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Improving the biomechanical performance of screws fixation in a customized mandibular reconstruction prosthesis based on reliability measure

Sahand Kargarnejad [1], Farzan Ghalichi [1*], Mohammad Pourgol Mohammad [2], Ata Garajei [3]

1. Faculty of Biomedical Engineering, Sahand University of Technology, Sahand, Tabriz, Iran.

2. Department of Mechanical Engineering, Sahand University of Technology, Sahand, Tabriz, Iran.

3. Department of Oral and Maxillofacial Surgery, School of Dentistry, Tehran University of Medical Sciences, Tehran, Iran; Department of Cancer Institute, Imam Khomeini Hospital Complex, Tehran University of Medical Sciences, Tehran, Iran.

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**Corresponding author:*
Farzan Ghalichi

Faculty of Biomedical Engineering, Sahand University of Technology, Tabriz, Iran.

Tel: +98-41-33459420
Fax: +98-41-33459490
Email: fghalichi@Sut.ac.ir

ABSTRACT

Background: The customized prosthesis is a new method for the reconstruction of large mandibular defects. The ability of dental rehabilitation to improve masticatory functions while maintaining the aesthetics of the main anatomy of the patient's jaw. But the most important problem with all custom prosthesis is the poor performance of screw fixation strength the connections at the bone-plate interface.

Materials and Methods: This study was performed to investigate the effect of the number and layout of screws to improve the strength of the bone–prosthesis interface. Due to the inherent variability of input parameters, Analysis of the biomechanical performance of screw fixation strength, a probabilistic finite element method approach has been used. Random input parameters include mechanical properties of the cortical bone, cancellous bone, titanium alloy (Ti6Al4V), and bite force. The layout of the screws was designed in 6 models. Criteria for evaluating the biomechanical performance of screw fixation strength include maximum stress and strain of von Mises cortical bone around the screws. The Monte-Carlo method was used for finite element simulation.

Results: The most critical screw in all models is screw No.1, which by increasing the number of screws and correcting the layout shape, the values of maximum stress and strain in the bone around screw No.1 has decreased by 26.7% and 46.3%, respectively, and increased the reliability of the screw connection performance by 25% and 28%, respectively.

Conclusion: Finally, in the reconstruction of a large lateral mandibular defect by the customized prosthesis, the strength of the prosthesis to connect to the remaining mandible bone can be improved by increasing the number and modifying the layout of the screws.

Keywords: Mandible reconstruction; Customized prosthesis; Probabilistic finite element method; Reliability.

Introduction

Large mandibular defects are caused by tumor resection factors, trauma, and congenital disease [1]. Various methods include free and pedicled bone grafts, plate reconstruction tools, and hardware tools [2]. Fibula Free Flap is a vascularized bone graft method and is a suitable method for repairing large defects [3], but it has limitations and is not suitable for patients with microcirculatory disease or advanced cancer [4].

It also causes movement complications in patients' lower limbs after surgery and cutting the fibula bone [5]. The method of using metal plates without bone grafting is a common method for mandibular reconstruction, with a significant percentage of failure reported after surgery [6,7]. The high rate of failure of reconstruction systems, especially in the lateral region, including plate fracture, plate exposure, and loosening of the screw has been reported [8]. The most important goal of reconstructing large mandibular defects is to improve masticatory functions while maintaining the aesthetics of the patient's face [9]. Dental rehabilitation is a major problem in mandibular reconstruction procedures. In customized prosthesis, this problem has been solved by designing holes that can be installed by the abutment [10]. Titanium customized prosthesis fits the anatomy of the patient's jaw can be fabricated using the computer-aided design (CAD) method and the three-dimensional (3D)-printing technique. This method is weak in the strength of the bone-prosthesis interface by screws fixation [11].

Studying the biomechanical behavior of the components of mandibular reconstruction systems is widely used according to the literature. This method is a deterministic numerical calculation method [12,13]. Input parameters such as material properties, loading conditions, and component geometry are considered constant. But in fact, the input parameters have inherent variability. A safety factor is used to cover this uncertainty that creates conservative limits for the design values [14]. This study was tried to improve the layout design and the number of screws to increase the strength of the bone–prosthesis interface to reconstruct a large lateral mandibular defect by a customized prosthesis with higher reliability. Therefore, a probabilistic approach has been used to study the biomechanical performance of the customized prosthesis model, which considers the uncertainties of variables using statistical distribution.

Materials and Method

The simplified three-dimensional (3D) defect mandibular model is extracted from Computed tomography (CT) images of a patient's jaw by MIMICS software. Hounsfield Unit (HU) cortical and cancellous bone were modeled by changing the threshold. The defect is selected in the lateral mandibular region and the most critical type of defect is class (I) Brown's classification for mandibular defects after oncological resection [15]. A customized prosthesis was designed using CATIA software and tailored to the anatomy of the patient's mandible and by modeling the placement of teeth on the intact side of the mandible, holes were designed for placing the dental on the prosthesis (Figure 1). The prosthesis is installed in the defect area precisely and from the condyle side with two screws. On the other side of the mandibular bone, the layout of the screws is designed in six positions according to the area of the prosthesis surface. In all models, bicortical screws are modeled in a cylindrical shape with an outer diameter of 2.0mm, which can be seen in Figure (2).

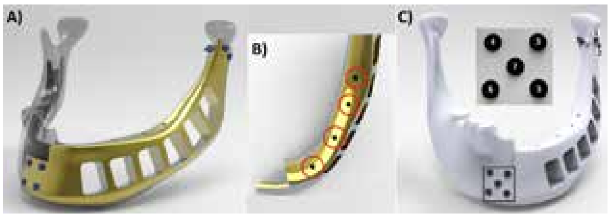

Figure 1. A) Customized prosthesis model, B) design of dental implant installation sites, and C) The numbering of screws holes.

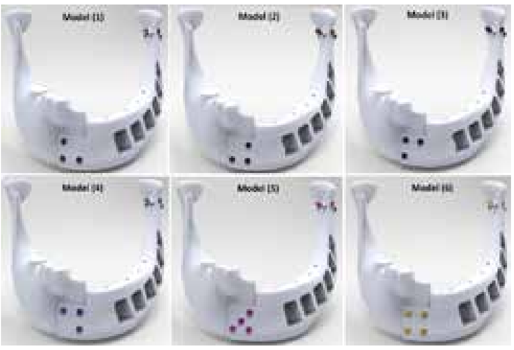

Figure 2. Six models of various modifications layout of screws for connection the prosthesis in rest mandibular bone.

- FE model of the mandibular customized prosthesis.

Failure analysis of six models with different types of screw layout is performed by finite element method (FEM). All components of the model were considered homogeneous, isotropic, and linear elastic. The mean values of the random variables applied to the finite element analysis are listed in Table 1 [16-18].

Input variables	*Mean*	*SD*	*Distribution*	*Reference*
Young's modulus of (Ti6Al4V) (GPa)	*110*	*3.5*	*Lognormal*	*[16]*
Young's modulus of Cortical bone (GPa)	*16.315*	*2.28*	*Normal*	*[17]*
Young's modulus of Cancellous bone (GPa)	*0.493*	*0.26*	*Lognormal*	*[17]*
Vertical occlusal Bite Force (N)	*300*	*102*	*Normal*	*[18]*

Table 1. Random variables and their distribution.

The bone, plate, and screw models were divided into 10-node 3-D tetrahedral elements with sizes 0.50mm (Figure 3A). The element size was chosen using a convergence analysis. The interface between all the materials is defined by using the "bonded" contact type in COMSOL 5.4. The chewing function is applied to the molar with a vertical force of 300 N and it is assumed that the upper surface of the two condyles is fixed in three directions (Figure 3B). The type of loading and analysis was evaluated using modal method [19,20].

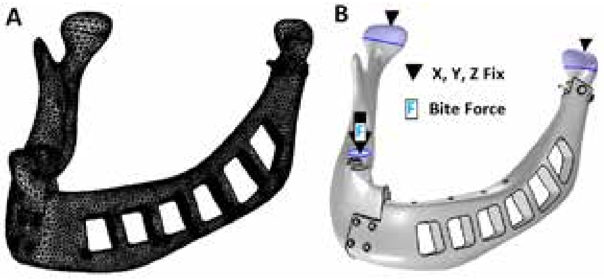

Figure 3. (A) FE model of the cemented hip prosthesis, (B) the boundary conditions applied.

- Probabilistic analysis of the customized prosthesis. Due to the presence of random factors in the failure mechanisms, the Probabilistic Physics of Failure (PPoF) method is used to apply the uncertainties [21]. Due to the inevitable stochastic variations, some factors involved in the failure process of the mandibular reconstruction system were identified by the finite element method. Model uncertainties can be calculated using probabilistic methods. In this analysis, the indictor of the strength of the bone-prosthesis interface is the maximum strain, and von Mises stress is located in the cortical bone around the most critical screw in all models. According to Li et al. [22], when the amount of stress on the bone around the screw exceeds the yield strength of the cortical bone, it causes the bone resorption around the screw, resulting in the loosening of the screw. Also, by evaluating the relationship between the amount of strain and the change in bone tissue around the screws, the performance of the screws can be predicted. Probabilistic physics of failure is a very useful approach in which uncertainties sources are incorporated into the failure physics method. The probabilistic response to the reconstruction system is as equation (1) [23]:

$$s\ (X)=s\ (X_1.X_2.....X_n) \tag{1}$$

Where the s(X) is the stress generated in an element and X_i (i=1.2.⋯.n) symbolizes the random variables of the model.

In this probabilistic analysis, a variety of models were considered from 4 random variables including applied bite force, Young's modulus of the cortical bone and cancellous bone, and Young›s modulus of titanium. The performance function of screw fixation strength in all models can be written as equation (2):

$$\begin{aligned} &g\ (X)=S\ (X)-s\ (X) \\ &F=\Pr\ (g\ (X)\leq 0) \end{aligned} \tag{2}$$

Here, s(x) stress is applied and S(x) represents strength. g(X) symbolize the biomechanical performance functions of the screws. In Equation (2), F represents the probability of system failure:

$$F=\iint\dots\int_{g(xi)<0} f\_X\ (x_1.x_2.\ \dots.\ x_n)\ dx_1.\ dx_2.\ dx_n \tag{3}$$

which f_x $(x_1\ x_2.\ \dots.\ x_n)$ is a function of the probability density, and $g(x_i)\leq 0$ is the failure area. This equation is known as the basic equation of reliability. The reliability of reconstruction systems is calculated using the Safety Margin (SM) factor. The reliability of all the mentioned systems is calculated and compared using Equation (4).

$$\begin{aligned} &SM=\ (E(S)-E(s))/\sqrt{}(var(S)+var(s)) \\ &R=1-\ \Phi(SM) \end{aligned} \tag{4}$$

In fact, the SM factor indicates a relative change between mean stress and strength and there is a direct relationship between this factor and system reliability. In other words, the high values of the SM factor indicate the high reliability of the system and R represents the reliability of the system [21]. In the above relation (E(s), var(s)) and (E(S), var(S)), which are taken from the normal distribution, represent the mean, variance, stress, and strength, respectively. φ=(SM) Cumulative Distribution Functions. The normal standard with Z=SM and R indicates the reliability of the system at that stress level. In this study, the probabilistic strength distribution function of cortical mandibular bone is obtained from the results of the literature. Strength cortical bone is assumed to be a normal distribution in the range of 141±28 MPa with a 95% confidence level and will play the role of strength in Equation (1) [24]. Evaluation of the reliability of various models based on the strain criterion, the range of strain range Normal physiological range between 100-2000μm/m is considered successful [25].

In all models, the critical position of the screws in terms of stress and strain created at the level of contact with the bone occurred in the screw No.1. The values of the random variables were determined according to the uncertainties governing the issue from the literature. Therefore, Young's modulus cortical bone and the amount of bite force are assumed to be a normal distribution [17,18]. Young's modulus cancellous bone and Young's modulus titanium alloy are also considered as normal log distributions. The characteristics of the distributions are summarized in Table (1) [16,18]. All of the above hypotheses were used for calculations using probabilistic finite element analysis. Then, to convert the failure physics model into a probabilistic failure physics model with uncertainty features and estimation of random parameters, it was determined. For each model, the simulation was calculated using the Monte-Carlo method and considering all variables using the finite element method. 1000 samples were used to analyze each model and the maximum stress and strain in the cortical bone around the critical screw were separately calculated and compared.

Results

- Results from the modal analysis

Table 2 and Figure 4 show the results of the first four modes natural frequency of the model (6) using modal analysis. The ratio of the applied occlusal load time to 1 second [26] to the longest natural frequency (3.7ms) was about 269.98 which this ratio is more than about four [19,20]. Therefore, the loading of the mandibular reconstruction model can be considered as the quasi-static and static analysis is acceptable, as confirmed by other researchers [1,13,22].

Figure 4. First four mode shapes of the customized prosthesis model 1.

Modal Number	*Mode 1*	*Mode 2*	*Mode 3*	*Mode 4*
Natural frequency (Hz)	*269.98*	*732.03*	*1058*	*1811.9*

Table 2. Four natural of customized prosthesis model (6) associated with natural modes.

- Results from the deterministic analysis.

To better understand the effect of parameter variability on the performance of mandibular reconstruction models, first, a deterministic finite element analysis was performed using the mean of random variables (Table 1) as input parameters for model analysis. Several failure states for the screw fixation strength have been proposed in the literature [22,27]. This study, two criteria of maximum stress and strain at the interface between cortical bone-screw No.1 (the most critical screw) have been considered. The maximum stress and strain in the two models 1 and 6 as shown in Figure 5.

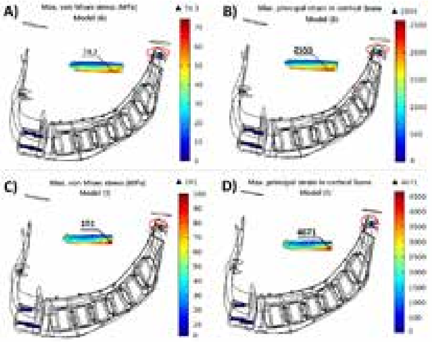

Figure 5. Max. stress and strain at the interface between screw-cortical bone (MPa) and (μm/m): A,B) Model 6; C,D) Model 1.

Table (2) shows the maximum stress and strain in the cortical bone around the screws for the six layout models of the screws by the finite element method. The highest stress and strain in model 1 and L-shaped layout mode with 3 screws are 101MPa and 4671μm/m, respectively, and the lowest stress and strain in and square layout mode with 4 screws are 74.3MPa and 2555μm/m, respectively. The amount of stress created in 4 models with 3 screws is significantly higher than models 5 and 6. In other words, the maximum stress created in the cortical bone around the critical screw for each of models 2, 3, 4 and 5 is equal to 97, 88.3, 86.8 and 76.3 MPa respectively.

- Results from the probabilistic analysis.

The reliability of mandibular reconstruction models was investigated using the stress model of the failure physics method and by applying the available uncertainties sources to the Monte Carlo method and by using the finite element analysis computational tool. Tables 3 and 4 show the mean, standard deviation, and reliability results of the connection performance in each model based on the maximum stress and strain in the cortical bone around screw No.1, which is obtained by analyzing the probabilistic finite element.

#	Model	Max. stress (MPa)	Max. strain (μm/m)	#	Model	Max. stress (MPa)	Max. strain (μm/m)
1	Model (1)	101	4770	4	Model (4)	86.8	3570
2	Model (2)	97	4535	5	Model (5)	76.5	2620
3	Model (3)	88.3	3745	6	Model (6)	74.3	2560

Table 2. The maximum stress and strain in the cortical bone around the screws for the six models.

#	Shape Models	Max. von Mises stress of the cortical bone-screw (MPa)		SM	R (%)
		Mean	S.d		
1	Model (1)	119.58	44.44	0.46	67.724
2	Model (2)	117.55	43.672	0.51	69.497
3	Model (3)	111.67	41.389	0.67	74.857
4	Model (4)	109.17	40.559	0.74	77.033
5	Model (5)	95.263	35.393	1.12	88.493
6	Model (6)	92.412	34.334	1.36	91.309

Table 3. Results of probabilistic FEM and reliability assessment based on maximum von Mises stress.

#	*Shape Models*	*Max. strain of the cortical bone-screw (µm/m)*		*R (%)*	*#*	*Shape Models*	*Max. strain of the cortical bone-screw (µm/m)*		*R (%)*
		Mean	*S.D*				*Mean*	*S.D*	
1	*Model (1)*	*1695.9*	*740.05*	*64.375*	*4*	*Model (4)*	*1492.1*	*651.52*	*76.585*
2	*Model (2)*	*1638.7*	*715.5*	*67.746*	*5*	*Model (5)*	*1307.4*	*570.84*	*87.029*
3	*Model (3)*	*1571.0*	*685.96*	*71.814*	*6*	*Model (6)*	*1252.9*	*547.06*	*89.644*

Table 4. Results of probabilistic FEM and reliability assessment based on maximum strain.

Figure 6 illustrates the Probability density functions of the reconstruction models. In all diagrams, the area between 100-2000 (µm/m) represents the resistance area of the model based on the maximum strain cortical bone around screw No.1 in all 6 reconstruction models, which shows the reliability of each model based on the strain criterion.

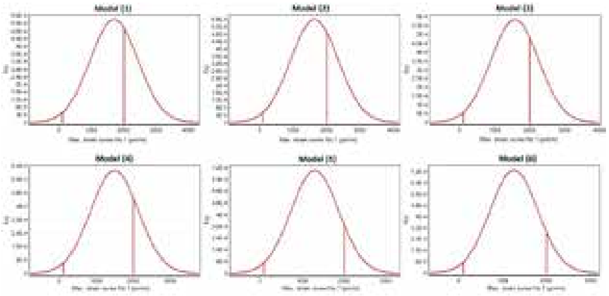

Figure 6. Probability density function of maximum strain the screw No.1 in all of six reconstruction models.

Tables 2 and 3 present the results of reliability values for six models are carried out by the criterion of maximum stress and strain using PFEM. The cortical bone stress has been created around screw No.1 in model 5 mean stress equal to 95.263 MPa and with a standard deviation of 35.393 MPa and mean and standard deviation of model 6 are 92.412 MPa and 34.334 MPa, respectively. The results of this work shows that by increasing the number of screws by one and modifying the layout of the screws. The reliability has increased from 67.72% in model 1 to 91.3% in model 6. Also, the reliability of four other models 2, 3, 4, and 5 are 69.49%, 74.85%, and 77.03%, and 88.49%, respectively which can be seen in table 2. According to Table 3, the maximum strain-based reliability values for the six models 1, 2, 3, 4, 5, and 6 are equal to 64.375%, 0.67.746%, 71.814%, 76.585%, 87.029%, and 89.644%, respectively.

Conclusion

Evaluating the performance of the biomechanical behavior of the components of mandibular reconstruction systems is an efficient method which inherent variability parameters of cortical and mandibular cancellous bone properties, as well as masticatory muscle forces, can be applied in numerical calculations and predict the reliability of the performance of reconstruction models. Increasing the number of screws as well as modifying the layout of the screws have a significant effect on the biomechanical performance of prosthesis connection at the defect site. Increasing the number of one screw increases the strength of the bone–prosthesis interface by 13.7%. Based on results, the most critical screw in all models is screw No.1, which by increasing the number of screws and correcting the layout shape, increased the maximum strain based reliability of the screw fixation strength by 28%. In the study of the strength of screw fixation using the probabilistic finite element method, the strain is an indicator in the cortical bone around the screw that is stricter than the maximum von Mises stress. Finally, the customized prostheses can be used to correct large lateral defects by modifying the screw fixation strength.

Conflict of Interest

There is no conflict of interest to declare.

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