RESEARCH ARTICLE

Design process of patient-specific osteosynthesis plates using topology optimization

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Abstract
To reduce complications related to the osteosynthesis plating system, the use of a patient-specific plate design was proposed. However, the issue of associated complications is still critical. Because existing patient-specific plate designs have mainly relied on parametric studies, a design method is needed that considers the complex factors influencing the performance of the reconstruction and that can be generalized for various patients. The goal of this study was to propose a design process that can strengthen the advantages of a customized plate to reduce patient discomfort and ensure the stability of surgery. We applied topology optimization to design a plate for a case of mandibular condyle fracture. The optimization problem was set to maximize the plate stiffness and minimize its volume. The performance of the designed plate was evaluated using finite element simulations, which approximated the various mastication states. Plate performance was then compared with the performance of two conventional plating systems: bent plates and computerized numerical control-machined plates. Each finite element model was appraised via masticatory simulations under static molar-jaw-closing conditions. Differences in stress concentration were noted between the model with bent plates and the model with computerized numerical control-machined plates. The conventional plate models used a pair of mini-plates, and the bent plate was modeled by conducting bending simulation. Each finite element model was appraised via masticatory simulations under static molar-jaw-closing conditions. Differences in stress concentration were noted between the model with bent plates and the model with computerized numerical control-machined plates. The most severe stress concentration occurred in the bent plate, which was affected by the residual stress from the bending process. In comparison with the two conventional plates, the newly designed plate exhibited significantly improved biomechanical stability in terms of stress and stiffness and had approximately twice the endurance capability against fractured bone separation. The newly designed plate was designed to have a balance between volume and plate stiffness, and it showed superior stability over the conventional plates. The proposed plate design process using topology optimization is an effective method not only because it enhances the advantages of the patient-specific plate but also because it can be applied in various reconstruction cases.

Keywords: topology optimization; surgical plate design; mandibular reconstruction; finite element analysis; stress analysis; biomechanical safety

1. Introduction
Condylar fracture accounts for 25–30% of all mandibular fractures (Scolozzi et al., 2000; Yang et al., 2012). The use of surgical plates is a standard treatment to repair fractured maxillofacial bones. Current surgeries primarily employ mass-produced straight plates, and surgeons bend those surgical plates to fit the shape of the defect site. Because of the complex anatomy
of the mandible, it is challenging for surgeons to bend the plate precisely during mandibular condylar reconstruction (Kim et al., 2016; Liu et al., 2016; Sawatari et al., 2016). In addition, more than 8% of the mandibular reconstructions suffer from complications because of failures in the plating system, such as plate fracturing or screw loosening (Liu et al., 2016). It has been reported that one of the main factors contributing to plate failure is the residual stresses that occur during the plate-bending process (Park et al., 2016, 2020; Lee et al., 2019). Therefore, a better choice of surgical plates for the treatment of condylar fractures is still a critical issue.

Previous studies have suggested patient-specific plate designs for mandible fracture cases (Mazzoni et al., 2013; Kozakiewicz & Świniarski, 2014; Narra et al., 2014; Aquilina et al., 2015; Qin et al., 2015; Pituru et al., 2016; Park et al., 2016, 2020). The designs of triangular-shaped plates were modeled with the same width, thickness, and screw hole size of the commonly used straight plates (Aquilina et al., 2015). Mazzoni et al. (2013) designed a plate by thickening the outer surface on the healthy side of the mandible to obtain an ideal esthetic contour and avoid bone deformities on the side affected by the tumor. Narra et al. (2014) reported patient-specific reconstruction plates designed by three surgeons and one engineer that were based on the clinical experience of the performing surgeons. The anterior cervical plate proposed by Kozakiewicz and Świniarski (2014) was designed based on the known compression and traction lines in the attached region (mandibular ramus) concerning the fracture of the right-side condyle. Because the patient-specific plate has a superior fit as compared with the mass-produced plates, it is expected to reduce operating time by skipping the manual plate-bending procedure and yield better postoperative results (Toto et al., 2015; Carfagni et al., 2019). In the study conducted by Pituru et al. (2016), the novel mini-plates were presented to maintain the maximum strains in the cortical bone near the fracture line, and the effect of the distance from the fracture line to the nearest screw was confirmed. Qin et al. (2015) determined that the fillet radius, cross-section, and countersink distributions of the fixing plate were the three most significant factors affecting the strength of the implant. They developed the structural design by combining the parameters of the theoretical calculations and FE analysis for various structures.

Previous research findings have offered valuable insights regarding the design of the patient-specific plates in their corresponding surgical cases; however, they are often difficult to generalize to different defect regions of the patient. These studies have been limited to parametric approaches that minimize or maximize the objective function by searching the design space spanned by the design parameters. Because the patient-specific plate has a superior fit as compared with the mass-produced plates, it is expected to reduce operating time by skipping the manual plate-bending procedure and yield better postoperative results. However, the optimization of design parameters (the material or geometric characteristics such as the plate thickness and hole size) is performed by the design procedure for new plates, starting from pre-existing templates. This optimization method made it difficult to generalize to different defective regions of the patient, even for the same type of surgery.

Common sense suggests that the largest plate possible would provide the most stable outcomes, although it is also desired to minimize the volume of the plate placed for better compliance and esthetics. Thus, an optimal bone plate design must provide stability sufficient to permit fracture healing while minimizing the surgical insult by reducing the volume of the plate. To satisfy these two opposing influences on plate design, this study proposed the use of the topology optimization technique with finite element (FE) analysis.

FE analysis has been conducted actively to assess the stability of various surgical treatments by analysing the biomechanical behavior of the structures (Bagheri et al., 2020; Lee et al., 2018, 2020, 2021; Park et al., 2021; Carfagni et al., 2019; Kim et al., 2020; Pirmoradian et al., 2020; Yoon et al., 2021). In addition, design methods with topology optimization have increasingly been adopted in a wide range of industries, particularly in the automotive and aerospace industries (Tejani et al., 2018; Wu et al., 2020). In an FE context, the topology optimization process modifies the initial design by changing the connectivity of elements to avoid residual stresses. The stability of the newly designed plate was compared with that of a bulky plate and that of conventional mini-plates by FE analysis. The bulky plate was used as the initial design space to perform topology optimization for the new design plate, as it has the largest area on the mandible surface near the defect site. To reflect the actual bending process of a straight plate, the bent plates were designed by conducting the bending simulation on conventional mini-plates. In contrast, computerized numerical control (CNC)-machined plates were designed without the bending simulation but have the same shape as the bent plates.

2. Materials and Methods

2.1 Three-dimensional (3D) FE models

As shown in Fig. 1, the surgical plate designs for reconstruction in a mandibular condylar fracture case were analysed by creating four FE models. The bent plates were designed using a bending simulation, which mimicked the actual bending process for the commercially available mini-plates (JEIL Medical Corp., Korea). After the bending simulation, the full frame plates were plastically deformed and retained the residual stress. The CNC-machined plates were contrasted with the bent plates to investigate the effect of the residual stress on plate stability.

The CNC-machined plates had the same shape as the bent plates but without the residual stresses. The shape of the bulky plate was designed to have sufficient space such that it could be changed during the optimization process. The newly designed plate was designed by using the topology optimization technique, the details of which will be provided in Section 2.4. The thickness of the plates was uniformly set to 0.96 mm, which is the same as the mini-plate thickness.

In this study, we used computed tomography to construct a 3D FE model of the mandible of a male patient. The maxillofacial model, with a layer of cortical bone and natural teeth, was modeled with Hounsfield units using a 3D modeling software (3-matic Research 9.0, Materialise Corp., Leuven, Belgium). A mandibular condylar fracture model (see the left-hand side of Fig. 1) was constructed by assuming an even gap of approximately 0.1 mm on the right-hand side of the condylar neck. The diagonal fracture lines initiated from the mandibular notch to the posterior border of the ramus. In all FE models, the
number and position of the screws were the same as those for the model with double mini-plates attached, as recommended by a previous study (Aquilina et al., 2013). To simplify the modeling process and reduce the analysis time, the screws were modeled by using cylindrical shapes. The tie connections were applied at the interfaces between the screw plate and the bone screw, assuming a perfect fit. We note that the cylindrically modeled screw less affects the stress distribution within the plate when the plate and screw are fixed by tie connections, while it reduces the computations due to the large number of FEs of screws.

Table 1 provides the details of the material properties of the components used in the FE model (Welsch et al., 1993; Li et al., 2014; Pinheiro et al., 2015). All components of the model were considered to be isotropic and homogeneous. To consider the plastic deformation during the plate-bending process, a simple bilinear material property of the titanium alloy was used. The plate, screw, and mandible models were divided into four-node tetrahedral structural elements, with sizes ranging from 0.08 to 0.5 mm, from 0.20 to 0.30 mm, and from 0.50 to 5.00 mm, respectively. The areas of expected stress concentrations on the mini-plates used in the model were divided into smaller elements. The element size was chosen based on the result of convergence analysis; that is, the increasing element density from the current mesh did not influence the predictive power of the FE analysis (Szwedowski et al., 2011). A commercially available FE software (ABAQUS version 6.14; SIMULIA Inc.) was used to build and analyze all FE models.

2.2 Plate-bending simulation

Because the initial mini-plate had a straight shape, a bending process was needed to fit the plate to the shape of the defect region. The bending simulation approximating the actual bending process was composed of three steps (see the left-hand side of Fig. 2). First, one side of the plate was fixed on the defect region, and the other side of the plate was connected to the center point by kinematic coupling. Then, a bending moment was applied to the center point to bend the plate to an appropriate bending angle. Lastly, the applied moment was removed. When the bending moment is removed, the plate partly returns to its original shape because of the elasticity of titanium (this recovery is also referred to as “spring-back”). Therefore, the plate-bending angle should be set higher than the final desired bending angle to compensate for the spring-back angle and allow for precise deformation of the plate.

In this study, the desired bending angles of the upper (lower) mini-plate were 28.15° (5.99°) on the x-axis and 8.18° (4.05°) on the y-axis. The spring-back angles were calculated for each direction of the rotation axis. The spring-back angles of the upper mini-plate were 2° on the x-axis and 1° on the y-axis, and those of the lower mini-plate were 1° in both directions. The final input
bending angles of the mini-plates were calculated considering the spring-back angles reported in a previous study. The CNC-machined plate model was created to provide the meshes of the corresponding bent mini-plates, although the residual stresses were omitted (Harith et al., 2016).

### 2.3 Mastication

Each FE model was evaluated via the masticatory simulations under static molar-jaw-closing conditions (see the right-hand side of Fig. 2). The applied muscular actions were similar to those reported in the dentomaxillofacial literature (Iwasaki et al., 2003; Ramos et al., 2011; Kozakiewicz & Swiniarski, 2014), and 10 principal muscles were included in the loading configuration (Table 2). As the boundary conditions, the upper sides of both condyles were fixed in all directions, and both molars were fixed in the z-direction.

### 3. Surgical Plate Design with Topology Optimization

To find an optimized plate without using a predetermined shape, we performed topology optimization by using the solid isotropic material with a penalization (SIMP) method. This section describes how the SIMP method is studied, taking into account the influence of surgical plate. SIMP-based topology optimization is a gradient-based optimization method, and it changes the density of each element in each iteration to minimize the objective function. The user defines a meshed design space in which the density of each element ranges between 0 and 1, where 0 is fully void and 1 is fully dense. Then, each iteration of the algorithm adjusts the density of individual elements based on sensitivities and the surrounding elements (Sigmund et al., 2013). The design process followed the workflow shown in Fig. 3. The process of the patient-specific surgical plate design consisted of three steps: constructing a bulky plate as the initial design domain; after setting the optimization problem, performing iterations required in the topology optimization to determine where to place the material (solid) and where not to (void); and redesigning the shape based on the topology optimization results.

First, the largest possible surface area on the defect was selected within the limits imposed by the surgical constraints to design a bulky plate. The bulky plate was constructed by using two offsets from the selected surface (0.3 and 1.26 mm). The resulting bulky plate was separated by 0.3 mm from the bone surface, as proposed by Kozakiewicz and Swiniarski (2014). The bulky plate had a volume that was about 2.1 times (202.74 mm³) than that of the mini-plates.

The bulky plate was attached to the mandibular condylar fracture model to constitute an initial configuration for optimization. The goal of the optimization was to shape the plate with the highest stiffness under adequate volume to satisfy the volume constraint. The strain energy of the plate was set as one of the design variables to ensure stability by increasing stiffness, and the volume of the plate was also considered simultaneously as the other variable. The objective function was the minimization of the strain energy stored in the plate, where a lower strain energy indicated greater stiffness. In addition, the
elements around the screw holes were defined as the non-response region to maintain the same number and position of screw holes as the other plates. As a constraint, the maximum volume of the final plate was set to 30% of the initial volume, excluding the non-response region. Then, the topology optimization process was performed by using the masticatory simulation iteratively until the solution was converged. An SIMP method-based topology optimization determined the optimum design by modifying the distribution of the relative material density in each element in the response region. The density variable ranged from 0 to 1; a density variable close to 0 represented the material to be removed, whereas a variable close to 1 represented the material to be retained.

The result of the topology optimization had a rough shape, which led to low manufacturability. Therefore, the newly designed plate was redesigned by controlling the iso-surface (ISO) value to 0.3. The ISO value represents the ISO degree that separates the hard and soft elements based on the relative density of the elements, as calculated by the topology optimization. When the extracted shape contained an ISO value closer to 1, the volume of the shape was further reduced.

To investigate the stability of the reconstruction based on the plate type, the distributions of the stress, strain, and displacement of each model were measured and analysed. In particular, the masticatory movements of the reconstructed models were compared with those of the intact model without defect.

4. Results

Figure 4 shows the von Mises stress distributions for each type of plate, and Table 3 lists the strain energy values. The results of the strain distribution along line 1 drawn on the outer surface of the mandible (in Fig. 1) are presented in Fig. 5. In addition,
Figure 4: Distribution of von Mises stress and maximum stress values for each model after masticatory simulation.

### Table 3: Plate volume and strain energy of the plate system after masticatory simulation.

| Model                | Volume (mm$^3$) | Strain energy (N mm) |
|----------------------|-----------------|----------------------|
|                      | Upper plate     | Bottom plate         | Screws    |
| CNC-machined plate   | 95.87           | 0.42                 | 1.76      | 0.86 |
| Bent plate           | 95.87           | 17.87                | 5.56      | 0.86 |
| Bulky plate          | 203.11          | 1.76                 | —         | 0.77 |
| Newly designed plate | 138.39          | 1.71                 | —         | 0.76 |

the displacement magnitude of the mandibular condylar fracture model along line 2 (in Fig. 1) is shown in Fig. 6.

Regardless of the bending process, the results of the model with bent plates were mostly similar to those of the model with the CNC-machined plates. However, the plate stress values were remarkably different. The maximum stress value of the bent plate model was higher than the value of the CNC-machined plates model by as much as 49.42 MPa (15.62 MPa) for the upper (lower) plate. The highest stress value was found at the bending area of the lower bent plate. Likewise, the strain energy stored in the screws of the model with bent plates was comparable with that of the model with the CNC-machined plates, whereas the energy stored in the plates was much higher within the bent plates than in the CNC-machined plates.

The volume of the newly designed plate was reduced to 139.46 mm$^3$, which is 68.79% of the bulky plate volume and satisfied the defined volume constraint. Note that, during the optimization process, the plate volume was first reduced by up to 30% in the response region (the volume of the nonresponse region was nearly 40% of the bulky plate volume) and then further reduced during the redesigning process. In addition, the plate topology was determined according to the objective function and maintained the strain energy of the initial design space (bulky plate), despite the volume reduction.

The newly designed plate model showed the lowest plate stress, and its displacement relative to the intact model was much smaller than that of the conventional mini-plates model. To be specific, the maximum relative displacement (separation) near the fractured interface of the bent plate model was 22.87 μm, whereas it was 10.38 μm for the newly designed plate. These results revealed that the newly designed plate had almost twice the separation-endurance capability as that of conventional plates.

### 5. Discussion

This study revealed that the newly designed plate had a similar influence on the biomechanical behavior of the bulky plate and had a larger region in terms of stress distribution and fixation within the bone. In this paper, we focus on applying topology optimization method to optimized plate design for a case of mandibular condyle fracture. We aim to (i) maximize the plate stiffness to improve separation-endurance capability and achieve stable reconstruction during the bone healing process between bone fragments, and (ii) reduce the weight as much as possible without increasing the plate thickness to improve the aesthetic and functional utility.
Rigid internal fixation is recognized as a standard procedure for the surgical management of mandibular fractures, because functional stability is provided during the healing process. When the decision is made to treat the condylar fractures with open reduction and internal fixation, a discussion might arise over the type of plate(s) as well as the number and configuration of plates to be used. Mini-plates are commonly used to treat cases of mandibular condylar fracture. In several studies, the use of a pair of mini-plates was suggested to achieve stable reconstruction based on the results of experimental and FE analysis (Yang et al., 2012; Aquilina et al., 2013).

However, in these previous studies, the approximated forces applied to the mandible and muscles during mastication were used for the plate bending simulation. Also, surgical plating system was evaluated under the assumption that the plastic deformation resulting from the bending process has a negligible

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**Figure 5**: Maximum and minimum principal strain distributions in the mandible along line 1 in Fig. 1.

**Figure 6**: Displacement magnitude of the mandible along line 2 in Fig. 1.
influence. In this study, the bending simulation was designed to consider changes in the mechanical property of the plate during the bending process, and the bent plate model was created by performing the bending simulation. At the same time, the CNC-machined plates were developed under the abovementioned assumption. When the result of the CNC-machined plate model was compared with that of the bent plate model, much higher stress and strain energy values were observed with the bent plates. These findings support the conclusion of numerous clinical experiences and relevant literature that the residual stresses result from the bending process may play a critical role in the fracture of the plate (Park et al., 2016, 2019, 2020).

Patient-specific plates have superior advantages as compared with conventional mini-plates, including accuracy, short operation time, and reasonable cost for the stability. The patient-specific design approach entails structural designs that can be implemented for individual anatomicities and does not require a preoperative bending procedure. Moreover, with the advances in additive manufacturing technology (e.g., 3D printing), the temporal and physical costs of reconstruction with patient-specific plates have decreased. Thus, patient-specific design approaches are increasingly preferred as a treatment option for mandibular reconstruction. The plate design approach proposed in this study is a leap forward from the current reliance on parametric custom-made plate designs. First, the advantages of patient-specific plates can be magnified. Second, apart from the specific case discussed in this study, the design approach using topology optimization is generally applicable to various reconstruction cases.

In the proposed design process, the design objective is set, which affects the plate stability (e.g., stiffness, stress, or displacement) and results in a plate design well fitted for the surgical site as well as increased stability. The results of this study support this fact by exhibiting a tenfold improvement in stiffness, a 50% reduction in plate stress, and an approximately twofold increase in the separation endurance of the newly designed plate in comparison with the conventional plate models. In particular, it was found that high separation endurance can have a positive impact on bone healing in the initial treatment phase (Narra et al., 2014). The result was identical to the conclusion that fracture gap size had a greater effect on the healing process than interfragmentary motion based on experimental results comparing healing with small, medium, or large gap size, subjected to small or interfragmentary motions using both sheep models (Gómez-Benito et al., 2005).

We note that, in this particular case of this study, a shape optimization scheme would provide a similar optimized design with the result of the topology optimization method since the topology of the plate was not changed during the iterations. However, in principle, the topology of the designed plate may be changed during the iterations in other cases, having different numbers and positions of screws, bone fracture shape, and optimization constraints. Therefore, the topology optimization method was set as the general design process to have a greater degree of freedom.

Although the results have interesting implications, the conclusions must be qualified by the limitations of the analysis procedure. First, the volume of a pair of conventional mini-plates was 47.20% of the bulky plate volume, which was smaller than that of the newly designed plate. The volume of the nonresponse region set in this study was similar to those of the mini-plates. In this study, the constraints were set taking into consideration both stability improvement and the assumptions that the position, number of screws, and thickness of all plates were the same. Therefore, additional research is needed regarding the dependence of the plate design on the number and location of plate screws. In addition, the geometry of the FE model was simplified for calculation. Second, the loading conditions applied for the masticatory simulation were the forces measured from an intact case. Thus, it should be noted that the findings of the current analysis assumed the use of maximum forces that can be applied to patients undergoing reconstruction.

In this paper, we presented a design procedure of a surgical plate for a case of mandibular condyle fracture. We aimed to (i) maximize the plate stiffness to improve separation-endurance capability and achieve stable reconstruction during the bone healing process between bone fragments, and (ii) reduce the weight as much as possible to improve the aesthetic and functional utility.

To satisfy the design goals, we aimed to maintain the stiffness of the newly designed plate as almost the same as that of the bulky plate used as the initial design space. The optimization problem was thus set to minimize strain energy to maximize the plate stiffness while satisfying the volume constraint.

We note that the presented procedure is assumed to be used by nonengineer (e.g., medical staff) for a specific purpose. Thus, all the measures used in the optimization process should be easily and correctly obtained in commonly used commercial software. Also, the procedure is designed to be simple for nonexperts. We targeted to remove the nonessential items in the process by considering the characteristics of the considered particular application. Therefore, we focused on the essential factors, the stiffness, and the volume of the plate, to present the practical design process of a surgical plate for mandibular condyle fracture.

A valuable future endeavor is to seek the effective and practical use of stress measures as in multivariable objective functions or a constraint for enhanced design (Zhang et al., 2017). Also, a more efficient design would be possible with the effective use of shell elements with proper treatments for the connections to screws. The optimal number and positions of the screw holes should be further investigated. The comparisons between the designed plate and the optimal conventional plates with its optimal hole positions for a given surgical site would also be highly valuable.

6. Conclusions

In this study, we found that after the bending procedure, conventional mini-plates demonstrated the most severe stress concentration, suggesting a high risk for plate fracture. The newly designed plate using topology optimization had a higher stiffness but similar stability as the bulky plate, despite its smaller volume. Within the limitations of this study, these findings suggest that including the topology optimization procedure in the design of the patient-specific plate can serve as a new, versatile paradigm for improving stability and can also be generalized for application in various reconstruction cases.

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**Conflict of interest statement**

None declared.

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