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Original Research Paper

Developing Polymeric Cranial Tracing Device with Incorporating an Innovative Design Strategy for Enhancing Patient Safety and Comfort

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ABSTRACT:
The cranial tracing device is a crucial guide in cranial surgeries during CT scanning, aiding accurate location identification with vertical and horizontal lines. However, current designs face challenges due to sharp edges, impacting usability and safety. This study introduces a novel cranial device developed from a medical-grade polymer with an innovative design, strategically addressing medical and physical comfort concerns by eliminating sharp edges and corners. The redesigned device offers significant benefits over existing edged and sharp-edged products by providing a smooth and edgeless structure. This modification aims to improve device reliability and streamline assembly, ensuring a more comfortable and reliable tool for precise marking and analysis of cranial regions during surgical procedures. The edgeless design mitigates safety concerns associated with sharp edges, enhancing patient safety and surgeon performance on a bald scalp during cranial surgery. Furthermore, the design modification prioritizes user convenience, contributing to improved device reliability and simplified assembly. This research emphasizes the critical importance of optimizing cranial tracing devices to empower surgeons with an efficient and comfortable tool for precise identification during surgical interventions. A simulation based data modeling test has been conducted to evaluate the introduced device's efficacy, further validating its performance. This novel design represents a significant advancement in surgical instrumentation, focusing on enhancing patient safety and surgeon performance while providing a comfortable and reliable tool for cranial surgeries.

Keywords: Cranial Tracing Device, Edgeless Design, Medical Grade Polymer, Surgical Instrumentation, Patient Safety and Usability Optimization

INTRODUCTION:

The cranial tracing device is integral in guiding surgeons through complex cranial procedures, particularly during CT scans, using vertical and horizontal lines for navigation. However, its significance is compromised by the inclusion of sharp edges, impacting usability and safety. Our research addresses this concern by introducing a revolutionary cranial device developed from a medical grade polymer, featuring an innovative edgeless design, a departure from traditional devices typically made from plastic or ceramic with edged corners.

Conventionally, the presence of sharp edges in cranial tracing devices shown in the figure 01 has raised concerns, leading to a transformative shift in design. Our research study introduces an innovative cranial device that deliberately eliminates sharp edges and corners, prioritizing both medical and physical comfort, particularly crucial when used on a bald scalp. This edgeless design represents a noteworthy advancement in surgical instrumentation, underscoring our dedication to excellence.

The primary objective of our modification is to offer a comfortable and reliable tool for precise identification and analysis of cranial regions during surgical procedures. By eliminating sharp edges, our design improves device reliability and streamlines the assembly process, ensuring a seamless experience for surgeons and patients. This evolution in cranial tracing technology enhances patient safety and surgeon performance.

In addition to addressing safety concerns related to sharp edges, our edgeless cranial tracing device undergoes simulation tests to validate its efficacy. These tests

reinforce the device's potential to redefine precision standards in cranial surgeries.

The innovation extends beyond the operating room, positioning our cranial tracing device as a pioneering force in the future of cranial surgery. Subsequent sections explore the specific features of our design, detailing its effective solutions to challenges and highlighting diverse applications across various medical scenarios. This research underscores the critical importance of optimizing cranial tracing devices for patient safety and empowering surgeons with an efficient and comfortable tool for precise identification during surgical interventions.

Figure 01 Conventional Cranial Tracing Device

MATERIALS AND METHODS:

- **Materials in Product Design and Development:**

In the creation of the innovative edgeless cranial tracing device, material selection is imperative to ensure both safety and optimal functionality across diverse medical scenarios. The structural components of the device benefit from the use of medical-grade polymers, specifically Polyurethane (PU), Polyether Ether Ketone (PEEK), and Polymethyl Methacrylate (PMMA) can be used.

Polyurethane (PU), known for its excellent biocompatibility, flexibility, and durability, proves ideal for long-term implantable applications. Its chemical and abrasion resistance further makes it suitable for sustained use. Polyurethane, with a balanced combination of mechanical strength and softness, ensures both comfort and performance, meeting rigorous medical standards for various healthcare applications.

PEEK, renowned for its exceptional biocompatibility, high strength, and wear resistance, imparts the necessary durability required for extended surgical procedures. Its radiolucent properties minimize interference with imaging techniques like CT scans, facilitating precise navigation through cranial anatomy.

PMMA, known for its transparency, ease of sterilization, and structural integrity, complements the design specifications of the cranial tracing device. Its compatibility with medical imaging technologies and non-reactive nature makes it a fitting choice for intricate surgical instruments. In addition to material selection, the incorporation of antimicrobial coatings or additives into the device enhances its biocompatibility, reducing the risk of infections in alignment with modern surgical standards.

Given the diverse applications of the edgeless cranial tracing device, the chosen materials not only prioritize safety and functionality but also contribute to streamlined pre-surgical procedures. The selected materials are efficient to sterilize, ensuring a reliable and standardized instrument for global neurosurgery. This comprehensive material strategy aims to elevate the device's performance, positioning it as a pioneering solution in the evolving landscape of cranial surgery.

- **3D Printing Method for Cranial Tracing Device Development:**

Designing the 3D Model:

The process of designing the 3D model commenced with the initiation of creating a comprehensive 3D model for the cranial tracing device using Solidworks software. The design considerations encompassed factors such as size, shape, structural integrity, and intricate details, all outlined in Table 1. The primary objective was to guarantee that the design adhered to the specified requirements of the cranial tracing device, facilitating precise and accurate representation. The schematic view of 3D Model of cranial tracing device is depicted in the figure. 01

Table 1 Encompassment of Dimensions for Design Considerations

Sr No.	Dimensions Type	Measurements
1.	Length	250 mm
2.	Width	120 mm
3.	Thickness	4 mm
4.	Edges Curve Angle	10 mm

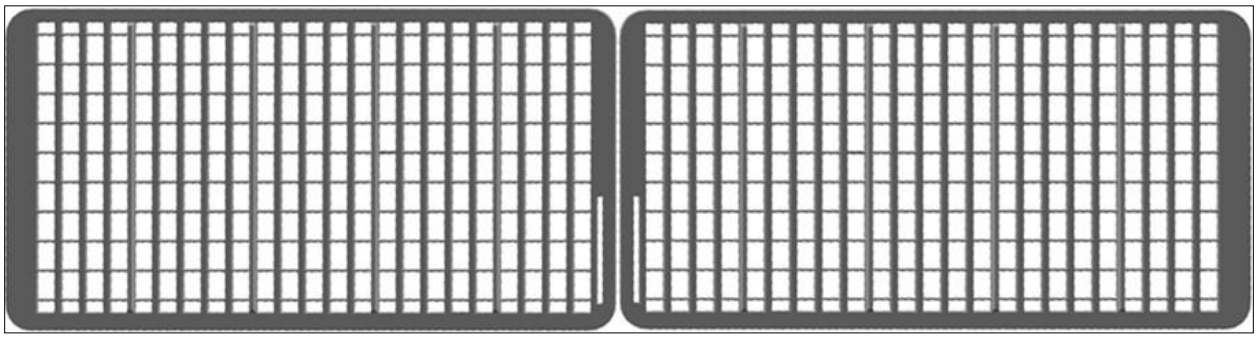


Figure.2 The Schematic Overview of 3D Printed Cranial Tracing Device

File Preparation:
After completing the design, the 3D model was converted into an STL (Standard Tessellation Language) file. This file format was chosen for its suitability for 3D printing, representing the geometry of the object in a way that could be easily interpreted by the 3D printer.

Selecting the Printing Material:
The printing material (filament) was chosen based on the specific requirements of the cranial tracing device. However material chosen for prototype development is the medical grade polymer. It can be Polyurethane (PU), Polyester Resin, or other composite material. Factors such as biocompatibility, durability, and flexibility were taken into account during the material selection process.

Setting Up the 3D Printer:
Setting up the 3D printer involved calibrating the machine to ensure precise printing. This required making adjustments to settings like bed leveling, nozzle temperature, and layer height. Proper calibration was crucial to achieving accurate dimensions and structural integrity in the printed cranial device's prototype.

Loading the Resin Tank:
To load the resin tank for a resin-based 3D printer, the chosen resin tank was inserted into the 3D printer. It was ensured that the resin was in a liquid form and ready for the printing process. Manufacturer guidelines were followed for the proper handling and loading of the resin tank.

Printing the Object:
Printing the object involved initiating the 3D printing process using the prepared STL file. During this phase, the cranial tracing device was created layer by layer, adhering to the instructions from the digital model. The printing progress was monitored, and any issues that arose during the printing process were addressed.

Post-Processing:
Post-processing activities were conducted upon the completion of 3D printing. The printed cranial tracing device was carefully removed from the print bed. Depending on the design complexity and material used, various post-processing steps were deemed necessary. These steps could involve the removal of support structures, sanding to smooth surfaces, or applying additional finishes for aesthetic or functional purposes.

Quality Control:
The printed cranial tracing device underwent a thorough inspection for defects or errors. Critical dimensions and overall quality were checked to ensure alignment with design specifications. Any discrepancies or imperfections were addressed promptly to maintain the accuracy and functionality of the prototype.

Final Finishing:
Additional finishing touches were applied as required for the cranial tracing device application. This involved rubbing, painting, coating, or assembly with other components to achieve the desired final appearance and functionality.

Fabrication for Cranial Tracing Device:

The 3D printing process was selected for the Cranial Tracing Device, utilizing a 3D printer to produce the prototype as shown in the figure. 3. This approach allowed for cost-effective and rapid development of the cranial tracing device while providing the flexibility to iterate on the design as needed.

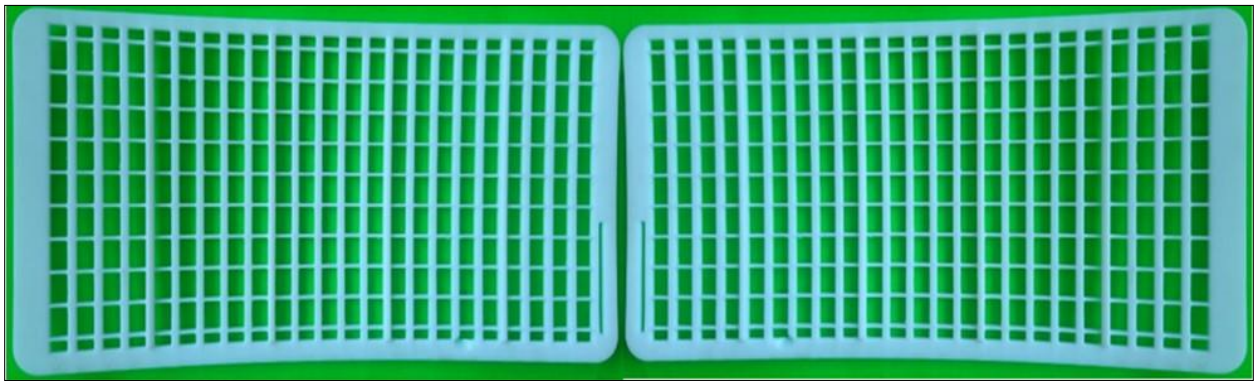


Figure.3 3D Printed Prototype of Cranial Tracing Device

RESULTS AND DISCUSSION:

Mechanical Compression Testing:

The mechanical compression analysis conducted through Finite Element Analysis (FEA) in SolidWorks aimed to evaluate the response of the cranial tracing device under compressive forces. The following sections present the outcomes of the digital modeling, simulation, and the subsequent evaluation of the results.

Digital Model Creation:

The initial step involved the construction of a precise 3D digital model of the polymer specimen using SolidWorks CAD tools. This step ensured that the model accurately reflected the geometry and dimensions of the cranial tracing device.

Material Assignment:

The Polymeric material was chosen for the cranial tracing device, with its mechanical characteristics such as elasticity and strength defined within the SolidWorks material database. This selection was made based on the desired properties for the device's intended application.

Constraints and Loads:

To replicate real-world conditions, constraints and loading conditions were applied to the digital model. The designed prototype's bottom side was fixed, while a compressive load of 100 N was gradually applied to the top. These conditions were chosen to mimic expected operational scenarios and environmental factors.

Meshing:

The digital model was discretized into finite elements through meshing, employing a solid mesh with curvature-based meshing. The mesh had a side length of 1 mm, and Table 2 provides detailed information about the mesh properties.

Table 2: Mesh Properties

S. No.	Properties	Trial Settings
1	Mesh type	Solid Mesh
2	Mesher Used:	Curvature-based mesh
3	Jacobian points for High quality mesh	16 Points
4	Maximum element size	10 mm
5	Minimum element size	10 mm
6	Mesh Quality	High
7	Total Nodes	70301
8	Total Elements	38639
9	Maximum Aspect Ratio	666.89
10	% of elements with Aspect Ratio < 3	9.81

11	Percentage of elements with Aspect Ratio > 10	46.8
12	Percentage of distorted elements	0
13	Time to complete mesh(hh;mm;ss):	00:00:37

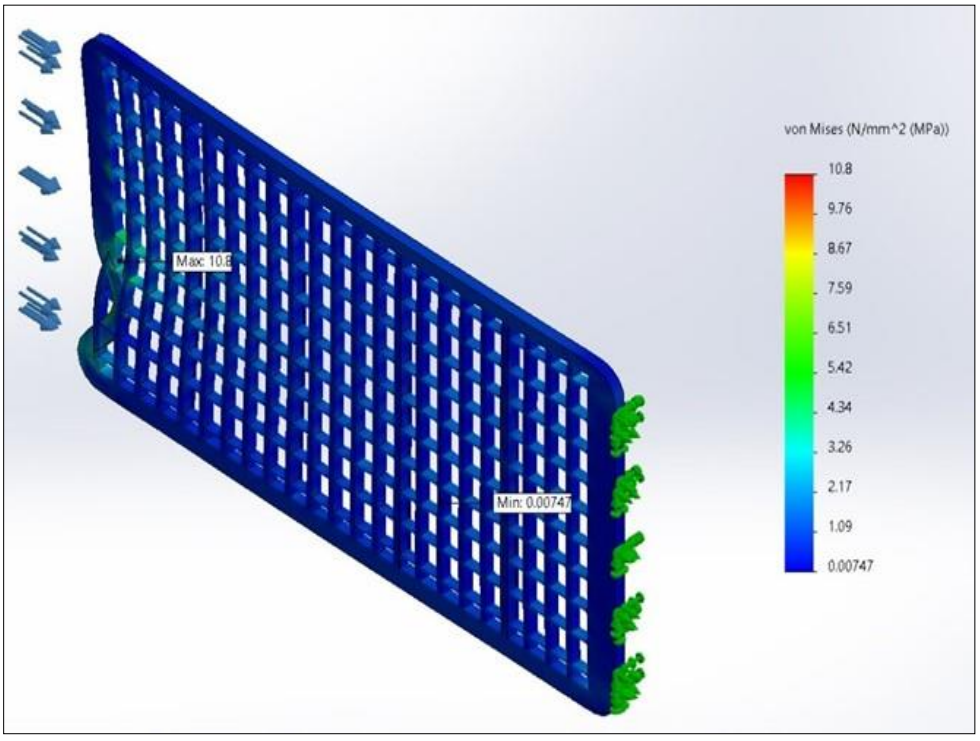
Simulation Setup:
SolidWorks Simulation tools were employed to set up the compression analysis. Parameters such as solver options, convergence criteria, and contact conditions were configured to ensure a precise and efficient simulation.

Analysis Run:
The compression analysis was executed within SolidWorks, calculating stress distribution, deformation, and safety factors throughout the polymer specimen under the applied compressive forces.

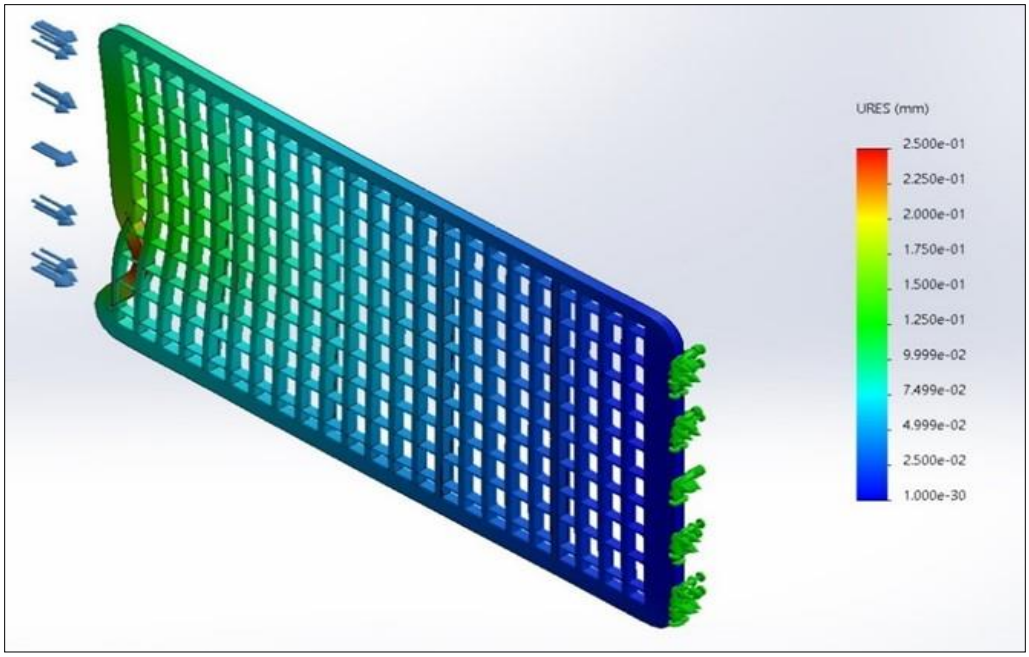
Results Evaluation:
The results of the simulation were evaluated to identify regions of high stress, potential deformation, and safety margins. The computational stress analysis, as summarized in Table 3 and in figure 4(A), (B) & (C) accordingly, focused on Von Mises Stress for compression.

Table 3 Computational Studies - Mechanical Compression for Cranial Tracing Device

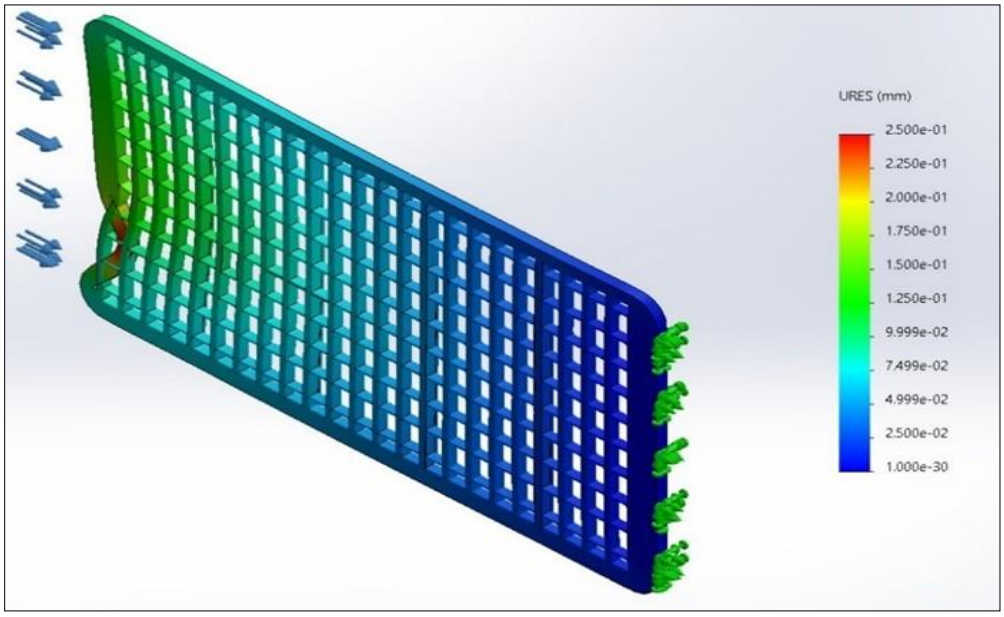
S. No.	Name	Type	Min	Max
1.	Compression Stress	Von Mises Stress	0.00747N/mm^2 (MPa)	10.8N/mm^2 (MPa)



(A)



(B)



(C)

Figure 4 Computational Stress Analysis

Optimization and Iteration:

Based on the simulation results, an iterative process of refinement was undertaken to optimize the model or adjust material properties. This aimed at enhancing the design for improved performance and reliability of the polymer specimen under compression.

In conclusion, the mechanical compression analysis provided valuable insights into the behavior of the cranial tracing device under realistic conditions. The results and subsequent optimization efforts contribute to the ongoing development and improvement of the device's structural integrity and overall performance.

CONCLUSION:

In conclusion, our study introduces a cranial tracing device developed from a medical-grade polymer, effectively addressing safety and comfort issues in existing models. The elimination of sharp edges represents a significant advancement in surgical instrumentation, improving usability, safety, and medical

comfort for heightened reliability. The device underwent a rigorous simulation test, including a mechanical compression analysis using Finite Element Analysis (FEA) in SolidWorks, providing valuable insights into stress distribution and safety margins. Subsequent optimization and material adjustments enhanced structural integrity and overall performance. This thorough computational analysis validates the modified design's virtual effectiveness, guiding ongoing development efforts. The findings affirm the reliability and performance of the developed device in surgical interventions. The device is now prepared for preclinical testing, representing a crucial advancement towards clinical application. Our research emphasizes the importance of optimizing cranial tracing devices to provide efficient, comfortable, and precise tools that prioritize patient safety and enhance surgeon performance in critical procedures.

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