



Evaluation of failure of a titanium conventional plate in mandibular reconstruction and improve the performance with fibula free flap

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ABSTRACT

Maxillofacial extensive defects are caused by various factors such as tumor, osteomyelitis and trauma. Reconstruction of such injuries become a major challenge for maxillofacial surgeons. Clinical experiments indicate that one of the serious problems associated with conventional plate systems is the frequent incidence of complications such as screw loosening, plate exposure and plate fractures. To improve the performance of reconstruction system with new procedure. A 42-year-old male patient suffering from Ameloblastoma tumor in the lateral large defect was selected as case study. Initially, after cutting the cancerous tissue, a titanium conventional plate (TCP) model had been utilized as mandibular reconstruction system which failed due to plate exposure.

Patient's CT-scan images were prepared, and geometry and shape of the plate were evaluated using computer-aided design & computer-aided manufacturing (CAD/CAM) and additive manufacturing (AM) technology. Then, its effect on the biomechanical performance of the failed system TCP model was investigated by finite element method (FEM). Fibula Free Flap FFF model as alternative and improved reconstruction system was selected. FEM evaluation of two models showed inevitable results which tip the scales in the favor of FFF model. The maximum Von-Mises stress had been exerted at the interface between screw-cortical bone. In TCP model, the peak value of Von-Mises stress exerted at the interface between screw-bone was 110 MPa, which exceeded the yield strength of the cortical bone, while, this factor fell to 68 MPa in FFF model. Furthermore, comparison with TCP model, the sensitivity of the plates and screws to the chewing load variations in FFF model decreased 20%. The results showed that the FFF model was more stable and flexible than the TCP model.

Keywords: Mandible reconstruction; Fibula free flap; Computer-aided design & computer-aided manufacturing (CAD/CAM); Finite element method (FEM); Loading sensitivity analysis.

Introduction

Maxillofacial extensive defects are caused by various factors such as tumor, osteomyelitis and trauma as well as genetic and congenital factors [1]. Malignant and benign tumors can cause structural and functional abnormalities in this organ. Surgeons

should first resect and remove the cancerous tissue causing a large defect in the mandibular bone [2]. Reconstruction models affect beauty and function of the mandible. Therefore, reconstruction of such injuries become a major challenge for maxillofacial surgeons [3]. Reconstruction can

be carried out using different methods including vascular and free bone grafting, titanium plates application, bone marrow transplantation and tissue engineering [4,5]. One of the most common methods is the use of titanium plates attaching to the two parts of the mandibular bone via screws. This type of treatment plan is commonly known as titanium conventional plate reconstruction system. Evidence has showed a significant percentage of these reconstruction systems failure and deterioration over time. The system mechanical failure modes are equivalent to ability loss due to mechanical factors. In most cases, systems failure and deterioration include plate fracture and exposure as well as screw fracture and loosening [6-8].

Vascularized bone graft is one of the practical methods of mandibular reconstruction systems, in which iliac crest, radius forearm, scapula, and fibula are the most common donor sites [9]. A combination of factors impacts on the selection of the donor site such as patient's state of the health, location and size of the defect of the mandible bone, to name but a few [10]. Surveying the literature of subject showed that Hidalgo [11] was the van of utilizing this method. He repaired damaged mandible bone using some pieces of the fibula free flap (FFF). Comparison with other methods of vascular free flap, FFF is more beneficial and successful [12-14]. In this regard, CAD/CAM and AM technologies assist surgeons greatly. Because these techniques help surgeons to examine virtually the patient's mandible before surgery and plan it ahead accurately in a short space of time.

The performance of treatment plans can be evaluated through their components biomechanical behavior examination by mechanical tests and finite element method (FEM). In this regard, many of researches has been brought about to study the biomechanical behavior of plates and screws in the mandibular reconstruction system. However, considering the high number of failures in these systems, there is an increasing need for further studies to provide new solutions [15-17]. Lee et al., (2014) [4] have conducted a research on conventional reconstruction system performance improvement using the FEM. Using this method, it has been shown that the stress distribution decreases with increasing plate height and thickness. Al-Ahmari et al., (2015) [18] have investigated the effect of customized plate shape on the reconstruction system performance with the aid of FEM. They showed that plate shape modification can lead to a reduction in the strain level at the contact surface between the screw and mandibular cortical bone as well as a decrease in the plate stress

resulting in the system performance improvement. Nathaniel et al., (2014) [19] have also studied the customized plate reconstruction system performance using FEM and reported that the plate geometry design alteration affects the induced stress on the plate and screw. Moreover, high non-physiological strains at the bone-screw contact surface result in surrounding bone small injuries and resorption and consequently reduce screw connection leading to screw loosening. Previously, Sato et al., (2012) [20] and Erkmen et al., (2005) [21] have compared the performance of various types of mandibular reconstruction systems using FEM as an indicator of plate stress and strain level. Reportedly, different models have been proposed to simulate the chewing process. In some cases, the components biomechanical behavior has been studied considering the two condyles as a fixed support along with vertical load induction on the molars [22] and the chewing process has been analyzed through applying active muscle forces in some other cases [23,24]. In present study, a failed reconstruction system of titanium conventional plate (TCP) is investigated and a fibula free flap reconstruction model which has been designed with CAD/CAM is replaced with failed one. Performance of the systems are compared through FEM and finally, sensitivity of both systems are analyzed.

Materials and Methods

The studied case is a 42-year-old male patient with osteosarcoma on the lateral of the mandible. After cancerous tissue resection and removal, reconstruction was performed using the conventional method and the system failure occurred due to plate exposure (Fig. 1).

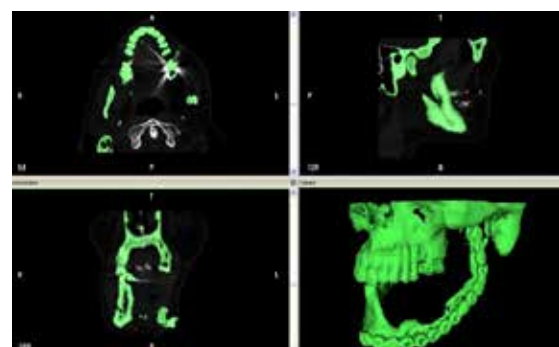


Fig. 1. The titanium plate exposure can be observed (arrow) using Mimics 20.0 software.

- Image processing and 3-D model

Initially, computed tomography (CT) images of the patient's craniofacial skeleton, with 1.0mm slice thickness and 512*512-pixel image resolution, was prepared and imported into MIMICS (version 20.0, Materialise,

Leuven, Belgium), with dicom (Digital Imaging and Communications in Medicine) format file. Isolation of the mandible and soft tissues was done by Hounsfield scale (range: 224-3071 HU) on the basis of threshold. A 3-D file of patients' craniofacial with STL format was generated. The 3-D model prepared by fused deposition modeling (FDM), and produced by 3-D printing (Quantum Generous Persia 3d printer) (Fig. 2).



Fig. 2. A 3-D model of the patient's artificial mandible made by the additive manufacturing technique.

- Reconstruction models

After that, the components of both systems were created in SolidWorks 2018 Software and the model of the two treatment plans was prepared after assembling the components. The two treatment plans the components specifications are as follows:

A) TCP model: This was included titanium plate with a thickness of 2.0mm and width of 9.0mm having 15 holes with six 2.7 x 11.0mm bi-cortical screws (3 screws on each side) are shown in (Fig. 3A).

B) FFF model: The FFF model was consisted of three fibula-flaps connected by three 2.0mm bi-cortical screws to a titanium plate with a thickness of 2.0 mm and width of 6.0mm having 21 holes. This set was mounted to the mandible by 8 bi-cortical screws (2.0x11.0mm) are shown in (Fig. 3B).

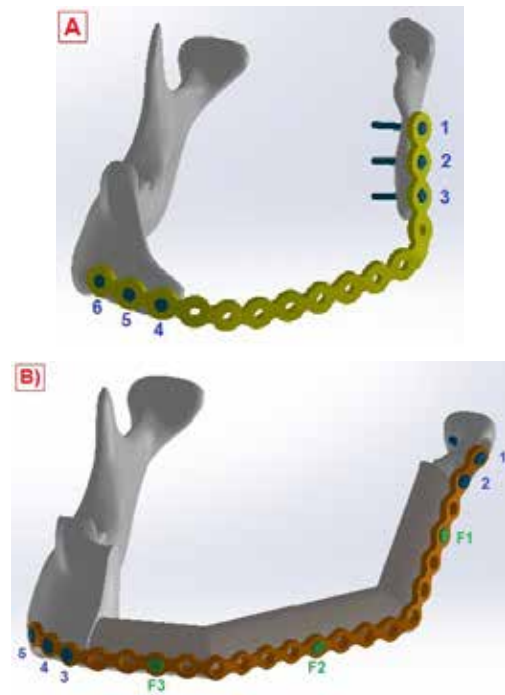


Fig. 3. Modeling of the treatment plans: A) TCP model, B) FFF model.

To increase the surgical accuracy and to be ensured about the correct selection of reconstruction system, a 3-D model of the patient's mandibular anatomy was constructed using additive manufacturing technique. Surgeons can choose the best treatment plan regarding the patient's situation through a 3-D model of virtual surgical planning [15]. Therefore, FFF model was suggested for re-treatment. Since length and angles of the flaps should be based on the patient's mandibular anatomy, the fibula cutting guide was designed and constructed using CAD/CAM method. The plate forming template is prepared in accordance with the assembled flaps and the patient's mandibular anatomy, so the surgeon can prepare the proper plate form, preoperatively (Fig. 4).





Fig. 4. The process of designing a free flap treatment plan.

- Material characteristics

The mandible and fibula-flaps are consisted of cortical and cancellous bones. The screw and plate components in two models were made of a titanium alloy (Ti6Al4V). According to Table 1, the behavior of these materials is assumed to be homogeneous, isotropic and linear elastic [25-28].

- Boundary conditions

The performance evaluation of the two models was assumed at the osseointegration stage. It was also presumed that complete and linear behavioral contacts are established between all surfaces of two parts of the cortical and cancellous bones, screw, plate and bone [16-18,29]. To simulate maximal chewing force, a vertical force (300 N) was directly induced on the molar tooth. The displacement in the two condyles in all three directions was assumed to be constant [16,18].

- Finite element method analysis

The actual patient's mandibular model was used to examine stress analysis in two treatment plans. The model meshing was very difficult due to complex geometry of the reconstruction system. The use of large and medium size elements was not possible for this model and fine elements application could increase the computational time. The mandible, plate and screws were modeled using 4-nodes tetrahedral elements with sizes ranging from 0.5 to 1mm.

- Model validation

The validation method in this study was based on the comparison of the results of laboratory simulation with the FEA results of polylactic acid ISO 10993-5:2009 [30] based synthetic mandibular model constructed through an augmentation method. To perform the mechanical test, a fixture with dimensions similar to those of the artificial mandible was designed and constructed. In this test, the condylar region was completely

fixed, displacement (1mm/min) was induced on the molar tooth using a lever and the amount of induced force and displacement was recorded during the loading process (Fig. 5). The induced force of the system was measured 300 N at a displacement (2.34mm). In conditions similar to the model prepared to be analyzed by COMSOL software, when the system reached the vertical force (300 N), A 2.47mm displacement was obtained. Considering the range of laboratory samples, this displacement was acceptable and therefore, the model was valid in terms of real sample behavior simulation.

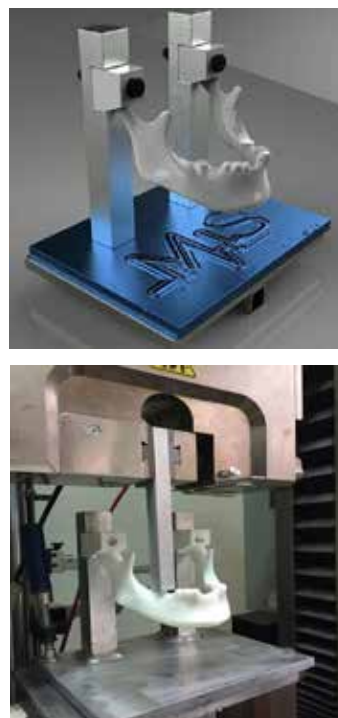
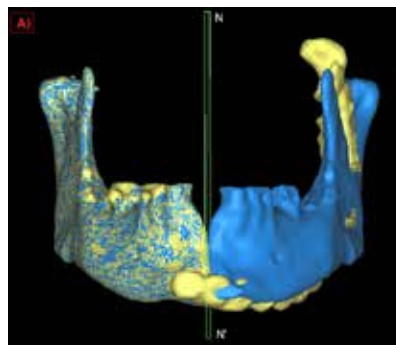


Fig. 5. Biomechanical test used for model validation.

Findings

Fig. 6 illustrates the state of the failed TCP model and complete disregard for the length of the damage in plate design which has caused replacement of condylar (15mm) from mandibular fossa.



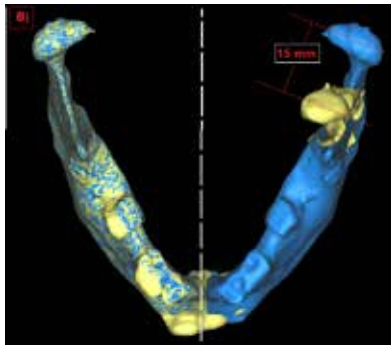


Fig. 6. A) The mirrored mandible and, B) replacement of condylar from the location of fossa.

The present study investigated the performance of two mandibular reconstruction systems using FEA method as well as the biomechanical behavior of system components. TCP model was a conventional reconstruction titanium plate system being failed due to plate exposure. To replace FFF reconstruction system an alternative treatment plan was chosen and surgery

was carried out. The CAD method and 3-D printing were then used to design and construct surgical guides and templates. The most critical Von-Mises stress values were observed at the contact surface between the screw and cortical bone in the TCP model at screws No. 4 and No. 1 (110 and 85 MPa), respectively. Also, the highest stress vales were seen at screws No. 1 (68 MPa) and No. 2 (38 MPa) of the FFF model (Fig. 7).

Material	Young's modulus (GPa)	Poisson's ratio
Cortical mandible bone	13.70	0.3
Cancellous mandible bone	1.37	0.3
Cortical fibula bone	28.60	0.3
Cancellous fibula bone	1.65	0.3
Ti-6Al-4V ELI	108	0.3

Table 1. Properties of material used in two models.

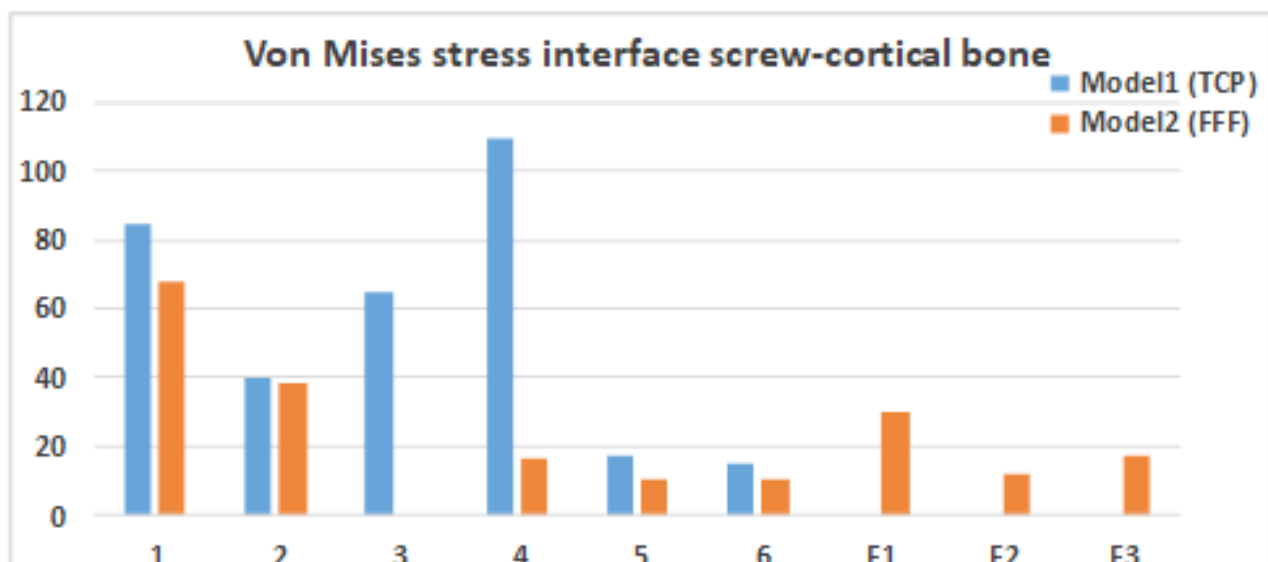


Fig. 7. Stress distribution at the screw-cortical bone contact surface (MPa). A) TCP model; B) FFF model.

As shown in Fig. 8A, the maximum Von-Mises stress (580 MPa) was occurred on the TCP model plate, at the back bent portion of plate and between holes 3 and 4. Moreover, in FFF model, the maximum stress value (277 MPa) was observed at the front bent portion between holes 1 and 2 (Fig. 8B).

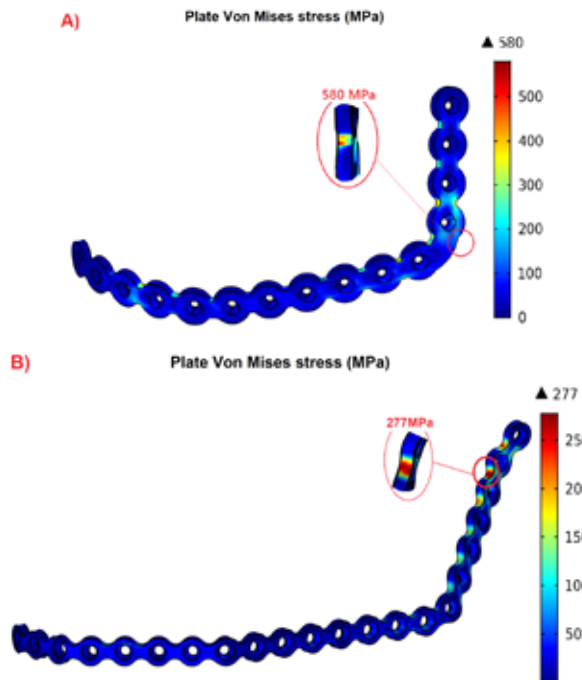


Fig. 8. Von-Mises stress distribution on plate. A) TCP model; B) FFF model.

- Loading sensitivity analysis

Muscle forces can vary in size and direction during the chewing process based on each person bony structure and foods with specific structural and mechanical properties can produce different forces. Therefore, loading sensitivity analysis was performed on two reconstruction systems components via changing the loading values by 30% [18]. The aim of loading sensitivity analysis was to determine the least sensitivity of treatment plan's plate and screws to loading changes during chewing. The vertical force along the Z axis was increased by 10% and two condylar regions were assumed fixed in three directions. Table 3 shows the variation values in the induced force. The maximum Von-Mises stress on plates and screws in two models was obtained with 10%, 20% and 30% variations following muscle force induction.

Fig. 8 shows the effect of 10%, 20% and 30% increases in the vertical loading force induced on the molar tooth on the percentage of maximum Von-Mises stress variations of plates and screws in two treatment plans.

	Force increase (%)	TCP model		FFF model	
		Max. plate stress	Max. screw stress	Max. plate stress	Max. screw stress
1	0	580	110	277	68
2	10	669	125.5	300.8	73.7
3	20	767.5	141.5	324	80.4
4	30	752	164.8	350	87.4

Table 3. Maximum stress in components of two models following induced force changes.

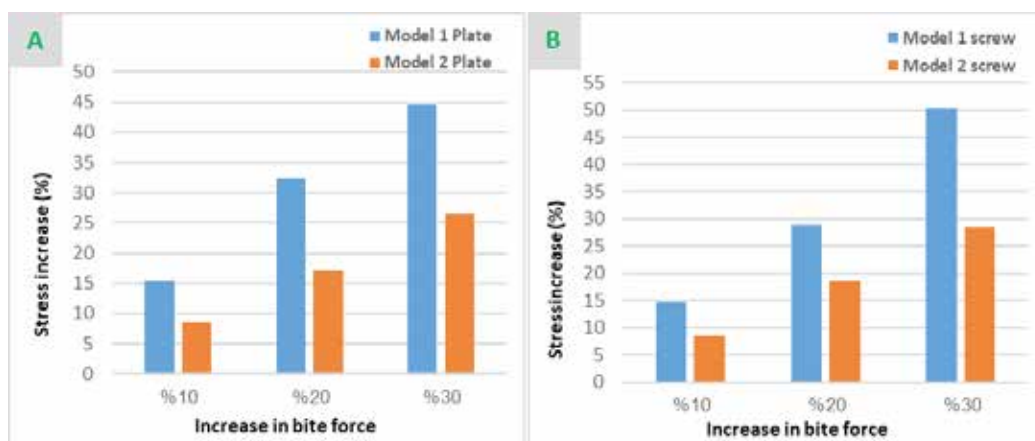


Fig. 9. Effect of force increase on Von-Mises stress of two models, A) Plate stress, B) Screw stress (%).

Discussion

Statistical evidence regarding mandibular reconstruction systems performance has indicated significant percentage of failures in these systems. Hence, the study of these systems performance affected by biomechanical behavior of their components is crucial. Accordingly, computational methods and mechanical tests have been used to evaluate these systems components behavior. The stress distribution in the screws can vary regarding damage type and stabilizer position. The screw-cortical bone surface contact stress value elevation (more than cortical bone yield strength; above 85 MPa) can cause bone resorption leading to screw loosening and deterioration. Thus, the plate and screw stress can be considered as a failure indicator.

Examination of the stress distribution of contact surface between screw and cortical bone showed that the maximum stress in TCP model was 110 MPa, which was higher than the cortical bone yield strength causing screw loosening. Consequently, it can be concluded that poor plate-mandibular bone connection can be one of the most important factors involving in plate exposure in the mandibular reconstruction systems. To overcome this defect, the treatment plan should be designed in a way to increase the number of screws or to use screws with higher diameter. The screw diameter in TCP model was 2.7mm, which was not much different from the maximum available screw diameter (3 mm). Based on this concept, the reconstruction system was designed in a way to be able to fasten more screws than previous plan to strengthen the connection. The number of screws was increased from 6 screws in TCP to 8 screws FFF model through attaching fibula-flaps at the mandibular defect site enabling a reduction in the screw diameter to 0.2mm due to better plate-bone connection.

The plate bending in TCP model was performed traditionally based on trial and error manner, therefore, the dimensions and shape of the plate were not suited for the patient's mandibular anatomy. While, the plate forming template used in FFF model was designed and prepared preoperatively according to the patient's mandibular contour with the aid of modern CAD technologies. Using this method, surgeons can be able to bend the plate precisely before operation with the aid of template based on the shape and anatomy of the patient's mandible. Sensitivity analysis also showed that plates and screws in TCP model were more sensitive to loading changes than FFF model. Accordingly, it can be concluded that the components of FFF model

reconstruction system have better flexibility than TCP. Figure 10 shows the clinical long-term success of the FFF model. No complication occurred in this model after 12 months follow-up.



Fig. 10. Photographs 12 months after surgery.

Conclusion

To sum up, one can conclude that inattention to the patient's anatomy in plate design is the most compelling reason for plate exposure in common TCP model which bring about unwanted outcomes such as loosening in screws performance. Collectively, the FFF model plus computer-aided design technique is more preferred than the conventional titanium plate in terms of stability and durability in extensive mandibular injuries reconstruction. Further, considering the stability of this system, plates with finer width can be used to facilitate the plate bending process. It should be noted that use of CAD/CAM technique in the reconstruction process has a significant impact on the beauty and appearance of the mandible. Free flaps application based on the height of remaining molar teeth in the mouth will allow the patient to use dental implants in the affected area after healing improving the patient's life quality after treatment.

Conflict of Interest

There is no conflict of interest to declare.

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