Journal Pre-proof

A critical review of 3D printed orthoses towards workflow implementation in the clinical practice.

Nashmi H. Alrasheedi, Mehdi Tlija, Nessrine Elloumi, Borhen Louhichi

PII: S2307-1877(24)00025-7

DOI: https://doi.org/10.1016/j.jer.2024.01.024

Reference: JER100340

To appear in: *Journal of Engineering Research*

Received date: 11 October 2023
Revised date: 21 December 2023
Accepted date: 29 January 2024

Please cite this article as: Nashmi H. Alrasheedi, Mehdi Tlija, Nessrine Elloumi and Borhen Louhichi, A critical review of 3D printed orthoses towards workflow implementation in the clinical practice., *Journal of Engineering Research,* (2024) doi:https://doi.org/10.1016/j.jer.2024.01.024

A critical review of 3D printed orthoses towards workflow implementation in the clinical practice.

Nashmi H. Alrasheedi[1], Mehdi Tlija[2], Nessrine Elloumi[3], Borhen Louhichi[1,4]

[1] Department of Mechanical Engineering, College of Engineering, Imam Mohammad Ibn Saud Islamic University (IMSIU), Riyadh 11432, Saudi Arabia

[2] Department of Industrial Engineering, College of Engineering, King Saud University, Riyadh 11421, Saudi Arabia

[3] SETIT, ISBS, University of Sfax, Sfax 3000, Tunisia

[4] Mechanical Laboratory of Sousse, University of Sousse, Sousse 4000, Tunisia

Corresponding author

Borhen Louhichi, blouhichi@imamu.edu.sa, +966 55 355 6733

Key words

Design; 3D Printing; Reverse Engineering; Orthoses; Biomedical Applications.

Funding

The authors extend their appreciation to the Deanship of Scientific Research, Imam Mohammad Ibn Saud Islamic University (IMSIU), Saudi Arabia, for funding this research work through Grant No. (221414010).

Abstract

The modern manufacturing industry is investing in new technologies to enhance production performance, expand information communication, and gain competitive advantages in the global market. Since the advent of 3D-printing technology, the integration of 3D-printed orthoses into current clinical practice has been hindered and delayed by several factors, including the high cost of the equipment, the absence of appropriate software and scanning tools, and the lack of highly

skilled clinicians. Recent scientific progress has been investigated in the circumvention or even elimination of some technological barriers to accelerate the implementation of orthoses in hospital practices. The overcoming of remaining obstacles and the refinement of the manufacturing workflow for orthotic devices require the identification of further improvement areas. This paper presents a review of modern designs and production workflows of 3D-printed orthoses. A short research classification according to the area of interest and a time production synthesis are presented to follow the workflow evolution during the last decades. This research work aims to assist in catalyzing more in-depth investigations and research efforts to accelerate and expand the implementation of 3D-printed orthoses in clinical practices.

1. Introduction

The most important functions of an orthosis are alignment, biomechanical function (movement), weight support, and protection [1, 2]. There is a large variety of orthosis designs aiming to achieve distinct therapeutic purposes. This study is limited to the case of static fixation of human organs. Traditional orthoses boast a well-established track record for effectively addressing musculoskeletal and neuromuscular conditions. Widely accessible, they offer a diverse range of options for patients through healthcare providers. Crafted from materials like thermoplastic and leather, their cost is relatively affordable. Clinicians are adept at applying and adjusting these devices, ensuring efficient and familiar patient care. The traditional process of manufacturing customized orthoses is established manually depending on orthotic technician skills [3]. The manual activities consist of a plaster cast-based anthropometric measurement; orthosis construction-based manual layering of thermoplastic and other materials, and manual shaping of orthosis socket. Delivery time, cost, and quality of product are the major weaknesses of the process. These orthoses are typically given to patients in separate appointments for initial evaluation, measurement, modification, and final supply, each of which takes about 40 minutes in a complex case [4]. In addition, the storage of equipment in clinic warehouses generally does not exceed two months given the constraint of storage space. For patients who need annual refitting, or the device rebuilt, the whole manufacturing process is re-executed since the splint is non-removable. The traditional splint can cause patient discomfort due to the device's heavyweight, bad air circulation (unventilated), keeping dry requirement, and cutaneous, muscle, joint, and vascular complications [5–7]. Aesthetically, the above traditional orthoses may not meet modern standards, impacting patient confidence in public settings. Cock-up splint was widely used to hold the hands and wrists in a single position and immobilize the wrist joint for restriction of motion during recovery from wrist harm [8]. The manufacturing process of cock-up splint comprises the putting of a paper towel under the hand/forearm, sketching an outline of the hand and forearm, cutting out the drawing, tracing the pattern on the orthosis material as plastic thermoplastic or plastic-coated malleable aluminum [9], heating the material, manually molding, and trimming the orthosis according to the shape of the patient organ, etc. The device is relatively heavy and usually causes the hand to sweat. The manufacturing process presents a safety risk, material waste, and poor accuracy, especially during the edge-cutting step [10]. Also, a different workflow is used to produce orthoses including the manufacturing of a patient-custom wood mold used in a vacuum thermoforming of 4 mm heated thermoplastic (as polypropylene (PP)) sheet [11]. A manual trimming step is required for patient fitting, and it is a time-consuming process [12]. Prolonged use of cock-up splint materials may also lead to skin irritation or pressure sores, compromising patient comfort [13]. The splint bulkiness and weight can lead to discomfort and reduced compliance, particularly for long-term wear. The are several alternatives to the above solutions, such as braces made of different materials: soft foam material [14], swelling and atrophy material (EXOS ®) [15], and soft microfiber [16]. However, despite design improvements, the prefabricated orthoses sometimes fail to correctly fit the patient's anatomy and cause patent discomfort, especially in the case of night use [17]. Indeed, mass-produced options may lack the level of customization required for individual patients, potentially resulting in suboptimal fit and effectiveness [18]. Traditional orthoses may be limited in functionality by their lack of advanced features, such as the capability to facilitate access to therapeutic windows.

Over the past few decades, the integration of 3D-printed orthoses in biomedical applications has emerged, strategically targeting the shortcomings associated with traditional and commercially available orthotic solutions mentioned earlier. This evolution has been primarily fueled by the intrinsic capabilities of the 3D printing process, enabling the creation of highly customized orthotic devices precisely tailored to individual anatomy. This not only ensures superior comfort and fit but also facilitates the development of intricate and sophisticated orthotic designs. The rapid prototyping feature further expedites adjustments, enhancements, and patient-specific modifications in orthotic design. Nevertheless, the advent of additive manufacturing has brought forth certain limitations. These include material restrictions that may potentially impact the overall strength and durability of the orthosis, a time-consuming nature, limited accessibility in certain healthcare settings, and the necessity for high skills, influencing the reliability of the process in medical practices. Additionally, challenges such as suboptimal product quality and surface finish can adversely affect patient comfort. In response to these limitations, ongoing research endeavors have delved into refining workflows by exploring alternative technologies for key steps, including data acquisition, 3D solid reconstruction, design specifications, and product analysis. This concerted effort aims to overcome the challenges associated with 3D-printed orthoses, fostering advancements in both technology and medical applications.

In the research track of static orthosis production, the enclosure of the four steps in a research work represents the inclusion criteria of the present paper. Among more than two hundred publications, only manuscripts that complied with the inclusion criteria were included in the in-depth review. The keywords representing improvements in the workflow step are shown in the following.

- Data acquisition: procedural process, assistive device enhancing process accuracy and patient comfort, etc.

- 3D solid reconstruction: design parameterization, reconstruction procedure automation, avoidance of 3D reconstruction, etc.
- Design specifications: material selection, lightweighting, topology optimization, etc.
- Product Analysis: gait analysis, mechanical behavior simulation, preclinical tests, etc.
- Manufacturing process: layer thickness, printing speed, hybrid process, manufacturing time and cost, etc.

Section 2 shows the diversity of orthosis designs and the concept's ability to support complex features and specifications. In Section 3, a review of production methodologies is investigated demonstrating alternative workflows. In Section 4, a discussion shows the research efforts and challenges for a smooth integration of 3D-printed orthosis in daily clinical practice. In the end, a conclusion is presented.

2. 3D Printed Orthoses in Biomedical Applications

The emergences of 3D scanning [19] and 3D printing technologies yielded the establishment of modern processes able to address the need for custom devices in medical applications, such as surgical lower jaw templates [20], customized split insoles [21, 22], facemasks [23, 24], central nervous system structures [25], bio-printed viability cells and tissues [26–28], orthopedic prostheses and orthoses [29–31]. When considering the design specifications, the increased design freedom and customization capabilities of 3D printed devices enhance their performance in comparison to traditional splints [32, 33]. Different classifications of orthoses in biomedical applications obtained by 3D printing are found in the research literature [31, 34–36]. Common orthoses can be classified as upper limb, lower limb, and cervical orthoses. In the following, a non-exhaustive list of orthosis designs is shown highlighting the 3D-printed device's ability and flexibility to support improvements in customization, innovation, comfort, and aesthetics.

2.1. Upper limb orthosis

Upper limb orthoses are externally applied devices that fix structural characteristics of the nervous and musculoskeletal systems and help restore or improve function [37]. Palousek et al. designed a 3D printing of custom-made Wrist-Hand Orthosis (WHO) [38]. For the patient’s comfort and safety and better device fixation, the orthosis was designed with Velcro straps, an eyelet in the area between the forefinger and thumb, two air vents, and rounded outline edges (Figure 1 (a)). In addition, a prosthesis interlayer between the brace and limb is designed for comfort during wear. The mechanical properties of layered Acrylonitrile Butadiene Styrene (ABS) plastic measured using the tensile and bending tests confirmed the suitability of the material for the studied biomedical application. The design proposed by Kim and Jeong. consists of an assembly of two parts [39]. A cover made of polycarbonate material serves to shield the injured organ (Figure 1 (e)). An inner part fabricated with ABS material aiming to best fit the patient hand. The orthosis is designed with a porous pattern yielding a total weight of 113 g. Choi et al. suggested a 3D-printed flat and thermoformed WHO [10]. The device is an open-work model (Figure 1 (b)). There is no specification about the used plastic type. Compared to the device obtained by the 3D scanning method, the proposed orthosis was evaluated as more durable, comfortable, effective, and with better service delivery. Guida et al. designed a device with two shells and openings and manufactured with recyclable material (ABS with polycarbonate) guaranteeing lightness, water-proof, and stiffness and allowing better skin visualization and ventilation [40]. The orthosis weight and cost are 120g and 13€, respectively (500g and 10€ for conventional plaster cast). Górski et al. proposed 3D-printed customized wrist-hand orthosis [41, 42]. The device design is based on the idea popularized by J. Evill [43]. In the experimental investigation, four materials are used for device printing: ABS, polylactide (PLA), nylon (PA12), and high-impact polystyrene (HIPS). Two printing orientations, horizontal and vertical, and three strategies (different layer thickness and infill density) are used in material building. The experimental results show that the production system with recommended manufacturing parameters fulfills economic and strength criteria. PLA material and economy strategy (15% infill, 0.3 mm layer thickness) are selected as default parameters (Figure 1 (d)). The vertical part orientation is recommended for better accuracy and surface quality, and the horizontal part orientation for better strength. The cost of selected orthosis is approximately 30$ (40% of the cost of an equivalent commercial product). Popescu et al. developed a design for hybrid WHO [44]. The device material is PLA for the rigid splint (3mm thickness) and a layer of medical-grade silicone (1mm thickness) on the side in contact with patient skin to avoid pressure ulcers. Two design variants, hexagonal and diamond-shaped pockets, are proposed. Figure 1 (c) shows the WHO design with diamond-shaped patterns. Production times and costs are computed for four production scenarios, such as design variants, simple and hybrid orthosis designs, and fast and normal prints. The cost ranges from 1.68$ for the simple diamond split to 15.10$ for the hybrid hexagonal splint. Poier et al. proposed a similar WHO design including a PLA rigid part, a Thermoplastic polyurethane (TPU) flexible part, and TPU fastening strips [45]. The material and manufacturing costs of rigid, flexible, and fastening components are 4.07$, 2.38$, and 1.04$ respectively.

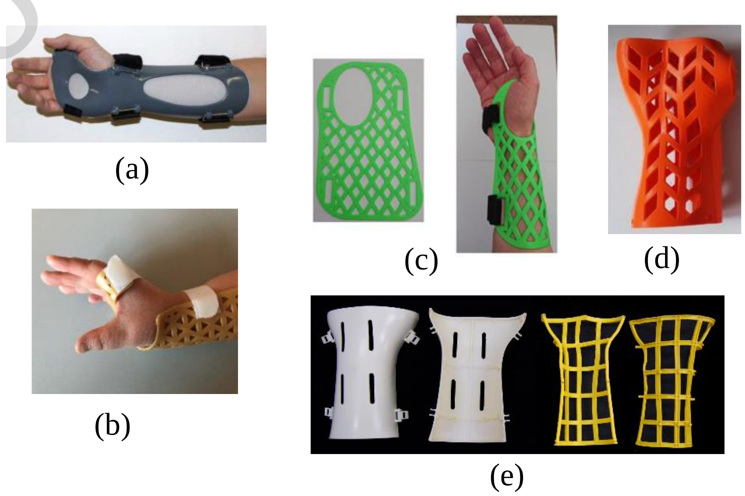


Figure 1 WHO designs in (a) Palousek et al. [38], (b) Choi et al. [10], (c) Popescu et al. [44], (d) Górski et al. [42] (e) Kim and Jeong [39].

2.2. Lower limb orthosis

Lower limb orthoses are external biomechanical devices and mainly include Ankle Foot Orthosis (AFO), Knee Orthosis, and Knee Ankle Foot Orthosis (KAFO). These devices enable the stabilization of the joints of the lower limb and improve the physical functioning of the affected lower limb and are designed according to specific biomechanical needs [18]. These orthoses are either passive or active. The active orthoses include actuators to assist the movements at the ankle joint [46]. The present study concerns the passive type. These passive orthoses are commonly classified into solid and dynamic according to the biomechanical purpose [47, 48]. Mavroidis et al. proposed two AFOs fabricated using the Viper SLA machine [3]. The first is a rigid AFO manufactured with the Accura 40 resin (Figure 2 (a)). The second is a flexible one fabricated using DSM Somos 9120 Epoxy Photopolymer. A gait analysis was conducted to compare the effectiveness of two-3D printed AFOs with a prefabricated one (the Type C-90 Superior Posterior Leaf Spring from AliMed). The analysis gait parameters comprise spatiotemporal, kinematics, and kinetics parameters of the hip, ankle, and knee of each leg in the sagittal plane. The proposed AFOs match the performance of the prefabricated polypropylene design. Santos et al. compared four alternative designs of customized knee positioning orthosis [49] (Figure 2 (b)). The user's comfort-based assessment method guided the selection of the fourth design. The design is modified progressively according to the clinical needs and patient feedback. The first design satisfies the need to stop the device from bending and being easy to wear and remove. The second concept yielded comfort, volume, and weight improvements. The third orthosis allows for the prevention of bending, decreased weight, and enhanced stability. The last alternative design is better for valgus deviation. In [50], the AFO design includes a flexible inner layer and a sub-assembly of three rigid outer parts made by FilaFlex and Polycarbonate, respectively. The splint includes openings designed for therapeutic purposes (the incorporation of the needed elements and accessories to permit the application of physiotherapy techniques and the visual inspection of the state of the wounded area) and device lightweighting. One of the rigid parts is a disassembled cover allowing access to therapeutic windows. Steck et al. focused on the use of Fiber-Reinforced PETG-CF15 for FDM printing of AFO [51]. The orthosis design, lightweighting, and comfort were improved through a topology optimization approach. The mechanical performance was validated through FEA and the gait analysis was limited to numerical simulations.

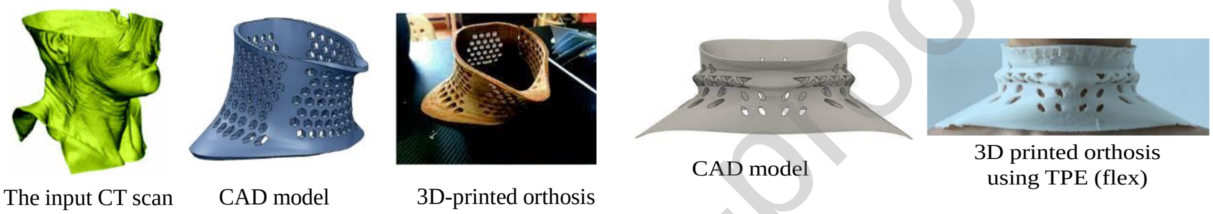
Rigid Flexible

(a) (b)

Figure 2 (a) AFO designs in [3], (b) KO designs in [49].

2.3. Cervical orthosis

Cervical orthoses are used when the rehabilitation from whiplash-like injuries, fractures, or surgical fusion necessitates immobilization [52]. Ambu et al. suggested a design of a customized neck orthosis [53] (Figure 3 (a)). After the reconstruction of the 3D model from Computerized Tomography (CT) scan data, an offset relative to the neck surface is attributed to the model to allow the positioning of a soft pad between the orthosis and the neck improving the patient comfort. The device's lightweighting and ventilation are ensured by the addition of an infill honeycomb or elliptical pattern to the CAD model. The model with a honeycomb pattern is selected for 3D printing according to the lightweighting criteria (Figure 3 (a)). A bio-based material, Hemp Bio-Plastic® (HBP) which is composed of PLA and hemp shives, is chosen as printing material due to its mechanical properties (30% more resistant than PLA), lightening advantage (20% lighter than ABS), and hygienic characteristic (antibacterial). The Fused Deposition Modeling (FDM) process is used for prototype manufacturing. Hale et al. designed a bespoke orthosis with Acrylic Styrene Acrylonitrile (ASA) material to satisfy strength and comfort requirements [54]. A reaction-diffusion algorithm and Finite Element Analysis (FEA) yielded to optimize the pockets design ensuring patient comfort and device stiffness and breathability. Sabyrov et al. designed a flexible neck orthosis [55] (Figure 3 (b)). The proposed design improves the model of a conventional rigid split on the market by extending the device support to cover the trapezius muscle and reducing the orthosis thickness to 4mm. Elliptical holes are included in the design for breathability, stiffness, lightweight, and ventilation purposes, as proposed by [53]. The Thermoplastic Elastomer (TPE) flex material was selected for 3D printing to obtain a flexible device. The lower density of flex material contributes to orthosis lightweighting. Thus, the proposed design modifications enhanced the device's comfort and stability. In a subsequent study [56], Ambu et al. refined the design in [53]. Instead of elliptical holes, they employed a Voronoi pattern to enhance neck ventilation and incorporated additional padding for improved patient comfort. Notably, this design modification resulted in a negligible increase in temperature. Sabyrov et al. cited that a convex shape with triangular pattern openings around the center of the device was used in the 1st design to facilitate the swallowing function and prevent neck skin damage caused by the split bending to the inside direction. However, an experimental test proved that the above slot features in the 1st design are useless. A second design was proposed with the extension of the front middle and additional elliptical and rectangular slots. The device's mechanical behavior under applied forces is evaluated using ANSYS software. Xu et al. developed an optimized design for cervical fixation orthosis [57]. The topology optimization contributed to reducing the device weight and ensuring the needed ventilation while respecting the required stiffness. The design includes slots located in the anterior area of the cervical spine allowing swallowing function. These slots with others located in the posterior area guarantee wound care and examination. Design features are added to decrease the fixation impact of the cervical spine in all directions and to improve cervical interbody fusion. The orthosis design is considered acceptable based on the results of the satisfaction questionnaire for one patient.



(a) (b)

Figure 3 Cervical orthosis designed in (a) Ambu et al. (modified from [53]) (b) Sabyrov et al. (modified from [55]).

3. Modern production process workflows

Inspired by the possibilities of freeform design and patient customization facilitated by additive manufacturing [58–60], novel workflows for orthosis production have emerged (Figure 4). These innovative approaches leverage the capabilities of additive manufacturing technologies to create orthoses that are tailored to the specific needs and anatomical characteristics of individual patients. By embracing the design freedom offered by 3D printing, orthosis production workflows have been revolutionized, allowing for the development of personalized and intricately designed orthoses that were previously unattainable with traditional manufacturing methods. These advancements in workflow design have opened new horizons for orthosis production, enabling healthcare professionals to provide enhanced patient care through the utilization of customized and precisely fitting orthotic devices.

Mavroidis et al. developed a computerized technique for fabricating patient-specific AFO [3]. Biomedical engineers digitally shape the customized devices by collecting and processing the 3D scan data (Figure 4 (b)). The human organ scan requires the positioning of the patient. The camera locations affect the data quality. The CAD model rebuilt from scan data allows the printing of the device using Stereolithography (SLA) technology. Using FDM technology, Palousek et al. provided a methodology for the design and manufacture of wrist orthosis [38]. The data acquisition needs only one 3D scan which simplifies and accelerates the whole process. During the data processing, the surface model was smoothed and converted to IGES format. Then, it is transformed into a volumetric model. The CAD model was modified in SolidWorks software. The deviations between the smoothed and the original shape were analyzed and demonstrated that the main function of the devices (the fixation of the position of the wrist and the forearm) is not affected. A similar workflow is presented by Santos et al. for KO manufacturing [49]. The surface reconstruction from 3D scanned images is established using Creaform's VXelements software. Santos et al. mentioned a highly time-consuming scan process. Both SolidWorks® ScanTo3D and Autodesk® MeshMixer are used for CAD model retrieval from surfaces and solid modifications. The concept development approach of Ulrich and Eppinger [61] drove the designs' improvements according to the patient's needs and generated four design candidates. Based on FDM technology, orthoses are split into three parts due to the product's large size and then printed with two materials ABS and TPU Ninjaflex® using Stratasys and Makerbot printers, respectively. The orthosis components are assembled by the gluing process. The manufacturing process could impact the product's strength and stability. Also, Sabyrov et al. designed a neck orthosis based on 3D scans and FDM technologies [55]. The data is acquired by the Sense (2nd generation) 3D scanner while using a sensor device located in a fixed position for better scan accuracy. For the patient's comfort during the scan process, the chair where he is seated is gradually rotated around its axis. The scan data is obtained in STL format, and then the 3D model is reconstructed and modified using Fusion 360 software. TPE (flex) material is used to print the first design. Based on the drawbacks of an experimental test, a second design is developed, and the mechanical behavior assessment is driven by FEA. Blaya et al. designed an AFO with functional features for the rehabilitation of the partial Achilles tendon [50]. The surface is rebuilt from 3D scan data using 3D Systems Geomatic Design X®. The 3D solid is modeled by Rhinoceros 5 software. FDM technology is used for device manufacturing. The orthosis design includes treatment windows allowing the use of physiotherapeutic techniques during the immobilization phase. Thus, further muscular complications that could arise from using traditional retention devices are avoided and the rehabilitation time is reduced by 30% compared to the application of plaster splints. A similar workflow is followed by Guida et al. for the clinical study of the application of 3D-printed orthoses [40]. The statistical analysis of the patient-rated wrist evaluation data and the visual analog scale indicate that the printed device-based treatment improved children's daily activities during immobilization. An Analogous roadmap was adopted by Abdalsadah et al. [62], Steck et al. [51], Fang et al. [63], and Ambu et al. [56] for 3D scanning and printing of AFOs, WHO and bespoke neck orthosis, respectively. In terms of assessing the performance of orthosis, Abdalsadah et al. and Steck et al conducted FEA to evaluate gait performance, Ambu et al. mechanical performance validation-based FEA and thermal comfort assessment-based thermal imaging, Steck et al. simulated the impacts of building orientation on mechanical performance. On the other hand, Fang et al. conducted clinical trials and demonstrated that 3D-printed braces exhibit satisfactory immobilization capability and functional effectiveness when compared to plaster casts. Creylman et al. [64] and Poier et al. [45] proposed an indirect anatomy acquisition technique for FDM printing of modular WHO. By employing this technique, the occupational therapist can ensure precise alignment of the individual's limb, effectively avoiding unwanted movements. Consequently, this approach minimizes errors that might arise from the inherent challenges of directly scanning the limb in an accurate position. In [65], the Selective Laser Sintering (SLS) process shows an acceptable dimensional accuracy (maximum dimension discrepancy of 1.5 mm). Thus, Ranz et al. investigated gait analysis of SLS-based-AFO (Intrepid Dynamic Exoskeletal Orthosis) [66]. Also, Deckers et al. proposed a pilot study of AFO fabrication using SLS printing technology [12]. The study is limited to a comparison of preclinical test results compared to orthoses made by vacuum thermoforming processes. In [53], the process workflow for the design and manufacturing of a customized neck orthosis was modified by using a Computer Tomography (CT) acquisition scan. Ambu et al. captured images (600 images) from the patient. Then, Materialise's Interactive Medical Image Control System (MIMICS) software allows the creation of a neck mesh in STL format to be imported into CAD software for the surface reconstruction process. FEA is established under extension, flexion, and lateral bending loading conditions proving that the two designs are adequate from a structural point of view. However, the accuracy of CAD model reconstruction from acquired data is not assessed. Similarly, Xu et al. adopted CT scan-based data acquisition in the design process of cervical fixation orthosis for AM [57]. Mimics 21.0, 3-matic 13.0, Geomagic Studio 2013, and Altair Inspire Studio software are used for the surface reconstruction process, rough outline generation, surface fitting and smoothing, and topology optimization (minimizing the design weight and maximizing the stiffness), respectively. Therefore, the model is adjusted and improved by adding a fixed buckle structure using 3-matic 13.0 software.

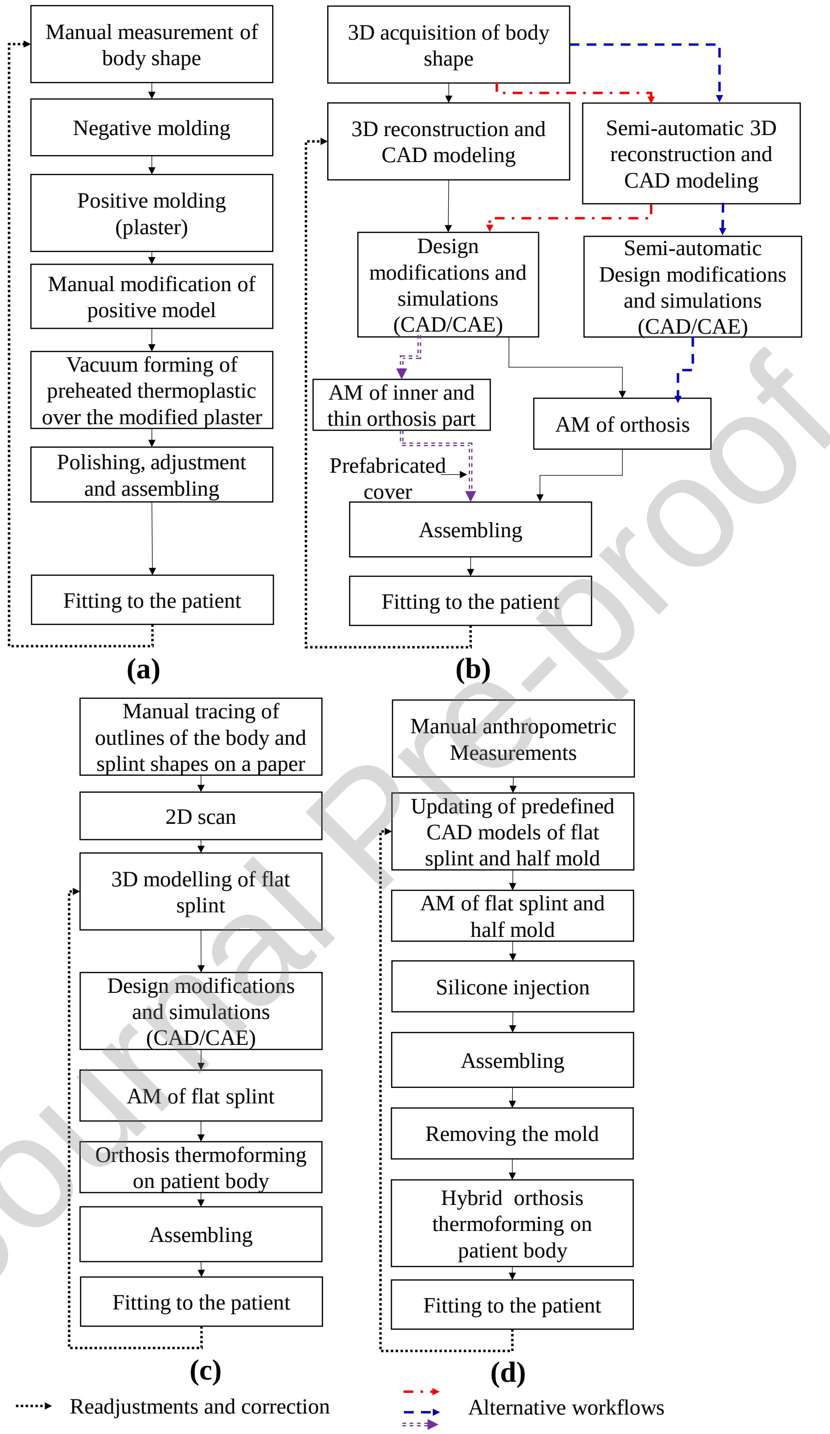


Figure 4. Orthosis production process workflows (a) Traditional process (plaster casting and vacuum thermoforming), (b) 3D scanning and 3D printing-based process, (c) 2D scanning, 3D printing of flat splint and thermoforming-based process, and (d) 2D measurements, 3D printing hybrid splint and thermoforming-based process.

The repeatability of the modern process is more acceptable than the traditional one. However, the delivery time remains relatively high. The process automation and improvement represented a research challenge to implement AM orthoses in clinical trials for orthopaedical treatments. The time-consuming issue was investigated according to three workflow levels: data acquisition, CAD modeling, and manufacturing process. Kim et al. suggested a hybrid orthosis aiming to reduce the cost of manufacturing time [39]. The device design includes two separate parts. The inner and outer components are manufactured by Ployjet printing and injection molding technologies, respectively. The inner component is designed according to the reconstructed surface from 3D scan data and a selected outer frame with predefined geometry and sizes. The proposed workflow allows exploiting advantages of both manufacturing processes: The inner part is fabricated with AM to produce a customized and thin product with a free-form shape and the cover is made by molding injection due to the low manufacturing cost of a thick product with a simple shape. This alternative workflow is illustrated with purple arrows in Figure 4(b). The photometric scanning type is chosen to ensure a fast and easy 3D scan process. Kim et al. cited that a guideline is needed to ensure the right position of the hand and arm during the 3D scan stage for clinical use. FEA is established by ANSYS to determine the cover thickness allowing the protection of the injured part from external forces. The polycarbonate and ABS materials are selected for the cover and inner frame, respectively. The inner frame is designed with an orthogonal mesh structure and channel cross-section. The orthosis weight is reduced by 1/8 compared with traditional cast weight. Li et al. addressed the scan and design time-consuming issues and skills requirements in the WHO design processing [67]. The 3D scan is assisted by a custom-made scanner mount to ensure the scan quality and minimize the data acquisition time. In the CAD environment (Rhino 3D V5), a general parametric model (pre-designed template) for WHO is designed with surface sweeping based on cross-section and guide curves, surface offsetting, Voronoi diagram-based engraving pattern, screw seats, and tube edges. A Graphical User Interface (GUI) is embedded in CAD software to assist in the automatic design of orthosis by clinicians. Equally, semi-automatic approaches to generate a 3D model of ankle-foot, foot, and finger orthoses using scanned data and predefined parameters, including thickness, shape, and material, are suggested by [13, 68, 69], respectively. Hale et al. implemented an enhanced process workflow for bespoke orthosis fabrication [54]. After the exportation of data acquired from the 3D scan to the Houdini software, the user places a cylinder, a straightforward guide geometry, over the 3D scan model. The 3D scan mesh is projected with this geometry. This projected geometry is brought away ('relaxed') from the body to form a comfortable orthosis because it perfectly matches the 3D scan. A position-based dynamics solver is employed to find the minimal surface. The deformation energy calculation allows adjusting the density of the porous pattern used for orthosis breathability and lightweighting. A uniform material density is assumed in the FEA, established to control the mechanical behavior of the device. Four concepts were designed. The first design, printed with a semi-flexible nylon material, was joined with a hinge along one side. A second model is designed to solve fitting issues observed during the previous prototype test. However, manual removal of material was required to better adjust the device. The 3D printing of the last orthosis considered the previous improvements. The two last prototypes are fabricated with Acrylic Styrene Acrylonitrile (ASA) selected on mechanical properties and surface finish criteria. For the sake of the patient's comfort and durability, commercial orthotic padding was inserted into the collar. A variational surface cutting algorithm optimizes padding cuts based on the fitted and relaxed collar geometry. The printing cost of the orthosis was £325. The time of reconstruction of the 3D parametric model from the scan is significantly minimized and the device weight is reduced by 13%. Also, Górski et al. defined an intelligent CAD modeling of a medical device to gather data from the 3D scan of a patient’s wrist hand, without any manual modification of the CAD model [41]. An automated algorithm for 3D scan data processing was established. In CAD software, the non-parametric model was constructed based on sketch curves defined on two sets of parallel planes (planes’ sets for forearm and hand). All the CAD model’s parameters were linked to an external data source (Excel spreadsheet). To build a digital orthosis, the coordinates of specific scan points are manually inputted into an Excel spreadsheet. Fitting results are confirmed based only on the lack of patient complaints. Chaparro-Rico et al. suggested a method for assisting the design of customized forefinger and thumb orthoses from 3D scans [70]. MATLAB software was used to rebuild the 3D scanned-point cloud. Using the SolidWorks software, a boundary surface is created based on the boundaries of cross-sections inferred from the reconstructed surface. The accuracy of the methodology was not evaluated. The PLACTIVE™ filament, which is antimicrobial, non-cytotoxic, and skin contact-approved material, is used in the FDM process. Chaparro-Rico et al. analyzed the PLACTIVE biocompatibility after the extrusion process and verified the orthosis stiffness using FEA. The two printed orthoses were fastened to the hand with rubber bands. Formisano et al. introduced an advanced method for designing and producing 3D orthosis [71], incorporating a semi-automatic workflow. The primary objective of their approach is to streamline various phases involved in the process, including scan setting, designing technique, and printing orientation, to minimize production time. The initial step involves capturing scan data using a cost-effective 3D scanner (Sense 2 by 3D Systems). The scan data is then processed using a semi-automatic algorithm, which reduces manual intervention and enhances the accuracy and efficiency of the procedure by segmenting, smoothing, and aligning the data. To design the orthosis, a parametric modeling technique is employed, which generates a cast model based on the scan data and user inputs. This technique empowers the user to customize the shape, thickness, and pattern of the cast to suit the specific requirements and preferences of the patient. To optimize the printing process, slicing software is utilized to determine the ideal printing orientation and generate support structures automatically. This optimization minimizes material waste and reduces printing time. The orthosis is 3D printed using PLA-FDM technology and is subsequently fitted onto the patient's limb, secured with Velcro straps. Sala et al. presented a comparable workflow for ABS-WHO FDM printing [72]. Their proposal involved a GUI incorporating semi-automatic routines, streamlining, and expediting the 3D model reconstruction from a 3D scan. Optimization of mechanical performances, manufacturing time, and cost was achieved through the adjustment of the layer thickness parameter. However, it's essential to note that the study did not encompass preclinical tests. The above workflow improvements for semi-automatic CAD model reconstructions and modifications are shown with red and blue arrows in Figure 4(b)

The selection of manufacturing parameters is a key step for the optimization of production time and quality. Górski et al. investigated experiments for the selection of material and parameters for WHO-3D printing which was designed automatically using a 3D scan [42]. The device stiffness is verified based on strength test results. Shih et al. investigated the improvement of four steps of the process planning for FDM-AFOs [73]. The part orientation is selected according to the support structure, layer number, surface quality, and bending strength criteria. The support volume is reduced using the sliced data-based support generation method. The adaptive slicing strategy minimizes the staircase effect by modifying layer thickness distribution based on the model geometry. The contour-parallel toolpath is used to deposit the boundaries to obtain decent surface smoothness and a wavy filling strategy is developed for layers with narrow and long cross-sectional shapes. Using a wavy toolpath, the flexural strength was increased by 6%, the build time diminished by 23% and the weight decreased by 17% compared with the zigzag toolpath.

For a successful reconstruction from the 3D scan, more acquisitions from different points of view are necessary due to the morphological complexity of human organs [74]. Unintentional movements result in scan misalignments, particularly if the organ is not tightly restrained. Thus, the 3D scan process requires keeping a static posture for a period and may cause a patient discomfort (pain, tremors, etc.). An accurate acquisition of patient anatomical data requires additional investment to purchase a specific scanner and/or additional holding equipment to manufacture a tailored device. Thus, new workflows for the design and manufacturing of customized devices were investigated aiming to avoid the 3D scan step. Choi et al. presented a pilot study for a 2D scan-based wrist-hand design [10]. Patient data acquisition is established by tracing an outline of the hand and forearm on paper, 2D scanning of the sketch (image in jpg format), and 3D modeling of the flat splint using the scanned image. The 3D scanning is bypassed in the proposed workflow (Figure 4 (c)). The printed device was thermoformed on the upper limb and then fastened. The thermoforming-based method was compared to the 3D scanning-based one through the two subject cases. The results of the comparison, which was limited to the averages of scores of product satisfaction, service satisfaction, and manufactured time, showed that the thermoforming method presents heigh scores. The production total time of the developed method (223min) is less than half of the 3D scanning-based method (529min). Popescu et al. improved the above thermoforming-based method and proposed advanced workflow [44] for the design and manufacturing of hybrid WHO (Figure 4 (d)). The data acquisition is established by the clinician who measures the patient’s hand using a caliper (11 measurements). In an online application, the clinician inputs the eleven measurement values defining the shape and dimensions of the flat splints and half mold templates. The CAD model, 3D print-ready STL file, and 2D drawing model are automatically generated. The manufacturing of hybrid orthosis comprises the following steps: 3D printing of a flat-shaped splint and a half mold, injecting the silicone into the rigid splint through interior channels, pouring the silicone into the half mold, clamping the half mold and the rigid splint together, removing the mold after curing the silicone, and thermoforming the hybrid splint on patient’s hand.

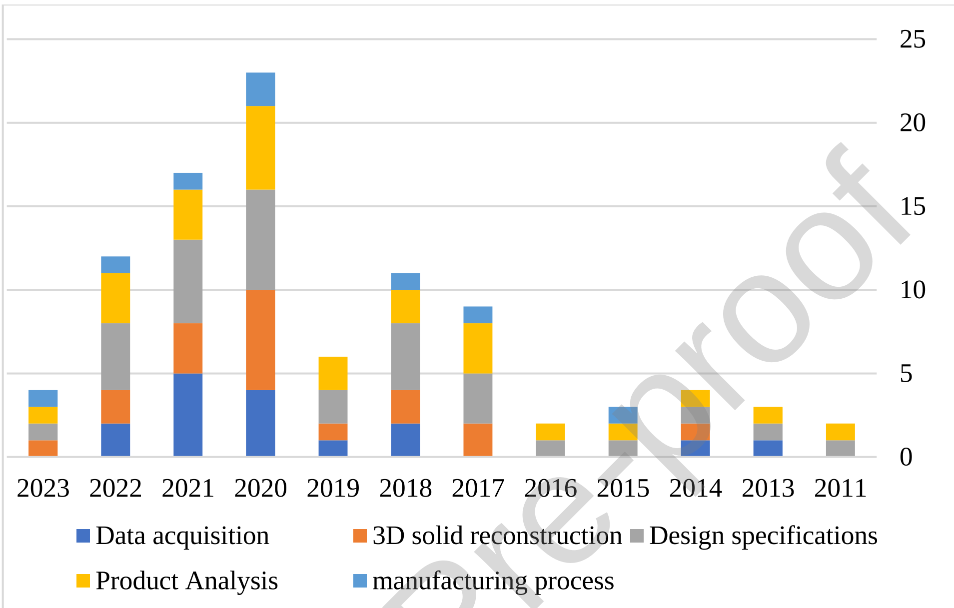
4. Discussion

A first classification of papers complied with the inclusion criteria is shown in Table 1 and Figure 5 based on the research area (keywords) interest and trend without representing an assessment of the workflow performance or the level of process improvements. Figure 2 (a) shows that interest in the manufacturing process decreased considerably from 2020 to 2022, yielding the neglect of the recent outcomes about the AM parameters selection [60, 75]. Figure 5 (b) shows a high interest in the improvement of design specifications. This interest is driven by the technical benefits of 3D-printing technology, especially the solid free-form fabrication capability. The 3D-printing advances are rapidly enabling a new generation of orthoses. Data acquisition and 3D solid reconstruction received less scientific interest delaying the feasibility of several developed workflows in clinical practices since health professionals are inexperienced with CAD software. Despite of few research investigations, the manufacturing process selection and manufacturing parameters optimization were overlooked. The improvements in data acquisition, 3D solid reconstruction, and manufacturing processes have been strongly linked and dependent on technological advances and innovations over the past few decades.

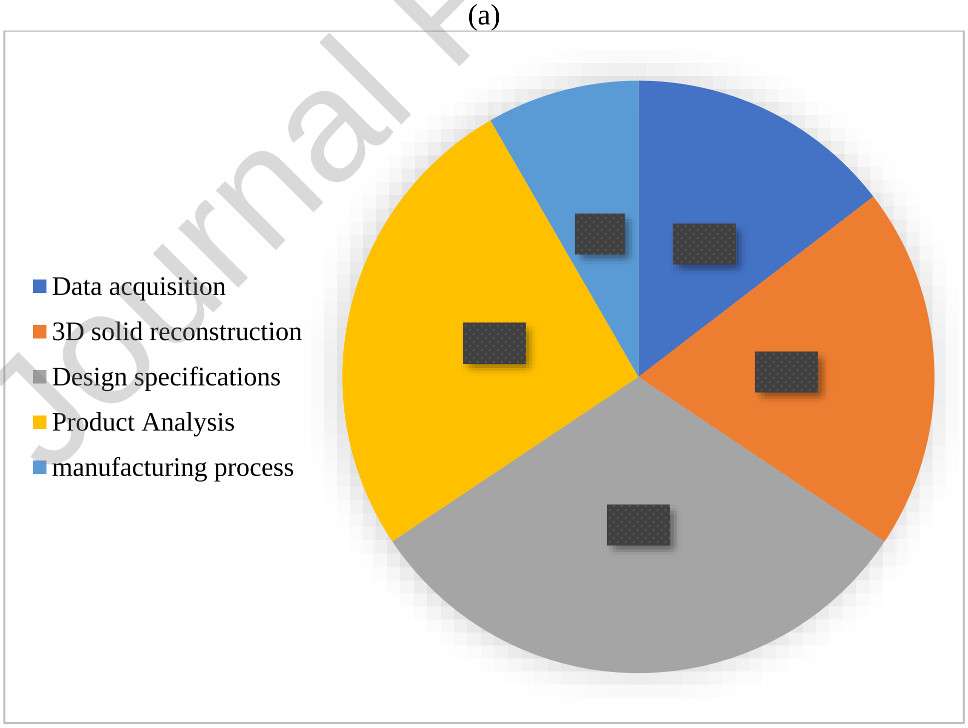
Table 1 The research area interest and trend.

Methods	Data acquisition	3D solid reconstruction	Design specifications	Product Analysis	manufacturing process
[3]	X	X	✓	✓	X
[64]	✓	X	✓	✓	X
[38]	✓	✓	✓	✓	X
[39]	X	X	✓	✓	✓
[66]	X	X	✓	✓	X
[73]	X	X	✓	✓	✓
[49]	X	✓	✓	✓	X
[68]	X	✓	✓	✓	X
[13]	X	✓	✓	✓	X
[12]	X	X	✓	✓	X
[67]	✓	✓	✓	X	X
[10]	✓	X	✓	X	✓
[50]	✓	X	✓	✓	X
[40]	X	✓	✓	✓	X
[69]	X	✓	✓	✓	X
[41]	✓	✓	✓	X	X
[42]	✓	✓	✓	✓	✓
[44]	✓	✓	✓	X	✓
[53]	✓	✓	✓	✓	X
[54]	X	✓	✓	✓	X
[76]	X	X	X	✓	X
[55]	✓	✓	✓	✓	X
[70]	✓	✓	✓	✓	X
[71]	✓	✓	✓	X	✓
[45]	✓	X	✓	X	X
[62]	✓	X	✓	✓	X
[57].	✓	✓	✓	✓	X
[63]	X	X	✓	✓	X

[56]	✓	X	✓	✓	X
[72]	X	✓	✓	X	✓
[51]	X	✓	✓	✓	✓



(a)



(b)

Figure 5 Literature classification by research area (a)research area trend, (b) research area proportions.

The suitability of software and hardware, and the feasibility on a clinical scale are the major contributors to the success and smooth integration of modern orthosis production in medical practices. Table 2 summarizes hardware, software, and main outcomes of relevant modern methods cited in Section 3. In comparison with the classical manufacturing processes, such as conventional plaster splint, and cock-up splint, the 3D or CT scan-based methods (as in [3, 12, 20, 38, 49, 50, 53, 55, 57]) are complicated and requires knowledge of data acquisition and CAD systems. Several 3D reconstruction techniques from CT scans have been developed, including methods like Contour-based Surface Rendering, the Marching Cube Algorithm [77], and Convolutional Neural Network (CNN) [78]. Comparative studies assessing the performance of 3D reconstruction techniques and software have been conducted in various applications, including surgical procedures [79] and dental implants [80]. However, in the context of orthosis, there remains a practical need for such studies to guide the selection of an efficient reconstruction process. The utilization of CT scans exposes patients to radiation, e.g., cancer risks due to ionizing radiation from CT scans [81], with the level dependent on scanning duration. While the extraction and reconstruction of external surfaces can be time-consuming, this method is convenient when prior CT scan acquisitions are available, as in the case of historical clinical diagnoses. However, for a more practical and health-conscious approach, 3D scanning via laser or structured light 3D scanners offer an alternative. This technique eliminates the radiation exposure concern and streamlines the process of capturing the human external shape, presenting a more efficient and safer method for orthotic design and fabrication. The consideration of these techniques-3D and CT scan- requires a high interest in hardware, materials, furthermore, preparation that might cause wavering from financial backers or orthotic professionals. Additionally, healthcare professionals are reluctant to alter their work routines. Despite recent improvements in 3D reconstruction accuracy from 3D scans using CAD software [82], essential skills for the task involve proficiency in CAD tools, comprehension of 3D scanning technologies, expertise in mesh manipulation, knowledge of geometric modeling principles, keen attention to detail, problem-solving abilities, and familiarity with software for data processing and model refinement. In recent years, data acquisition through smartphone-based photogrammetry has seen notable advancements [83] [84], presenting itself as a compelling alternative due to its low cost, user-friendly interface, and swift solutions compared to traditional 3D and CT scan methods [85]. However, it is crucial to note that despite its advantages, photogrammetry's accuracy still tends to be relatively lower [86]. The evaluation of these errors and their impact on 3D-printed orthoses requires thorough investigation. On one hand, interesting methodologies are established for the simplification and time reduction of the data acquisition and CAD modeling phases, as in [41, 54, 67, 70]. On the other hand, the hybrid methods for customized 3D printed plastic orthosis without 3D scan, as in [10, 44], are balanced solutions yielding time and cost reduction. The data acquisition is a key step of orthosis design since the model quality directly affects the patient’s comfort and further mathematical analysis. A systematic assessment of current software and the establishment of easier protocols for data acquisition and post-processing remains a research gap.

Regarding manufacturing process selection, the researchers employed various 3D printing technologies, including FDM [10, 13, 53–55, 57, 67, 71–73, 38, 40–42, 44, 45, 49, 50], PolyJet [39], SLA [3], and SLS [12, 66]. It is noteworthy that FDM is more frequently utilized compared to the other 3D printing technologies, mainly due to the FDM's recent technological advances: the low-cost equipment, minimum restrictions in the geometric definition, accuracy, and diversity of supported materials. The optimization of FDM parameters was investigated by [42, 73]. The structure produced by FDM is anisotropic, and its strength varies depending on the orientation of the extruded filament deposition [87, 88]. A more accurate simulation could account for this anisotropy by optimizing the orientation of the deposited material according to the load direction. Combinations of manufacturing processes such as thermoforming/FDM [10, 44] and molding injection/FDM [39] yielded the establishment of alternative workflow reducing the production cost and time. The selection of manufacturing process and parameters is a vital step in product development [60] and must consider economic, environmental, and social impacts [89, 90]. Notably, in-depth investigations on the selection of additive manufacturing processes and parameters for sustainable 3D orthosis printing will expand its practicality.

The advancement in 3D printing technology has facilitated the better utilization of materials, including composites [91, 92], and smart materials like shape memory polymers (SMPs) [93], liquid crystal elastomers (LCEs), biocompatible polymers, magnetic shape memory alloys (MSMAs), and cell-laden materials. This improved exploitation of materials holds the potential to significantly enhance the performance of orthoses. By leveraging the capabilities of 3D printers, orthotic devices can be fabricated using composite materials, which combine the properties of different materials to achieve superior strength, durability, and flexibility. These composites can be tailored to specific requirements, such as optimizing stiffness or providing targeted support, resulting in functionally superior orthoses compared to traditional materials. The recently conducted pilot study in [51] utilizing fiber-reinforced PETG-CF15 material demonstrated promising results, providing a roadmap for further investigation. In the realm of regenerative medicine, smart materials play a vital role in advancing 4D printing. Their versatility is ideal for crafting personalized scaffolds and implants. However, the application of these smart materials in orthotic fabrication is an untapped area. While the orthopedic device proposed by Gorokhova et al. [94], is limited to theoretical investigations. Toth et al. designed a functional dynamic orthosis [95] comprising passive (FDM-printed TPU sheets and SLS-printed biocompatible polyamide (PA 2200)) and active (nitinol smart memory alloy plates) parts. Experiments confirmed smart materials' mechanical suitability in place of actuators. Further research is imperative for incorporating smart materials into 3D printed-static orthosis applications, capitalizing on their switchable mechanical properties [96]. However, a significant challenge is the sensitivity of smart materials to environmental factors like temperature, humidity, and pH levels [95] [97]. Addressing this challenge is crucial for the broader integration of smart materials into orthotic applications.

The orthosis design specifications commonly focused on material selection (material strength, biomaterial, flexibility, etc.), lightweighting, and topology optimization. Notably, the limited utilization of the Design for Additive Manufacturing (DfAM) approach in the reviewed research studies on orthosis design is affecting the overall product performance. FEA or experimental tests are used to verify the device's stiffness. The patient’s feedback is used for product assessment and further design modifications. Although scientific and academic research attempted to ensure close communication between engineering, as in [40, 49, 50, 57, 63, 67], the clinical team, and the patient in the workflow, an automatic and systematic aided tool for converting both the patient's anatomy and needs and health professionals requirements into design specifications remains a clinical need.

Table 2 Hardware, software, materials, and main outcomes

Orthosis/3D printer/Material	Patient data acquisition and CAD modeling	Main outcomes
AFO [3]/ Viper SLA machine/ 2 materials: Accura 40 resin and DSM Somos 9120 Epoxy Photopolymer	▪ Three images were captured by a 3D FaceCam 500 scanner. ▪ CAD model post-processed using the software Rapidform. ▪ Obtaining of CAD model requires manual intervention to merge the individual surface meshes.	▪ Devices' validation by gait analysis. ▪ Heigh manufacturing time (16.7 hours). ▪ RP AFOs match the performance of the prefabricated device.
AFO [73]/ FDM	▪ Building orientation is selected according to the support structure, layer number, surface quality, and bending strength. ▪ Support structure volume is minimized. ▪ An adaptive slicing strategy is established to reduce the errors from the staircase effect. ▪ The tool-path generation is established by an innovative wavy structure filling pattern.	▪ Improve the FDM process by decreasing the build time, enhancing the structural strength, and improving surface quality.
AFO [13]/ FDM (FB9600)/ thermoplastic polyurethane	▪ 3D scanner, Eva (Artec™ Eva, Artec Group, Luxembourg). ▪ CAD modeling using orthosis software (MediACE3D®).	▪ Facilitate the reconstruction process using a preprogrammed orthotic template design. ▪ Mechanical (durability) tests, gait analysis, and user evaluation surveys were investigated to evaluate the 3D-printed AFO.
AFO [12] / SLS / polyamide 12 (PA12)	▪ 3D scanner with Artec Studio software. ▪ The three software 3-Matic® and SolidWorks®, and Rhinoceros® for CAD modeling.	▪ Preclinical tests show that SLS-based AFO manufacturing requires lower fitting time compared to the AFO-based vacuum thermoforming process, but the device strength must be enhanced. ▪ No design optimization regarding weight, strength, and comfort.
AFO [50] /FDM /FilaFlex and Polycarbonate	▪ The 3D Systems Sense® scanner ▪ Surface creation and 3D solid modeling by 3D Systems Geomatic Design X® and to Rhinoceros 5, respectively.	▪ The design and use of functional immobilization splints enable a reduction of at least 30% in the duration of the treatment.
WHO [38] / Dimension SST1200 printer (FDM)/ ABS	▪ Only one scan is needed with the use of di3D FCS-100 photo scanner. ▪ Scan data is processed using ATOS 6.3 software.	▪ The material proprieties are sufficient to use in the application. ▪ The proposed method is more complicated than the classical one and requires additional time and skills (knowledge of CAD systems). ▪ Heigh manufacturing time (23.7 hours).
WHO [39]/ Ployjet technology (Objet500 Connex of Stratasys Inc.)	▪ Photometric 3D scanner, (REXCAN4).	▪ New hybrid model. ▪ The separation of the orthosis into two parts: a cover with several sizes already fabricated with molding

		injection and 3D printing of only the inner part, reduces considerably the patient waiting time.
WHO [67] / FDM (Quditech1)	▪ 3D scanner Sense (3DSystem) with custom-made scanner mount.	▪ Automatic design of engraved orthosis based on the 3D scan.
WHO [10] / FDM	▪ An outline of the hand and forearm is drawn on paper, the resulting sketch is 2D scanned, and the flat splint is 3D modeled (without 3D scan).	▪ 3D scanning is avoided. ▪ The thermoforming-based method showed higher satisfaction scores than the 3D scan-based method (only two parts for two subjects).
WHO [40] / FDM (Z-UltraT filaments)/ thermoplastic modified ABS manufactured with other organic forms (polycarbonate)	▪ 3D Laser scanner (3D Sense) ▪ Rhinoceros 5.0 software for CAD modeling.	▪ Sustainable material. ▪ Feasibility study of the implementation of 3D-printed WHO in a pediatric center.
WHO [41], [42]/ FDM (Raise 3D Pro machine) / 4 materials: ABS, PLA, nylon (PA12), and high-impact polystyrene (HIPS).	▪ The automated algorithm allows 3D scanning data processing. ▪ The intelligent CAD model uses 11 sets of scanned points to automatically create the 3D model.	▪ Material and manufacturing parameters are selected, based on experimental results (cost, time, fit/surface quality, and strength).
WHO [44]/ QidiTech 3D printer/ PLA for rigid splint and 'Dragon Skin 10 Very Fast' silicone for soft layer.	▪ 11 measurements are manually taken using a caliper to define the dimensions and shape of the hand. ▪ Web application generates 3D models (Catia V5 software), 2D drawings, and STL files from data inputs.	▪ Hybrid WHO ▪ Online application to assist the 3D reconstruction from measured anthropometric data. ▪ The 3D printing of flat splints is cheaper and faster compared to 3D-printed pre-formed splints, which may involve building supports.
WHO [45]/ FDM (Open source machine ANET® A8 DIY) / PLA and TPU	▪ Indirect 3D scan (data acquisition from cast splint) using Desktop 3D® 2020i laser scanner from NextEngine. ▪ CAD modeling using 3ds Max® 2018, from Autodesk Inc and SolidWorks® 2018.	▪ The technique employed for anatomical acquisition through plaster casts has its limitations due to the messiness associated with the plaster material and the time-consuming process. However, it offers the advantage of minimizing noise and inaccuracies resulting from movements during the acquisition process.
WHO [71]/ FDM (Ultimaker S5 by Ultimaker)/ PLA	▪ A low-cost 3D scanner (Sense 2 by 3D Systems). ▪ CAD software Rhinoceros. ▪ A slicing software (Cura by Ultimaker)	▪ Optimization of the printing orientation and support structures. ▪ The designing technique is automated by using a parametric modeling tool. ▪ The design phase is empowered by a semiautomatic process developed in Grasshopper®. ▪ Material waste, design, and printing times are reduced.
WHO [72]/FDM (Ultimaker S5)/ ABS	▪ Hexagon Absolute Arm 7-Axis equipped with RS5 Laser Scanner. ▪ STL format is generated using PolyWorks Modeler.	▪ A GUI and semi-automated commands are developed to facilitate the CAD modeling step. ▪ The layer thickness is selected to reduce production time and enhance tensile and flexural strengths.

		▪ Reduced production time (2.46h) and cost (25.84 €).
Cervical Orthosis [53] / FDM (Printer D300 Technology®)/ HBP® material	▪ CT acquisition scan. ▪ MIMICS software to obtain STL format from scanned data.	▪ Innovative composite material contributes to improving the neck Orthosis's lightweight, superficial finish, and antibacterial properties.
Cervical Orthosis [57]./ FDM/ ABS	▪ CT scan-based data acquisition. ▪ Altair Inspire Studio for topology optimization. ▪ 3-matic software for CAD modifications.	▪ The reduction of the design volume by 30% yields a lightweight device (477 g). ▪ The CAD model reconstruction required several steps. ▪ The comfort evaluation is based only on the result of one patient survey.
Cervical Orthosis [55]/ FDM/ TPE (flex)	▪ 3D scan (Sense (2nd generation) 3D scanner). ▪ Fusion 360 for CAD model reconstruction and design modifications.	▪ Flexible orthosis. ▪ The comfort assessment of a 1st prototype is experimentally tested (1 user). ▪ A second improved design is proposed, and FEA is investigated.
Cervical Orthosis [54]/FDM: (Stratasys Fortus 380mc)/ nylon 12 for one design and Acrylic Styrene Acrylonitrile (ASA) for two prototypes.	▪ 3D scan (The Artec EVA 3D) with an accuracy of 0.1 mm. ▪ Houdini software (SideFX software, ▪ version 16.5) for CAD model reconstruction.	▪ The scanning time is considerably reduced. ▪ The engraved pattern design is optimized.
KO [49] / FDM (2 printers): Dimension sst768 from Stratasys & Replicator 2 from Makerbot/ materials: ABS & TPU Ninjaflex®.	▪ 3D scan (ZScanner™ 700 with the software ZScan™). ▪ Both SolidWorks® ScanTo3D and Autodesk® MeshMixer are used as CAD software.	▪ Orthosis design is selected according to a patient-specific need. ▪ No improvement in scanning and CAD reconstruction. ▪ No optimization of the manufacturing process. ▪ No simulation of mechanical behavior.

Delivery time is a major constraint to embed the 3D printed orthoses in clinical applications. Table 3 shows an aggregation of available data about orthoses production times. The building time changes significantly according to the device volume and manufacturing parameters. The volume depends on design specifications and orthosis types. Figure 6 shows that the total production time of WHO has decreased over the last few decades: from 1422min in 2014 to 50min in 2020. This contribution is due to the design optimization followed by the increase in equipment and software performances, such as CAD software, 3D scanners, and printers. The production time decrease was accompanied by a reduction in the cost of materials and equipment leading to competitive product prices in the market. Although a comprehensive economic analysis is crucial for the integration of 3D-printed orthoses in clinical settings—requiring meticulous evaluation of initial investments, potential long-term savings, scalability, Life Cycle Assessment (LCA), and production efficiency—the positive results, particularly regarding production time and cost, encourage to expand the application of the entire process for other types of more complex orthopedic treatments. The Long-term sustainability hinges on the durability and biocompatibility of materials, necessitating thorough examinations of wear resistance and patient comfort over extended periods. The process of 3D-printed orthoses is intertwined with technological advancements, and a forward-looking approach must consider future innovations to stay abreast of evolving industry standards.

Table 3. Production Times

Device	Methods	Data acquisition (min)	data post-processing and 3D parametric modeling (min)	Manufacturing (min)
WHO	Traditional process-based on low-temperature plastic moldable [38].		60-180	
	Traditional process-based high-temperature thermoplastic or Laminate [38].		300-600	
	Cast-molded conventional orthosis [98]		239	
	[38]	12	540	870
	3D-printed WHO [98]		112	
	WHO Thermoforming method [10]	9	11	203
	WHO 3D scanning method [10]	28	17	484
	[67]	0.33	8-20	180
	[40]	12	60	600-720
	[39]	12	222	276
	[44]	15		157 (Hybrid-hexagonal-fast) 407 (Hybrid-hexagonal) 35 (Simple-diamond-fast) 73 (Simple -diamond)
	[41]	5	25	360
	[45]	180	285	270

	[71]	1	3	485
	[72]	1.83	14.432 (average)	132
AFO	[3]	Not mentioned.	Not mentioned.	1002 (for rigid AFO)
	[73]	Not mentioned.		The build time decreased by 23% compared to zigzag toolpath-based fabrication.
Cervical Fixation Orthosis	[57].	Not mentioned.		274
	[54]	10–15 min	2.75min	2880
KO	[49] Concept 1	10	60-120	2867
	[49] Concept 2			458
	[49] Concept 3			1180
	[49] Concept 3			761

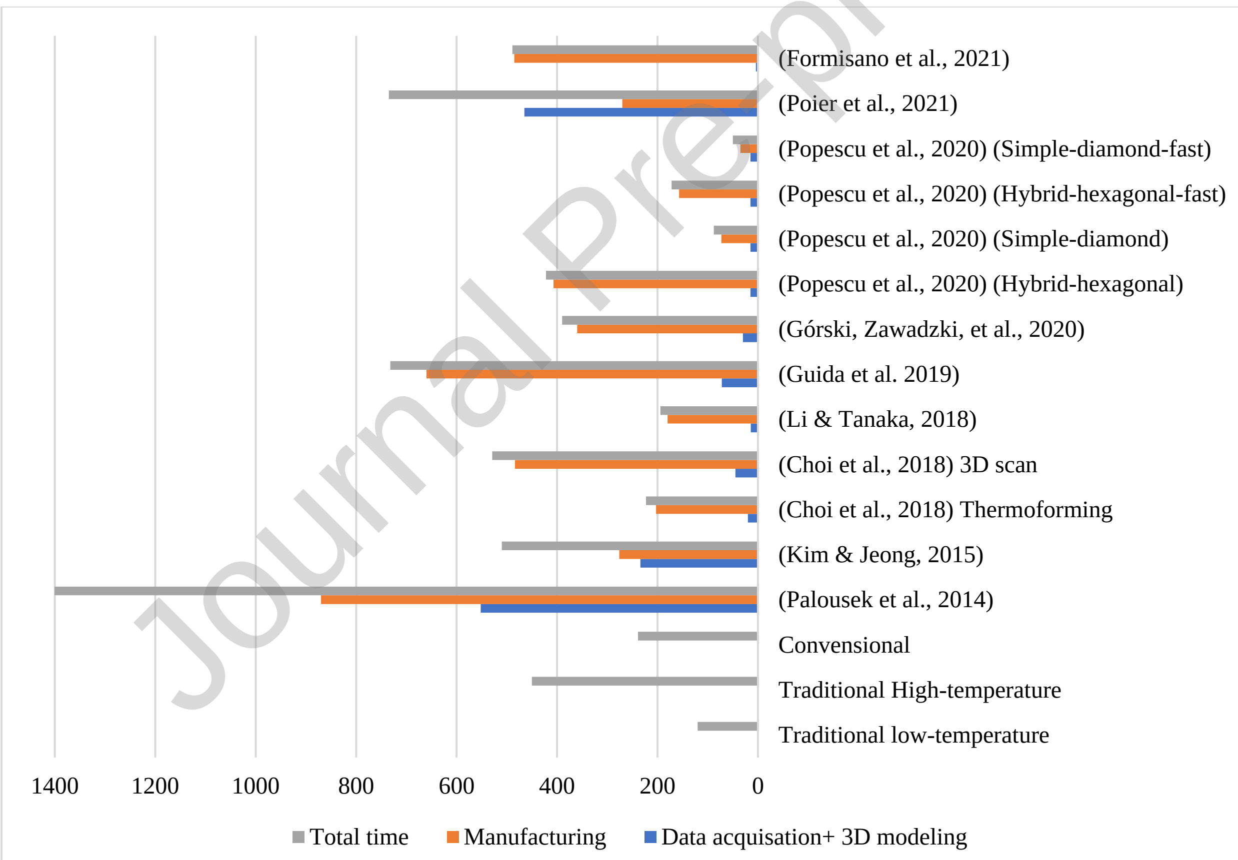


Figure 6. Production Time of WHO.

5. Conclusion

3D-printed orthoses have demonstrated advancements in customization, innovation, comfort, aesthetics, and effectiveness in rehabilitation. Delivery time and production cost of modern orthoses have become competitive in the market. The affordability, increased accuracy, and expanded range of supported materials have favored the use of FDM in orthosis printing. The integration of semi-automatic CAD model reconstruction and modification techniques into the production workflow, along with alternative workflows surpassing the challenges of 3D scan and reconstruction issues, has resulted in a reduction in time and simplification of tasks. The above advantages will ensure that modern orthoses are among the best next-generation bone treatment tools.

The expediteness of the implementation and industrialization of 3D printed orthoses requires maintaining continuous vigilance over technological advancements in additive manufacturing. Some technological obstacles still prevent the 3D-based approach from being clinically viable and sustainable, despite efforts to perfect customized orthoses. The data acquisition process necessitates further investigation to explore emerging techniques such as smartphone-based photogrammetry, addressing user-friendly concerns in clinical practices. The selection of manufacturing processes and parameters requires additional research investigations to encompass the three pillars of sustainability frameworks: social, environmental, and economic. This decision-making process must account for the emergence and effectiveness of materials, including composites and smart materials. The rise of the potential in prescription orthoses by orthopedic doctors requires a fully automatic aided tool for translating both the patient's anatomy and treatment needs into design specifications.

References

1. Edelstein JE (2007) Orthotics. In: Physical Rehabilitation. Elsevier, pp 897–917

2. Kemker BP, Kankaria R, Patel N, Golladay G (2021) Hip and Knee Bracing: Categorization, Treatment Algorithm, and Systematic Review. JAAOS Glob Res Rev 5:e20.00181-12. https://doi.org/10.5435/JAAOSGlobal-D-20-00181

3. Mavroidis C, Ranky RG, Sivak ML, Patritti BL, DiPisa J, Caddle A, Gilhooly K, Govoni L, Sivak S, Lancia M, Drillio R, Bonato P (2011) Patient specific ankle-foot orthoses using rapid prototyping. J Neuroeng Rehabil 8:1–11. https://doi.org/10.1186/1743-0003-8-1

4. British Association of Prosthetists and Orthotists (2018) The British Association of Prosthetists and Orthotists. Glasgow, Scotland.

5. Boyd AS, Benjamin HJ, Asplund C (2009) Splints and casts: Indications and methods. Am. Fam. Physician 80:491–499

6. Fitzpatrick AP, Mohanned MI, Collins PK, Gibson I (2017) Design of a Patient Specific, 3D printed Arm Cast. In: n International Conference on Design and Technology, KEG. pp 135–142

7. Walthall J, Adame JD, Varacallo M (2021) Long Arm Splinting

8. Jung H-Y, Jung N-H, Chang M-Y (2013) Comparison of Muscle Activation while Performing Tasks Similar to Activities of Daily Livings with and without a Cock-up Splint. J Phys Ther Sci 25:1247–1249. https://doi.org/10.1589/jpts.25.1247

9. Medisist Surgicals (2018) Cock-up Splint |. https://medisistsurgicals.com/product/cock-up-splint/. Accessed 6 Sep 2022

10. Choi WS, Jang WH, Kim JB (2018) A Pilot study for Usefulness of Customized Wrist Splint By Thermoforming Manufacture Method Using 3D printing : Focusing on Comparative Study with 3D scanning Manufacture Method. J Rehabil Welf Eng Assist Technol 12:149–158. https://doi.org/10.21288/resko.2018.12.2.149

11. Bedard GG (2012) Thermoplastic materials for orthoses and prostheses. 7

12. Deckers JP, Vermandel M, Geldhof J, Vasiliauskaite E, Forward M, Plasschaert F (2018) Development and clinical evaluation of laser-sintered ankle foot orthoses. Plast Rubber Compos 47:42–46. https://doi.org/10.1080/14658011.2017.1413760

13. Cha YH, Lee KH, Ryu HJ, Joo IW, Seo A, Kim D-H, Kim SJ (2017) Ankle-Foot Orthosis Made by 3D Printing Technique and Automated Design Software. Appl Bionics Biomech 2017:1–6. https://doi.org/10.1155/2017/9610468

14. Apollo® Universal Wrist Brace – Breg, Inc. https://www.breg.com/products/elbow-wrist-bracing/wrist/apollo-universal-wrist-brace/. Accessed 13 Dec 2022

15. Exos FORM II 631 | DJO Global. https://www.djoglobal.com/products/exos/exos-form-ii-631. Accessed 13 Dec 2022

16. Push med Elbow Brace Epi | Performance Health. https://www.performancehealth.com/push-med-elbow-brace-epi. Accessed 13 Dec 2022

17. Healing in the dark: Night use of orthoses | Lower Extremity Review Magazine. https://lermagazine.com/cover_story/healing-in-the-dark-night-use-of-orthoses. Accessed 17 Dec 2022

18. Wojciechowski E, Chang AY, Balassone D, Ford J, Cheng TL, Little D, Menezes MP, Hogan S, Burns J (2019) Feasibility of designing, manufacturing and delivering 3D printed ankle-foot orthoses: a systematic review. J Foot Ankle Res 12:11. https://doi.org/10.1186/s13047-019-0321-6

19. Tzou CHJ, Artner NM, Pona I, Hold A, Placheta E, Kropatsch WG, Frey M (2014) Comparison of three-dimensional surface-imaging systems. J Plast Reconstr Aesthetic Surg 67:489–497. https://doi.org/10.1016/j.bjps.2014.01.003

20. Górski F, Wichniarek R, Kuczko W, Banaszewski J, Pabiszczak M (2019) Application of low-cost 3D printing for production of CT-based individual surgery supplies. In: IFMBE Proceedings. Springer Verlag, pp 249–253

21. Ranganathan R, Ganesan S (2018) Design and development of customised split insole using additive manufacturing technique. Int J Rapid Manuf 7:295. https://doi.org/10.1504/IJRAPIDM.2018.10016859

22. Anggoro PW, Tauviqirrahman M, Jamari J, Bayuseno AP, Bawono B, Avelina MM (2018) Computer-aided reverse engineering system in the design and production of orthotic insole shoes for patients with diabetes. Cogent Eng 5:1470916. https://doi.org/10.1080/23311916.2018.1470916

23. Alhazmi B, Alshomer F, Alazzam A, Shehabeldin A, Almeshal O, Kalaskar DM (2022) Digital workflow for fabrication of bespoke facemask in burn rehabilitation with smartphone 3D scanner and desktop 3D printing: clinical case study. 3D Print Med 8:12. https://doi.org/10.1186/s41205-022-00140-0

24. Wei Y, Wang Y, Zhang M, Yan G, Wu S, Liu W, Ji G, Li-Tsang CWP (2018) The application of 3D-printed transparent facemask for facial scar management and its biomechanical rationale. Burns 44:453–461. https://doi.org/10.1016/j.burns.2017.08.006

25. Koffler J, Zhu W, Qu X, Platoshyn O, Dulin JN, Brock J, Graham L, Lu P, Sakamoto J, Marsala M, Chen S, Tuszynski MH (2019) Biomimetic 3D-printed scaffolds for spinal cord injury repair. Nat Med 25:263–269. https://doi.org/10.1038/s41591-018-0296-z

26. Kantaros A, Piromalis D (2021) Fabricating Lattice Structures via 3D Printing: The Case of Porous Bio-Engineered Scaffolds. Appl Mech 2:289–302. https://doi.org/10.3390/applmech2020018

27. Kantaros A (2022) Bio-Inspired Materials: Exhibited Characteristics and Integration Degree in Bio-Printing Operations. Am J Eng Appl Sci 15:255–263. https://doi.org/10.3844/ajeassp.2022.255.263

28. Kantaros A (2022) 3D Printing in Regenerative Medicine: Technologies and Resources Utilized. Int J Mol Sci 23:14621. https://doi.org/10.3390/ijms232314621

29. Grazioso S, Selvaggio M, Caporaso T, Di Gironimo G (2019) A Digital Photogrammetric Method to Enhance the Fabrication of Custom-Made Spinal Orthoses. JPO J Prosthetics Orthot 31:133–139. https://doi.org/10.1097/JPO.0000000000000244

30. Barrios-Muriel J, Romero-Sánchez F, Alonso-Sánchez FJ, Rodríguez Salgado D (2020) Advances in Orthotic and Prosthetic Manufacturing: A Technology Review. Materials (Basel) 13:295. https://doi.org/10.3390/ma13020295

31. 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 6:1258–1266. https://doi.org/10.1016/j.eng.2020.07.019

32. Khodaei B, Saeedi H, Jalali M, Farzadi M, Norouzi E (2017) Comparison of plantar pressure distribution in CAD–CAM and prefabricated foot orthoses in patients with flexible flatfeet. Foot 33:76–80. https://doi.org/10.1016/j.foot.2017.07.002

33. Sakib-Uz-Zaman C, Khondoker MAH (2023) Polymer-Based Additive Manufacturing for Orthotic and Prosthetic Devices: Industry Outlook in Canada. Polymers (Basel) 15:1506. https://doi.org/10.3390/polym15061506

34. Kumar R, Sarangi SK (2021) 3D-Printed Orthosis: A Review on Design Process and Material Selection for Fused Deposition Modeling Process. In: Lecture Notes in Mechanical Engineering. pp 531–538

35. Hasibuzzaman M, Wahab AA, Seng GH, Ramlee MH (2021) Three-dimensional printed orthosis in biomedical application: A short review. J Phys Conf Ser 2071:012025. https://doi.org/10.1088/1742-6596/2071/1/012025

36. Wixted CM, Peterson JR, Kadakia RJ, Adams SB (2021) Three-dimensional Printing in Orthopaedic Surgery: Current Applications and Future Developments. J. Am. Acad. Orthop. Surg. Glob. Res. Rev. 5:00230–00211

37. Fatone S (2006) Orthotics. In: Wiley Encyclopedia of Biomedical Engineering. John Wiley & Sons, Inc., Hoboken, NJ, USA

38. Palousek D, Rosicky J, Koutny D, Stoklásek P, Navrat T (2014) Pilot study of the wrist orthosis design process. Rapid Prototyp J 20:27–32. https://doi.org/10.1108/RPJ-03-2012-0027

39. Kim H, Jeong S (2015) Case study: Hybrid model for the customized wrist orthosis using 3D printing. J Mech Sci Technol 29:5151–5156. https://doi.org/10.1007/s12206-015-1115-

40. Guida P, Casaburi A, Busiello T, Lamberti D, Sorrentino A, Iuppariello L, D'Albore M, Colella F, Clemente F (2019) An alternative to plaster cast treatment in a pediatric trauma center using the CAD/CAM technology to manufacture customized three-dimensional-printed orthoses in a totally hospital context: A feasibility study. J Pediatr Orthop Part B 28:248–255. https://doi.org/10.1097/BPB.0000000000000589

41. Górski F, Zawadzki P, Wichniarek R, Kuczko W, Żukowska M, Wesołowska I, Wierzbicka N (2020) Automated Design of Customized 3D-Printed Wrist Orthoses on the Basis of 3D Scanning. In: Mechanisms and Machine Science. Springer Science and Business Media B.V., pp 1133–1143

42. Górski F, Wichniarek R, Kuczko W, Zukowska M, Lulkiewicz M, Zawadzki P (2020) Experimental studies on 3D printing of automatically designed customized wrist-hand orthoses. Materials (Basel) 13:. https://doi.org/10.3390/ma13184091

43. Etherington Rose Cortex 3D-printed cast for fractured bones by Jake Evill. https://www.dezeen.com/2013/06/28/cortex-3d-printed-cast-for-bone-fractures-jake-evill/. Accessed 27 Aug 2022

44. Popescu D, Zapciu A, Tarba C, Laptoiu D (2020) Fast production of customized three-dimensional-printed hand splints. Rapid Prototyp J 26:134–144. https://doi.org/10.1108/RPJ-01-2019-0009

45. Poier PH, Arce RP, Rosenmann GC, Carvalho MGR, Ulbricht L, Foggiatto JA (2021) Development of modular wrist, hand and finger orthesis by additive manufacturing. Res Soc Dev 10:e333101522707. https://doi.org/10.33448/rsd-v10i15.22707

46. Surmen HK, Akalan NE, Arslan YZ (2017) Design, Manufacture, and Selection of Ankle-Foot-Orthoses. In: Encyclopedia of Information Science and Technology, Fourth Edition. IGI Global, pp 298–313

47. Choo YJ, Chang MC (2021) Commonly used types and recent development of ankle-foot orthosis: A narrative review. Healthc 9:. https://doi.org/10.3390/healthcare9081046

48. Rogati G, Caravaggi P, Leardini A (2022) Design principles, manufacturing and evaluation techniques of custom dynamic ankle-foot orthoses: a review study. J Foot Ankle Res 15:1–12. https://doi.org/10.1186/s13047-022-00547-2

49. Santos S, Soares B, Leite M, Jacinto J (2017) Design and development of a customised knee positioning orthosis using low cost 3D printers. Virtual Phys Prototyp 12:322–332. https://doi.org/10.1080/17452759.2017.1350552

50. Blaya F, Pedro PS, Pedro ABS, Lopez-Silva J, Juanes JA, D'Amato R (2019) Design of a Functional Splint for Rehabilitation of Achilles Tendon Injury Using Advanced Manufacturing (AM) Techniques. Implementation Study. J Med Syst 43:. https://doi.org/10.1007/s10916-019-1247-z

51. Steck P, Scherb D, Witzgall C, Miehling J, Wartzack S (2023) Design and Additive Manufacturing of a Passive Ankle–Foot Orthosis Incorporating Material Characterization for Fiber-Reinforced PETG-CF15. Materials (Basel) 16:3503. https://doi.org/10.3390/ma16093503

52. Leung AKL, Lee WCC (2012) Prosthetics and orthotics. In: Orthopaedic Biomechanics. W.B. Saunders, pp 583–602

53. Ambu R, Motta A, Calì M (2020) Design of a Customized Neck Orthosis for FDM Manufacturing with a New Sustainable Bio-composite. In: Lecture Notes in Mechanical Engineering. pp 707–718

54. Hale L, Linley E, Kalaskar DM (2020) A digital workflow for design and fabrication of bespoke orthoses using 3D scanning and 3D printing, a patient-based case study. Sci Rep 10:7028. https://doi.org/10.1038/s41598-020-63937-1

55. Sabyrov N, Sotsial Z, Abilgaziyev A, Adair D, Ali MH (2021) Design of a flexible neck orthosis on Fused Deposition Modeling printer for rehabilitation on regular usage. Procedia Comput Sci 179:63–71. https://doi.org/10.1016/j.procs.2020.12.009

56. Ambu R, Oliveri SM, Calì M (2022) A Bespoke Neck Orthosis for Additive Manufacturing with Improved Design Method and Sustainable Material. In: Rizzi C, Campana F, Bici M, Gherardini F, Ingrassia T, Cicconi P (eds) Design Tools and Methods in Industrial Engineering II. Lecture Notes in Mechanical Engineering. Springer International Publishing, Cham, pp 50–58

57. Xu Y, Li X, Chang Y, Wang Y, Che L, Shi G, Niu X, Wang H, Li X, He Y, Pei B, Wei G (2022) Design of Personalized Cervical Fixation Orthosis Based on 3D Printing Technology. Appl Bionics Biomech 2022:1–8. https://doi.org/10.1155/2022/8243128

58. Salem H, Abouchadi H, El Bikri K (2020) Design for additive manufacturing. J Theor Appl Inf Technol 10:3043–3054. https://doi.org/10.1201/9780429466236-7

59. Oh Y, Zhou C, Behdad S (2018) Part decomposition and assembly-based (Re) design for additive manufacturing: A review. Addit. Manuf. 22:230–242

60. Tlija M, Al-Tamimi AA (2023) Combined manufacturing and cost complexity scores-based process selection for hybrid manufacturing. Proc Inst Mech Eng Part B J Eng Manuf 237:1473–1484. https://doi.org/10.1177/09544054221136524

61. Ulrich K, Eppinger S (1995) Ulrich & Eppinger, 1995 - Product architectures. McGraw-Hill, New York

62. Abdalsadah FH, Hasan F, Murtaza Q, Khan AA (2021) Design and manufacture of a custom ankle–foot orthoses using traditional manufacturing and fused deposition modeling. Prog Addit Manuf 6:555–570. https://doi.org/10.1007/s40964-021-00178-2

63. Fang J-J, Lin C-L, Tsai J-Y, Lin R-M (2022) Clinical Assessment of Customized 3D-

Printed Wrist Orthoses. Appl Sci 12:11538. https://doi.org/10.3390/app122211538

64. Creylman V, Muraru L, Pallari J, Vertommen H, Peeraer L (2013) Gait assessment during the initial fitting of customized selective laser sintering ankle foot orthoses in subjects with drop foot. Prosthetics Orthot Int 37:132–138. https://doi.org/10.1177/0309364612451269

65. Schrank ES, Stanhope SJ (2011) Dimensional accuracy of ankle-foot orthoses constructed by rapid customization and manufacturing framework. J Rehabil Res Dev 48:31–42. https://doi.org/10.1682/JRRD.2009.12.0195

66. Ranz EC, Russell Esposito E, Wilken JM, Neptune RR (2016) The influence of passive-dynamic ankle-foot orthosis bending axis location on gait performance in individuals with lower-limb impairments. Clin Biomech 37:13–21. https://doi.org/10.1016/j.clinbiomech.2016.05.001

67. Li J, Tanaka H (2018) Feasibility study applying a parametric model as the design generator for 3D–printed orthosis for fracture immobilization. 3D Print Med 4:1. https://doi.org/10.1186/s41205-017-0024-1

68. Fantini M, De Crescenzio F, Brognara L, Baldini N (2017) Design and Rapid Manufacturing of a customized foot orthosis: a first methodological study. In: Lecture Notes in Mechanical Engineering. Springer Heidelberg, pp 457–467

69. Portnoy S, Barmin N, Elimelech M, Assaly B, Oren S, Shanan R, Levanon Y (2020) Automated 3D-printed finger orthosis versus manual orthosis preparation by occupational therapy students: Preparation time, product weight, and user satisfaction. J Hand Ther 33:. https://doi.org/10.1016/j.jht.2020.03.022

70. Chaparro-Rico B, Martinello K, Fucile S, Cafolla D (2021) User-Tailored Orthosis Design for 3D Printing with PLACTIVE: A Quick Methodology. Crystals 11:561. https://doi.org/10.3390/cryst11050561

71. Formisano M, Iuppariello L, Casaburi A, Guida P, Clemente F (2021) An industrial oriented workflow for 3D printed, patient specific orthopedic cast. SN Appl Sci 3:830. https://doi.org/10.1007/s42452-021-04816-w

72. Sala F, Carminati M, D'Urso G, Giardini C (2022) A feasibility analysis of a 3D customized upper limb orthosis. Procedia CIRP 110:207–212. https://doi.org/10.1016/j.procir.2022.06.038

73. Shih A, Park DW, Yang Y-Y (Dory), Chisena R, Wu D (2017) Cloud-based Design and Additive Manufacturing of Custom Orthoses. Procedia CIRP 63:156–160. https://doi.org/10.1016/j.procir.2017.03.355

74. Baronio G, Harran S, Signoroni A (2016) A Critical Analysis of a Hand Orthosis Reverse Engineering and 3D Printing Process. Appl Bionics Biomech 2016:1–7. https://doi.org/10.1155/2016/8347478

75. Doshi M, Mahale A, Singh SK, Deshmukh S (2022) Printing parameters and materials affecting mechanical properties of FDM-3D printed Parts: Perspective and prospects. Mater Today Proc 50:2269–2275. https://doi.org/10.1016/J.MATPR.2021.10.003

76. Chae DS, Kim DH, Kang KY, Kim DY, Park SW, Park SJ, Kim JH (2020) The functional effect of 3D-printing individualized orthosis for patients with peripheral nerve injuries: Three case reports. Medicine (Baltimore) 99:e19791. https://doi.org/10.1097/MD.0000000000019791

77. Kumar TS, Vijai A (2012) 3D Reconstruction of Face from 2D CT Scan Images. Procedia Eng 30:970–977. https://doi.org/10.1016/j.proeng.2012.01.952

78. Lun Z, Gadelha M, Kalogerakis E, Maji S, Wang R (2017) 3D Shape Reconstruction from Sketches via Multi-view Convolutional Networks. In: 2017 International Conference on 3D Vision (3DV). IEEE, pp 67–77

79. Bailer R, Martin RCG (2019) The effectiveness of using 3D reconstruction software for surgery to augment surgical education. Am J Surg 218:1016–1021. https://doi.org/10.1016/j.amjsurg.2019.07.045

80. Mora MA, Chenin DL, Arce RM (2014) Software Tools and Surgical Guides in Dental-Implant-Guided Surgery. Dent Clin North Am 58:597–626. https://doi.org/10.1016/j.cden.2014.04.001

81. Cao C-F, Ma K-L, Shan H, Liu T-F, Zhao S-Q, Wan Y, Jun-Zhang, Wang H-Q (2022) CT Scans and Cancer Risks: A Systematic Review and Dose-response Meta-analysis. BMC Cancer 22:1238. https://doi.org/10.1186/s12885-022-10310-2

82. Keyvanfar A, Shafaghat A, Rosley MS (2022) Performance comparison analysis of 3D reconstruction modeling software in construction site visualization and mapping. Int J Archit Comput 20:453–475. https://doi.org/10.1177/14780771211066876

83. Mazzonetto I, Castellaro M, Cooper RJ, Brigadoi S (2022) Smartphone-based photogrammetry provides improved localization and registration of scalp-mounted neuroimaging sensors. Sci Rep 12:10862. https://doi.org/10.1038/s41598-022-14458-6

84. Jasińska A, Pyka K, Pastucha E, Midtiby HS (2023) A Simple Way to Reduce 3D Model Deformation in Smartphone Photogrammetry. Sensors 23:728. https://doi.org/10.3390/s23020728

85. Bragonzoni L, Ingrassia T, Marannano G, Nigrelli V, Ricotta V (2022) A New Approach for CAD Modelling of Customised Orthoses by Generative Design. In: Rizzi C, Campana F, Bici M, Gherardini F, Ingrassia T, Cicconi P (eds) Design Tools and Methods in Industrial Engineering II. Springer International Publishing, Cham, pp 175–182

86. Barbero-García I, Lerma JL, Miranda P, Marqués-Mateu Á (2019) Smartphone-based photogrammetric 3D modelling assessment by comparison with radiological medical imaging for cranial deformation analysis. Measurement 131:372–379.

https://doi.org/10.1016/j.measurement.2018.08.059

87. Dey A, Yodo N (2019) A Systematic Survey of FDM Process Parameter Optimization and Their Influence on Part Characteristics. J Manuf Mater Process 3:64. https://doi.org/10.3390/jmmp3030064

88. Al-Tamimi AA, Tlija M, Abidi MH, Anis A, Abd Elgawad AEE (2023) Material Extrusion of Multi-Polymer Structures Utilizing Design and Shrinkage Behaviors: A Design of Experiment Study. Polymers (Basel) 15:2683. https://doi.org/10.3390/polym15122683

89. Hegab H, Khanna N, Monib N, Salem A (2023) Design for sustainable additive manufacturing: A review. Sustain Mater Technol 35:e00576. https://doi.org/10.1016/j.susmat.2023.e00576

90. Slama H Ben, Gaha R, Tlija M, Chatti S, Benamara A (2023) Proposal of a Combined AHP-PROMETHEE Decision Support Tool for Selecting Sustainable Machining Process Based on Toolpath Strategy and Manufacturing Parameters. Sustainability 15:16861. https://doi.org/10.3390/su152416861

91. Wickramasinghe S, Do T, Tran P (2020) FDM-Based 3D printing of polymer and associated composite: A review on mechanical properties, defects and treatments. Polymers (Basel) 12:1–42. https://doi.org/10.3390/polym12071529

92. Patel R, Desai C, Kushwah S, Mangrola MH (2022) A review article on FDM process parameters in 3D printing for composite materials. Mater Today Proc 60:2162–2166. https://doi.org/10.1016/j.matpr.2022.02.385

93. Dayyoub T, Maksimkin A V., Filippova O V., Tcherdyntsev V V., Telyshev D V. (2022) Shape Memory Polymers as Smart Materials: A Review. Polymers (Basel) 14:3511. https://doi.org/10.3390/polym14173511

94. Gorokhova N, Perepelkina S, Sundkvist I (2021) The Usage of Smart Materials for Development of Rehabilitation Orthopedic Device for Plantar Fasciitis Treatment. IOP Conf Ser Mater Sci Eng 1079:032067. https://doi.org/10.1088/1757-899X/1079/3/032067

95. Toth L, Schiffer A, Nyitrai M, Pentek A, Told R, Maroti P (2020) Developing an anti-spastic orthosis for daily home-use of stroke patients using smart memory alloys and 3D printing technologies. Mater Des 195:109029. https://doi.org/10.1016/j.matdes.2020.109029

96. Zhao D, Pang B, Zhu Y, Cheng W, Cao K, Ye D, Si C, Xu G, Chen C, Yu H (2022) A Stiffness-Switchable, Biomimetic Smart Material Enabled by Supramolecular Reconfiguration. Adv Mater 34:. https://doi.org/10.1002/adma.202107857

97. Kantaros A, Ganetsos T (2023) From Static to Dynamic: Smart Materials Pioneering Additive Manufacturing in Regenerative Medicine. Int J Mol Sci 24:15748. https://doi.org/10.3390/ijms242115748

98. Oud T, Kerkum Y, Groot P, Gijsbers H, Nollet F, Brehm M (2021) Production time and user satisfaction of 3-dimensional printed orthoses for chronic hand conditions compared with conventional orthoses: A prospective case series. J Rehabil Med – Clin Commun 4:jrmcc00049. https://doi.org/10.2340/20030711-1000048

Conflicts of interest

We have no conflicts of interest to disclose