A Systematic Review of Differences between Conventional Orthoses and 3D-Printed Orthoses

Ana Cláudia Tavares Rodrigues[1,*], Letícia Vasconcelos Morais Garcez[1], Fausto Orsi Medola[1,] Luciana Ramos Baleotti[2], Frode Eika Sandnes[3,4], Atiyeh Vaezipour[5]

[1] São Paulo State University (UNESP), Graduate Program in Design – PPGDesign-UNESP, Bauru, Brazil
[1] São Paulo State University (UNESP), Graduate Program in Human Development and Technologies, Rio Claro, Brazil
[2]Oslo Metropolitan University (OsloMet), Oslo, Norway
[3] Kristiania University College, Oslo, Norway
[4] University of Queensland, RECOVER Centre, Brisbane, Australia
{LNCS}@Springer.com

Abstract. Rapid prototyping and 3D printing technologies have been innovative options for orthotic development, that are assistive devices applied to any part of the body to different disabilities or injuries. The aim of the study was to investigate scientific evidence about the effectiveness of using 3D printed orthoses in relation to conventional orthoses, through a systematic literature review in the years 2010 to 2020. Scientific evidence identifies that there are improvements associated with the development and use of rapid prototyped and 3D printed orthoses however the publications found present were small in sample sizes and lack comprehensive end-use evaluation.

Keywords: Orthosis ·3D printing · Assistive Technology · Rapid Prototyping

1 Introduction

Currently, more than one billion people worldwide live with some form of disability, of which around 200 million experience considerable functional difficulties [1]. With the aim of improving the functioning of people with disabilities, Assistive Technology (AT) resources are individually customized to assist the independence and autonomy of users. Successful AT initiatives often require interdisciplinary practices among professionals from the areas of Rehabilitation, Health Sciences, Product Design and Engineering, with a view of sharing knowledge and ideas in the developing of products that can have a positive impact on the quality of life, participation and social inclusion for people with disabilities [2]. Interdisciplinarity approaches have given positive results in minimizing gaps in the development and improved usability of Assistive Technology, favoring quality in research and innovation and exploring the different perspectives of the interface between the auxiliary device and the user [3. 4].

Orthoses are assistive devices applied to any part of the body, alone or covering more than one joint [5]. With the aim of meeting the individual needs of each person, orthoses may perform several functions including maintaining or promoting the range of articular movement, preventing or correcting deformities, protecting against injuries, assisting in rehabilitation, and maximizing function [6]. Orthotic devices are essential components of a rehabilitation program. Although the use of such devices has increased over the years, the range of materials used in the manufacture are still limited and costly [7].

An orthosis requires proper adjustment to the limb, since inappropriate fit can lead to discomfort, pain and skin lesions [8]. Such problems can result in early abandonment of the orthosis by the user before the rehabilitation program is completed. Shaping the device on the subject's limb requires extensive experience of the rehabilitation professional [9]. Moreover, the manufacturing process is laborious and time-consuming [10].

To reduce the costs and increase user satisfaction, 3D printing technologies have been indicated as innovative options for orthotic development [10]. Although the literature presents studies about the process of creation and development of customized prostheses through 3D printing [11], there are still few studies that have compared their effectiveness to the orthotic devices made by conventional process.

Therefore, this study reports a systematic review aimed to answer the following questions: Are the 3D printed orthoses better than conventional orthoses? What evaluation measurement have been used to compare these types of orthoses?

2 Method

A systematic review of the literature was conducted through several steps. First, a search for scientific articles published in the last ten years in the Scopus and Pubmed databases was conducted. We used the query terms “Orthosis; 3D printing”, “Splint; 3D printing”, “Orthosis; Rapid Prototyping”, “Orthosis; Assistive Technology; 3D printing”, “Orthosis; Assistive Technology; Rapid Prototyping”, “Splint; Assistive Technology; 3D printing”, plus the Boolean operator “and”.

Next, the abstracts of the studies found were read to verify which ones met the inclusion criteria, namely scientific articles reporting the manufacture of orthoses with rapid prototyping and 3D printing technologies; comparative evaluation of orthotic devices made through conventional methods and 3D printing and rapid prototyping technologies.

After discarding duplicate studies and studies that did not meet the inclusion criteria, article data were tabulated in a Microsoft® Excel spreadsheet. The tabulated data included the year of publication, the type of orthosis addressed, the number of participants of the study and the evaluation and comparison measures used.

3 Results and Discussion

Study Selection

A total of 87 articles were found using Pubmed and 117 articles where found using Scopus, totaling 204 hits (Figure 1). The descriptor pair that returned the highest number of results was "Orthosis and 3D Printing", with 77 results.

Of the 204 studies, 147 studies were excluded as they reported (a) literature reviews, (b) other types of Assistive Technologies such as prostheses; (c) prostheses and dental implants, (d) items not considered assistive technology resources, (e) internal prostheses and surgical procedures, (f) reported only the software and processes used to develop the final product, or (g) no evaluation tests. Thus, 57 studies were classified as being within scope of this study. However, after the detailed reading, only 9 were finally selected for discussion herein, as they met all inclusion criteria.

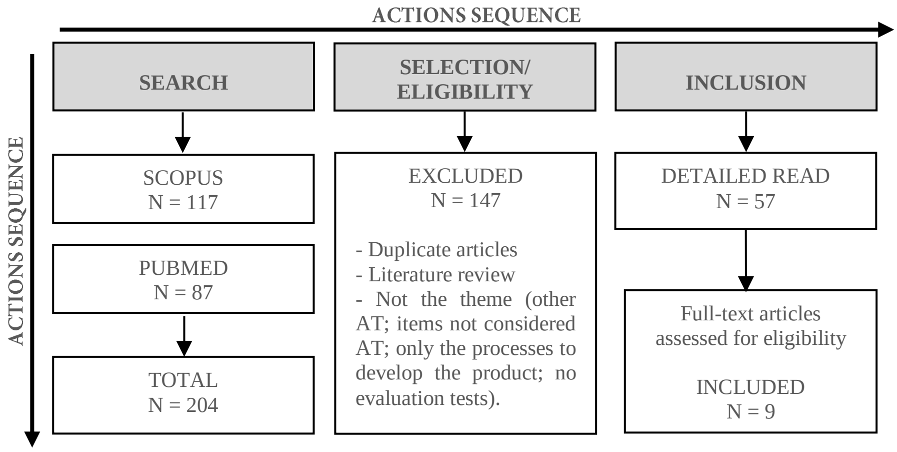

Fig. 1. Procedure.

Study characteristics

The characteristics of the selected articles were that 3D printing was used in the development of orthoses. Moreover, tests were reported comparing orthoses made by conventional methods (prefabricated (canvas or thermoplastic) or made to measure) of upper or lower limbs with orthoses by means of 3D printing (see Table 1).

Table 1. Studies that met the inclusion criteria.

Title	Authors (year), country	Type of Orthoses
Effects of a 3D-printed orthosis compared to a low-temperature thermoplastic plate orthosis on wrist flexor spasticity in chronic hemiparetic stroke patients: a randomized controlled trial	ZHENG, Y. et al (2020), China	WHFO (Upper limb)
Personalized assistive device manufactured by 3D modelling and printing techniques	LEE, K. H. et al (2019), Republic of Korea	Cock-up (Upper limb)
The biomechanical difference between running with traditional and 3D printed orthoses	MO, S. et al. (2019), China	AFO (Lower limb)
Small splint external fixation combined with 3D printing brace for the treatment of Colles fractures	ZENG, T. et al. (2019), China	Cock-up (Upper limb)
Effect of 3D Printing Individualized Ankle-Foot Orthosis on Plantar Biomechanics and Pain in Patients with Plantar Fasciitis: A Randomized Controlled Trial	XU, R. et al. (2019), China	AFO (Lower limb)
Fabrication and stress analysis of ankle foot orthosis with additive manufacturing	BANGA, H. et al. (2018), India	AFO (Lower limb)
Effect of personalized wrist orthosis for wrist pain with three-dimensional scanning and printing technique: A preliminary, randomized, controlled, open-label study	KIM, S. J. et al. (2018), Republic of Korea	Cock-up (Upper limb)
Analysis and comparison of wrist splint designs using the finite element method: Multi-material three-dimensional printing compared to typical existing practice with thermoplastics	CAZON, A. et al. (2017), United Kingdom	Cock-up (Upper limb)
Patient specific ankle-foot orthoses using rapid prototyping	MAVROIDIS, C. et al. (2011), United States	AFO (Lower limb)

According to the year of publication (see Figure 2) there was a increase in publications addressing the comparison of 3D printing orthoses with conventional orthoses from 2017 and onwards. In 2019, 44,4% of the publications [12,13,14,15] were on this topic. Expectations for 2020 are there the number of publications on these topics will increase. Note that the data collection presented herein was carried out during January 2020, and only one publication [16] was included in the graph. However, an increase in research related 3D printed orthoses was identified.

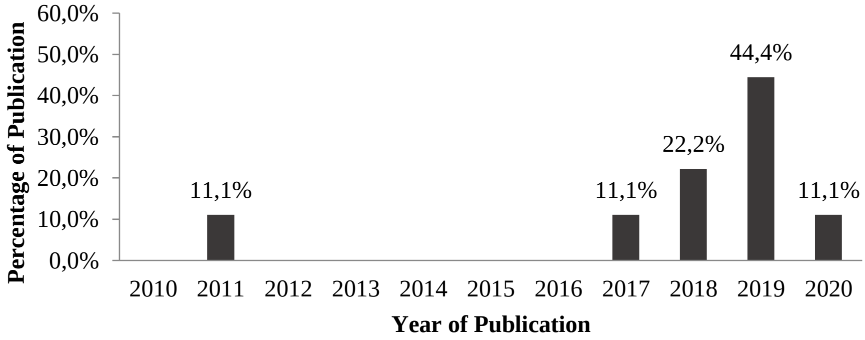

Fig. 2. Publications in chronological order.

Regarding the type of orthoses (see Figure 3), we observed that there was a balance in publications related to the target limbs, where 55,5% of the papers addressed upper limb orthoses and 44,4% of the papers addressed lower limb orthoses. Additionally, we found few variations as all the lower limb orthoses studies (*n* = 4) covered ankle-foot orthoses (AFO) [13, 15, 19, 20]. The other 5 studies addressed upper limb orthoses. The majority (*n* = 4) of these discussed the wrist orthoses, called “cock-up” [12, 14, 17, 18] and one study documented a wrist, hand and fingers orthosis (WHFO) [16].

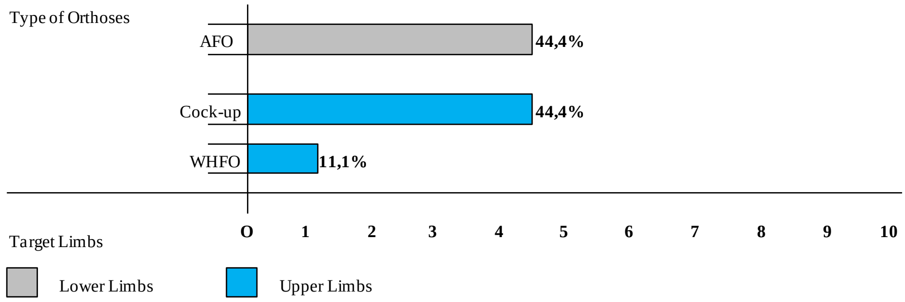

Fig. 3. Orthosis types.

Evaluation Measurement

The evaluation measurement methods used varied greatly. Table 2 lists details about the evaluation and comparison measures used, as well as the number of participants involved and the summary of findings.

Table 2. Evaluation and comparison measures used and the number of participants.

Evaluation and Comparison Measures	Participants	Summary of Findings
Modified Ashworth Scale, Fugl-Meyer Assessment, Visual Analogue Scale, Goniometry and Edema level	40	3D orthosis showed greater changes in reducing spasticity and motor function.
Jebsen-Taylor Hand Function Test and Quebec User Evaluation of Satisfaction with Assistive Technology (QUEST 2.0)	1	3D printed devices showed better results in the JHFT score and in the most of QUEST items than ready-made assistive devices.
Measurement of the Hindfoot Eversion Angle and Comfort level	13	No significant differences between the two types of orthosis.
Visual Analogue Scale, Edema level, Cooney Modification of the Green and O’Brien Score and Patient-Rated Wrist Evaluation	60	VAS and edema level did not show significant differences; the Green and O’Brien Score and PRWE had better results with the 3D orthosis.
Footscan® recorded Maximum Pressure, Maximum Force and Contact Area at specific points, in addition to Visual Analogue Scale and Comfort Level	60	Higher level of comfort in the 3D orthosis.
Biomechanical Tests (Deformation of material, Constant Load, Mechanical Properties and Custom Product)	0 (4 simulations)	The 3D orthosis corresponded to the physical and mechanical aspects of the conventional; presented less weight, greater thermal comfort and good cost-wise.
Patient-Rated Wrist Evaluation, Jebsen-Taylor Hand Function Test and Orthotics and Prosthetics Users' Survey	22	The 3D cock-up was better in relation to wrist pain and 2 OPUS tasks.
Performance Level in displacement and Stress values	0 (40 simulations)	The 3D orthosis remains at the same or even better performance level.
Gait Analysis	1	The 3D orthosis provided a better fit of the individual's anatomy.

Table 2 reveals that only a handful of studies compared 3D printed orthoses and conventional orthoses. In addition, several studies did not evaluate the orthoses with participants or end users [18, 19]. Others relied on case studies [12, 20].

Regarding the measures of evaluation and comparison of upper limb orthoses, it was possible to observe better results in goniometry, Modified Asworth Scale, Fugl-Meyer Assessment, Edema Level [16]; Jebsen-Taylor Hand Function Test, Quebec User Evaluation of Satisfaction with Assistive Technology (QUEST 2.0) [12]; Cooney Modification of the Green and O'Brien Score, Patient-Rated Wrist Evaluation [14] and Orthotics and Prosthetics Users' Survey (OPUS) [17] with the use of 3D orthoses, pointing out benefits in such orthoses with regard to range of motion, manual function, spasticity, satisfaction and performance in Activities of Daily Living (ADLs).

The Visual Analogue Scale, Edema Level (in one of the studies) and biomechanical tests (tension/resistance) did not present statistically significant differences between the two types of orthoses [14, 18].

As for publications about lower limb orthoses, it was possible to identify improvements with 3D printed orthoses over conventional orthoses in items of adjustment of the equipment to the user [20], comfort [15] and cost-wise [19].

4 Conclusions

With the worldwide increase of life expectancy and increase of individuals who experience disabilities or reduced functioning, it is expected that an increasing number of people will need orthoses. There has been an increasing use of Rapid Prototyping and 3D printing technologies in the field of Assistive Technologies, with a great potential for the development of personalized devices that are more likely meet the users' needs and preferences. It is therefore important to investigate the effectiveness and potential benefits of these devices.

The results of systematic review indicate that there are improvements associated with the development and use of rapid prototyped and 3D printed orthoses compared to conventional orthoses in terms of upper limb range of motion, manual function, spasticity, satisfaction, performance in activities of daily life, comfort and low cost. Although, the number of publications were low, there has been an increase in recent years, with a sharp increase expected in the coming years. Also, some studies found no significant differences between the two orthosis types.

In conclusion, the field of orthosis 3D printing is rapidly evolving and has presented important benefits for the users of such resources. However, there is insufficient evidence in support for the claim that 3D printed orthoses is better than conventional orthoses, due to the low number of publications on this topic. In addition, the studies included in this review were small in sample sizes and lack comprehensive end-use evaluation which would be critical for the uptake of Assistive Technologies.

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