Post-surgical stability in mandibular advancement using postsurgical versus presurgical computer guided functional appliance

(RANDOM IZED CLINICAL TRIAL)

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ABSTRACT

Purpose: Class II patients presenting with retrognathic mandible tend to conceal their deformity by protruding the mandible forward to achieve a more esthetic profile. Thus, they present with an unstable condylar position. This study aimed to assess the post-surgical stability in mandibular advancement using pre-surgical versus post-surgical computer guided functional appliance.

Methods: Eighteen patients with skeletal class II malocclusion were randomly allocated to two groups. Group (A): 9 patients treated with orthognathic surgery combined with presurgical computer guided functional appliance. (control group). Group (B): 9 patients treated with orthognathic surgery combined with postsurgical computer guided functional appliance (study group).

Results: All patients obtained an esthetic facial profile after orthognathic surgery with normal occlusion. Mean advancement of the mandible immediately following surgery (y-axis B, T1-T0) was 8.13±3.42 mm for the control group and 7.32±3.82 for the study group. There was a statistically significant increase in sagittal mandibular position ($p1 < 0.05$) from T0 to T1, and no significant change from T1 to T2.

Conclusion: Functional splint therapy could be a promising adjuvant management in terms of class II cases undergoing mandibular advancement surgery and could offer postsurgical skeletal stability.

KEYWORDS: Computer guided functional appliance; Postsurgical stability; Orthognathic Surgery; Mandibular advancement; Bilateral Sagittal Split Osteotomy.

1. Introduction

Skeletal class II malocclusion is a frequent deformity caused by a combination of skeletal and dental components occasionally accompanied by cosmetic, functional, and psychiatric troubles. Severe forms of mandibular retrognathism occasionally need both orthodontic and surgical management to bring approximately optimum functional cosmetic outcomes. Bilateral sagittal split osteotomy (BSSO) has been considered a widely utilized

surgery in the context of the correction of mandibular deformity and is identified as a very stable and predictable surgical orthodontic approach in terms of mandibular advancement.[1, 2] The surgical approach was first discovered in 1957 by **Trauner and Obwegeser** [3] and afterwards was adjusted by multiple investigators.[4, 5]

With the development of 3D virtual surgical planning and computer-assisted approaches, the orthognathic treatment plan could be transferred to cases with great precision.[6, 7]

In contrast, prolonged stability remains a great issue following mandibular advancement by BSSO.[1, 8] Relapse could be classified as (1) short-term or long-term relapse according to the onset, (2) skeletal or dental relapse according to the anatomic landmark, and (3) horizontal or vertical relapse according to the direction. Short-term relapse occasionally occurs within six months postsurgical. It could be reduced by proper operative condylar positioning and rigid fixation. In addition, dental relapse could be compensated with postsurgical orthodontic management when the skeletal element isn't significant. On the other hand, long-term relapse that could be continued for numerous years post surgically is difficult to predict and manage as it may develop due to several causes.[9]

Class II cases presenting with retrognathic mandible try to hide their deformity by induction of mandibular protrusion to accomplish a more cosmetic profile. As a result, they present with an unstable condylar position.[10]

To enhance the postoperative skeletal stability and decrease horizontal relapse following mandibular advancement, splint therapy could be considered as a presurgical temporary non-surgical repositioning modality together with its adjunctive action for pain management in TMJ symptomatic cases. **Ha, Hong** [10] used functional appliance to obtain a stable presurgical condylar position and demonstrated that functional splint therapy before BSSO for mandibular advancement could be a promising adjuvant management.[10] On the other hand, studies evaluating postsurgical skeletal relapse following mandibular advancement and using postsurgical functional appliance therapy have never formerly been performed. As a result, our study aimed to compare between postsurgical stability in

mandibular advancement using pre-surgical versus post-surgical computer-guided functional splint.

PATIENTS AND METHODS

2.1. Study Design

This was randomized, single-blinded, clinical study comprising samples from cases with skeletal class II. They were chosen from the cases presenting to the Faculty of Dentistry's Outpatient Clinic at Cairo University, to the Oral & Maxillofacial Surgery Department, for evaluation and management of their malocclusion, between June 2021 and May 2023. Inclusion criteria were: (1) The patient is older than eighteen; (2) Cases requiring BSSO for mandibular advancement; (3) Entire cases were free from any illness that could interfere with bone healing; (4) Adequate dentition to reform the occlusal relationship and (5) Informed consent from all cases to contribute. Subjects were ruled out from study enrollment if they had: (1) any underlying illness that could interfere with normal healing process; (2) Intra-bony disorders or infections which could affect the surgical procedures; and (3) Preceding orthognathic operations. The sample size was calculated suing PS software by adopting an alpha level of (0.05) a beta of (0.2) in other words power eighty percent and an effect size (d) of (1.76) calculated according to the results of **Ha, Hong** [(10)] and on expert's opinion; the sample size was eighteen cases (n=18).[(11)]

Eligible patients were allocated randomly into two equal groups using a simple random sequence with an allocation ratio of 1:1 generated by a web site (www. random. org). Group (A): 9 patients treated with orthognathic surgery combined with presurgical computer guided functional appliance. (Control group). Group (B): 9 patients managed with orthognathic surgery combined with postsurgical computer guided functional appliance (study group). This study was conducted in agreement with Ethics Committee– Faculty of Oral and Dental Medicine – Cairo University.

2.2. Presurgical preparation and virtual planning

A thorough clinical examination was performed; presurgical photographs and plaster dental cast models were obtained for all enrolled patients. Patients were sent for orthodontic leveling, alignments and decompensation of malposed teeth. Following orthodontic adjustment CT was requested using a MSCT machine (I-CAT®, Hatfield, PA). DICOM files were utilized through mimic's software (Mimics nineteen, , Belgium). Stone dental models were fabricated, and scanned three dimensionally. Using the planning software digital dental models was aligned over the teeth of the CT skull model to obtain an artifact-free composite/dentition skull model. Using mimics, skeletal relations were analyzed, virtual surgical planning and simulation of the mandibular orthognathic operation was performed for all patients. Cutting guides and custom-made repositioning/fixation plates were made using 3D software (Blender software) on the three-dimensional model with jaws in the final position. Fig 1

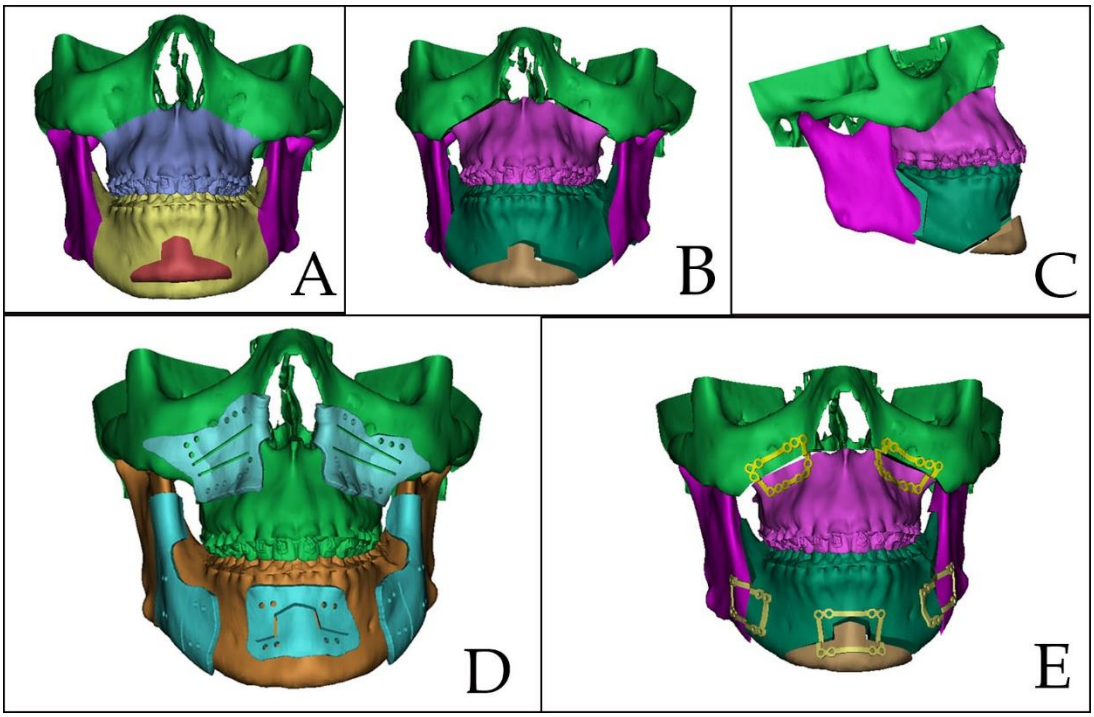


Figure 1 : virtual surgery, CAD of the cutting guides and customized plates.

2.3. Functional Splinting

Presurgical computer guided functional appliance (control group)**:**

By the aid of the software, 3D digitized mandible was repositioned (in a virtual manner) in perfect centric relation via precise positioning of the condyle in the glenoid fossa. In order to create a presurgical CAD/CAM splint on the correct centric occlusion, the dental casts were scanned, digitalized into a virtual 3D model, and overlaid on the CT slices within the virtual plan software. Patients were informed to wear the splints in continuous manner for three months, being permitted to take them off only to eat and brush their teeth. Fig (2)

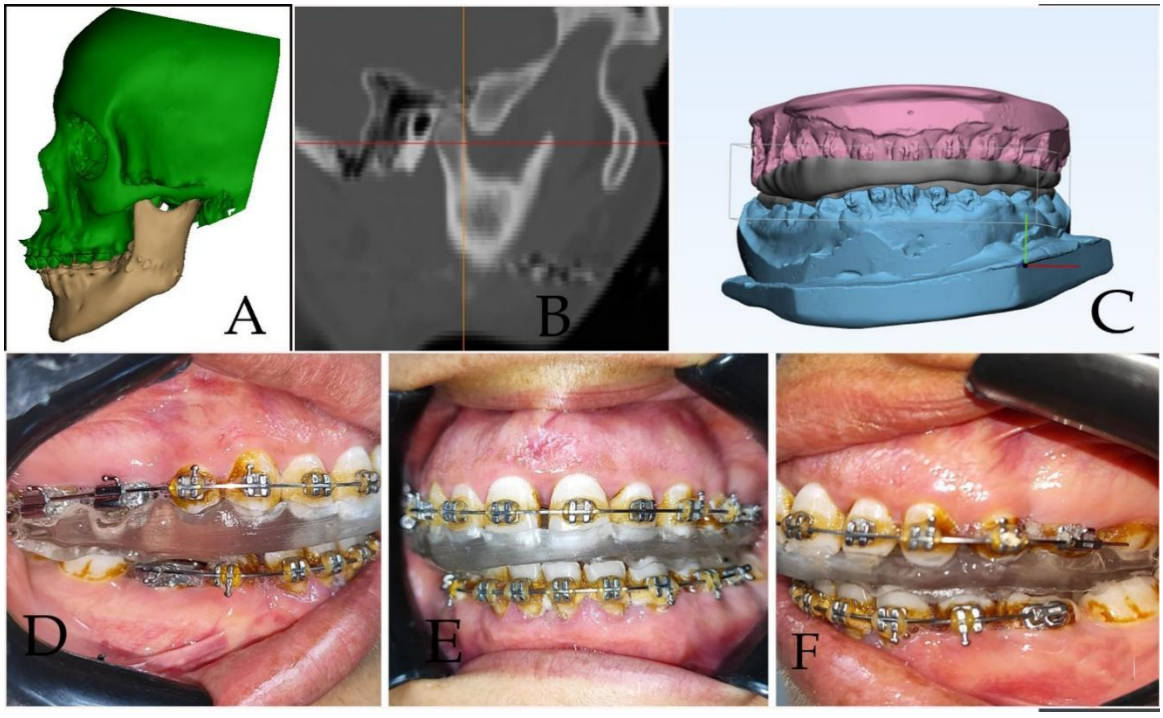


Figure 2 : presurgical computer guided functional splint.

Postsurgical computer guided functional appliance (intervention group):

Utilizing the virtual corrected 3d model with the condyle seated in centric relation, the postsurgical splint was fabricated. Fig (3)

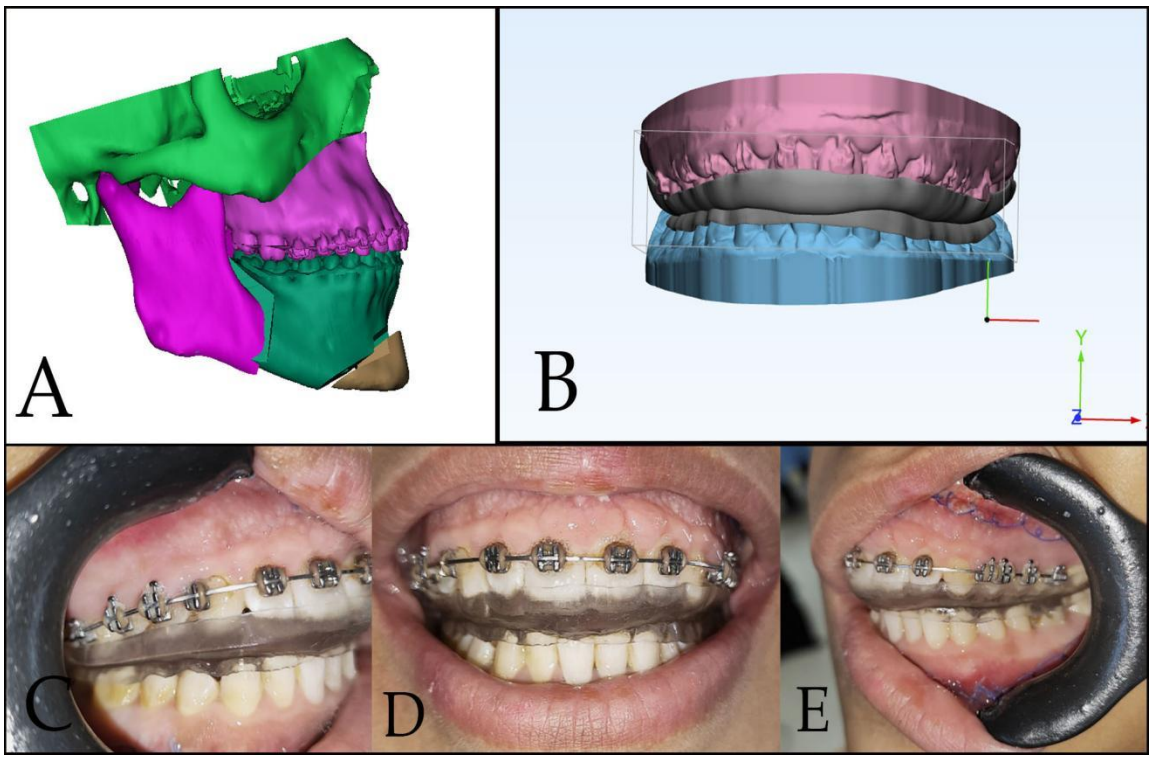


Figure 3 : Computer guided post surgical splint

2.4. Surgical Procedures

BSSO buccal incision was conducted to expose both aspects of the mandibular ramus area. Osteotomy/ screw holes locating surgical guide was seated and fixed in place (Figure 3). The medial, vertical and connecting oblique osteotomies were performed using reciprocating saw guided by the osteotomies' markings, then the screw holes were performed guided by the reference screw holes. The osteotomy/ screw holes locating guide was then removed and the splitting was completed. Using the previously established reference holes and the custom-made plates, the distal segment was oriented to the planned position and fixed using 2.0 mm screws, eight on each side. Finally, all incisions were sutured with 3–0 resorbable sutures (Polyglycolic acid coated braided suture, CFIRM esnet Kratznedel fabrik, Germany.) Fig (4)

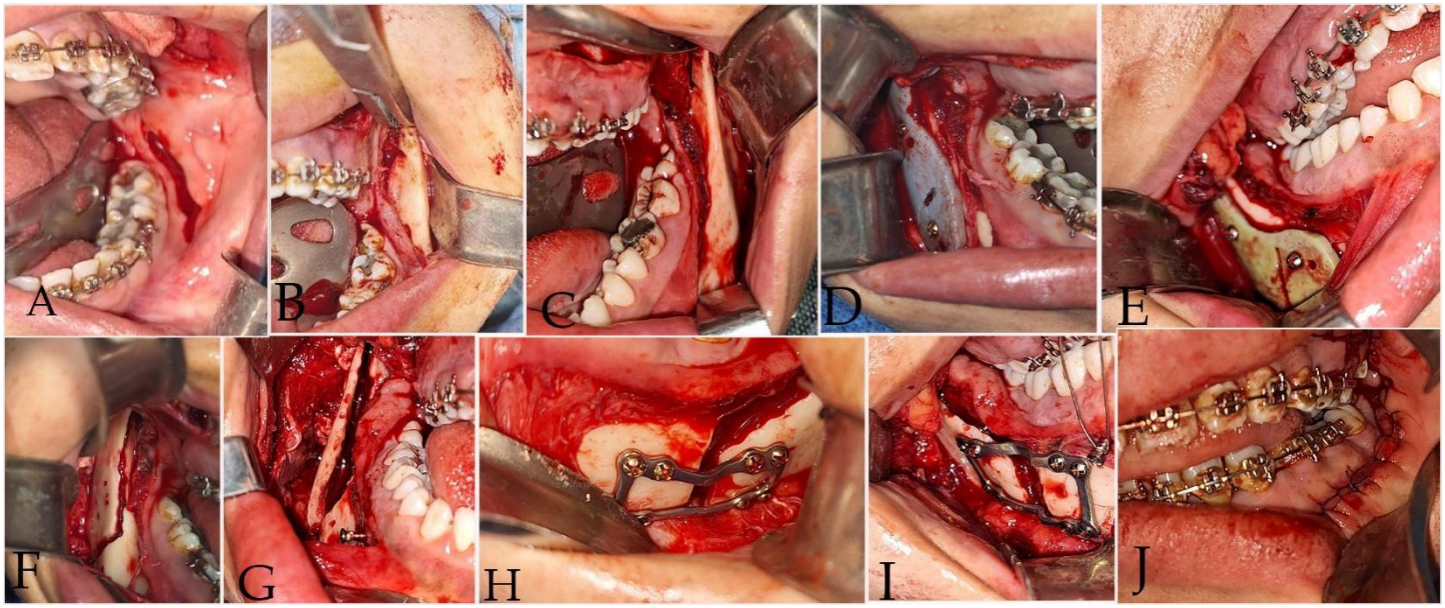


Fig 4 : surgical procedures

2.5. Postsurgical follow up and outcomes

Elastoplast strip was applied to the cheek region for 48 h after the operation. The patients were informed to place ice-packs over the cheek region for twenty minutes every hour for 12 hours post surgically and to use warm saline solution mouth wash starting on the 2nd day following surgery. Soft diet intake was ordered for the 1st two weeks. Postsurgical anti-microbial, pain relieving, and anti-inflammatory medications were ordered for 5–7 days. The patients were reviewed weekly in the 1st two months after surgery for clinical assessment regarding; occlusal harmony, temporomandibular joint functions and inferior alveolar nerve function. The final orthodontic adjustment was started at the beginning of the 1st month post surgically.

A CT was acquired within one week post surgically for all patients. Condylar deviation was assessed through automatic software superimposition of presurgical and postsurgical CTs using fixed alignment points in the skull for registration and anatomic reference points and planes in the osteotomized segments for comparison.(12)

With regard to the xy- coordinate system, the horizontal plane is represented by the x-axis, whereas the coronal plane is represented by y-axis that passes across the sella turcica, and is vertical to the x-axis. Y-axis-B) represents the sagittal position of the

mandible. Mandibular stability could be described as maintenance of the sagittal position of the mandible, which was assessed through measuring the y-axis-B change.

Mandibular distal segment deviation of the actual postsurgical position from the presurgical virtual planning assessed through comparing postsurgical CT with the virtual plane. Linear deviation was assessed using lower central incisors contact point (Inc), right mesio-buccal cusp tip (MB1) and left mesio-buccal cusp tip (MB2) as dental anatomical reference points in addition to menton (Me), pogonion (Po) and B-point as bony anatomical reference points regarding Frankfort (FHP), midsagittal (MSP), and coronal (CP) planes. Angular deviation was assessed using occlusal (OCCP), and mandibular (MP) planes with Frankfort (FHP), midsagittal (MSP), and coronal (CP) planes.

Measurements were reported at the next time points: presurgical (T0), immediately postsurgical (T1), and 1 year postsurgical (T2).

2.6. Statistical analysis

The collected data were analyzed by SPSS software (PASW version 25. Chicago:SPSS.Inc.). Qualitative data were defined using number and per cent. Quantitative data were defined using mean±SD. Significance of the results was set at the (0.05) level. Wilcoxon signed Rank test (W) was utilized for comparison between 2 studied periods (two related samples). Paired t test (t) was used when each subject has a pair of measurements.

3. Results

This clinical trial was conducted on eighteen cases with the mean age of 23.8±3.2 years for the intervention group, and 21.6±3.3 years for the control group. BSSO was performed in all cases who were run uneventful with no excessive bleeding. The degree of mandibular advancement was comparable for both groups (4.9±1.3 mm in the intervention group, and 4.3±1.1 mm for the control group), and there was no statistically significant difference between both groups (P-value 0.27). The follow-up of entire cases displayed ordinary healing with no recorded dehiscence, or infections. Oedema resolved in all cases

within 14 days. All cases revealed transient paresthesia directly following the surgical approaches with full resolution within 60 days post surgically. Patients were referred back to the orthodontist to receive his postsurgical orthodontics five weeks post surgically.

The postsurgical stability was assessed by comparing the outcomes acquired at T1 and T2. As a result, the change between T2 and T0 represented the last amount of movement acquired with operation following ultimate relapse adjustment. At T0, mean y-axis B distance was 52.58±4.47mm for the controls and 53.14±4.81 for the study group. Sagittal mandibular position was significantly increased (mean 8.13±3.42mm for the control group and 7.32±3.82 for the study group; $p1 < 0.05$) from T0 to T1, and insignificant difference was recorded from T1 to T2.

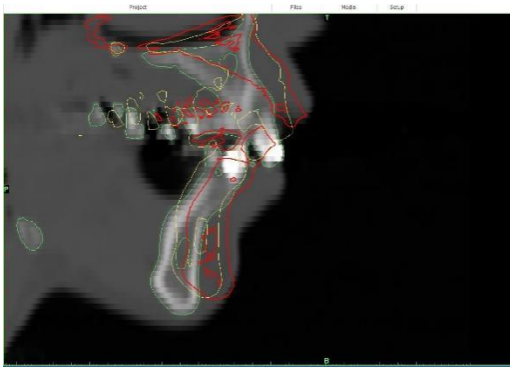
Concerning forward movement, Distal segment position in the presurgical functional splint group displayed linear deviation ranging from 0.148 to 0.356 mm. While the distal segment position in the postsurgical functional splint group displayed linear deviation ranging from 0.102 to 0.296 mm. No significant difference was detected between immediate and one year postsurgical for both groups. Also, insignificant difference was determined between both groups.

For vertical plane movement, Distal segment position in the presurgical functional splint group displayed linear deviation ranging from 0.231 to 0.644 mm. While the distal segment position in the postsurgical functional splint group displayed linear deviation ranging from 0.151 to 0.407 mm. No significant difference was detected between immediate and one year postsurgical for most points for both groups. Also, insignificant difference was detected between both groups.

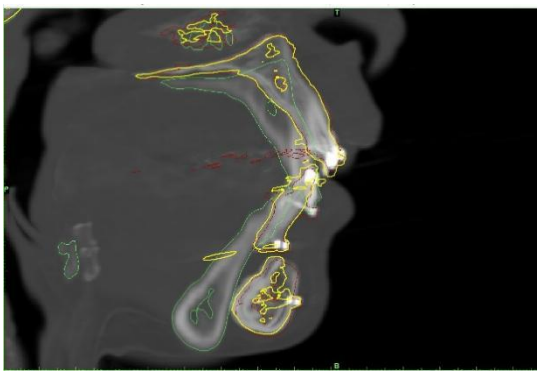
However, the vertical distance from pogonion to the Frankfort horizontal plane displayed statistically significant decrease between immediate and one year postsurgical for both groups ($p=0.001$). Also, the vertical distance from menton to the horizontal plane displayed statistically significant decrease between immediate and one year postsurgical for both groups ($p=0.001$).

Regarding the transverse movement in relation to the midsagittal plane, Distal segment position in the presurgical functional splint group displayed linear deviation ranging from 0.02 to 0.307 mm. While the distal segment position in the postsurgical splint

group displayed linear deviation ranging from 0.028 to 0.225 mm. No significant difference was detected between immediate and one year postsurgical for most points for both groups. However, the left mesiobuccal cusp tip distance to the midsagittal plane displayed significant decrease between immediate and one year postsurgical for both groups ($p<0.05$). table (1)



Fig(5) a representative case of the presurgical splint group



Fig(6) a represenative case of the postsurgical splint group

TABLE (1) Showing linear deviations of the distal segment between the immediate postsurgical and 1 year postsurgical

point	Plane	Time of assessment	Control group	Study group
B point	CP	T1-T0	8.13±3.42	7.32±3.82
		T2-T1	-0.35±0.204	-0.277±0.17
	Paired t test		P1=0.001* P2=0.001* P3=0.578	P1=0.001* P2=0.001* P3=0.345

	FHP	T1-T0	-5.10±4.53	-5.37±4.1
		T2-T1	-0.231±0.11	-0.227±0.206
	Paired t test		P1=0.01* P2=0.008* P3=1.0	P1=0.005* P2=0.003* P3=1.0
	MSP	T1-T0	-3.24±3.95	-3.92±4.88
		T2-T1	-0.033±0.03	-0.031±0.03
	Wilcoxon signed rank test		P1=0.039* P2=0.037* P3=0.879	P1=0.042* P2=0.04* P3=0.881
Pogonion	CP	T1-T0	12.21±5.96	10.99±6.89
		T2-T1	-0.304±0.10	-0.192±0.056
	Paired t test		P1=0.001* P2=0.001* P3=0.725	P1=0.001* P2=0.002* P3=0.479
	FHP	T1-T0	-2.38±3.48	-1.91±4.07
		T2-T1	-0.316±0.143	-0.251±0.08
	Paired t test		P1=0.074 P2=0.051 P3=0.001*	P1=0.198 P2=0.149 P3=0.001*
	MSP	T1-T0	-4.14±6.51	-5.81±8.55
		T2-T1	-0.02±0.03	-0.029±0.03
	Wilcoxon signed rank test		P1=0.094 P2=0.091 P3=0.965	P1=0.076 P2=0.074 P3=0.822
Menton	CP	T1-T0	12.78±4.91	11.57±5.64
		T2-T1	-0.208±0.08	-0.15±0.053
	Paired t test		P1=0.001* P2=0.001* P3=0.425	P1=0.001* P2=0.001* P3=0.371
	FHP	T1-T0	-2.40±2.78	-1.89±3.41
		T2-T1	-0.233±0.07	-0.151±0.06
	Paired t test		P1=0.03* P2=0.02* P3=0.001*	P1=0.135 P2=0.111 P3=0.001*
	MSP	T1-T0	-4.14±6.52	-5.81±8.55
		T2-T1	-0.029±0.034	-0.028±0.03
	Wilcoxon signed rank test		P1=0.094 P2=0.091 P3=0.781	P1=0.076 P2=0.074 P3=0.780
	CP	T1-T0	5.53±2.98	4.71±2.79
		T2-T1	-0.28±0.17	-0.17±0.08

Incisal contact point	Paired t test		P1=0.001* P2=0.001* P3=0.782	P1=0.001* P2=0.001* P3=0.845
	FHP	T1-T0	-4.65±3.16	4.34±3.59
		T2-T1	-0.277±0.16	-0.237±0.19
	Paired t test		P1=0.002* P2=0.001* P3=0.788	P1=0.007* P2=0.005* P3=0.898
	MSP	T1-T0	-2.80±3.37	-3.47±4.23
		T2-T1	-0.042±0.03	-0.046±0.036
	Wilcoxon signed rank test		P1=0.037* P2=0.036* P3=0.958	P1=0.039* P2=0.038* P3=0.966
Right mesiobuccal cusp tip	CP	T1-T0	4.64±3.81	4.35±2.46
		T2-T1	-0.148±0.038	-0.102±0.08
	Paired t test		P1=0.006* P2=0.007* P3=0.457	P1=0.001* P2=0.001* P3=0.652
	FHP	T1-T0	-2.46±4.37	-2.07±4.94
		T2-T1	-0.26±0.06	-0.22±0.046
	Paired t test		P1=0.129 P2=0.001* P3=0.586	P1=0.244 P2=0.001* P3=0.672
	MSP	T1-T0	-0.472±1.08	-0.444±1.04
		T2-T1	-0.214±0.15	-0.143±0.08
	Paired t test		P1=0.225 P2=0.108 P3=0.315	P1=0.236 P2=0.124 P3=0.401
Left mesiobuccal cusp tip	CP	T1-T0	2.65±5.2	2.45±4.91
		T2-T1	-0.356±0.26	-0.296±0.23
	Paired t test		P1=0.164 P2=0.214 P3=0.004*	P1=0.173 P2=0.220 P3=0.005*
	FHP	T1-T0	-2.99±1.80	-3.36±1.59
		T2-T1	-0.644±0.926	-0.407±0.496
	Paired t test		P1=0.001* P2=0.001* P3=0.07	P1=0.001* P2=0.001* P3=0.04*
	MSP	T1-T0	2.75±2.75	2.43±2.54
		T2-T1	-0.307±0.21	-0.225±0.146
	Paired t test		P1=0.017* P2=0.028* P3=0.002*	P1=0.02* P2=0.03* P3=0.002*

t: Paired t test, W: Wilcoxon signed rank test, p1: difference between presurgical and Immediate postsurgical, p2: difference between directly after operation and 12 months after that , p3: difference between directly after operation and 12 months after that

4. Discussion

Mandibular position stabilization is of a distinctive significance in surgical orthodontics as the usage of a stabilization splint prior to the surgical approaches could encourage post-surgical stability by decreasing unpredicted condylar remodeling. The mandibular stabilization could not only be achieved as surgeons locate the condyles forcedly in the most antero-superior position throughout the operation. In cases with disc displacement and the articular joint is in disorder, a minor condylar malposition could bring adverse compression and torque, ultimately causing remodeling of the condylar heads.[13, 14]

To our knowledge, mandibular stabilization doesn't denote manipulation of the position of the condyle to the exact location. Instead, it refers to a proper correlation of nearby tissues of the TMJ comprising mandibular condyles, discs, retro-discal tissues, muscles, and ligaments. Unfortunately, in cases when the surrounding TMJ structures aren't appropriately programmed, mandibular stabilization can't be assured, not even by skilled surgeons.[15]

Splint therapy has been considered a presurgical transient non-surgical condylar repositioning modality together with its adjunctive action for pain management in temporomandibular joint symptomatic cases. To reduce such relapse, preoperative splint therapy is suggested and has demonstrated talented results.[10]

With regard to cases with an open bite, asymmetry in the face and skeletal Class II high angle are often demonstrated to have unsteady condylar position.[15] As a result, in our study, we investigated the role of presurgical vs. postsurgical functional splint therapy.

Computed guided splints were used because they have a greater degree of precision compared to the traditional splints.[16]

Concerning forward movement, sagittal mandibular position was significantly increased from T0 to T1, while no significant difference was detected from T1 to T2 in both groups.

As mentioned before, there are several causes for relapse following mandibular advancement. According to such relapse predisposing factors, the next main points were taken into consideration to evade relapse for any other cause. Relapse may be secondary to postsurgical loss of stability of the occlusion, and for this cause all recruited cases had ended the active orthodontic management.[17] With regard to errors from different anatomical shifts associated with the chin, condyles, maxilla, or tooth, the landmarks were set in the mandible.[18] The B point was chosen as the most frontal landmark to evade the effect of the chin operation on the pogonion. To accomplish a homogeneous sample, all chosen cases underwent bimaxillary surgery. In terms of changes linked to mandibular maturation, skeletally mature cases were chosen. As a result, it could be presumed that age didn't reveal any association with surgical relapse. In addition, the pterygomasseteric was carefully detached from the inferior border of the distal segment to avoid excessive muscular pull.[19]

Even though bone healing happens prior to six months post surgically, the 3rd registration time point (T2) was chosen as 1 year post surgery as delayed relapse could happen very slowly from the stomatognathic system's imbalanced forces.[20]

The functional splint also played a role in maintaining stability of the distal segment after mandibular advancement. The presurgical splint therapy demonstrated the actual degree of the skeletal deformity by deprogramming of the muscles of mastication from the protruded mandibular position to centric relation. Following splinting, physicians have the ability to offer a more precise treatment plan in terms of mandibular advancement, as a result decreasing the likelihood of orthognathic re-operation following relapse.

Also, the post-surgical splint offered a programmed path of mandibular movement to counteract the soft tissue contraction, muscular pull and gravitational displacement.

In the current study, authors used two bone supported surgical guides (osteotomy and screw holes locating guide). These guides together with the customized plates were utilized to guarantee the exact condyle to fossa relationship and the exact amount of planned surgical correction.[21]

Plate osteosynthesis with mono cortical screws was utilized instead of biocritical screw osteosynthesis to avoid the risk of nerve injury and need for nerve tracing.[21]

5. Conclusion

This study showed that patients who underwent mandibular advancement surgery in combination with computer-guided functional splint therapy revealed a stable postoperative outcome at the one-year follow-up. This denotes that functional splint therapy combined with BSSO for mandibular advancement could be a promising adjuvant management in terms of class II cases undergoing mandibular advancement surgery and could offer postsurgical skeletal stability.

Competing interests

The authors declare that they have no competing interests.

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