INTRODUCTION

The goal of orthognathic surgery is to correct aesthetic and functional problems of the jaw by reshaping the maxilla and mandible within a short period. Sagittal split ramus osteotomy of the mandible is the most frequently used method for correcting retrognathic and prognathic mandibles. Rigid fixation with plates or screws has been widely favored for stabilization in the sagittal split ramus osteotomy [1]. However, this has several sequelae, including temporomandibular joint (TMJ) dysfunction.
and postoperative relapse, as the proximal condylar segment is movable in 3 dimensions after osteotomy of the mandibular ramus, which affects the condylar head position.

Many studies have investigated the factors that impact postoperative sequelae, including a displaced condylar head, method and duration of intermaxillary fixation, magnitude and direction of mandibular movement, orthodontic treatment, incomplete bony union, and masticatory function [2]. It is especially evident that a displaced condylar head is a major factor. Therefore, it is important to maintain the anatomic position of the mandibular condyle within the glenoid fossa during orthognathic surgery in order to reduce the relapse rate and minimize the risk of TMJ dysfunction [3].

Numerous condylar repositioning methods have been reported, including a manual method, rigid retention, navigation, and sonographic monitoring in order to limit the movement of the condyle [4]. In addition, various means of evaluating the efficacy of these methods have been proposed, which have been largely unsuccessful due to image distortion resulting from the complex anatomic structure around the TMJ, irreproducible preoperative and postoperative images, and multidirectional displacement of the condylar head [5]. Most condylar repositioning methods are 2-dimensional or require complex procedures involving a long operation time and a highly trained surgeon.

This study aimed to introduce a new technique using a centric relation (CR) splint to achieve a centric relationship and a simple 3-dimensional condylar repositioning plate, validated by an objective evaluation method.

**METHODS**

The subjects were recruited from among patients who underwent surgery for skeletal jaw deformities between January 2008 and December 2011. All of them were operated on by the same surgeon. A total of 387 patients (199 male and 188 female) were followed up in our outpatient clinic for more than 1 year. The average age of the patients was 22.3 years (range, 17–52 years). The preoperative procedures included presurgical orthodontics, final surgical treatment objectives, manufacture of CR splints, and model surgery, including facebow transfer, impression model mounting, and manufacture of final intermediate and centric occlusion splints.

The sequence of operative procedures was based on the preoperative planning and model surgery. The main procedures performed were Le Fort I osteotomy and bilateral sagittal split ramus osteotomy. First, a condylar repositioning plate was applied between the maxilla and mandible after a CR splint was placed (Fig. 1A). The drilling holes for the plate were set above the Le Fort I osteotomy line and behind the sagittal split ramus osteotomy vertical line. Two 4-mm screws were usually utilized on each side to hold them firmly (Fig. 1B, C). After removing the condylar repositioning plate and CR splint, Le Fort I osteotomy was usually performed first. An intermediate splint was then used to guide the movement of one jaw relative to the other jaw. Four 4-hole L-type mini-plates were used for the Le Fort I osteotomy. The remaining jaw was then repositioned based on the final splint. Once the proximal segment of the mandible was repositioned, the condylar repositioning plate was applied on the same drilling hole and bicortical screws 2 mm in diameter and 12–18 mm long for bilateral sagittal split ramus osteotomy were used for rigid fixation. The condylar repositioning plate was removed immediately after the rigid fixation of the mandible [6].

The following evaluation methods were used: (1) physical examination to detect preoperative and postoperative TMJ dysfunction, (2) 3-dimensional computed tomography (3D-CT) and oblique transcranial TMJ radiography to measure 3-dimensional condylar head movement (Figs. 2, 3), and (3) standard posteroanterior and lateral cephalometric radiography to identi-
The postoperative 3D-CT and other radiographs were typically taken 3 months and 1 year after the operation during follow-up examinations at the outpatient clinic. The radiologic findings were measured by two plastic surgeons and one orthodontist, and the mean values were used for the statistical analysis.

On the frontal view of the 3D-CT images, the angles between the line between the frontozygomatic sutures (FZ) and the vertical ramus line (VR) from both sides were measured. On the lateral view of the 3-dimensional scan, the angles between the line between the external acoustic meatus and inferior orbital rim (HL) and posterior ramus line (PR) were measured. On the basal view of the 3D-CT, the angles between the line between the anterior surfaces of mastoid process (MM') and the line connecting the medial and lateral ends of the condylar head were measured, along with the distances between the MM' and the outer/inner pole of the condyle on the 2-dimensional transverse view.

The landmarks were defined and abbreviated as follows: RVR, right vertical ramus line; LVR, left vertical ramus line; FRA, angle between FZ and RVR; FLA, angle between FZ and LVR; RVR, right vertical ramus line; HL, line between the external acoustic meatus and inferior orbital rim; LRA, angle between HL and PR; PR, posterior ramus line; RCA, right condylar axis angle to MM'; LCA, left condylar axis angle to MM'; MM', line between the anterior surfaces of the mastoid process.

Skeletal relapse was measured by changes in the position of the supramentale (B), pogonion (Pog), and menton (Mn) points, while dental relapse was measured by the changes in the position of the tip of the upper and lower incisors.

Statistical analysis was performed with SPSS Ver. 22.0. (IBM Corp. Armonk, NY, USA). A subgroup analysis was performed using the paired t-test. Statistical significance was set at P < 0.01.
RESULTS

The average period of postoperative intermaxillary fixation was only 1 day, with no additional splint for occlusal stability. The average follow-up duration was 15.3 months. Of the 387 patients, 34 had a reciprocal click sound accompanied by TMJ pain, 78 had a closing click sound without any subjective symptoms, and the rest had no symptoms before surgery. The patients with preoperative click sounds retained them after surgery, while 6 patients exhibited a new click sound without any clinical symptoms.

In the preoperative 3D-CT scans, the average vertical axis angle was $82.73^\circ \pm 4.47^\circ$ (FRA) on the right and $83.32^\circ \pm 4.24^\circ$ (FLA) on the left on the frontal view, $84.35^\circ \pm 5.49^\circ$ (LRA) on the right and $85.58^\circ \pm 5.04^\circ$ (LLA) on the left on the lateral view, and the average long-axis angle of the condylar head was $20.93^\circ \pm 5.55^\circ$ (RCA) on the right and $19.89^\circ \pm 5.40^\circ$ (LCA) on the left on the basal view. In the preoperative 2-dimensional computed tomography images, the average vertical distances between the MM' and the inner and outer pole of the right condyle (RMD and RLD, respectively) were $13.56 \pm 3.83$ mm and $19.69 \pm 4.62$ mm, respectively. The average vertical distances between the MM' and the inner and outer pole of the left condyle (LMD and LLD, respectively) were $13.31 \pm 3.34$ mm and $19.58 \pm 3.86$ mm, respectively.

In the postoperative 3D-CT scans, the average vertical axis angle was $80.25^\circ \pm 4.74^\circ$ (FRA) on the right and $80.58^\circ \pm 4.30^\circ$ (FLA) on the left on the frontal view, $81.26^\circ \pm 5.72^\circ$ (LRA) on the right and $81.87^\circ \pm 5.48^\circ$ (LLA) on the left on the lateral view, and the average long axis angle of the condylar head was $21.24^\circ \pm 5.58^\circ$ (RCA) on the right and $20.72^\circ \pm 5.44^\circ$ (LCA) on the left on the basal view. In the long-term postoperative 2D-CT images, the average vertical distances between the MM' and the inner and outer pole of the right condyle (RMD and RLD, respectively) were $13.56 \pm 3.83$ mm and $20.40 \pm 4.92$ mm, respectively. The average vertical distances between the MM' and the inner and outer pole of the left condyle (LMD and LLD, respectively) were $13.84 \pm 3.18$ mm and $20.18 \pm 3.79$ mm, respectively. Significant differences were found between the preoperative and postoperative measurements (Table 1).

In addition, the average distance at the AJS was $2.48 \pm 0.41$ mm on the right and $2.32 \pm 0.34$ mm on the left, the average distance at the SJS was $2.32 \pm 0.39$ mm on the right and $2.40 \pm 0.36$ mm on the left, and the average distance at the PJS was $21.79^\circ \pm 6.04^\circ$ (RCA) on the right and $21.21^\circ \pm 5.52^\circ$ (LCA) on the left on the basal view. In the postoperative 2D-CT images, the average vertical distances between the MM' and the inner and outer pole of the right condyle (RMD and RLD, respectively) were $14.03 \pm 3.78$ mm and $20.94 \pm 4.43$ mm, respectively. The average vertical distances between the MM' and the inner and outer pole of the left condyle (LMD and LLD, respectively) were $14.40 \pm 3.24$ mm and $20.86 \pm 3.82$ mm, respectively.

In the long-term postoperative 3D-CT scans, the average vertical axis angle was $81.35^\circ \pm 4.55^\circ$ (FRA) on the right and $82.49^\circ \pm 4.21^\circ$ (FLA) on the left on the frontal view, $83.24^\circ \pm 5.31^\circ$ (LRA) on the right and $84.36^\circ \pm 5.53^\circ$ (LLA) on the left on the lateral view, and the average long axis angle of the condylar head was $21.24^\circ \pm 5.58^\circ$ (RCA) on the right and $20.72^\circ \pm 5.44^\circ$ (LCA) on the left on the basal view. In the long-term postoperative 2D-CT images, the average vertical distances between the MM' and the inner and outer pole of the right condyle (RMD and RLD, respectively) were $13.56 \pm 3.83$ mm and $20.40 \pm 4.92$ mm, respectively. The average vertical distances between the MM' and the inner and outer pole of the left condyle (LMD and LLD, respectively) were $13.84 \pm 3.18$ mm and $20.18 \pm 3.79$ mm, respectively. Significant differences were found between the preoperative and postoperative measurements (Table 1).

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Table 1. Mean measurements and statistical results of preoperative, 3-month postoperative, and 1-year postoperative 3-dimensional and 2-dimensional computed tomography imaging

| Measurement | T0 (mean) | T1 (mean) | TL (mean) | Paired t-test | T0–T1 | T1–TL | T0–TL |
|-------------|-----------|-----------|-----------|--------------|-------|-------|-------|
| FRA         | 82.73     | 80.25     | 81.35     |              | <0.01*| <0.01*| <0.01*|
| FLA         | 83.32     | 80.58     | 82.49     |              | <0.01*| <0.01*| <0.01*|
| LRA         | 84.35     | 81.26     | 83.24     |              | <0.01*| <0.01*| <0.01*|
| LLA         | 85.58     | 81.87     | 84.36     |              | <0.01*| <0.01*| <0.01*|
| RCA         | 20.93     | 21.79     | 21.24     |              | <0.01*| <0.01*| 0.03  |
| LCA         | 19.89     | 21.21     | 20.72     |              | <0.01*| 0.03  | <0.01*|
| RLD         | 19.69     | 20.94     | 20.40     |              | <0.01*| 0.12  | 0.02  |
| RMD         | 13.48     | 14.03     | 13.56     |              | <0.01*| <0.01*| 0.18  |
| LMD         | 13.31     | 14.40     | 13.84     |              | <0.01*| <0.01*| <0.01*|
| LLD         | 19.58     | 20.86     | 20.18     |              | <0.01*| <0.01*| <0.01*|

T0, preoperative; T1, 3 months postoperative; TL, 1 year postoperative; FRA, angle between FZ and RVR; FLA, angle between FZ and LVR; LRA, angle between HL and PR on the right on the lateral view; LLA, angle between HL and PR on the left on the lateral view; RCA, right condylar axis angle to MM'; LCA, left condylar axis angle to MM'; RMD, distance between MM' and the outer pole of the right condyle; RLD, distance between MM' and the inner pole of the right condyle; LMD, distance between MM' and the inner pole of the left condyle; LLD, distance between MM' and the outer pole of the left condyle; FZ, line between the frontozygomatic sutures; RVR, right vertical ramus line; LVR, left vertical ramus line; HL, line between the external acoustic meatus and inferior orbital rim; PR, posterior ramus line; MM', line between the anterior surfaces of the mastoid process.

*P < 0.01.
2.35 ± 0.37 mm on the right and 2.43 ± 0.41 mm on the left in
the preoperative oblique transcranial TMJ radiographs. In the
postoperative oblique transcranial TMJ radiography, the average
distances at the AJS were 2.25 ± 0.41 mm on the right and 2.12 ± 0.38 mm on the left, 2.66 ± 0.37 mm on the right and 2.68 ± 0.43 mm on the left at the SJS, and 2.73 ± 0.41 mm on the right and 2.76 ± 0.40 mm on the left at the PJS. In the long-
term postoperative oblique transcranial TMJ radiography, the average
distances at the AJS were 2.25 ± 0.41 mm on the right and 2.12 ± 0.38 mm on the left, 2.66 ± 0.37 mm on the right and 2.68 ± 0.43 mm on the left at the SJS, and 2.73 ± 0.41 mm on the right and 2.76 ± 0.40 mm on the left at the PJS. Statistically
significant differences were found between the preoperative and
postoperative measurements (Table 2).

Standard anteroposterior and lateral cephalic radiography
scans were performed in order to analyze 3-dimensional bony
movement and relapse. The reference points were the sella tur-
cica (S), nasion (N), B, Pog, Mn, and the vertical reference
plane (VP). The VP was orthogonal to the horizontal reference
plane (HP), which was rotated 7° clockwise from the line connect-
ing S and N. The distances from VP to Po and Mn were
designated as hPo and hMn, respectively. The distances from N
to the projections of Po and Mn onto the VP were designated as
vPo and vMn, respectively.

| Table 2. Mean distance of joint space on oblique transcranial radiographs |
|---------------------------------------------------------------|
| **Measurement, mm** | **T0 (mean)** | **T1 (mean)** | **TL (mean)** | **Paired t-test** |
| AJS (R) | 2.48 | 2.25 | 2.43 | <0.01* | <0.01* | 0.02 |
| AJS (L) | 2.32 | 2.12 | 2.29 | <0.01* | <0.01* | 0.34 |
| SJS (R) | 2.32 | 2.66 | 2.46 | <0.01* | <0.01* | <0.01* |
| SJS (L) | 2.40 | 2.68 | 2.50 | <0.01* | <0.01* | <0.01* |
| PJS (R) | 2.35 | 2.73 | 2.46 | <0.01* | <0.01* | <0.01* |
| PJS (L) | 2.43 | 2.76 | 2.52 | <0.01* | <0.01* | <0.01* |

T0, preoperative; T1, 3 months postoperative; TL, 1 year postoperative; AJS, anterior joint space; (R), right side; (L), left side; SJS, superior joint space; PJS, posterior joint space.

| Table 3. Changes in landmarks on lateral cephalic radiographs |
|---------------------------------------------------------------|
| **Measurement, mm** | **T0 (mean)** | **T1 (mean)** | **TL (mean)** | **Paired t-test** |
| SNB | 81.34 | 78.04 | 78.31 | <0.01* | 0.05 | <0.01* |
| hPo | −2.95 | −8.45 | −8.22 | <0.01* | 0.45 | <0.01* |
| hMn | −10.34 | −14.98 | −14.58 | <0.01* | 0.50 | <0.01* |
| vPo | 126.72 | 125.97 | 125.54 | 0.21 | 0.08 | 0.04 |
| vMn | 134.31 | 132.74 | 132.38 | 0.01 | 0.05 | <0.01* |

The reference points were the sella turcica (S), nasion (N), supramentale (B), pogonion (Pog), menton (Mn), and the vertical reference plane (VP). The VP was orthogonal to the horizontal reference plane (HP), which was rotated 7° clockwise from the line connecting S and N. The distances from VP to Po and Mn were designated as hPo and hMn, respectively. The distances from N to the projections of Po and Mn onto VP were designated as vPo and vMn, respectively. T0, preoperative; T1, 3 months postoperative; TL, 1 year postoperative.

*P < 0.01.

DISCUSSION

Many clinicians are concerned that rigid internal fixation can

In the preoperative images, the mean SNB angle was 81.34° ±
6.24°, hPo was −2.95 ± 14.62 mm, hMn was −10.34 ± 14.83 mm,
vPo was 126.72 ± 8.66 mm, and vMn was 134.31 ± 8.95 mm. In
the postoperative images, the mean angle was 78.04° ± 4.85°, hPo
was −8.45 ± 10.91 mm, hMn was −14.98 ± 11.27 mm, vPo
was 125.97 ± 7.89 mm, and vMn was 132.74 ± 7.94 mm. In the long-
term postoperative images, the mean angle was 78.31° ± 4.85°,
hPo was −8.22 ± 10.77 mm, hMn was −14.58 ± 11.74 mm, vPo
was 125.54 ± 7.56 mm, and vMn was 132.38 ± 7.76 mm.

A relapse rate of 0.3% was observed in the coronal plane, while
a relapse rate of 2.8% was observed in the sagittal plane. This
cannot be distinguished from the dental relapse rate in orth-
odontic treatment (Table 3). The condylar repositioning plate
was unable to fully prevent the movement of the condylar head,
but the relapse rate was minimized. This implies that the move-
ment of the condylar head was controlled within tolerable limits.
duce significant changes in the position of the condyle.

Although the use of condylar positioning devices (CPDs) seems reasonable from this point of view, no critical evaluation of their use is currently available. In particular, the effects of a condylar repositioning plate on condylar position and relapse have never been studied in detail. In a review by Costa et al. of the English-language literature since 1990, only 6 papers comparing the use of CPDs with traditional methods were found since a comprehensive review on the use of CPDs in orthognathic surgery was published in 1994 by Ellis [4,7].

To summarize these 6 studies, the outcomes of 141 patients with CPDs were compared with those of 112 patients treated using conventional manual repositioning. Three studies supported the use of CPDs, 1 study supported the use of CPDs only in patients with temporomandibular disorders (TMDs), and 2 studies did not support the use of CPDs because they failed to improve skeletal stability or TMJ function, irrespective of the skeletal deformities treated [4,8-13].

In our study, for the determination of acceptable patient outcomes and patient suitability for the procedure, we used broader criteria than those used in previous studies of orthognathic surgery that used only simple numeric criteria. The criteria took into account the patient’s aesthetic requirements as the most important factor, followed in order by morphological esthetics, jaw deformities not being overcome by correction, and asymmetry exceeding 3 mm and 3°. In order to statistically verify the outcomes with multiple variables, a large sample size and a sufficient follow-up period were incorporated into the study design.

With respect to outcome evaluation, X-ray based methods have been used frequently, and CT-based methods are also used. Accordingly, we used both X-ray and CT imaging.

The present study was not designed as a comparative study between a group that used CRP and a group that did not use CRP. Instead, it was a study of the usefulness of a novel method of CRP design and placement, in contrast to the overly complicated conventional methods currently in use. Now that we have shown that this novel method was successful and not time-consuming, a future study is being planned to compare this group to those who did not use a CRP.

The time required in using a CRP was not measured each time, but it generally took 5–10 minutes for the first CRP and 1–2 minutes to fix the distal segment to the proximal segment and to fix the sagittal split ramus osteotomy. This occurs because the proximal segment is fixed to the upper jaw, meaning that it is more stable than fixation without a CRP, which consequently shortens the time for fixation to the lower jaw. Therefore, it is believed that this novel method has virtually no effect on operative time. However, it should be mentioned that the CR splint must be produced prior to the surgery, which requires approximately 20–30 minutes.

The key goal of this article was to establish the usefulness of using a CRP. Although various factors are involved, we analyzed a large number of patients treated by a single surgeon when studying the effects of the CRP, in order to link measureable outcomes to the effects of the CRP. Of course, this study has limitations, but to study all the factors that could affect this operation would be very difficult. Accordingly, the present study aimed to clarify the effects of CRP as meaningfully as possible.

Controversy exists about the appropriate management of patients with preexisting TMDs who require orthognathic surgery for the correction of malocclusion and jaw deformities. Two significantly different philosophies exist: although Wolford et al. [14] contended that orthognathic surgical procedures help in the reduction of TMD dysfunction and symptoms, Cottrell et al. [15] showed that orthognathic surgery in such patients caused further deleterious effects on the TMD and thus worsened the symptoms and dysfunction after surgery. The latter philosophy proposes surgical management of the TMD pathology as an initial separate procedure or one that may be performed concomitantly with orthognathic surgery when indicated [14]. However, a retrospective analysis has suggested that orthognathic surgery itself improves the symptoms of TMD. In that analysis, 53% of patients undergoing orthognathic surgery had signs and/or symptoms of TMD and 78% of those patients reported an improvement in symptoms after surgery [16]. These findings are, however, not applicable to this study because the patients had no clinical problems and were accustomed to a symptom-free TMJ.

In this study, the effect of the condylar repositioning plate on condylar position and relapse was evaluated by the paired t-test and regression. The condylar repositioning plate could not entirely prevent the movement of the condylar head, but did minimize the relapse rate according to our statistical analysis. This implies that the condylar head movement was within tolerable limits.

Although some researchers do not support the use of CPDs, their main objection is not the precision of such devices, but rather the amount of time that they add to procedures. Once less time-consuming methods are available, there are likely to be few objections to the use of CPDs. Our condylar repositioning method using a CR splint and mini-plate in orthognathic surgery was simple and effective in patients suffering from skeletal jaw deformities. The CT scans, transcranial TMJ radiographs, and cephalometric radiographs all confirmed that condylar head movement was within acceptable limits. Therefore, we believe that this method is effective and reliable.
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