Chapter 2
Advances in Orthotic Prosthetic Design: Challenges and Applications

Arnab Chanda, Biswarup Mukherjee, and Subhodip Chatterjee

1 Introduction

Devices like prostheses and orthoses assist disabled individuals and reach out to their biomechanical requirements. Health clinicians utilize prosthetics to restore lost lower limb or upper-limb body parts. As an illustration, consider the artificial limb socket, a cup-shaped device that adjusts around an amputee's damaged limb and moving mechanical loads from the body appendages to the prosthesis. Braces and other similar terms for orthoses hold up and modify the human musculoskeletal system's structure and functional characteristics. Depending on the part of the body that is afflicted, orthoses can be categorized as top half, spinal, or lower-limb orthoses. They can also be termed after the joints they support, such as ankle–foot orthoses, lumbar orthoses, and wrist orthoses [1]. The fact that both orthotic (orthosis) and prosthetic (prosthesis) devices are made to support a particular body component to help the patient walk properly is one of their similarities. Both orthotics and prosthetics should meet the same ideal criteria, including being lightweight, rigid enough to resist shear stress, strong enough to withstand impact, affordable, and simple to connect to and remove from the injured body part. The primary distinction betwixt an orthotic device and a prosthetic device is that the former is applied to entirely substitute the missing limb, forasmuch as the latter is used to improve the functionality of limbs with defects or abnormalities that prevent proper function. Pre-engineered orthotics and prosthetics are more commonly accessible and less expensive than custom products on the market, but customized products that take the most important

A. Chanda (✉) · B. Mukherjee · S. Chatterjee
Centre for Biomedical Engineering, Indian Institute of Technology Delhi, New Delhi 110016, India
e-mail: arnab.chanda@cbme.iitd.ac.in

A. Chanda · B. Mukherjee
Department of Biomedical Engineering, All Indian Institute of Medical Sciences Delhi, New Delhi 110029, India

component in user satisfaction is how well a product fits a patient's body given their individual qualities [2]. Plaster casting which is a highly personalized, patient-centered procedure, is the most common and conventional method of producing custom orthoses and prostheses.

When compared to traditional manufacturing, additive manufacturing drastically lowers material waste, accelerates the fabrication process, and does away with the majority of human tasks that require skill. A patient in need of a prosthetic goes to the orthopedic or trauma specialist to have the necessary human body measurements taken in the traditional fabrication process. Plaster bandages are applied to the body part that is injured in order to fabricate a cast mold. The negative cast mold is subsequently filled with plaster to create a positive mold. The next step is to perform the heating and vacuum-forming of thermoplastic sheets (often polypropylene or polyethylene) onto the positive plaster mold in order to produce the prosthesis or orthosis. After the sheets have cooled and been cut to the proper shape, they are then trimmed. The plaster cast may be altered, or another element may be added, depending on the loading on the human body's sensitive and bearing parts. Then after, straps and accessories are added to complete the fabrication. The patient must go to the fitting session. Most of the time, more alterations are needed to assure the product's comfort and functionality. This process wastes materials and costs a lot of money in labor and time.

The ability and experience of the prosthetist or orthotist have a significant impact on the quality of the products [3]. Complex structures may be produced with additive manufacturing while reducing money and labor costs. The adaptability of additive manufacturing enables customization for unique applications or taking into account individual traits. It opens up new possibilities for design flexibility, minimization of resource surplus and waste, and cost effectiveness in creating unique products. Precision replicas of current products are possible because of additive manufacturing [4] and enable weight reduction while increasing functional performance. Additionally, the incorporation of AM functions might lessen the requirement for assembly processes [5].

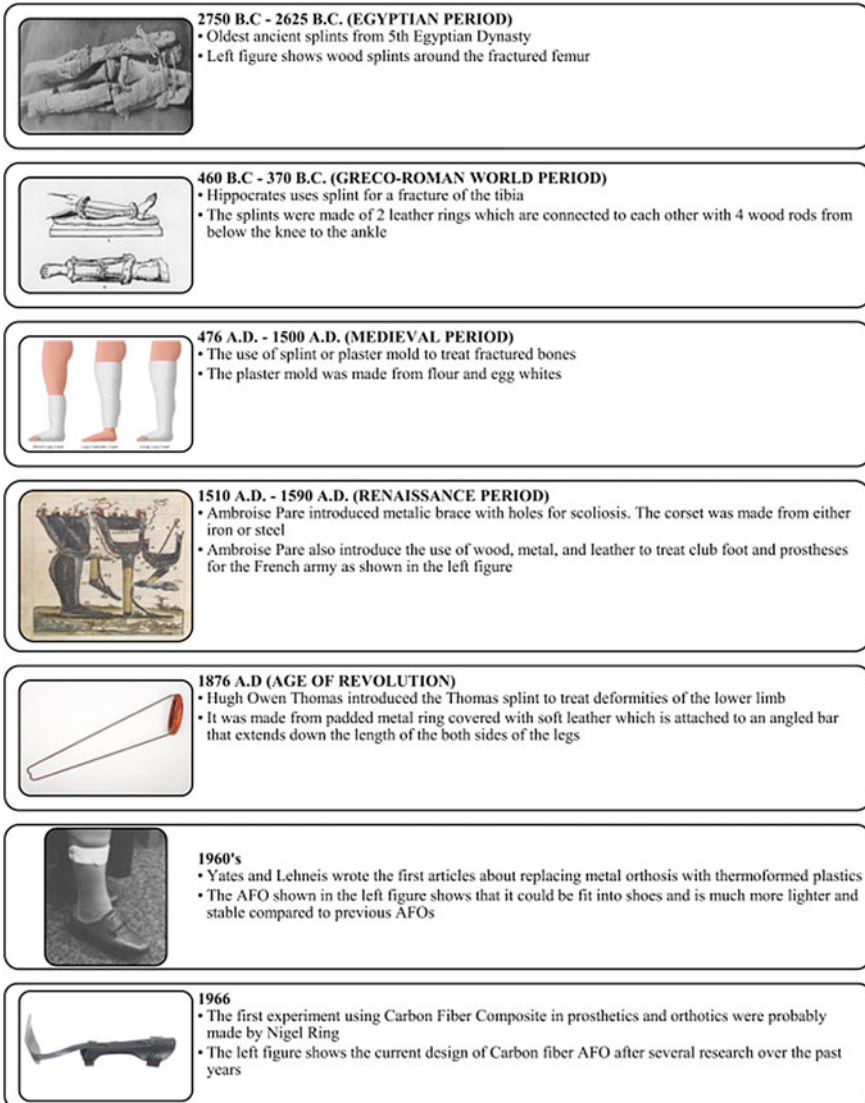## 2   Historical Development of Orthotics and Prosthetics

Since the art of making splints and braces has been used on limbs with fractures. They were discovered in 20th-century excavations by the Hearst Egyptian Expedition of the University of California led by Dr. George A. Reisner, the history of orthotics can be tracked back to the ancient Egyptian age, which is thought to have occurred around 5000 years ago. The 5th Egyptian Dynasty, which corresponds to 2750–2625 B.C., was said to have produced these splints, making them the earliest splints ever discovered. By employing the radiologic study of two mummies, Brier and his team made another significant discovery in 2015 that further establishes the existence of prosthetics dating back to the ancient Egyptian era [6]. Following the discovery of two more artificial toes, which are currently on display at the British

Museum, the artificial toe's operation was further explained. Since 1981, both the toes have been housed in the museum. The Greco-Roman World was still prospering between the years 1000 BC and 476 AD, and throughout this time, medical practices had a considerable impact on modern medicine. During this time, many well-known doctors were born, including Hippocrates, Herophilos, Dioscorides, and Galen of Pergamon. The "Father of Medicine," Hippocrates, was the most notable physician who had a significant impact on the evolution of medical procedures. Hippocrates employed wooden and leather splints to treat a fractured tibia from about 460 BC until 370 BC [7]. Two leather rings were used to make the splints, one of which was wrapped around the knee and the other over the ankle. A long cherry wood rod served as the link connecting the two rings. In order to give the ankle unfettered movement and a little skin exposed to facilitate scrutiny when necessary, the rods were positioned lateral to the ankle and knee. The world began the Renaissance era following the mediaeval era, which signifies the change from the Middle Ages to Modernity. This period lasted from about the year 1500 to 1800. Ambroise Pare, a French surgeon, invented the modern amputation techniques in the middle to late 1500s. He then developed prosthetic devices with characteristics such an engineering component such as a flexible harness, knee clamp control, and others that are still present in modern devices today. His primary driving force behind developing prosthetics was to aid the soldiers who had experienced traumatic events during the war. Hugh Owen Thomas created the Thomas splint in 1876, which is used to treat lower limb abnormalities. The main goal of the straightforward design was to immobilize the lower body appendages. The splint was made of a leather strap attached to an inclined rod that extends from both sides of the waist to the bottom of the foot. Yates and Lehneis published the initial article on how to use thermoformed plastics to replace metal orthoses in the 1960s. Many researchers argued and continually contrasted conventional metal and thermoformed plastics at the beginning of its use as an orthotic material substitute. Nonetheless in the following research, it was discovered that plastic had more benefits than metal.

It is clean, light, comfortable, and quiet. Plastic orthoses are more aesthetically pleasing than metal orthoses since they can be worn below the user's clothing. Since then, thermoformed plastics have taken over as the primary material for orthotics and prosthetics. Nigel Ring conducted the first experimental tests on carbon fiber composites in 1966. It was well-known that composites are a strong-to-weight ratio material. In other words, depending on how it was created and developed, it has the durability of a metal and the lightness of plastic. As a result, aside from plastics, carbon composites have emerged as one of the most advantageous materials (Fig. 1).

3 User Needs Analysis and Current State-of-the-Art

A substantial revolution is currently taking place in the fields of rehabilitative and assistive robotics, where technologies are being developed to actively aid or restore legged movement to those with muscle impairments or weakness, neurologic injury,

2750 B.C - 2625 B.C. (EGYPTIAN PERIOD)
• Oldest ancient splints from 5th Egyptian Dynasty
• Left figure shows wood splints around the fractured femur

460 B.C - 370 B.C. (GRECO-ROMAN WORLD PERIOD)
• Hippocrates uses splint for a fracture of the tibia
• The splints were made of 2 leather rings which are connected to each other with 4 wood rods from below the knee to the ankle

476 A.D. - 1500 A.D. (MEDIEVAL PERIOD)
• The use of splint or plaster mold to treat fractured bones
• The plaster mold was made from flour and egg whites

1510 A.D. - 1590 A.D. (RENAISSANCE PERIOD)
• Ambroise Pare introduced metalic brace with holes for scoliosis. The corset was made from either iron or steel
• Ambroise Pare also introduce the use of wood, metal, and leather to treat club foot and prostheses for the French army as shown in the left figure

1876 A.D (AGE OF REVOLUTION)
• Hugh Owen Thomas introduced the Thomas splint to treat deformities of the lower limb
• It was made from padded metal ring covered with soft leather which is attached to an angled bar that extends down the length of the both sides of the legs

1960's
• Yates and Lehneis wrote the first articles about replacing metal orthosis with thermoformed plastics
• The AFO shown in the left figure shows that it could be fit into shoes and is much more lighter and stable compared to previous AFOs

1966
• The first experiment using Carbon Fiber Composite in prosthetics and orthotics were probably made by Nigel Ring
• The left figure shows the current design of Carbon fiber AFO after several research over the past years

Fig. 1 Summary of the orthotic material development timeline [8]

or lower limb amputations. Energy-passive bionic devices have been used for a certain amount of time with varying levels of success [9]. For many disorders, passive devices provide a practical solution to enable efficient gait restoration, in part due to their relative simplicity, low initial cost, and strong construction. There are a number of inherent problems with these technologies, including their incapacity to generate mechanical power, their inability to automatically adapt to the user's changing needs,

and their dearth of sensory feedback on the state of the limb and the device. For a perfect mental and physical connection between the user and the device, each of these elements must be present. Orthotics and prosthetics that are portable and intelligent have the potential to significantly increase a person's mobility and, consequently, their quality of life. The end-users will once again be able to engage in daily activities As these devices begin to approach the power output, efficiency, and adaptability of the limbs that they help or replace, they should be utilized for activities that demand total combined energetic output (e.g., stair ascending, sprinting, hopping) in the same ways as their able-bodied counterparts. In comparison to their passive counterparts, active prosthetics and orthotics may also be able to lower metabolic cost while increasing the self-selected gait speed [10–12]. These devices may help improve gait symmetry and lessen the risk of compensatory movements damaging the user's unaffected joints. Numerous mobile robotic systems for assisting and restoring human movement have been created. With improvements in computer technology, miniaturized sensors, energy storage, automatic pattern recognition and actuation it is possible that within the next ten years, numerous further active lower extremity prosthetics, robotic arms, and orthotic devices will be developed and made commercially available (Fig. 2).
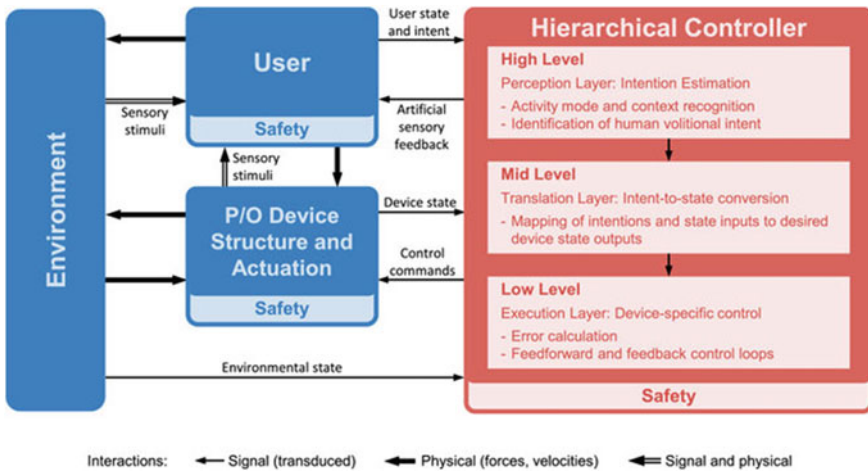
Fig. 2 Generalized control framework for active lower limb prosthesis and orthotics [13], CC-BY-4.0

4 Process of Development of Prosthesis and Orthotics for Patients

4.1 3D Anatomical Data Acquisition Technologies

New design guidelines for orthotic devices can be created by combining the use of rapid prototyping techniques with various methods for assessing and modeling the human body. The information can be represented as a data cloud, picture elements, or space coordinates of various physiological points, depending on the data gathering technique utilized. However, there are a number of acquisition ways that facilitate production employing fast prototyping techniques in the area of modeling of bionic devices. These acquisition methods include computer low dose CT scanning, polygonal scanning, and various visual aid movement capture systems.

4.1.1 Computed Tomography

The sophisticated tool of computed tomography (CT) is used for both surgical planning and diagnostic purposes. Historically, the axial or transverse planes were where recorded images were placed. Modern scanners can now create volumetric restorations for 3D representations by capturing images along many planes. CT has been used in numerous research to manufacture bionic devices. Taking for example, Tang et al. [14] not long ago suggested making diabetic insoles using CT and additive manufacturing (AM) methods. As a result of their research, which was capable of decreasing the apex plantar pressure by 33.67%, they were able to correlate pressure and tissue tension along the plantar foot with the treatment response of footwear and specially constructed orthotic inserts. But there are several difficulties that are worth highlighting. Radiation is the primary issue, and the dose is inversely related to the scanning time. Another downside is the partial pixel effect, which leads to a blurred boundary since different densities share shared pixels [15].

4.1.2 Three-Dimensional Scanning

3D scanning has emerged as the most convenient and comfortable method for capturing human morphology or the external contour. In order to establish the spatial location in three dimensions of all the points that together make up a material's surface, volumetric scanning systems use optical-based approaches. A CAD model is then obtained after using computer tools to recreate features from the point cloud. Currently, single image restoration, structured light technologies, lasers, and other stereo reconstruction methods are all used in 3D scanners for human assessment. Structured light and photonic technology are the most often utilized tools for reshaping the human body [16]. The laser method creates a laser dot or line with a

portable device. A sensor-often a spot or charge-coupled device-measures the separation from the surface. Optical imaging techniques broadcast predetermined wave patterns onto the object moving using a projector-camera system. In the groundbreaking work of Chee Kai et al. [17], a volumetric method was chosen rather than employing more traditional methods like blockwork impressions, Magnetic resonance, and Computerized tomography for prosthetic modeling. Mavroidis et al. [18] developed patient-specific foot orthoses using 3D laser scanning. Through the use of designing software and a rapid prototyping tool, exterior characteristics of the patient's anatomy were optimized. Comparing the prototype to ankle–foot orthoses available for sale, the prototype more accurately fits the subject's anatomy. A drawback of this technology is its inability to record certain topographical human biological features with intricate wrinkles and folds, including the space between both the fingers when the palm is neutral, the back of the leg when flexed, or the armpits.

4.2 Rapid Prototyping Technologies for Orthotic Devices

In the field of orthotic devices, a well-known approach that is gaining greater attention is the substitution of traditional craft methods with Design software and computer-aided fabrication.

The following processes are required for customized production using rapid prototyping, according to Ciobanu et al. [19]: CAD modeling, translation to stereolithography format (STL), 3D scanning of the biological surface, 3 dimensional restoration, and, lastly, machining utilizing a specialized additive manufacturing machine (i.e., a 3D printer) operated by a system. For the construction of custom-fit orthotic devices, rapid prototyping offers benefits such as more design freedom, the production of functional requirements, higher accuracy and cost effectiveness, faster delivery, and enhanced user experience. A physical product is created layer by layer from a realistic virtual 3D CAD model using a rapid prototyping manufacturing technique [20]. An optical model of the component is created using a designing software and transformed during the rapid prototyping process into the STL file format, which is the default standard file format for RP systems. Depending on the type of the fabrication method, such as laser, printer, and extrusion technologies, additive manufacturing can be classed in a variety of ways [21]. There are numerous varieties of additive manufacturing techniques. In the early nineteenth century, Kruth [22] recommended using various additive manufacturing techniques, categorized based on the element employed for the model (Table 1). However, Paterson et al. [23] showed that only a few of them could be utilized in the creation of orthotic and prosthetic devices. Orthoses and prostheses are made utilizing solid-based processes like laminated object manufacturing (LOM) or liquid-based processes like stereolitography (SLA), solid ground curing (SGC), UV light curing (ULC), and ballistic particle manufacturing (BPM). However, 3D printing with a powder bed and inkjet head, selective laser sintering (SLS), and fused deposition modeling (FDM) are the most often employed

Table 1 Rapid Prototyping techniques available for prosthetics

Material	Process
Liquid base	• Stereolithography (SLA) • Solid ground curing (SGC) • UV light-curing (ULC) • Ballistic particle manufacturing (BPM)
Solid base	• Laminated object manufacturing (LOM) • Fused deposition modeling (FDM)
Powder base	• Selective laser sintering (SLS) • 3D printing (Polymer injection)

production techniques for orthotic and prosthetic devices (3DP). These methods show an ideal trade-off between price, turnaround time, accuracy, and comfort.

4.2.1 Fused Deposition Modeling (FDM)

In the FDM procedure, a quasi-material is pushed through an extrusion head that moves in the X and Y axes (see Fig. 3a) to produce a two-dimensional layer of the intended object. The moveable material pushing head is made up of two extrusion nozzles: one to hold the support material and the other to place the building materials. Typically, the extruder head fills the delimited zone created by the preceding extrusion by adhering to a predetermined pattern after extruding the perimeter of each layer. The support platform descends after the layer is finished, and another layer is extruded. Layer after layer, the technique goes on until the item is finished. Polycarbonate (PC) and Acrylonitrile Butadiene Styrene (ABS), or a combination of the two, are the most often used materials for FDM. These materials resemble thermoplastic polymers for injection molding in their characteristics. It is also possible to use other materials, including polymers or nylon-based compounds. The utilization of inexpensive materials is the main benefit of FDM technology. Tan et al. [24] were innovators in the application of utilized FDM for the manufacture of tibial prostheses and came to the conclusion that the prosthetics' functional qualities were appropriate for usage in clinical settings. On the other hand, production times are lengthy. Since then, more and more biomedical uses for FDM have emerged, including medication delivery systems, hand and facial prostheses, upper and lower limb orthoses, and hand prostheses.

4.2.2 Selective Laser Sintering (SLS)

In the 1990s, the DTM Corporation, which is now a part of 3D Systems, unveiled the first SLS technology. By employing a CO_2 laser to selectively fused granular polymer-based materials, such as nylon/polyamide, the SLS process produces volumetric solid objects or parts (Fig. 3b). In order to create a 2D profile, a CO_2 laser
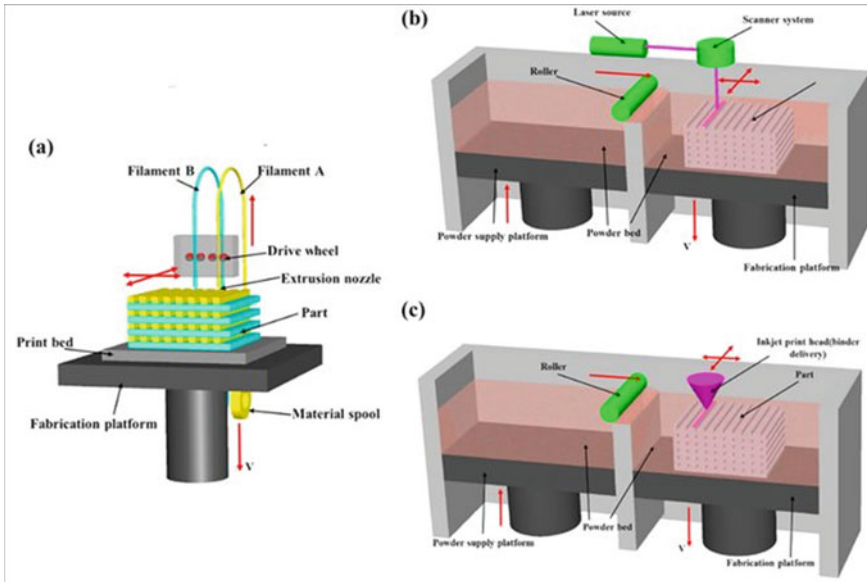
Fig. 3 Comparison among the rapid prototyping operations of fabricating prosthetics and orthosis **a** Fused deposition modeling (FDM), **b** Selective laser sintering (SLS), **c** 3DP [31], CC-BY-4.0

moves throughout the powder bed in the X and Y axes, selectively sintering designated portions. The platform descends, a fresh layer of powder is applied, and the sintering procedure is repeated when the 2D profile has already been finished. The procedure is afterwards referred to as a granular-based fusion technique. Generally speaking, all materials are thermoplastics, with polyamide 12 (PA), acrylonitrile butadiene styrene (ABS), and polycarbonate being the most popular ones (PC). The useability of the rehabilitation devices is improved by these materials' significant weight reduction. Schrank and Stanhope [25] assessed the accuracy of the SLS manufacturing method of foot prosthetics as an illustration of the use of this method in the fabrication of custom prosthetics. In this study, the divergence between the final product created using SLS and the CAD model was recorded using the Faroarm 3D scanner (accuracy of 25 m). The results revealed values that were less than 1.5 mm. Deckers et al. [26] created and evaluated an SLS-based AFO, underlining the necessity of accurately characterising the AFO's mechanical attributes such as strength, fatigue, and impact resistance. Following testing of a polyamide-based orthosis produced using SLS, Vasiliauskaite et al. [27] came to the conclusion that the features were comparable to those of a polypropylene orthosis formed by the process of thermoforming, with the first being more rigid than the second but still suitable for reclamation.

### 4.2.3 Powder Bed and Inkjet Head 3D Printing: 3DP

Three-dimensional printing, often known as 3DP, is the process of creating fabricated goods out of powder layers adhered together using glue. In this procedure, the build platform is first covered with a powder layer. Second, by adhering to a textured layer in the horizontal plane, a liquid agent is selectively placed by an inkjet print head. The platform descends when the 2D pattern has been created, following the granular layer is spread, and so on. Some people refer to this technology as "3D printing with a powder bed and an inkjet head" (or 3DP). It should not be mistaken with the widely accepted description of 3D printing, which includes any processes of additive manufacturing that produce three-dimensional things. The 3DP process is comparable to SLS in certain ways (Fig. 3b, c). In 3DP, the material is infused with liquid adhesive using a printing head, whereas in SLS, the layers are fused using a CO_2 laser. Although this method's precision is lower than that of SLS, it is nevertheless popular since it is quick and inexpensive. Due to these characteristics, 3DP already dominates the prototyping sector. The materials utilized (mostly thermoplastics like ABS) provide the necessary characteristics to be used for application in bionics. Herbert et al. [28] explored even if this technique was appropriate for producing functioning prostheses, and they suggested that, despite the low fabrication levels, patients preferred 3DP machine-made prostheses (Corporation Z402) over conventionally created ones. Unfortunately, the resistance was not investigated in that investigation, so the product's durability is uncertain. Utilizing this technology, Saijo et al. [29] created patient-specific maxillofacial implants and reported a decrease in procedure times. Because of its digital accuracy, control, and adaptability, The use of 3DP in bioengineering and recuperative medicine is particularly exciting., according to Ventola [30].

5 Materials Used for Fabricating Prosthetics and Orthotics

Figure 4 illustrates how materials used for orthotics and prosthetics have changed over time, progressing from wood, metal, and leather to plastic and carbon fiber composite.

5.1 Wood Prosthetics and Orthotics

Wood orthoses have been around since the dawn of humanity. Wood has several advantages over other materials for making orthoses, including renewability, machinability, superior strength to weight ratio, resistance to rusting, and aesthetic appeal. The disadvantage is that wood's characteristics are extremely varied. The species of wood, the amount of moisture in it, or even how the load is oriented against the grain, can all have an impact on how variable the mechanical properties of
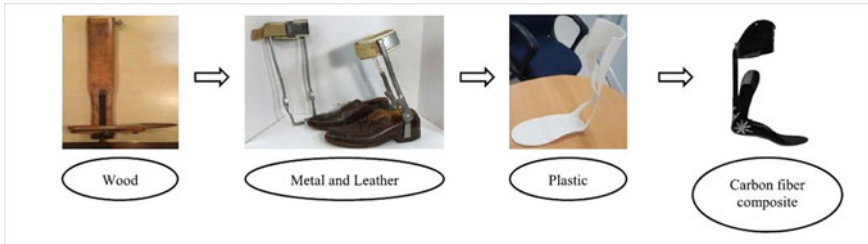
Fig. 4 Different types of materials used in orthotics and prosthetics [8]

wood are. Tension, compression, flexure, and finally shrinking and expanding make up the mechanical properties of wood. Typically, woods range in density from 160 kg/m^3 to 1350 kg/m^3. The bark of an oak tree, an oak tree's cork, or balsa wood were the most often utilized categories of wood. An orthosis must have adequate tensile strength, compressive strength, and flexural strength in order to assure welfare and stability. The two types of wood's tensile and compressive strengths are those that are perpendicular to the grain and those that are parallel to the grain, respectively. The strength is greatest when tension is exerted orthogonal to the grain. Consequently, depending on the wood species and its mechanical strength, the material may or may not be suitable for use as a prosthetics material. The type of wood that will be used will depend greatly on the prosthetics that will be created.

5.2 Metal and Leather Prosthetics and Orthotics

Leather is one of the earliest materials that has ever been utilized. Leather is made from animal skin, which is subsequently chemically synthesized during the tanning procedure. The tanning process will make the skin well built, more expandable, and more resilient. The cuffs that keep the appendages in place were created to mimic textiles or straps with laces, in contrast to the leathers used in the prosthetic design, which will always resemble a pair of shoes. High tensile strength, tear resistance, and efficient heat insulation are typical properties of modified leather. The drawbacks of utilizing leather are its limited biodegradability and the pollution that chemical wastes from each tanning operation will generate. The density of leather is 860 kg/m^3 on average, roughly. In order to endure the stress exerted towards the lower limbs, leather was typically combined with metal supports while making lower limb prosthetics. Metal alloys, steels, and any lightweight metal with a high tensile strength are the most often utilized metals in the manufacture of orthoses. Metals can exhibit densities ranging from 1700 kg/m^3 for a magnesium alloy to 20,000 kg/m^3 for a tungsten alloy. The fact that metal-leather orthoses frequently have a modular construction makes them advantageous to use. As a result, the shoe can be taken off of the metal supports or fixtures and be replaced with another shoe. This style of orthosis has the drawback of being bigger than any other orthosis and having no cosmetic appeal.

Additionally, the density including the combination of metal and leather added to an orthosis makes this kind of orthosis exceedingly having high weight and requiring more effort. As a result, walking while wearing these AFOs requires more effort from the wearer. Additionally, leather and metal are inappropriate for use as clothing in an environment with significant humidity due to their thickness. The wearers would experience extreme sweating and a terrible stench as a result of the sweat being absorbed by the leather.

5.3   Plastic Prosthetics and Orthotics

Most people are familiar with plastics as semi-synthetic materials. There are two main categories that it falls under: thermoplastics and thermosets. Thermoplastics are types of plastic that, when heated, can transform into a liquid and, when appropriately cooled, can solidify into a glassy substance. This substance is useful for making orthotics since it is simple to form into a plaster model which can be used to create prosthetics. Acrylic, Polypropylene (PP), Polyethylene (PE), and Nylon are a few thermoplastic examples. Thermosets are frequently in a liquid state before curing and can be molded into their final form once curing has taken place. Once thermoset has been molded, it cannot be changed. Thermosets including polyester resin, polyurethane, silicone, and epoxies are frequently utilized in orthotic devices. The fact that plastics are combustible, insignificant heat and electricity conductors, and do not corrode or rust make them advantageous for use in orthotics. These characteristics will guarantee that the manufactured orthosis won't hurt the users, whether physically or chemically. Because of its excellent moldability, the orthosis could be customized to just about any shape or size that would ideally fit the wearers. Plastics are also lightweight, strong, simple to color, and energy efficient. Thus, among orthoses made of various materials, those made of plastic are the lightest and most aesthetically beautiful. They also preserve their strength. Plastics have a density that ranges from 36 kg/m^3 to 2200 kg/m^3. Tensile strength ranges from 0.24 MPa to 170 MPa for this material. The modulus of elasticity of plastics can vary greatly depending on the kind of resins, reinforcing agents, and manufacturing methods employed. It is between 0.7 MPa and 4100 MPa. Plastic's indestructibility and potential for environmental pollution are its drawbacks. Despite the fact that the garbage is melted to eliminate it, the gas created during the melting process is still extremely detrimental to human health and may contribute to the weakening of the ozone layer. Plastics are typically lighter than the other materials used to make AFOs that are sold on the market. However, repeated use over a lengthy period of time also results in skin irritation. Plastic is currently the most desirable material due to the development of additive manufacturing. An orthosis is created via rapid manufacturing, which makes use of 3D printing and 3D CAD models. The 3D reconstruction created by CAD/CAM software will be used to print the orthosis layer by layer on the printer. Since a plaster cast model is not required as in the typical procedure, this could eventually lower the expense of producing the orthosis. The ability to redesign and do endless

optimization also contributes to creating an advanced and more useful prosthetic while lowering the risk of a bad design.

5.4 Carbon Fiber Reinforced Polymer (CFRP) Composite Prosthetics and Orthotics

A composite is a substance that combines multiple materials with contrasting features in order to enhance each other and produce characteristics that are entirely separate from those of the constituent materials. The majority of orthotics products are constructed of polymer composites. The matrix of polymer composites is often made of thermoset or thermoplastic resins, with reinforcement elements including Aramid, carbon fiber, and glass fiber. Among all other polymer composites with the exception of that of plastics, CFRP is one of the most suitable materials utilized to make a prosthetic. Carbon fiber serves as the composite's reinforcement while polymers serve as the matrix. This kind of substance is as strong as metal while yet being lightweight. In comparison to other materials, it is also far more aesthetically pleasing. From 1500 kg/m^3 to 1600 kg/m^3, CFRPs have a density range. Tensile strength measurements range from 550 to 1100 MPa. Finally, it had an elastic modulus that ranged from 69,000 MPa to 150,000 MPa. The use of composites in this application has both benefits and drawbacks. The ability to reduce weight while maintaining good strength is one of the benefits. Additionally, it resists corrosion and wear. A composite mechanical behavior can be customized to meet the needs of a client or an application because of how it was manufactured. As a result, it can be used in applications where it is necessary to have two opposing features without surrendering any of them. The creation of composites is expensive, not always environmentally benign, and has a poor reusability rate as drawback (Table 2).

6 Finite-Element Modeling of Prosthetics and Orthotics

The performance of orthoses and prostheses can be predicted with great value using finite-element models. A paradigm that took the size and orientation of orthoses into account has been proposed by researchers. This substructure showed the dimensional precision of additive manufacturing but did not include biomechanical design optimization. In order to properly adjust and forecast the biomechanical properties of a passive-dynamic ankle–foot orthosis, a novel virtual functional prototyping procedure was created. It consists of finite-element model and digital model construction. The performance of the design was then evaluated after it was FDM-fabricated using medical-grade polycarbonate. The manufacturing precision, dimensional accuracy, and bending stiffness were all judged to be satisfactory. Instead of a structured procedure, this method was a collection of technologies. Any kind of surface form

Table 2 Summary of current prosthetics and orthosis materials

Materials	Advantages	Disadvantages
Wood	• It is renewable and having adequate strength to weight ratio • It does not undergo corrosion and is visually appealing	• Wood exhibits variable qualities
Metal and leather	• It is having high tensile strength and exhibits sufficient tear resistance • It is also having good heat insulation properties • It also comes in a customizable design	• Hazardous chemical wastes are created during the process of manufacturing • It has negligible biodegradability • It is overweight • It is having low visual value • Substantial energy is spent in fabricating them
Plastics	• It is simple to mold and speeds up manufacturing • Insignificant heat and electricity conduction ability • It is inflammable • It is having corrosion resistant properties • It is lightweight and strong	• It may result in excessive perspiration and foul odor • It is unbreakable and contributes to environmental degradation • The creation of hazardous gases during orthosis manufacturing is undesirable
Carbon fiber composite	• It exhibits good strength to weight ratio • It portrays substantial aesthetic value • It portrays fatigue resistance • It is corrosion resistant	• Involves high production cost and low rate of reusability • The design and manufacturing time is very extensive

imaging or scanning should work with the image processing and scanning package. For data with intricate inner structures, such as computerized tomography, electromagnetic resonance imaging, and acoustics, as well as point cloud surface data, such as photogrammetry, photogrammetry, and millimeter wave, geometric reconstruction would be acceptable. Based on the image processing and scanning data, the 3D geometry of the afflicted body part is recreated, and then a physical model of the prototype prosthetic is created. To create the initial design model, computerized manipulation based on the prosthetist's experience and fundamental design concepts is used. Models of the affected body part and the initial prosthetic design are further evolved into finite-element models and combined to simulate wearing and movement activities. For patient fitting and measurement trials, a realistic model of the prosthesis or orthosis' original design is used. Measurements of the biomechanical factors, such as the contact surface, contact pressure, shear force, temperature, and humidity, must be made during the experiments.

Motion analysis is done on people wearing orthoses or prostheses to assess kinetic and kinematic behavior in order for subsequent computational simulation and the creation of perimeter and load application conditions. The finite-element models

are validated by comparing measurements taken at the contact interface with the outcomes of the computer analysis. In addition to the perimeter conditions, loading, and validation conditions that were obtained from the tests, the computer analysis also requires input from the biomechanical properties. Whenever the material for the design is confirmed, the product's material attributes are established. In the study of biomechanics, tissue attributes, particularly those of muscular tissues, present a problem. The mechanical characteristics of soft tissues can be measured in vivo using an ultrasound indentation device, which is simple and rapid to use. The inner workings of the body, contact behavior at the contact region, and biological details of a prosthesis or orthosis can all be learned through computational simulation. These numbers, along with the characteristics measured throughout the experiments, would be reviewed and compared in order to discover unjustifiable performance, such as stress distribution, excessive loading in a loading-sensitive spot, or limited deformation during motion. The model representing the basic design of the prosthesis or orthosis would undergo structural or material alteration if the finite-element analysis anticipated overall performance that was unrealistic. The next finite-element model would then be again meshed and assembled with the model of the affected human body part, and the same procedures would be repeated until the parameters indicate an acceptable and gratifying overall performance. Digital modification would be applied to the particular area, followed by the revised meshing, modified assembly, and movement simulation, if the results of the finite-element analysis only show specified illogical behavior, such as stress concentration in a local area. Finite-element simulation can react to such model changes quickly. The augmentation cycle would be continued until all investigated parameters of the computational prediction showed reasonability and were congruent with experimental data. Topology maximization would be used to redistribute materials such that the products would be lighter while still meeting the required strength (Fig. 5).

7 Neural Prosthetics and Signal Processing

By converting cortical cerebral activity into measurable signals, a new family of prosthetics aims to enable command by computers, prosthetic arms, and paralyzed upper-limbs. Only after the anticipated quality of life gain overcomes the possible dangers are neural prosthetic devices clinically viable. Internal body, electrode-based techniques have emerged as a key area of research because they offer much clearer signal quality and the promise for enhanced performance compared to exterior body options. Noninvasive techniques are appealing because of their lower surgical risk. For instance, the most advanced electrode-based system now used in laboratories can transport information at a rate of 6.5 b/s, which is far higher than previous invasive and noninvasive systems. However, intrusive approaches come at a high price and higher surgical risk. Congenital prosthetics based on sensors are therefore now a substantial strategy, with possible near-term applications being restricted to only the most seriously injured patients. It will be necessary to balance performance,
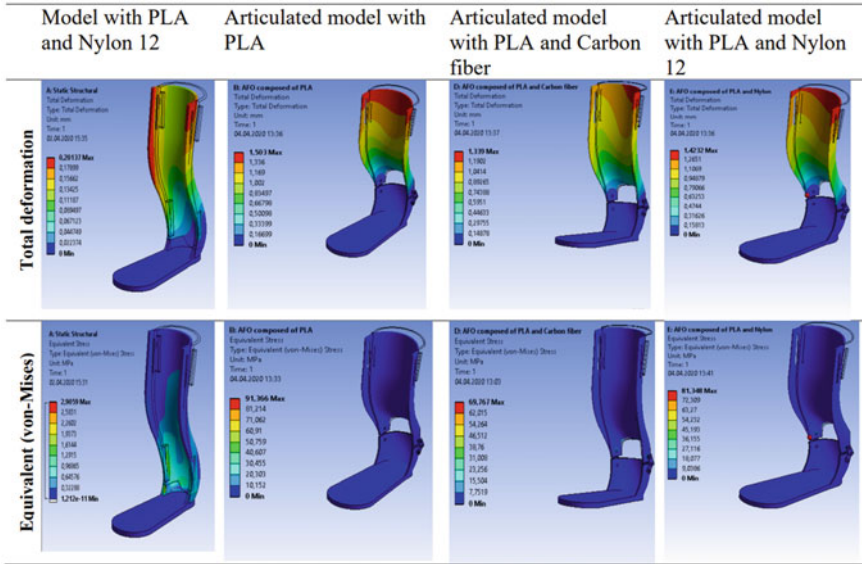
Fig. 5 Simulation results for the conventional and articulated AFO model [32], CC-BY-4.0

risk, and cost by raising total bionic performance and lowering operative risk and device cost through system integration in order to go from research to mainstream usage [33, 34]. The performance of the prosthesis is enabled by high-quality brain signal monitoring and sophisticated signal processing techniques, including rigorous real-time action potential identification (peak sorting) and probabilistic movement decoding algorithms. These methods differ from others in that they can extract more distinct neurons with greater accuracy during the spike identification process, and they can incorporate more neural activity during the decoding phase while doing it more effectively. It is believed that with additional advancements in brain measuring and signal processing techniques, >10 b/s systems would be feasible. While not always the most accurate representation of a clinical setting, equipment-intensive, laboratory-based trials in which a controlled subject completes a strictly regulated task while being watched by a research scientist are a potent experimental platform. Clinical systems must be independent and able to recognize patient responses, specifically if neural activity genuinely reflects the desired movement, based solely on that neural activity. They cannot rely on trained operators or external control. Furthermore, rather than merely during the brief, distinct daily recording intervals utilized in present experimental techniques, prosthetic systems must offer these capacities reliably and constantly (24 h per day, every day). Unsupervised learning-based spike sorting algorithms eliminate the need for an expert operator and have the potential to produce robust, adaptable algorithms that can react on their own to changes in the brain recordings. Similar to this, decoding algorithms that automatically recognize

neural states (whether movement is intended or not) do away with the requirement for outside cues to pinpoint times when significant neural activity is occurring.

By enabling system integration and getting rid of persistent transcutaneous linkages, prosthetic systems need to lower the risk of surgery and device costs. The ultimate goal is an implantable system with electrodes, wireless telemetry, digital post-processing, and cutting-edge functionality in a self-contained container with a significantly reduced size and no chronic tissue holes. However, in this method, a very constrained power budget must be followed for signal collecting and processing. A significant difficulty is the transmission of brain information away from the electrode implantation site. Current wireless networks can provide the necessary bandwidth, but their high power requirements make them impractical. It is imperative to reduce bandwidth in some way. There are several ways to accomplish this reduction, but many of them use lossy compression, which can compromise the performance of prosthetics. High performance signal processing methods can be employed to lower the necessary bandwidth by a factor of 106 in the implanted system while still meeting power requirements, with the aim of not sacrificing any prosthetic performance. Signal processing engineers face a difficult design problem due to the confluence of stringent power limits, aggressive performance goals, and demands for resilience and autonomy. New algorithms and implementations will be required in the future.

8   Chronic Electrode-Based Prostheses

Figure 6 depicts the fundamental design of motor and communicative prostheses (a). While communicative prostheses try to create an interconnecting route similar to "typing" on a computer, motor prostheses strive to restore neurological control to the paralyzed limb. A sample of these estimate (decoding) algorithms is illustrated in Fig. 6, and they leverage the link between such a motion and the neural response (tune) to produce the desirable output from just the brain activity. After that, the system can generate the requisite control signals to continuously move a paralyzed or bionic arm in space (arm prosthesis) or position a computer cursor over the necessary key on a computer (communication prosthesis). The plan activity, which is active from shortly after the reach objective is established until just before the movement starts, is specific to the movement's target. Movement activity, on the other hand, is present from just after the movement begins. Almost all of the neural activity detected in the motor and dorsal premotor (PMd) cortex is spiking activity. Although the local field potential has been demonstrated to be able to anticipate the direction of movement in other cortical regions, its function in M1 and PMd is still unknown. Communication prosthesis can be driven by decoding this information; they simply have to estimate the movement terminus. As the intended movement is to be replicated, the motor prosthesis must have movement activity. However, a planned activity can contribute to motor prosthesis by giving a priori information, such as a target estimation, that limits movement estimation.
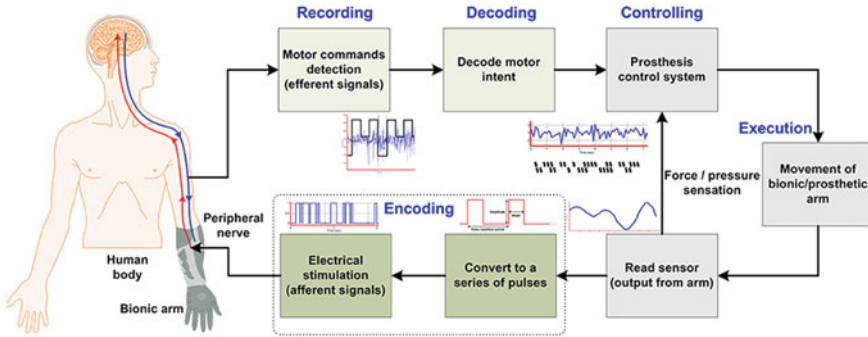
Fig. 6 Concept of bi-directional control for bionic arm systems [35], CC-BY-4.0

9 Application of Machine Learning in Prosthetics

For those who have had amputations, upper-body prosthetics are intended to replace bygone hand and related arm functions. The upper-body is complicated in structure and can make coordinated motions across numerous ways of freedom, making it difficult to recreate dexterous hand function. These ways include finger joint movements, forearm extension, and more. Robotic devices (equipped with actuators, circuits, and control systems) known as "myoelectric prostheses" are intended to imitate the movement and functionality of a biological arm and hand. A specially made socket is used to attach the bionic device to a user's remaining body appendages. Surface electrodes in the socket pick up EMG signals when the user actively contracts specific muscles in the residual limb. These muscle signals are then sent to the prosthetic controller, which filters the raw data, extracts signal features from them, and uses signal processing techniques and a control algorithm to identify the intended movement. The resulting control signals are then converted to electrical signals, and the device motors execute the commands. People with upper-limb amputations now have hopeful restorative movement alternatives thanks to years of developments in signal-actuated prosthetic control. However, there are several major limits to the accurate practical deciphering of motion intent from EMG signals, and it is still difficult to achieve accurate and natural prosthesis control. Customary myoelectric prosthesis control strategies can be broadly divided into two categories: 1) on/off, which allows for the binary closing and opening of a hand when EMG signals direct the triggering potential, or 2) quantifiable, which regulates the velocity of the opening and closing of a hand and enables much smoother movement control. With each of these standard strategies, the contraction of two distinct residual muscles normally initiates the "hand open" and "hand close" movements (with two different electrodes used to detect these opposing actions). Therefore, the activation of extra residual muscles is required to regulate additional joint movements. The amount of distinct muscle impulses in a user's remaining limb that can control each DOF limits the robustness of the on/off and proportional control techniques. Given that

modern upper-part myoelectric prosthetics often offer higher DOF than the number of separate EMG signals that a device user may create, this constraint poses an operating problem. Additionally, to this restriction, the intrinsic unpredictability in EMG signals might result in inconsistent prosthesis control and unintentional movements of the prosthesis. Modifications in the user's limb posture, variations in the force of the muscle contractions, weariness, ambient conditions, humidity, electrode movement, as well as other within-/between-day changes can all cause variations in EMG signals. Despite giving users functional dexterity, traditional myoelectric prosthesis control algorithms do not yet enable physiologically normal upper-limb movements.

Since the 1970s, upper-body part prosthetic scientists have been looking into the use of EMG signal-actuated machine learning methods to enable more flexible and intuitive myoelectric device control. Due in major part to developments in signal processing techniques, cognitively capable processors, and improved battery technology, these algorithms have shown promise in terms of enhancing prosthesis control accuracy and user friendliness. However, due to their alleged lack of resilience, devices that use algorithms for machine learning are frequently not deployed in clinical settings. To get over this restriction, prosthesis researchers are still looking into different EMG signal-driven device control mechanisms. The majority of available commercially upper-body part myoelectric devices employ an open-circuit control technique, in which the device is unable to be responsive to its surroundings. However, due to their alleged lack of resilience, devices that use machine learning programs are frequently not deployed in clinical settings. To get over this restriction, prosthesis researchers are still looking into different EMG signal-driven device control methods. The majority of upper-body part myoelectric devices that are commercially available employ open-loop control techniques, in which the device is not given feedback from its surroundings. Instead, after purposefully tightening a muscle in the remaining limb to begin and maintain control of the device's movement, a user is left to rely solely on optical feedback. Raw EMG signals are produced as a result of the electrical potentials created by this contraction. Typically, these signals are altered at a steady alteration between 200 and 1,000 Hz (depending on the category of EMG electrodes attached in the prosthetic socket). After that, the raw signals are analyzed, which involves cleaning and feature extraction. In order to make upper-limb prosthesis controls more "intelligent," or able to anticipate users' intended actions, machine learning is applied in the design of these controls. Researchers working on myoelectric prostheses presently employ a variety of machine learning techniques (based on concepts from statistics and computer science) to create more user-friendly device controls. Each technique calls for the creation of a systematic model that may be implemented to foretell the prescribed device movements using EMG signals recorded while wearing a prosthesis. As a result, a model acts as a tracing function that can convert Neuromuscular input signals from electrodes to instructions for a device's motor.

10 Conclusion

This chapter gives us an overview to the design and fabrication advances in prosthetics and orthotics. The different steps involved in fabricating a prosthetic such as creation of the three-dimensional model to the rapid prototyping operation of actually making the prosthetic part for the patient have been highlighted here. The different materials employed for making orthotics and prosthetics have also been discussed. Towards the end of the chapter, new age prosthetics such as neural prosthetics have been covered, and how they will affect patients with disability. Additionally, the application of machine learning in prosthetics has been touched briefly.

References

1. Wang Y, Tan Q, Pu F, Boone D, Zhang M (2020) A review of the application of additive manufacturing in prosthetic and orthotic clinics from a biomechanical perspective. Engineering 6(11):1258–1266. https://doi.org/10.1016/J.ENG.2020.07.019
2. Berke GM et al (2010) Comparison of satisfaction with current prosthetic care in veterans and servicemembers from Vietnam and OIF/OEF conflicts with major traumatic limb loss. J Rehabil Res Dev 47(4):361–372. https://doi.org/10.1682/JRRD.2009.12.0193
3. Totah D, Kovalenko I, Saez M, Barton K (2017) Manufacturing choices for ankle-foot orthoses: a multi-objective optimization. Procedia CIRP 65:145–150. https://doi.org/10.1016/J.PROCIR.2017.04.014
4. Yan Q et al (2018) A review of 3D printing technology for medical applications. Engineering 4(5):729–742. https://doi.org/10.1016/J.ENG.2018.07.021
5. Weller C, Kleer R, Piller FT (2015) Economic implications of 3D printing: market structure models in light of additive manufacturing revisited. Int J Prod Econ 164:43–56. https://doi.org/10.1016/J.IJPE.2015.02.020
6. Brier B, Vinh P, Schuster M, Mayforth H, Johnson Chapin E (2015) A radiologic study of an ancient egyptian mummy with a prosthetic toe. Anat Rec 298(6):1047–1058. https://doi.org/10.1002/AR.23135
7. Bisaccia M, Ao LM, Pio S, Rinonapoli G, Colleluori G (2016) The history of external fixation, a revolution idea for the treatment of limb's traumatized and deformities: from hippocrates to today supracondylar fractures of the humerus, Gartland 3: pediatric urgency. Case report and leterature review. View project c
8. Shahar FS et al (2019) A review on the orthotics and prosthetics and the potential of kenaf composites as alternative materials for ankle-foot orthosis. J Mech Behav Biomed Mater 99:169–185. https://doi.org/10.1016/J.JMBBM.2019.07.020
9. Prosthetics and Orthotics : Lower Limb and Spinal | Download file Author : Ron Seymour Pages : 540 pages Publisher : Lippincott Williams and Wilkins Language : English, p 13 (2002)
10. Au SK, Weber J, Herr H (2009) Powered ankle-foot prosthesis improves walking metabolic economy. IEEE Trans Robot 25(1):51–66. https://doi.org/10.1109/TRO.2008.2008747
11. Martinez-Villalpando EC, Mooney L, Elliott G, Herr H (2011) Antagonistic active knee prosthesis. A metabolic cost of walking comparison with a variable-damping prosthetic knee. Proc Annu Int Conf IEEE Eng Med Biol Soc EMBS, pp 8519–8522. https://doi.org/10.1109/IEMBS.2011.6092102
12. Chuang CH, Ko LW, Lin YP, Jung TP, Lin CT (2014) Independent component ensemble of EEG for brain-computer interface. IEEE Trans Neural Syst Rehabil Eng 22(2):230–238. https://doi.org/10.1109/TNSRE.2013.2293139

13. Tucker MR, Olivier J, Pagel A, Bleuler H (2015) Control strategies for active lower extremity prosthetics and orthotics: a review. J NeuroEngineering Rehabil 12:1. https://doi.org/10.1186/1743-0003-12-1
14. Tang L et al (2019) Functional gradient structural design of customized diabetic insoles. J Mech Behav Biomed Mater 94:279–287. https://doi.org/10.1016/J.JMBBM.2019.03.003
15. Diwakar M, Kumar M (2018) A review on CT image noise and its denoising. Biomed Signal Process Control 42:73–88. https://doi.org/10.1016/J.BSPC.2018.01.010
16. Haleem A, Javaid M (2019) 3D scanning applications in medical field: a literature-based review. Clin Epidemiol Glob Heal 7(2):199–210. https://doi.org/10.1016/J.CEGH.2018.05.006
17. Chua C, Meng CS, Ching LS, Teik LS, Aung SC (2000) Facial prosthetic model fabrication using rapid prototyping tools. Integr Manuf Syst 11(1):42–53. https://doi.org/10.1108/09576060010303668/FULL/PDF
18. Mavroidis C et al (2011) Patient specific ankle-foot orthoses using rapid prototyping. J Neuroeng Rehabil 8(1):1–11. https://doi.org/10.1186/1743-0003-8-1/FIGURES/10
19. Ciobanu O, Ciobanu G, Rotariu M (2013) Photogrammetric scanning technique and rapid prototyping used for prostheses and Ortheses Fabrication. Appl Mech Mater 371:230–234. https://doi.org/10.4028/WWW.SCIENTIFIC.NET/AMM.371.230
20. Lantada AD, Morgado PL (2012) Rapid prototyping for biomedical engineering: current capabilities and challenges 14:73–96. https://doi.org/10.1146/annurev-bioeng-071811-150112
21. Thompson MK et al (2016) Design for additive manufacturing: trends, opportunities, considerations, and constraints. CIRP Ann 65(2):737–760. https://doi.org/10.1016/J.CIRP.2016.05.004
22. Kruth JP (1991) Material incress manufacturing by rapid prototyping techniques. CIRP Ann 40(2):603–614. https://doi.org/10.1016/S0007-8506(07)61136-6
23. Paterson AM, Bibb R, Campbell RI, Bingham G (2015) Comparing additive manufacturing technologies for customized wrist splints. Rapid Prototyp. J. 21(3):230–243. https://doi.org/10.1108/RPJ-10-2013-0099/FULL/PDF
24. Herbert N, Simpson D, Spence WD, Ion W, A preliminary investigation into the development of 3-D printing of prosthetic sockets 42(2):141–146. https://doi.org/10.1682/JRRD.2004.08.0134
25. Schrank ES, Stanhope SJ (2011) Dimensional accuracy of ankle-foot orthoses constructed by rapid customization and manufacturing framework. J Rehabil Res Dev 48(1):31–42. https://doi.org/10.1682/JRRD.2009.12.0195
26. Deckers JP, Vermandel M, Geldhof J, Vasiliauskaite E, Forward M, Plasschaert F (2017) Development and clinical evaluation of laser-sintered ankle foot orthoses 47(1):42–46. https://doi.org/10.1080/14658011.2017.1413760
27. The 16th National Day on Biomedical Engineering
28. EBSCOhost | 17191301 | A preliminary investigation into the development of 3-D printing of prosthetic sockets
29. Saijo H et al. (2009) Maxillofacial reconstruction using custom-made artificial bones fabricated by inkjet printing technology. J Artif Organs 123, vol 12(3):200–205. https://doi.org/10.1007/S10047-009-0462-7
30. Lee Ventola C (2014) Medical applications for 3D printing: current and projected uses. Pharm Ther 39(10):704
31. Barrios-Muriel J, Romero-Sánchez F, Alonso-Sánchez FJ, Salgado DR (2020) Advances in orthotic and prosthetic manufacturing: a technology review. Materials (Basel) 13(2):295. https://doi.org/10.3390/MA13020295
32. Ali MH, Smagulov Z, Otepbergenov T (2021) Finite element analysis of the CFRP-based 3D printed ankle-foot orthosis. Procedia Comput Sci 179:55–62. https://doi.org/10.1016/J.PROCS.2020.12.008

33. Santhanam G, Ryu SI, Yu BM, Afshar A, Shenoy KV (2006) A high-performance brain–computer interface. Nat 4427099, 442(7099):195–198. https://doi.org/10.1038/nature04968
34. Wolpaw JR, McFarland DJ (2004) Control of a two-dimensional movement signal by a noninvasive brain-computer interface in humans. Proc Natl Acad Sci USA 101(51):17849–17854. https://doi.org/10.1073/PNAS.0403504101/SUPPL_FILE/03504MOVIE1.MOV
35. Ghafoor U, Kim S, Hong KS (2017) Selectivity and longevity of peripheral-nerve and machine interfaces: a review. Front Neurorobot 11:59. https://doi.org/10.3389/FNBOT.2017.00059/BIBTEX