SSRG International Journal of Mechanical Engineering
ISSN: 2348-8360/ https://doi.org/10.14445/23488360/IJME-V11I8P108

Volume 11 Issue 8, 68-73, August 2024

Original Article

Design and Development of a Flexible and Reusable Neck Orthosis Using Thermoplastic Polyurethane

G. H. Waghmare[1], Achal S. Shahare[2], Sachin T Bagde[3], Kanak G. Waghmare[4]

[1,2]Department of Mechanical Engineering, G H Raisoni University, Amravati, India.
[3]Department of Mechanical Engineering, YCCE Nagpur, Maharastra, India.
[4]Sharad Pawar Dental College and Hospital, DMIHER, Sawangi Wardha, Maharastra, India.

[1]Corresponding Author : gwaghmare@gmail.com

Received: 11 June 2024 Revised: 19 July 2024 Accepted: 12 August 2024 Published: 31 August 2024

Abstract *- This research presents the design of a flexible and reusable neck orthosis using Thermoplastic Polyurethane (TPU). Traditional cervical collars often face challenges such as poor ventilation, generalized sizing, odor retention, and reduced stiffness after washing. This study aimed to address these issues by creating a custom-fitted orthosis that enhances patient comfort and support. The design, created using CATIA software, incorporated an elliptical hole pattern to improve flexibility and breathability while maintaining structural integrity with a reduced thickness of 3.5 mm. Finite Element Analysis (FEA) was performed using ANSYS software to assess the mechanical behavior of the orthosis under various load conditions (40N, 60N, 80N, and 100N). The results showed that stress was effectively distributed, with the highest concentrations at the upper side edges of the model. Mechanical properties, including equivalent stress, maximum shear stress, total deformation, and equivalent elastic strain, were evaluated, demonstrating the orthosis's capability to withstand significant forces while maintaining flexibility. The study concludes that the developed neck orthosis offers a promising alternative to conventional collars by addressing critical issues of comfort, breathability, and durability. These findings support the potential for additive manufacturing in producing custom-fitted, patient-specific orthotic devices that improve clinical outcomes and patient satisfaction.*

Keywords *- Flexible neck orthosis, Thermoplastic Polyurethane (TPU), Finite element analysis, Custom-fitted cervical collar, Orthotic design.*

1. Introduction

Neck orthoses, also known as cervical collars, play a crucial role in treating different conditions affecting the cervical spine, such as traumatic injuries, degenerative diseases, and post-operative recovery [1]. These devices are specifically engineered to immobilize the cervical spine, thereby diminishing pain and averting additional harm while facilitating the process of recovery. Conventional cervical collars, despite being widely used, encounter various obstacles, such as a lack of personalization, discomfort, limited longevity, and environmental issues related to disposable versions.

The emergence of Additive Manufacturing (AM), commonly referred to as 3D printing, offers a revolutionary prospect in the realm of orthotic design and production. Additive manufacturing enables the production of intricate, personalized devices that are lightweight, pliable, and can be used multiple times. This technology enables the creation of neck orthoses that can be customized to fit the specific anatomical and therapeutic requirements of individual patients, potentially improving the effectiveness of treatment and patient adherence [2].

Traditionally, cervical collars have been made from inflexible materials like plastic and foam, providing stability but frequently causing discomfort and noncompliance in patients. A study conducted by Gavin et al. [3] emphasized the trade-offs between immobilization and comfort, specifically pointing out that rigid collars frequently result in pressure sores and decreased patient compliance with prescribed wearing durations. The absence of personalization in conventional collars can lead to inadequate fitting, which not only undermines the effectiveness of therapy but also intensifies discomfort. Recent advancements have prioritized enhancing the suitability and comfort of cervical collars by utilizing custom-molded designs. Paterson and Bib [4] investigated the utilization of custom-fitted orthoses madethrough conventional molding techniques, which showed enhanced patient results in comparison to ready-made models. However, these methods are labor-intensive and not an easy task of scalable, highlighting the need for more efficient production techniques. Additive Manufacturing (AM), also known as 3D printing, has emerged as a groundbreaking technology in the medical device industry, providing unparalleled possibilities for customization and rapid prototyping. The study conducted by Wazeer et al. [5]

examined the wide range of uses for Additive Manufacturing (AM) in the healthcare industry. The research highlighted the ability of AM to create intricate and customized medical devices with complex shapes, which would be challenging to achieve using traditional manufacturing techniques. The incorporation of pliable materials in Additive Manufacturing (AM) has shown great potential in the advancement of orthotic devices. In their study, S. Mian et al. [6] investigated the application of thermoplastic elastomers in 3D-printed orthoses. They found that these materials, which are flexible and adaptable, led to notable enhancements in patient comfort and compliance. The flexibility of the orthosis enables it to better adapt to the patient's anatomy, offering support while maintaining comfort. The ecological ramifications of medical devices are a progressively significant factor to take into account. Conventional disposable cervical collars contribute to the accumulation of medical waste, which has led to the investigation of reusable alternatives. In a study conducted by Barros et al. [7], the life cycle of reusable orthotic devices was examined. The study concluded that Additive Manufacturing (AM) has the potential to greatly decrease environmental impact by allowing the production of long-lasting, reusable orthoses. The capacity to sterilize and reuse these devices is in accordance with worldwide sustainability objectives and diminishes long-term healthcare expenses. Empirical research has commenced to substantiate the advantages of orthoses produced through 3D printing in practical environments. Xu et al. [8] performed a comparative analysis between 3D-printed cervical collars and traditional models. The study revealed that patients expressed greater satisfaction and achieved superior overall results with the 3D-printed versions. These findings highlight the capacity of AM to improve both the effectiveness of medical treatment and the satisfaction of patients. Choosing appropriate materials for 3D printing neck braces is crucial to ensure that they are compatible with the human body, long-lasting, and environmentally friendly. A study conducted by Bernard et al. [9] highlighted the significance of utilizing biocompatible materials in medical devices to avoid negative reactions and guarantee the safety of patients.

Additionally, the study by Subramani et al. [10] explored the use of eco-friendly and biodegradable materials in 3D printing, highlighting the potential for developing sustainable medical devices that minimize environmental impact without compromising performance. While the initial costs of implementing additive manufacturing in medical device production can be high, long-term economic benefits are significant. A cost-benefit analysis by Kumar and Chhabra et al. [2] demonstrated that the use of 3D printing for custom orthoses can reduce overall healthcare costs by minimizing the need for adjustments and replacements, improving patient outcomes, and reducing recovery times. Moreover, the ability to produce orthoses locally using digital designs can enhance accessibility, particularly in underserved regions where access to specialized medical devices is limited. The adoption of additive manufacturing in the medical field also brings regulatory and standardization challenges. The study by Palo et al. [11] discussed the need for clear regulatory frameworks to ensure the safety and efficacy of 3D-printed medical devices.

The development of industry standards and guidelines is essential to facilitate the widespread adoption of this technology while maintaining high-quality standards. The ability to create patient-specific devices is one of the most significant advantages of additive manufacturing. Customization ensures that the orthosis fits the unique anatomical structure of the patient, providing better support and comfort. A study by Hale et al. [12] demonstrated that 3D-printed orthoses tailored to individual patients' measurements significantly improved clinical outcomes, including reduced pain and faster recovery times. Customization also allows for modifications to accommodate varying degrees of injury or recovery stages, enhancing the therapeutic efficacy of the device. Customized orthoses produced through additive manufacturing have shown promise in improving rehabilitation outcomes.

According to Zheng et al. [13], patients using 3D-printed orthoses reported improved mobility and functional performance compared to those using standard devices. This improvement is attributed to the precise fit and tailored support provided by the custom devices, which help maintain proper alignment and prevent further injury during the rehabilitation process. Patient compliance with prescribed orthotic devices is crucial for effective treatment. Comfort plays a significant role in compliance, and studies have shown that discomfort is a major reason for noncompliance with traditional cervical collars. Research conducted by Herke et al. [14] found that 3D-printed neck orthoses made from flexible materials were significantly more comfortable than conventional rigid collars, leading to higher patient adherence to wearing schedules and better overall treatment outcomes. A study by Elhadad et al. [15] explored the use of multi-material 3D printing for orthopaedic applications, demonstrating that this approach can produce more effective and comfortable devices.

Although traditional cervical collars and support belts are commonly used, they have several significant drawbacks. These include inadequate ventilation, which can cause skin problems, standardized sizes that do not guarantee a proper fit, absorption of sweat leading to unpleasant odors, and a decrease in necessary stiffness after washing. Furthermore, continuous contact with the affected area can exacerbate the discomfort. The objective of this study is to tackle these problems by creating a versatile and recyclable neck brace using additive manufacturing methods. This brace will provide a personalized fit, good airflow, and cleanliness while also maintaining the necessary rigidity and enhancing patient comfort and medical results.

Table 1. Mechanical properties of TPU

Property	Value
Density	1.2 g/cm³
Tensile Strength	30 MPa
Elongation at Break	500%
Shore Hardness (A)	85-95
Flexural Modulus	25 MPa
Compression Set (70°C)	25%

2. Materials and Methods

2.1. Material

The primary material used in this study for the development of the cervical collar is Thermoplastic Polyurethane (TPU). TPU is chosen for its flexibility, durability, and biocompatibility, making it suitable for medical applications such as orthotic devices. The mechanical properties of TPU used in this study are summarized in Table 1.

2.2. Methods

The cervical collar was designed using CATIA software, following the structure of conventional rigid orthoses available on the market, which typically support the neck from the chest up to the base of the skull. Figure 1 shows the designed model of the cervical collar.

The design aimed to enhance flexibility and breathability while maintaining sufficient support. The central bending region around the neck was designed without solid fill to allow for better flexibility.

Oval-shaped holes were incorporated to improve bending characteristics and reduce the force required for neck movement. An elliptical pattern of holes was preferred over a honeycomb pattern, as it showed better performance in terms of total displacement under load conditions. The collar's thickness was set at 3.5 mm, which is thinner than most market-prefabricated models, providing a balance between lightweight and structural strength.

Finite Element Analysis (FEA) was conducted using ANSYS software to assess the mechanical behavior of the developed model. A fine mesh consisting of 3889 elements and 8089 nodes was created to ensure accurate simulation results (Figure 2a).

The boundary conditions were applied to simulate realistic usage scenarios. The model was subjected to four different loads: 40N, 60N, 80N, and 100N (Figure 2b). Various mechanical parameters were calculated, including total deformation, von Mises stresses, equivalent elastic strain, maximum shear stress, and equivalent stress. The numerical assessment aimed to observe how the neck orthosis behaves under different applied forces, focusing on deformation patterns, stress distribution, and the overall structural integrity of the design.

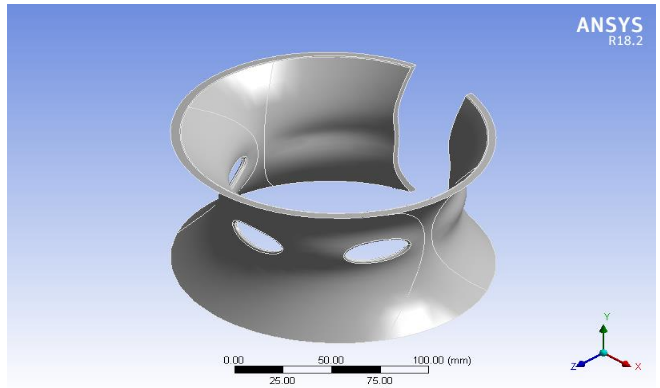

Fig. 1 Neck orthosis design model

3. Result and Discussion

3.1. Stress Distribution Analysis

The influence of the applied force on stress distribution in the cervical collar model is depicted in Figure 3, which uses an Iso-colour view to represent the stress levels. The color bar on the left side of the figure indicates that red represents the highest pressure, while blue represents the lowest pressure, with stress measured in megapascals (MPa). The analysis shows that the regions most affected by pressure are the upper side edges of the model. In contrast, the left and front sides of the model experience significantly lower stress levels. This distribution suggests that the collar design effectively channels the stress to the structurally reinforced upper edges, ensuring the stability and support required to immobilize the neck effectively.

3.2. Mechanical Properties Under Various Load Conditions

The mechanical properties of the cervical collar model under different load conditions (40N, 60N, 80N, and 100N) are summarized in Table 2. These properties include total deformation, equivalent elastic strain, equivalent stress, and maximum shear stress.

The results indicate that as the applied force increases, the equivalent stress and maximum shear stress also increase proportionally. At 40N, the equivalent stress is 0.87104 MPa, and the maximum shear stress is 0.45588 MPa. Under the highest applied load of 100N, these values increase to 2.1776 MPa and 1.1397 MPa, respectively. This trend demonstrates that the cervical collar's material and design can withstand varying load conditions while maintaining its structural integrity.

The equivalent elastic strain values also increase with the applied load, suggesting that the TPU material's elasticity effectively manages the deformation without causing permanent damage. For instance, the equivalent elastic strain at 40N is 0.0004618 mm/mm, which increases to 0.0011546 mm/mm at 100N. This indicates that the collar can accommodate significant deformation while maintaining its return to its original shape.

Table 2. Mechanical properties of the cervical collar under various load conditions

Load (N)	Total deformation (mm)	Equivalent Elastic Strain (mm/mm)	Equivalent Stress (MPa)	Maximum Shear Stress (MPa)
40	0.33488	0.0004618	0.87104	0.45588
60	0.50232	0.0006927	1.3066	0.68383
80	0.66976	0.0009236	1.7421	0.91172
100	0.8372	0.0011546	2.1776	1.1397

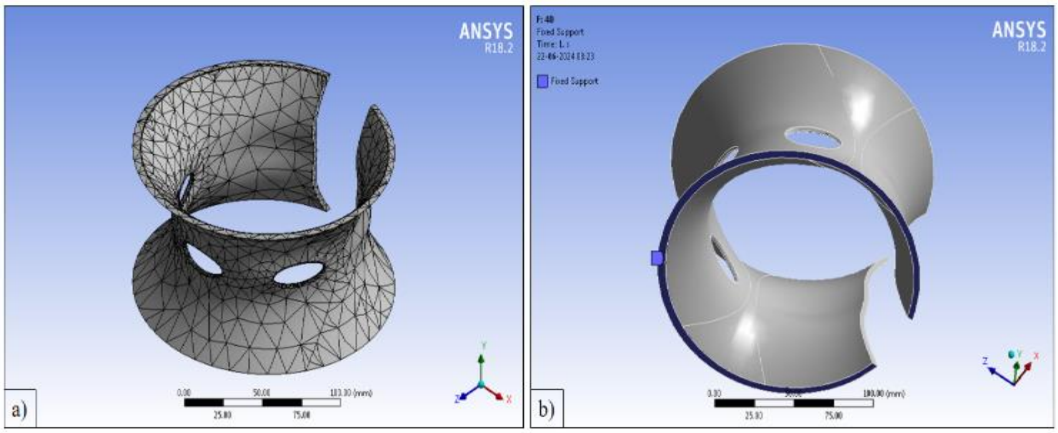

Fig. 2 (a) Mesh view of design, (b) applied boundary condition over the model

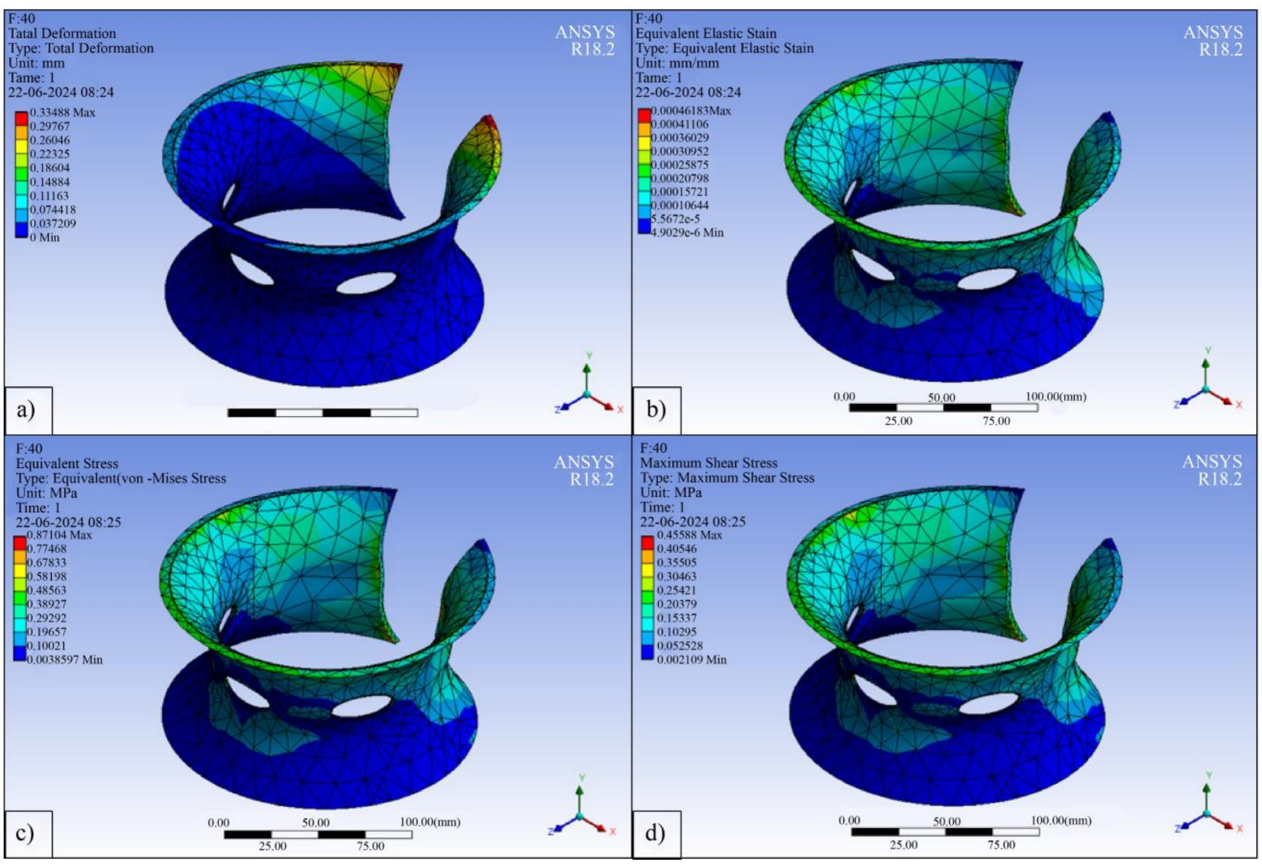

Fig. 3 (a) Total deformation, (b) equivalent elastic strain, (c) equivalent stress, (d) maximum shear stress under the load of 40 N

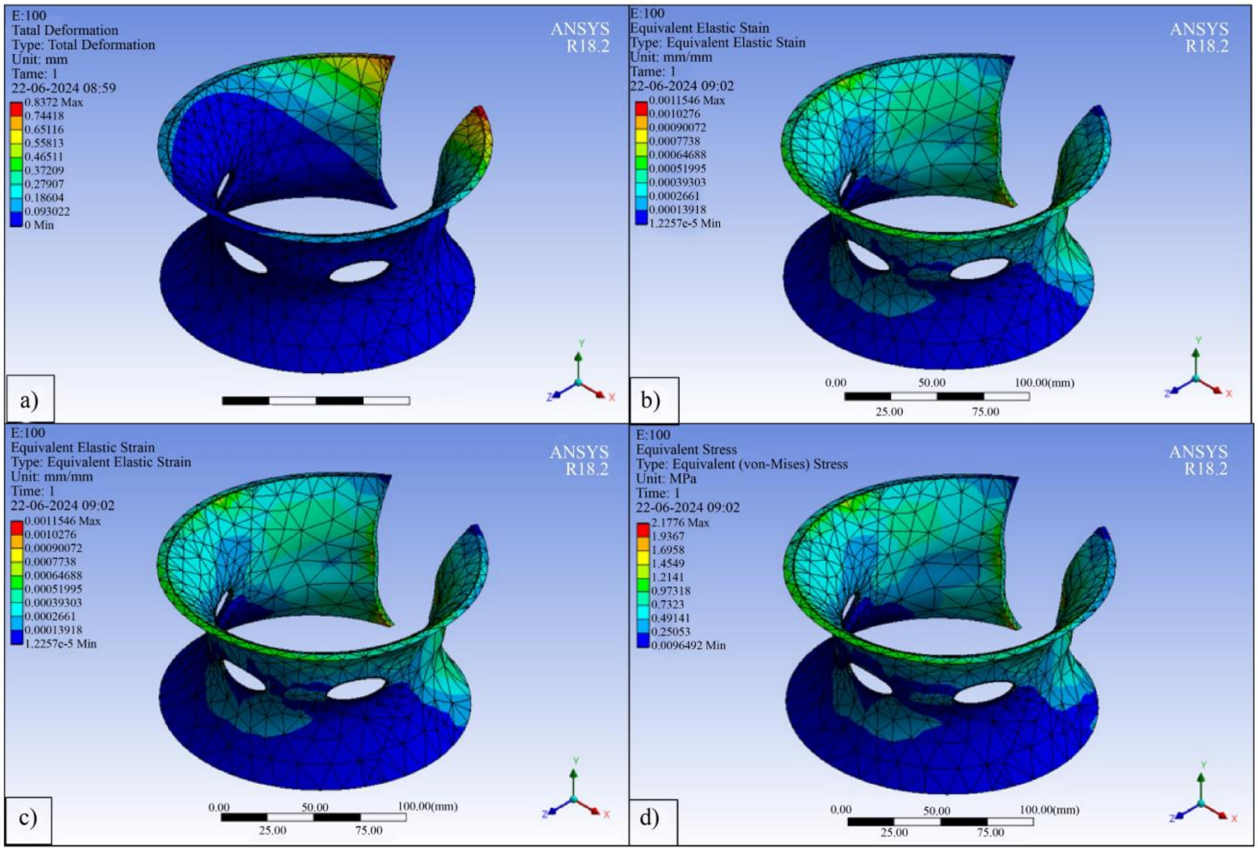

Fig. 4 (a) Total deformation, (b) Equivalent elastic strain, (c) Equivalent stress, (d) Maximum shear stress under the load of 100N

The cervical collar's total deformation is directly proportional to the applied load, demonstrating the collar's flexibility and ability to adjust to varying levels of stress. When a force of 40N is applied, the amount of deformation is 0.33488 mm. This deformation increases to 0.8372 mm when the force is increased to 100N. The controlled deformation is essential for ensuring the required support and comfort, as excessive rigidity may cause discomfort and insufficient support.

The incorporation of elliptical apertures in the design substantially decreases the amount of force needed for neck mobility, thereby augmenting comfort. The arrangement of these apertures guarantees that the collar maintains a high level of breathability, effectively resolving prevalent problems such as inadequate air circulation and skin irritation.

The analysis confirms that the developed cervical collar design successfully achieves a harmonious combination of structural robustness, flexibility, and breathability. The slim 3.5 mm profile guarantees a lightweight device without compromising on sufficient support. The arrangement of holes in an elliptical pattern not only enhances mechanical properties but also improves breathability, which is essential for prolonged use.

4. Conclusion

This study successfully designed a flexible and reusable neck orthosis using Thermoplastic Polyurethane (TPU). The design aimed to address common limitations of traditional cervical collars, including poor ventilation, generalized sizes, and reduced stiffness after washing. The developed model incorporated innovative features such as elliptical hole patterns and a reduced thickness of 3.5 mm to enhance breathability, flexibility, and patient comfort.

FEA revealed that the orthosis effectively distributes stress, with the highest pressures concentrated on the upper side edges, ensuring robust support where it is most needed. The mechanical properties under various load conditions demonstrated the collar's capability to withstand significant forces while maintaining structural integrity and flexibility. The equivalent stress, maximum shear stress, total deformation, and equivalent elastic strain values increased proportionally with applied loads, confirming the material's and design's resilience and adaptability. The study highlights the potential of additive manufacturing in creating custom-fitted, patient-specific orthotic devices that significantly improve user comfort and clinical outcomes. The findings support the feasibility of using TPU for medical applications, providing a balance between lightweight design and necessary mechanical strength. Future research should include clinical trials to validate these results in real-world scenarios and investigate the long-term effects on patient recovery and compliance. Overall, the developed neck orthosis offers a promising alternative to conventional cervical collars, addressing critical issues such as comfort, breathability, and durability. This advancement in orthotic design can lead to better patient adherence, improved therapeutic outcomes, and enhanced quality of life for individuals suffering from cervical conditions.

References

[1] John Freeman et al., "The Role of Orthoses in Chronic Axial Spinal Conditions," *Current Pain and Headache Reports*, vol. 28, pp. 501-506, 2024. [CrossRef] [Google Scholar] [Publisher Link]

[2] Ashwani Kumar, and Deepak Chhabra, "Adopting Additive Manufacturing as a Cleaner Fabrication Framework for Topologically Optimized Orthotic Devices: Implications Over Sustainable Rehabilitation," *Cleaner Engineering and Technology*, vol. 10, pp. 1-15, 2022. [CrossRef] [Google Scholar] [Publisher Link]

[3] Thomas M Gavin et al., "Biomechanical Analysis of Cervical Orthoses in Flexion and Extension: A Comparison of Cervical Collars and Cervical Thoracic Orthoses," *Journal of Rehabilitation Research & Development*, vol. 40, no. 6, pp. 527-537, 2003. [CrossRef] [Google Scholar] [Publisher Link]

[4] A.M.J. Paterson, R.J. Bibb, and R.I. Campbell, *Orthotic Rehabilitation Applications*, Medical Modelling: The Application of Advanced Design and Rapid Prototyping Techniques in Medicine, Elsevier Science, pp. 283-351, 2014. [Google Scholar] [Publisher Link]

[5] Adil Wazeer et al., "Additive Manufacturing in Biomedical Field: A Critical Review on Fabrication Method, Materials Used, Applications, Challenges, and Future Prospects," *Progress in Additive Manufacturing*, vol. 8, pp. 857-889, 2023. [CrossRef] [Google Scholar] [Publisher Link]

[6] Syed Hammad Mian et al., "An Insight into the Characteristics of 3D Printed Polymer Materials for Orthoses Applications: Experimental Study," *Polymers*, vol. 16, no. 3, pp. 1-30, 2024. [CrossRef] [Google Scholar] [Publisher Link]

[7] Kleber Da Silva Barros, "*Identification of Contributors to Environmental Impacts Linked to the Use of Additive Manufacturing Technologies*," Grenoble Alpes University (ComUE), 2017. [Google Scholar] [Publisher Link]

[8] Yangyang Xu et al., "Design of Personalized Cervical Fixation Orthosis Based on 3D Printing Technology," *Applied Bionics and Biomechanics*, vol. 2022, no. 1, pp. 1-8, 2022. [CrossRef] [Google Scholar] [Publisher Link]

[9] Mélisande Bernard et al., "Biocompatibility of Polymer-Based Biomaterials and Medical Devices – Regulations, in Vitro Screening and Risk-Management," *Biomaterials Science*, vol. 6, no. 8, pp. 2025-2053, 2018. [CrossRef] [Google Scholar] [Publisher Link]

[10] Raja Subramani et al., "Exploring the Use of Biodegradable Polymer Materials in Sustainable 3D Printing," *Applied Chemical Engineering*, vol. 7, no. 2, pp. 1-14, 2024. [CrossRef] [Google Scholar] [Publisher Link]

[11] Mirja Palo et al., "3D Printed Drug Delivery Devices: Perspectives and Technical Challenges," *Expert Review of Medical Devices*, vol. 14, no. 9, pp. 685-696, 2017. [CrossRef] [Google Scholar] [Publisher Link]

[12] Luke Hale, Emma Linley, and Deepak M. Kalaskar, "A Digital Workflow for Design and Fabrication of Bespoke Orthoses Using 3D Scanning and 3D Printing, a Patient-Based Case Study," *Scientific Reports*, vol. 10, no. 1, pp. 1-7, 2020. [CrossRef] [Google Scholar] [Publisher Link]

[13] Yanan Zheng et al., "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," *Clinical Rehabilitation*, vol. 34, no. 2, pp. 194-204, 2020. [CrossRef] [Google Scholar] [Publisher Link]

[14] Patrick Herke, Abhishek Kumar, and Hunter B. Gilbert, "Using Granular Jamming and a Parallel Compliant Mechanism to Provide a Rapidly Deployable, Custom-Fitted Cervical Collar," *ASME International Mechanical Engineering Congress and Exposition*, vol. 86663, 2022. [CrossRef] [Google Scholar] [Publisher Link]

[15] Amir A. Elhadad et al., "Applications and Multidisciplinary Perspective on 3D Printing Techniques: Recent Developments and Future Trends," *Materials Science and Engineering: R: Reports*, vol. 156, pp. 1-44, 2023. [CrossRef] [Google Scholar] [Publisher Link]