization, AI customization, and embedded electronics will permit SMP devices that self-monitor themselves, self-adjust or autopilot fit and functionality. Once such innovations have reached the maturity, SMP devices may transform a personalized rehabilitation process into more responsive, adaptive, and user-friendly solutions.

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Emerging Research Perspectives and Future Opportunities

Future research should focus on translating shape-memory polymer (SMP) technologies from laboratory prototypes to clinically validated prosthetic and orthotic devices. Multi-material 4D printing offers opportunities to fabricate devices with spatially controlled stiffness and programmable shape recovery, enabling improved anatomical conformity and functional adaptation. Artificial intelligence (AI)-assisted patient-specific optimization can further enhance device design by integrating anatomical imaging, gait analysis, and biomechanical data to optimize material selection and programming conditions. In addition, multifunctional SMP composites incorporating conductive nanofillers, embedded sensors, or self-healing components may provide real-time monitoring, adaptive actuation, and extended device lifespan. Despite these advances, evidence regarding long-term in vivo reliability, cyclic performance under physiological loading, and long-term biocompatibility remains limited. Future investigations should, therefore, include standardized mechanical testing protocols, long-term clinical validation, and internationally accepted performance benchmarks. Furthermore, clear regulatory pathways and standardized evaluation criteria are essential to ensure the safety, reproducibility, and clinical translation of next-generation SMP-based prosthetic and orthotic devices.

CONCLUSION

The Shape-memory polymer systems are changing the process of designing and producing the personalized prosthetic and orthotic equipment. They may transform shape in a reversible manner, be customized to fit the body, and offer adjustable mechanical strength, indicating that they are ideal in the field of patient-centered technology in rehabilitation. Recent advances in polymer chemistry, composite engineering, 4D printing, and digital design, have expanded their potential, enabling extremely personal devices providing tradeoffs between comfort and structural strength as well as short- and long-term adaptability. The clinical applicability of SMP-powered sockets, adjustable orthoses, adaptive liners and bio-inspirated soft-robotic systems demonstrate the increase in clinical relevance of these materials as it provides a means to challenge the historic restraints of traditional rigid or semi-rigid products. However, the problems remain regarding endurance, cyclical functionality, authorization, and whether standardized guidelines of design are necessary to ensure the congruent clinical results. Continuous interdisciplinary interconnection will be necessary in perfecting SMP properties, enhancing fabrication and adding real-time sensing and actuation. With these innovations being in their maturity phase, SMP-based products and devices will be central to the next generation of a recombination of personalized rehabilitation solutions, offering enhanced comfort, functionality and life quality to the people who require the assistance of a prosthetic and orthotic.

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