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Review

Innovations in Orthotic Devices: Additive Manufacturing, Auxetic Materials and Smart Sensors for Enhanced Rehabilitation

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Abstract

Orthoses are external devices designed to provide structural and functional support for disorders affecting the musculoskeletal or nervous systems. While these devices have a long history, recent technological advancements offer significant opportunities to enhance their therapeutic performance. This review examines three key innovations shaping the future of orthotic devices: additive manufacturing, auxetic metamaterials, and smart sensors. Additive manufacturing (AM), commonly known as 3D printing, is gaining prominence for its ability to create patient-specific solutions, improve design flexibility, and reduce production time. Despite these advantages, traditional fabrication methods remain dominant due to cost and regulatory challenges. Auxetic metamaterials, characterized by a negative Poisson's ratio, allow an orthosis to dynamically conform to the patient's anatomy and movements while maintaining stability and comfort. Thanks to synclastic deformation, auxetic structures reduce the formation of wrinkles during motion, improving body fit, and potentially enhancing comfort as well as adherence to orthosis usage recommendations. However, their integration into orthoses is still in the early stages, requiring further research and clinical validation. Finally, smart sensors have been extensively studied for the real-time monitoring of joint movement and rehabilitation progress, enabling personalized therapy and improved clinical outcomes. In conclusion, these emerging technologies—additive manufacturing, auxetic metamaterials, and smart sensors—hold great promise for next-generation orthotic devices, but widespread adoption will depend on addressing technical, economic, and practical limitations.

Keywords: additive manufacturing; auxetic materials; FBG sensors; orthotics; wearable systems and sensors; embedded systems; medical devices and equipment; rehabilitative and assistive technologies

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1. Introduction

According to ISO standard 8549, an *orthosis* is a "medical device applied externally to a patient to compensate for impairments of the structure and function of the neuromuscular and skeletal systems" [1]. As a result of their consistent use over many decades, the effectiveness of these devices in supporting rehabilitation is well established. For instance, in 2016 the World Health Organization included them in the list of priority assistive products [2]—this list aimed at enumerating 50 priority assistive devices based on widespread need and impact on people's lives. Furthermore, the UK government allocated about GBP 15.1 million in 2022 for supporting research on orthotic devices [3]. Those are just a few examples, but they show that fruitful research in orthoses can have a significant positive impact on people's lives and well-being.

It should be noted that the term *orthoses* encompasses a broad range of devices used for various purposes. For example, braces are employed to stabilize the spine or correct deformities such as scoliosis, while knee and ankle sleeves are commonly used to support joints after an injury. Furthermore, orthotic helmets are utilized in the treatment of plagiocephaly. Thus, orthoses are commonly made using a plethora of standard materials selected for their strength, flexibility, comfort, and specific application. Thermoplastics like polypropylene are widely used for their moldability, while metals such as aluminum and stainless steel provide structural support. Foams like EVA and Plastazote offer cushioning and shock absorption, and carbon fiber composites are favored for lightweight, high-performance designs. Additional materials like leather, fabrics, silicone, and rubber are used for comfort, flexibility, or cosmetic purposes, depending on the orthosis type and patient needs [4].

One of the main issues for orthoses is compliance, which is defined as the adherence of the patient to the advice of the prescriber. Knowing the level of compliance of the patient to the therapy can aid the clinician in evaluating the efficiency of the healing process [5]. It is possible to consider compliance from two different points of view, the first one being related to the will of the patient to not wear the orthosis as a result of any discomfort/inability to perform daily activity [6–8], or for aesthetic and psychological reasons [9–11]. On the other hand, there are factors intrinsic to the devices which impinge on compliance, e.g., the complexity of usage makes it difficult to wear the device correctly, or it can move during the daily activity, resulting in a wrong working position [12].

In this framework, the emergence of new technologies and material advancements, including the use of auxetic metamaterials, can improve the design and features of orthoses, as well as fostering compliance. Auxetic materials are a class of mechanical metamaterials that shows a negative Poisson ratio. They were discovered in 1987 by Lakes [13], and in the last ten years they have gained the attention of researchers for their peculiar properties and their possible fields of application. Figure 1 shows that the number of publications related to the keyword *auxetic materials* has increased exponentially from 1991 to 2025.

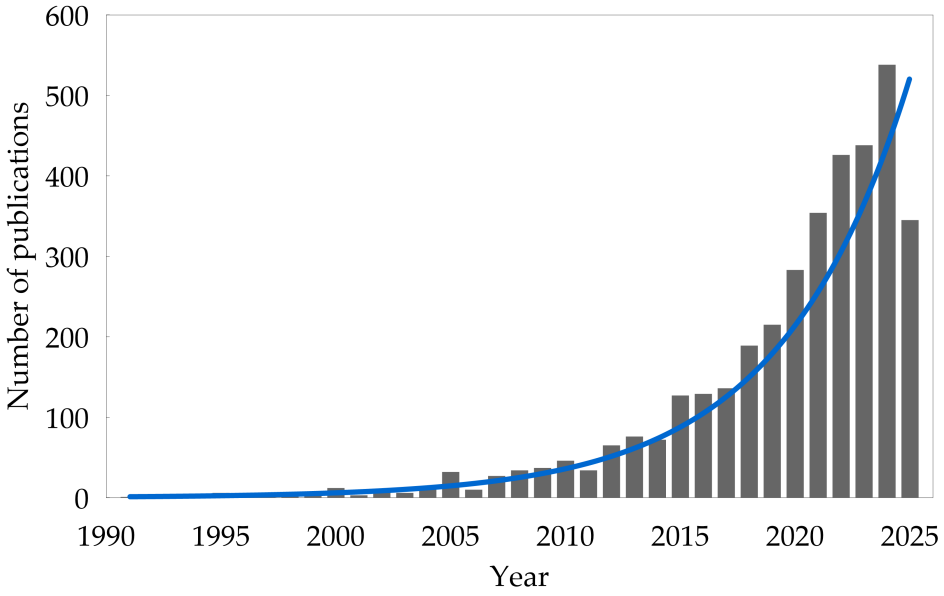

Figure 1. Publications related to the keyword *auxetic materials* from 1991 to 2025 (taken from Web of Science, accessed on July 2025).

Auxetics are already exploited in several fields such as robotics [14,15], transportation [16,17], and aerospatial [18], and they can have many applications in the biomedical field as well. As an example, different types of devices have been developed using auxetic materials such as prosthesis [19], stents [20], osteosynthesis devices [21], and scaffolds [22].

As a further development, additive manufacturing (AM) can be exploited for realizing orthoses with increasingly complex functionality and design, enabling their complete personalization and matching of the patient's needs, improving therapeutic effects and overall compliance.

Another important innovation in orthoses is the integration of embedded sensors to collect data during treatment. These sensors enable clinicians to assess the effectiveness of therapeutic interventions and continuously monitor the patient, thus preventing potentially dangerous situations. For instance, pressure or temperature sensors embedded in insoles for diabetic foot help with tracking foot health in real time, allowing physicians to respond quickly to any sign of ulceration or abnormal pressure distribution, avoiding foot gangrene and saving patients from amputation. Moreover, it is possible to use them for controlling the adherence of the patient to therapy. As a matter of fact, a wide range of sensors can be embedded into orthoses [23–27], enabling diverse applications from pressure monitoring to motion analysis. However, this research focuses specifically on sensors used for monitoring joint activity, as joint behavior is a critical indicator of functional recovery and therapeutic progress in many musculoskeletal and neurological conditions. Moreover, joint injuries are usually painful and can heavily affect life for an extended time. Figure 2 shows a taxonomy of the sensors that can be embedded within orthoses.

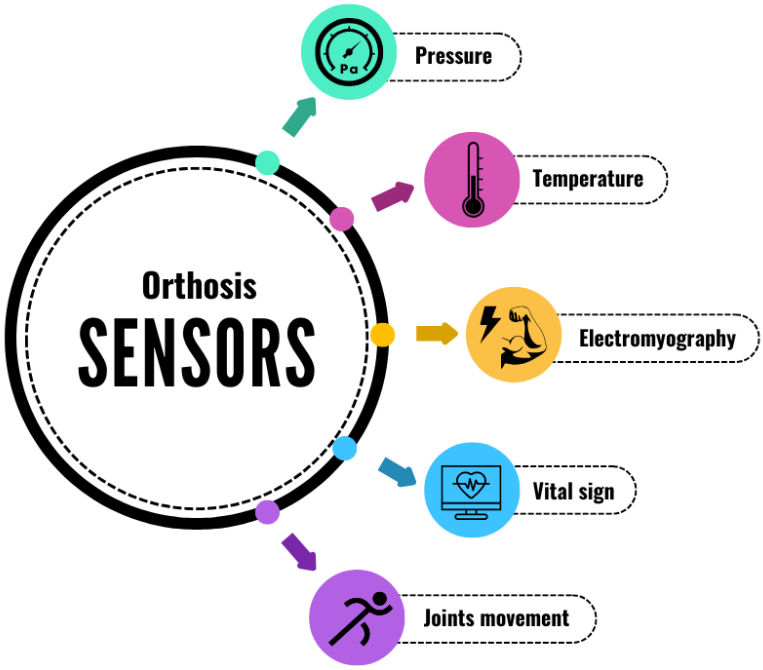

Figure 2. Different types of sensors that are possible to embed into an orthosis.

Thus, the goal of this review is twofold:

- Showing how the use of auxetic metamaterials, AM, and sensors, improves orthoses performance (considering applications in any body district: upper limb, lower limb, and spinal) by analyzing the existing literature in the field;
- Highlighting the new possibilities and challenges for the full exploitation of the aforementioned technologies in the design of a new generation orthoses.

Another recent innovation in the orthotic field is the contribution of artificial intelligence (AI) to optimize the design, process [28–31], data collection, and analyses [32–35]. Given the broad scope of this topic, it is not included in this review.

On top of that, the joints' anatomy and functionalities will be introduced as well—this is thought to be pivotal for understanding how orthoses work and how these devices can leverage recent advancements in the reported technologies. A graphical summary showing the key points of this review is shown in Figure 3.

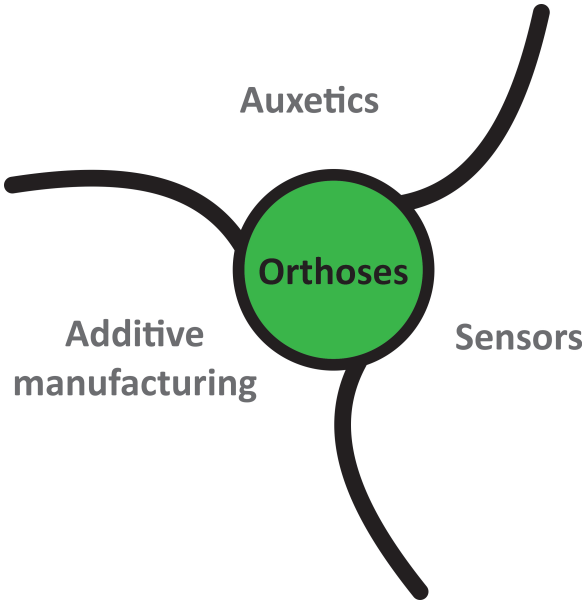

Figure 3. Possible innovations in orthoses field.

2. Joints

The human locomotor apparatus is composed of two parts, i.e., the actuating part, which is formed by muscles, and the passive one, which is composed of tendons, skeleton, and ligaments, all of them undergoing the action of muscles. As shown in Figure 4, these two components work in symbiosis to enable body movement.



Figure 4. Components of the locomotor system [36]. (Image credit: Andrzej Bogusz, licence: https://creativecommons.org/licenses/by/3.0/deed.en (accessed on: 1 April 2025) CC BY 3.0.

2.1. Anatomy

Joints can be split into three different kinds [37]:

1. Fibrous: These joints do not permit any movement. Bones are connected thanks to the presence of fibrous tissue, e.g., skull bones.

2. Cartilaginous: In this case, the bones are joined by cartilage, e.g., intervertebral joints.
3. Synovial: The most common type of joint. They make the reciprocal motion of bones possible with minimum friction. A joint capsule containing synovial fluid avoids direct contact between bones, reducing friction. There are six different types of synovial joints; see Figure 5.

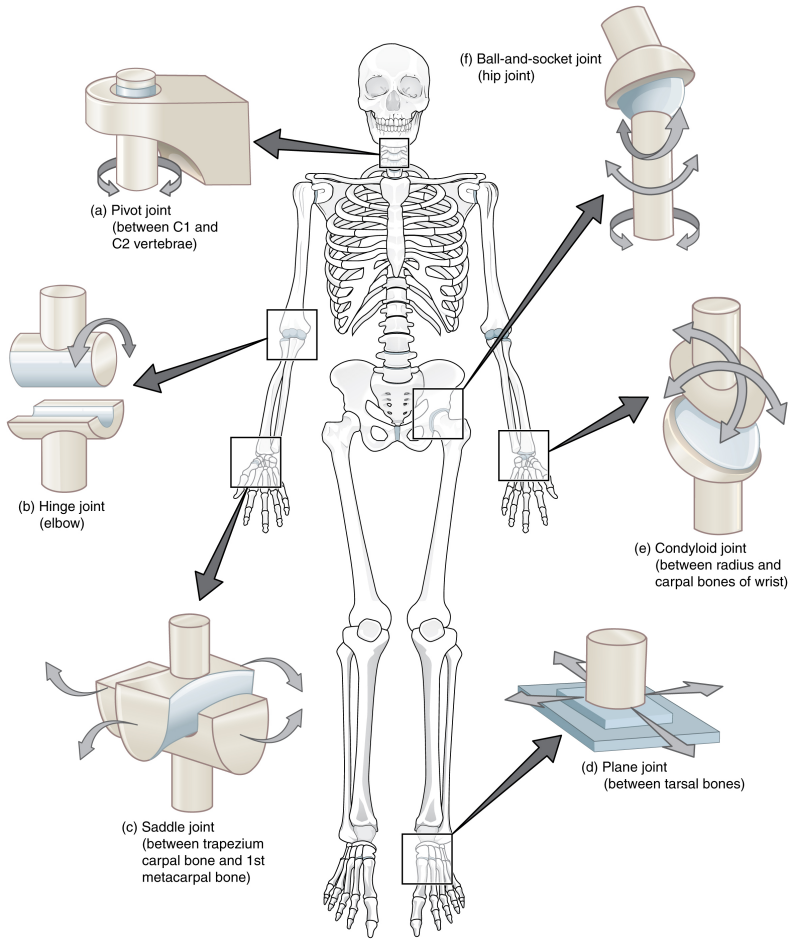

Figure 5. Different kinds of synovial joint in human body [38]. (Image credit: "Types of Synovial Joints" by OpenStax is licensed under https://creativecommons.org/licenses/by/4.0/ (accessed on 1 April 2025) CC BY 4.0.

Due to their ability to facilitate a wide range of motion, synovial joints are of particular interest in this work, and they are described here in detail.

Synovial joints are extremely intricate. Among their many components is articular cartilage, an avascular tissue that, despite lacking blood supply, effectively cushions the joint and enables smooth movements. In synovial joints, articular cartilage covers the bone surfaces and has a strong capacity to retain fluids due to the presence of proteoglycans. This fluid retention enhances load transmission and improves frictional properties at the bone-to-bone contact points. There are no nerves within cartilages such that any damage is painless until the underlying bone is unexposed. The synovial membrane plays a pivotal role by producing and containing synovial fluid, which lubricates the joint. Tendons, primarily made of collagen, transmit forces from muscles to bones, enabling movement. Ligaments connect bones and help stabilize joints by limiting abnormal motion. However, tendons and ligaments have limited healing capacity when injured due to their low cellularity and poor vascularization.

As shown in Figure 5, synovial joints can have different shapes, allowing in turn for different movements to be performed [39]:

1. Ball and socket: This is a bone with a round end that fits with a convex bone. These joints are multi-axial and permit the maximum range of motion, an example being the shoulders and hip joints.
2. Plane or gliding: Here, the only permitted movements are sliding between them and, in some cases, rotation. In this case, the motion is strictly limited by ligaments.
3. Pivot: A rounded portion of a bone is enveloped by the presence of a ring formed by another bone and a ligament. The permitted motion of the bone is the rotation within this ring, hence being a uni-axial joint.
4. Hinge: As its name suggests, this type of joint acts as a hinge. This joint works only for bending or straightening motions along a single axis, so they are considered uni-axial.
5. Saddle: In this case, bones forming the joint have a saddle shape: concave in one direction and convex in the other. Thanks to their shape, they allow movements on two different axes to be performed, so they are classified as bi-axial joints.
6. Condylar: Also known as condyloid joints, their structure resembles that of ball-and-socket joints. In this case, the joints are composed of an oval surface bone opposed to a round one. These are bi-axial joints that allow for movement to be made on the sagittal and frontal planes.

In Table 1, the information related to the different types of synovial joints is listed together with some examples.

Table 1. Different types of synovial joints..

Synovial Joint	Anatomic Reference	Number of Rotation Axis	Permitted Movement
Ball and socket	Shoulder (glenohumeral), hip (acetabulofemoral)	3	sagittal, frontal, horizontal
Plane	Intercarpal, acromioclavicular	none	varies
Pivot	Radioulnar, atlantoaxial	1	horizontal
Hinge	Elbow (humeroulnar), knee (tibiofemoral)	2	sagital, frontal
Saddle	Carpometacarpal, sternoclavicular	2	sagittal, frontal
Condylar	Wrist (radiocarpal), atlanto-occipital	2	sagittal, forntal

2.2. Traumatic Injuries in Joints

Many types of pathologies can affect joints—these can be divided by their origin: inflammatory, traumatic, degenerative, congenital, and secondary disease [40]. Due to the clear connection between the type of traumatic injuries and the choice/use of a given orthosis, these are explained here in detail:

- Sprain [41,42]: It is a temporary dislocation with a spontaneous reduction, sometimes affecting the tendon as well. In some cases, damage to the ligamentous structure of the joint can occur. Based on the severity of the sprain, ligaments can be stretched or torn. Ligament injuries can be difficult to heal due to their poor vascularization.

- Dislocation [41,42]: It is a displacement of the bones—which compose a joint—in an unnatural way, causing damage to joint tissue. It requires the intervention of the clinician to reduce the luxation. As for sprains, dislocations may provoke damage to ligaments, and more rarely to tendons.
- Fracture [43]: An external load applied to the bone or to the cartilage can create a discontinuity/crack in these structures. The fracture can affect the joint functionality if it happens very close to it. In such an event, usually, braces are used to immobilize bones in the correct position and to protect the damaged zone.
- Strain [44]: It can involve both muscles and tendons, and it happens when these structures are stretched in a severe way. In the case of the tendon, the action of the muscle is intense enough to elongate and damage the tendon.

3. New Technologies for Orthoses

3.1. Additive Manufacturing

As with many medical devices, orthoses are either the outcome of an industrial process or a custom-made product. In the first case, products are available in different sizes to suit the needs of the patient at the best. In addition, they are cheaper and readily accessible. Instead, personalized orthoses match the anatomical characteristics of a given individual, improving the overall comfort and effectiveness of the device. The process for obtaining customized orthoses is extremely complex in general and time-consuming, and requires highly skilled personnel. So, in the case of tailor-made orthoses, rapid prototyping and realization via AM can make the process simple and less expensive.

AM is a group of processes characterized by the fact that the product is built layer by layer. There are many techniques of AM, mainly divided by the type of material used: liquid based, powdered based, solid sheet based, and filament based [45]. On the other hand, according to ISO/ASTM 52900:2021 [46], it is possible to categorize AM into eight groups based on the production process:

1. Binder jetting: A powder bed is created during the printing process, and the printing head jets the liquid binder on the powder according to the desired shape [47].
2. Directed energy deposition: An electric arc or a laser is exploited to melt the feed materials locally, which is in the form of powder or wire [48].
3. Material extrusion: A commonly used family of AM that involves the selective extrusion of material to obtain the printed object [49].
4. Fused Deposition Modeling: A widely utilized material extrusion technique—it is easy to be mastered and used, and cost effective [50,51]. In this specific case, the object is built by an extruder which deposits a polymeric filament on a heated bed.
5. Material jetting: This exploits piezo-based inkjet technology, i.e., the one used also by inkjet printers, to generate a single layer by depositing thousands of droplets at the same time. After the deposition of each layer, the entire structure is cured using UV light [52].
6. Powder bed fusion: This exploits thermal energy to melt areas of the powder bed selectively. The difference between this technique and directed energy deposition is that, in this case, the powder is previously deposited on a bed, whilst the feed materials are melted as soon as they are deposited in directed energy deposition [53]. A common powder bed fusion process is Selective Laser Sintering. In this system, a thin, uniform layer of material in the form of powder is created, and a laser beam sinters the points which will compose the product locally.
7. Sheet lamination: A machine deposits a sheet of materials and then heats, compresses, and cuts each layer to create the desired 3D object. It is considered one of the quickest AM techniques to create composite parts [54].

8. Vat photopolymerization: This utilizes light to cure liquid photopolymers to build a 3D device [55].

In the last decade, many research groups have explored the possibility of constructing orthotic devices by AM. For example, Dal Maso et al. [56] produced an ankle foot orthosis (AFO). Using photogrammetry, they acquired geometrical data from the patient's feet. Then, AFO was designed and optimized based on the foot mesh, and finally printed using an FDM printer, resulting in a highly comfortable orthosis. They also suggested that the use of AM can be less expensive than the traditional one and require less time.

Oud et al. [57] proposed a comparison between a traditionally made and a 3D-printed wrist orthosis. In this case, the geometrical data of the patient were acquired through a 3D scanner. It turned out that the AM process requires less time, and it shows better results in the final satisfaction scores compared with that realized via standard means.

The possibility of reducing plantar flexion in the drop foot gait using a 3D printed AFO was explored by Vasiliauskaite et al. [58]. Firstly, they found the optimal ankle stiffness using a hinged AFO. After that, they designed leaf-spring-type AFO with the optimal ankle stiffness, and printed it. They obtained a reduction in the excessive plantarflexion problem. Nonetheless, the authors remarked on the importance of further investigating the impact of the realized device on the gait cycle to understand which parameters influence it the most.

In 2024, Popișter et al. [59] developed a smart knee brace. Also in this case, the patients' knee anatomy was acquired with a 3D scan and then printed by FDM using two different polymers. They obtained an orthosis that increases the wearer's comfort and proposed a further upgrade, i.e., testing their prototype in a rehabilitation clinic under clinician supervision.

Banga et al. explored the possibility of improving AFO using AM and finite element modeling. The idea came from evaluating the feedback of the patients, which claimed that the long-term use of AFO increased heating and seating. After a series of mechanical tests, they concluded that the realized prototype acted as good as, or even better than, the traditional AFO counterpart [60].

A 3D-printed finger orthosis was developed by Portnoy et al. [61]. The peculiarity of this study is that some occupational therapy students were involved for the experimental part. These students were asked to prepare the finger orthosis both via the standard manufacturing technique and AM. To the students, 3D-printed orthoses showed a higher level of satisfaction from both the fit and aesthetic points of view. Overall, they were more satisfied with the entire AM process and with the resulting product.

Furthermore is the improved capability of additive manufacturing to provide a great control over composite materials in terms of material composition, internal structure, and geometry [62]. Thanks to this, it is now possible to produce new wearable devices with embedded sensors. For example Valentine et al. [63] developed a sleeve with an embedded sensor to evaluate the motion of the elbow in real time.

3.2. Auxetic Metamaterials

Metamaterials are a class of materials that, thanks to their structure, show properties that cannot be found or achieved using standard materials. Research on metamaterials started in 1968 with the pioneering work of V.G. Veselago [64], which theoretically foresaw that materials with a negative refractive index would achieve extraordinary optical properties. Starting from that, in 1996 Pendry et al. proposed a design for a material that exhibits a negative refractive index [65].

The research then went on quickly, and now the concept of metamaterials has been extended to other materials like acoustic metamaterials for manipulating sound waves or phonons, and mechanical and auxetic materials [66,67]. Auxetic materials are a class of

materials that, thanks to their structure, show a negative Poisson ratio—when compressed in one direction, they collapse in the orthogonal directions and vice versa; see Figure 6. These materials have interesting properties that can be exploited to improve orthoses—those are detailed in Section 3.2.1.

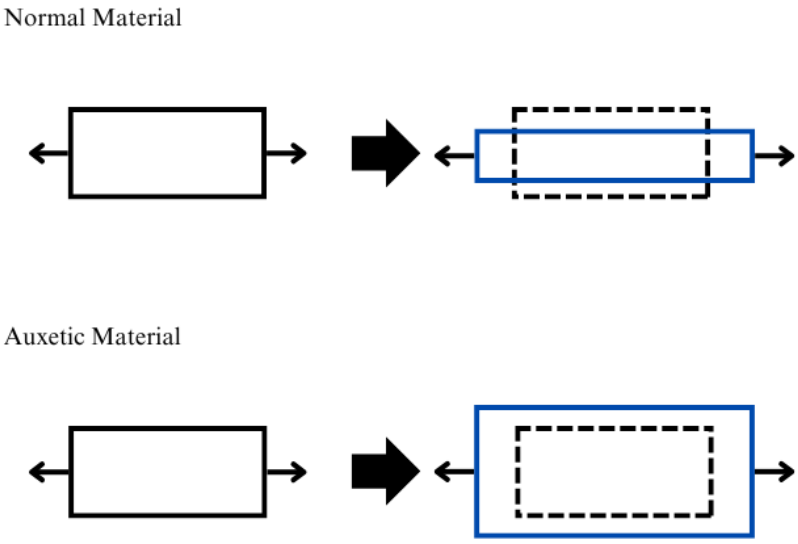

Figure 6. Comparison between normal and auxetic material subjected to tensile strain.

3.2.1. Properties

1. Shear resistance: when loaded with shear forces, auxetic materials show more resistance than regular materials. This can be demonstrated by looking at the relation between the shear modulus (G), Poisson ratio (ν), and Young's modulus (E) [68]:

$$G = \frac{E}{2(1+\nu)} \tag{1}$$

where it can be noted that G is inversely proportional to ν. In particular, when $\nu = -1$, then $G \to +\infty$.

2. Indentation resistance: In an indentation scenario, a conventional material would spread in the direction perpendicular to the applied load. Conversely, if the same compression acts on an auxetic material, it contracts laterally, drawing material inward toward the point of impact. This inward flow increases the local density and provides greater resistance to indentation, making auxetic materials particularly useful for applications requiring enhanced impact or puncture resistance. According to the classical theory of elasticity, the indentation resistance is correlated with material hardness (H), which is linked to the Poisson ratio (ν) through [69]

$$H \propto \left[\frac{E}{(1-\nu^2)}\right]^{\gamma} \tag{2}$$

where γ is a parameter that considers the different indentation scenarios, i.e., $\gamma = 1$ for uniform pressure distribution, or is equal in value to 2/3 for Hertzian indentation. It is possible to see that when $\nu = -1$, then $H \to +\infty$.

3. Fracture resistance: Auxetic materials have a better fracture resistance and, generally, cracks propagate less than in bulk material [70].
4. Synclastic behavior: When subjected to an out-of-plane bending moment, auxetic materials exhibit a dome shape [71]. Conversely, regular materials show a saddle

shape. Exploiting this feature, it is possible to design sleeves that do not show wrinkles during limb movement [72] and also to build orthoses with a more complex and tailored shape [73], which allows them to adapt easily to the user's body shape and to better follow joint movements.

5. Variable permeability: Thanks to their porous microstructure, which changes when tensile or compressive stress is applied, auxetic materials can be suitable to build filters [74].

3.2.2. Auxetic Geometries

There are different possible geometries and spatial arrangements which can lead to auxetic behavior, the most researched being the following [75]:

1. Re-entrant structures: These structures present some ribs directed inward. In this case, the auxeticity is guaranteed by the realignment of ribs.
2. Chiral structures: The unit cell is composed by a central cylinder with some ligaments connected tangentially to the cylinder. They can be constructed as right-hand or left-hand unit cells. If the lattice is composed of right-hand or left-hand cells only, then it is a proper chiral structure. Conversely, if right-hand cells are connected with left-hand cells, then it is an anti-chiral lattice. In this case latter case, the cylinder rotates when mechanically stressed, flexing in turn the ligaments. Hence, ligaments fold on the cylinder when facing a compression load, and they unfold during elongation.
3. Rotating polygons: These are made by polygons connected on their vertexes by hinges. Here, the reciprocal rotation allows for an auxetic behavior to be obtained.

Figure 7 depicts all the mentioned geometries.

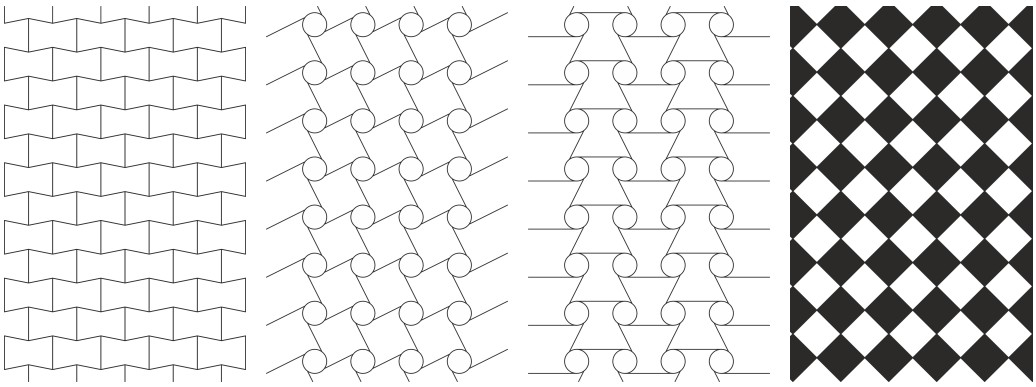

Figure 7. From left to right: re-entrant structure, chiral structure, anti-chiral structure, and rotating square structure.

3.2.3. Auxetic Orthoses

Application cases of auxetic materials for orthoses are reported in what follows. Interestingly, only eight papers were found [76–83] over the time interval 2017–2023. It should be emphasized that this small number of publications represents only a very minor part of the 2426 scientific papers related to orthotics available on the Scopus database within the same time frame. Surprisingly, the earliest identified study dates back to 2017. Nonetheless, six out of the eight articles were published in the last three years (2021–2023), indicating that the integration of auxeticity into orthotic design is still in its embryonic stage. This fact is particularly noteworthy given that the integration lies at the intersection of two well-established fields of research.

The first article related to orthotics dates back to 1945 [84]. It is possible to divide the evaluated papers into three groups. In the first one, there are articles related to Kinesio Taping (KT), which is a technique invented by Kenzo Kase in 1973. This technique makes

use of tape stuck onto the the skin of the patient, which can stimulate muscles, reduce swelling, and support joints depending on how they are applied, e.g., position, direction, and potential pre-strain of the tape prior the application. Two articles related to the application of auxetics to KT were found:

1. The KT by Meeusen et al. [76] shows the possibility of exploiting the negative Poisson ratio of an auxetic structure to obtain a tape that stimulates the skin in two directions. A re-entrant structure, i.e., the simplest and most studied auxhetic geometry, was here exploited. Furthermore, the synclastic characteristic of auxetic structures allows for obtaining a tape with interesting form-fitting properties, improving the adherence of the tape to the body. The tape was obtained by cutting a KT with a laser. Then, a layer of thermoplastic polyurethane (TPU) by fused filament fabrication (FFF) technology was deposited onto it.
2. Hedayati et al. [77] studied the possibility of creating a tape capable of mimicking the Poisson ratio of the Achilles tendon, as it naturally shows an auxetic behavior [85]. Therefore, the authors designed a 2D auxetic structure with the same shape as the Achilles tendon. Then they discretized the tendon in many rectangular regions, and they calculated the average Poisson ratio for each of them. After that, they fine-tuned the Poisson ratio of the cell to mimic the characteristics of the tendon by changing the geometrical properties of the unit cell.

Authors who employed auxetic structures for the brace design are included in the second group:

1. Panico et al. [78] developed a device to aid neck muscles in performing their physiological functions, correct neck posture, and support the head. Auxetic materials were considered here due to their capability to fit the neck anatomy perfectly, and they allow for skin transpiration thanks to their perforated architecture. Furthermore, they provide support to the neck muscles while still allowing neck movement, an essential element for the healing process.
2. Park et al. [79] designed a brace for people affected by carpal tunnel syndrome. It is a disease of symptomatic compression neuropathy characterized by pain, numbness, tingling, thus resulting in a reduction in hand function and grip capacity [86]. In this case, the auxetic material was used for its capability to absorb energy, and so to protect the patient from potential impacts.

The last group of papers reported the use of auxetic materials for insoles and heel pads in orthotics. Among these, three articles show the development of insoles capable of preventing ulcer formation due to diabetic foot. In this case, the role of the auxetic structure was to replace the plantar tissue, which gets stiffer and incapable of absorbing impacts physiologically/during the gait cycle as a consequence of the diabetes. Although the devices are similar, they have different approaches:

1. Hinrichs et al. [80] designed a heel pad to improve the Achilles tendon healing process. To reach this goal, they exploited auxetic materials to better redistribute pressure on the heel.
2. Chen et al. [81]'s work consists of an insole composed of three areas. The forefoot and the heel areas were made of auxetic material, whilst the middle zone leveraged a honeycomb structure. In the middle zone, a foot arch support was inserted, which was designed to fit the patient's foot.
3. Leung et al. [82] designed a support for the heel with an auxetic material, whilst the remainder of the insole was composed of non-auxetic foam.
4. Zhang et al. [83] proposed to design an insole completely made of auxetic materials.

It can be noticed that most of these studies adopted re-entrant structures for the auxetic materials, except for Chen et al. [81] and Panico et al. [78]. The former group built their unit cell based on a rotating square mechanism, whilst the latter developed an interesting fractal unit cell that shows a hybrid mechanical behavior between a re-entrant and a rotating square. All the devices presented in this section are listed in Table 2.

Table 2. Auxetic materials in the orthotic field.

Year	Device	Geometry	Reference
2017	Neck Brace	Fractal unit cell	Panico et al. [78]
2018	Heel Pads	Re-entrant	Hinrichs et al. [80]
2021	Insole	Re-entrant	Zhang et al. [83]
2021	Insole	Rotating Square	Chen et al. [81]
2022	Insole	Re-entrant	Leung et al. [82]
2022	Kinesio Tape	Re-entrant	Meeusen et al. [76]
2022	Wrist Brace	Re-entrant	Park et al. [79]
2023	Kinesio Tape	Re-entrant	Hedayati et al. [77]

3.3. Sensors

Many different kinds of orthoses are available on the market, and a range physiological parameters can be measured to verify the effectiveness of the device or the healing progress of the patient. For this reason, this section will consider only sensors used for joint monitoring. A complete recovery of joints after an injury or a disease is important to restore the life quality of the patient. Thus, tracking articular movement can be useful for many reasons. Firstly, precise information could be given to the clinician during the rehabilitation process, allowing progress in the rehabilitation process to be checked, as well as monitoring patient posture. Moreover, data from sensors can be used to build a model of the joint that allows for evaluating their health status. Finally, it is possible to analyze the patient' movement during an exercise session, giving feedback on the workout execution.

The first part of this section will expose the parameters examined during the joint monitoring. After that, the possible technological solutions will be presented, with some examples to show potential applications in this field.

3.3.1. Monitoring Parameters

To obtain a comprehensive description of joint form from a kinematic point of view, three parameters should be considered, i.e., (i) the range of motion, (ii) the joint motion, and (iii) skeletal tracking. Each parameter helps to assess the state of the joint, the muscle activity during movement, and potential postural defects [87].

i. Range of motion (ROM): It is the measure of the maximum amplitude of movement that a joint can reach during a particular movement. Every joint has its particular ROM. This parameter is also influenced by many other individual characteristics like age, sex, physical structure, and daily activity. ROM can be altered due to injuries, joint pathologies, or incorrect posture. A good rehabilitation process aims to restore the complete ROM of the articulation.
ii. Joint motion: It is conceptually similar to the ROM, but it considers how the joint moves in 3D space, therefore describing more complex movements.
iii. Skeletal tracking: It is a technique that allows for the reconstruction of bone positions during movement to be obtained so that clinicians can exploit it to analyze the body posture. The study and knowledge of the body posture are of the utmost importance—an incorrect body posture can cause (or can be caused by) some joint morbidities.

3.3.2. Monitoring Tools

Sensors are the heart of the monitoring system, and different technologies have been exploited to develop an effective sensing system. Each of these have different pros and cons, and hence a proper sensor selection is pivotal for the design of a sensing system. In fact, a monitoring system must guarantee high efficiency and accuracy at the same time. It must be small and sufficiently light as well to not affect joint motion, and user-friendly (comfortable). Furthermore, it should require low processing resources and consume as little energy as possible.

What follows is a list of the main categories of sensors that can be applied in combination with orthoses to build a joint monitoring system.

1. Optical sensors: devices based on an optical fiber. Thanks to a laser system, light is conveyed into the optic fiber, while a detector receives the transmitted signal. It is then possible to detect the motion of the joint by post-processing the acquired data. The pros of this type of sensor are the small size (grating length, typically 1–20 mm), high resolution, flexibility, light weight, and immunity to electromagnetic noise. In recent years, many different types of monitoring systems have been introduced. For example, Pedro et al. [88] developed a device capable of measuring knee flexion. In this case, a fiber Bragg Grating (FBG) sensor was used. The FBG sensor is an optic fiber that has a grating inscribed, working in turn as a filter reflecting waves with wavelengths satisfying Bragg's condition:

$$\lambda_B = 2n_{eff}\Lambda \tag{3}$$

where λ_B is the Bragg wavelength, n_{eff} is the effective refraction index of the fiber core, and finally Λ is the grating pitch. Stretching or compressing the sensor affects the grating pitch, causing a shift in λ_B. In this case, this sensor was embedded in a polyvinyl chloride (PVC) rectangular sheet, and the knee movement during walking or running was measured by it, assessing the capability of the sensing tool. A Fabry–Pérot interferometer was used by Domingues et al. [89] to develop a sensor for ankle rehabilitation. This type of sensor exploits the presence of micro-voids, which create a resonant system reflecting light differently depending on the wavelength. When subject to a mechanical load, a change of the void shapes occurs, provoking the reflected interference to change as well. Here, the optic fiber was embedded in a polymeric matrix and then fixed on a Kinesio tape.
Another type of optic sensor is a fiber optic curvature sensor. To obtain these sensors, an optic fiber is etched, usually forming teeth. These teeth are present on a single side of the fiber and impinge both the cladding and the core layer of the fiber. When they bend, the obtained gaps can be either on the convex or on the concave side. If they are on the convex side, the teeth will be more open, decreasing the capability of the fiber to transfer light. On the other hand, if the etchings are on the concave side, they will be closed, increasing in turn the intensity of the transmitted light. This kind of sensor was used by Stupar et al. [90] to develop a knee monitoring system. When using this type of technology, laser sources for the interrogating system can be avoided, opening room for employing simple and low-cost LED chips. Thanks to this feature, the authors were able to develop a wireless monitoring system.
2. Textile-based sensors: In this case, an electronic sensor or a net of sensors is embedded in a textile material. These kinds of sensors are based on electromechanical sensor technology, and they can be divided into four groups based on the transduction systems [91].

Firstly, piezoresistive sensors convert deformations into an electric signal. The working principle is based on the second Ohm law, i.e., the relation between electrical resistance and the shape of the conducting fiber. Therefore, any change in the conducting fiber shape will trigger a change of the resistance value. An innovative system of wearable goniometers was developed by Tognetti et al. [92] using this technology. In their study, they assessed the possibility of obtaining a goniometer that, for quasi-static measurement, shows performance that is comparable with those accepted for goniometry applications but is still worse than that of the commercial electro-goniometers. From a dynamic point of view, this device was compared with an inertial measurement unit (IMU) system, and a complete correspondence was found. Another example was shown by Ge et al. [93]. The idea behind this study was to mimic the sensing apparatus of the human skin. It highlighted the form-fitting capability of this sensor, and the possibility of monitoring the posture and joint movement was shown by applying it onto a finger. Capacitive sensors, on the other hand, take advantage of capacitors made of properly designed elastic materials to correlate strain changes with capacitance variation. Yao et al. [94] designed this kind of sensor to detect multiple stimuli, i.e., they were able to track the flexion of the thumb and the flexion of the knee when the patient was subjected to the patellar reflex test. Instead of using silver or gold nanoparticles to produce a capacitive sensor, Sheng et al. [95] employed a gallium (Ga)–indium (In)–tin (Sn) alloy. This metal is liquid at room temperature, so they painted a thin layer of metal on tape (3M VHB 4905) to build the sensor, and this was used to measure finger and wrist bending. Piezoelectric sensors exploit the piezoelectric phenomena—when the sensor is stretched, it generates an electric potential that can be measured and correlated to the imposed deformation. Guo et al. [96] investigated the opportunity of creating a device capable of communicating wirelessly by Bluetooth technology. This tool can acquire motion data and send it to the smartphone of the patient. It was tested by analyzing human motions, i.e., walking, running, and elbow flexion. Kim et al. [97] developed a sensing system inspired by ligament anatomic structure. Its capability to acquire biometric data was tested by creating a system of seven sensors that collected the movement of the entire left upper limb. A data processing algorithm was then exploited to produce an avatar that mimics the patient's motion. The triboelectric effect is a contact electrification phenomenon. In this case, a transfer of charges between two materials when contact is made is involved. A voltage signal is formed and detected, and it is possible to store it in batteries. As a result, this type of sensor can be self-powered. C. Li et al. [98] designed a triboelectric sensor to monitor different human joints in real time. This study aimed to develop a system that could be used to monitor the spine during daily activity to prevent the occurrence of disease, to help during rehabilitation, or for diagnoses. They obtained a wireless sensor with high precision, high measurement repeatability, and high robustness to environmental noise. W. Li [99] designed a sweat-resistant triboelectric sensor. To this aim, they produced two superhydrophobic and self-cleaning triboelectric layers, taking inspiration from the hierarchical organization of the lotus leaf. This device showed excellent humidity resistance.

3. Inertial measurement unit (IMU): It is a combination of three sensors (accelerators, gyroscopes, and magnetometers) and it can be used to measure 3D displacements, velocity, magnetic field vector, and energy consumption. Thanks to their high accuracy, low-cost design, and portability, they are very interesting in the orthoses framework. Nevertheless, they are sensitive to electromagnetic fields and affected by drift effect and high rigidity, which can limit their use in everyday life [91]. Bonnet et al. [100] developed an IMU-based device to monitor hip and knee joint angle during lower limb

rehabilitation exercise. They proposed a novel algorithm to estimate joint dynamics using the data acquired by IMU sensors. They obtained good accuracy, though some limitations were present due to some approximation necessary to simplify calculations. Ianculescu et al. [101] introduced a novel system called "re.flex". This system is based on two IMU sensors and a mobile application that uses sensor data to visualize real-time joint motion.

Table 3 reports a comparison among the different types of sensors presented in this review in terms of dimensions and the connection between the sensors and the processing unit. Regarding the sensitivity of FBG sensors, in the literature it is generally indicated that those sensors have a sensitivity on the order of pm/με [102]. Additionally, Domingues et al. [89] reported a sensitivity of 0.0296 ± 0.001 mW/° for a Fabry–Pérot sensor. For an optical curvature sensor, Stupar et al. reported a sensitivity of 20 mV/°. In the case of textile sensors, piezoelectric types showed sensitivities of 11.950 Ω/mm and 763 Ω/mm for two different configurations [92]. For capacitive sensors, the reported sensitivity ranges between 0.57 MPa^{-1} and 1.62 MPa^{-1} [94]. For piezoelectric sensors, a sensitivity of 0.017 kPa^{-1} was reported [96], while triboelectric sensors showed a sensitivity of 8 V/mm [98]. Finally, for IMU sensors, no sensitivity values were provided in the reviewed articles, but a resolution of 0.01° was reported in another study [103].

Table 3. Sensors comparison.

Sensor	Dimensions	Connection	Reference
Optical sensor	125 μm	Physical connection with an interrogator	[88–90]
Textile-based sensor	Dimensions depend on a sensor design—a sensor net is embedded in a device	Physical or wireless connection with processing unit	[92–99]
IMU	40 × 30 × 15 mm	Physical or wireless connection with processing unit	[100,101]

3.3.3. Biofeedback

An effective way to utilize the collected data is by creating a biofeedback system. In this context, the data gathered can be processed to provide the patient with information about the functionality of the device. For example, an ankle–foot orthosis (AFO) can be used to monitor the load applied to the ankle and provide the patient with acoustic feedback if the load exceeds a certain threshold [104]. In this study, two groups were compared: one group used an AFO with a feedback system, while the other used a standard orthosis. The group with the enhanced orthosis demonstrated a 57% utilization rate, compared to just 29% for the control group and also an increased adherence to the prescribed load. In another study, two different spinal orthoses for the correction of increased kyphosis were compared [105]. The first one is a semi-rigid orthosis which helps to improve posture both sustaining spine and also increasing the proprioception. The second one is a soft orthosis with a feedback system which alert the patient when she/he is maintaining a bad posture, using a vibration. This system does not sustain the spine; the support is provide by the muscles of the patient. In this study, no significant differences are highlighted between the devices for what concerns the balance and gait parameters. Hsu et al. showed the possibility to design a AFO with motion feedback to improve the rehabilitation process for people affected by stroke-related hemiplegia [106]. They demonstrated that their devices can improve the gait pattern and weight shifting to the hemiparetic lower limb, and as a consequence, a more symmetric gait cycle is obtained. In this case the feedback is given

not by a sensor system but from a patient-specific dynamic system which acts on the ankle of the patient to improve patient proprioception. Finally, we present a study which involves the use of electromyography to collect data during the rehabilitation process [107]. In this study, the goal was to demonstrate that biofeedback can be beneficial for patient rehabilitation after anterior cruciate ligament (ACL) reconstruction. It was shown that it is beneficial in the early phase of the therapy after ACL reconstruction, as it is useful in enhancing knee extension. In this case the sensor was not embedded into an orthotic device; however, the proposed solution is important to assess the importance of biofeedback in rehabilitation process.

4. Conclusions

A good rehabilitation process is crucial for a complete restoration of the joints' functionality. However, this is complex due to the intricate anatomy of articulations, in which, for example, ligaments receive few nutrients, thus hampering quick healing. Additionally, the human brain often triggers a compensation mechanism that shifts the load from one joint to another. This can lead to overloading of the compensating joint, potentially causing impairment, while the injured joint may experience stress shielding—a reduction in stimulation that can hinder the regeneration process. Hence, finding an effective solution to these interconnected problems is of the utmost importance. In this framework, traditional orthoses made of standard materials are a well-known device in clinical practice, but they come with a lot of limitations, particularly concerning customization, effectiveness, and patient comfort. This article reviews some of the most promising innovations in orthotics, i.e., auxetic metamaterials, the embedding of sensors, and additive manufacturing, reporting and discussing the recent advancements in the field.

Thanks to their light weight, breathability, and synclastic behavior, the use of auxetic materials can improve the wearability of the orthosis and their overall functionality.

Sensors allow a complete analysis of the movement of joints to be achieved, aiding clinicians in assessing progress in the rehabilitation process and investigating the presence of compensations. Moreover, they allow the patient to have feedback during their workout sessions.

Finally, AM paves the way for the widespread use of customized orthoses, reducing costs and production time, and providing a higher-quality product overall. Furthermore, AM can open room for a higher usage of auxetic materials, as intricate geometries can be effectively realized easily with such a technology. As it is summarized in Table 4, the integration of these technologies in orthotic design and production could lead to significant advancements in the rehabilitation process, bridging the gap between innovation and practical implementation in clinical settings. On the other hand, the introduction of these new technologies can reveal different challenges. For example, the use of auxetic materials needs to be looked into further to obtain approval from the regulatory systems. In addition, the use of sensors results in a better rehabilitation process on the one hand, while on the other, it increases the cost of the produced devices. Furthermore, the introduction of additive manufacturing improves customization of the orthoses but does not have the possibility to be based on a large economic scale, so the produced devices may be more expensive.

Table 4. Comparison (pros and cons) between traditional and innovative orthoses.

Aspect	Orthotic Devices	
	Traditional	**Innovative**
Technology Used	Conventional materials (plastics, metals, foams) and handmade (casts)	Auxetic materials, smart sensors, additive manufacturing
Customization	Standardized sizes with some manual adjustments or handmade casts	Highly personalized through 3D scanning and additive manufacturing
Manufacturing Process	Labor intensive, requires skilled professionals for customized ones, industrial process for the others	Automated with additive manufacturing
Cost	Often lower due to mass production	Potentially higher due to advanced materials and technology
Effectiveness	Proven through decades of clinical use	Promising but requires more clinical validation
Availability	Widely available, covered by insurance in many cases	Limited availability, adoption still in progress
Patient Comfort	May lack ergonomic design, less adaptive materials	Improved fit, lighter, breathable materials

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