ASSISTANCE EQUIPMENT USED IN SPINE DISEASES

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ABSTRACT: Orthosis technology can help patients return to near-normal mobility and limb function after stroke or amputation. However, the method of developing specially designed devices requires time and effort. Research has shown that more than three-quarters of patients with dementia need to recover in the long term, many of whom have individual orthoses. Three-dimensional (3D) printing is a collection of practices for producing a model consisting of a physiological component or an installation in a short period of time, using 3D computer aided design (CAD) software. Usually, the creation of components or assemblies is done using 3D printing or "Additive Manufacturing" technology. 3D printing improves the performance of parts, speeds up the manufacturing process and progresses in reducing costs, which is a very significant factor for today's society.

KEY WORDS: spinal orthosis; adolescent idiopathic scoliosis; 3D printing.

1. Introduction

Spine orthosis is an effective non-surgical treatment, especially for children with adolescent idiopathic scoliosis. This treatment is prescribed for the patient with a moderate curvature (Cobb angle of 25-40 °), which presents a high risk of curve progression. Wearing the orthosis can range from a few hours only at night to full time, up to 23 hours a day. A spinal orthosis is made of rigid plastic, customized according to the shape of the patient's body, usually made of thermoplastic, such as polypropylene, with a thickness of 4 to 5 mm [2]. The orthosis has several pressure points to apply loads on the trunk to counteract the scoliotic curves. The mechanical load applied to the torso aims to stop the progression of the curve during the rapid period of growth of adolescence. The effectiveness of spinal orthosis treatment depends on the risk of progression of the curve, the correction in the orthosis, and the observance of its behavior.

However, compliance with a spinal orthosis is a problem, as current corsets are bulky, uncomfortable, and visible, which leads to decreased self-confidence that directly affects the outcome of treatment. A randomized control study with 116 patients recruited showed that the average percentage of patients wearing spinal orthoses is only 67% of the prescribed time [6]. Another study with 40 patients recruited showed an average of 55% of the wear time in the prescribed tightness interval, determined by the orthotist [3]. In addition, the conventional corset design process can be cumbersome, time-consuming, and costly for both the patient and the orthodontist. Currently, several steps are required to reach the final product. The manufacturing process may require packing a patient with plaster to obtain a negative body mold or the computer-aided design / computer-aided manufacturing (CAD / CAM) method that obtains a patient's body shape through a 3D scanner. The body shape file is then exported to a computer and goes through several manufacturing steps to create the orthosis [2].

With the rapid advancement of 3D printing technologies, clinical applications can create positive changes in the healthcare industry. A CAD / CAM system can create a 3D-printed orthosis directly by capturing a shape and sending the stereolithographic output file (STL) to a 3D printer. Currently, some companies have started developing 3D printed corsets for the treatment of adolescent idiopathic scoliosis with this CAD / CAM approach. This new approach offers a new economical solution, reduces production steps, requires less labor, and also has the potential to reduce the time it takes to prescribe the orthosis to obtain it [2].

This research hypothesizes that a 3D printed spinal orthosis will be more comfortable, therefore, it increases compliance with wearing time, which leads to a more effective treatment. It can be lighter and does not cause profuse perspiration, being more breathable with the help of the design. Traditionally, 3D printing applications have been used primarily for rapid prototyping before the final design is completed. However, with the advancement of 3D printing technology, it has become a new method of additive manufacturing in the creation of functional parts.

Through this research, I propose to pursue the main objectives, such:

1. Investigate the proper method of 3D printing, the orientation, material, and thickness of a spinal orthosis;

2. Investigate the effectiveness and evaluate the manufacturing process of the 3D printed orthosis.

3D printing could reduce costs, increase the efficiency of orthoses and reinvent the innovative design industry, as 3D printing of custom orthoses has advantages over traditional orthosis manufacturing, which can produce custom shapes and geometries that are not possible with traditional orthopedic techniques. manufacturing, devices can be made faster and are easier to modify and reproduce. In addition, 3D printing can replace unsightly, itchy, itchy plasters. The 3D printed spinal orthosis is light, personalized, and comfortable and, for optimal hygiene, can be worn in the shower [4]. The advantage of 3D printing includes that it does not require specialized tools, such as molds. It is also very cost-effective to create custom parts compared to existing manufacturing methods. In the biomedical field, 3D printing applications include assisted bone healing with printed bone scaffolding for patients with fractured or diseased bone structures, hearing aids, anatomical models for surgical training, and orthoses for various anatomical segments [2].

On the other hand, for 3D printing to be used on a larger scale in orthoses, development and manufacturing times and the associated costs must be reduced. After examining the factors that influence the cost-effectiveness and feasibility associated with new 3D printing equipment, it is clear that there are still some technical limitations to printing custom orthoses. However, these limitations can be overcome and the associated costs can be reduced as technology evolves and as future innovations produce larger and faster 3D printers [4].

2. The current stage

A recent study [5] was based on the fact that the introduction of additive manufacturing, also known as three-dimensional printing (3DP), has shown great potential for medical solutions. This technique allows the creation of complex and customized devices based on digital models. 3D printing is an environmentally friendly process, producing limited waste and does not require molds. Each part can be customized and replicated at no extra cost. Less manual labor is needed, reducing the risk of human error and improving interoperability. Several 3DP methods have been applied in the healthcare field, such as poly jet modeling (PJM), selective laser sintering (SLS), stereolithography (SLA), and fused deposition modeling (FDM). The study considered the evaluation of variables such as durability, printability, toughness, hydrophobicity, flexibility, strength, chemical inertia, and even biocompatibility.

The study focused on testing a 3D printed orthosis on a patient diagnosed with scoliosis, a patient who had been wearing a classic corset for a year. The patient in the study had to be able to orthosis for two weeks, with the clinical indication to wear it for at least 22 hours a day. At the end of the 2 weeks, the patient completed a short questionnaire about the acceptance, safety, and satisfaction of the 3D printed orthosis, compared to the traditional device produced by thermoforming. Overall, the study showed that the production of 3D printed corsets is feasible and was evaluated positively by the patient and the orthotist. The results provide encouraging preliminary findings and a clear direction for further improvement and the use of virtual modeling and 3D printing in the field of orthosis for the treatment of spinal diseases.

The cost analysis showed that about half of the cost was attributed to the cost of labor. This preliminary analysis also highlighted the significant influence of construction time on operating costs, highlighting the importance of high print speed [5].

Table 1. Detailed costs of 3D orthosis [5]

	Value		
Layer height [mm]	0.4	0.6	0.8
Machine cost – P [€]	1.08	0.69	0.56
Build time – T_b [h]	8.30	5.30	4.30
Purchase price – P_c [€]	7000	7000	7000
Expected life – Y_{life} [years]	7	7	7
Operative cost – O [€]	39.43	25.18	20.43
Operation rate – C_o [€ /h]	4.75	4.75	4.75
Build time – T_b [h]	8.30	5.30	4.30
Material cost – M [€]	19.07	19.07	19.07
Support material factor – K_s	1.2	1.2	1.2
Number of parts – N	1	1	1
Part volume – ν [cm^3]	417	417	417
Material rate per unit weight – C_m [€/kg]	30	30	30
Material density – ρ [g/cm^3]	1.27	1.27	1.27
Labor cost – L [€]	50.00	50.00	50.00
Labor time – T_l [h]	2	2	2
Labor rate – C_l [€/h]	25	25	25
Overall Cost – C [€]	109.57	94.93	90.05

Another study conducted in 2020 by Youyu Zhang [9] exposes an experiment based on the 3D printed spinal orthosis. The study was a prospective one, with two groups: the control group (named the TLSO group) and the experimental group (3D group). Participants enrolled in the TLSO group will be prescribed a conventional thoracic-lumbar-sacral orthosis (TLSO) after obtaining informed consent for the observational study, and participants in the 3D group will be allowed to choose between a TLSO and a 3D printed orthosis, after obtaining informed consent for the clinical trial. Parameters and radiographs for orthoses were obtained at hospitalization.

The orthoses were fitted with a temperature data logger. The latter was implanted in both 3D-printed orthoses and TLSO to record the date, time, and temperature every 15 minutes. The raw data has been downloaded for tracking and the battery will be replaced every 6 months. Participants were informed about the skin temperature monitoring logger so that the condition of the orthosis could be assessed; however, they were not informed about the time logger. The compliance result from the data logger will be statistically analyzed [9].

In most previous studies on the orthosis for adolescent idiopathic scoliosis, the result was evaluated on radiography, which cannot provide adequate information about the impact of the corset on patients. Adolescence is a period of transition that involves both physical growth and psychological instability. An externally visible device could further cause patients to comply with AIS. In this study, compliance (mean time to wear orthosis per day) and progression of the Cobb angle of the primary curve were measured. At the same time, the study did not include any non-interventional groups to increase the acceptability of randomization among participants. The progression of the curve above 5 ° as a primary outcome and the conversion rate to surgery (usually recommended for the main curve above 45 °) as a secondary outcome was measured in this study. In addition, it should be noted that the team approach (physicians, kinesiologists, and licensed prosthetists / orthoses) may also play an important role in patient compliance [9].

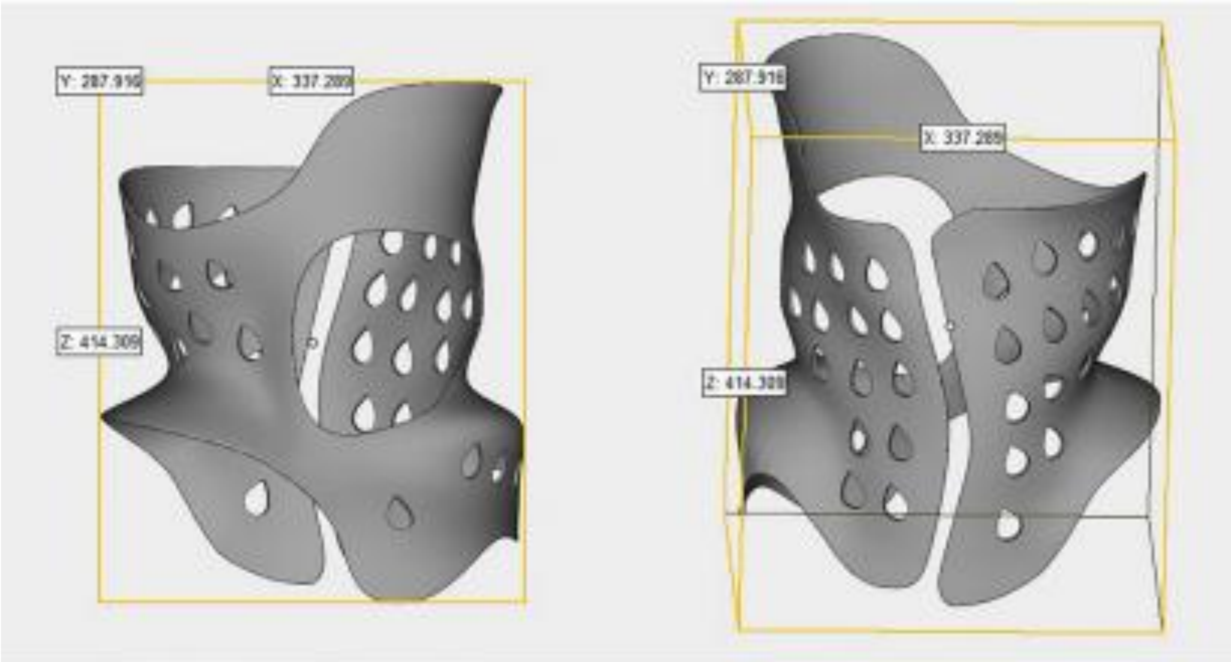

Fig**. 1: 3D-printed orthosis design [9]**

3D printing technology is computer-aided manufacturing and all are digitally controlled, it could avoid the accumulated error caused by various manual manufacturing procedures. Thus, it is assumed that the vertebral column orthosis manufactured by 3D printing deviates less from the original design of the 3D model, compared to the conventional orthosis manufactured by the conventional manual method. Most procedures can be performed on your computer, including positive casting has been replaced by 3D scanning; positive manual casting could be sculpted under a computer-controlled machine. Thus, the accumulated error could be mitigated by avoiding manual manufacturing, which is mainly based on experience [8].

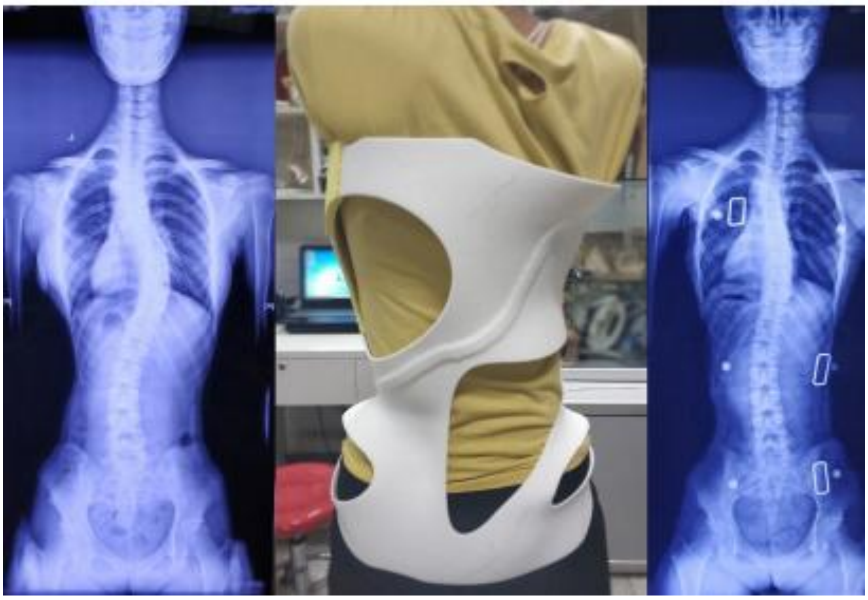
FIG. 2: Correction after treatment with 3D-printed orthosis [9]

Both the 3D printed orthosis and the conventional orthosis could offer similar durability without significant deformations. He indicated that the 3D printed orthosis was able to provide a durable orthotic treatment for clinical application. However, the level of deformation was more severe in the 3D printed orthosis compared to the conventional orthosis. One of the possible reasons was the significantly smaller thickness of the 3D printed orthosis (2.5 vs. 6 mm), which could influence the roughness [8].

Regarding the level of comfort when patients wear orthoses, the peak value and changes in temperature and humidity may show the difference in the level of ventilation of the orthoses. According to the results of the laboratory tests, the peak temperature value did not show any significant difference between the 3D printed orthosis and the conventional orthosis, due to the constant skin temperature and the ambient temperature. However, the heat dissipation speed was better on the 3D-printed orthosis. One of the possible reasons was the reduced thickness [8].

A fundamental part of the custom adjustment of a spinal orthosis is the individual shape of the patient. Three-dimensional scanners are devices used to capture and digitize objects and are used in a wide range of applications: they can be portable devices, or small or large fixed systems. Preparing a trunk model requires a scanner to act as a digital camera by capturing an image to be loaded into the CAD software for manipulation. The literature reports examples of 3D laser scanners used to capture body data for the creation of foam trunk models; Previous studies have shown positive results in reproducing the accuracy of matching with digital corrections. Digital scanning approaches for data acquisition can help with health outcomes, examples include computed tomography (CT), photogrammetry for facial prostheses, and laser scanning for the development of 3D printed wrist splints. The typical 3D laser scanner captures a "dot cloud" or voxels (3D volumetric pixels) of data (3D dots in space, referenced by XYZ coordinate values in sections). The distance between them, points refers to the resolution. "Point clouds" are transformed into 3D surfaces by a method called "polygonization". The point cloud is then used to generate a virtual network [1].

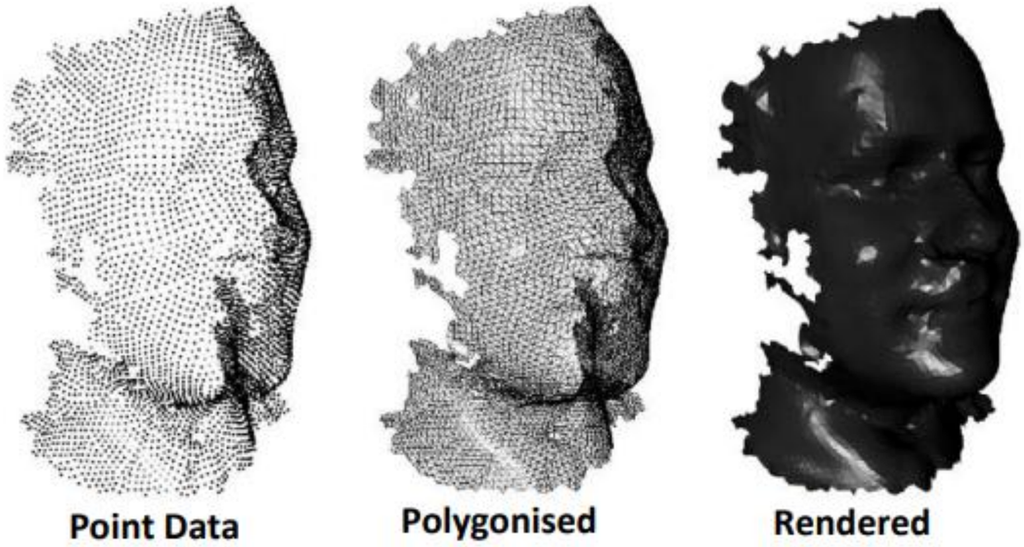

Fig. 3: A triangular polygon mesh created from a point cloud [1]

Wong summarized the benefits of 3D scanning compared to traditional techniques such as: ***"Allows a larger number of patients to be scanned faster and easier; data can be analyzed and stored more easily; maximizes time and provides cost savings; reduces the waste of gypsum and foam materials. "*****[7]**

Using the 3D scanner to perform anthropometric measurements may be necessary to consider repeatability of measurements, standardization of the capture position, orientation of scales, and calibration of instruments. Applying pressure to soft tissues can be a problem for replicability (a significant factor when considering adolescent idiopathic scoliosis), and patients may become tired and therefore may change their torso position if they are uncomfortable [1].

Some of the problems that might be encountered when scanning the trunk areas are [1]:

- The scanner beam may be divergent due to dust or high levels of ambient light;
- Postural balancing and breathing movements can affect the scan;
- Depending on the type of scanner, the methodology of building point clouds may affect some measurements;
- The resolution, color perception, luminance, and shading of body parts can influence the final data.

3. Conclusions

The application of 3D printing technology in the design and manufacture of spinal orthosis for AIS is feasible and some benefits can be obtained. As a spinal orthosis, the 3D printed orthosis can meet some of the requirements, such as the absence of toxic substances, it does not cause allergies easily, it is flexible enough, but also rigid, and it is durable for about 2 years. In addition, studies have shown that 3D printed orthoses can provide effective treatment results similar to conventional orthoses. The benefits of applying 3D printing technology can also be reaped. For example, spine orthosis is tailored for each patient with AIS, and usually, a patient may need to have 1-2 orthoses throughout the treatment period.

Another advantage is the flexibility of the design. Spine orthosis can be designed with models according to the patient's preference to improve acceptance and ventilation; this may be difficult to achieve by the conventional method. Moreover, the thinning can also be adjusted according to the need to increase the thickness in the corresponding apical area and to reduce the thickness in the other area, such as the abdomen and the posterior area.

In addition, the workforce can be reduced by applying 3D printing technology, which for most of its manufacturing time has been automatically controlled by the computer. In terms of clinical efficacy, 3D printing technology can meet the need for current clinical services. Thus, there is a trend of applying 3D printing technology in the orthosis of the spine in the near future, expecting an increased manufacturing speed and a low cost.

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