

Multi-Factor Biomechanical Assessment of Patient Specific Cranial Implants Using Finite Element Analysis

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ABSTRACT

Personalized surgical interventions have been revolutionized by integration of finite element analysis in design and evaluation of craniomaxillofacial patient specific implants. This study aimed to investigate the effect of implant sizes, material type, fixation devices and number of fixations points on biomechanical behavior of cranial implant. Finite element analysis was used to simulate physiological loading conditions. Detailed geometries of implant assembly were included. 144 assembly combinations were analyzed to obtain the maximum Von Mises stresses and total deformation. Single-Factor without Replication ANOVA was used to analyze the results. They showed that material types have a major impact on both stress distribution and deformation. At the same time, screw and miniplate type haven't drastically affect the stress distribution or deformation. Other factors like defect size, fixation points and implant texture have significant effect on both stress distribution and deformation. this means that the null hypothesis is rejected.

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1. INTRODUCTION

Craniomaxillofacial implants are fundamental in treating various clinical conditions in the cranial and facial regions like fractures, deformities, and trauma [1]. Using advanced imaging and bone segmentation technologies, these implants are designed to allow for patient-specific plans without the need for physical models [2]. Simulation using three-dimensional (3D) Image-based applications has considerably contributed to implant design, especially in cases requiring mandibular or cranial bone resection and reconstruction due to trauma or tumors [3]. Implants that meet patient specific needs created through (3D) printing offered precise adaptations, reduced surgical time and cost, lowered infection risk, and improved patient satisfaction and aesthetic outcomes [4]. This technology facilitated printing implants with complex anatomical structures, improving functionality and ensuring desired form. The biomechanical behavior of customized implants is affected by many factors like implant size, shape and material which highly affected the stress distribution and deformation in implant and surrounding bone [5]. In the same context, an implant bone interface is an important point that should be underlined [6].

The material type used in CMF implants has an important role in biomechanical performance of these Implants, Which subject to numerous investigations [7]. Historically bone graft is supposed to be the gold standard for reconstruction of bone defects. Traditional materials like titanium were favorable because of their mechanical strength [8].

Recently, more accurate results are captured because of the advanced development in Computer Aided Design (CAD) and 3D printing technologies. It facilitated the use of many novel materials like titanium alloy (Ti6Al4V), polyether ether ketone (PEEK), and polymethyl methacrylate (PMMA) to print patient tailored implants [9]. Noteworthy, titanium characterized by stiffness seven folds greater than the stiffness of bone which may lead to stress shielding and cause gradual weakening of surrounding bone [10, 11].

Finite element analysis could be considered as an important tool in evaluation of biomechanical performance for different body prosthesis, where functional loads could be simulated. Many studies investigated the how implant shape, implant material and fixation method can influence the stress distribution in implants and surrounding bones [12, 13, 14, 15].

In this context, the structural integrity is highly dependent on the number and location of fixation point of CMF implant. Many studies revealed that increase number of fixation points offers better stress distribution from implant to surrounding bones [16]. In other hand, factors like surrounding bone quality and architecture of trabecular bone can influence the mechanical fixation and stability of implant [17]. During impact the loads should be transferred smoothly transferred to surrounding bone with reducing stress concentration in screws and mini plates and best stress distribution [18]. So, significant interest should be given to fixation components, which are an integration of titanium mini-plates and micro-screws [19].

This study aims to study the mechanical behavior of CMF implant assembly in response to shape, size, material type, external loads, distance between fixation points and type of fixation screws. A statistical evaluation combined with a computer modeling technique of the implant assembly is simulated including the precise geometry of attaching mini-plates and micro screws which are thought to be important parts for accurate evaluation biomechanical response within the implant.

2. METHOD

Topographic images characterized by its high inherent contrast between bone and soft tissues. This makes it possible to segment bone from surrounding tissues, which makes it possible to generate accurate skull geometrical data. Many steps followed during this investigation:

A. Data acquisition. Patients computed tomography followed by saving acquired information in Digital Imaging and Communications in Medicine (DICOM) file format. Voxels with 512 x 512 x Z, where Z varies from 150 to 520 slices using Radi Ant DICOM viewer, Figure 1. Then the bone regions were segmented using thresholding and region growing techniques using Mimics research 21.0 (Materialise, Leuven, Belgium). In the current study, the CMF bone model is segmented using values ranging from 211.73 to 2755.0 HU. While areas with artifacts due to dental restorations were edited using edit mask, 3D interpolate, and multiple slices edit tools. The resultant model was saved as Stereolithography or Standard Tessellation Language (STL) file.

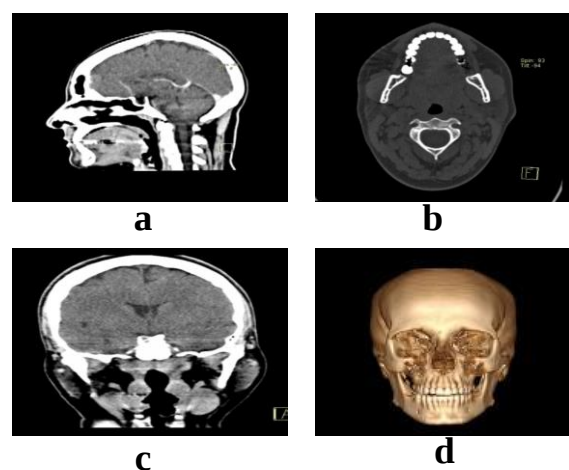


Figure 1. Different views of CT scan (a), coronal view; (b), axial view. (c), sagittal view; (d), 3D rendered CMF model.

B. CMF implants design: Different parts in CMF region were chosen such as cranial, mandibular, zygomatic and infraorbital regions to design implants. STL files that consist of 3D representation of CMF bones were imported to materialize 3Matic research. All patient skulls under study were supposed to be symmetrical to ensure the best cosmetic and functional outcomes. This allowed the replication of missing bone fragments. Design steps are shown in Figure 2.

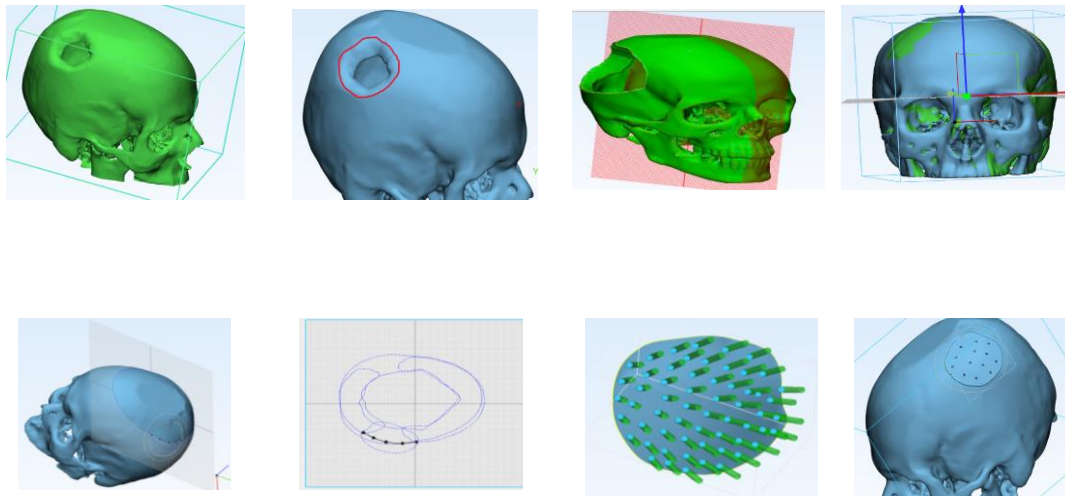


Figure 2. Design steps of cranial implants.

1. The initial stage of creating a customized implant is drawing a closed curve to represent the damaged area. A curve offset from the gap borders has been applied.
2. constructing a mid-plane to divide the two halves by cutting through the center of the skull.
3. use the created plane as a mirroring tool to reflect the healthy side of the skull onto the damaged side.
4. It has been determined which plane crosses the transverse plane perpendicularly. This plane is then used to draw a reference sketch later.
5. Along the mirrored side's profile and between the places of junction, a spline has been drawn. The spline serves as a guide for the final prosthesis profile, and the closed curve is used as the surrounding entity for building the implant surface.

C. Implant texture and size:

Two defects were generated with two sizes, small with () surface area and large with (mm) surface area. To study the effect of implant texture, solid and honeycomb textured implants were created as shown in Figure 3.

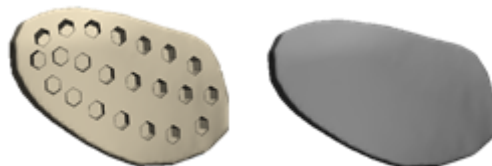


Figure 3. Tested implant texture.

D. Fixation Miniplates and screws:

Mini-plates, and micro-screws required for CMF implant fixation were created using Autodesk fusion 360 software.

E. Fixation points:

The effects of the number of fixations positions were studied, the circumference around each implant was measured and divided into the number of desired fixation points to determine their position as shown in Figure 4.

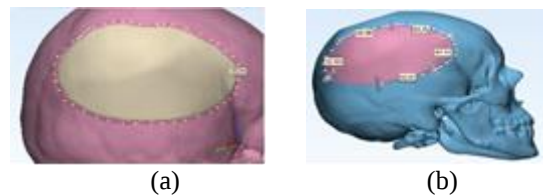


Figure 4. The measured circumference and fixation positions for cranial implant.

The large cranial implant was fixed to the skull using six and eight fixation points with different configurations as shown in Figure 5. The smaller defect was fixed using six and four fixation points as shown in Figure 6.

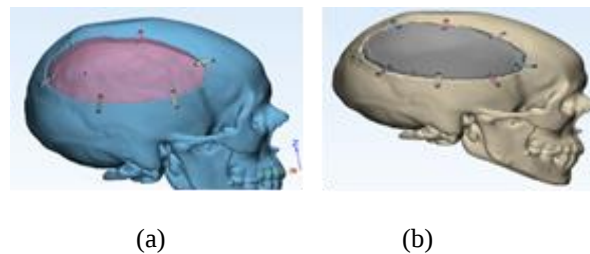


Figure 5. Number and orientation of fixation points for large cranial defects.

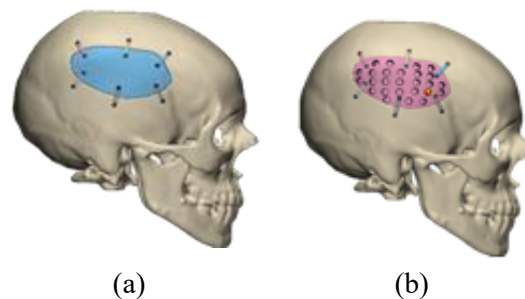


Figure 6. Number and orientation of fixation points for small cranial defects.

Three different screw designs are used to assess the effect of screw diameter and thread shape on implant response to loading conditions. All screws are made of titanium alloy (Ti6Al4V). Titanium screws are used for their lightweight properties and compatibility with medical imaging (they do not cause artifacts in CT or MRI scans). Technical drawings of used screws are shown in Figure 7. a shows the dimensions of first screw figure a show the top view with head diameter of 5mm, central hole diameter 1.5 mm and thickness of 0.89 mm. figure 5 b. shows side view shows the conical shape of screw head with 90° angel and thickness of 1.5 mm. screw diameter is 2.5 mm and thread pitch is 0.45 mm.

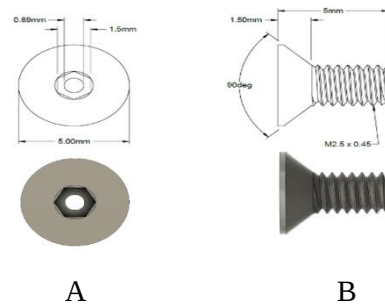


Figure 7. Technical drawing of first screw (A) top view (B) side view.

To study the effect of screw diameter, the Second screw used in implant design assembly is identical first one. Figure 8 (a) shows the top view shows head diameter of 6mm and thickness of 1.7 mm. Figure 8 (b) shows the side view shows screw 3mm screw diameter and 0.5 pitch size.

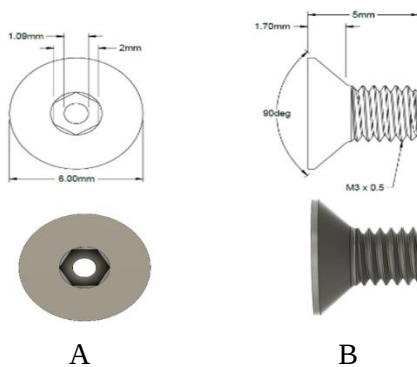


Figure 8. Technical drawing of second screw (A) top view (B) side view.

To determine the effect of thread, size the third screw dimensions where used. Figure 9 (A) shows the top view of the screw head diameter of 3 mm and figure 9 (B) shows the side view with screw diameter of 1.74, head angle of 90°, 1.74 major diameter and 5mm total length

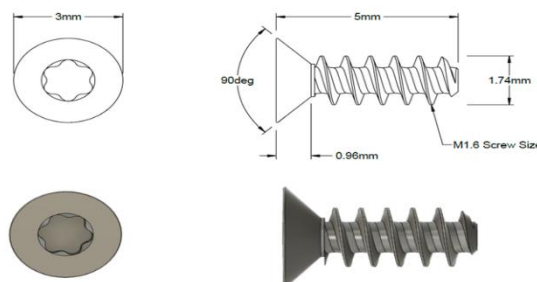


Figure 9. Technical drawing of third screw (a) top view (b) side view.

According to screws diameter two miniplate designed according to the hole size with two shapes. Miniplate shapes and their dimensions are all shown in Figure 10.

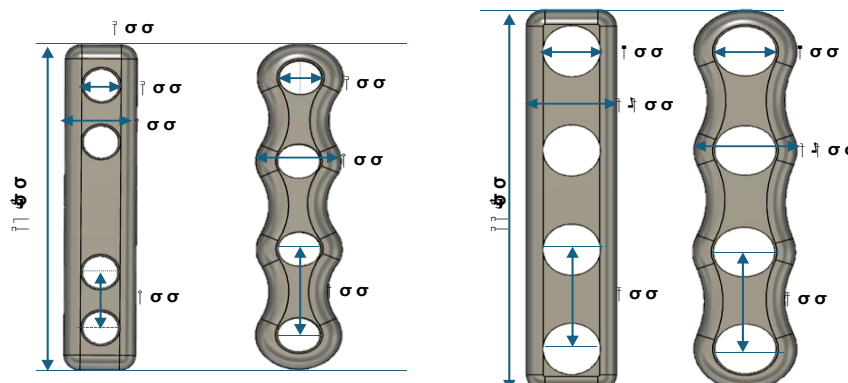


Figure 10. shapes and dimensions of used miniplates.

F. Meshing:

After creation of full implant assembly, removing unnecessary details the lower half of the skull become a significant need by guidance of datum plane in order to reduce time and computation processing as shown in Figure 11. A non-manifold assembly consists of cranial bone and PSI was created using grid-based method with grid resolution of 0.2 in 3Matic research software. Grid resolution represents the size of grid used to convert parts to grid structure. Where, large grid size could result in large change in parts size and small grid size could result in long computational time. So, the choice of grid size is based on a balance between geometrical accuracy and computational time. A surface mesh was created with a maximum triangle edge of 3 mm. In critical regions like bone implant interphase and bone screw hole interphase triangles edge was set to be 0.7 mm with influence area of 4 mm. with growth rate of 25%, which denotes the rate at which triangles get larger as moving away from critical regions. as these regions are expected to be subjected to higher stress. Meshed implant assembly is shown in Figure 12.

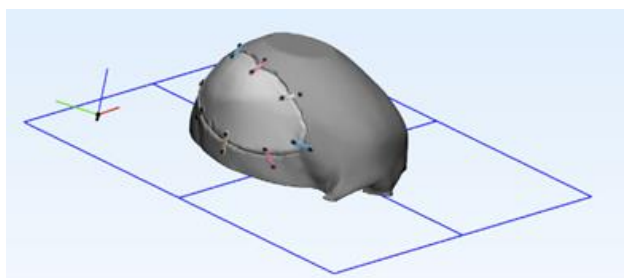


Figure 11. implant assembly with removed unnecessary parts.

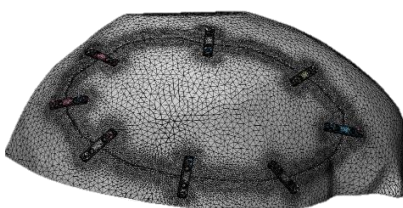


Figure 12. Meshed implant assembly

The second step is the generation of volume mesh starting from generated surface mesh with maximum triangle edge slightly higher than surface mesh. Element type was 10 nodes tetrahedral elements where this type of element is commonly used stress analysis of contact problems [20]. maximum edge length for implant and cranial bone was 2.5 and 4.2 respectively. Edge length in critical regions increased to 1.2 with same influence area and growth rate. Table 1 summarizes surface and volume mesh parameters.

Table 1. surface and volume mesh parameters, with an approximate number of triangles used in meshing processes

		Edge length [mm]	Influence area [mm]	Growth rate [%]
Surface mesh	Implant	2.3	0	25
	Cranial bone	4.0	0	25
	Bone implant and bone screw interfaces	0.7	4	25
Volume mesh	Implant	2.5	0	25
	Cranial bone	4.2	0	25
	Bone implant and bone screw interfaces	1.0	4	25

3. RESULTS AND DISCUSSION

The obtained results of total of 144 combinations of bone-implant assemblies were analyzed, as shown in Figure 13. For simplicity, the combinations are labeled as follows: large implants as L, small implants as S, 8 fixation points as 8F, 6 fixation points as 6F, miniplate types 1, 2, 3, and 4 as P1, P2, P3, and P4, respectively, and screw types 1, 2, and 3 as S1, S2, and S3, respectively.

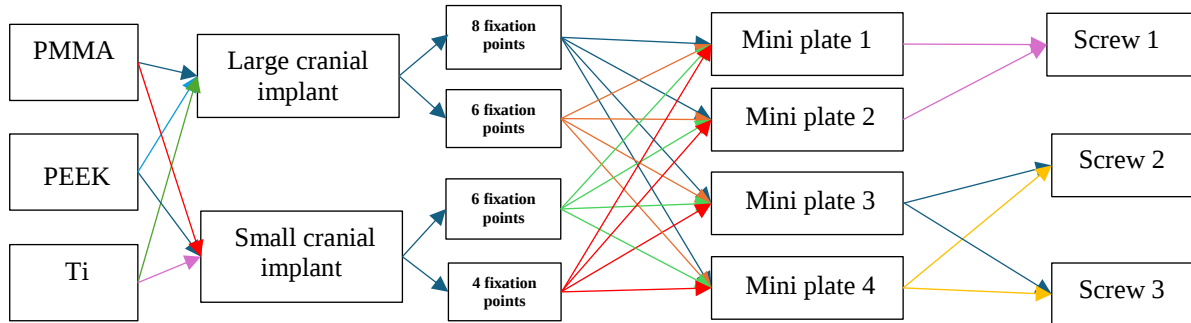


Figure 13. combinations of implant bone assembly according to material type, implant size, fixation points, miniplate type and screw type.

The implant material predominantly influences their deflection [21]. Due to the known high mechanical stability of Ti6Al4V alloy, it showed expected least deformation values with lower response to different loading combinations. PMMA and PEEK implants exhibited greater deformation compared to Ti6Al4V (titanium alloy) implants of the same thickness. The highest deformation values as expected were observed in the PMMA implants. which makes it less ideal in application where high rigidity is needed. While the lowest deformation values were in (Hc 6F P4 S2) combination in small implants and in (solid + Hc 4F P4 S2) combinations in large implant, Figures 14 and 15 shows clearly comparable behaviors of PEEK and PMMA in different combinations of with higher stability in Ti6Al4V.

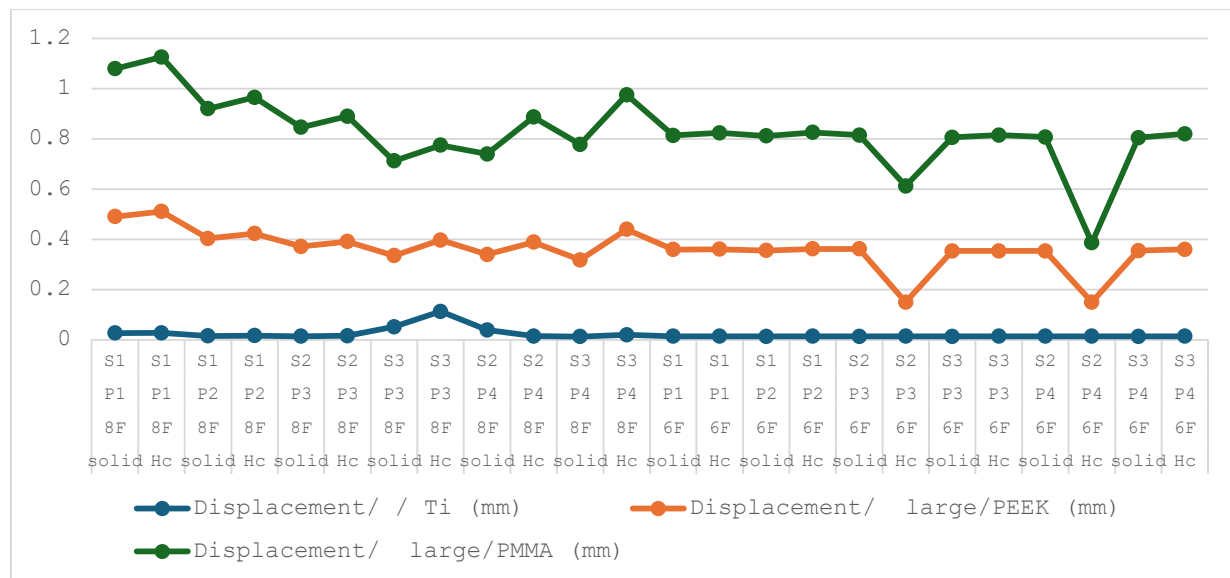


Figure 14. Displacement of implant materials used (Ti6Al4V, PEEK, PMMA) in large cranial implants.

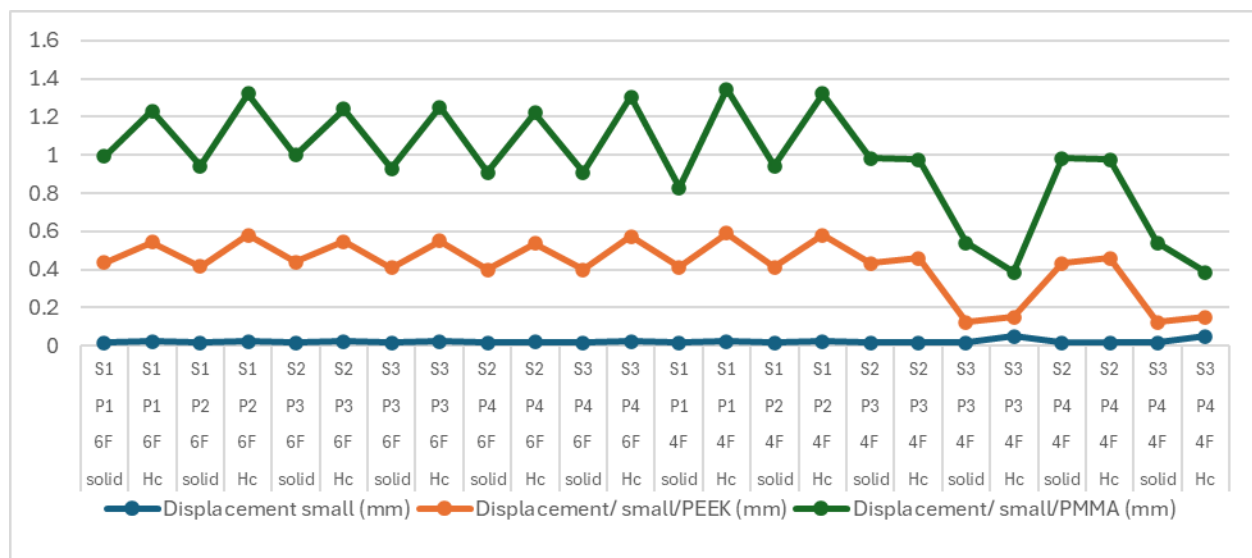


Figure 15. Displacement in used implant materials (Ti6Al4V, PEEK, PMMA) in small cranial implants.

The slight difference in displacement behavior under the same loading scenarios could be due to the difference in their elastic moduli. As the material is in the elastic range, according to Hook's law, displacement is related to the material's ability to resist deformation, which makes the material more sensitive to material stiffness [22, 23]. Figure 16 shows displacement of different materials in sample of FEA results. It's clear that there's no significant difference in deformation between different materials and the maximum deformation occurred slightly deviated from point of force application this could be due to that the implant created with varying thickness and the point in which the maximum deformation occurred is with lower thickness.

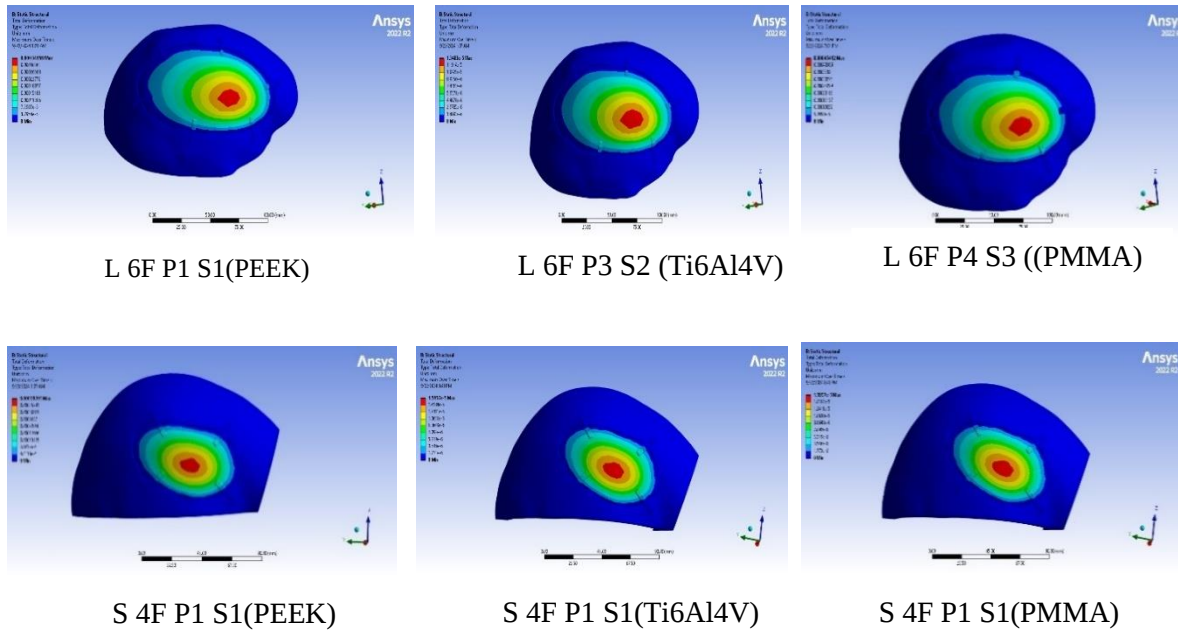


Figure 16. Displacement distribution for different materials (sample of FEA results).

While for stress Ti6Al4V showed lower stresses in both solid and HC combinations. Ti6Al4V, due to its high mechanical strength, could withstand much more biomechanical stress than maximum value. Also, its mechanical stiffness makes it the least sensitive to loading conditions which maintain its stability through different loading scenarios. In other hand the stress behavior in all material types was almost comparable, this could be due to the fact that the subjected loads are small normal physiological loads. According to the behavior of elastic modulus of used materials and dominance of elastic performance, stress behaviors were minimizing variability [24, 25].

A consistent trend could be observed for both stress and displacement. Also, it aligned with known material properties. Understanding how these materials behave under different loading scenarios is helpful in different cases where restorations are needed. Also, they show the complexity of material behavior, where for the same combination, material could exhibit lower stresses due to its ability to distribute loads, but its deformation behavior could vary depending on its stiffness and elasticity.

Both stress and deformation for all combinations and material types was lower in larger implants. Ti6Al4V was least sensitive to these changes, While PEEK and PMMA, displacement decreases significantly for both solid and HC conditions. The lower displacement for larger implants highlights the ability of these materials adaptation with increased surface area. Indicating more efficient load distribution with higher surface area [26, 27].

Regarding the effect of screw type For Ti6Al4V both small and large implants screws have a minimal effect on displacement. But for PEEK and PMMA screws (S1, S3) reduced deformation significantly indicating that they had better anchor than S2.

In most combinations titanium showed consistent maximum stress in most combinations for all screws (S1, S2, S3). It is indicated that the mechanical stability and rigidity have dominant performance regardless of screw diameter or thread shape. These results show that screw diameter has no significant effect on maximum stresses in all combinations (comparison of higher stresses screw 1 and 2), as larger diameter could decrease localized stresses and distribute stresses to broader area. The finer threads of screw 3 leads to higher structure stability by reducing both maximum von mises stresses and displacement. These findings show that geometric parameters of screw threads, such as pitch and contour, has good role in bone engagement and stress distribution, which can greatly influence the stability and longevity of cranial implants [28,29].

For the Effect of fixation points, in small implants Ti6Al4V fixation points had a significant effect on stress and displacement for titanium for both large and small implants for both configurations (solid, HC). But for PEEK and PMMA both stress and displacement were lower in 4 fixation points than 6 fixation points in all configurations. This

could be due to the fact that the lower number of fixation points may offer more uniform distribution. Moreover, the higher number of fixation points could lead to higher stress constructions and uneven load distribution [30]. Also, **Ulmeanu et al. (2001)** highlighted that increasing mechanical constraints in small implants may lead to loosening of fixation screw due to stress accumulation at these regions [31].

While in large implants increase number of fixation points led to lower stress and displacement for all materials, this was more significant in more flexible materials (PEEK, PMMA). As larger implants have a wider surface area this leads to that stress distributed to larger area [32,33]. Increasing the number of fixation points may enhance stress distribution to multiple contact areas and reduce the possibility of stress concentration at fixation points [34]. In addition to that, the absence of sufficient fixation points results in higher displacement values, which could lead to implant instability and micro-movements that could disrupt implant-bone integration. This underscores the importance of securing large implants with an adequate number of fixation points, ensuring both stability and biomechanical compatibility [35].

Decreasing stress with increasing number of fixations points in large implants while potentially increasing number of fixation points can increase stress level in small implants. This could be due to the complexity of cranial regions with different thicknesses and curvatures [36].

In the other hand Chamfered miniplates facilitate a more natural load transfer in bone-implant interface, preserving bone-implant integrity. Chamfering refers to cutting an angled edge along the borders of the miniplate. This process reduces the expected sharp stresses, that can lead to localized stress concentration at edges, a common issue in craniofacial implants. Studies, like those by **Khader et al.** and **Pathak et al.**, highlighted that miniplates with chamfered edges loads distributed more uniformly, this leading to decreased peak stress at fixation sites. Where chamfered miniplates could decrease the stress shielding that may cause bone atrophy over time. Which reduces implant related complications, improves implant stability and reduces stress accumulation at miniplates edges [37, 38]. **Lee et al.** mentioned that miniplates with sharp edges may be more susceptible to microfractures and fatigue failure due to irregular stress distribution [39]. These literatures support the obtained results of this study that miniplates with chamfered edges led to lower maximum equivalent Von Mises stresses and lower deformation in all combinations. The comparison was conducted between miniplate 1(with chamfered edges) and miniplate 2 (with sharp edges), and between miniplate 3(with chamfered edges) and miniplate4 (with sharp edges).

The last part of this investigation is about the importance of texture; the question was when designing PSI is it important to take care of implant texture? As it will be lighter in weight. In this study we found that in majority of combinations that textured implant has higher equivalent, Von mises stresses in both large and small implant assemblies. At the same time, they have higher displacements in small and large implants. The stress distribution in some implants assemblies. Many studies support these findings, **Timoumi et al. (2022)** used FEA to compare the effect of implant texture on stress distribution, they found that HC textured implants showed higher peak stresses than solid implants [40]. **Shin et al. (2017)** study showed that HC and porous implants showed higher stress due to structural discontinuities [41]. **Sivakumar et al. (2023)** their results revealed that HC textured implants have lower ability to distribute mechanical loads evenly with higher stress values. **Carter et al. (2020)** study showed that honeycomb-based implants experience increased stress in MRI environments [42]. Contrary to many studies like **Khan et al. (2023)**, **Haddani et al. (2022)**, **Lim et al. (2017)**, showed that the HC textured implants showed better stress distribution and lower maximal stresses [43, 44].

Table 2 shows one way ANOVA for effect of different independent variables on stress while table 3 shows the effect of these variables on deformation. In this analysis the P value assumed to be 0.05, if it's lower that would mean there are a significant effect, and the null hypothesis is rejected. Both tables showed that material types have a major impact on both stress distribution and deformation. At the same time screw and miniplate type hasn't not drastically\ affect the stress distribution or deformation. In addition, screw and miniplate type haven't drastically affected the stress distribution or deformation. That means will be null hypothesis is rejected.

Table 2: Significance of independent variable's effect on stress. The p-value is based on one-way ANOVA.

Variable	F -Statistics	P-Value	Significance
Material type	55.07	5.06 E-15	Yes
Defect size	12.307	0.0007	Yes
Screw type	1.08	0.172	No
Fixation points/ large	5.868	0.024	Yes
Fixation points/ small	3.632	0.0498	Yes
Miniplate type	2.02	0.185	No
Implant texture	1.488	0.023	Yes

Table 3: Significance of independent variables effect on deformation. The p-value is based on one-way ANOVA.

Variable	F -Statistics	P-Value	Significance
Material type	306.48811	4.7 E-35	Yes
Defect size	3.332	0.0032	Yes
Screw type	2.502	0.097	No
Fixation points/ large	5.868	0.024	Yes
Fixation points/ small	5.621	0.026	Yes
Miniplate type	5.621	0.026	yes
Implant texture	1.422	0.024	Yes

4. CONCLUSION

1. Segmentation process is a crucial step in transferring the virtual surgical plans to real world patient cases.
2. While small implants require stable fixation, over-fixation may paradoxically weaken the overall structural integrity by creating points of excessive stress, particularly in non-metallic biomaterials. Surgeons should carefully consider the balance between fixation stability and stress distribution when determining the number of fixation points in small cranial implants. Surgeons are more comfortable in using the new surgical instrument than the traditional one because of its problems in terms of discomfort during work.
3. Textured implants biomechanically better than solid implants, even they are lighter in weight that does not mean they has better stress distribution.

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