Three-dimensional printed orthosis in biomedical application: A short review

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Abstract. The three-dimensional (3D) printing in medical implants unlocks unparalleled opportunities to completely configure the product to the patient's measurements and needs. To be noted, the use of personalized 3D printed orthosis used in regeneration for serious orthosis implants of specific patients is growing to date. The 3D printed is unique to the patient instruments that can be used to facilitate correct positioning of implants and improved functional outcomes. The 3D printing, also defined as 'rapid prototyping' and 'additive manufacturing' is widely regarded as the ‘second technological revolution. The orthosis is an "externally applied mechanism used to alter the structural and functional properties of the musculoskeletal and skeletal system". Applications in orthosis healthcare that are pioneering the way 3D printing is performed, changing the orthosis implant markets. This paper is reporting literature on the development of orthosis using 3D printing technology that could make the users more comfortable and easier to maintain. From the literature search, this paper summarises some important information about the use of 3D printing for orthosis development where it focuses on specific regions of human body, the materials for the 3D printed orthosis and further directions of this technology and research. In conclusion, the findings from this review paper may lead to a future recommendation and study in providing better treatment for patients.

Key Words: 3D Printing, Biomedical Applications, Orthosis, Rapid Prototyping.

1. Introduction

Orthosis is normally used in clinical practice to facilitate alignment, avoidance, or correction of deformities to enhance the roles of the movable parts of the body [1, 2]. The orthosis technology can help patients return to a nearly normal mobility and post-stroke limb function or amputation. However, the method of developing specially designed devices takes time and effort. Research has shown that over three quarters of dementia patients need to be recovered long term, many of whom are supported by individual orthotics [3-5]. To be noted that the orthosis could also allow children with cerebral palsy, myelomeningocele, and other disorders to achieve stability and walk more comfortably. Therefore, printed prototypes may deliberately have widely valued after properties for biomedical applications. Customized clinical equipment, engineered tissues, bone replacement scaffolds, prosthesis sockets, orthoses, drug delivery, or undergoing surgery and implantable devices are some examples [6, 7]. Three-dimensional (3D) printing is a collection of practices for producing a model consisting of a physiological component or installation in a short period of time using a 3D computer-aided design (CAD) software. Usually, component or assembly creation is carried out using 3D printing or "Additive Manufacturing" technology [3, 8]. The 3D printing enhances the performance of the parts, speeds up the manufacturing process and progresses in cost reduction, which is a very significant factor for society today. So, one of the criteria to be met is to build an orthosis that is affordable for all.
To date, there are many printed orthoses used by patients to facilitate their bodies. From the conventional method of costing and modelling, the current technology of 4th industrial revolution allows engineers and scientist to produce more convenient and faster product of orthosis via 3D printing process [9]. Apart from that, it is found that the 3D printing and scanning not only can reduce time of fabrication process, but it can accommodate paints or users with optimum time of manufacturing process thus eliminating excessive time for waiting [10]. This review paper is discussing about findings on the use of 3D printing technology for developing orthosis that facilitate all regions of human bodies [11]. Apart from that, this paper is discussing about the available materials of orthosis and future directions of research and study in providing a better healthcare services to patients and user. It is hoped that this study could give new insight to researchers for developing a optimum orthosis for patients.

2. Methods

2.1. Strategy of literature search
Searches were conducted in this review using a variety of keywords and search engines. To review existing evidence from the literature, the following basic search techniques were used:

The following keywords were used: included in the search terminology “biomedical applications” as well as specialized words like “3D printed orthosis”, “orthosis”, “orthosis implant”, “adaptive orthosis”, “3D orthosis”.

Engines of discovery: Web of science, ScienceDirect, Medline, IEEE Explore, Google Scholar, and Research Gate are some of the resources available.

2.2. Criteria for inclusion and exclusion
We defined inclusion and exclusion requirements because of our inquiry and study. In terms of the inclusion requirements, previous research was evaluated and included if they fulfilled the following relevant expectations: (1) Papers which are published only in English; (2) The study was carried out and published between January 2009 and December 2020; it discovered over 300 papers and chose approximately seventy different publications. (3) All forms of 3D orthosis were considered; (4) The research covered elements of orthosis biomedical application. (5) Research was conducted towards the creation of a prototype and its use on patients. (6) The nature of the papers, such as case studies, conference presentations, patents, original research work, and review articles. In terms of exclusion requirements, the following are focused on: (1) Articles that are duplicated; (2) Experiments on animals were not considered.

3. Results and discussion

3.1. 3D Printed orthosis in Biomedical Applications.
Presently seven distinct proven methods are available for additive manufacturing, according to the ISO/ASTM 52900 standard [12]. There is different orthosis in biomedical applications found from the literature research. Among them we bring most advanced biomedical application are used in 3D printed orthosis.

3.2. Upper limb orthosis
Kim et al. developed a 3D printed orthosis with a slightly dorsiflexed wrist joint, free finger motions, and a duration to the forearm's middle in 2018. The monitoring group wore a cock-up splint that had been prefabricated [13, 14]. Zheng et al. in 2020 developed a 3D manufactured orthosis that mimicked a functioning arm movement (10° to 15° arm expansion, 40° to 45° flexing its palm abduction, proximal interphalangeal, and metacarpophalangeal. [14]. A treatment design used a thermoset layer orthosis at low temperature. In 2017, Chen et al. has developed 3D printed for an orthosis that extended beginning of the middle arm towards the metacarpophalangeal, apart from thumb [15]. Furthermore, an arm part featured numerous tiny holes for airflow and user comfort, as well as the covers protecting the top and bottom upper arm parts were partitioned and flexible with a better grip. A wrist-driven orthosis in utilization by Portnova et al. in 2018 was manufactured, and each part was designed in multiple lengths to form specific consumers [16].

(a) Arm Orthosis
Airy Arm is an exoskeletal aid as shown in figure 1a where it is intended to help people who have an intact but non-functioning limb. When the device is worn, the user extends his or her elbow, and the device extends their fingers through cables. No electronic components are used. Users used 3Dhubs site Zortrax highly rated the Polish company Zortrax's 3D printer for the printing [17]. Many printings were carried out on a Raise 3D Pro computer
(Raise 3D Technologies, Inc., Irvine, CA, USA) with a working chamber scale of 305×305×605 mm and a dual extruder with a diameter of 0.4 mm. The ABS, PLA, nylon (PA12) (Spectrum Group, Pecice, Poland), and high-impact polystyrene (HIPS) were used as 1.75 mm-diameter filaments (MakerBot, New York, NY, USA) [18]. All materials, except for nylon (40 mm/s), were thought to have an extrusion speed of 80 mm/s [19].

(b) Wrist/Hand Orthosis
Hand/Wrist Despite some degree of hand paralysis, this device is used to provide grip, release, comfort the wrist mobility and can be use as alternate of plaster. The hand 3D orthosis was printed using DuraForm ProX on a ProX SLS 500 printer. The orthosis prototype's final measurements are 91.93 x 92.37 x 181.62 mm, with a thickness of 2.5 mm and a weight of 45 grams [20].

Figure 1. (a) 3D printed airy Arm [17] and arm [21]. (b) A cyborg beast is a hand prosthesis powered by the user's own body. Zuniga's permission was obtained for this release[22].

3.3. Lower limb orthosis
In 2017, Telfer et al. created an additive manufacturing innersole from 3D scanned bubble-box leg observations [23]. Mo and colleagues published their findings in 2019 which was created an additive manufacturing leg orthosis from the hip joint located rationally. The foot orthosis now has a 3-mm PORON cover [24, 25]. Xu et al. published two studies in 2019. One of them was designed for people who had plantar fasciitis [26, 27]. The use of longitudinal straps in the sole and metatarsus layer of the insole increased pressure balance. A modified 3D printing technology insole that overwhelmingly supported the middle arched knee and prevented it from collapsing was created in a study of patients with long-term knee pain [27].

(a) Knee Orthosis (KO) Brace
Knee Orthosis Brace (KO) is a form of knee brace used only to strengthen its knee. It works by putting pressure on the injured region of the elbow joint, which is usually caused by inflammation and osteoporosis figure 2: MIT researchers created 3D-printed stretchy meshes with personalized designs that are versatile and durable enough to be used in ankle and knee braces [28].

(b) Ankle-Foot Orthosis
Foot loss induced by peroneal neuropathy is commonly treated with an ankle-foot orthosis [29]. As a form of ankle-foot orthosis, it is usually made by hand mold forming, shaping thermoplastics, as well as slicing it that requires dexterity or a lot of work. Young et al. created an integrated computer application of orthosis develop or used the 3D printing technique to produce the orthosis. To create an ankle-foot orthosis using 3D printing, a 3D printer, Eva (ArtecTM Eva, following classes Unit, Luxembourg) was being utilized to test the patient's lower right leg in order to build the ankle-foot orthosis. The screening process was applied throughout the static position with such a 3D model, as well as the screening process was followed in the sitting position also for covered regions of a lower leg which were not apparent in the static position. The scanning can capture upward to 16 frames a second, so these pictures become automatically synchronized in real time, making screening quick and easy [30].
Figure 2. Printed foot orthosis. (a) MIT researchers created 3D-printed stretchy meshes [28], (b) For the sake of strength, a regular ankle-foot orthosis without a joint made of polypropylene was used and (c) the 3D-printed ankle-foot orthosis was worn with shoelaces [29, 31].

(c) Foot Orthosis

Foot orthosis can help with overpronation, underpronation, flat feet, neuroma, plantar fasciitis, arch pain, heel pain, dorsum of the foot pain, and toe pain, among other foot problems [32]. It is intended to support the foot by adding pressure to places to promote proper gait [33]. The BFB 3D Touch printer has multi-material flexible formation features, a 3D printing capacity of 275x275x210mm³, and a surface diameter of 125mm [34]. The surfaces of such object are generated by the printer using melting or smoothing material (ABS or PLA). Figure 2c depicts a 3D foot soles produced by a 3D printer.

(d) Knee Ankle Foot Orthosis (KAFO)

The joint used at knee height is the focal point. Recent advances in digital scanning and additive manufacturing technologies have opened up new avenues for producing low-cost, fully configurable KAFOs [35]. Alam et al. successfully tested a human adult foot and used it to establish an KAFO [36]. They then used prototyping techniques to produce an KAFO that included a foot plate, side bar, and calf string. This KAFO provided adequate airflow and power, but provided only minor shaping to the patient's foot [37]. The AFO was manufactured on an atomic layer printing 3D printer (FB9600®, TPC Mechatronics Corp., Incheon, Korea). As the thermoplastic filaments melt, the process builds up them layer by layer. One of several thermoplastic filaments used in this analysis was thermostlastic polyurethane (Shenzhen Esun Industrial Co. Ltd, Shenzhen, China), which was nontoxic and highly flexible (diameter 1.75 mm, extruders temperature 210–230°C) [38].

(e) Hips Orthosis

Hips used after a complete hip replacement to avoid hip flexion, adduction, and internal rotation, which can lead to dislocation. The hardness of titanium-based alloys, cobalt-chrome alloys, and 316L stainless steel, which are commonly used in hip implants, is much higher than that of bone. When a metal implant is inserted into the femur, the majority of the physiological load is transferred to the implant, rather than the more compliant underlying tissue [39]. Timbleston et al. utilized stereolithography in a blended fluid design formation (CLIP) method that outperforms traditional 3D printing techniques in terms of fabrication time. To achieve the desired resolution, it takes longer to construct a new layer by layer. With a cured phase density of about 20m, the polymer height of optical absorption is 100m, and the printing speed was more than 300m, compromising higher resolution for a speed that reaches 1000 mm/h as compared to normal layer by layer 3D printing, which fabricates in a few millimetres per hour [40].

Figure 3. (a) 3D printed foot orthotic [41], (b) Knee Ankle Foot Orthosis [42, 43] and (c) Hip Orthosis implant [44].

3.4. Spinal Orthosis

Kuo et al. tested a neck spine with a 3D printed orthosis. Unlike a traditional spinal orthosis, which covers all over the body, the 3d printing technology orthosis being utilized in this experiment also supported the leading side [45]. At both ends of the mandibular base, mandibular and transverse assists collapsed to a collarbone. Furthermore, the mandibular support of the 3d printing technology orthosis featured, including support gaps. A brace could be used to protect the individual and keep the orthosis from sliding off the spine [46, 47].

(a) Spine Orthosis

A spine orthotic is a device that is attached to spine to limit the mobility of fixing disfigurement in, reduce axial
forces on or enhance the functioning of a particular spinal segment. Photogrammetric scanner machines have been shown to be helpful for the creation of 3D spinal orthoses, especially for patients with limited mobility, since they instantly and precisely identify the spinal form (< 1 mm) [48]. Milwaukee brace [49, 50], manufactured in the United States in 1945, was made of polyethylene, aluminum, and steel. Wilmington brace [51] and Boston brace [51, 52] were both manufactured in the United States using polyethylene in 1969 and 1972, respectively. Cheneau and derivatives [53, 54] formed alliances with France and Germany in 1960.

(b) Cervical Orthosis
Cervical orthoses are used to help maintain a stable spine state. The CAD model the cervical collar is envisioned as an orthosis that suits across the neck, first from jaw towards the chest. When treating a cervical injury, fracture, or surgical procedure, it is used to limit mobility and stabilize the neck to enable healing. Soft cervical orthoses, on the other hand, with a lighter geometrical shape, aid in the prevention of chronic neck injuries, protect the neck, which regulate discomfort after such a fracture [55]. The 3D shape was created with the Printer D300 Technology, that employs the FDM manufacturing procedure. The printer’s specifications are frame delta, printed area 250×300mm, max temperature 100°C, nozzle size 0.6mm max nozzle temperature 260°C, max nozzle resolution 0.1mm [55].

(c) Cervical Thoracic Orthosis (CTOs)
Cervical Thoracic Orthosis are used in fractures that are only somewhat unstable. Both CTOs are better at controlling flexion than extension. Sharpe et al. revealed that the USMC CTO configuration limited each flexion and extension to 22 percent of uncontrolled motion when measured using the standard radiographic endplate measurement technique. According to the results of the report, the Aspen 4-post CTO restricted flexion to 8% of unrestricted motion and extension to 23% (19%) of unrestricted motion [56]. Figure 4 illustrated the previous type of orthoses used for spine region.

Figure 4. (a) Spine 3D printed orthosis, (b) Cervical 3D printed orthosis, (c) Cervical Thoracic 3D printed (Aspen 2-post CTO and Aspen 4-post CTO) orthosis [57].

3.5 Most recent developed orthosis
Prof. Jumpei Arata and his group developed a robotic hand orthosis for therapy and assistance in daily activities in 2021 with the collaboration of Kyushu University, Japan, and Gregory Fischer at Worcester Polytechnic Institute, USA, which was published in the ETH Zurich rehabilitation engineering laboratory. This hand orthosis will help and measure real-time EMG of hand movement [69]. Paulo and his colleagues produced an electronic design and validation of a powered knee orthosis system incorporated with wearable sensors, which was reported in the IEE international conference on Autonomous Robot System and Competitions. This orthosis will help patients’ knees and will measure real-time EMG of knee movement [70]. Powered lower limb exoskeleton leg orthosis developed by Stefan and his group to assist knee compliance reduces peak swing collision forces in lower limb so that it can help to lower risk of failing patients [71, 72].
Figure 5. (a) EMG sensor-based hand orthosis; (b) EMG sensor-based knee orthosis; (c) powered knee orthosis.

4 Directions for further study

Although current publications provide useful information and facts, further research is needed to provide comprehensive prescriptive advice regarding the biomedical application of 3D printed orthosis. Nowadays, 3D printing is gaining popularity due to its ease of production and implementation, as well as its long cost-effectiveness. As a result, possible future research might use composite materials reinforcement in 3D - printed technology to reduce development time and cost.

5 Limitations of this review

In this review paper, we try to bring most advanced and recent 3D printed technology used in biomedical applications in healthcare especially in the development of orthosis. We hope that this brief overview will be beneficial not just to engineers or researchers, but it will be useful for clinicians to justify their choices of orthosis in treating patients. The study concentrated solely on emerging methods for developing 3D printed orthosis technology. A more detail about the analysis on the orthosis, either experimental work or simulation (finite element analysis) could be discussed in the future to justify the best design [73].

6 Conclusion

This review explored 3D printing technology and its applications in biomedical and healthcare, as well as how it is comparable to standard manufacturing methods and the need to discover different biomaterials. Parts that reflect the condition can be manufactured and delivered to the healthcare center in the shortest amount of time. Existing manufacturing takes about six weeks, while 3D printing can be finished in as little as ten days. The 3D printed orthosis has been using in various application in biomedical field. All mentioned here in this paper are the most recent and advanced used biomedical application of 3D orthosis which are supporting our daily life. As a conclusion, it can be stated that a revolutionary technology has been achieved, and it will also support human livelihoods by assisting them throughout their everyday activities, despite having to give up such easy tasks as a simple dive in the water.

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