Acta Tecnología - International Scientific Journal about Technologies
Volume: 10 2024 Issue: 4 Pages: 109-113 ISSN 2453-675X

https://doi.org/10.22306/atec.v10i4.211 *Received: 26 June 2024; Revised: 20 Sep. 2024; Accepted: 09 Nov. 2024*

Design and production of personalized cervical orthosis using CAD/CAM systems

Bibiana Ondrejova
Department of biomedical engineering and measurement, Faculty of mechanical engineering, Technical university of Kosice, Letna 1/9, 04200, Kosice, Slovak Republic, EU, bibiana.ondrejova@tuke.sk (corresponding author)
Branko Stefanovic
Department of biomedical engineering and measurement, Faculty of mechanical engineering, Technical university of Kosice, Letna 1/9, 04200, Kosice, Slovak Republic, EU, branko.stefanovic@tuke.sk
Viktoria Rajtukova
Department of biomedical engineering and measurement, Faculty of mechanical engineering, Technical university of Kosice, Letna 1/9, 04200, Kosice, Slovak Republic, EU, viktoria.rajtukova@tuke.sk
Jozef Zivcak
Department of biomedical engineering and measurement, Faculty of mechanical engineering, Technical university of Kosice, Letna 1/9, 04200, Kosice, Slovak Republic, EU, jozef.zivcak@tuke.sk

Keywords: cervical orthosis, personalized orthotics, CAD/CAM, 3D scanning.
Abstract: The aim of this work was to design and manufacture a personalized cervical orthosis using CAD/CAM systems through additive manufacturing technology. Cervical orthoses are practically used to ensure the stability of the cervical spine. The work was motivated by recent research into personalized orthoses made using additive manufacturing technologies. This study describes the methodology of 3D scanning the cervical area, CAD design, and CAM manufacturing of a personalized cervical orthosis. As a basis for modelling the orthosis, a 3D scan of the subject's head, neck, shoulders, and upper chest was obtained using an optical 3D scanner Artec Eva. The scan was processed in CAD software Meshmixer and served as a basis for the modelling of a personalized cervical orthosis, considering the support points. The orthosis was made by additive manufacturing technology Multi Jet Fusion (MJF) on a HP 5200 3D printer from biocompatible polymer PA12. The advantage of manufacturing a cervical orthosis using MJF technology is the individualized design, improved production efficiency, as well as increased quality and comfort in using the orthosis. It meets attributes such as copying the subject's morphology, airiness, lightness, and easy fastening.

1 Introduction

Cervical orthoses, which provide mechanical support and stabilization of the cervical spine, are key tools in the rehabilitation and treatment of various neurological and musculoskeletal diseases [1]. A cervical orthosis provides relief and support for the neck [2], limiting cervical spine movement or immobilizing it, depending on the medical condition [3]. Cervical orthoses are divided into three categories: soft (basic, made of foam rubber covered with a soft lining), semi-rigid (padded mandibular and occipital supports), and cervico-thoracic orthoses (support comparable to column braces with rigid metal linkage between the front and back parts) [2,3].

Traditional methods of manufacturing these aids, often based on manual measurement, plastering and manual finishing, are time-consuming and can be limiting in creating a unique design. Cervical orthoses made using traditional methods are commonly available and crafted from thermoplastics or leathers. The traditional process of custom orthosis manufacturing is manual and relies on the orthotic technician's skills. The disadvantages of these orthoses include delivery time, cost, and the quality of the orthosis [4].

Innovative technologies such as 3D scanning and CAD/CAM (Computer Aided Design/Computer Aided Manufacturing) technologies offer new possibilities in the personalization of orthopaedic aids, thereby improving the comfort and effectiveness of treatment [5].

The development of personalized cervical orthoses using these technologies is a subject of several scientific studies [5-8]. These studies show that the use of adittive manufacturing technology and advanced software tools can reduce manufacturing time and costs, improve fitting and patient comfort, and even contribute to the environmental sustainability of orthopaedic devices. These methods were used in studies especially for subjects with complex clinical needs, where previous designs were insufficient. The predominant technology for production was FDM (Fused Desposition Modelling) technology, and CT tomography as the technology for obtaining measurement data, in addition to 3D scanning [9].

In this work, the Multi Jet Fusion (MJF) technology was used, where the manufacturing method involves uniformly heating the applied powder using a thermal head. Printing heads are used to apply agents that support the 3D printing process. The first agent is applied to the surface of the model to enhance the absorption of thermal radiation. The second agent is applied to the outer contours of the produced model to facilitate the separation of the unfused powder from the final model [10].

The MJF technology enables production using polyamide - PA12. This material is characterized by high mechanical, thermal, and fatigue strength, as well as resistance to less aggressive chemicals. PA12 is highly hygroscopic, quickly absorbing water from the environment. A significant property of this material is its skin-contact biocompatibility according to ISO 10993-1, and it is also approved for food contact according to EU directive 2002/72/EC (excluding alcoholic products). An essential property that the orthosis should meet also relates to the aesthetics of its production. PA12 offers many possibilities for finishing parts, such as polishing, dyeing, painting, powder coating, or gluing products [10].

The aim of this study was to design and manufacture a personalized cervical orthosis using innovative technologies. Our approach seeks to demonstrate the implementation of CAD/CAM technologies in the production of custom cervical orthoses, showcasing a more efficient and precise alternative to conventional methods.

2 Methodology

The design and manufacturing of an individual cervical orthosis consists of 3 steps:

1. 3D scanning of the cervical area,
2. CAD design and creation of a 3D model of the cervical orthosis,
3. Additive manufacturing of the cervical orthosis.

2.1 Methodology of 3D scanning of the cervical spine

A handheld optical 3D scanner ArtecEva (Artec 3D, Senningerberg, Luxembourg) was used for data obtainment. This scanner uses structured light technology which is used to obtain the shape and texture of area of interest. This technology is suitable for use in the field of prosthetics and orthotics, based on it´s resolution [9]. With the help of a 3D scanner, the topography of the neck can be digitalized [10].

The scanning was done while the subject was sitting, which is more practical for the 3D scanner operator. At the same time, sitting minimizes unwanted micro-movements of the scanned subject, which increases the overall accuracy of the scanning process. In the case of 3D scanning the neck area, it is important that the person being scanned has their hair tied back and has jewellery on the neck or ears. Due to the volume of hair and the impossibility of capturing the surface of the occipital part of the head, the scan was performed in a tight-fitting swimming cap. It is also necessary that the face, neck, shoulders and chest areas are uncovered. The subject being scanned should be instructed not to move and possibly keep their eyes closed due to the intense flashing light during the scanning process. The movement with the 3D scanner should be smooth and slow so that the scanner has time to capture all the details of the surface.

After the scanning process, the resulting 3D scan isedited and processed in the Artec Studio 13 software (Artec 3D, Senningerberg, Luxembourg). The Artec Studio software then automatically fills in the missing parts of the scan that were not captured. The modified file is subsequently exported in STL format and further adjustments were made in Meshmixer (Autodesk Inc., San Francisco, CA, U.S.A.), which is a freely downloadable CAD software suitable for 3D scans editingand has the necessary functions to create a 3D model of a personalized orthosis.

2.2 Design of a personalized cervical orthosis using CAD systems

The editing of the 3D model itself consists in thoroughly smoothing the surface so that the subsequently modeled orthosis is smooth and without defects. Before CAD modelling of the orthosis, it is necessary to identify the areas that need to be fixed. Cervical braces should limit head and neck movements, as well as to mechanically limit flexion, extension, lateral flexion, and rotation of the head and cervical spine [1].

Because the orthosis supports part of the weight of the head, the cervical spine is partially relieved. The basic support points of cervical orthoses include the shoulders, chin, head and jaw. The upper limbs can provide some support, depending on its design, contributing to overall stability. A chin rest or collar helps keep the chin in a neutral position and prevents excessive movement. Supporting the back of the head is important for distributing pressure and increasing stability. These support points, or landmarks, are designed to improve overall posture and alignment.

After smoothing the surface and determining the support points, the actual modelling of the orthosis follows, as shown in Figure 1. This procedure involves several steps. First, a sketch of the orthosis is created on the 3D model, including ventilation holes that improve comfort and reduce the weight of the orthosis; the middle hole is intended for a possible tracheostomy. The pattern is then extruded with the thickness of the brace set to 4 mm. Subsequently, a drawing of the back part of the orthosis is created on the scan. The orthosis is designed in two parts for improved positioning and easier fitting.

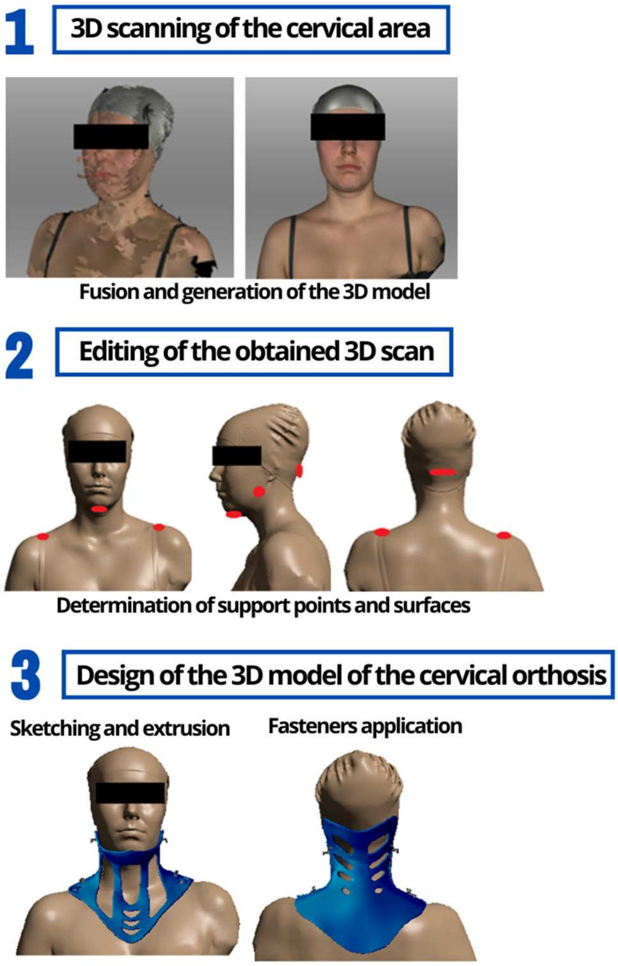

Figure 1 Step-by-step design methodology

Since the orthosis has two parts, the fastening component was created in SOLIDWORKS software (Dassault Systems, Waltham, USA) to allow both parts to be joined. The connection shown in Figure 2 was simple and functional and was designed to be suitable for additive manufacturing. The joint consists of two parts: the gear teeth and the locking tooth.

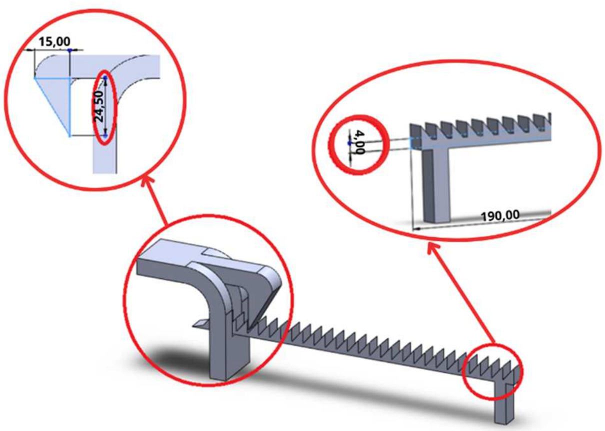

Figure 2 3D model of the fastening component and its dimensions

2.3 *Additive manufacturing of the cervical orthosis*

The proposed orthosis was manufactured using MJF (Multi Jet Fusion) additive manufacturing technology, on a HP MJF 5200 (Hewlett Packard Enterprise, Houston, Texas, USA) 3D printer from the Nylon 12 (PA12) material, which was chosen for its high applicability in medical practice and mechanical properties for the development of such device. The printer manufacturer states that this technology and material allow the creation of parts with fine details, dimensional accuracy of ± 0.2 mm and optimal mechanical properties, which are suitable for prosthetics and medical equipment. The build volume of the printer is 380 x 284 x 380 mm, with a tolerance of ± 0.2% (minimum 0.2 mm), and the print price starts at €0.29 per cm^3. [11] After manufacturing the orthosis (Figure 3) using MJF technology from PA12 material, the surface of the raw product was gray and rough. To achieve a uniform and aesthetically appealing surface, the orthosis was painted black. This finishing process is referred to as HQ Black (Figure 4).

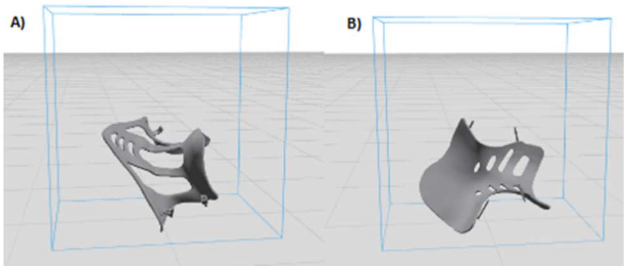

Figure 3 Two-part orthosis position simulation in the space for printing the part on the official website of the HP company [12]

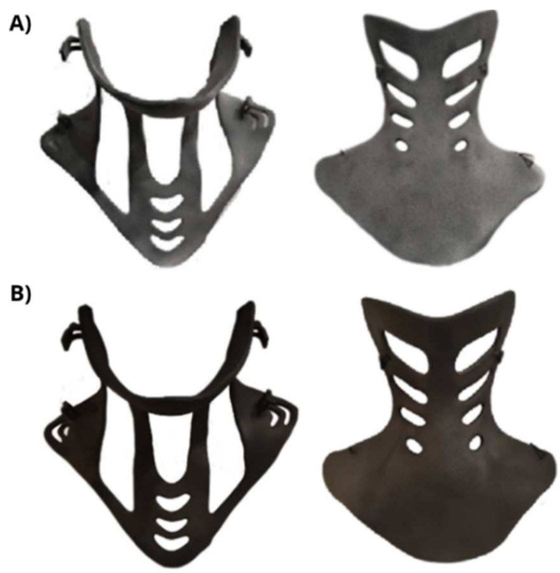

Figure 4 Both parts of the cervical brace before and after finishing

3 Results and discussion

The manufactured two-part cervical brace is designed to stabilize the cervical spine with a chin support and is equipped with a simple and customizable fastening. It is intended for use in post-traumatic conditions, postoperative immobilization, degenerative diseases and discopathy. The orthosis has a tracheostomy opening and maintains a neutral position of the cervical spine, limiting flexion in every direction.

In terms of the time efficiency of designing and manufacturing a personalized orthosis, additive technology appears to be much faster. This two-piece brace was designed and manufactured within approximately 72 hours of scanning the subject. The maximum length of MJF printing of the entire build is 12.5 hours [11], while it is possible to print several prosthetic and orthopedic aids at the same time. On the other hand, the production of a personalized orthosis by the conventional method according to Hale et al. it takes about 6 days [5], which is due to the collection of measurement data and subsequent adjustments. The cervical brace 3D scanning process can take approximately 15 minutes, including subject preparation. The innovative method eliminates the need for manual casting and mold making, saving time while being more environmentally friendly and economical. According to Hale et al., the total price of such a device made by the Fused Filament Fabrication (FFF) method was approximately 386 €, while they stated that this method is inherently slow compared to the Selective Laser Sintering (SLS) method. According to them, this price of the orthosis is comparable to an estimate of 415 € for similar aids made by conventional methods in their hospital [5]. The total price of the proposed two-part cervical orthosis is 273.29 € and it weight 295 g.

To ensure the comfort of the patient, the material "SOHATEX" is recommended as a lining, which is commonly used in the production of prosthetic-orthopedic aids due to its ability to remove moisture well and provide excellent air circulation. With the help of CNC (Computer Numerical Control) cutting technology, it is possible to automatically cut the desired shape of the lining according to the 3D model. CNC machines are commonly used in prosthetic-orthopedic companies in the production of orthopaedic footwear and bandage aids.

The manufactured plastic two-part cervical orthosis, even with the fastening component, is also compatible with an MRI examination, because it has no metal parts. Although this fixation component is designed to be easy to put on and take off, it is not necessary to take it off before this examination.

4 Conclusions

This study successfully demonstrated the application of advanced CAD/CAM systems and additive manufacturing technology in the design and production of a personalized cervical orthosis. Utilizing the Multi Jet Fusion (MJF) manufacturing process with PA12 material, the study highlighted significant improvements in production efficiency, achieving a complete orthosis development within 72 hours—a notable reduction from the conventional six-day timeframe. The resulting orthosis was anatomically precise, lightweight, and customizable, meeting the essential requirements for cervical spine stabilization. Additionally, the integration of these technologies provides a scalable approach to personalized medical care, offering potential ecological and economic benefits.

Future research could explore the use of low-cost 3D scanners for data acquisition, potentially expanding the accessibility of this workflow in hospitals and other clinical settings. By lowering the input costs, these technologies could be more widely implemented, allowing a broader range of healthcare facilities to benefit from personalized orthotic solutions. This could lead to greater practical aplication of advanced manufacturing techniques in medical practice, further enhancing patient care and operational efficiency across diverse healthcare environments.

Acknowledgement

This work was supported by the Slovak Research and Development Agency under the contract No. APVV-22-0340. This research was supported by project KEGA 044TUKE-4/2022 Implementation of progressive technologies in prosthetics and orthotics education and support integration with practice. This research was supported by project VEGA 1/0599/22 Design and biomechanical analysis of personalized instruments for arthroscopic applications.

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Review process

Single-blind peer review process.