J. Maxillofac. Oral Surg.
https://doi.org/10.1007/s12663-023-01926-3

REVIEW PAPER

Validation of Low Cost Patient Specific Implant Design Using Finite Element Analysis (FEA) for Reconstruction of Segmental Mandibular Defects: A Case Report and Literature Review

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Received: 29 November 2022 / Accepted: 18 April 2023
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Abstract
Introduction Mandibular continuity defects can cause functional and cosmetic deformities affecting a patient's quality of life. Reconstruction of such defects can be intricate even for the most seasoned maxillofacial surgeons. Reconstruction plates were the standard of care in the past, followed by a secondary reconstruction using autogenous grafts.
Materials and methods Novel technological upgrades like customized computer-designed patient-specific implants (PSIs) have overtaken these stock reconstruction plates to enhance the aesthetics and address the individual clinical situation. Affirmation of the above plate design using biomechanical analysis can further improve the efficacy of PSIs.
Discussion The present case report describes a novel combination of an autogenous graft and a low-cost patient-specific implant with the prosthesis design validated using finite element analysis. The authors have also reviewed the biomechanical evaluation of PSIs design and its uses in treating mandibular continuity defects.
Conclusion Use of FEA helped to inspect the potential weakness and stress distribution through out the implant due to this there was no sign of hardware failure.

Keywords Mandibular reconstruction · Patient-specific implants · Biomechanicalanalysis · Finite element analysis

Introduction

Mandibular reconstruction in patients after trauma or tumor resection presents a challenging concern for a reconstructive surgeon to preserve masticatory and speech functions and retain the cosmetic appearance [1]. Recent technological advances in computer-assisted maxillofacial surgeries, especially virtual surgery, have been a valuable tool for diagnosis, treatment planning, and outcome evaluation, simplifying the overall treatment procedure in a relatively shorter duration. These virtually assisted surgeries allow high precision and predictability to position the jawbones to achieve

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satisfactory occlusal functionality and facial aesthetics [2]. It also helps in preoperative planning and allows surgeons to predict the intervention outcome before the actual surgery [2, 3].

Earlier several materials and techniques have been used to reconstruct mandibular continuity defects that are cosmetically acceptable, including different bone grafts. However, due to associated drawbacks with the previous techniques, a more neoteric development led to the fabrication of biocompatible 3D printed patient-specific implants (PSIs) to restore these bone defects with promising results [3].

However, it is vital to understand that the design of PSIs ideally should achieve both strength and aesthetic functionalities for a more successful outcome. Furthermore, strength and resistance are determined by understanding the biomechanical stability, which helps prognosticate the prosthesis's longevity to withstand the stresses due to repetitive forces of mastication. Therefore, it is of prime importance for a successful reconstruction to inspect the areas of potential weakness and to analyze the biomechanical performance of the designed prosthesis before fabrication for the ideal stress distribution evading unwanted mechanical failures during the procedure [4].

With this concept in mind, the present case report has employed a low-cost 3D printed customized patient-specific implant (PSI) as the treatment approach in a case of mandibular discontinuity due to tumor resection, with its design ratified and modified using FEA on the virtual prosthesis to reduce the stress concentration. The fabricated PSIs consisted of 2 parts: the prosthesis's body for bridging the continuity defect and wing extensions to fix the screws on the intact mandibular stumps. We also provide a literature review addressing the use and biomechanical evaluation of PSIs in treating mandibular continuity defects.

Case report

A 22-year-old male patient presented to the Oral and Maxillofacial Surgery department with the chief complaint of facial asymmetry due to a slowly expanding mass over six months (Fig. 1). A thorough clinical examination showed an expansile lesion in the right mandibular posterior region involving the buccal and lingual cortex, causing a lingual displacement and grade III mobility of the molars (Fig. 2). An Orthopantomogram (OPG) revealed an osteolytic lesion extending from the second premolar to the ramus region distal to the third molar tooth (Fig. 3). There was a complete expansion of the buccal, lingual, and inferior borders with perforation of the bone seen in some places. An incisional biopsy was done, which confirmed the diagnosis of the osteolytic lesion as Ameloblastoma. Due to aggressive nature of the lesion and extensive osteolysis of the bone, segmental resection of the mandible was planned. As the patient was young, resection of this type could be disfiguring and may lead to a loss of masticatory function; therefore, reconstruction of the defect was considered a point of paramount significance. Using a reconstruction plate was ruled out as it was not effective aesthetically or functionally and would require a second surgery for a definitive reconstruction later.

Although microvascular bone flaps would have been ideal for reconstructing the mandible, financial constraints did not allow us to opt for this choice. Therefore, an inexpensive long term hybrid solution was designed to incorporate an autogenous nonvascular iliac graft placed in the

Fig. 1 Pre-operative frontal view showing facial asymmetry on right side

Fig. 2 Pre-operative intraoral view showing displacement of teeth due to expansile lesion on lower right mandibular region

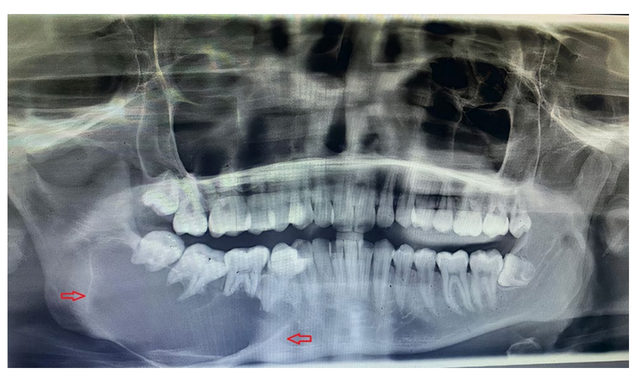

Fig. 3 Pre-operative OPG. Red arrows revaling an osteolytic lesion in the right mandibular region

reconstruction of the alveolar portion of the mandible along with a low-cost biocompatible PSI, which would not only support the graft but also give the facial contour, maintain the aesthetics and facial symmetry of the young patient. An autogenous iliac graft was chosen for its ability to rehabilitate with dental implants later on. A reverse planning sequence was done, which involved first placing a repositioning jig, then cutting guides, and lastly, the PSI into the continuity defect in the mandible.

Pre-operative Planning

The first step to virtual surgical planning was data acquisition via a Computed Tomography (CT) scan that was done using a 128-slice spiral CT scanner (*Siemens Somata Perspective No: 76970*), and the data acquired was converted into a Digital Imaging and Communications in Medicine (DICOM) format. Next, the data was examined and segmented, and ideal thresholding was done using a 3D slicer (*ITK-SNAP version 3.8.0*), followed by open-source software (*grants of the US National Institute of Health*) was used to create a virtual surgical model of the hard tissue in ".*stl*" format.

Designing of PSI

The resection margins were planned and validated by the surgeon. In the reverse planning sequence, a PSI was designed using the mirroring function from the opposite side mandible to reproduce the perfect hard tissue contour of the lower border. The wings of the PSI extended such that three screws could be fixed on either side of the defect, extending proximally and distally onto the sound bone. A low-cost PSI was planned with medical-grade SS316 stainless steel and fabricated using investment casting. The PSI was designed (*Autodesk Meshmixer 3.4.53*) using the previous step's ".*stl*" data. The inner margin at the inferior border of the PSI was made concave to support the iliac graft, and holes were designed at regular intervals to reduce the PSI's weight and enable the hitching of the muscles and soft tissues around the placed implant.

Biomechanical Testing

CT scan data of the mandible was converted into DICOM format, and the hard tissue was isolated from the soft tissues using the thresholding operation. The mandible was meshed using the surface triangulation technique, and its outer surface was generated. The virtually designed prosthesis was imported and assembled along with the mandible using a Boolean operation. This assembled model was again imported into the FEA ANSYS software workbench in IGES (Initial Graphics Exchange Specification) format, and specific regions of the prosthesis were analyzed to maximize the FEA predictions using convergence analysis. The mechanical properties of the assembled model were defined based on the data for bone and SS316 medical grade stainless steel planned for the prosthesis. Boundary constraints were implemented on the condylar and the osteotomised body segments on the other side and considered as fixed points. These constraints allowed the reconstructed mandible to deform elastically when a load was applied, assuming the mandible and the prosthesis as a single unit. The bite force in the mandible ranged from 244 to 2143 N, which was reduced significantly after resection. An average force of around 300N of the vertical load was applied on the posterior mandible to compute Von Misses stress concentration and evaluate displacement of the mandible. As a result, stress concentration was reported in the angle region, so the prosthesis was increased in thickness to reinforce and improve its strength to withstand masticatory forces. (Fig. 4*).*

Design of the Cutting Guides and Repositioning jig

Post-resection, a repositioning jig was designed to maintain the condylar position and the exact length and position of the continuity defect in the mandible. In addition, the jig was intended to be fixed on the lower border of the mandibular stumps. Also, cutting guides were fabricated on the mesial and distal osteotomy sites, which had two areas for stabilization, one on the lower border sharing the same screw hole as the repositioning jig and the other on the buccal aspect of the mandibular stumps coinciding with the holes of the PSI to be held in the same position (Fig. 5). These were fabricated using selective laser sintering (SLS), a relatively inexpensive metal additive manufacturing process with cobalt-chromium powder material.

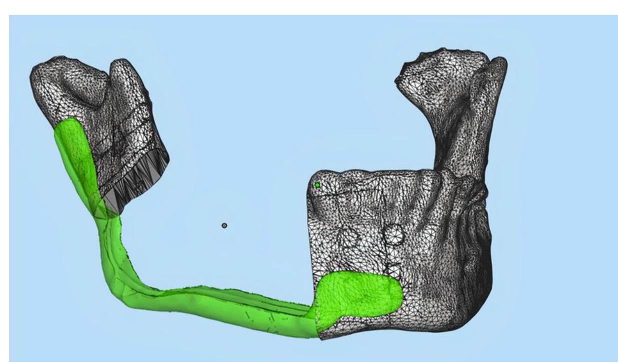

Fig. 4 Finite element analysis for the virtual implant design

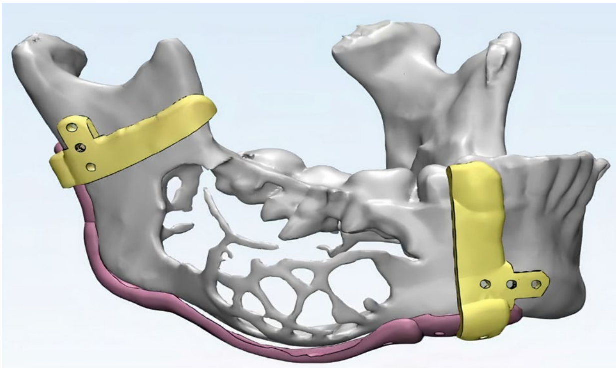

Fig. 5 Virtual Design of cutting guides and repositioning jig

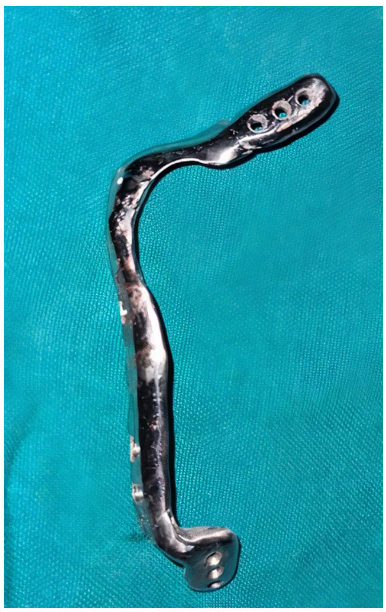

Fig. 6 Stainless steel Patient specific implant (PSI)

Fabrication of Prosthesis

The guide designs were exported to a 3D resin printer (*ProJet MJP 2500 W*) and fabricated using castable resin (*GC Corp.*), which were invested in silica (*Bellasun, Bego & Co.*) and placed in a furnace similar to the procedure followed for casting dental crowns. It was initially heated to 150º C to melt the resin and create a mold. Then, the temperature was raised to 930º C to burn out any residual wax [5]. Next, medical-grade stainless steel 316 was heated to a temperature of 1800º C and cast into the mold, created using vacuum casting. Weight reduction was made by drilling holes as designed after the FEA. The post-processing involved grinding, buffing, and polishing PSI to get a perfectly smooth finish (Fig. 6). Later, it was autoclaved at 121˚C and pressure of 15 psi for 15 min prior to its use in surgery.

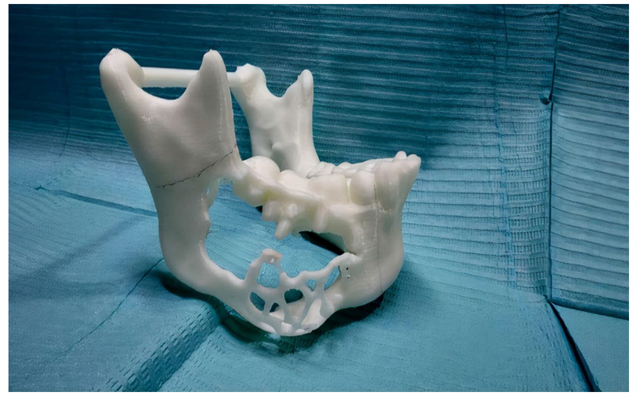

Fig. 7 Pre-operative surgical planning using 3D printed models

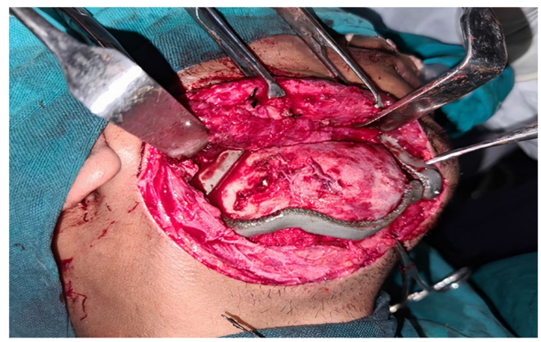

Fig. 8 Repositioning jig firmly fixed followed with cutting guides placed on either side of tumor

Mock Surgery

The entire surgical procedure was recreated to confirm a perfect fit of the reposition jig, cutting guides, and the PSI on FDM models *(*Fig. 7*)* fabricated using clear resin (*Formlabs*).

Virtual surgical planning and mock surgery revealed a continuity defect in the mandible of about 8 cm.

Surgical Sequence

Under General Anesthesia, the mandible was approached through an extraoral submandibular incision, and the soft tissue was reflected, exposing the entire buccal and lingual expanded body of the mandible. The mental nerve and inferior alveolar nerve were identified and carefully ligated during the procedure. The repositioning jig was fixed firmly, followed by the surgical cutting guides on either side of the tumor as planned (Fig. 8). The osteotomy was similarly executed as planned in the mock surgery, and the mandibular segment was excised. The marginal gingiva was also excised along with some areas

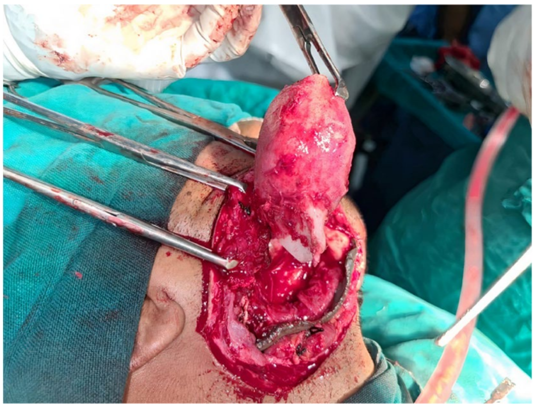

Fig. 9 Excision of the tumour with repositioning jig maintaining the length of the defect

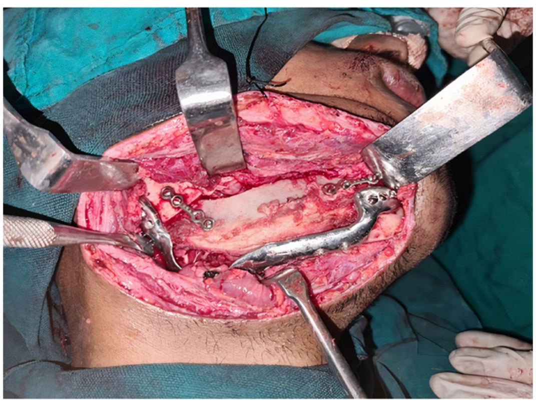

Fig. 10 Nonvascular iliac graft placed and PSI fixed in position

of mucosal perforation, followed by the removal of surgical cutting guides, leaving the stable lower border repositioning guide in place (Fig. 9).

The PSI was then placed in position, which adapted perfectly into the gap, held in position by the repositioning jig, and stabilized with 8 mm screws placed in the already drilled screw holes on the mandible. Three screws were placed on either side of the mandible. The repositioning jig was removed after checking for stability and mouth opening to ensure the condyle was in position. Later, a nonvascular iliac autograft was placed into the PSI concave slot and stabilized using mini plates to reconstruct the alveolar part of the mandible (Fig. 10). Finally, a drain was planted, and the wound was closed in layers to give an adequate soft tissue cover on the PSI.

Excellent patient satisfaction was attained postoperatively with uneventful recovery and no significant complications reported (Fig. 11).

Fig. 11 Post-operative frontal view showing satisfactory facial contour

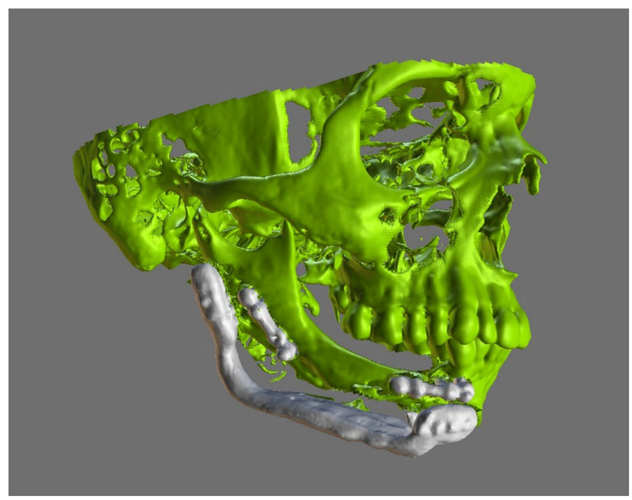

Fig. 12 Post-operative CT scans showing good stability of PSI with no hardware failure

Discussion

Computer-aided surgery continues to impact all areas of the surgical field, with maxillofacial surgery significantly benefiting from such technological advancements. Using this technology, the ability to three-dimensionally visualize a tumor in its entirety and its influence on the surrounding anatomy allows the surgeon to determine the resection procedure, plan for the reconstruction of the acquired defect [1, 2, 4], and anticipate the outcome for the same (Fig. 12).

Reconstruction of continuity defects using traditional pre-bent implants is challenging for any maxillofacial surgeon as it needs to reproduce the aesthetics and function of the mandible accurately. However, advances in imaging

Table 1 Relevant articles of past 10 yrs as found in dental literature categorised and summarized

Sl. no	Journal and author details	Study details	Evaluation done	Conclusion
A. *Biomechanical analysis of prosthesis Using FEA in mandibular reconstruction*				
A.1	Analysis of mechanical stress in reconstruction plates for bridging mandibular angle defects [10] *Wolf-Dieter Knoll et al 2006*	Evaluate the mechanical stress on screw-plate-bone interference in reconstruction plate in angle defects using FEA	Angle defect bridged by a titanium reconstruction plate was generated and exposed to chewing force evaluated by FEA	FEA revealed the stress from functional loading Hence, to optimise design of reconstruction plates stress can be decreased to half by increasing the diameter of screw threads by 1.5 times
A.2	Finite element analysis of customized reconstruction plates for mandibular continuity defect therapy [13] *Nathaniel Narra 2014*	Assess the design of two customized plates fabricated for reconstruction of the lower left mandibles of two ameloblastoma cases	The Chewing was simulated on FEA model of mandible and plates by applying mechanical forces corresponding to the muscles of the mandible	There is an influence of design on stresses induced in the bone at the screw interface leading to bone resorption and affecting the anchorage
A.3	The feasibility of a custom-made endoprosthesis in mandibular reconstruction: Implant design and finite element analysis [14] *Manuel Pinheiro 2015*	Feasibility of custom made endoprosthesis	FEA was used for validating the biomechanical behaviour of mandibular endoprosthesis for three masticatory tasks, namely incisal, right molar and left group clenching	Stress distribution in endoprosthesis was found to be similar to intact mandible Shows that it might be a reliable alternative to other prosthetic reconstruction in the mandible
A.4	Biomechanical evaluation of a novel hybrid reconstruction plate for mandible segmental defects: A finite element analysis and fatigue testing [15] *Cheng-Hsien Wu 2017*	Developed a novel hybrid recon plate with load bearing strength, secure bone transplant and maintain contour compared to a commercial straight recon plate	Finite element models of 2 mandibular defects using novel hybrid plate in one and commercial straight plate in another were generated for biomechanical fatigue testing	Stress in custom plate is 4.5 time more than hybrid plate and exceeded bone limit value Hence novel hybrid plate has superior mechanical strength
A.5	Implementation of Computer-Assisted Design, Analysis, and Additive Manufactured Customized Mandibular Implants [16] *Khaja Moiduddin 2018*	Customized an implant based on a patient's DICOM images that can precisely fit bone contours and can effectively withstand chewing load conditions	Simulated the mechanical behavior of chewing load conditions on 3D finite element model of implant and fabricated the final implant using electron beam melting and AM technology	The site of the maximum strain on Plate is away from the screw holes, therefore better stability and minor chances of screw loosening
A.6	Biomechanical Assessment of Design Parameters on a Self-Developed 3D-Printed Titanium-Alloy Reconstruction/Prosthetic Implant for Mandibular Segmental Osteotomy Defect [17] *Sheng-Ni Huang et al 2019*	To evaluate the biomechanical performance of a 3D printed titanium alloy implant for reconstruction of mandibular segmental defects	parameters assessed in FE models (1) Two prosthesis designs, one with complete resection and other with residual mandibular bone (2) Two lengths of prosthesis- 20 and 25 mm (3) Three thicknesses of prosthesis- 0.8, 1, and 1.5 mm A 45∘lateral bite force (100 N) was applied to the top of the prosthesis condition	The stress of implants that required complete resection was higher than the other prosthesis The stress of implants with a length of 25 mm was higher than 20 mm implant Implant stress decreased as implant thickness increased

Table 1 (continued)

Sl. no	Journal and author details	Study details	Evaluation done	Conclusion
A.7	Improving the biomechanical performance of screws fixation in a customized mandibular reconstruction prosthesis based on reliability measure [12] *Sahand Kargarnejad et al 2020*	To study the effect of number and layout of screws to increase strength of bone prosthesis interface	The biomechanical performance of screw fixation strength was done by finite element method	Increasing the number and layout of screws enhances the biomechanical performance of prosthesis connection at defect site strength of bone-prostheses interface increases by 13.7% by increasing one screw Customised prosthesis can be used to correct large lateral defects by modifying screw fixation strength
B. *Biomechanical analysis done using FEA for previous failed endoprosthesis*				
B.1	Optimal design of an individual endoprosthesis for the reconstruction of extensive mandibular defects with finite element analysis [18] *Peng Li et al 2014*	FEA was done to assess the biomechanical performance of PSI and explore available strategy for optimal design ofprosthesis	Previously used, failed endoprosthesis was evaluated to analyse potential cause of failure and final implant design was modified based on FEA	FEA approach can optimize the design of individual endoprostheses and give the reconstructed mandible improved biomechanical performance
B.2	Failure location prediction by finite element analysis for an additive manufactured mandible implant [4] *Jinxing Huoa et al 2015*	To investigate reason for failure and predict the mechanical properties of implant prior to surgery	Stresses produced during mastication were assessed on finite element model of patient's reconstructed mandible and implant	Comparison between stress concentration and region of fracture showed that implementing finite element analysis is useful for optimizing implant design
C. *Biomechanical analysis of prosthesis using topology optimization and FEA*				
C.1	Design of a patient-specific mandible reconstruction implant with dental prosthesis for metal 3D printing using integrated weighted topology optimization and finite element analysis [6] *Chia-Hsuan Li et al 2020*	Weighted topology optimisation was used to design a patient specific mandibular implant	Implant included a body,fixation wing and dental prosthesis which was subjected to topology optimization to identify optimal fixation wing structure which was then fixed on the resting acrylonitrile butadiene styrene (ABS) bone to perform fracture testing	There was decrease in the weight of optimal model from original model by 73.14% and provided good biomechanical performance
C.2	Design of Bone Plates for Mandibular Reconstruction Using Topology and Shape Optimization [19] *Michael Seebach et al 2018*	Evaluated the Patient specific bone plate by topology optimization	Design of the final bone plate was established using FEA and the areas of the plate were reduced using topology	Topology optimized bone plate decreased total implant volume by 44.9%,proved high flexibility, sufficient stabilization of the bone fragments, high stiffness and durability of the implants and also uneven load on screws was reduced by 73% preventing screw failure
D. *Reconstruction of mandible using PSIs without any biomechanical analysis*				
D.1	Patient Specific Three-Dimensional Implant for Reconstruction of Complex Mandibular Defect [20] *Vignesh U, 2019*	using patient-specific three-dimensional (3D) titanium implant for mandibular reconstruction	3D virtual planning was done and a customized implant was designed by superimposing the unaffected mandible on the defect side Evaluated for the improvement in mandibular function, facial esthetics and quality of life	PSI achieved a good facial profile, esthetics and dental rehabilitation preventing the complications associated with autologous grafts

Table 1 (continued)

Sl. no	Journal and author details	Study details	Evaluation done	Conclusion
D.2	Reconstruction of mandible using a computer-designed 3D-printed patient-specific titanium implant: a case report [1] *Khaldoun Darwich, 2020*	Case of a large mandibular tumor resection and reconstruction of customized 3D-printed titanium implant	Computer aided design of implant fabricated by CAD-CAM using DICOM images obtained from CBCT of patient	Postoperative evaluation showed good facial symmetry with normal mouth opening and no complaints in TMJ The pre-operative 3D planning provided higher accuracy and better outcome
D.3	Patient-specific implants for maxillofacial defects: challenges and solutions [2] *Nasser Alasseri et al 2020*	Experience with PSI and evaluation of patient satisfaction	Six cases with maxillofacial defects were included 10 implants were fabricated where PEEK was used in 8, while titanium was used to fabricate 2 implants	No complications noted and patients reported a high level of satisfaction both functionally and cosmetically

modalities, improvements in CAD-CAM designing, and improved additive manufacturing techniques have facilitated the fabrication of customized PSIs for reconstructing complex defects**.** [1, 2, 6] Compared to traditional approaches, it emulates the healthy side and offers the advantage of better accuracy, more accessible surgical adaptation, and customization, which significantly improves the patient's aesthetics producing satisfactory results.

In our case, we proposed a hybrid approach with a combination of autogenous bone graft in the alveolar part and a stainless steel PSI [7–9] for the lower border contour that offered us the dual advantage. It is also imperative to balance the weight of the prosthesis, its contour, and its stability on fixation after mandibular resection, as a suboptimally designed PSI can create a local concentration of stresses leading to the fracture of the prosthesis and excessive mandibular resorption to a surgical failure of the implant in the long term due to masticatory forces on mandibular stumps [1]. Thus, biomechanical analysis prior to surgical placement allows us to predict these areas of excessive stress accumulation and modify the design accordingly, therefore balancing the prosthesis's weight to fabricate the implant's optimal design [6]. In present case, biomechanical analysis of the PSI with an affirmation of prosthesis design was done using FEA.

It was reported that FEA could reduce the mechanical stress to half by increasing the diameter of the screw threads by 1.5 times when used for screw plate interference in reconstruction plated for angle defects [10]. Similarly, when used to improve the strength of bone prosthesis, it showed a significant effect on the biomechanical performance of the connection at the mandibular defect site [11].

We had also assiduously reviewed dental literature of the past ten years using Pubmed and Medline database sources with the keywords Patient-specific implant, mandible continuity defect, FEA, and biomechanical analysis. As a result, relevant articles were found and categorized into four groups, summarized in Table 1.

Relevant articles were found which have done biomechanical analysis using FEA and topology optimization to compute the masticatory stress, predict the longevity, and prevent the biomechanical failures of the prosthesis. On the contrary, only few articles were found without any biomechanical evaluation using FEA or other evaluation methods to optimize the PSI design or validate its efficiency. However, long-term analysis was not observed in these articles to draw any further conclusions.

To the best of the author's knowledge, despite the various studies documented in dental literature on PSIs, this is the first report to evaluate stainless steel PSI for mandibular continuity defects fabricated using a metal casting process. In addition, this bioinert material is relatively inexpensive and has been used for orthopedic [12] and maxillofacial implants

[8, 9] for a long time. Furthermore, due to the similar advantages to other PSI, it can act as a suitable alternative treatment modality for those patients who cannot afford a more expensive implant like titanium, hence providing the use of the latest technological advances in surgery at an affordable cost.

The present case report not only fabricated a low-cost surgical guide using investment casting, repositioning jig, and an affordable, biocompatible PSI but also optimized and validated the design with a biomechanical analysis using FEA. This reinforces that optimization of the design using FEA can improve the biomechanical performance and minimize the risk of mechanical failure, forming a valuable addition to computer-assisted mandibular reconstruction surgery.

In our study, use of FEA helped to inspect the potential weakness and stress distribution through out the implant. Due to this there was no sign of hardware failure or screw loosening even after 2 and half years of treatment.

Post-operative evaluation showed good facial symmetry with normal mouth opening and no complaints in mastication/ TMJ problems. Post-operative CT scan has been taken which suggests accuracy and stability of PSI with continuity of lower border of the mandible. not be prosthetically rehabilitated

Patient could not be prosthetically rehabilitated due to financial constraints on his part.

Funding None.

Declarations

Conflict of interest None.

Ethical Approval This article does not contain any studies with animals performed by any of the authors. All procedures performed in study involving human participant were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. The study is approved by Institutional Ethical committee of Navodaya dental college and Hospital, RGUHS University.

Informed Consent Informed consent is obtained from the participant included in the study.

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