Progress in Additive Manufacturing (2020) 5:85–94
https://doi.org/10.1007/s40964-019-00104-7

REVIEW ARTICLE

A review on the use of additive manufacturing to produce lower limb orthoses

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Received: 15 May 2019 / Accepted: 22 October 2019 / Published online: 8 November 2019

Abstract
Orthoses (exoskeletons and fracture fixation devices) enhance users' ability to function and improve their quality of life by supporting alignment correction, restoring mobility, providing protection, immobilisation and stabilisation. Ideally, these devices should be personalised to each patient to improve comfort and performance. Production costs have been one of the main constraints for the production of personalised orthoses. However, customisation and personalisation of orthoses are now possible through the use of additive manufacturing. This paper presents the current state of the art of additive manufacturing for the fabrication of orthoses, providing several examples, and discusses key research challenges to be addressed to further develop this field.

Keywords Additive manufacturing · Exoskeleton · External fixation · Orthoses · Personalisation

1 Introduction

According to a report from the Centre for Disease Control and Prevention, only in The United States (USA), more than 17 million adults present locomotion problems [1]. These problems are mostly caused by falls, ageing-related diseases or accidents. One of the common methods in treating orthopaedic leg injuries is wearing orthopaedic devices [2]. Orthoses are orthopaedic devices designed to help patients with difficulties to walk or semi-paralysed due to spinal cord injuries (SCI) or stroke [3, 4]. These devices are designed to provide support, stabilisation and immobilisation. Generally, there are two main groups of orthotic devices: exoskeletons and fracture fixation devices. The main difference between these two groups lies on the purposes of using them. Exoskeleton devices are mainly designed to restore/reinforce the human performance [5, 6], whereas the fracture fixation devices (e.g. Ilizarov, splints, casts) are designed for immobilisation/stabilisation of the fractured bones and correction of specific deformities [7, 8].

Exoskeletons are being used for medical (e.g. rehabilitation) [9], military (e.g. carrying heavy weapons) [10, 11] and industrial (e.g. handling cargo) applications [11–14]. External fixation devices were developed for the treatment of different bone fractures, limb deformity and soft tissue pathologies, playing a critical role in preventing amputation [15, 16]. The concept was introduced as an alternative to immobilisation in a plaster cast, internal fixation and traction, providing support to a limb using rings and/or wires secured to external scaffolding [17, 18]. These devices can be used for temporary treatment, providing provisional alignment stability, or for permanent treatment in cases such as pelvic fractures, open long bone fractures and periarticular fractures [17, 19].

The most commonly used external fixator in the treatment of complex fractures is the Ilizarov device, and is shown in Fig. 1. It is a circular external fixator worn around the defect or injured part, providing stabilisation to bone segments and immobilisation. The Ilizarov frame was proposed

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Fig. 1 The Ilizarov frame [22]

by the Russian surgeon Gavril Abramovich Ilizarov in 1950 [20]. It consists of rings, pins, wires and rods, and was based on the discovery that it is possible to induce new bone formation by the gradual distraction of the fracture through the manipulation of the connectors between the rings [21].

The Ilizarov is mainly used to hold broken bones together, correct bone deformities, lengthen the shortened limb and address soft tissue atrophy. However, one of the main limitations of this device is the risk of infections as a result of the use of pins and wires. Additionally, this device causes patient discomfort, requires prolonged treatment and a manual lengthening process [23].

Orthoses are a good example of personalised products. To be effective, they must be designed considering the anatomic characteristics of the user and they must fit the corresponding applications (e.g. rehabilitation or supporting activities). However, due to technological limitations and associated costs, personalisation was not explored before. This paper discusses the implementation of mass personalisation to produce orthotic devices, focusing on the emerging use of additive manufacturing. The most commonly used techniques are discussed, and examples provided. Finally, some research challenges are presented.

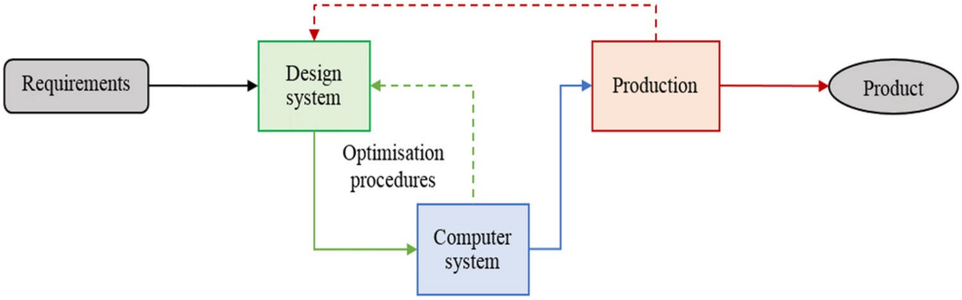
2 Mass personalisation of orthoses

The implementation of a mass personalisation system comprises three main domains: design, computational modelling and optimisation, and production (Fig. 2). In this approach, the system not only must present enough flexibility to design an individual product based on the user requirements/constraints but also must be able to fabricate a lot size of one in a cost-effective way, being able to materialise whatever shape is designed. Such need for formal flexibility is now possible through the use of additive manufacturing.

To assist the design phase of orthoses, Shih et al. [24] proposed a cloud-based design system called Cyber Design and Additive Manufacturing (CDAM). The CDAM system aims at shortening the delivery and improving the fit and comfort of custom orthoses and prostheses. The system is composed of four main features: (1) the digital scanning of foot and leg geometry using a stand with transparent foot plate and ergonomic procedure for 3D optical scanning, (2) a cloud-based design software that enables clinicians to access scanned point cloud data on the geometry of patients' feet as well as create 3D models for ankle–foot orthoses (AFOs) based on patients' needs, (3) a cloud-based manufacturing software that generates tool paths and process parameters for additive manufacturing to fabricate the AFO, and (4) the evaluation using Inertia Measurement Unit (IMU) for measurement of the AFO motion for gait analysis [24]. Figure 3 illustrates the proposed cloud-based design system.

Additive manufacturing systems are capable of producing any geometric form independent of its complexity. Therefore, novel design schemes have been implemented and combined with additive manufacturing, topological optimisation schemes, to produce lightweight medical devices with minimum compliance [25]. According to the ASTM (American Society for Testing and Materials)

Fig. 2 Mass personalisation implementation model



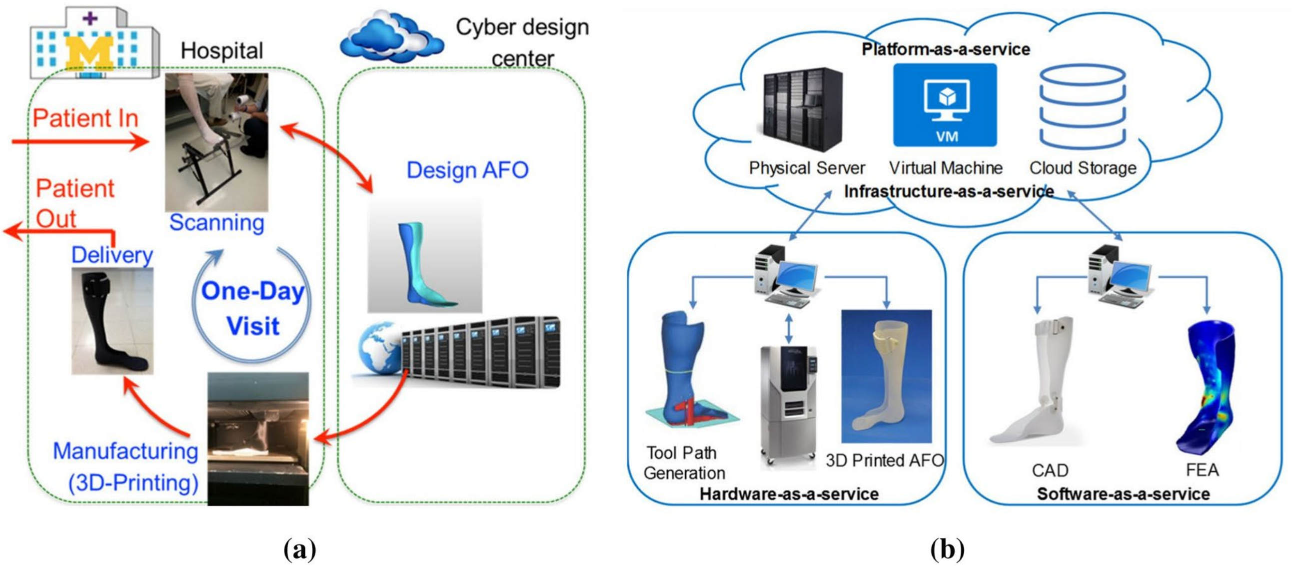


Fig. 3 **a** Overview of the CDAM system for custom AFOs. **b** Illustration of the interaction between the hardware and software systems with the cloud storage system [24]

committee, additive manufacturing describes a group of processes that create an object by adding materials in a layer-by-layer way. This technology allows the fabrication of objects of virtually any shape without the need for tooling, reducing assembling requirements and process steps. Additionally, complex objects can be produced without a significant increase in costs [26, 27]. Additive manufacturing minimises material waste and enables the fabrication close to the clients. It allows the fabrication of multi-material components with embedded sensors and morphing components [28–30], and it is suitable for the fabrication of products that require customised features, low volume production and/or increased geometric complexity [31]. Seven different technologies can be considered (Fig. 4):

- Vat photo-polymerisation: an additive manufacturing method in which a liquid polymer contained in a vat is selectively cured using UV radiation from a laser or a lamp.
- Material jetting: an additive manufacturing process in which droplets of build material are selectively deposited through a nozzle.
- Material extrusion: an additive manufacturing process in which melted material is selectively dispensed through a nozzle.
- Powder bed fusion: an additive manufacturing in which thermal energy (laser or electron beam) selectively fuses regions of a powder bed.
- Binder jetting: an additive manufacturing process in which a liquid binder is selectively deposited to join powder materials.
- Sheet lamination: an additive manufacturing process in which sheets of materials are bonded to form a 3D component.
- Direct energy deposition: an additive manufacturing process in which thermal energy is used to fuse materials by melting them as the material is being deposited.

However, among these technologies, only vat photo-polymerisation, powder bed fusion and material extrusion have been explored to produce orthoses.

Figure 5 provides a general overview of the necessary steps to produce orthoses using additive manufacturing. The first step is the generation of the corresponding digital solid model through one of the currently available medical imaging techniques, such as computer tomography (CT) or magnetic resonance imaging (MRI) or 3D data scanning. However, these techniques usually produce large data sets that require post-processing to produce useable output information and involve expensive hardware and sophisticated software to process the data [32]. The obtained data are then processed to create the 3D digital orthoses. Software tools such as Mimics (Materialise, Belgium), In Vesalius (CTI, Brazil) and Rhinoceros (Robert McNeel& Associates, USA) are used. These geometric data are then tessellated and sliced before fabrication. The STL (Stereo Lithography) file format, which is the standard format for additive manufacturing, is a polyhedral representation of the surface of models using triangular facets [33]. The STL file format corresponds to a simple first-order approximation of the original CAD model but presents several limitations such as the high degree of redundancy and the impossibility to

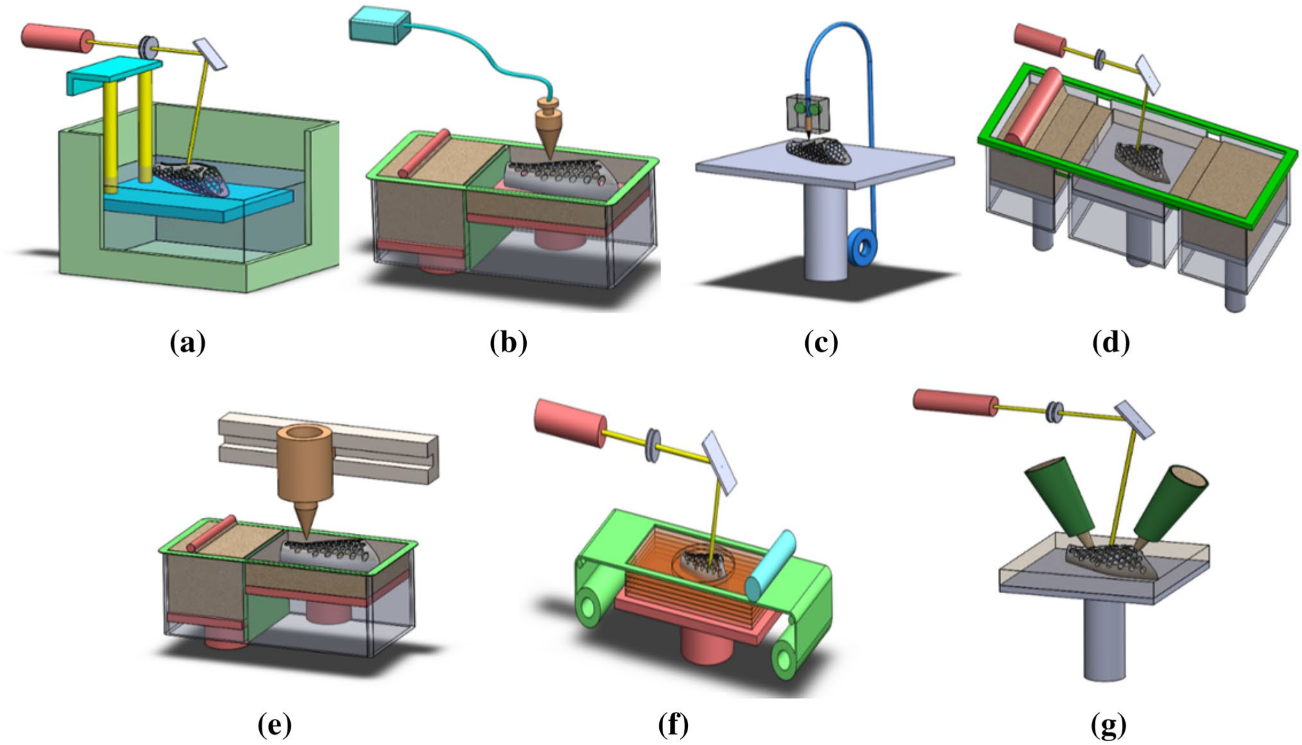


Fig. 4 Different additive manufacturing technologies: **a** vat photo-polymerisation, **b** material jetting, **c** material extrusion, **d** power bed fusion, **e** binder jetting, **f** sheet lamination, **g** direct energy deposition

include material information. Alternative file formats, such as the Additive Manufacturing File format (AMF), have been proposed to address these limitations [34]. Depending on the additive manufacturing technology selected for the fabrication of the orthoses, support structures must be considered. Component orientation in the working platform is also import as it determines the amount of supports, fabrication time and mechanical properties. After the fabrication stage, components must be submitted to post-processing (e.g. post-curing, support removal, polishing).

3 3D-printed orthoses

3.1 Vat photo-polymerisation

Vat photo-polymerisation uses photo-curable polymers which are relatively expensive compared to other polymer-based techniques. Therefore, the use of vat phot-polymerisation for the fabrication of orthoses is limited. Mavroidis et al. [35] compared AFOs produced through different techniques. A conventional casting process was used to produce Poly-Propylene (PP) AFO. Vat photo-polymerisation (Viper SLA machine) was also used to produce AFOs using both Accura 40 and Somos 9120. Gait analyses were carried out on one subject at the Spaulding Rehabilitation Hospital, Boston, with the aid of a motion capture system. Results showed that the performance of additive manufactured custom-fit ankle–foot orthoses is similar to the standard orthosis in terms of controlling the kinematics and kinetics of the ankle with an equivalent walking speed and the step length for all ankle–foot orthoses [35]. No differences in terms of performance were observed between the two additive manufactured orthoses.

Regarding the external fixation devices, to the best knowledge of the authors, there is only one study conducted on the application of vat photo-polymerisation for the fabrication of external fixators (Ilizarov). This study presented the first customised external fixation device, named Q-Fixator, for fixation and fracture reduction (Fig. 6) [36, 37].

The QF fixator uses the same principle of the Ilizarov fixator and thus it provides good stability, strong anti-rotation and anti-bending, preventing shear forces and rotational forces on the healing bones. The QF is composed of two frames (proximal and distal) fabricated using vat photo-polymerisation (Shaanxi Hengtong Intelligent Machine Co., Ltd. SPS600) [37]. To simplify the assembly of the fixator, each frame is divided into two components as shown in Fig. 7 and joined by bolts. Each frame has three to four mounting holes to connect these frames with the bone by inserting pins into the holes. The two frames are connected by four parallel threaded rods. Moreover,

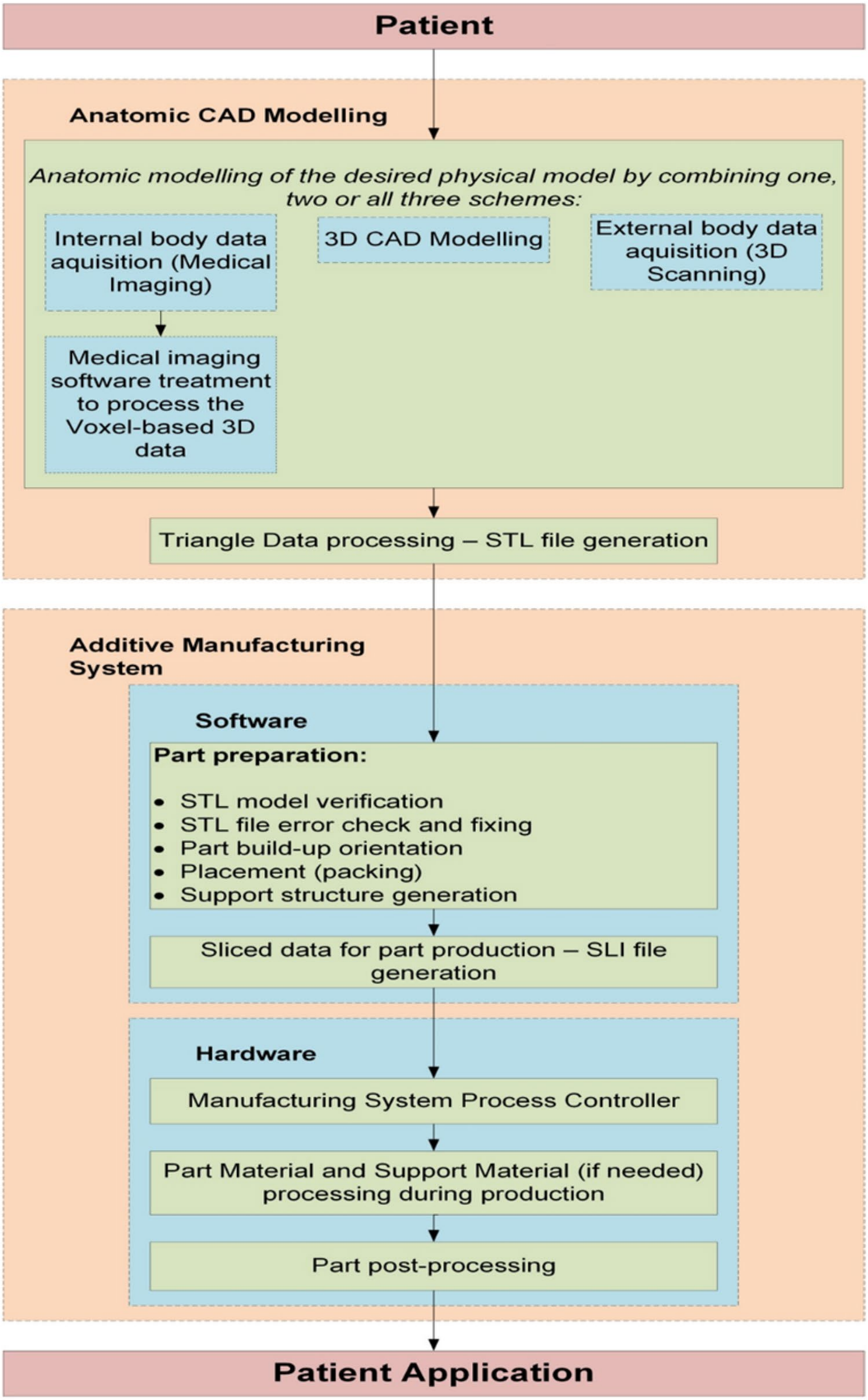


Fig. 5 Information flow using additive manufacturing for the fabrication of orthoses

adjustable nuts are also used to adjust the distance between the frames. Two metal rings are also integrated into the proximal and distal frames to strengthen the fixator [36].

The QF fixator was used to treat three male patients with tibial fractures due to traffic accidents. This study shows good results in terms of accuracy of reduction and operation

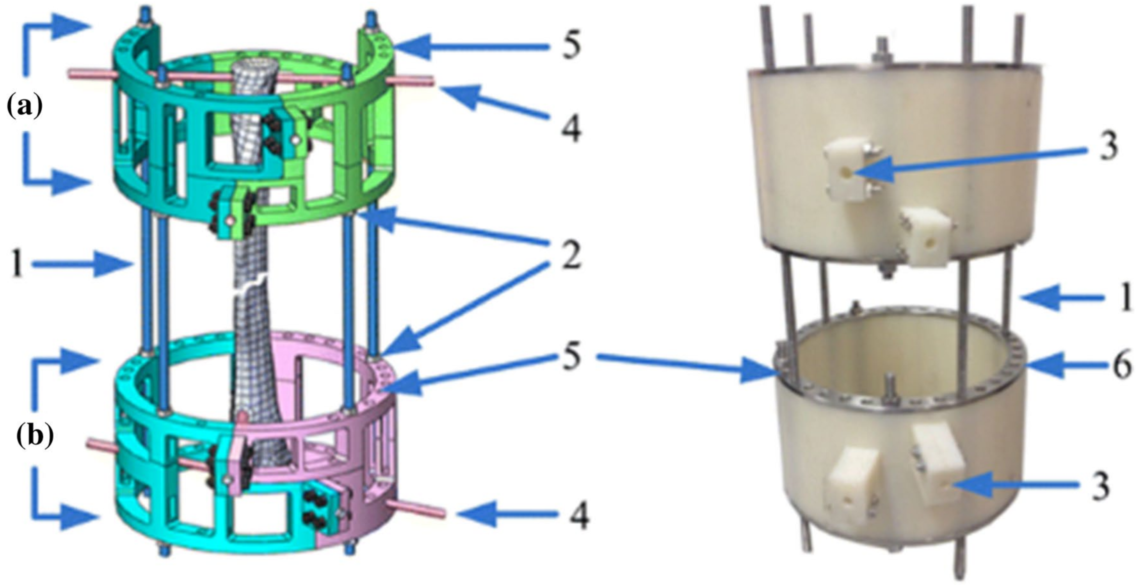


Fig. 6 Structure of the Q-Fixator. **a** Proximal frame. **b** Distal frame. (1) threaded rods; (2) adjustable nuts; (3) mounting holes; (4) pin and half-pin; (5) connecting holes; (6) metal rings [37]

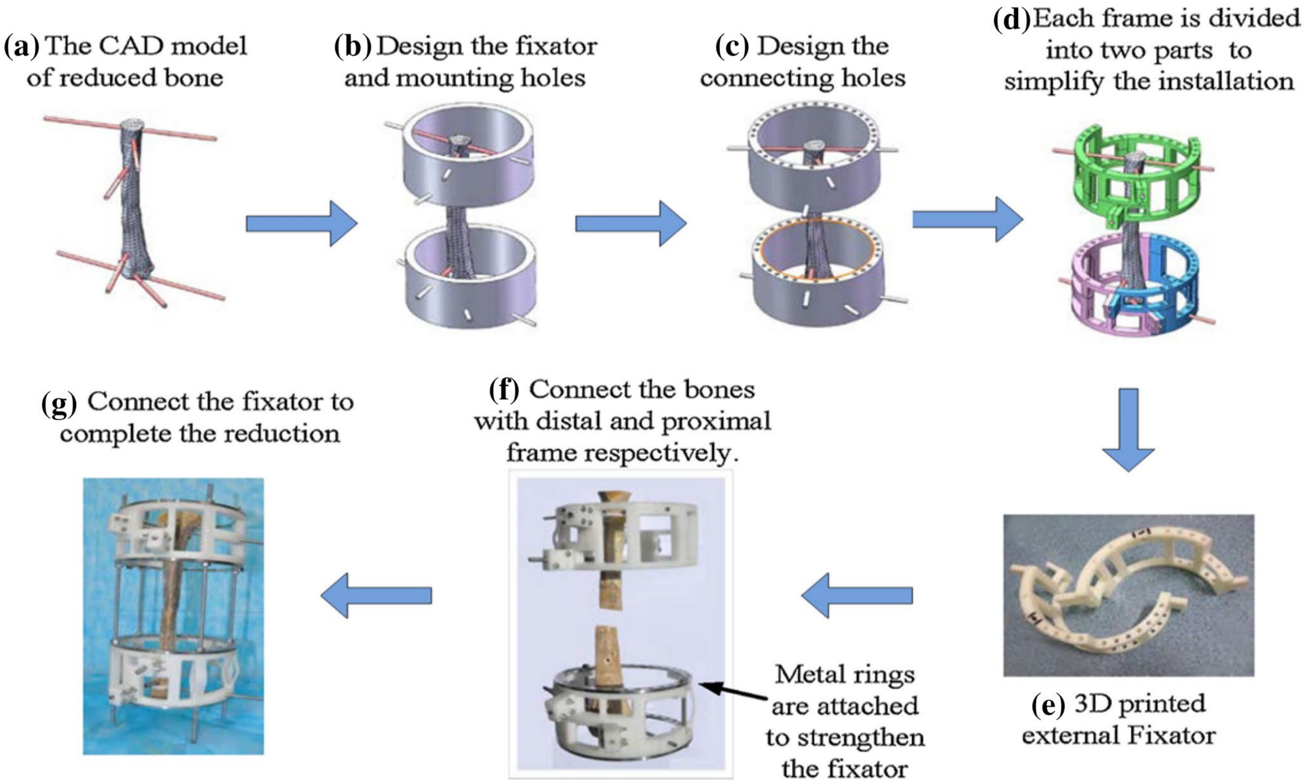


Fig. 7 The procedures of designing and manufacturing the 3D-printed proximal and distal frames of Q-Fixator [36]

time. In addition, no pin loosening, pin site infection or any other complications were observed. Moreover, the QF presents other advantages including easy assembly and cleaner X-ray images due to the reduced imaged scattering [37].

3.2 Material extrusion

Material extrusion is the most popular additive manufacturing technique due to its relatively low cost and a wide range of materials that can be processed. Patar et al. [38] produced customised dynamic ankle–foot orthoses and Balamurugan and Arumaikkannu [39] produced a knee exoskeleton both in Acrylonitrile Butadiene Styrene (ABS). The exoskeleton was designed to aid the knee joint in walking, sitting and standing activities. Similarly, McDaid et al. [40] designed and produced a robot exoskeleton which acts as a knee brace to provide lower limb gait training and rehabilitation. The exoskeleton was printed using Polylactic acid (PLA) and a low-cost RepRap machine. In both cases, fully functional exoskeletons were produced. McDaid et al. [40] also showed that extrusion-based additive manufacturing allows producing lightweight devices, overcoming one of the main design limitations of current devices. Churchwell et al. [41] designed, manufactured and tested a 3D-printed structural component for the Joint Torque Augmentation Robot (JTAR) hip exoskeleton. The component was designed to replace an aluminium CNC-machined part and it was made in PLA material. A significant weight reduction was achieved (the CNC Part weighed 62 grams, whereas the 3D-printed part weighed 56 grams), contributing to an overall weight reduction of the hip exoskeleton. The development process was also significantly reduced from 6 weeks to less than 1 week. Finally, the cost was reduced in around 25% by replacing the aluminium component. Figure 8 shows both the CNC-machined and 3D-printed parts.

Chen et al. [42] used CNC machining and extrusion-based additive manufacturing to produce an AFO. Conventionally manufactured orthosis was in PP, while additive manufactured orthoses were made in Polycarbonate (PC)-ABS and ULTEM. A finite element model was used to calculate the static and dynamic loading during the gait cycle supporting the design phase. Results showed that the additive manufactured AFOs present lower strain during the gait cycle than conventionally manufactured ones. Additionally, the ULTEM ankle–foot orthosis has the lowest strain among the three orthoses. This work also shows that material extrusion can be used to fabricate orthoses with sufficient strength and stiffness [42].

Vijayaragavan et al. [43] used the extrusion process to produce a corrective orthosis for the treatment of clubfoot in children. The authors used CT data for both the internal and external definition of the foot. The internal data were used for the definition of the bone structure, while the external data comprised the skin providing the geometrical volume of the foot.

Blaya et al. [44] designed and fabricated novel splints for the partial rupture of Achilles tendon. The designed splint was produced using both FilaFlex and Polycarbonate materials that guarantee comfort and resistance at the same time. In addition, the authors performed material optimisation studies to reduce the weight of the splint and manufacturing costs.

Fig. 8 The CNC-machined part (left), the 3D-printed part (right) [41]

Jin et al. [45] investigated the effect of different processing conditions to produce Ankle–Foot Orthoses with improved mechanical properties. The study focused on the following issues: (1) optimal orientation in the working platform, (2) support generation, (3) slicing and (4) tool path generation. Optimal orientation was selected based on the improvement of the build time, part strength and surface finish, and minimising support structures. Adaptive slicing strategies were considered to reduce fabrication time and to improve surface quality. Finally, a contour-parallel tool-path strategy was adopted for the device fabrication.

Turk et al. [46] combined extrusion-based additive manufacturing with Carbon Fibre-Reinforced Polymers (CFRP) in an autoclave pre-impregnated process for the development of complex-shaped hybrid AM-CFRP structures. Powder bed fusion and extrusion-based additive manufacturing were also used to create titanium functional parts and ST-130 polymeric parts, respectively. The printed components were assembled and over-laminated with a carbon fibre-reinforced polymer and consolidated in an autoclave. A significant weight reduction (28%) was achieved compared to commercial available devices, without compromising mechanical performance.

3.3 Powder bed fusion

Powder bed fusion can be used to produce both polymeric and metallic parts. Bhatia and Sharma [47] used this technology to print a robotic for a woman who was paralysed from the waist down, enabling her to walk and to perform daily activities (Fig. 9). The patient was scanned on the thigh, shin and spine, and then the scanned data were used to design and print the components of the robotic suit. Finally, the printed components were assembled with actuators and controls [47].

Orthoses are commonly prescribed for Rheumatoid arthritis which causes inflammation in the joints, leading to pain, stiffness and deformity. A customised device can be an effective tool to improve function and mobility of patients suffering from this disease. Pallari et al. [48] investigated the feasibility of using powder bed fusion for the fabrication of customised foot orthosis, showing that the 3D-printed orthoses are as effective as currently prescribed orthoses. Drop foot is another disease that affects the ability of patients to raise their foot at the ankle. In this case, Milusheva et al. [49] and Faustini et al. [50] designed and fabricated personalised ankle–foot orthosis, based on a 3D laser scanning model of the patient's ankle–foot, to assist and restore the ankle–foot movements. These orthoses also used a passive component (e.g. spring) to provide support during the stance phase (Fig. 10).

Creylman et al. [51] evaluated the clinical performance of ankle–foot orthoses manufactured through powder bed fusion. The experiment was conducted on eight subjects with unilateral drop foot. Two AFOs were fabricated for each subject (Fig. 11): one additive manufactured in Nylon 12 (polyamide—PA) and the other conventionally casted in PP. The results show that all produced AFOs have a beneficial effect regarding the spatial–temporal gait parameters (e.g. step length, speed) and the ankle kinematic parameters (joint angle, joint rotation) in comparison to the barefoot gait of adults with drop foot gait. Results also show that additive manufactured AFOs present at least equivalent clinical performance as clinically prescribed ones. Additionally, additive manufacturing allows reducing the fabrication time and

Fig. 9 The robotic suit [47]

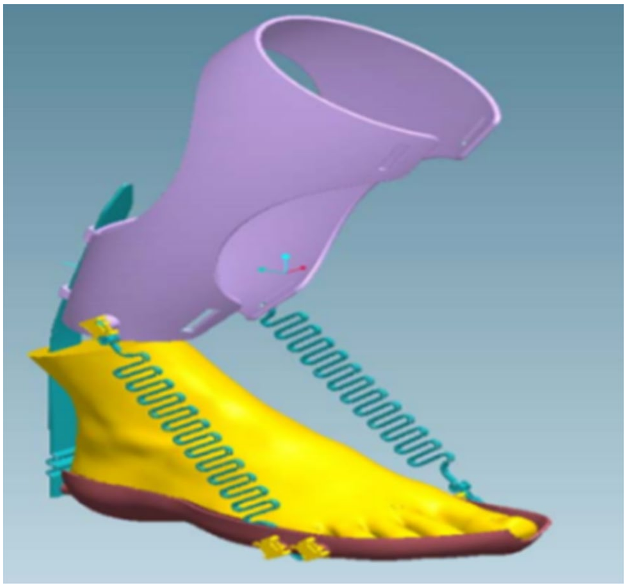


Fig. 10 The customised ankle–foot orthosis [49]

Fig. 11 The PP ankle–foot orthosis (left) and the additive manufactured ankle–foot orthosis (right) [51]

guarantees the consistency of shape compared to the traditional process [51].

4 Challenges and conclusions

Commercially available orthoses are not fully customised devices. They are produced using conventional machining and/or casting process, which does not have the capability to produce small and intricate features. Ideally, orthoses must be fully personalised to be efficient for the treatment of an individual patient with different diseases and injuries. Technological limitations were the main constraint for mass customisation and personalisation. The emergence of additive manufacturing technologies allows the fabrication of custom-made orthoses in a cost-effective way. The combination of additive manufacturing and individual anatomic data allows the fabrication of complex and more comfortable devices reducing cost and development time.

Among the different additive manufacturing techniques currently available, only vat photo-polymerisation, material extrusion and powder bed fusion have been explored. Material extrusion is the most affordable one but limited to the use of polymers.

Orthotic devices can be produced through the use of a wide range of materials such as plastics (thermoplastics and thermosets), metals, synthetic fabrics and combinations of these materials. The most commonly used additive manufacturing materials are ABS, PLA and PA as they can be easily processed and provide adequate mechanical properties. These materials can also be combined with soft natural polymers (hydrogels) able to absorb moisture, reduce friction, reduce skin irritation and increase patient's comfort.

The examples provided in this paper clearly indicate the potential of additive manufacturing for the fabrication of orthoses. However, there are challenges to be considered:

- Most additive manufacturing machines have a working volume smaller than the dimensions of the exoskeleton. In this case, different components must be considered, printed and finally assembled. This increases labour time and cost.
- Additive manufacturing has been used to produce small-scale passive orthoses or components for large-scale passive orthoses. The use of additive manufacturing for the fabrication of active exoskeletons is an important challenge requiring not only in printing the built material but also to embed sensors and actuators during the fabrication process.
- Additive manufacturing allows freedom of design. In the case of the design of orthoses, this means that new functionality can be considered. The combination of the shape or topology optimisation tool with additive manufacturing, for example, allows the fabrication of lightweight structure without compromising the mechanical performance. Therefore, the design of orthoses to be produced through additive manufacturing must also take into consideration the characteristics and constraints of each technique (design for additive manufacturing).

Acknowledgements The first author acknowledges the support received by The King Saud University to conduct his PhD studies.

Funding This research was funded by Saudi Arabian government.

Compliance with ethical standards

Conflict of interest No potential conflict of interest was reported by the authors.

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