Original Article

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Design and Development of a 3D Printable Neck Brace- A Finite Element Approach

Others Section

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ABSTRACT

Introduction: Neck braces are commonly used to immobilise and support the neck and spinal cord. Even though neck brace has given significant assistance for proper management of cervical spine injuries, it offers a false sense of security where it might prevent additional and further spinal cord injury. Customised neck brace can provide additional comfort. Furthermore, doctor's views and opinions were taken into consideration and the design has been altered and also can be made customisable to suit every patient, ensuring their comfort at the same time.

Aim: To design a 3D printable neck brace and to evaluate it numerically by means of Finite Element Modelling (FEM).

Materials and Methods: The model was designed in Autodesk Fusion 360 software and then was imported into HyperWorks for further analysis. Polylactic Acid (PLA) was assigned as a material to the model and it was analysed under two conditions after assignment of materials properties such as young's modulus, density and Poisson's ratio. HyperView was utilised to visualise the results of the linear static analysis to further enhance the model.

Results: The maximum displacement, stress and strain of the model was observed in the posterior and interior segments which was found to be 1.813E-06, 1.109E+0, 4.805E-02, respectively upon application of a force of 20 N and 1.656E-06, 1.202E+03, 2.286E-07 respectively when a force of 100 N was applied.

Conclusion: The study found varying stress, strain and displacement values upon application of an external force which was used in the evaluation of the model. It was also found that PLA material led to better alignment and strength of the overall model and a mixture of PLA and natural rubber can be used as a viable 3D printing filament.

Keywords: Additive manufacturing, Computer aided designing, Finite element analysis, Fused deposition modeling, Neck pain

INTRODUCTION

In the adult population, neck pain is one of the most common musculoskeletal conditions. In many nations, neck pain is a significant contributor to morbidity and disability in both daily life and the workplace. A cross-sectional study with an objective to confirm the prevalence of neck pain in a population of adults aged 20 years and more was conducted by a group of researchers. The survey showed that the prevalence of neck pain ranged from 17.3-23.7% among a sample of adults aged 20 and more [1]. In cases of people experiencing chronic neck pain, a procedure of immobilising the neck is advised to be done. The immobilisation in such cases is done by neck braces which are also called a cervical collar or a cervical orthosis [2]. It is a common treatment option for neck injuries and neck surgeries. A neck brace is an orthosis that is generally designed to stabilise, immobilise, prevent deformity or protect against injury [3].

The two major types of neck collars are soft and rigid cervical collars. Soft collars are flexible and offer the widest range of motion possible, while the latter provides more cervical stabilisation. However, it was proposed that both types of collars provide the same range of motion in the frontal plane [2]. Neck braces are typically worn for an extended time; therefore, it should restrict the head and neck mobility without impeding normal activities. In recent times there has been a surge in demand for both types of neck brace among the younger generation, as the increased use of smartphones had a significant impact on the spine [4].

Recently, in a study it was reported that Additive Manufacturing (AM) has grown in recent times and a similar assessment of a neck brace was carried out using Finite Element Analysis (FEA) and 3D printing was done using Fused Deposition Modeling (FDM) [3].

Even though neck brace has given significant assistance for proper management of cervical spine injuries, it offers a false sense of security where it might prevent additional and further spinal cord injuries. Furthermore, prolonged usage of a collar may cause skin pressure points and ulcer formation, as well as a delay in weaning a patient off a ventilator. There may also be a risk of blood-borne infection transmission [5]. Therefore, the type of brace to be prescribed is based on the diagnosis and treatment goals.

It is necessary to assess the prescribed type of neck brace, and it can be done by the method of FEA. It helps the designer to find the balance between a medical device's stability for its expected life. A study was performed on cervical traction therapy with and without neck support where an FEA of the biomechanics of cervical traction therapy was performed. It was discovered that in clinical practice, the usage of neck support is recommended to avoid any soft tissue injury [6].

One of the advantages of the brace over the conventional one is that it is fully aerated and is customisable and an additional advantage is that the Computer Aided Designing (CAD) i.e. CAD designs can be freely shared through various platforms and then can be customised by the end-user. Therefore, according to the user's demand, the design can be adjusted before it is 3D printed which would greatly improve compliance. This is the major contrast with conventionally manufactured neck braces with a 'one-size-fits-all' approach which is also a cost-ineffective [7].

In the proposed work, the design and development of the neck brace and the evaluation of its mechanical strength and material properties have been performed and analysed. The customised neck brace was designed for optimal performance by selecting the appropriate configuration for its function while also enhancing aeration for additional comfort. The filament material recommended for use in printing of the neck brace is PLA [3].

MATERIALS AND METHODS

Additive Manufacturing-3D Printing

The process of Additive Manufacturing (AM) is a process in 3D printing, where 3D solid objects are built from a digital file [8]. Every year, 3D printing develops new uses for the healthcare industry that help save and enhance lives in ways that were previously unimaginable. The principle direct uses of 3D printing in the realm of medicine and surgery include the opportunity to make a decision or customise before manufacturing the size of the orthosis or prosthetics' parts with extreme precision. Customising orthosis, braces, prosthetics etc. thus results in cost savings with AM methods and hence one can swiftly create prototypes of fresh design ideas or upgrades to current equipment [9].

Negru N et al., stated that AM offers a lot of advantages and aims to cut expenses, simplify difficult procedures, and accelerate implementation [10]. The design of the proposed 3D printed neck brace uses AM method because of its various advantages as stated above. In this process, the neck brace is proposed to be created by building up layers of material until it is complete. Each of these layers can be thought of as a thin cross-section of the overall entity. Using CAD the printable file is generated. The proposed work aims to export the 3D model as a printable file to the 3D printer which uses AM for printing [11]. The overall block diagram of the 3D printing process is shown in [Table/Fig-1].

[Table/Fig-1]: Workflow of the AM process.

Material extrusion: Fused Deposition Modeling (FDM) is a process in AM that can be used to produce plastic and its composite parts [12]. FDM is also used in the medical industry to create moulds for casting implants, medical equipment, and other implants [13]. A plastic filament is unwound from a spool and is supplied to an extrusion nozzle, which turns the flow on and off. The nozzle is heated to melt the material, and it may be moved in both horizontal and vertical directions using a numerically controlled motor. The material is melted to extrude it to produce layers, the material then hardens immediately after extrusion from the nozzle [8]. FDM are trademarks owned by Stratasys Inc.

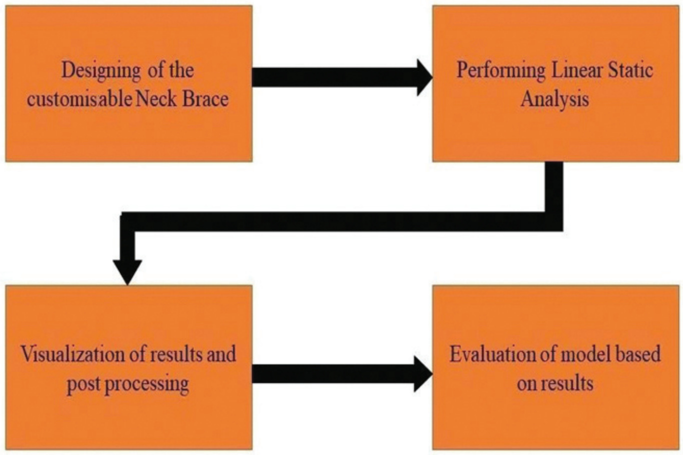
Investigations done in a study concluded that the method of FDM is an applicable option for the cervical region [3,14]. It is regarded as a viable option because of the complex functionality of a neck brace which has to support, prevent, immobilise or correct the spine. Other than the clinical aspects of the neck brace other factors such as the sensation of comfort and the aesthetic appearance are also achieved with the help of FDM [14]. But the major challenge with the FDM process is the achievement of accurate measurements, surface roughness, and tensile properties of the components [15].

Material used: PLA is a biodegradable thermoplastic polyester offering huge range of benefits. It is produced by the polymerisation of the lactic acid monomer, which is generally obtained from starch-rich renewable resources (e.g., sugar beets, sugarcane etc.) through fermentation [16]. This filament is widely used for residential 3D printing since it is simple to print, has an extrusion temperature between 180°C and 210°C, and can be sanded for surface finishing [15]. It is also found that thermoplastics like PLA liquefy instead of burning, allowing them to be readily injection molded and recycled [17]. Since the material is non toxic and bioplastic, it has extensive biomedical applications [18]. Furthermore, PLA can be recycled like any other thermoplastic polymer or can also be composted [19].

However, despite its widespread use, its shortcomings include a low elongation at breakpoint value, poor impact resistance, and a greater price than readily available commodity plastics. But these shortcomings can be overcomed by pairing it with other polymeric materials or fillers. By converting the PLA into a ductile polymer, the brittleness of PLA can be overcomed. It is achieved by pairing it with an immiscible, elastomeric (rubber-like) material. Since natural rubber proved to be an effective toughening agent of PLA-based printing filament, the resultant PLA can thus be used as printing material [19].

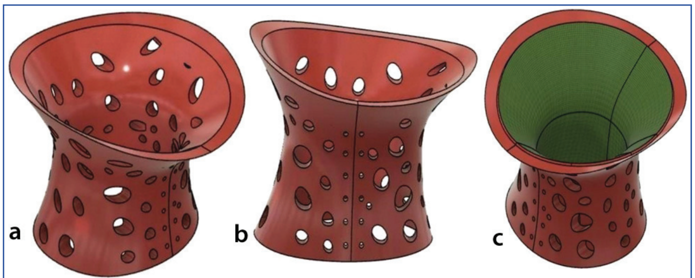
Design (CAD Prototype)

[Table/Fig-2] depicts the overall process of the work. The initial step consisted of the 3D modeling of the customisable neck brace. In the CAD model, different geometrical patterns are introduced for lightening the structure and improving breathability. The models obtained are numerically assessed through FEA to globally evaluate the proposed geometrical configuration. Finally, a 3D printable structure is created, and its material evaluation has been carried out in the HyperWorks software version 2021.



[Table/Fig-2]: Overall block diagram of the proposed work.

The neck brace was designed using the Autodesk Fusion 360 software. In this work, the height and diameter of the neck brace was assumed to be 10 cm and 35.5 cm, respectively since these dimensions corresponds to the length and height of an adult's neck. Also, an attempt has been made to determine the size of the brace using a software called the Automated Reconstructed Conduit (ARC3D) as stated by Tingdahl D and Van Gool L [20]. The proposed model was created with the primary goal of supporting the cervical lordotic spine, therefore it would have a curve on the posterior side as shown in [Table/Fig-3a]. It also has holes on it with arbitrary diameter to facilitate aeration. A provision for rubber attachments and detachments are provided on the model's lateral side so that it can be removed when required as seen in [Table/Fig-3b]. On the internal side of the model, 0.25 cm of padding was added to act as a cushion while supporting the neck as shown in [Table/Fig-3c]. The



[Table/Fig-3]: The design of the neck brace: (a) The neck brace model with a curvature on the posterior side to support the lordotic spine. (b) Equally spaced holes can be seen on the lateral side through which adjustments can be made by the patient. (c) A 0.25 cm padding is provided on the interior side to provide comfort.

developed model was transformed into a step file, which was then imported into the HyperWorks software for additional analysis and evaluation of its strength. Among the problems usually associated with the use of a cervical orthosis such as pin infection, pressure sores, and dysphagia [21], there is a lack of breathability which can result in discomfort therefore the proposed model has holes on it to promote aeration.

Finite Element Analysis (FEA)

FEA is a method for simulating mechanical parts and systems to provide information on failure, deformation, and stresses under a variety of loading conditions. Hence, the failure that can result in the neck brace can be analysed using FEA [6].

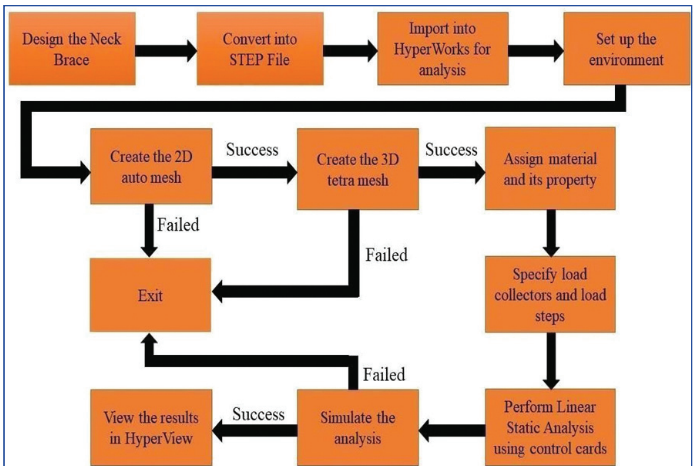
The overall process of FEA is divided into four steps:

1- Defining the problem and creating the geometry.
2- Solving the problem.
3- Postprocessing for outputs.
4- Analysing the results.

HyperWorks provides a comprehensive platform for visualising, querying, and processing results. It supports a wide range of Computer Aided Engineering (CAE) data sources, including video files and photos, and allows for full postprocessing and data analysis, including advanced table and curve graphing, as well as 3D visualisation and photo-realistic depiction of complex simulations. It also allows users to customise and share working sessions via customisable templates and infrastructure descriptions. In this work, a linear static analysis has been performed to determine the strength of the model.

Linear Static Analysis

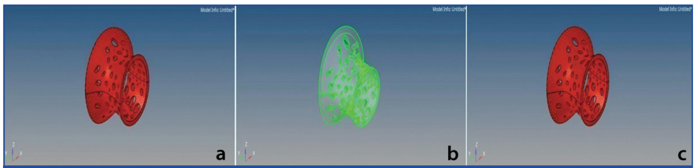
The overall workflow of the Linear Static Analysis conducted in HyperWorks is shown in [Table/Fig-4]. The model was analysed using the HyperWorks software after the neck brace has been designed as shown in [Table/Fig-5a].



[Table/Fig-4]: Overall flowchart of linear static analysis performed in the software.

The model was imported as a STEP file into the software for examination in Optistruct mode/interface. The creation of mesh over the model is the initial phase. A simple 2D Automesh is allocated to the entire model/surface, with surface deviation selected and properties like mesh type and element size specified, as well as standard settings for growth rate, minimum element size, and maximum deviation. As a result, a 2D mesh with a total number of 9660 nodes and elements were created. The 2D mesh was formed as shown in [Table/Fig-5b]. The surface deviation parameters are given in [Table/Fig-6].

Since the model is a 3D printable neck brace, 3D meshing is essential and crucial. Tetramesh is allotted for the neck brace model. The Tetramesh panel can be used to fill a volume with first or second-order tetrahedral pieces. If a region is contained by a shell mesh (tria and/or quad components) while maintaining all other attributes, it is deemed enclosed. While the mesh is getting allocated, different errors might turn up. For instance, it may show a decelerated meshing or a pop-up stating that the meshing has failed or stopped. This can be rectified by assigning a different mesh type such as R-trias and quads. As a result, the 3D mesh is formed once the meshing is completed as shown in [Table/Fig-5c].



[Table/Fig-5]: The overall process of meshing:(a) Image of the model imported into the Hyperworks software for analysis. (b) The process of 3D meshing after the completion of 2D Automesh is shown. (c) 2D Automesh and 3D Tetramesh are created.

Parameters	Values
Element size	10.000
Growth rate	1.230
Minimum element size	0.500
Maximum deviation	0.100
Maximum feature angle	15.000
Mesh type	Trias

[Table/Fig-6]: Parameters assigned in surface deviation for the process 2D auto mesh.

Since this work proposes to print the neck brace using PLA, the next step in the analysis is to assign the PLA material to the neck brace in HyperWorks using the MAT1 card picture. The mechanical properties for the material were obtained as mentioned: According to literature, the material's young's modulus, Poisson's ratio, and density were chosen as 4.107 GPa, 0.35, and 1.25 g/cc, respectively [22-24] as given in [Table/Fig-7].

Material assigned	PLA (Poly Lactic Acid)
Property	Material properties-PLA
Load collectors	Nodes and Forces
Load step	Linear static

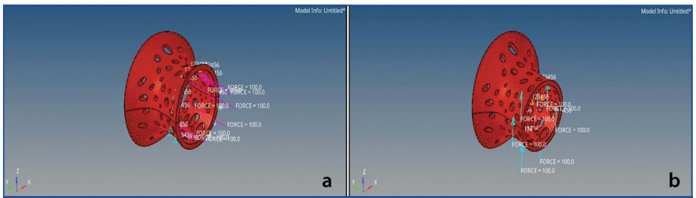
[Table/Fig-7]: Material and property that were assigned to the model.

After the material has been assigned, the PLA material has to be given a property. The card images should be assigned to PSOLID, and PLA should be selected in the material section. PSOLID is a card image used to describe solver-specific data and examine card information. PSOLID is chosen because the model is made up of a single solid body rather than a shell with surfaces.

Two assumptions were considered to determine the mechanical strength of the neck brace.

First case: Initially two load collectors were assigned. Creation of Single Point Constraints (SPC) is the first method, in which nodes were assigned at eight locations with a relative size of 10.000, considering all Degrees of Freedom (DOF) in all the three planes. The load collector was named SPC. The usage of SPC restricts one or several DOFs from specific movements. The elements are then built by assigning connectivity to the nodes. Finally, the boundary conditions and loads were applied. The nodes were created on the outer surface of the neck brace and were evenly distributed. In the x-z plane, the nodes were in the N, NE, E, SE, S, SW, W, NW directions of the model. The nodes were allotted in the constraints section of the analysis. The second load collector was named Force which was applied at eight points symmetrically in the same directions with relative size 100.000 and a magnitude of 20.000 N. The force was then exerted on the inner surface of the neck brace in the respective directions. The process can be seen in [Table/Fig-8a]. SPC and Force were allocated to each of the load collectors. The load step was then formed, and the load collectors were assigned following the analysis requirements. The analysis type was changed to linear static, and the SPC and Force were to be reassigned.

Second case: The second case started with assigning two load collectors. SPC was the first method incorporated, in which nodes were created at eight locations with a relative size of 10.000, considering all DOF in all three planes. The nodes were allocated on the inner side of the neck brace and were evenly distributed. In the x-z plane, the eight nodes were in the N, NE, E, SE, S, SW, W, NW directions of the model. The nodes can be allotted in the constraints section of the analysis. The second load collector was named Force, which was assigned at eight places symmetrically in N, NE, E, SE, S, SW, W, NW directions with the relative size of 100.000 and magnitude 100.000 N. The force was applied on the outer surface of the neck brace in the above-assigned directions as shown in [Table/Fig-8b]. SPC and Force were allocated to each of the load collectors. The load step was then formed, and the load collectors were assigned for the analysis requirements. The analysis type is changed to linear static, and the SPC and Force were reassigned.



[Table/Fig-8]: (a): The figure depicts nodes created at the outer segment of the neck brace and force exerted on the inner surface in an outward direction. (b): The figure depicts the nodes created at the inner segment of the neck brace and the force being exerted on the outer surface in an inward direction.

The assignment of control cards is the most crucial stage of this investigation. The control cards plays an important role in the findings section of the analysis. The proposed model was subjected to a linear static analysis. Global output request was selected in the control cards section. The required analysis for the result section, such as displacement, tension, and strain, can be assigned here. Each analysis has its format, and here the h3d format was allotted. This is the linear static analysis, and it is used to determine the neck brace's mechanical strength. After this step, Checkel was chosen from the param (parameters) section, and the request was assigned as yes. Checkel is used to verify that proper element checks are carried out and that all elements are considered in the final analysis. After allocation of the control cards, a separate page was opened to view the analysis.

The final step in this investigation was to visualise the results. The analysis output follows a series of steps. The main analysis section was chosen followed by the Optistruct option. The run option was set to 'analysis', while the export option was set to 'all'. The model was then simulated. After the analysis was successful the interface switches to HyperView to view the results. The Contour option was selected at this stage, and any analysis can be chosen to run to see the results and to diagnose the neck brace model. This produces a thorough and detailed analysis of the neck brace. This analysis is a great tool to plan the diagnosis procedure of a patient.

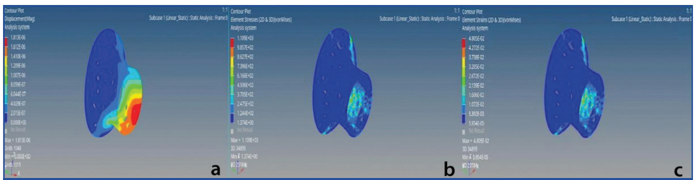
RESULTS

Linear static analysis has been performed to determine the baseline building properties provided for use in motion assessment and also to visualise the equivalent stress, strain and displacement that the model experiences. The model obtained was examined in HyperView to determine the results. The displacement analysis was then selected. The model's maximum displacement was located at the top posterior chunk, while the model's least displacement was detected in the posterior and anterior segments of the bottom portion of the model.

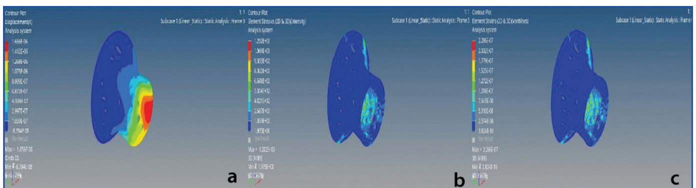
The model was subjected to an external force of 20 N in the first case and the maximum displacement produced was seen at the posterior section with a magnitude of 1.813E-06. The safe displacement value as shown in the colour contour was 8.059E-07. The results of displacement analysis can be seen in [Table/Fig-9a]. When a force of 100 N was applied to the model in the second case, the highest directional deformation was found to be 1.656E-06 on the inferior segment, as illustrated in [Table/Fig-10a] by the red patch. The safe value of displacement was recorded as 6.872E-07.

The stress distribution on the model was then visualised and the values were recorded for the first case. On closer inspection, the stress was found to be homogeneous throughout the model, with no localised or concentrated stresses. When a force of 20 N was applied, the maximum stress (Von Misses) was found to be 1.109E+03 which was detected at one small site in the posterior region of the brace. The brace's maximal stress is indicated by the red hue in the contour plot. The safe value of stress was found to be 6.166E+02. The stress analysis concluded that the neck brace experienced slight stress at one point on the inner surface. The results of element stress analysis are shown in [Table/Fig-9b]. In general, the model's overall stress was found to be evenly distributed. In the second case, the maximum stress possessed a magnitude of 1.202E+03. The red colour in the contour plot indicates the maximum stress experienced by the brace. The safe value of stress was found to be 6.688E+02 as shown in [Table/Fig-10b]. The stress analysis concluded that the model experienced uniform stress throughout and maximum stress at only some points upon the application of a force of magnitude 100 N.

The visualisation of strain was the final step. The results of the analysis fully met the standard and material strength requirements. The results of the strain analysis were very similar to that of the stress analysis for both the first and second cases. The maximum strain possessed a magnitude of 4.805E-02 at certain points on the inner and outer surface of the brace that can be seen in [Table/Fig-9c]. The safe value of strain was found to be 2.672E-02. The model did not experience strain in limited areas, and the strain was homogeneous throughout, according to the study. In the second case, the maximum strain was observed to possess a magnitude of 2.286E-07 and the safe value strain was observed to be 1.272E-07. Overall, the model encountered a very minimum amount of strain as shown in [Table/Fig-10c]. The overall results of the first and second case are tabulated in [Table/Fig-11,12].



[Table/Fig-9]: Results section for the first case: (a) Results of displacement analysis, (b) Results of stress analysis, (c) Results of strain analysis.



[Table/Fig-10]: Results section for the second case: (a) Results of displacement analysis, (b) Results of stress analysis, (c) Results of strain analysis.

Analysis	Maximum	Safe value
Displacement	1.813E-06	1.007E-06
Stress	1.109E+03	6.166E+02
Strain	4.805E-02	2.672E-02

[Table/Fig-11]: Finite element analysis results for the first case.

Analysis	Maximum	Safe value
Displacement	1.65E-06	6.872E-07
Stress	1.202E+03	6.688E+02
Strain	2.286E-07	1.272E-07

[Table/Fig-12]: Finite element analysis results for the second case.

DISCUSSION

This design of a neck brace with a major focus on the cervical lordotic spine was modeled since the neck brace suits only the cervical area of the spine. Custom fitting becomes a major element since neck braces are employed when there is neck pain, a misalignment, or fracture in any of the cervical vertebrae. In a similar study, the neck was 3D scanned to ensure precise measurements, and the cast was produced after obtaining the geometric configurations. There was an improved correction noticed in the cervical and lumbar vertebra after the application of the cast [7]. However, 3D scanning is quite a long process and it requires the patient to stay still for a long time to obtain the dimensions. For that purpose, the size of the neck brace can be predetermined and categorised into three sizes namely Small, Medium and Large based on the orthopaedist's insights. Following a visual assessment of the patient's neck, the appropriate size can be selected in accordance with that, and minor adjustments can be made to guarantee a proper and snug fit.

Custom fitting becomes crucial since it provides stabilisation to the injured area, thus enhancing the overall recovery process. Tight fit could be achieved by making proper adjustments with the help of small screws on the lateral side of the neck brace. A customisable hand orthosis was 3D printed in a comparable study, and it was adjusted using tiny metal screws to ensure a comfortable fit [25]. The 3D printing process is a cost-effective process and there are no possibilities of incurring significant expenses which makes the method more feasible and viable. CAD designs can be altered and modified easily which improves the overall compliance of the structure. The neck brace has been evaluated by means of FEA and the results have corroborated that the model is capable of withstanding high amount of force which was visualised in terms of decreased stress, strain and displacement.

Limitation(s)

1) The size of the neck brace was defined based on measurements made on a particular age group.
2) The FEA was carried out based on a few cases. Different considerations by varying the magnitude and direction of force could have been done.

CONCLUSION(S)

In this study, the design and development of a 3D printable neck brace has been carried out and the process of analysing the structure has been evaluated by the method of FEM. The developed model was structurally analysed under two cases wherein the point of application of force was varied thus producing different stress, strain, and displacement values which was used to enhance the evaluation of the model. The FEA analysis conducted on the neck brace emphasised the fatigue and failure that can result in the model upon application of an external force. It was also found that manufacturing the neck brace using PLA material led to better alignment and strength of the overall model. The study also found that a mixture of PLA and natural rubber can be used as a viable 3D printing filament. The neck brace model was examined visually and validated by an Orthopedic Surgeon to gain a clinical viewpoint that eventually culminated in an innovative design.

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