# Three-Dimensional Analysis of Long-Term Stability After Bilateral Sagittal Split Ramus Osteotomy Fixed With a Single Miniplate With 4 Monocortical Screws and 1 Bicortical Screw: A Retrospective 2-Center Study

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**Purpose:** This study evaluated the long-term stability of bilateral sagittal split ramus osteotomy fixed with a single miniplate with 4 monocortical screws and 1 bicortical screw (hybrid technique [HT]) using 3-dimensional (3D) analysis and an objective measuring tool, cone-beam computed tomography (CBCT).

**Materials and Methods:** Sixty-four patients who underwent bimaxillary surgery with mandibular advancement fixed with the HT were selected from 2 different institutions and enrolled in this retrospective study. All patients underwent CBCT preoperatively, 1 month after surgery, and 12 months after surgery. To estimate the long-term stability of the HT, volumetric comparisons were performed using the following measurements: distance between the gonion and the B point in the sagittal plane; distance between the right and left gonion transversally; and the angle of the line connecting the mandibular notch and the gonion and the line connecting the gonion and the B point vertically.

**Results:** Statistical analysis showed no relevant relapse (<1 mm or <1°) when using the HT. However, a positive correlation between the amount of advancement and the amount of postoperative relapse was observed.

**Conclusion:** The HT produces stable postoperative 3D results after 12 months.

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Rigid internal fixation (RIF) is an essential tool to achieve stability in orthognathic surgery (OS). It has become the standard method for securing the position of the skeletal segments against unbalanced forces in the stomatognathic system, muscular pull, contraction of soft tissues, and gravitational displacement.[1] Specifically, the goals of RIF with OS are *1)* to achieve primary stability to promote rapid bone healing and prevent pseudoarthrosis or malunion phenomena; *2)* to avoid postoperative intermaxillary fixation, thus initiating postoperative mandibular function as soon as possible and improving postoperative oral hygiene care; and *3)* to increase long-term skeletal stability, thus averting relapse and decreasing the possibility of displacement of the bony segments, particularly the condylar proximal segment.[1,2]

Mandibular advancement is an orthognathic procedure with a very high risk of skeletal relapse because of the anatomic features mentioned earlier and the gap between proximal and distal bony segments.[3] Therefore, several RIF protocols after bilateral sagittal split ramus osteotomy (BSSO) have been described and applied clinically with success, with most of them using bicortical screws (BSs) or at least 1 miniplate with monocortical screws (MSs) with different patterns of placement, size, and number.[1,4]

To achieve the objectives of RIF, the authors routinely use the "hybrid technique" (HT), first described by Luhr et al[5] in 1986 and primarily designed for handling unfavorable splits or bone gaps from third molar sockets.[2] Placing a supplementary BS in the retromolar area increases the stability of 1 MS, maintains its technical advantages, and leaves enough condylar flexibility for postoperative passive accommodation at the glenoid fossa.[6,7]

Stability after BSSO has been widely assessed in recent years, as have the many different possibilities for its RIF.[1,6-10] The most common analysis applied is 2-dimensional (2D) evaluation through lateral cephalometry, although 2D radiography is considered outmoded in OS. Surgical planning and assessment of treatment outcomes can be performed more accurately with software applied to facial cone-beam computer tomography (CBCT).[11]

In this context, this study evaluated the long-term stability of the HT after BSSO using CBCT, a 3-dimensional (3D) and objective measuring tool.

## Materials and Methods

### SAMPLE SELECTION

To address the research goals, the authors designed and implemented a retrospective 2-center study of patients treated for any dentofacial deformity from January 2011 to April 2015. Subjects were selected from 2 institutions (Maxillofacial Institute, Barcelona, Spain; and the Face Surgery Center, Parma, Italy) and operated by their respective main surgeons (F.H.A. and M.R., respectively) who had more than 20 years of clinical experience. A retrospective evaluation of all consecutive patients who underwent treatment for an underlying dentofacial deformity during this period was performed, and only those who fulfilled the following criteria were selected. Inclusion criteria were *1)* bimaxillary surgery with BSSO and mandibular advancement, *2)* RIF using the HT, and *3)* age at least 16 years with mandibular growth cessation at the time of surgery. Patients were excluded as study subjects if they had *1)* any craniofacial syndrome or *2)* pathologic background that could compromise bone healing, *3)* a bad split during BSSO or mandibular reshaping of the B point or angles, *4)* an incorrect surgical plan or primary RIF technique, or *5)* not completed the active orthodontic treatment and postoperative follow-up.

The study was approved by the ethics committee at the Quirón-Teknon Medical Center Barcelona (Barcelona, Spain; number 3DRIF) and performed in accordance with the ethical standards laid down in the 1964 Declaration of Helsinki and its later amendments, and all participants accepted an informed consent agreement.

### SURGERY

Patients were operated on under general anesthesia. In all cases, the mandible was operated on first and BSSO was performed using the Dal Pont-Obwegeser technique. Rigid fixation was achieved using a single 4-hole straight titanium miniplate (2.0-mm BSSO plate; OSA System, OsteoMed, Dallas, TX) along the oblique ridge of the mandible fixed with 4 MSs and 1 BS (2.0-mm width; OSA System) placed at the proximal segment posterior to the last tooth and superior to the inferior alveolar nerve (Fig 1). All patients were extubated in the operating room, and dynamic intermaxillary fixation was maintained with guiding elastics.

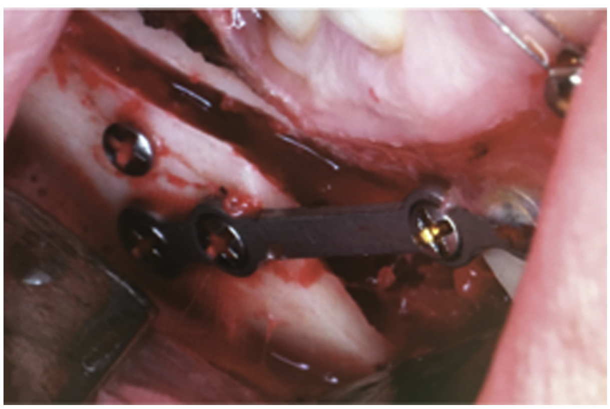

**FIGURE 1.** Hybrid technique.

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### POSTOPERATIVE MANAGEMENT

All patients wore a closed-circuit cold mask (17°C) during hospital admission and were discharged 24 hours after surgery. Standard antibiotic and anti-inflammatory medication for OS was prescribed. Functional training with light guiding elastics was followed for 1 month, and a soft diet was prescribed for the same period.

### EVALUATION

To evaluate the stability of mandibular advancement, linear and angular measurements were performed by superimposing CBCT images (iCAT Vision-Q 1.8.0.5, Imaging Sciences International, Hatfield, PA) obtained preoperatively (T0), 1 month after surgery (T1), and 12 months after surgery (T2). Two postoperative time points were chosen to evaluate the long-term stability of the rigid fixation system. CBCT images were collected in Digital Imaging and Communications in Medicine (DICOM) format and processed with Dolphin 3D Orthognathic Surgery Planning Software 11.8 (Patterson Dental Supply, Chatsworth, CA; Pentium 4 Processor 3.8 GZ, W/SP5 Windows XP Professional, 120-GB memory, 2-GB RAM). A 3D volume was created with hard tissue reconstruction in the T0, T1, and T2 databases.

Two authors (A.P.S.G. and A.S.M.) with a high level of experience with 3D superimposition techniques and virtual treatment outcome evaluation in general evaluated the imaging parameters using a landmark-based method.[12] To ensure truly accurate and reproducible measurements, the examiners tagged all virtual models independently on 2 separate occasions (2 weeks apart), thus avoiding inter- and intra-observer differences, respectively.

Preliminarily, the first postoperative CBCT image was superimposed on the preoperative virtual treatment plan using the anterior cranial base as a template. Patients in whom an important discrepancy (>2 mm in any plane of the space) was detected at this point were excluded from further evaluation to avoid mistakes from a bad surgical plan or suboptimal RIF technique.

The following landmarks were first registered on each virtual model:

1. most inferior point of the left mandibular notch
2. left gonion ($Go_L$)
3. B point
4. right gonion ($Go_R$)
5. most inferior point of the right mandibular notch

The B point was selected as the most anterior landmark to avoid the influence of chin surgery on the pogonion.[13]

From these landmarks, the following linear and angular measurements were obtained in all 3 planes to evaluate the stability of the surgery (Figs 2 and 3):

- sagittal plane: distance between the $Go_R$ and the B point and between the $Go_L$ and the B point
- transverse plane: distance between the $Go_R$ and the $Go_L$
- vertical plane: angle of the line connecting the mandibular notch and the gonion and the line connecting the gonion and the B point (N-Go-B) on the right and left sides

Variations of these parameters were determined at 2 different intervals: T0 to T1 (ΔT1, amount of surgical movement) and T1 to T2 (ΔT2, postoperative relapse of the RIF system). The superimposition of the T0, T1, and T2 volumes, based on mandibular landmarks 1, 2, and 5, was ensured to standardize measurements and to not consider false volumetric changes owing to other condylar or maxillary shifts.

### STATISTICAL ANALYSIS

Descriptive analysis was used for the most relevant statistics for all analyzed variables: mean, standard deviation, minimum, maximum and median for continuous variables, and absolute and relative frequencies (percentages) for qualitative variables.

The *t* test for paired data was used to compare the mean change in mandibular movement at each time point. Two-way analysis of variance for repeated measurements was used to assess differences in the stability of parameters according to gender and age and the Bonferroni test was applied for multiple comparisons. The Pearson correlation coefficient was estimated to assess the relation of movements in the short and long term after surgery.

According to the literature, postoperative relapses of 2° and at least 2 mm for angular and linear measurements, respectively, were considered clinically relevant.[14-18] For all tests, 2-sided $P$ values less than .05 were considered significant, and statistical power reached 0.98 for differences of 0.75 mm per degree, assuming a standard deviation of 1.5 mm per degree.

## Results

### SAMPLE CHARACTERIZATION

According to the inclusion and exclusion criteria, of the 1,010 patients scheduled at the 2 centers (489 in Spain and 521 in Italy) for OS from 2011 to 2015, only 64 patients were enrolled in this 2-center study: 530 patients were excluded because of insufficient data, 165 because they underwent monomaxillary surgery, 63 because they underwent mandibular setback,

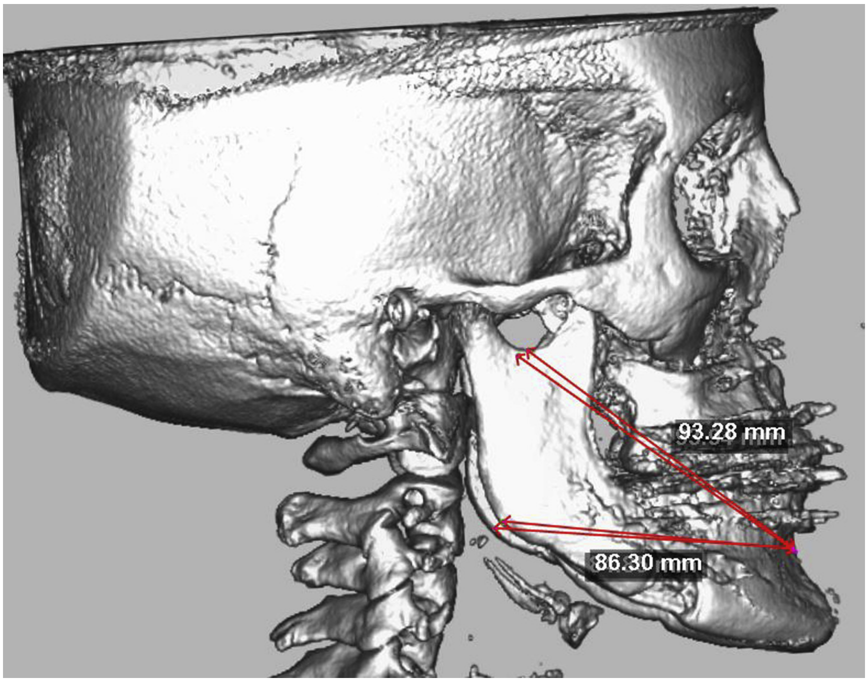


**FIGURE 2.** Lateral view of registration of linear and angular measurements on a virtual model.

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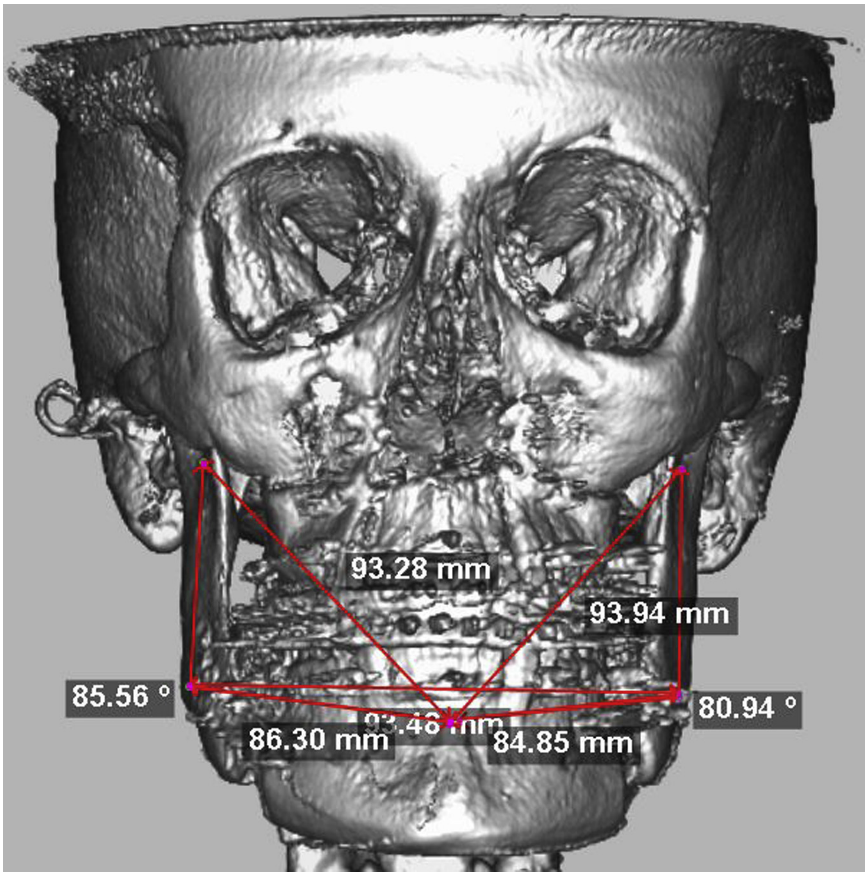


**FIGURE 3.** Frontal view of registration of linear and angular measurements on a virtual model.

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**Table 1. THREE-DIMENSIONAL CHANGES OVER TIME**

| | Sagittal Right, $Go_R$-B (mm) | | Sagittal Left, $Go_L$-B (mm) | | Vertical Right, N-$Go_R$ + $Go_R$-B (°) | | Vertical Left, Angle N-$Go_L$ + $Go_L$-B (°) | | Transverse, $Go_R$-$Go_L$ | |
|---|---|---|---|---|---|---|---|---|---|---|
| | Mean | SD | Mean | SD | Mean | SD | Mean | SD | Mean | SD |
| T0 | 76.52 | 7.24 | 75.77 | 6.74 | 87.10 | 5.89 | 87.82 | 5.82 | 91.69 | 5.74 |
| T1 | 83.95 | 7.07 | 82.74 | 6.98 | 87.39 | 5.45 | 88.22 | 6.09 | 96.34 | 5.72 |
| T2 | 83.60 | 7.40 | 82.37 | 6.72 | 87.66 | 5.94 | 88.48 | 6.48 | 95.77 | 5.61 |
| ΔT1 (T0 vs T1) | 7.43 | 4.23 | 6.97 | 4.67 | 0.29 | 3.92 | 0.40 | 4.23 | 4.65 | 3.00 |
| ΔT2 (T1 vs T2) | −0.35 | 1.55 | −0.37 | 1.62 | 0.27 | 2.21 | 0.26 | 2.04 | −0.57 | 1.16 |
| ΔT3 (T0 vs T2) | 7.08 | 4.25 | 6.61 | 4.00 | 0.56 | 3.97 | 0.66 | 4.16 | 4.08 | 2.81 |

Abbreviations: ΔT1, amount of surgical movement; ΔT2, postoperative relapse of rigid internal fixation system; ΔT3, final amount of movement obtained with surgery after eventual relapse adjustment; $Go_L$-B, distance between left gonion and B point; $Go_R$-B, distance between right gonion and B point; $Go_R$-$Go_L$, distance between right and left gonion; N-$Go_L$ + $Go_L$-B, angle of line connecting the mandibular notch and left gonion and the line connecting the left gonion and B point; N-$Go_R$ + $Go_R$-B, angle of line connecting the mandibular notch and right gonion and the line connecting the right gonion and B point; SD, standard deviation; T0, preoperatively; T1, 1 month after surgery; T2, 12 months after surgery.

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78 because they underwent mandibular reshaping of the B point or angles, 9 because they had a bad split during sagittal osteotomy, 98 because they underwent another kind of RIF, and 3 because they underwent surgery in the context of a craniofacial syndrome.

The first postoperative CBCT image and the preoperative virtual treatment plan of the remaining 64 patients were matched according to the sample selection criteria (<2 mm in all planes). No patients were excluded because of an important discrepancy, so no bias related to an incorrect surgical plan or suboptimal RIF technique was introduced.

Forty-four patients (68.8%) were operated on at the Maxillofacial Institute and the remaining 20 patients (31.2%) were operated on at the Face Center. The studied sample consisted of 50 women (78.1%) and 14 men (21.9%) with a mean age of 29.4 years (range, 17 to 68 yr).

## SURGICAL CHANGES

All selected patients underwent bimaxillary OS, of whom 34 (53.1%) had a genioplasty and 45 (70.3%) had segmentation of the maxilla. All underwent mandibular advancement, that is, pure advancement or counterclockwise rotation. Results from T0 to T1 (ΔT1) indicate the amount and direction of mandibular changes achieved during surgery (Table 1).

No complications occurred during the perioperative period. However, the following postoperative disturbances were reported: alveolar nerve neurosensory deficit occurred in 9 patients and symptoms remained in 4 cases during the follow-up period. Lingual nerve neurosensory deficit occurred in only 2 patients and resolved during the follow-up period. No patients reported postoperative temporomandibular disorder symptoms.

## POSTOPERATIVE STABILITY

The postoperative stability of the mandible fixed with the HT was evaluated by comparing the results obtained at T1 and T2 (ΔT2; Table 1). Thus, the difference between T2 and T0 (ΔT3) indicated the final amount of movement obtained with surgery after eventual relapse adjustment.

Concerning forward movement for the right and left sides, the mean relapses were −0.35 ± 1.55 and −0.37 ± 1.62 mm, respectively (Fig 4). The $t$ test for paired data showed no significant changes between T1 and T2 in the right side (−0.74 to 0.04; $P = .076$ by $t$ test) or left side (−0.77 to 0.04; $P = .075$ by $t$ test). According to the estimated 95% confidence interval, it can be concluded that the mean relapse was far below the cutoff value of 2 mm for the 2 sides

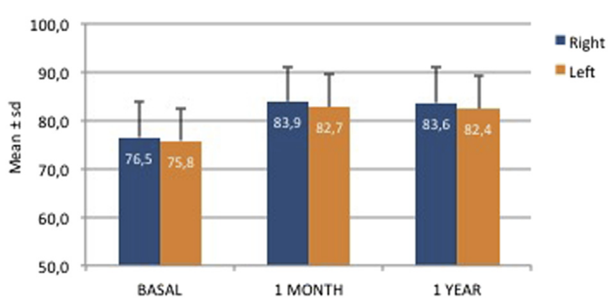


**FIGURE 4.** Changes in the sagittal plane (millimeters) over time. sd, standard deviation.

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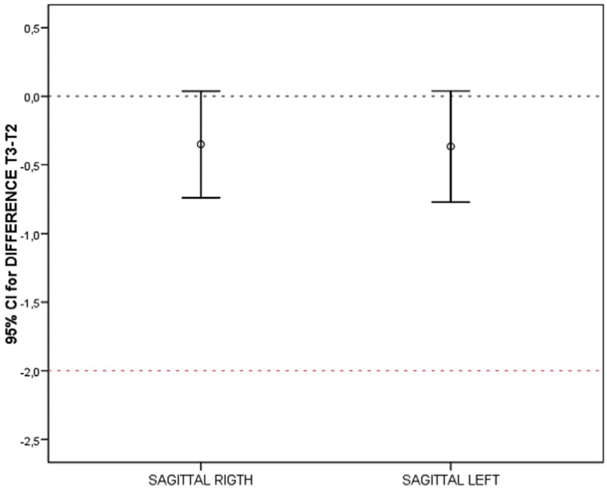


**FIGURE 5.** Mean relapse in the sagittal plane. CI, confidence interval; T2, postoperative relapse of rigid internal fixation system; T3, final amount of movement obtained with surgery after eventual relapse adjustment.

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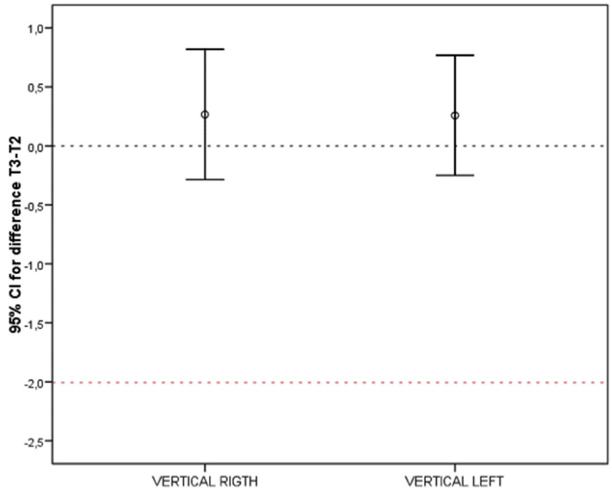


**FIGURE 7.** Mean relapse in the vertical plane. CI, confidence interval; T2, postoperative relapse of rigid internal fixation system; T3, final amount of movement obtained with surgery after eventual relapse adjustment.

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($P$ = .001 by $t$ test), and it might even be argued that relapse in the sagittal plane was significantly lower than 1 mm ($P$ = .05 by $t$ test; Fig 5).

For vertical plane movement, changes during the postoperative period were in the opposite direction, with the mean angles of the N-Go-B increasing by 0.27 ± 2.21° on the right side and 0.26 ± 2.04° on the left side (Fig 6). The $t$ test for paired data showed no significant changes between T1 and T2 on the right side (−0.29 to 0.82; $P$ = .339 by $t$ test) or left side (−0.25 to 0.77; $P$ = .375 by $t$ test). The estimated 95% confidence interval showed that the mean relapse was far below the cutoff value of 2° for the 2 sides ($P$ = .001 by $t$ test), and it can even be assumed that it was significantly lower than 1° ($P$ = .001 by $t$ test; Fig 7).

Results from the transverse plane were comparable to those from the sagittal plane. The mean relapse was −0.57 ± 1.16 mm (Fig 8). The $t$ test for paired data showed no significant changes between T1 and T2 (−0.86 to −0.28; $P$ = .076 by $t$ test). According to the estimated 95% confidence interval, it can be stated that the mean relapse was far below the cutoff value of 2 mm ($P$ = .001 by $t$ test) and, hence, that it was significantly lower than 1 mm ($P$ = .004 by $t$ test; Fig 9).

Thus, stability provided by fixation using the HT was proved in 3 dimensions. Moreover, no relevant differences related to age and gender were found. Any possible correlation between the amount of movement and relapse for the 3 planes also was evaluated. For all studied measurements, there was a positive correlation after performing a simple linear regression. All were statistically significant ($P$ < .01) except for the right sagittal side. Thus, for all cases, greater mandibular movements yielded greater relapses over time (Figs 10-14).

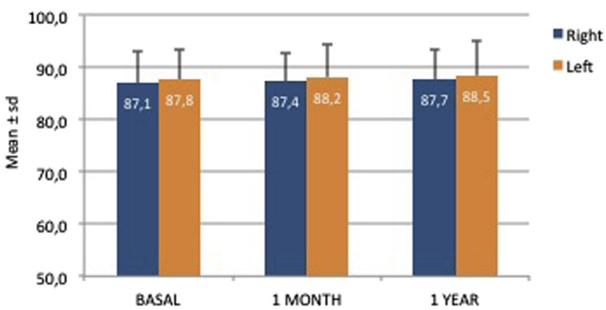


**FIGURE 6.** Changes in the vertical plane (millimeters) over time. sd, standard deviation.

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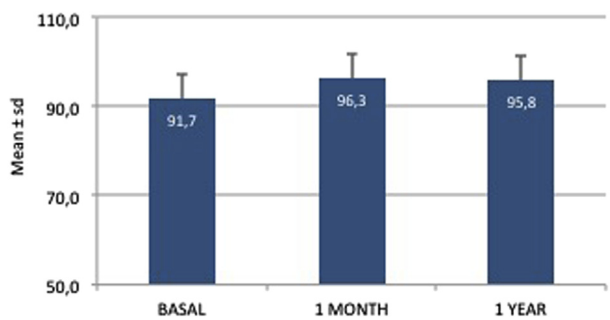


**FIGURE 8.** Changes in the transverse plane (millimeters) over time. sd, standard deviation.

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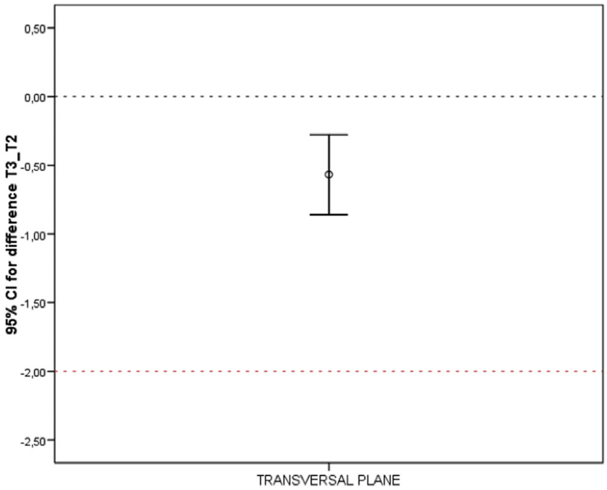


**FIGURE 9.** Mean relapse in the transversal plane. CI, confidence interval; T2, postoperative relapse of rigid internal fixation system; T3, final amount of movement obtained with surgery after eventual relapse adjustment.

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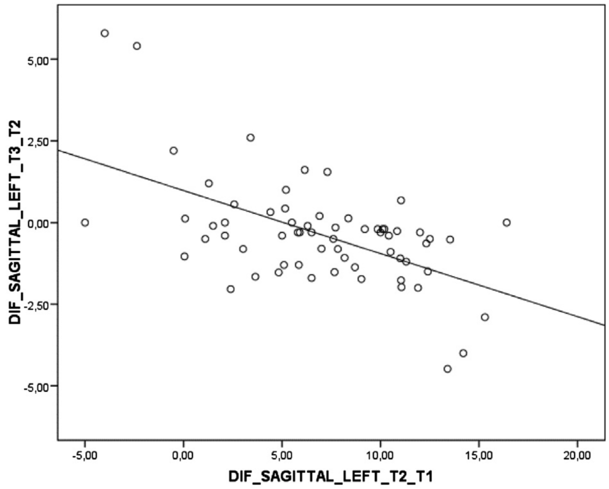


**FIGURE 11.** Correlation between the amount of movement and relapse for the left sagittal plane. T1, amount of surgical movement; T2, postoperative relapse of rigid internal fixation system; T3, final amount of movement obtained with surgery after eventual relapse adjustment.

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Furthermore, the 2 groups of patients from each institution were studied separately to evaluate the effect of the surgeon: differences were found only for the left vertical parameter, in which the mean change was positive for surgeon F.H.A. and negative for M.R. ($P$ = .032).

No differences between clockwise and counterclockwise movements were detected. However, the power of the test is decreased because it is such a small group (7 patients received clockwise rotation, whereas 40 received counterclockwise rotation).

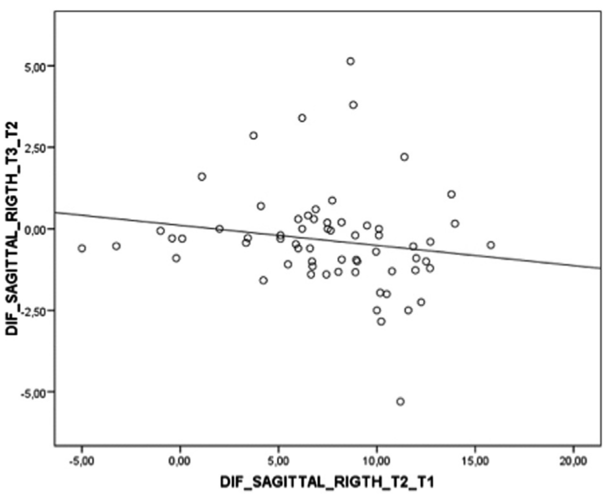


**FIGURE 10.** Correlation between the amount of movement and relapse for the right sagittal plane. T1, amount of surgical movement; T2, postoperative relapse of rigid internal fixation system; T3, final amount of movement obtained with surgery after eventual relapse adjustment.

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Changes from condylar, chin, or maxillary shifts were analyzed: neither upper maxilla segmentation nor genioplasty was related to increased mandibular relapse rates. None of the patients complained of temporomandibular joint discomfort and none of the patients' CBCT images showed condylar resorption.

## Discussion

The ability to rigidly fix the fractured segments at the time of BSSO surgery enables greater predictability and generally improves the final outcome globally. However, to date, there is no agreement on the best RIF method for the stability of the components.

Although bite forces registered in the early postoperative period are less powerful than the preoperative bite forces,[19] absorbable miniplates with absorbable MSs are not included in the range of options. When used, intermaxillary fixation is required to stabilize the bony fragments in the early postoperative period,[20] and initiating postoperative mandibular function as soon as possible is a mainstay of RIF after OS.

Many protocols after BSSO have been described, but the most popular are the use of BSs or one four-hole miniplate with MSs. Although each has pros and cons, there is a wide consensus in the literature that they are similar in stability.[21,22]

Several studies have reported that applying the BS presents better mechanical resistance owing to superior bone contact in the osteotomy region.[16,23] However, stronger RIF is associated with decreased flexibility of postoperative functional adjustment of a

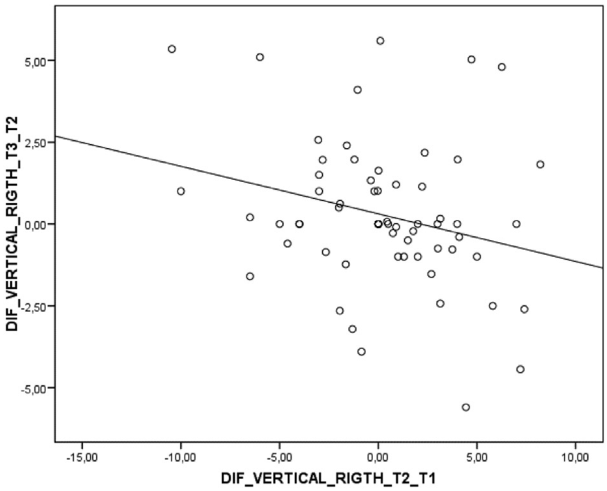


**FIGURE 12.** Correlation between the amount of movement and relapse for the right vertical plane. T1, amount of surgical movement; T2, postoperative relapse of rigid internal fixation system; T3, final amount of movement obtained with surgery after eventual relapse adjustment.

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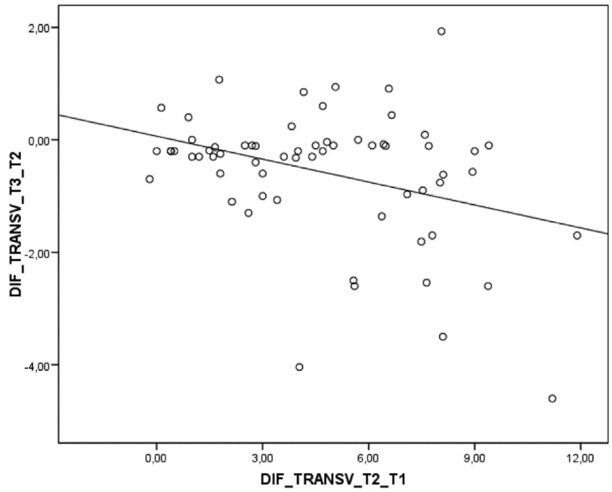


**FIGURE 14.** Correlation between the amount of movement and relapse for the transverse plane. T1, amount of surgical movement; T2, postoperative relapse of rigid internal fixation system; T3, final amount of movement obtained with surgery after eventual relapse adjustment.

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displaced condyle to the preoperative condylar position.[8] In addition, BSs are considered highly traumatic because they compress the bone and increase the risk for fracture and inferior alveolar nerve damage.[4] Moreover, when there is insufficient overlap of bone between the proximal and distal segments for the placement of BSs, the single-MS technique should be considered.[21] The latter technique has shown equivalent stability properties after BSSO[21] and even

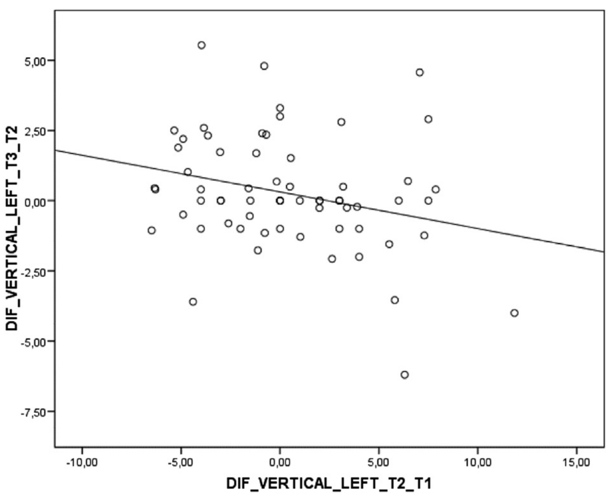


**FIGURE 13.** Correlation between the amount of movement and relapse for the left vertical plane. T1, amount of surgical movement; T2, postoperative relapse of rigid internal fixation system; T3, final amount of movement obtained with surgery after eventual relapse adjustment.

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more equally distributed strain,[4] despite some technical advantages compared with BSs: easy access, user-friendly fixation allowing an intraoral route, less risk of root and lingual and inferior alveolar nerve injury,[24] fewer length restrictions for forward mandibular movement, fewer drawbacks when third molars need to be removed, and better handling of the proximal segment and condyle seating.[25] The authors do not advocate the routine removal of titanium hardware; however, when necessary, access is easier and less traumatic with the HT compared with the BS or double-MS fixation. In patients with unstable postsurgical occlusion, especially in those who received an overcorrection, osteosynthesis should be performed bicortically.[26]

Furthermore, the HT has been proposed to increase single-MS stability and maintain its benefits. Although some reports have suggested that placing an additional BS adds little benefit,[4] others have stated that it contributes to increased stability by inhibiting the displacement tendencies through its resistance to axial and shear forces[7] and sustains its technical advantages by leaving enough condylar flexibility for postoperative passive accommodation at the glenoid fossa.[6]

For many surgeons, the HT is a popular choice because it is a stable and minimally traumatic procedure with several technical benefits, thereby facilitating surgery and generally improving the final outcome. According to the authors' clinical observation, this fixation method is very stable during surgery and effectively reliable for operating on the mandible first.

The stability of BSSO using the HT has 3D and dynamic particularities over time. For these reasons, in the present study a clinical 3D approach was used to analyze the long-term stability of cases, as described in detail below.

Two-dimensional cephalometric analyses have been used extensively in orthodontic and craniomaxillofacial studies. Because this is a projection image of 3D structures, 2D analysis has several disadvantages, such as inaccurate landmark location from overlapping structures. However, a 3D radiologic examination permits a comprehensive evaluation of the patient's anatomy, enables virtual simulation of the surgical procedure, and avoids the concerns mentioned earlier. Moreover, to the best of the authors' knowledge, no previous study has analyzed the clinical long-term rigidity of the HT after BSSO using CBCT as a 3D and objective measuring tool.

With regard to the dynamic feature, biomechanical studies with mechanical and photoelastic tests have special relevance in first grade studies before clinical decisions are made. Nevertheless, human clinical trials are essential to draw firm conclusions because the stability of human in vivo tissues is influenced by specific conditions and behavior changes over time. In other words, the etiology of the relapse after mandibular advancement is multifactorial: apart from the RIF system used, it depends on the accuracy of the surgery, occlusion stability, proper seating of the condyles and upper jaw, remaining growth and remodeling activity, muscle pull, soft tissue contraction, gravitational displacement, and the amount of advancement.

Based on these relapse risk factors, the following key points were considered in the present study to avoid relapse for any other reason. Very experienced surgeons performed all procedures and bad split cases were excluded. Relapse can be due to postoperative instability of the occlusion, and for that reason all recruited patients had completed the active orthodontic treatment, as specified in the inclusion criteria.[27] For mistakes from other anatomic shifts related to the chin, condyle, maxilla, or teeth, the landmarks were fixed only in the mandible.[13] The B point was selected as the most anterior landmark to avoid the influence of chin surgery on the pogonion. However, as noted earlier, genioplasty procedures did not alter the long-term stability of mandibular length in the present patients. All selected patients underwent bimaxillary surgery with the aim of including the potential impact of the upper maxilla on surgical stability in the entire sample. At the authors' respective institutions, more than 90% of patients receive double-jaw surgery. Hence, this series contains only a few cases of single-jaw BSSO. To achieve a homogeneous and sufficiently large sample, only double-jaw cases were included. Specifically, these results illustrate that upper maxilla segmentation was not related to increased mandibular relapse. For changes related to the process of mandibular maturation, mandibular growth cessation was determined according to the improved version of the cervical vertebral maturation method,[28,29] so it can be assumed that age did not show any correlation with surgical relapse. Furthermore, the masticatory musculature was thoroughly detached from the basal border of the mandible but at the antegonial notch before BSSO to avoid excessive muscular pull. Unfortunately, nothing could be done to reverse soft tissue contraction, gravitational displacement, and the necessity of large advancement movement. Indeed, a positive correlation between the magnitude of advancement and the relapse rate was found in this analysis, as other studies in the literature have reported.[16,21] It is important to highlight that the amount of advancement also was positively correlated with progressive condylar resorption, which is considered a major relapse factor.[25]

Although bone healing occurs before 6 months postoperatively, the third registration time point (T2) was selected as 12 months after surgery because late relapse can develop more slowly from the unbalanced forces in the stomatognathic system.[30]

The results of the present study show the long-term stability of the HT after BSSO with mandibular advancement. There also is evidence that the amount of advancement is positively related to the amount of relapse. Despite the statistically relevant results, the main limitation of this report is the lack of a control group.

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