Experimental validation of 3D printed patient-specific implants using digital image correlation and finite element analysis

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A B S T R A C T

With the dawn of 3D printing technology, patient-specific implant designs are set to have a paradigm shift. A topology optimization method in designing patient-specific craniofacial implants has been developed to ensure adequate load transfer mechanism and restore the form and function of the midface. Patient-specific finite element models are used to design these implants and to validate whether they are viable for physiological loading such as mastication. Validation of these topology optimized finite element models using mechanical testing is a critical step. Instead of inserting the implants into a cadaver or patient, we embed the implants into the computer-aided skull model of a patient and, fuse them together to 3D print the complete skull model with the implant. Masticatory forces are applied in the molar region to simulate chewing and measure the stress–strain trajectory. Until recently, strain gages have been used to measure strains for validation. Digital Image Correlation (DIC) method is a relatively new technique for full-field strain measurement which provides a continuous deformation field data. The main objective of this study is to validate the finite element model of patient-specific craniofacial implants against the strain data from the DIC obtained during the mastication simulation and show that the optimized shapes provide adequate load-transfer mechanism. Patient-specific models are obtained from CT scans. The principal maximum and minimum strains are compared. The computational and experimental approach to designing patient-specific implants proved to be a viable technique for mid-face craniofacial reconstruction.

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1. Introduction

Craniofacial segmental defects that are caused due to blast injury or tumor ablation require reconstructive procedures involving large bone replacement implants. Such defects remain a challenging problem for reconstructive surgeons as it is difficult to create a complicated 3D structure that satisfies significant functional and aesthetic roles of the midface. Proper reconstruction and replacement are needed not only to obliterate the defect, but also to address the issues of swallowing, orbital function, vision, mastication, speech and restoration of facial contour and self-image [1]. These defects are patient-specific and the implants should depend on the loads and the dimensions of the missing bone defect. Large segmental bone defects of the midface typically require bone grafts for a successful outcome and, advances in microvascular free flaps have greatly increased reconstructive options. Virtual surgical planning, stereolithography modeling, and prefabricated osteotomy bone cutting templates have made surgical planning of osteotomies easier [2–4]. However, for most of these cases, no structural analysis or design principles are used which often results in unfavorable circumstances such as fracture or high stress concentrations. Advances in 3D printing technology have opened a new dawn in patient-specific implant design. Recently, a bioreabsorbable airway splint has been successfully created and implanted in an infant using a 3D printer [5]. This work demonstrated innovative creation of implants for patient-specific anatomical condition using a multi-disciplinary approach involving high-resolution imaging, computer aided design and biomaterial based 3D printing. For a large segmental defect, finding the correct and optimized shape of the bone replacement still remains a question. Reconstruction is typically done heuristically without adequate surgical preplanning and structural analysis. To address this problem, a technique named topology optimization has been introduced into designing bone replacement in our previous work [6,7]. Topology optimization is a method of finding a structure with optimal load paths to transfer a number of loads to defined supports. This method is widely used...
in designing components for the automobile industry and lately in designing aircraft components. For example, it has been successfully applied to design the main wing box rib of Airbus A380 [8].

Surgical outcome can be enhanced by taking an interdisciplinary approach. Custom tissue fabrication can be considered an option to replace bone formation technique to patient specific solutions obtained from computer aided design (CAD) with computational methods [7]. The solution is optimized for functional restoration when combined with soft tissue repair and appropriate prosthetics even though the design may deviate from the original human bone geometry. The objective function of topology optimization algorithm is to minimize compliance within the structure. Although only mechanical loadings were considered, it was found that topology optimization gives a shape similar to human natural skeleton without a defect when applied to cross-section on a vertical plane through first molar [7]. Understanding how functional physiological loads (e.g., required for biting) are transferred to the bone-implant interface enables better design of implant supported prosthesis as well [10,11].

Traditional strain measurement technique in experiments uses strain gauges. Although they are known to be reliable and robust [12], strain gauges only give discrete data by averaging the real strains between the tips of strain gauge. The result of this technique tends to be affected by environment and requires preparation of the surface and wiring [13]. In general, local strain measurements are essential because complexity in geometries and inhomogeneity result in substantial variation over the structure. Recently, a technique named Digital Image Correlation (DIC) has been developed that captures full field strain data with a good resolution on the surface of the model from images. This relatively new method can be applied to complex geometries. Theories and detailed information of the method can be found in Refs. [14,15]. This DIC technique is used extensively in experiments to characterize the specimen’s behavior. Using this method, full field strain of splinted and non-splinted implant prostheses has been captured [16]. Also, various kinds of computational models for composite hemipelvis [12] and, proximal femur [12,17] have been validated with DIC.

The principal aim of this paper is twofold. (i) To experimentally validate that the finite element model correctly captures the stress strain contour of the skull model subjected to masticatory forces and (ii) to validate that the designed implant appropriately transfer the masticatory forces by keeping the maximum stress below ultimate stress. In order to do this, a bone replacement shape for a patient with massive facial injury with large bone loss in midface is designed using the topology optimization method. The solution is then embedded in the skull with computer-aided engineering software to obtain a skull model. Then, the skull model with the embedded implant is fabricated by a 3D printer. Mastication activity is simulated in the experiment and also modeled by finite element analysis (FEA). This work is expected not only to evaluate the solution of topology optimization but also to appraise the idea of using topology optimization to design macroscopic bone replacement shapes for midface defects. The full field strain data from mechanical testing via DIC is compared with that from FE (Finite element) model under same boundary and loading conditions to validate the FE model. FE model of skull is further analyzed to investigate the practicality of the skull in terms of load transfer mechanism and structural integrity.

2. Materials and methods

2.1. Model preparation

A skull model of massive facial injury with large bone loss in the midface is extracted from the CT scan using software Amira (FEI Visualization Science Group, MA, USA) as shown in Fig. 1. The defect is in the center of midface and is asymmetrically extended bilaterally. Using measurement tools, the appropriate design domain is extracted. Within the design domain, supports are provided on the lateral surfaces for contact and fixation between the implant and uninjured portion of facial skeleton. A set of upward forces representing the forces of mastication are applied on bottom surface in the dental profile and, another set of downward forces are provided in the center of the top surface to simulate the trauma forces that may be transferred from the upper region of skeleton. Appropriate holes are embedded to mimic eye, nasal cavities and space for hard palate. The illustration of design domain and respective boundary conditions are shown in Fig. 1.

2.2. Topology optimization

Topology optimization suggests the best material distribution within a design domain by seeking where to put the material (solid) and where not to (void). The topology can be defined by the density at different locations within the domain. The density is usually considered a design variable and can assume 0 or 1 with 0 representing the void and 1 representing the solid. The topology

![Fig. 1. Selection of design domain and required design considerations to obtain boundary and cavity information.](image-url)
optimization method used in this work iteratively optimizes the elemental densities in the design domain to minimize the compliance (maximize the stiffness) of the final structure while satisfying the volume fraction constraint. This objective function and constraints can be mathematically expressed as follows,

\[
\text{minimize } C(\rho, u_d) = \mathbf{f}^T u_d
\]

subject to:

\[
K(\rho) u_d = \mathbf{f}
\]

\[
V(\rho) = \int_{\Omega} \rho \, dV \leq V_s
\]

where \( C \) is the compliance, \( \rho \) is the density vector, \( \mathbf{f} \) is the global load vector and \( u_d \) is the global displacement vector. \( K \) is the global stiffness matrix, \( \Omega \) is the design domain, and \( V_s \) is the volume fraction constraint. Employing the Solid Isotropic Material with Penalization (SIMP) method \([18,19]\), the problem is relaxed for density to have any value between 0 and 1 with a small lower bound of \( \rho_{\text{min}} = 0.001 \) to avoid singularities during calculating for equilibrium. Also, a parametric equation of Young’s modulus for local stiffness is defined. Thus, following is added in the problem.

\[
0 < \rho_{\text{min}} < \rho < 1
\]

\[
E(x) = \rho(x)^p E_0
\]

where \( p \) is the penalization factor and \( E_0 \) is the Young’s modulus of the material in the solid phase.

In this work, we used the multi-resolution topology optimization (MTOP) method \([20]\). In MTOP, different discretizations are employed for analysis, design and optimization. The details of this method can be found in \([7,20]\) and for basic theory and introduction of the topology optimization the readers are referred to \([21]\). Two level of discretization are used in MTOP, B8 elements for displacement (analysis) and 125 density elements inside a B8 element for density (visualization) and design variable (optimization). Based on conditions shown in Fig. 1, a total of \( 28 \times 20 \times 12 = 6720 \) B8/n125 elements are used in the topology optimization algorithm. The design parameter \( V_s \) (volume constraint) is chosen as 12%. The penalization factor \( p \) is selected as 3 to satisfy the Hashin–Shtrikman bounds \([19]\). The load ratio between the top and the bottom forces depends on the relative importance given to them for different patient-specific conditions. The load ratio between top and bottom forces is chosen to be 10 and the number of iteration is limited to 50 with a condition to terminate the process if density change in domain between iterations is less than 0.001. The result is shown in Fig. 2(a). Also, if the user wants to emphasize the equal importance between the top and bottom forces, load ratio of the top and bottom forces can be changed to 1. In this case, a different solution is obtained which is depicted in Fig. 2(b). Both the respective topology optimization solutions in Fig. 2 are represented with isosurfaces with density of 0.25.

In order to embed the topology optimized bone replacement into the skull, the mandible is separated by cutting the image data near upper condyles in mandible via image segmentation. The bone replacement implant is then scaled and positioned. A denture is included during the embedding process. Once all the components are properly positioned, their stereolithography are combined in a Boolean fashion. Note that the embedded model is re-meshed to alleviate the discrepancies in mesh size between components. The procedure is visually shown in Fig. 3.

\[\text{Fig. 2. Implant shapes from different load ratios considered in the design process. Multiresolution topology optimization (MTOP) is used in both scenarios (a) } F1/F2 = 10, \text{ (b) } F1/F2 = 1.\]

\[\text{Fig. 3. Embedding MTOP solution into the skull to acquire final skull model for mechanical investigation.}\]
region in the skull model. Aluminum cylindrical load applicator (see Fig. 4(b)) is used. This load applicator is hinged in the middle so that the top portion is flexible to ensure better contact with the skull model. The cross sectional area of the load applicator is comparable to the area of two molar teeth in the skull model. The final configuration is shown in Fig. 4(b).

The mechanical behavior of skull model is analyzed by measuring full-field strain using the 3D digital image correlation technique in the region where most deformation is expected as depicted in Fig. 4(a). Successive images are taken at the constant speed of 2 frames per second with a pair of GRAS-20S4M-C (Point Grey Research, BC, Canada) cameras (resolution: 1624

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**Fig. 4.** (a) Proposed scenario (mastication) for the mechanical testing, (b) setup for mechanical testing of the skull model.

**Fig. 5.** (a) The final configuration of the mechanical testing and data capturing cameras, (b) schematic of the final configuration, (c) load history applied in the model during mechanical testing for three consecutive tests.
Fig. 6. Deformation of specimen (ABSplus) under uniaxial compressive loading (a) before loading, (b) after loading, (c) stress strain curve obtained from compression testing.

Fig. 7. (a) Finite element mesh of the skull model, (b) boundary and loading conditions for finite element model.
equipped with 35 mm Schneider (Schneider Optics, NY, USA) lenses. The final configuration of the cameras in the experiment is shown in Fig. 5. The external surface of the skull model is sparingly painted with black and white spray paint to give a speckle pattern. The deformation of the model surface is calculated by the Vic-3D software (Correlated solutions, Inc., SC, USA) by monitoring the changes in this speckle pattern in the digital image sequence.

A calibration panel that has a set of points with known spacing is used to calibrate the data acquisition system. The calibration panel is oriented differently in each calibration images from both cameras so that they can be used to define 3D Cartesian coordinate system in Vic-3D. The contour of the skull model is captured by stereo triangulation in the defined 3D Cartesian coordinate system. The MTS FlexTest (MTS, MN, USA) controller is set to apply a linear ramp load on the skull model with a maximum magnitude of 120 lbs (≈ 534 N) starting from 5 lbs (≈ 22.2 N) of preload through cylindrical load applicator. Load histories of the three mechanical tests are shown in Fig. 5.

### 2.4. 3D printing and material property

In order to successfully replicate the mechanical testing, the material property of the printing material (ABSplus) is required. The tensile property of ABSplus which can be obtained from the manufacturer (Stratasys Ltd., MN, USA), could not be directly applied because compressive stress dominates in the study. Hence, we performed our own mechanical testing to obtain the compressive material properties of ABSplus material used in the 3D printing. Additional cylindrical specimens with 12 mm diameter and 24 mm height are 3D printed to characterize its property under compression. Printing layer with respect to load of this specimen is controlled such that it is consistent with the skull model. Similar setup with that of the mechanical testing of skull model is employed. A ramp load that generates strain rate of 8.33E-4 is chosen (50% strain in 600 s) (see Fig. 6). 3D digital image correlation technique is used to capture the mechanical behavior of the specimen during loading. In the sequence of the images, a virtual extensometer is positioned in specimen’s longitudinal direction to extract engineering strain. Stress and strain relationship is extracted by correlating extracted engineering strain with the loading profile. The testing is repeated three times

<table>
<thead>
<tr>
<th>Test 1</th>
<th>Test 2</th>
<th>Test 3</th>
<th>Average</th>
<th>Max % difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>$e_1$</td>
<td>0.0191</td>
<td>0.0177</td>
<td>0.0165</td>
<td>0.01777</td>
</tr>
<tr>
<td>$e_2$</td>
<td>-0.0282</td>
<td>-0.0233</td>
<td>-0.0233</td>
<td>-0.02610</td>
</tr>
<tr>
<td>$e_{yy}$</td>
<td>-0.0218</td>
<td>-0.0198</td>
<td>-0.0198</td>
<td>-0.02067</td>
</tr>
</tbody>
</table>

Fig. 8. (a) Maximum principal strain distribution, (b) minimum principal strain distribution, (c) vertical strain component distribution in the skull model under mastication simulation at approximately 530 N.

Table 1

Quantitative comparison of strain values from three specimens in mechanical testing.
with the three specimens. The resulting three true and engineering stress strain plots are shown in Fig. 6. The average elastic modulus of the ABSplus from the three samples is computed to be 2.074 GPa.

2.5. Finite element analysis

The stereolithography of the skull model is meshed using 3D volumetric elements. The mesh consists of 155195 linear tetrahedral (C3D4) elements and 41492 nodes in the skull model. Commercial FEA software Abaqus (Dassault Systèmes, Vélizy-Villacoublay, France) is used for the simulation of the experiment. Elastic modulus of 2.074 GPa and material yield strength using 0.2% offset method of 53 MPa from the compressive specimen testing are used with manufacturer provided Poisson’s ratio of 0.35. Plastic behavior is also taken into account in the FE model by introducing plastic strain values. The boundary conditions to match the mechanical testing of skull model are employed. They include four areas in upper cranium and two areas in the bottom most portion of skull model. Their movement and rotation under the load is prohibited by fixing the nodes in these areas. A load of

![Fig. 9. Vertical strain distribution comparison between (a) FEA, and (b) mechanical testing. Horizontal strain distribution comparison between (c) FEA, and (d) mechanical testing at approximately 267 N.](image)

![Fig. 10. (a) Five selected elements in the skull model for quantitative comparison of vertical strain with the mechanical testing results, (b) tabulated values show the comparison.](image)
267 N which is the half of the maximum load in the mechanical testing is applied on 23 nodes in the region of first and second molar teeth as concentrated forces (magnitude of 11.61 N each in vertical direction). (See Fig. 7(b)).

3. Results and discussion

The full field strains captured from mechanical testing on three skull models are compared with one another to ensure the reliability of the 3D printed skull models as well as the setup of the mechanical testing. Maximum and principal strains and vertical strain components in the area of interest (as shown in Fig. 4(a)) are calculated. The applied loading resulted in positive maximum principal strain (tensile), whereas minimum principal strain was negative (compressive) in most areas of the domain. The strain fields from the three tests match quite well qualitatively as shown in Fig. 8. Quantitative comparisons of strains generated in the Vic-3D are tabulated in Table 1. The maximum difference of approximately 10% is observed in the minimum principal strain (compressive). The heterogeneity of the printed material is a probable factor of this discrepancy. The way fused decomposition works; it creates anisotropy in the object due to the voids in the direction parallel to the printing layers. Also, any mismatch in the alignment of skull model with the load applicator may affect the result. The direction of load depends on how the skull is fixed. During the testing preparation, skull models may have a minor shift from their initial position. Overall, the results from three mechanical testing match well.

The result from the finite element analysis shows that the model will not experience any plastic deformation with a load of 267 N as the maximum von-Mises stress is 41.74 MPa which is less than the experimental yield stress of 53 MPa. Recognizing compression in vertical direction dominates in this study, vertical strain component is compared between the results from the mechanical testing and the FEA. Quick visual comparison demonstrates that FEA of skull model successfully follows the strain contours from mechanical testing (see Fig. 9). Five elements that are located in the most critical region as shown in Fig. 10 are selected to check the quantitative agreement between FEA and the mechanical testing. In these locations, the maximum difference between the vertical strain results from FEA simulation and the

<table>
<thead>
<tr>
<th>Tangential compressive property</th>
<th>No. of specimens</th>
<th>No. of donors</th>
<th>Mean</th>
<th>Standard deviation</th>
<th>Skull to skull significant differences</th>
</tr>
</thead>
<tbody>
<tr>
<td>Modulus (GPa)</td>
<td>219</td>
<td>14</td>
<td>5.584</td>
<td>3.034</td>
<td>Yes</td>
</tr>
<tr>
<td>Poisson’s ratio</td>
<td>327</td>
<td>18</td>
<td>0.22</td>
<td>0.11</td>
<td>No</td>
</tr>
<tr>
<td>Ultimate strength (MPa)</td>
<td>210</td>
<td>14</td>
<td>96.53</td>
<td>35.85</td>
<td>No</td>
</tr>
<tr>
<td>Ultimate strain ($\times 10^{-3}$)</td>
<td>210</td>
<td>14</td>
<td>51</td>
<td>32</td>
<td>No</td>
</tr>
</tbody>
</table>

Table 2: Mechanical properties of human skull bone from [25].

Fig. 11. A cross section of a 3D printed specimen showing printed material heterogeneity.

Fig. 12. (a) Plot of stress directional components (potential new load transfer paths), (b) possible load transfer paths in the MTOP solution with the same load ratios between top and bottom forces, (c) load transfer paths (buttresses) in uninjured human skull.
Transfer to restore the functional role such as proper load transfer, model effectively can represent the compressive behavior from discrepancies are between 2% and 6% which indicate that FEA would have been obtained. Also, using material of skull model was purely isotropic, a better agreement geneity during the 3D printing process as shown in Fig. 11. If the disagreement is possibly due to the material inhomogeneity in real life, major mastication forces are applied on the posterior zone of the maxilla in the molar area. For the presented example, the created topology might produce an unfavorable Anterior–Posterior (AP) spread with more tensile strains on the anterior portion. This might induce bone loss in the future. These specific situations can be easily dealt with patient-specific cases, and defect dimensions. Based on these different scenarios, the location of the loading may be critical to avoid unfavorable AP spread.

Using an engineering technique like the topology optimization to design bone replacement shapes can alleviate the uncertainty that exists when deciding on an implant shape for adequate load-transfer. The designs can be used as guidelines for osteotomies as well as in designing tissue engineered scaffolds for bone regeneration. The main purpose for repairing damaged and missing tissue is to preserve a three-dimensional space that will maintain structural integrity by providing an efficient load-transfer mechanism under physiological loading.

4. Conclusion and future work

In this work, the mechanical feasibility of implants designed by the topology optimization method for craniofacial reconstructive surgery is examined. A mastication simulation using a finite element model that was generated from patient’s CT scan is validated with mechanical testing. The specimen for the mechanical testing was obtained using a 3D printer. The FEA results show that topology optimized solutions have the potential to restore damaged buttress systems and recover structural integrity of the facial skeleton to endure a maximum masticatory force around 534 N. In this work, the mechanical properties of human skull were obtained experimentally and it was inferred that the skull bone is fairly isotropic in direction tangent to the skull.

In the era of patient-specific implant designs, using topology optimization method in order to find the structurally optimized solution can eliminate the uncertainty of choosing heuristic shapes for critical surgeries like mid-face reconstruction. This
will also help in designing fixation and additional prosthesis to improve the quality of life for the patients.

Currently, we are exploring to include biological variables (e.g., oxygen level) in the topology optimization algorithm for the bone replacements [27]. Also, we are looking into different impact loading configurations, stress concentrations and fracture analysis in the implants.

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Conflict of interest statement

None.

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