# Evaluation of Rapid Prototyping of Orthosis during the Design Process: Analysis of Verification Models

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**Abstract.** Accessing physical prototypes is possible to test an idea quickly with models that look like the final product. Rapid Prototyping (RP) based on additive or subtractive technology permit to conduct trial tests of usability in order to avoid errors and failures before the final product production. Those technologies are increasingly in orthosis's production. Ergonomics field involved in the design process with RP can facilitate usability tests providing comfort, safety, and performance in the development of orthoses. The objective of this study is to review, accessing the specialized literature, the use of RP for prototypes' production for user's evaluation of orthoses. The results showed that the most common technique used was FDM. Half of the studies involved user's participation or evaluation in the design processes, although, only three out of thirty-eight studies used RP to proof of concept's production, indicating little use of proof-of-concepts models.

**Keywords:** Rapid Prototyping • Prototype • Orthotic Device • Orthosis • 3D Printing

## 1 Introduction

Time has been the main factor to determining the direction and success in the development of a product. In this way, prototypes can be used for testing and proofing ideas related to the final product. Rapid prototyping (RP) comes in this sense as a technique that aims to optimize product development by reducing production time and minimizing human error, having a fast growth amplifying the range of materials used in the last years.

Rapid prototyping technologies are fabrication methods based on additive and subtractive fabrication principles. The use of RP technologies allows researchers to create parts of almost any geometrical complexity in a short period of time, with reduced cost and precision using computer-aided design (CAD), computer-aided engineering (CAE), and computer-aided manufacturing (CAM) programs (Lantada & Morgado, 2012; Giannatsis & Dedoussis, 2009). According to Petrzelka and Frank (2010), the subtractive

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rapid prototyping (SRP) techniques, the laminated object manufacturing (LOM), also has been used as the similar principle of the additive layer-based manufacturing process. Some of the major RP technologies used worldwide include stereolithography (SLA), selective laser sintering (SLS), fused deposition modeling (FDM), multi-jet modeling (MJM) and laminated object manufacturing (LOM), and they can manufacture with precision prototypes in a wide range of materials such as metals, ceramics, or polymers - that can have either a synthetic or biological origin (Lantada & Morgado, 2012; Giannatsis & Dedoussis, 2009).

These technologies are mostly applied in product development and the design process. In addition, they are also used in the fabrication of several types of models and prototypes for concept evaluation, presentation, and functional testing of new products, which helps to optimize design interactions, allowing early detection of errors and speeding up the development process (Lantada & Morgado, 2012; Giannatsis & Dedoussis, 2009). According to Lantada and Morgado (2012), the use of RP technologies has dramatically improved the relationship between customers and suppliers and promotes improvements in both the design and production processes.

Due to the continuous improvements of RP systems accuracy and material, their high speed and flexibility, they have been expanded gradually their application in other fields, including medicine and health care (Giannatsis & Dedoussis, 2009). Within the medical field, RP can be applied to the design and fabrication of customized orthoses. Such devices are used for many purposes such as rehabilitation device, to improve gait performance or to support a limb (Miclaus, Repanovici & Roman, 2017).

Orthoses can be manufactured by two different methods - the traditional one and by using additive manufacturing (AM), also known as layer upon layer manufacturing. The fabrication by means of the traditional process involves manual processes and requires specific skills, which can be exhausting, time-consuming and expensive. The use of AM technologies, on the other hand, does not require specific skills, it needs less time of production and it is cheaper, which is why it has been increasingly used in the biomedical field (Aydin & Kucuk, 2018).

In this way, projects involving medical assistance device have to take into account such aspects as comfort, functionality and overall product satisfaction. Detailing user needs, focusing on ergonomics, usability, body metrics, adequacy to user's feeling the result can be safer products and faster learning curves for the user. Such elements are key drivers of the final product properties and should be considered from the very early design stages (ARRIGHI et al., 2015; FARRIS et al., 2011; MARTIN et al., 2008;). One approach to guarantee a better final product - from an ergonomic perspective - is the use of verification models in order to conduct trial tests of usability to avoid errors and failures before the final product is delivered to the final consumer (Kai et al., 2003 ). RP technologies have great potential in the area of medical and health-care and they have been increasingly attracted attention by the scientific community (Dedoussis, 2009; Martin, 2008). However, what advantages/disadvantages the methods used during the development of these devices represents and how the studies about the application of RP are conducting trial tests of usability is still unknown. Given the above, this search aims to review existing research in RP and assistive technology in order to define the best processes for the use of usability models or proof-of-concept in the orthoses design process.

## 2 Methods

The methodology employed in this study was a literature search through the electronic databases to verify the state-of-art about the development of orthosis using proof-of-concept prototypes and rapid prototyping technologies in the design process. The search was conducted through the month of January 2019 in three electronic databases: Web of Science, Pubmed, and Scopus. This search was conducted to answer the following research question: how do different technologies in the field of development of orthosis influence prior to the validation of the final product?

Based on the research question the search terms were elected: “orthosis”; “prototype”; “rapid prototyping”; “customized”; “proof-of-concept”; “additive technology”; “3D printing”; “rapid subtractive technology”. The search was conducted in order to attend the following inclusion and exclusion criteria:

1. papers disclosure about the development of orthosis;
2. papers must focus on the development or evaluation;
3. papers about devices for rehabilitation exercises, mechanical or robotic orthosis were not considered;
4. papers about robotic or mechanical were not considered;
5. papers must focus on humans;
6. review papers were excluded;
7. non-English papers were excluded.

Combining the main search terms and inclusion and exclusion criteria, the generated search string was “orthosis” AND “prototype”; “rapid prototyping” AND “orthosis”; “Orthosis” AND “prototype” AND “customized”; "orthotic device" AND “prototype”; “orthotic device” AND “prototype” AND “customized”; “orthotic device” AND prototype AND “rapid prototyping”; “orthosis” AND “prototype” AND "rapid prototyping"; “orthotic device” AND "rapid prototyping"; “orthosis” AND “3D printing”; "orthosis" AND "proof of concept"; "Subtractive rapid prototyping" AND orthosis; and "Subtractive rapid prototyping" AND “orthotic device”.

## 3 Results and Discussion

The searches in the databases using the combinations resulted in 1290 documents. After removing duplicate documents, the total result was 700 documents. The abstracts were read and screened to determine if they meet all the inclusion criteria and exclusion criteria. In this first analysis,125 papers were removed due to being review studies. Other papers that did not fit the inclusion criteria, such as or papers related to exoskeletons, mechanical or robotic orthosis or mechanical devices used for patient rehabilitation were also excluded. Therefore, after the analysis of the abstracts, 645 articles were excluded.

In a second analysis, the papers that fit all the mentioned criteria were selected for detailed verification. In this way, it was possible to exclude those articles with blocked access to full-text. Lastly, 38 papers were included as relevant. Fig. 1 illustrates the process using PRISMA flow diagram (Moher et al., 2009).

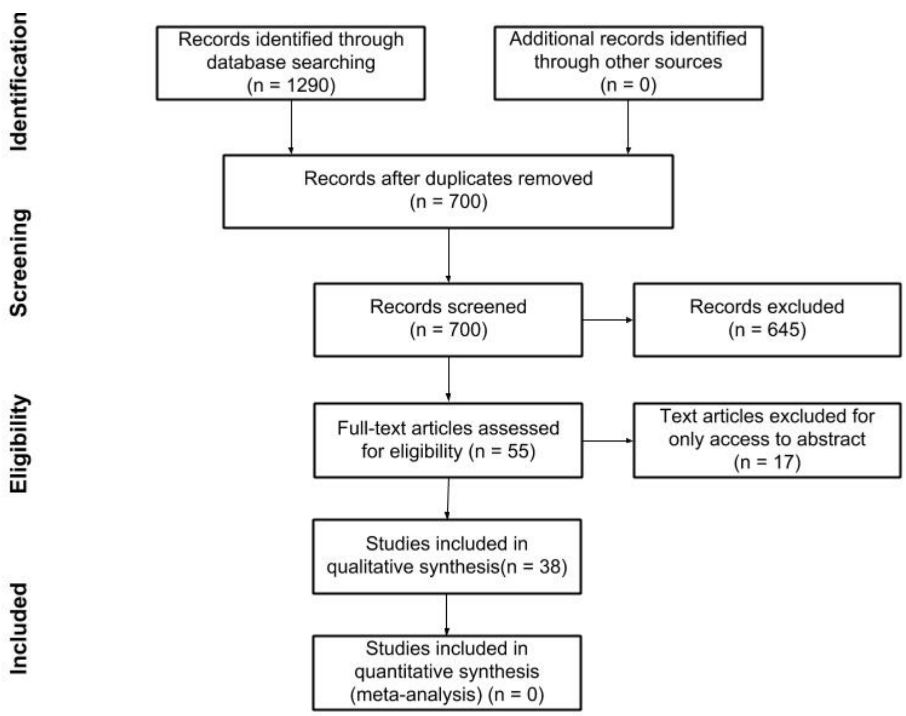


**Fig. 1**. Process of review using a PRISMA flow diagram.

Analysing the results it can be observed an increase in the numbers of publications about the subject over the years (Fig. 2) especially between the years of 2017 and 2018 (55.2% of the total results founded), showing an increased interest in the field which corroborates with Dedoussis, (2009) and Martin, (2008).

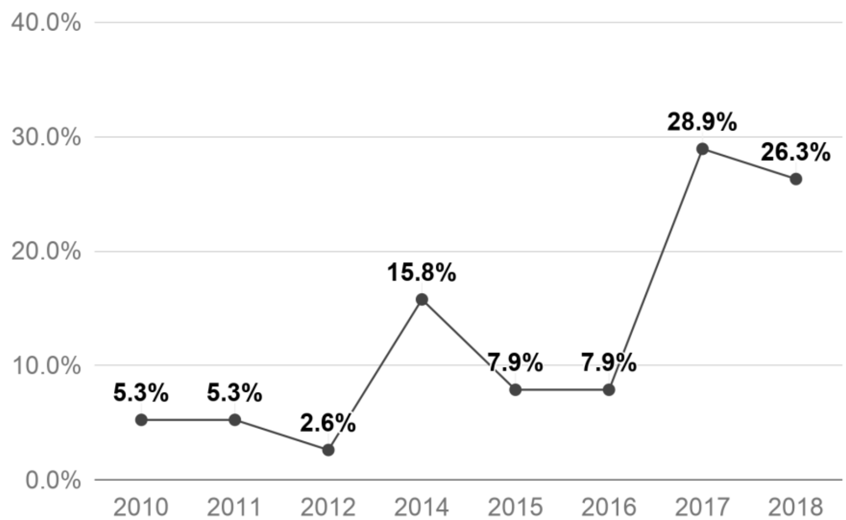


**Fig. 2**. Categorization of the publications by year.

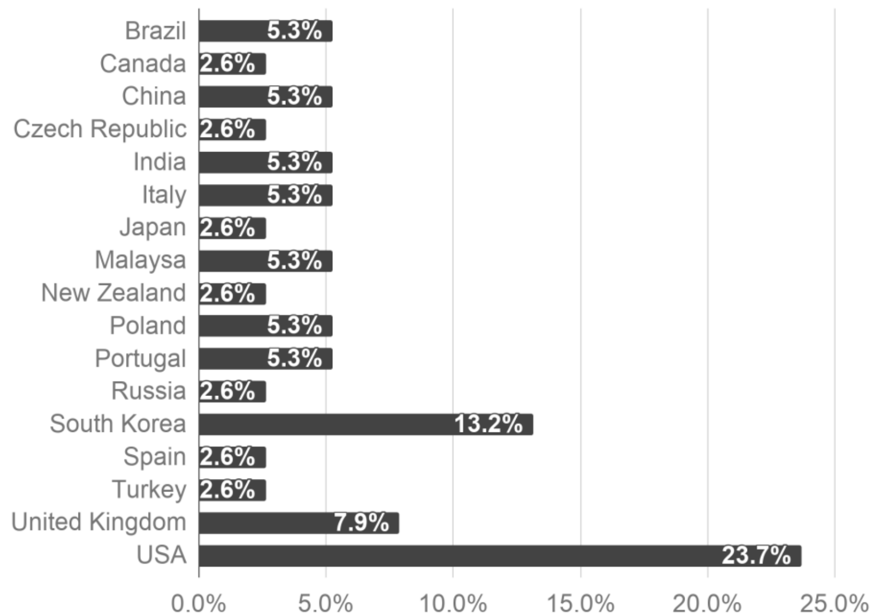


**Fig. 3.** Categorization of the publications by country.

Regarding the publication by country, we can observe that the US is the country with most publications in the field, with 23.7% of the publications, followed by South Korea with 13.2% and the UK with 7.9%. It is interesting to highlight the production among the developing countries - Brazil, China, India, Malaysia, Russia, and Turkey according to the UN list - that represent 26% of the publications.

During the analysis, it was observed the use of multiple technologies in the development of the orthosis as well as the use of RP technologies on the fabrication of molds, that would result in the orthosis. Among the technologies most employed in the studies, we can highlight the use of Fused Deposition Modelling (FDM), applied in 28 studies, followed by Selective Laser Sintering (SLS), with 9 studies, and Stereolithography (SLA) used in 5. These results disagree with Mavroidis et al.' study (2011) that states that SLA and SLS are the most used techniques in the medical field. One possible explanation could it be the fact that the study was done in 2011 and that FDM has been used in the last years, as we can observe with the results. Wierzbicka et al. (2017) explain that FDM is one of the most widespread technologies due to its low cost of purchase and maintenance, simple and friendly manufacturing process, and mate-rial strength and dimensional accuracy. The materials most used by FDM are the thermoplastics Acrylonitrile-butadiene-styrene (ABS) and Poly-lacticacid (PLA) in a form of filaments, but the range of materials available are expanding. The authors also highlight its use for the fabrication of parts or whole products for the prosthetic and orthopedic applications.

**Table 1.** Technologies employed in the studies.

| **Technology** | **# of studies** |
|---|---|
| Fused Deposition Modelling (FDM) | 28 |
| Selective Laser Sintering (SLS) | 9 |
| Stereolithography (SLA) | 5 |
| Selective Laser Melting (SLM) | 1 |
| Laser-cut | 1 |
| Not specified | 1 |

Among the 38 papers included in this search, 20 papers used users to produce and evaluate the orthosis (51.2%). Orthosis developed for the upper limbs was presented in 19 papers (50%) and 19 (50%) was about lower limbs. Among the papers which presented upper limbs devices, 9 (23.6%) used real users to produce and evaluate the product developed while papers which presented lower limbs orthosis 11 (28.9%) used real users in the presented studies. And just 3 papers (7.9% of the total) presented a proof-of-concept during the design and fabrication process of the orthosis, none of those involved real users in the development of the prototypes.

Papers that disclosures about the use of proof-of-concept did not use user-centered methods. The work presented by Wu et al. (2018) entitled “Mechanical Analysis of a Customized Hand Orthosis Based on 3D Printing” disclosures about a hand orthosis to relieve the finger spasm of stroke patients. The proof-of-concepts models were used to test the mechanical properties of different materials of fabrication to the prototype, and the bending strength was calculated to verify the better material for this specific pathology. Palousek et al. (2014) presented the paper “Pilot study of the wrist orthosis design process” in which they described a manufacturing methodology for a wrist orthosis. Although the authors did not present usability tests with the prototype and final user - because the orthosis was not developed for a specific person - they highlighted the importance of such tests during the design process. The study presented by Aydin & Kukuk (2018) aimed to compare Finite Element Analysis (FEA) results of an additive manufactured Ankle Foot Orthosis (AFO) model under two different value sets, namely default material-based mechanical properties and measured mechanical properties. The process of fabrication for the tests included: scanning, modeling, slicing, printing, and finishing stages for successfully manufacturing the AFO prototype, and FEA was performed.

With the reverse engineer techniques, the participation of the user is necessary at least in the scanning stage. However, users participation restrict to this phase is not enough to guarantee the satisfaction and efficacy of the device. When the study's proposal is to evaluate the influence of an orthotic device in a biomechanical aspect, the evaluation can be lead with healthy participants, as presented by Choi et al. (2017) in the study named "Impact of ankle-foot orthosis stiffness on Achilles tendon and gastrocnemius function during unimpaired gait". In this case, although an evaluation had been conducted, it was not focused on a real user.

On the other hand, some biomechanical studies can evaluate the prototypes with the final user, as an example of a study entitled "Functionally optimized orthoses for early rheumatoid arthritis foot disease: A study of mechanisms and patient experience" (Gibson, Woodburn, Porter & Telfer, 2014), that evaluated the effects of foot orthosis among participants with Rheumatoid Arthritis diagnosis. Those type of studies reveals that even with scanner's accuracy, device's evaluation, whether with a prototype or the final product, is important to understand the interaction between user and device.

Both approaches are relevant regarding different objectives and contribute to the development of those devices, but still, leave gaps in regards to user satisfaction with the device. In "Effect of personalized wrist orthosis for wrist pain with three-dimensional scanning and printing technique: A preliminary, randomized, controlled, open-label study", Kim, Kim, Cha, Lee and Kwon (2018) evaluated, besides the functional influence of customized wrist orthoses, the user's satisfaction with the devices through the application of Orthotics and Prosthetics Users' Survey (OPUS). This approach is able to reveal the perception of a real user regarding the orthosis in clinical, functional and of satisfaction aspects.

## 4 Conclusion

The results of this review indicate little use of proof-of-concepts models. During the search using three databases and the terms elected, results were 55 papers of which only 38 fulfilled all the inclusion and exclusion criteria, and just 3 papers presented proofs-of-concept involved in the process of the development of the prototype. These results show the lack of research in using usability models or proof-of-concept in the orthoses design process. Many research works showed the process of fabrication of an orthosis but not involving test with users which, from a ergonomic point of view, is not the ideal situation to result in safer products. Rapid Prototype of orthosis significantly accelerates the process of delivering of the final product to the users which results in a faster reintegration in their social environment. Increase the comfort and improve the quality of orthotic devices are a very important issue and studies of usability models are necessary to improve this multidisciplinary field, bringing knowledge to implementation of new technologies and manufacturing process of orthotic devices.

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