Optimizing cranial implant and fixture design using different materials in cranioplasty

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Abstract

Cranial implants are used to secure intracranial structures, reconstruct the skull contour, normalise cerebral hemodynamic, and repair cranial defects. Larger bone defects require intervention for repair from an implant made from autologous bone or other material. To repair such defects using implants, materials necessitate biocompatibility with the natural bone. Patient Specific Implants (PSI) are designed to repair specific cranial defects following standard procedures for implant design, fabrication and cranioplasty.

Autologous bone, bone cement comprising HydroxyApatite (HA), Poly methyl methacrylate (PMMA), Medical Grade Titanium Alloy (Ti-6Al-4V) and Polyether-ether-ketone (PEEK), are widely used to fabricate PSI for repairing different types of bone defects. To optimize a PSI for shape, size and weight, it is essential to design the implant using 3D modelling and fabrication techniques. Effective attachment of an implant material with a defective skull is also influenced by the joints and fixture arrangements at the interface, these fixtures can be of various types, materials and have different joining procedures.

In this study, a comparative analysis of different cranial implant materials (Autologous Bone, PMMA, PEEK and Ti-6Al-4V) attached to a defective skull with Ti-6Al-4V and PEEK fixture plates has been performed, using Finite Element Analysis (FEA). Two types of fixture designs were used as Square 'X' and Linear shapes, which were fixed along the interface between implant and the skull. Four fixture plates were fixed symmetrically along the boundary for maximising stability.

The findings suggested that all the implant materials were able to sustain extreme boundary conditions such as external loads of 1780N and IntraCranial Pressure (ICP) of 15mmHg without failures. PEEK implants exhibited 13.5 % to 35% lower von Mises stresses in comparison to autologous bone implants and Square 'X' fixture design provided higher stress relieving results in comparison to Linear fixtures by nearly 18.4% for Ti-6Al-4V fixture material and 10.9% for PEEK fixture material, thereby, encouraging PEEK as an alternative to conventional cranial implant and fixture materials.

Keywords: Cranial implants, FEA, von Mises stresses, Fixture, Patient-specific implants, PEEK, PMMA, Ti-6Al-4V

1. Introduction

The portion of the skull that protects a human brain is called a cranium and is made up of cranial (bones surrounding the brain) and facial bones (bones forming the eye sockets, nose, cheeks, jaw, and other parts of the face). The surgical procedure for repairing cranial defects by precisely replacing the missing bone is called Cranioplasty.[1] An estimated 69 million individuals suffer from traumatic head injuries globally, every year.[2] The global cranial implants market was valued at USD 1.05 Billion in 2020 and is projected to reach USD 1.77 Billion by 2028 and growing at a Compound Annual Growth Rate (CAGR) of 6.67% from 2021 to 2028.[3] The increasing prevalence of neurological diseases, injuries, wounds and road accidents are expected to further increase these numbers.

Cranial defects are generally caused by trauma, diseases (osteomyelitis of bone), infection, injury or malignancy; these can be repair naturally or require implants for conditions where the fracture gaps are large. Cranioplasty not only improves the cosmetics of the skull but serves as a protective cover for the brain and maintains stability under standard atmospheric pressure conditions. An aesthetically designed cranial implant provides psychological relief and increases social performance.[4] To relieve IntraCranial Pressure (ICP) and save patients inflicted with severe head injuries neurosurgeons perform cranioplasty using preserved bone (autologous bone) from the patient as the implant.[5] Though an autologous bone is always the first choice for repairing a cranial defect in many cases this is not feasible due to a large sized or irregular shaped defect, infection or bone resorption.[6] In the absence of autologous bone cranial implants are used. Traditionally generic mesh and plate implants have been used which have various drawbacks including improper fitment, and poor postoperative complications. With the advancement in imaging techniques such as Computed Tomography (CT) and Magnetic Resonance Imaging (MRI) computational tools like Computer Aided Design (CAD)/ Computer Aided Manufacturing (CAM) Techniques and rapid prototyping techniques, including Additive Manufacturing (AM) and 3D printing; patient-specific implants (PSI) have become the preferred choice of surgeons. PSI manufactured implants using AM techniques provide an ideal fitment, aesthetics, saving of time and cost and are also improved therapy success rates .[7-8] The most prevalent biomaterials for fabricating a PSI are bone cement consisting of HydroxyApatite (HA), Poly methyl methacrylate (PMMA), Medical Grade Titanium Alloy (Ti-6Al-4V) and Polyether-ether-ketone (PEEK).[9]

PMMA is an easy to use, readily available biocompatible material that can be moulded intra-operatively. It is a relatively low-cost option with an extensive track record dating back to the 1940s. Traditionally, PMMA powder and methyl methacrylate liquid are hand-mixed and cured directly within the cranial defect and the high temperatures reached during curing is a disadvantage as it can inadvertently be transferred to the bone and brain. Today, a 3D mould of the cranial defect can be manufactured to produce PSI's. PMMA is pressed into a mould and cured and after cooling minor adjustments are made to the implant before it is placed into the cranial defect. Extensive literature is available linked to the behaviour of PMMA; however, toxicity is a cause of concern to many. The material behaviour of PMMA in non-load-bearing locations within the human body including the calvarium is unknown.[10-11] Additionally, PMMA is weaker in terms of its mechanical properties when compared to cortical bone. Its low elastic modulus helps to transfer stress to the bone gradually, however the major drawback of PMMA is that it traps air bubbles which increases the risk of infection.[12]

Traditional metal implants made of Ti-6Al-4V have a far higher elastic modulus than bone resulting in a "stress shielding" effect. The stress stimulation value of bone around the implant is significantly lower than required for bone regeneration, hence bone tissue around the implant is absorbed resulting in the loosening and eventual failure of the implant. Furthermore, metal implants can emit toxic ions causing osteolysis and allergenicity that are incompatible with CT and MRI procedures making it difficult to track the healing process.[13]

PEEK is a thermoplastic engineering polymer with excellent biological, mechanical and chemical properties and has shown to have biomechanical properties close to human bones, which can reduce the risk of bone resorption and osteolysis caused by the stress shielding effect of implants. PEEK polymer has a high thermal stability inside the human body (melting point 334–343°C, instantaneous use temperature can reach 300°C), high toughness and rigidity, excellent fatigue resistance, creep resistance, chemical resistance, is non-toxic and has excellent sterilisation performance.[13] PEEK does not have any harmful reaction or release any harmful constituents thus making it a bioinert material but reducing the wound healing capacity on osseointegration. Its elastic modulus and tensile properties are analogous to those of bone; it demonstrates a high resistance to gamma and electron beam radiation with PEEK and its composites possess also having natural radiolucency, X-ray, CT, Ultrasonic and MRI compatibility. It has many advantages for cranioplasty, including strength, stiffness, durability, and inertness; with a success rate of approximately 93.7% and a complication rate of 15.4%. PEEK is superior to titanium in both cosmetic satisfaction outcomes and brain function improvement. Additionally, titanium is more easily deformed by the same high external forces, changing the appearance and potentially giving patients brain damage with a requirement for implant replacement surgeries.[14] PEEK material is a benchmark for deformations in the skull and is receptive to titanium fixations.[12]

Medical 3D-printing technology offers a possibility of manufacturing PSI with benefits of shorter operational durations and superior clinical results at an affordable cost.[15] The primary reasons for selecting PEEK 3D printed implants over standard implants are for its improved fitment with the skull and other improvised design aspects related to shape, size and weight.

PEEK material-based implants are an attractive proposition for cranioplasty procedures due to their natural appearance with excellent safety characteristics, superior mechanical properties, thermal stability, high rigidity, lower moisture absorption, flexibility, low toxicity, higher abrasion resistance and lower moisture absorption.[16] Surgeons could perform better surgeries using PEEK based implants as stress shielding effects are substantially reduced to a median of 1% in comparison to 56% for the cobalt–chromium implants with the failure rate of PEEK cranioplasty (12.5%) being half that of Ti-6Al-4V (25%). PEEK is compatible with bioactive materials such as HA and Bioactive Glass (BG).[17] Fused Deposition Modelling (FDM) is the best technique for 3D printing PEEK which further supports the use of PEEK as an implant for cranioplasty as its complex shapes can be reproduced using CAD and FDM for fabricating PSI.[18]

The choice of a material used for cranial reconstruction is governed by its availability, cost, biomechanical properties and the method identified for fabricating the implant. As numerous materials are available it's always a difficult decision for surgeons to choose which material to employ for cranioplasty. An ideal material for cranioplasty should be radiolucent, resistant to infections, not thermally conductive, resistant to biomechanical processes, malleable enough to fit defects with complete closure and be readily available and inexpensive.[19] An implant should also be able to withstand the impact of external loads that human skulls may encounter during daily routine or emergencies without failure or complications.

To examine the biomechanical performance of various implant materials Finite Element Analysis (FEA) has been widely adopted. With recent advancements FEA is widely recognized for the solution of biomechanical problems by doctors and researchers with many commercial software applications incorporating specialised analysis tools utilising different skull models, materials and loading criteria. There are minimal FEA studies on cranial implants, however, Tsouknidas et al.[20] evaluated the mechanical strength, shock resistance, and critical deflection of cranial implants made of PMMA and Ti-6Al-4V. The highest produced cranial stress was detected in the contact region of the implant to the skull for a reference load of 100N, and the stress distribution remained the same for all cases. Although titanium-based alloys outperform PMMA in terms of mechanical strength and shock resistance they can still be used as their mechanical properties are similar to those of vicinal bone tissues, thereby providing adequate neurocranial protection. Shweta, Anburajan[21] created a 3D model of skull implant from a patient's CT scan data and used FEA to compare three biocompatible materials, namely, titanium, steel, and PMMA for their strength, displacement, and stress strain distribution under different static load conditions. These values were used to determine the implant's viability, and it was discovered that finite element analysis was beneficial for studying skull defects and designing implants. Ridwan-Pramana et al.[10] found that the complexity of implant design increases as the size of the defect increases in addition to a need for higher mechanical stability. Therefore, the use of computational techniques to determine the best possible configuration prior to a surgery is beneficial in such cases since as it would reduce intra and post-operative effort. Bogu et al.[9] designed cranial implants with eight to ten fixation points. The mechanical deformation and equivalent stress (von Mises) were calculated in ANSYS 15 software with distinctive material properties such as Ti-6Al-4V, PMMA and PEEK. Ti-6Al-4V material had shown low deformation while PEEK material showed a lower equivalent stress. Across materials PEEK demonstrated markedly good results and hence a concept was established with more clinically relevant results expected with the implementation of realistic 3D printed models in the future. This will allow physicians to gain knowledge and decrease surgery time with the appropriate planning. Ameen et al.[22] used FEA in order to assess the quality of the developed implant design under different loading conditions. Their results demonstrated the successful fabrication of 0.5 mm thick custom titanium alloy cranial implant for skull defect reconstruction via Electron Beam Melting (EBM) technology while also maintaining the structural strength requirements for the reconstruction of skull defects. The main advantage of this approach for skull defect reconstruction was the customizability, flexibility and the reduced lead time for implant fabrication. However, this technology was still expensive and required a significant amount of validation and testing before the implant was finally used for reconstruction of the defect. Wan et al.[23] undertook stress-strain FEA of PEEK and titanium to analyze the shock resistance, ability of absorbing concussion and the stability after the implantation of four different skull implants so as to select the implant with the best biological-mechanical properties. The mechanical properties of PEEK were found to be superior to the titanium implant as it could provide superior brain protection. Carpenter et al.[24] analyzed the effects of materials and porous structures on the stress loading distribution at the bone ingrowth interface. It was found that regardless of the pore structure or the bone ingrowth level of PEEK and titanium materials porous PEEK could increase the load sharing of adjacent bone tissues. However, most of the load in porous titanium was shared by the implant and the tissue strain generated by it increased the risk of bone resorption. Their results indicated that compared to existing 3D printed porous titanium the lower elastic modulus of the porous PEEK structure may contribute to bone formation. Marcián et al.[7] provided evidence that increasing implant thickness could be more advantageous than changing the implant material in terms of maximum von Mises stress in all the components that were investigated. However, when a change of implant deflection is required it should be considered that implant material has a slightly higher noticeable effect on the change than the implant thickness. These observations might affect the surgeons' decision-making process when recommending cranial implants for designing and manufacturing. Santos et al.[25] found that design of implants can be modified to create material properties similar to the adjacent skull, making PEEK cranial implants more suitable than titanium implants. Since PEEK has a lower stiffness (resulting from a lower Young's modulus), a damping effect was verified, reducing brain motion. Hence, the modelled cranial implant when subjected to impact load retained its structural integrity and ensured brain protection. Mian et al.[26] concluded that the aesthetic results or the fitting accuracy for PEEK is adequate, with a minimum deviation. Their study illustrated that utilising a 3D reconstruction method and PEEK material would minimise time-consuming alterations while also improving the implant's fit, stability, and strength. Msallem et al.[27] demonstrated that an implant thickness of 3 mm for a temporoparietal skull defect can withstand sufficient force to protect the brain. Greater implant weight and, therfore higher material content increases thickness, resulting in greater resistance. The loading and boundary conditions vary greatly amongst these studies and there is no consensus on identifying a single material as different sets of materials have been suggested by these studies. In addition to implant materials, method, design, and the arrangement of fixtures is also important. A fixation system should have the following characteristics: it should be made of biologically inert materials; be rigid and long-lasting; permit precise repositioning of the bone flap with no offset between the surface of the bone flap and the surface of the surrounding bone and should be convenient to attach.[28] Sutures and steel wire were the first method to be used in skull bone fixation however, from a mechanical perspective they could not provide a safe and reliable system to prevent cranial flap dislocation. Titanium fixation systems (plates, screws, and clamp like devices) have good mechanical properties. Wang et al.[29] claimed that the titanium clamp cranial flap fixation system was easy to use, significantly faster and had better cosmesis and strength. Further, as per Yang et al.[30], the titanium clamp offered a rigid fixation with satisfactory strength, good spring-elastic reserve and proved to be a reasonable alternative method of fractured cranial flap fixation with respect to ease of use, time consumption, accuracy and strength. A titanium miniplate cranial fixation system is found to be better than stainless steel wires[31], however, these studies have not focused on the role of fixation plates and have used a simple design for the micro plate. Fixtures are an important consideration for cranioplasty as they are used to fix the implant on the skull bone whilst also acting as a support. The stability of the implant depends on the fixture and in case of any external load the fixtures are the most affected with the failure of even a single fixture potentially leading to implant failure which could be catastrophic.

Therefore, the present study is aimed at using FEA for analysing design suitability of cranial implant fixation for repairing a defective skull by using different types of implant materials and fixture design arrangements. Attachment of different shapes of fixture plates at various locations could play a significant role in optimising the design of a cranial implant material in terms of material and load-bearing aspects for a successful cranioplasty procedure.

2. Material and Methods

Cranioplasty was performed on a subject suffering from a cranial defect, caused during a severe road accident. The subject was a young male, who was prescribed cranioplasty at the Government Medical College and Hospital, Sector-32, Chandigarh, India.

To suggest a best fit PSI for this procedure, various design options and fixture arrangements were explored. Therefore, CT images of the defect were used in this research work with due informed consent from the subject for using this data while maintaining data privacy.

CT scans of the subject in Digital Imaging and Communications in Medicine (DICOM) format were used for designing the custom implant. The DICOM data which consisted of images acquired from various angles was utilised in generating a 3D assembly CAD model of the defective skull, PSI and fixtures using Finite Element Modelling (FEM). This CAD model was simulated using FEA for evaluating an optimized PSI-fixture assembly subjected to boundary conditions of 1780N external load and 15 mmHg ICP. [5,9,20,32]

An implant that could sustain external and internal pressures, without any failure is desirable. Designs that lead to reduction in stresses within implants, are preferred, as these could reduce the overall failure rates of implants during any loading conditions, therefore, optimization of its design for light weight and bone like materials such as PEEK, has been studied further by using FEM/FEA.

2.1 Finite Element Modelling (FEM)

2.1.1 Defected Skull Model

The DICOM files, which contained a 2D image dataset of the subject's skull, were imported into an open-source 3D slicer computing platform. After validation, a threshold was set to differentiate between the skull bone, tissues, and noise. Following a denoising process and segmentation a Standard Tessellation Language (STL) file was generated which was then used to construct a solid model in Ansys® SpaceClaim. In SpaceClaim, the mesh file was examined for flaws and a solid body was generated by merging all the faces. The solid body thus created was exported in Initial Graphics Exchange Specification (IGES) format as shown in Figure 1.

Figure 1: Three-dimensional model of the defected skull based on CT

The skull bone is composed of an external layer of cortical bone and a core of cancellous bone.[6] Cortical bone is treated as a compact bone that acts as the outer layer of the skeleton, surrounding the trabecular bone and providing a hard covering for the skeleton. Alternatively trabecular bone is a sponge-like tissue configured in a lattice consistency situated in the core of a bone. Due to the higher mechanical strength qualities of the cortical bone, studies that analyze the behaviour of the cancellous bone during simulation disregard it as a fracture criterion in various loading scenarios. In addition, we have considered the properties of cortical bone as a whole in the model as screws are inserted in outer cortex based on the monocortical fixation principle.[33-34] Cortical bone has also been considered to be homogeneous, linear, elastic, and isotropic to simplify the problem when dealing with complex geometry.[23,24,32]

2.1.2 Implant Model

The IGES file of the defective skull was imported into the Autodesk® Fusion 360 which converts IGES to STL for further processing. A 3D CAD model of the implant was designed by considering a mirror image[35] of the skull defect (Figure 2). During this process, challenges such as obsolete and non-functional parts, irregular sizes, holes, sharp edges were carefully handled and resolved to design an accurate implant model. Four different implant materials- PEEK, Autologous bone, PMMA and Ti-6Al-4V were considered for this study, their properties considered in this study as shown in Table 1.

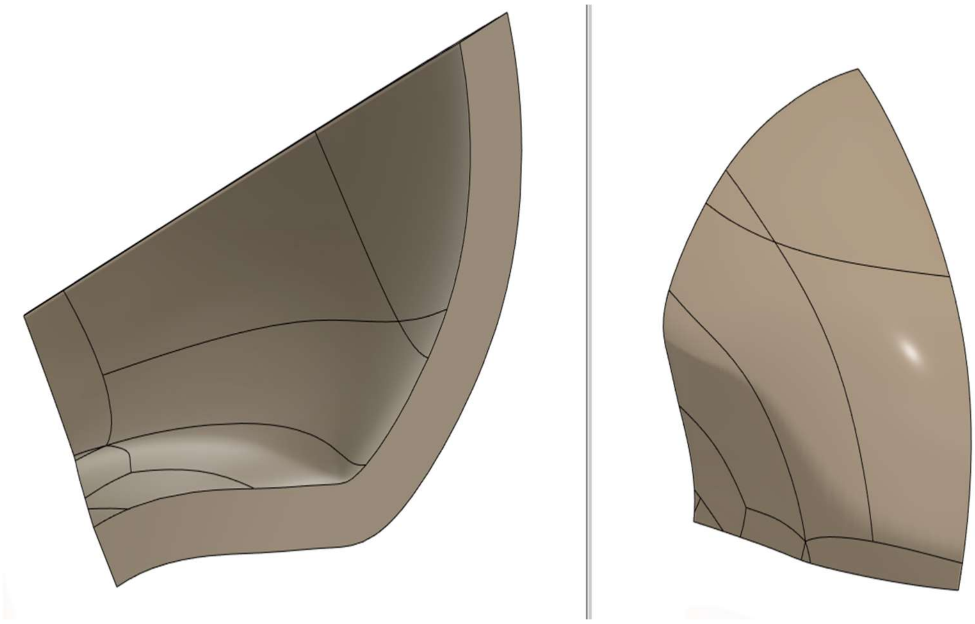


Figure 2: PSI reconstructed for repairing the skull defect

Table 1: Material Properties

Material	Density (g/cm^3)	Elastic Modulus (MPa)	Poisson's Ratio	Yield Strength (MPa)
Autologous Bone(defected skull) Jindal et al.[36]	4.43	15000	0.30	133
PMMA(implant) Bogu et al.[9]	1.19	3000	0.38	72
Ti-6Al-4V(implant) Bogu et al.[9]	4.50	110000	0.30	800
PEEK(implant) Bogu et al.[9]	1.24	4000	0.44	100

2.1.3 Fixture Design and Arrangement

To ensure tight and stable implant fixation within a defective skull specific fixture arrangements were required. Depending upon the implant size and material there are various options for fixing an implant within the skull. Two types of fixation systems were used for this study, namely Square 'X' shaped and Linear shaped fixture plates made of PEEK and Ti-6Al-4V, from which

Ti-6Al-4V based fixture plates are commonly used.[37-38] Figure 3 shows the isometric views of the two fixtures and detailed views are represented in Figure 4. Figure 5 shows details of micro screws that were used to attach the implant with the fixture and bone with fixture. Both the skull and the implant have M2 tapping, and the M2 bolt has a tight rotation free fitting so that when stress is applied the bolt holds the implant, skull, and fixture assembly as an integrated unit without slip. The micro screw did not penetrate the thickness of the skull and implant.
Fixture plates were fixed at different locations on the implant-skull interface as shown in Figure 6 (a). Linear distances between extremities of the defect were divided into equal segments and to form a minimum support structure condition, four outer locations were selected to formulate a symmetrical arrangement and to evenly distribute the stresses along the implant circumference. Within the fixture, an equal number of screws were located as two on each side of the implant and the skull surface, which further created symmetry and hence reduced probabilities of stress concentration sites. This fixture design, fixture numbers and their placement were validated and approved by an experienced neurosurgeon with a baseline condition of a minimum three-point fixation. Marcian et al.[7] have used three and four linear fixtures across a circular and an elliptical defect respectively which followed a similar principle. Similarly, Ridwan et al.[39] used only three linear fixtures in a symmetrical manner, for fixing regular shaped minor defects.

More such plates could be added to form a more secure attachment at other locations across the interface, however, that could add to the overall weight without significantly improving the stress reduction within the implant. Figures 6(b)(c) show the arrangements of both Square ‘X’ and Linear fixture plates on the implant-skull assembly respectively.

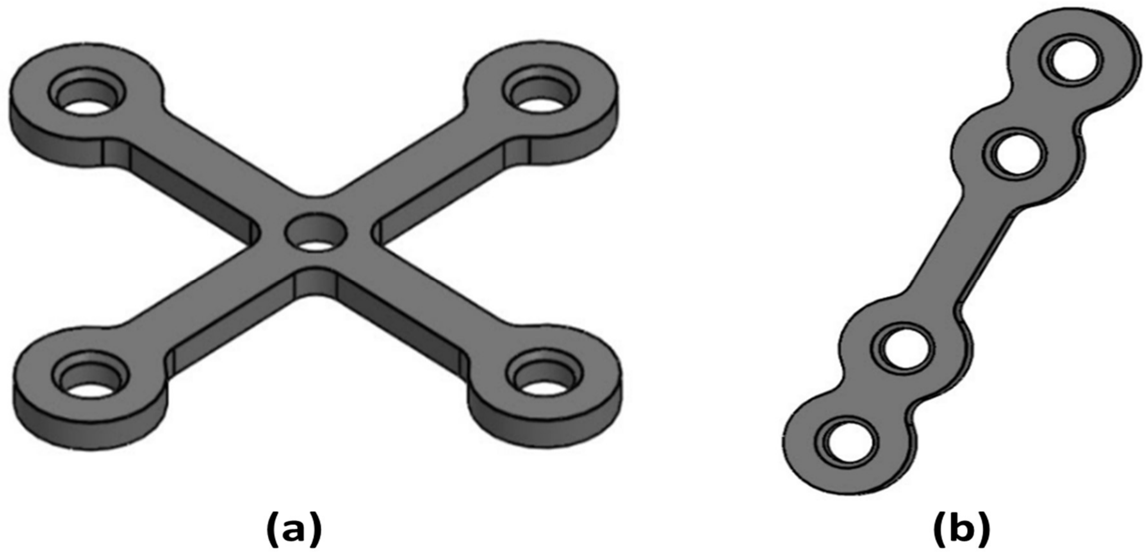
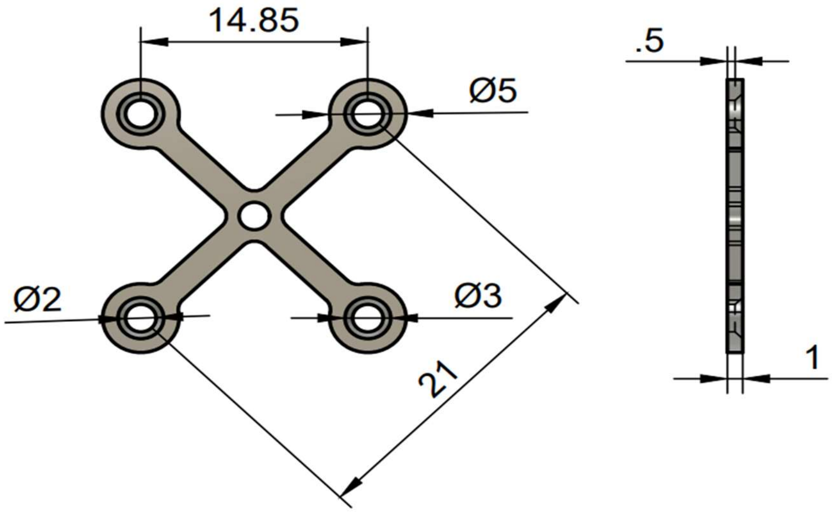
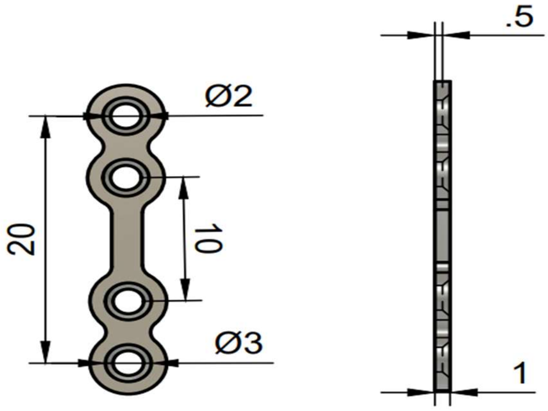


Figure 3: Isometric views of fixture plates **(a)** Square ‘X’ **(b)** Linear



(a)



(b)

Figure 4: Front and side views of fixture plates **(a)** Square 'X' **(b)** Linear [all dimensions are in mm]

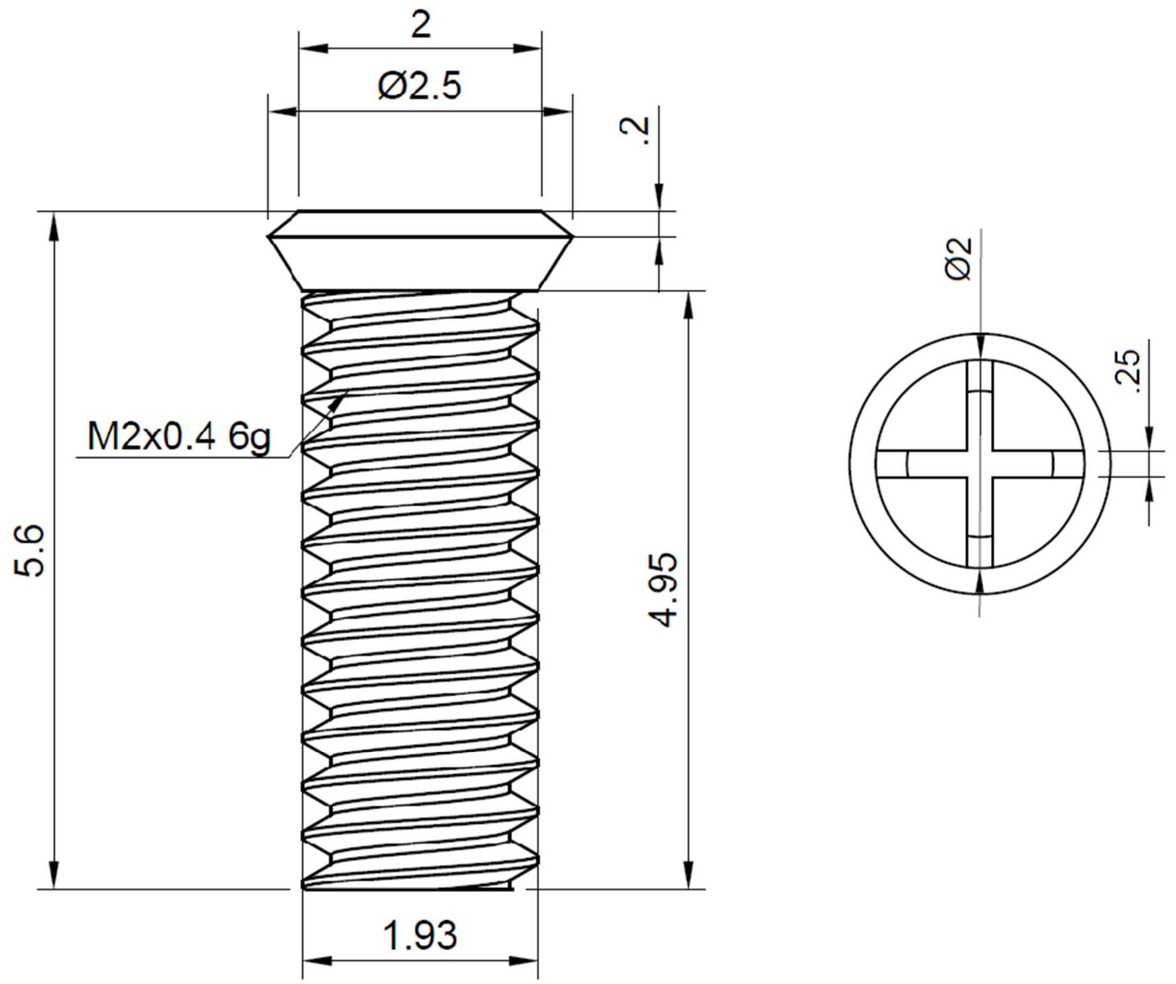


Figure 5: Front and top views of micro screws [all dimensions are in mm]

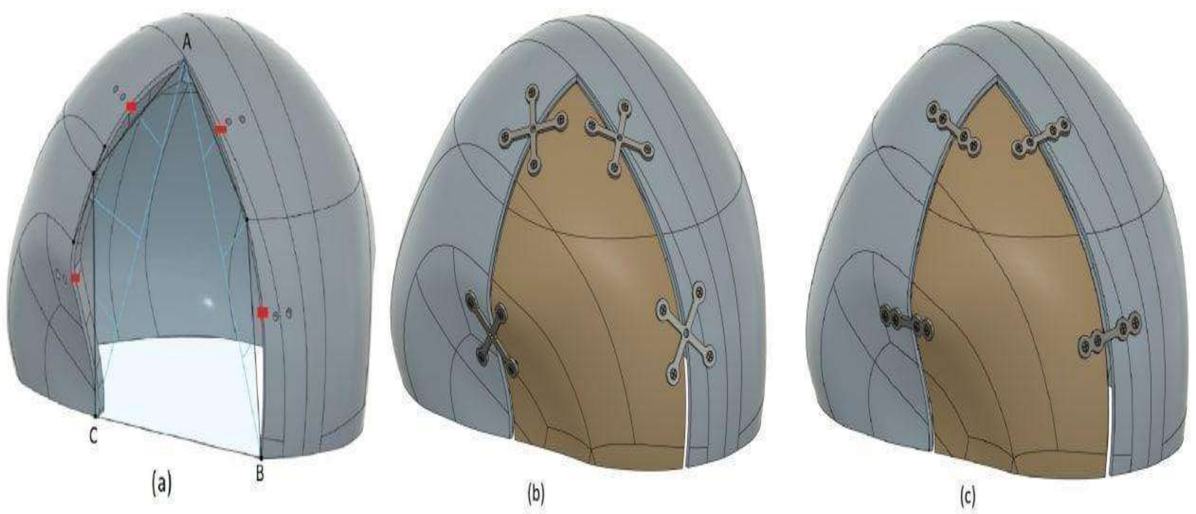


Figure 6. Implant-skull assembly for different fixture arrangements **(a)**Placement locations of fixtures **(b)** Square 'X' **(c)** Linear

2.2 Finite Element Analysis (FEA)

An FEA simulation was run in ANSYS 2021 R2 to evaluate the designed PSI's performance within the assembled implant-skull-fixture arrangement models. The complete lifecycle of the simulation has been represented in Figure 7.

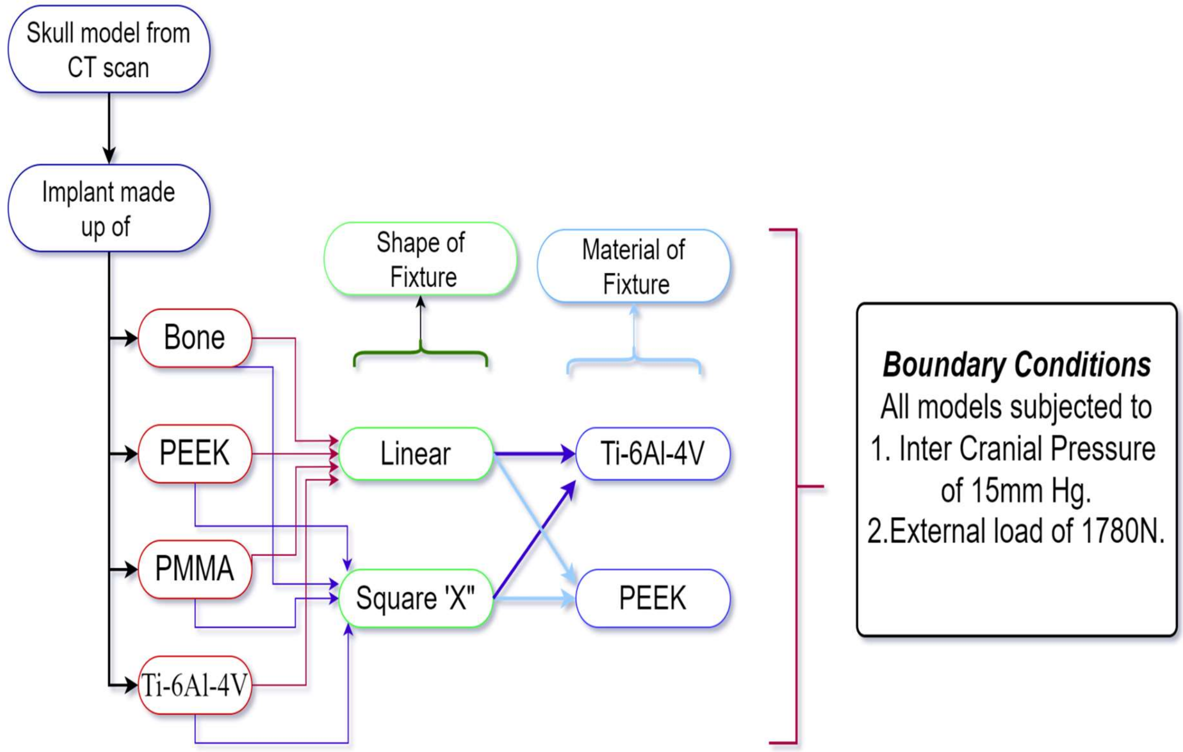


Figure 7: Schematic of simulation case studies that were undertaken.

2.2.1 Mesh Design

A mesh was created from the assembly of the models. For the simulation, a quadratic tetrahedral mesh element with a size 1mm was specified. The simulation's span center angle was also adjusted to fine (12°- 36°) and the smoothing factor was set high to cover every region of the cranial implant. Table 2 gives the details of nodes and elements for the mesh designs of both assembly arrangements and Figure 8 represents mesh transition across the different components of the assembly.

Table 2: Number of nodes and elements in mesh assemblies

Implant-Skull assembly with	Number of Nodes	Number of Elements
Square 'X' Fixtures	832285	465421
Linear Fixtures	418795	234847
Micro-screw	12061	3231

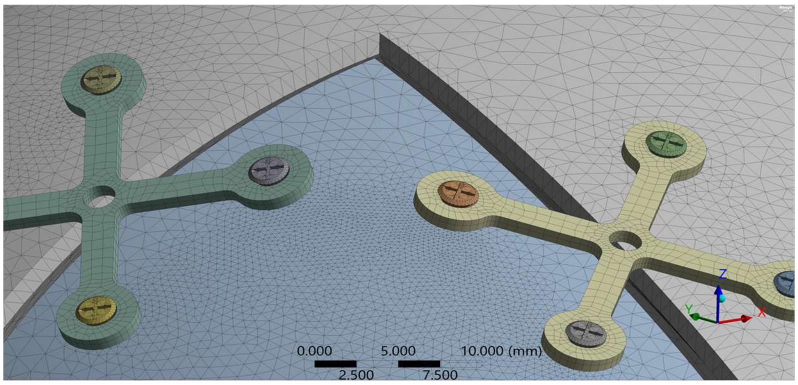


Figure 8: Mesh transition across different components of the assembly.

2.2.2 Boundary and Loading Conditions

For evaluating implant material performance, specific boundary conditions, namely external force, intracranial pressure and fixed support were specified. The boundary conditions were captured with the base of the skull as a fixed plane.

An external force of 1780 N was implemented on the assembled implant-skull model as shown in Figure 9(a) which is experienced by human skulls during real world scenarios related to collision forces during trauma cases, including free falls, road accidents. [5,20,32]

The natural pressure inside the cranial cavity is called intracranial pressure (ICP). It varies with age, body position and affects the cranial implant after surgery. A normal range of ICP is 7–15 mm of Hg for an adult.[9] In this study, an upper limit of ICP as 15 mm Hg (1.998x 10^{-3} MPa) was used as a boundary condition as shown in Figure 9(b).

A fixed support was applied on the bottom part of the skull model as shown in Figure 9(c). After setting the boundary conditions the mechanical ANSYS Parametric Design Language (APDL) was used for static structural analysis.

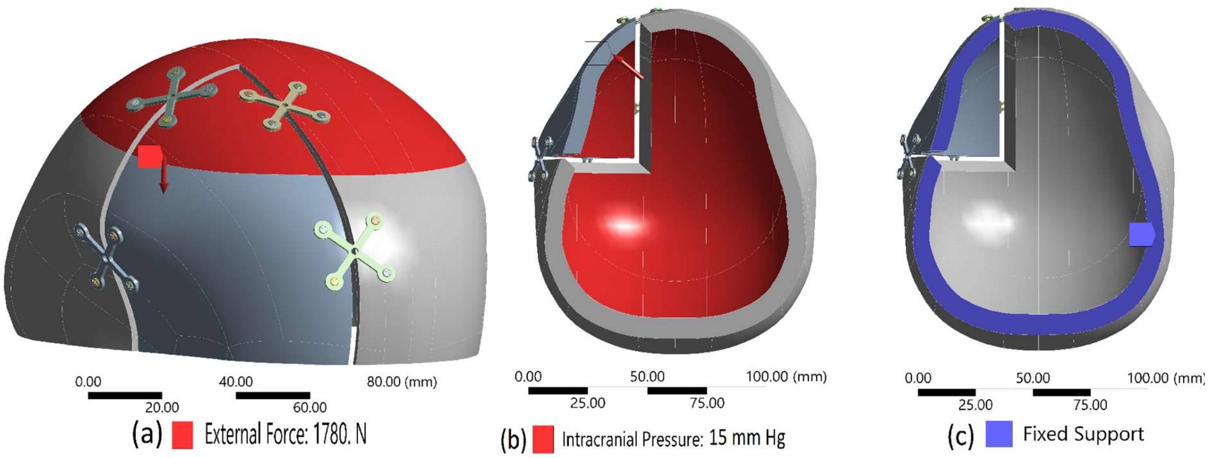


Figure 9: Boundary conditions on implant-skull assembly for all cases (a) External Force (b) ICP (c) Support given to the case.

3.Results

With respect to the application of external loads and ICP the total maximum deformation and equivalent von Mises stresses on various implant materials were calculated. A comparison of different implant materials with different fixture types and design arrangements was performed to ascertain the most efficient implant material and fixture design assembly. Table 3 shows the stress and deformation values calculated for the implant fixed using Linear fixtures with nomenclature.

Table 3: Comparative analysis of total deformation, equivalent stress on implant with Linear fixture

Implant Material*	Implant Mass (g)	Fixture Material	Fixture Mass (g)	Combination Cases of Implant and fixture**	Total Implant Maximum Deformation (x 10^{-2} mm)	Equivalent von Mises Stress at Maximum Deformation (x 10^{-2} MPa)
L1	140.41	PEEK	0.0176	L1-P	14.091	2.79
		Ti-6Al-4V	0.061	L1-Ti	6.187	2.69
L2	41.205	PEEK	0.0176	L2-P	16.325	2.52
		Ti-6Al-4V	0.061	L2-Ti	7.434	1.74
L3	37.655	PEEK	0.0176	L3-P	19.339	2.62
		Ti-6Al-4V	0.061	L3-Ti	8.810	2.53
L4	142.63	PEEK	0.0176	L4-P	1.950	1.73
		Ti-6Al-4V	0.061	L4-Ti	0.891	1.55

*L1: Autologous bone, L2:PEEK, L3:PMMA, L4:Ti-6Al-4V

**L1-P -Autologous bone implant with PEEK linear fixtures, L1-Ti -Autologous bone implant with Ti-6Al-4V linear fixtures, L2-P: PEEK implant with PEEK linear fixtures, L2-Ti: PEEK implant with Ti-6Al-4V linear fixtures, L3-P: PMMA implant with PEEK linear fixtures L3-Ti: PMMA implant with Ti-6Al-4V linear fixtures, L4-P: Ti-6Al-4V implant with PEEK linear fixtures, L4-Ti: Ti-6Al-4V implant with Ti-6Al-4V linear fixtures

Figures 10 and 11 represent the deformation of implant materials of autologous bone and PEEK respectively with Ti-6Al-4V fixtures. As indicated from Table 3, the maximum deformation within the bone implant was 6.187×10^{-2} mm while for PEEK it was 7.434×10^{-2} mm, which is within limits of elasticity. Here, von Mises stresses were determined with PEEK implant (1.74×10^{-2} MPa) indicating nearly 35% reduced stresses in comparison to bone (2.69×10^{-2} MPa). In addition, as PEEK (41.205 g) is nearly 70% lighter in overall mass in comparison to bone (140.41 g) it provides an excellent alternative implant material that could relieve the implant from higher stresses while being lighter in weight than bone.

The PMMA implant (37.655 g) is also nearly 73% lighter in mass in comparison to bone, however, the reduction in stress is only 6% when compared to the bone implant. Ti-6Al-4V has been the most prominent and commercially available implant material due to its biocompatibility and improved mechanical properties. As shown in Table 3, Ti-6Al-4V implant (1.55x 10^{-2} MPa) reduces stress by nearly 42.3%, with a negligible deformation as compared to bone (2.69x 10^{-2} MPa). However, in comparison to PMMA and PEEK, Ti-6Al-4V implant mass (142.63 g) was similar to that of bone (140.41 g).

L1-Ti

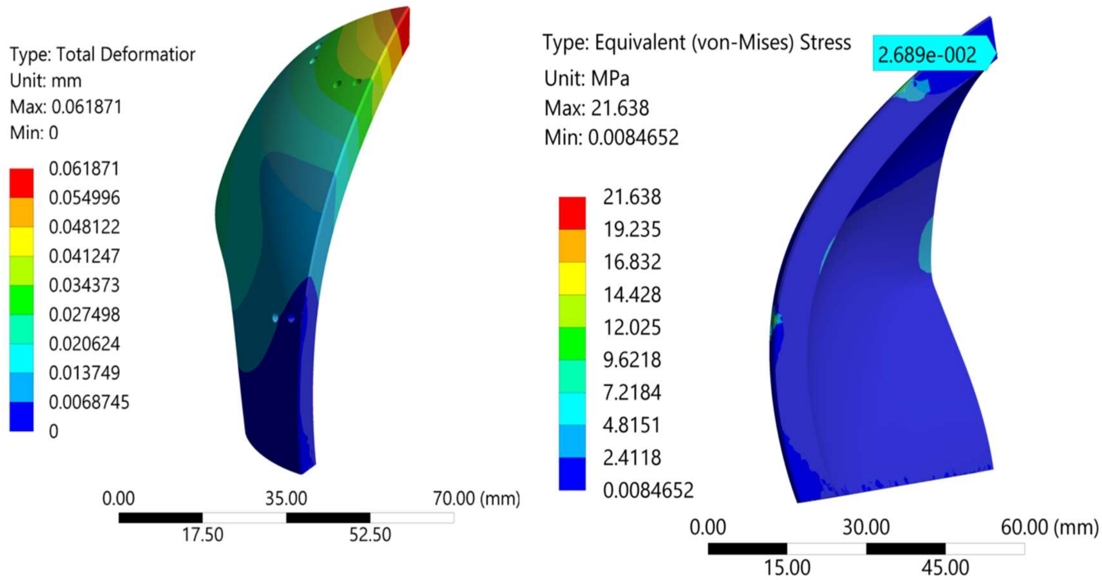


Figure 10: Total deformation and Equivalent stress for case L1-Ti.

L2-Ti

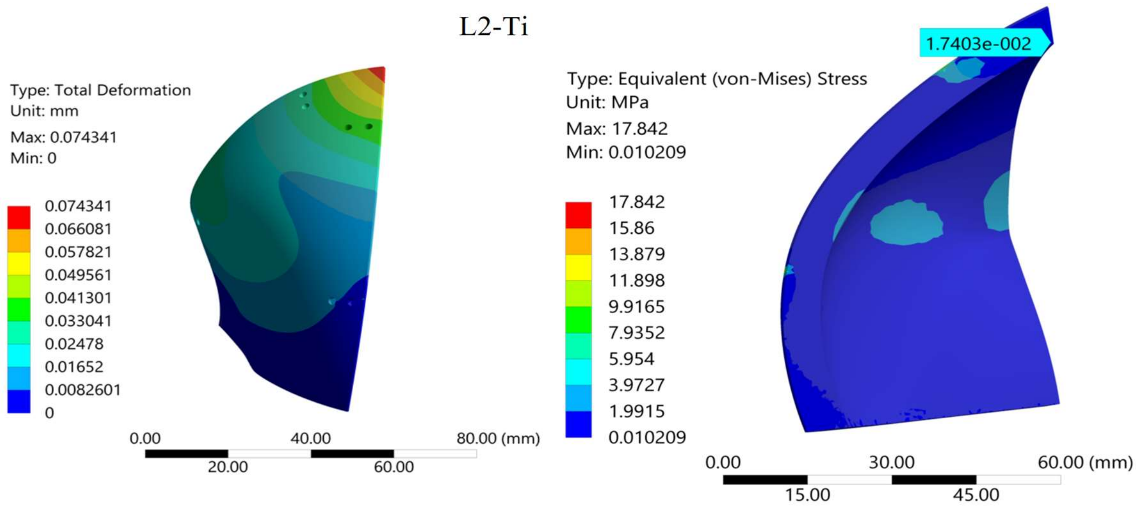


Figure 11: Total deformation and Equivalent stress for case L2-Ti.

Linear fixture design arrangements reduced stresses in implant materials significantly. A Square 'X' design arrangements were also FEA simulated and the results are shown in Table 4.

Table 4: Comparative analysis of total deformation, equivalent stress on implant with Square 'X' fixture

Implant Material Implant*	Implant Mass (g)	Fixture Material	Fixture Mass (g)	Combination Cases of Implant and fixture**	Total Implant Maximum Deformation (x 10^{-2} mm)	Equivalent Stress at Maximum Deformation (x 10^{-2} MPa)
S1	140.41	PEEK	0.153	S1-P	14.555	2.00
		Ti-6Al-4V	0.556	S1-Ti	6.926	1.92
S2	41.205	PEEK	0.153	S2-P	16.927	2.10
		Ti-6Al-4V	0.556	S2-Ti	8.139	1.66
S3	37.655	PEEK	0.153	S3-P	21.558	2.06
		Ti-6Al-4V	0.556	S3-Ti	9.436	2.00
S4	142.63	PEEK	0.153	S4-P	1.914	1.82
		Ti-6Al-4V	0.556	S4-Ti	0.920	1.61

*S1:Autologous bone , S2:PEEK, S3:PMMA, S4:Ti-6Al-4V

S1-P -Autologous bone one implant with PEEK square fixtures, S1-Ti -Autologous bone implant with Ti-6Al-4V square fixtures, S2-P: PEEK implant with PEEK square fixtures, S2-Ti: PEEK implant with Ti-6Al-4V square fixtures, S3-P: PMMA implant with PEEK square fixtures S3-Ti: PMMA implant with Ti-6Al-4V square fixtures, S4-P: Ti-6Al-4V implant with PEEK square fixtures, S4-Ti: Titanium implant with Ti-6Al-4V square fixtures.**

Figures 12 and 13 represent the deformation of implant materials of autologous bone and PEEK respectively with Ti-6Al-4V fixtures. As indicated in Table 4 the maximum deformation within bone implant was 6.926x10^{-2} mm while for PEEK it was 8.139x10^{-2} mm, which is within their limits of elasticity. The von Mises stresses for the PEEK implant (1.66x10^{-2} MPa) indicated nearly 13.5% reduced stresses in comparison to bone (1.92x10^{-2} MPa). For this fixture design PMMA did not relieve stress significantly in comparison to bone making it an unsuitable alternative to bone. Ti-6Al-4V(1.61x10^{-2} MPa) indicated a reduced stress by nearly 16.1% in comparison to bone with a negligible deformation.
Comparing both fixture designs (Table 3 and Table 4), for all implant material combinations with Ti-6Al-4V fixture materials, a Square 'X'(1.79x10^{-2} MPa) reduces stress at an average of nearly 18.4% in comparison to Linear (2.13x10^{-2} MPa) fixture design arrangement.

PEEK based fixtures for both designs have also shown reduced stresses(17.64x10^{-2} MPa) within all implant materials. Though in comparison to Ti-6Al-4V(15.7x10^{-2} MPa) fixtures, their stress($15.7x10^{-2}$ MPa) reduction is on average 10.9 % lower. However, PEEK fixtures for the case of bone implant material in Square 'X' design arrangement (S1-P $2.0x10^{-2}$ MPa) reduces stress by nearly 25.6% in comparison to Ti-6Al-4V fixtures with bone implant material in Linear design arrangement (L1-Ti $2.69x10^{-2}$ MPa). Similarly, PEEK fixtures reduce stresses by nearly 18.56% for S3-P ($2.06x10^{-2}$ MPa) in comparison to L3-Ti ($2.53x10^{-2}$ MPa), thereby suggesting an effective fixture material alternative to Ti-6Al-4V, provided the design arrangement of fixtures are optimized.

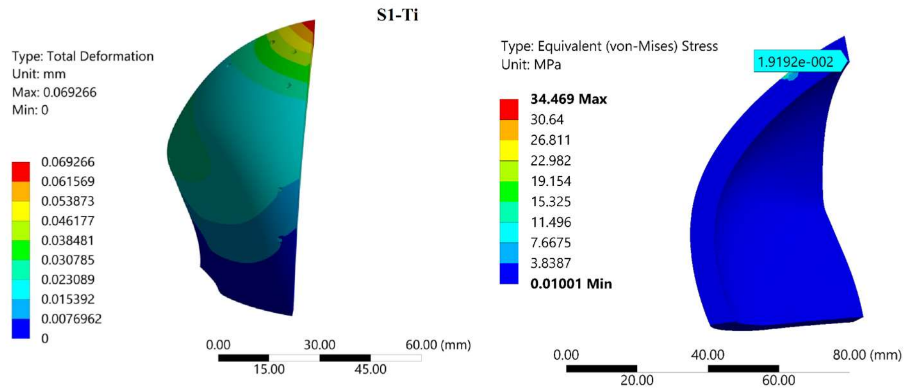


Figure 12: Total deformation and Equivalent stress for case S1-Ti.

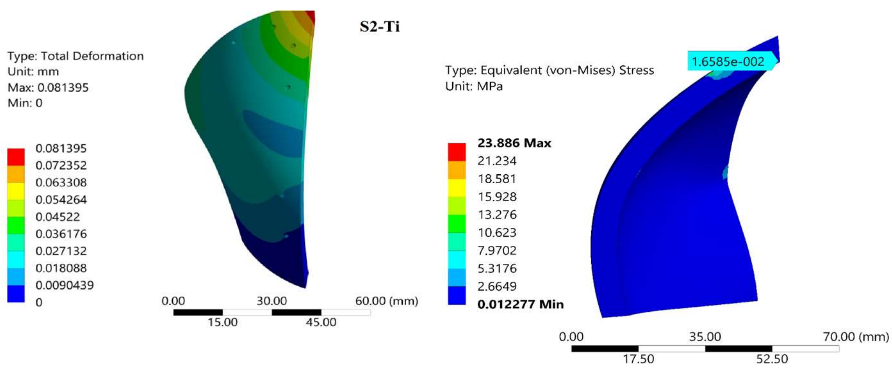


Figure 13: Total deformation and Equivalent stress for case S2-Ti.

The peak stress values generated in all these implant materials were safely within their yielding limits, as indicated in Table 2. Therefore, these results supported the effectiveness of both types of fixture design arrangements in relation to reduced stress values within the four implant materials, thereby keeping them safe for use in cranioplasty when subjected to major loading conditions.

4.Discussion

Alternative implant materials to autologous bone used in cranioplasty require important aspects including biocompatibility, mechanical strength, lightweight and ease of fitment. Considering that Ti-6Al-4V has been one of the most reliable alternatives to autologous bone for designing cranial implants, it still has its own limitations related to stress shielding effect, emission of toxic ions causing osteolysis and allergenicity, incompatibility with CT and MRI, weight and long-term stability within the body. [13,17]

Results show a Linear and Square 'X' shaped fixture design arrangements for fixing autologous bone, PEEK, PMMA and Ti-6Al-4V cranial implants with a defect skull. Fixture materials commercially available Ti-6Al-4V and 3D printable customisable medical grade PEEK fixture materials were investigated.

Tables 3 and 4 indicated that both Linear and Square 'X' fixture design arrangements were effective in relieving stresses from all types of implant materials, thereby encouraging both PEEK and PMMA to replace autologous bone as a cranial implant. In comparison to bone implants PEEK showed superior results by reducing stresses in a range of 13.5 % to 35%, while PMMA implants could reduce stresses by only around 6%. However, both implant materials weighed nearly 70% less in comparison to bone, therefore, their prospects for replacing bone are encouraging. Their superior performance as implant materials in comparison to bone could be attributed to the fixture material and innovative design arrangements. Ti-6Al-4V based fixtures ensure that implants are relieved of major loads with Elastic modulus of 115 GPa. PEEK has an elastic modulus of only 4 GPa, but also successfully relieved implants from peak stresses due to its application in a specifically designed fixture arrangement.

The two designed fixture arrangements (Linear, Square 'X') were strategically located at key stress concentration points between implant and the defective skull, where maximum deformations were observed. To provide a symmetrical stress distribution across the implant material, all four fixtures were placed uniformly supporting joints that would distribute stresses encountered at the boundaries between skull and implant uniformly to avoid sudden failures.

Square 'X' provides higher stress relieving results in comparison to Linear fixtures by nearly 12.5% for Ti-6Al-4V fixture material and 15.3% for PEEK fixture material. As the implant materials were relieved from higher levels of stresses, Ti-6Al-4V based fixtures exhibited peak von Mises stresses within a range of 145.6MPa to 422.87MPa across all implant materials, fixture shapes and placement arrangement combinations which was well within safety limits(110GPa). In circumstances where load bearing parameters surpass unexpected levels the failure of fixation plate would be preferred over a cranial implant material failure as conducting a fixture replacement procedure would be far less complex than replacing a cranial implant.

Marcian et al.[7] used a cranial implant-fixture-skull assembly using PMMA, PEEK and Ti-6Al-4V implant materials with mini plates and micro screws made up of Ti-6Al-4V alloy subjected to external loads of 50N and ICP 15mmHg. Implant thicknesses varied up to 4mm which were attached with fixtures, symmetrically at the skull-implant interfaces. Only linear shaped fixture designs were used, which indicated peak von-Mises stresses as >80MPa in PMMA and >127MPa in PEEK, thereby causing implant failures mainly due to limited thickness of the implant in comparison to the skull bone. A Ti-6Al04V based implant induced 329MPa which was within safe limits, however, our findings suggested that if an implant thickness is similar to the skull bone thickness then the stresses induced within the implant for all the above materials remain within yielding limits as 0.0155MPa to 0.0279MPa. Marcian et al, went on to suggest that increased thickness of implant would relieve stresses significantly from the implants ensuring that they do not fail when subjected to enhanced loading conditions.

Eight to ten fixation points were considered for evaluating von Mises stresses on various implant materials, including, Titanium alloy, PEEK and PMMA, which varied between 0.1801 MPa to 0.4626MPa for all these materials when subjected to ICP of 7mmHg to 15mmHg.[9] In comparison a heavy external load was considered of 1780 N with an extreme ICP of 15mmHg for the same implant materials and the results for von Mises stresses were found to vary between 0.0155MPa to 0.0279MPa, which were significantly lower. The primary reason suggested for this reduction is the fixation design and the arrangement adopted in this study. A symmetrical presence of both linear and square shaped fixtures ensured that stress distributions were uniform and most importantly concentrated the critical stresses away from the implant material.

A static load of 50N on a PEEK cranial implant with Titanium micro screws only attached at symmetrical locations across the implant-skull interface showed that von Mises stresses within the PEEK implant peaked at 8.15MPa.[26] In our study, a PEEK implant with Ti-6Al-4V fixation systems remained within range of 0.0166MPa to 0.0174MPa. This significant reduction of stress in the implant could be predominantly due to a larger surface area of the fixation plates which concentrates critical stresses away from the implant towards the plate.

Chamrad et al.[38] used PMMA material to design a cranial implant and used different fixation shapes using Ti-6Al-4V. Since the defect was smaller only two locations were selected for placing these fixation plates. Similar to the analysis performed in this study where a PEEK implant was used with Ti-6Al-4V fixtures the equivalent von-Mises stresses within the implant were found to be 0.0182MPa and 0.0253MPa for X and Linear fixations in comparison to X(25MPa) and I(40MPa) shape fixations as reported by Chamrad et al., and were much lower. This suggested that the PMMA implant experienced much lower stresses when more fixtures were attached at the interfaces. In addition, other fixture materials such as PEEK with PMMA implants also induced smaller levels of von Mises stresses, therefore providing alternate materials and design methods for sustaining external loads.

A static load condition of 50N maximum stresses introduced in Titanium alloy weighing only 41grams exhibited maximum stress of 1MPa with inbuilt asymmetrical Titanium alloy-based fixtures.[40] In comparison to our study, fixture shapes were similar to the Linear shapes, while placement of fixations followed by us was symmetrical around the implant, which resulted in maximum stresses of approximately 0.0025MPa to 0.0026MPa for PEEK and PMMA based implant materials respectively. The weight of these implants were 41grams(PEEK) and 37 grams(PMMA), thereby, providing an excellent alternative to the Titanium alloy implant and fixation system with much lower von mises stresses exhibited within the implant. It is suggested that since fixtures were designed for different shapes such as Linear and Square ‘X’ and, also placing them at symmetrical extremities of the implant shape ensured that these implants were relieved from critical stresses and deformations.

It has been suggested that since Square 'X' provides two plates instead of a one single plate as in the case of Linear it provides a larger contact surface area[41] with the implant, thereby, providing greater stability and strength to the interface. Two screws on each side of the Linear plate provides greater stability and reduces failure chances of a single screw during major load bearing conditions. However, plate failure occurrences[42] would remain higher in comparison to Square 'X' Fixture plates that would undergo bending when subjected to severe external loading conditions which can only be countered by providing a stable design in terms of symmetry for smoother stress distribution.[40] Since every Square 'X' design has four joint locations it provides a more efficient option for relieving the implant from peak stresses that can lead to its failure.

As suggested, Square 'X' provides a superior fixture design for stress reduction in implant materials in comparison to Linear fixture design arrangement, this also creates an opportunity to replace Ti-6Al-4V fixture material by others such as PEEK. As indicated in Tables 3 and 4, for autologous bone and PMMA implant materials, a PEEK based Square 'X' fixture design relieved stresses by 25.6% and 48.5% respectively in comparison to Ti-6Al-4V based Linear fixture design arrangement. Despite the lower Elastic Modulus of PEEK it proves to be a more reliable and stress relieving material when used in a Square 'X' design arrangement, for reasons as already suggested above. In addition to the fixture design aspects, PEEK has been reported to exhibit superior load sharing characteristics in comparison to titanium materials due to its porous structure.[24] With PEEK being used in implants due to its biocompatibility, and since it can also be 3D printed its probability in replacing native bone and the heavier Ti-6AL-4V as an implant and fixture materials are supported.

Although the Square 'X' design arrangement indicates improved results, from a clinical perspective there are limitations of fitment on a curved surface. During fixing procedures, surgeons often require flexibility in the plates for compliance of plate with the irregular shaped bone surfaces. A Linear fixture plate due to the presence of a single plate surface would be easier to deform or bend, thereby, providing a more uniform surface fixture arrangement in comparison to a Square 'X' fixture plate.

5. Conclusion

Patients undergoing cranioplasty always aspire to relive a normal life, post reconstructive surgery and avoid revisits in future that may arise due to infections or bone growth. Autologous bone has been the most favoured cranial implant material, but in cases where it cannot be used, medical grade titanium implants have been preferred. Apart from being expensive, these materials have their own long-term performance limitations and to alleviate patients from issues faced in such cases, other biocompatible materials such as PEEK and PMMA have been explored for implant applications. An innovative design arrangement of fixtures between the implant and defective skull, showed that implants made of PEEK and PMMA perform superior to autologous bone implants and could be favoured as an alternative to medical grade titanium. Fixture designs and placement arrangements played a significant role in stress distribution and concentrations. As the implant is desired to be lightweight but free from excessive stresses, if a strong material-based fixture is selected with an optimized placement design then an even weaker implant material could be used for cranioplasty.

In this study, it has been suggested that both Linear and Square ‘X’ design fixture arrangements successfully relieve stress from different types of implant materials, hence enhancing their prospects to be used as cranial implants instead of conventional implant materials.

PEEK being a biocompatible, light weight and 3D printable material can be suitably utilised as implant and fixture material to replace bone or medical grade titanium by fixing it to the defective skull using optimized fixture design arrangement such as Linear and Square ‘X’.

Based on the size of defect in a skull, implant and fixture arrangements need to be designed so that stress concentration sites are minimised and stress distribution is smooth. Fixture design aspects include contact surface area and symmetry of location which play a significant role in relieving the implant material from extreme stress conditions. The number and location of fixtures, also assist in uniform stress distribution, thereby, keeping the implant-skull assembly safe. Significant findings of this research work have been to present a wider choice of materials that can be safely used for designing implants that are lightweight and stronger by suggesting innovative fixture materials, shapes and design arrangements.

In addition to the favourable simulation results, clinical aspects also need to be ascertained, where a surgeon’s feedback in terms of the fitment of these fixtures needs to be determined. The number of screws used in the fixtures are beneficial in forming a stronger joint, however using additional screws leads to overall increased material costs, and for the surgeon additional time to complete the surgical procedure. Also, flexible plate materials allow surgeons to bend or deform the plates more easily for shape compliance in terms of the implant-skull assembly, where rigid plates despite possessing more strength could be discouraged. A hybrid fixture in terms of its shape, material, location points and design could also be explored for optimising a cranial implant fixing procedure. Ultimately, the choice of materials and the design of implants and fixtures rests with the surgeon and their assessment of a specific surgical case.

Authorship statement:
Prashant Jindal: Conceptualization; Data Investigation; Writing - review & editing; Supervision; Project administration.
Chaitanya: Writing: original draft; Methodology; Data validation and curation.
Shreerama Shiva Sai Bharadwaja: Software; Methodology; Formal analysis, Visualisation.
Shubham Rattra: Writing - original draft; Methodology; Data validation and curation.
Deval Pareek: Software; Formal analysis; Data Visualisation.
Vipin Gupta: Problem formulation; Clinical assessment.
Yvonne Reinwald: Manuscript editing and reviewing, Project administration.
Philip Breedon: Writing - review & editing; Supervision; Mentorship.
Mamta Juneja: Methodology; Formal analysis; Validation; Writing - original draft; Supervision; Project administration.

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Conflicts of interest

The authors confirm that there are no known conflicts of interest associated with this publication and there has been no financial support for this work that could have influenced its outcome.

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