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Which fixation methods are better between three-dimensional anatomical plate and two miniplates for the mandibular subcondylar fracture open treatment?

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ABSTRACT

Purpose: To compare the clinical outcomes of a single three-dimensional (3-D) anatomical plate versus two conventional straight miniplates for the open treatment of mandibular subcondylar fractures.

Methods: This retrospective clinical study included patients with mandibular subcondylar fractures treated by the retromandibular transparotid approach using a 3-D plate or two straight miniplates. Outcome variables included preoperative conditions of patients and fractures, extent of postoperative bone healing, and incidence of complications. Other variables included age, sex, fracture site, and follow-up duration. Variables were evaluated using descriptive statistics and compared between groups.

Results: Twenty-eight fractures were analyzed: 13 fractures using 3-D plate and 15 fractures using two straight miniplates. None of the assessed variables showed significant differences between the two groups ($p < 0.05$). Unfortunately, in the 3-D plate group, reoperation was necessary for nonunion owing to plate breakage in one case with a bone defect around the fracture.

Conclusion: The 3-D plate and two straight miniplates were equally effective for the surgical management of mandibular subcondylar fractures. Although a 3-D plate is sufficient for a typical simple fracture, in cases with a bone defect around the fracture, selection of the plate fixation method should be carefully considered.

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1. Introduction

Mandibular condylar fractures account for 18%–45% of all mandibular fractures (Gassner et al., 2003; Stacey et al., 2006; Morris et al., 2015). Mandibular subcondylar fractures are the most common fractures of the mandible. However, it remains controversial whether closed or open treatment is best for the management of subcondylar fractures (Cascone et al., 2008). When mandibular subcondylar fractures cause dysfunction, surgical treatment may be needed for better occlusion because accurate

reduction and rigid fixation allow good anatomical repositioning and immediate function (Xin et al., 2014). Surgical treatment for subcondylar fractures has become the standard option because of advancements in technology, development of indigenous osteosynthesis devices, and enhancement of surgical techniques owing to a better understanding of the surgical anatomy (Jacobovicz et al., 1998; Kanno et al., 2016). Currently, the most frequent osteosynthesis procedure is the use of two miniplates fixation secured with screws. The concept of this surgical technique is in accordance with the following principles. One of the great principles of miniplate osteosynthesis, commonly called dynamic osteosynthesis (Champy and Lodde, 1976), stipulates that plates must be placed along the physiological tension lines, which appear during function. When the position of osteosynthesis plates and the physiological strain lines were superimposed in this technique, the posterior plate was aligned along the compression strain lines and its anterior plate

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located the tensile strain lines below the mandibular notch. From a mechanical point of view, this technique of two miniplates is favorable and helps to satisfy the dynamic osteosynthesis principles (Kanno et al., 2014) (Meyer et al., 2006).

Two-plate techniques are typically required to achieve stable fixation (Darwich et al., 2016). However, a frame-like three-dimensional (3-D) anatomical plate has been introduced and was found to provide better stability than conventional two-plate techniques (Cortelazzi et al., 2015). Three types of titanium subcondylar plates (a box plate, strut plate, and lambda plate; MatrixMANDIBLE Subcondylar Plates, DePuy Synthes, Raynham, MA, USA) are currently available on the market. Recent studies have evaluated the usefulness of 3-D anatomical plates as osteosynthesis materials for the repair of mandibular subcondylar fractures using a computed tomography (CT)-based finite element model (Murakami et al., 2017). However, few studies have evaluated the usefulness of 3-D plates in actual clinical practice. Therefore, the aim of the present study is to compare the clinical usefulness of the conventional two-miniplate method versus 3-D anatomical plate fixation for the open treatment of mandibular subcondylar fractures.

2. Materials and methods

2.1. Patients

The study cohort included 30 patients presenting to the Division of Oral and Maxillofacial Surgery of Kagawa Prefectural Central Hospital (Kagawa, Japan) from January 2009 to December 2017 with subcondylar mandibular fractures requiring open reduction and internal fixation (ORIF) surgery.

The inclusion criteria were as follows: available CT images acquired before, immediately after, and at least 3 months after surgery, and a minimum follow-up duration of 6 months. Patients who did not meet the inclusion criteria and those who did not regularly attend follow-up evaluations for up to 6 months were excluded. In this study, other additional standard exclusions for ORIF surgery included serious cardiovascular diseases, respiratory diseases, current use of bisphosphonates, immunosuppressed status, and insulin-requiring diabetes. Patients were divided into two groups according to the material used for internal fixation: a 3-D plate (3-D) group (use of 3-D subcondylar plates) and a miniplate (MP) group (use of two straight titanium miniplates).

2.2. Surgical procedure

All procedures were performed under general anesthesia via nasal endotracheal intubation. The surgeries were performed by two expert facial trauma maxillofacial surgeons (SS and TK) at a single institution. To achieve preinjury occlusion, maxillomandibular fixation (MMF) was performed with the use of an arch bar or bone screws (Dual Top Anchor System; Jeil Medical, Seoul, South Korea) for skeletal anchorage. The selection of an MMF device was determined according to the extent of trauma to the teeth and the prosthesis before the injury. Before the start of each surgery, stable occlusal conditions were restored, and the dentition was secured. Then, the subcondylar fractures were treated.

The surgical procedures were performed as described in previous reports by Ellis and Zide, 2006. Surgeries were performed via the retromandibular transparotid approach with a facial skin incision of about 30 mm placed approximately parallel to the posterior border of the mandible and beginning below the earlobe. Dissection was performed along the subdermal fat plane. Then, the parotid capsule was incised, and the parotid gland was bluntly dissected in an anteromedial direction toward the posterior border

of the mandible by inserting and spreading a curved hemostat so that it was parallel to the expected direction of the facial nerve branches. We did not identify all the facial nerves, although when encountered, the nerve was retracted from the surgical site. The posterior border of the mandible was identified, and the pterygomasseteric sling was incised. The masseter was stripped with the periosteum from the mandibular angle along the posterior border. We clarified the fracture site and anatomically reduced the fractured condylar segment. In patients with subcondylar dislocation or displacement, inferior distraction of the mandibular ramus was often necessary to anatomically reposition and reduce the fractured condylar process, which was achieved using a straight-forward technique (Cascone et al., 2008; Lindahl, 1977). With this technique, the mandibular ramus is pulled down and distracted inferiorly to enable reduction of the condylar process.

We then selected one of two plate fixation methods: a one-plate fixation method using a 3-D subcondylar locking miniplate (AO; MatrixMANDIBLE Subcondylar Plates System) (Fig. 1) or a two-plate fixation method using 2.0-mm locking miniplates (AO; LOCK Mandible 2.0, MatrixMANDIBLE 2.0; De Puy Synthes, Paoli, PA, USA). Occlusion and condylar position were confirmed including intraoperative plain facial roentgenography before wound closure. The wound was irrigated and checked for hemostasis.

2.3. Data collection

For data collection, an evaluation grid was created to ensure that all pertinent information (patient background data and plate type) and any abnormal postoperative clinical events were correctly documented. Patients were followed up postoperatively, and the functional status and incidence of treatment complications (e.g., postoperative infection, facial nerve paralysis, nonunion, malunion, and occlusal insufficiency) were assessed through clinical and radiographical examinations using CT or plain roentgenography at 1, 3, and 6 months postoperatively.

2.4. Predictive variables

The outcome variables for the study included the preoperative condition of the patient and fracture, extent of postoperative bone healing at the fracture site, and postoperative complications (e.g., infection, facial nerve paralysis, nonunion, malunion, occlusal insufficiency, foreign body sensation by an osteosynthesis plate, and plate removal). To assess the fracture preoperatively, CT images were obtained to classify the subcondylar fracture (Lindahl, 1977), detect the presence of accompanying mandibular fractures, and discern the direction and extent of fracture displacement. Postoperative stability was assessed by the evaluation of postoperative occlusal changes or the need for occlusal adjustments and comparisons of fracture segments on immediate postoperative CT images. Bone healing was defined as complete bone formation between and around the fracture lines, as demonstrated on CT images. Postoperative complications were evaluated during the follow-up period. Other assessed variables included clinical data (i.e., age, sex, cause of injury, fracture site, associated mandibular fractures, time between injury and surgery, presence of teeth, and total follow-up duration).

2.5. Radiological evaluation

In the radiological evaluation by postoperative panoramic X-ray, the vertical height of the ascending ramus from the condylar surface to the level of the lower border of the horizontal ramus was measured on both sides on the basis of previous research (Eckelt et al., 2006). In addition, two angles affected by mandibular

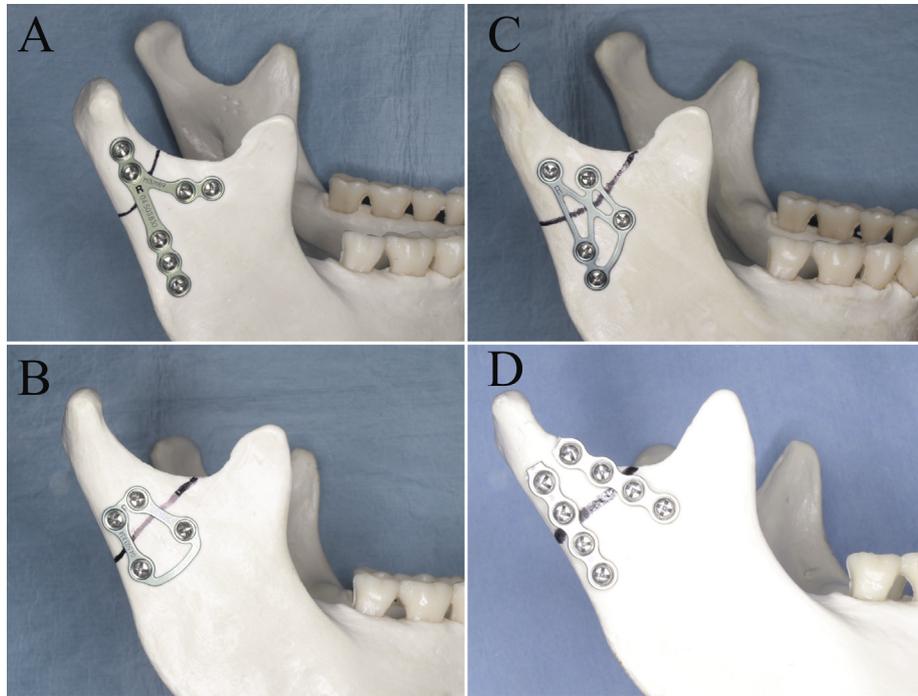


Fig. 1. Photograph showing the 3-D anatomical miniplate (MatrixMANDIBLE Subcondylar Plates; Johnson & Johnson) used in this study. Three types of titanium condylar plates: (A) lambda plate, (B) box plate, and (C) strut plate, (D) two straight miniplates.

condylar fracture were measured. Condylar angle was defined as the angle formed by the upper and lower border of mandibular flexure. Mandibular angle was defined as the angle formed by the posterior plane of mandibular ramus and the bottom plane of the mandibular corpus (Fig. 2).

2.6. Data sampling

All data were retrieved from clinical records by the same investigator. The study protocol was approved by the Ethics Committee of Kagawa Prefectural Central Hospital (approval no. 725).

2.7. Statistical analysis

Data were recorded and entered into an electronic database over the course of the study using Microsoft Excel (Microsoft, Inc., Redmond, WA, USA). The mean values (\pm standard deviations, SD) were used where distribution was compatible with normality.

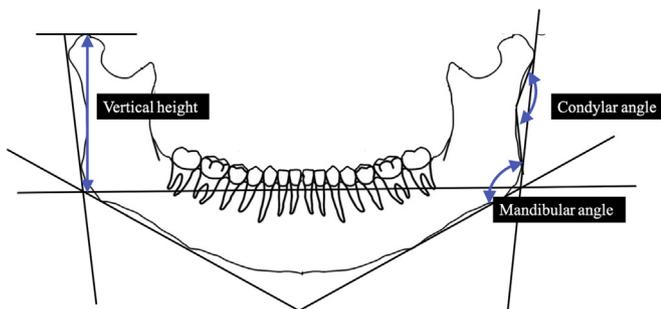


Fig. 2. Measurements in the panoramic X-ray. Vertical height; distance of the ascending ramus from the condylar surface to the level of the lower border of the horizontal ramus. Condylar angle; the angle formed by the upper and lower border of mandibular flexure. Mandibular angle; the angle formed by the posterior plane of mandibular ramus and the bottom plane of the mandibular corpus.

Parametric and nonparametric tests were used for comparisons between the 3-D and MP groups. The database was transferred to JMP version 11.2 software for Macintosh computers (SAS Institute Inc., Cary, NC, USA) for statistical analysis. A probability (p) value of <0.05 was considered statistically significant.

3. Results

A total of 26 Japanese patients (28 fractures) were analyzed: 14 patients (15 fractures) who underwent ORIF with fixation using two straight titanium miniplates (MP group) and 12 patients (13 fractures) who underwent ORIF with 3-D subcondylar plate fixation (3-D group). The MP group consisted of 9 (64.3%) males and 5 (35.7%) females with a mean age of 47.64 ± 22.93 years and a mean follow-up period of 256.5 ± 226.8 days. The 3-D group consisted of 7 (58.3%) males and 5 (41.7%) females with a mean age of 41.67 ± 21.66 years and a mean follow-up period of 231.5 ± 207.2 days. In each group, the plates were fixed to the bilateral subcondylar fractures on both sides in one patient. There were 15 fracture sites (right: 5, 33.3%; left: 10, 66.7%) in the MP group and 13 (right: 6, 46.2%; left: 7, 53.8%) in the 3-D group (Table 1).

The outcome variables are summarized in Tables 2 and 3. Evaluation of preoperative CT images revealed no significant differences in the preoperative conditions of the mandibular subcondylar fractures between the two groups with regard to accompanying mandibular fractures, fracture site, direction of subcondylar fragment dislocation, or fracture classification ($p < 0.05$; Table 2). Nonunion occurred in only one patient in the 3-D group due to plate breakage, which was repaired during a second surgery (Fig. 3). Other than this case, there were no other complications requiring a second surgery in either group. There were two instances of plate breakage in the 3-D group and none in the MP group. One of these patients required reoperation due to failure of bone union as described above. In another case, a break in the plate was revealed during plate removal, but this complication did not

Table 1

Clinical characteristics of patients with mandibular subcondylar fractures who underwent ORIF using two straight miniplates or a 3-D subcondylar plate.

Variable	Two titanium miniplates fixation group	Three-dimensional subcondylar plate fixation group
	14 patients, 15 fractures	12 patients, 13 fractures
Age	47.64 ± 22.93	41.67 ± 21.66
Sex		
Male	9 (64.3%)	7 (58.3%)
Female	5 (35.7%)	5 (41.7%)
Fracture site		
Right	5 (33.3%)	6 (46.2%)
Left	10 (66.7%)	7 (53.8%)
Follow-up duration (day)	256.5 ± 226.8	231.5 ± 207.2

Table 2

Summary of outcome variables of preoperative fracture conditions for mandibular condylar fractures repaired by ORIF using two straight miniplates or a 3-D subcondylar plate.

Variable	Two titanium miniplates fixation group	Three-dimensional subcondylar plate fixation group	P value
Accompanying mandibular fracture			0.366
Isolated condyle	6 (40.0)	4 (30.8)	
Condyle plus symphysis	5 (33.3)	9 (69.2)	
Condyle plus parasymphysis	1 (6.7)	0 (0.0)	
Condyle plus ramus	1 (6.7)	0 (0.0)	
Condyle plus angle	1 (6.7)	0 (0.0)	
Bilateral condyle symphysis	1 (6.7)	0 (0.0)	
Fracture site			0.410
Condylar base	3 (20.0)	5 (38.5)	
Condylar neck	12 (80.0)	8 (61.5)	
Direction of condylar fragment dislocation			0.181
Medial	1 (6.7)	1 (7.7)	
Lateral	6 (40.0)	2 (15.4)	
Dislocated	6 (40.0)	10 (62.5)	
None	2 (13.3)	0 (0.0)	
Fracture classification			0.121
Deviation	1 (6.7)	3 (23.1)	
Displacement	9 (60.0)	4 (30.8)	
Lateral Override	3 (20.0)	6 (46.2)	
Nondisplacement	2 (13.3)	0 (0.0)	

Table 3

Summary of outcome variables of postoperative complications for mandibular subcondylar fractures repaired by ORIF using two straight miniplates or a 3-D subcondylar plate.

Variable	Two titanium miniplates fixation group	Three-dimensional subcondylar plate fixation group	P Value
Complication			0.827
No	11 (73.3%)	10 (76.9)	
Yes	4 (26.7%)	3 (23.1)	
Plate breakage	0	2 (15.4%)	0.115
Nonunion	0	1 (7.7%)	0.274
Foreign body sensation	1 (6.7%)	1 (7.7%)	0.916
Screw loosening	1 (6.7%)	0	0.343
Facial nerve paralysis	2 (13.3%)	0	0.172
Removed plate	7 (46.7%)	7 (53.9%)	0.705
Symptomatic	2 (28.6%)	3 (42.9%)	
Asymptomatic	5 (71.4%)	4 (57.1%)	

affect bone healing. In this case, the plate was removed at the request of the patient, even though there were no clinical symptoms. In the MP group, screw loosening was observed in one case, but the fracture had been healing well. Postoperative foreign body sensation occurred in one patient in each group, and, in both cases, symptoms had improved by removing the plate after fracture healing. There were no significant differences in any of the assessed variables between the two groups ($p < 0.05$; Table 3).

In the radiological evaluation of this study, the following were excluded from the measurement: fractures which could not be evaluated on the other side due to preservative treatment for mandibular condylar head fracture (MP group; 2 fractures, 3-D group; 3 fractures) and plate broken before 6 months postoperatively (3-D group; 1 fracture). The vertical height difference

between the ORIF side and the healthy side was 0.29 mm (range -4.4 – 3.4 mm, SD 2.1 mm) in the MP group and 0.37 mm (range -2.6 – 1.7 mm, SD 1.3 mm) in the 3D group (Fig. 4). The condylar angle difference was 0.58° (range -8.1 – 3.9° , SD 2.7°) in the MP group and 0.32° (range -2.4 – 1.2° , SD 1.3°) in the 3D group. The mandibular angle difference was 0.14° (range -3.6 – 2.3° , SD 2.1°) in the MP group and 0.7° (range -3.9 – 4.2° , SD 2.7°) in the 3D group. There were no significant differences in the vertical height, condylar angle, and mandibular angle (Fig. 5).

4. Discussion

Surgical treatment for mandibular subcondylar fractures should prevent long-term severe drawbacks such as asymmetry, growth

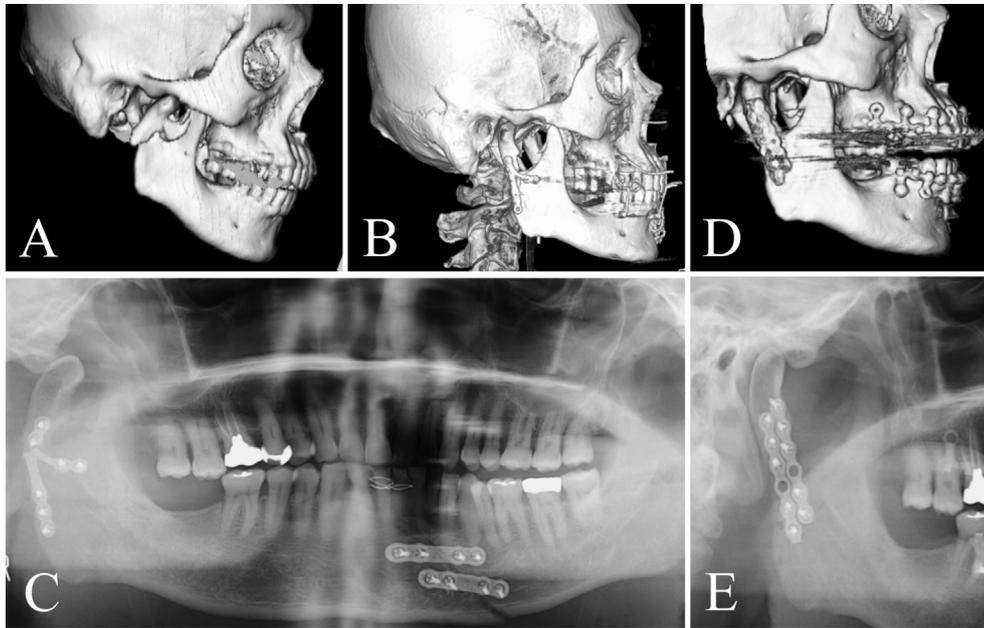


Fig. 3. A 67-year-old male with a right subcondylar fracture with a left parasymphysis mandibular fracture due to a traffic accident. (A) Preoperative 3-D CT image showing a right subcondylar fracture with a mesial free bone fragment. (B) Intraoperative 3-D CT image. (C) Postoperative 1.5-month panoramic X-ray photograph showing 3-D lambda plate breakage and mesial dislocation of the subcondylar segment. (D) Post-reoperative 3-D CT image showing reoperation with the two-straight-plate technique. (E) Post-reoperative 5-month panoramic X-ray photograph showing good bone healing at the fracture site and without an osteosynthesis plate.

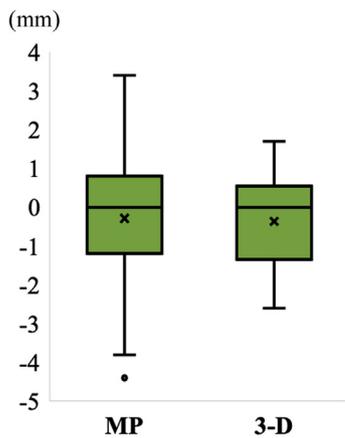


Fig. 4. The vertical height difference between the ORIF side and the healthy side in MP and 3-D group.

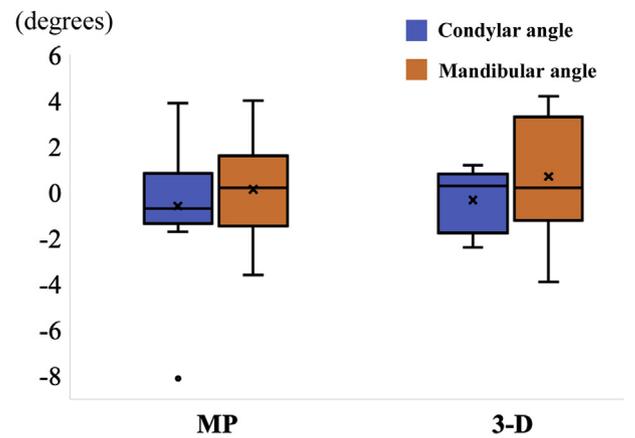


Fig. 5. The condylar angle and mandibular angle between the ORIF side and the healthy side in MP and 3-D group.

deficiency, temporomandibular joint pain, malocclusion, anterior open bite, and reduced protrusion, as well as laterotrusion, fibro-osseous, and osseous ankylosis of the temporomandibular joint (Cortelazzi et al., 2015). Indeed, a recent meta-analysis and a multicenter collaborative study (Worsaae and Thorn, 1994; Eckelt et al., 2006) demonstrated the usefulness of ORIF as a treatment choice for this fracture. In this study, the prognosis and treatment outcome were both good as long as the osteosynthesis plate itself did not fracture. These results not only demonstrate the usefulness of surgical treatment but also suggest the importance of plate selection to achieve optimal treatment.

Numerous mandibular subcondylar fractures are treated by oral and maxillofacial surgeons around the world through various surgical approaches, including retromandibular, anteroparotid trans-masseteric (Wilson et al., 2005), submandibular, endoscope-assisted intraoral (Arcuri et al., 2012), transoral approaches

(Pereira-Filho et al., 2011) (Kanno et al., 2011), and high subman-dibular approach (Meyer et al., 2008). However, each has known advantages and disadvantages. In our clinic, research is directed toward treating subcondylar fractures through the retromandibular approach. There was no instance of continual salivary leakage, salivary fistula development, or Frey syndrome in this cohort. However, two patients in the MP group developed partial paralysis of the facial nerve after surgery, which was found to be completely resolved at the 6-month follow-up. Regarding the paralysis of the facial nerve, which was discussed during the retromandibular transparoid approach, there was no significant difference between the 3-D and MP groups. Hence, these two cases of transient paresis of the facial nerve may be attributed to the manipulation of the surrounding soft tissue during retraction to visualize the operating area, as proposed in a few previous reports (Sikora et al., 2015; Hou et al., 2014). In both groups, the bone was joined with maximum

five screw holes, as there was no considerable difference in the maximum diameter or in the extent of pulling of the soft tissue. Hence, these findings suggest that obtaining a field-of-view equivalent to that with conventional surgery is possible despite the increased width of the 3-D plate. Alternatively, in the high submandibular approach method, the surgical field-of-view is secured in a similar manner as that in other surgical operations; additionally, this surgical approach without facial nerve injury is considered effective (Al-Moraissi et al., 2018). Because it does not affect 3-D plate shape, this procedure may be a safe option.

For the open treatment of mandibular subcondylar fractures, it is particularly important to consider the design of the plate, as the osteosynthesis device must be sufficiently rigid to withstand the physiological masticatory forces applied to the subcondylar region and the plate design must adapt the strain pattern occurring in the condylar region during function (Ahuja et al., 2018). Fracturing of the plate and loosening of the screws may be considered signs of insufficient stiffness of the plate or incorrect fracture reduction. The two-straight-miniplate technique with monocortical screws was proved to be the most reliable and functionally stable osteosynthesis procedure for subcondylar fractures and is considered to be more useful than before (Meyer et al., 2002) (Kanno et al., 2011) (Kanno et al., 2016). Meanwhile, it has been reported that the more recently developed 3-D plates that are currently available for clinical use are also useful. An important feature of this plate is the given basic anatomical shape, which renders adjustment unnecessary (Cortelazzi et al., 2015). In other words, if fitting of the 3-D plate is possible, anatomical reduction of the fracture segments could be performed without experiencing serious problems. In our study, good morphological recovery was observed in the X-ray evaluation at 6 months postoperatively, which passed without problem. This also suggested that the 3D plates were effective for treatment of mandibular subcondylar fractures.

In mandibular fracture open treatment, occlusal force is strongly influenced by stress to the plate, which can result in plate breakage and failure (Murakami et al., 2015). These complications usually manifest as occlusal deviation or temporomandibular joint pain before fracture healing and can be observed during tracing of X-rays or removal of plates after fracture healing. In our study, a plate fracture occurred before fracture healing in one patient in the 3-D group. The results of finite element analysis of the treatment of mandibular fractures showed that the compressive stress generated in the plate is significantly larger than the tensile stress (Murakami et al., 2017; Meyer et al., 2006). Regarding the distribution of stress, the tensile stress was concentrated on the outside of the anterior plate below the mandibular notch, whereas the compressive stress was concentrated inside the posterior plate along the condylar axis (Meyer et al., 2006). A study by Murakami et al. (2017) compared von Mises' stress, calculated tensile stress, and compressive stress with the intensities described in the previous reports and found that the strength of two straight plates and that of the 3-D plate were sufficient to ensure the safety of either technique. In our study, a fracture occurred in a lambda-type 3-D plate at 1 month after surgery. Ellis and Throckmorton (2001) reported that the maximal bite force at 6 weeks after surgery was approximately 60% of that at baseline and had significantly increased between 6 weeks and 6 months. However, Murakami et al. (2017) stated that, theoretically, there is no problem in plate strength when studying the bite force of a healthy person. The major difference is that in our case of a break in a 3-D plate, the small free bone fragment at the site of the mandibular notch was removed during a second surgery. In other words, the mandibles were not consecutive only in the posterior direction. Therefore, it is believed that the stress was concentrated only inside the posterior plate on the condylar axis and was strictly caused by the recovered

bite force, which resulted in the break. Interestingly, we performed the second surgery with the two-straight-plate technique, and the patients achieved good results with no further problems. This is the first report as a reference for plate selection in cases of mandibular subcondylar fractures with free bone fragments. We experienced another case of breakage of a 3-D subcondylar strut miniplate. However, an important difference from the above case is that the fracture had healed well in the previous case. Kanno et al. (2016) reported that plate breakage was that even greater bite force with earlier healing occurred, followed by greater mechanical stress loaded on the plate, causing higher continuous fatigue. At the posterior border of the condylar region, large compressive strain with torsion stress load might be focused along the posterior mandibular border, parallel to the condylar axis (Seemann et al., 2009; Murakami et al., 2015). In our case, this could have been a contributing factor toward the breakage of the posterior plate part. However, because of the mechanical support provided by cross-linking within the 3-D plate, the fractured segments would have healed satisfactorily without any problem.

In this study, 57.1% of patients in the 3-D group and 71.4% in the MP group requested plate removal, which were unexpectedly high rates. As a possible explanation, we considered national characteristics as well as patient needs. In this study, the clinical successes of the MP and 3-D techniques were equivalent probably because it is possible to avoid concentrating the stress of the plate by devising an appropriate shape of the 3-D plate (Cortelazzi et al., 2015; Murakami et al., 2017). Resorbable plates have been developed and studied in recent years, and absorptive plates with high strength and bioactive activity are now available in the market (Sukegawa et al., 2016; Sukegawa et al., 2017; Sukegawa et al., 2016). In the near future, we expect the development of absorptive plates for the repair of mandibular subcondylar fractures with high plate strength without the need for bending to devise an appropriate plate form.

There were some limitations to this study. First, these results need to be confirmed in future clinical trials with larger samples and extended methodologies to further assess the advantages of both systems. In addition, *in vitro* studies are needed to obtain better biomechanical performance with internal fixation of subcondylar fractures and to enable the development of ideal osteosynthesis materials and techniques, particularly as this topic, in relation to subcondylar fractures, is one of the most controversial in maxillofacial surgery.

5. Conclusions

The results of this study indicate that the 3-D plate and the two-straight-plate systems are equally effective in terms of clinical success in the surgical management of mandibular subcondylar fractures. However, a 3-D plate might have a precontoured curved profile to anatomically fit the fracture area, which is superior in terms of handling characteristics and easy confirmation for bone fragment reduction. Regarding plate strength, however, a 3-D plate is sufficient for a typical simple fracture, but in cases with a bone defect around the fracture, selection of the plate fixation method should be carefully considered.

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Conflicts of interest

The authors state that there are no conflicts of interest.

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