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Editorial

Dr. Rob Pasch
Editor

Nem beginnings, days are lengthening, and from where I am, it is getting warmer. Of late I have been learning about Artificial Intelligence and its connection with dentistry. This is not the future – it is the present and dentists must embrace this technology for fear of falling behind.

Realizing this technology is now has been likened to teaching fish how to recognize water. The technology has been all around us forever and now the algorithms utilize this data stream to generate outcomes that may enhance diagnosis and treatment protocols. Now there is need for cyber security insurance and patient consent is non-negotiable, for the technology doesn't recognize when it is wrong. That is where your expertise as the dental provider comes in.

Does AI quietly compete with your expertise? It may, but the profession should not look at it this way. Rather, it should recognize that this technology is about enhancing your expertise. It will not replace it.

The FDI (World Dental Federation) has made the following 4 suggestions:

1. Acquire a basic understanding of AI (i.e., learn enough to make informed decision; learn how to prompt).
2. Critically evaluate AI (assess accuracy, applicability and costs).
3. Use evidence based judgments. (Base AI decisions on solid research, vetted through your expertise)
4. Use AI as a tool, not a replacement. (Stay aware of biases, for the final responsibility rests with you, the dentist/practitioner/provider.)

It has been said that if you want to start something new, you have to stop doing something old. For if you aren't the lead dog the view forward never changes. Therefore, it is important to make a transformational change to the AI mindset. And it matters because it is not about installing new equipment or learning new software, it's about having an intelligent assistant that can enhance everything we already do.

Like everything else, there is an obverse side to this technology. Insurance companies can use it to assess procedural competency by requiring final imaging that will be scrutinized by AI as well, and compare it to the data pool at large. It would not be great to be consistently in the bottom of the list of certain procedures, you may be singled out for remedial upgrading courses to keep your license recognition. This assessment does not take into account the clinical/physical environment that the procedure was performed in, the patient may not have been compliant with instructions or had poor appointment frequency, etc. etc. AI can generate deep-fake images as well to send to lawyers and insurance companies.

There are AI-powered micro communities that can emulate you and create a bot that resembles you and make decisions that are eerily close to what you would do. Character AI is one such micro-community.

The development of this AI world will be interesting to say the least. However, the key take home message is to expect continual change and embrace experimentation. Not all aspects of care will benefit from AI. Traditional methods may still be preferable in many situations. Expertise will even be more specialized in the advent of AI technology, and always ensure professional obligations are met. Yours for accredited GP orthodontic education and better patient care.

I remain
Respectfully,
Dr. Rob Pasch DDS MSc IBO General Practitioner.
Spring, 2025

Successful Treatment of Class II Malocclusion in a Young Patient with Headache and Cervical Dystonia Using the Herbst Appliance: A Case Report

by Maryam Bakhtiyari, DDS, IBO, Shahrzad Sadeghi, BS, and Mehrnaz Bakhshzad

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Abstract:

This study demonstrates the successful use of the Herbst appliance to manage class II malocclusion and related craniofacial issues. After a comprehensive assessment and appliance treatment, the patient experienced significant improvements in malocclusion, cervical dystonia, and headaches. This multi-faceted approach highlights the importance of individualized treatment planning and specialized orthodontic appliances.

Objective: This study aims to demonstrate the efficacy of the Herbst appliance in managing patients with class II malocclusion and associated craniofacial discomfort manifesting as occasional headaches and cervical dystonia. The primary objectives of this treatment include addressing malocclusion and associated symptoms while simultaneously achieving comprehensive aesthetic and functional dental rehabilitation.

Methods: A comprehensive patient assessment was conducted, including records for the patient's bite by guiding the mandible more forward to a better physiological position as well as increasing the vertical dimension of occlusion. This record was then sent to the orthodontic lab to construct a Herbst appliance with bilateral molar bands and an occlusal rest. The appliance was subsequently cemented in the patient's mouth. The appliance was worn by the patient for 12 months, followed by orthodontic braces and removal of the appliance once the desired bite was established.

Results: Following treatment, a night retainer was used to maintain the achieved tooth alignment. The patient became asymptomatic for cervical dystonia within a week after the appliance was delivered, with a resolution of headaches, and these improvements persisted throughout the treatment. The patient remained asymptomatic after two years of follow-up, and the class II malocclusion was effectively corrected.

Conclusion: Following a thorough clinical evaluation, a custom Herbst appliance with bonded crowns on permanent molars was created. This one-year treatment successfully corrected class II malocclusion. Subsequently, orthodontic braces aligned the dentition, emphasizing the importance of individualized treatment and specialized appliances.

Keywords: Herbst appliance, Class II malocclusion, Mandibular Advancement Repositioning Appliance, cervical dystonia

Conflict of interest: None

Introduction:

Malocclusion is characterized by tooth misalignment or an abnormal relationship between the dental arches that deviates from what is considered within the normal range.[1] At the mixed dentition stage, the global prevalence rates of Class I, Class II, and Class III malocclusions are 72.74%, 23.11%, and 3.98%, respectively.[2] Class II malocclusion is a frequently encountered clinical issue affecting approximately one-third of the population in the United States.[3] Symptoms of malocclusion affect various aspects of oral and facial health. These include irregular tooth alignment, resulting in an abnormal facial appearance, discomfort or difficulty while biting or chewing, and, in rare cases, speech difficulties, such as lisping. Mouth breathing, characterized by the habitual inhalation and exhalation of air through the mouth without lip closure during respiration, is another symptom. Additionally, malocclusion can lead to an open bite, making it challenging to bite food correctly.[4] Recent research has explored the influence of dental occlusion on body balance. Furthermore, dental occlusion can influence muscle tension in both the jaw-related and postural muscles, which are essential for maintaining balance. A thorough examination of the impact of malocclusal characteristics on muscle properties demonstrated that factors such as Angle's classes of malocclusion, crowding, midline deviation, anterior open bite, overbite, overjet, and tooth alignment significantly affect the frequency, stiffness, elasticity, and relaxation time of the muscles (sternocleidomastoid [SCM], erector spinae [ES], and masseter [M]).[5] When neck muscles, particularly the SCM and upper trapezius, are affected on one side, they can lead to alterations in the shape of the facial and cranial structures, such as the temporal and occipital bones, as well as the cervical spine. This can result in an abnormal head posture and give rise to symptoms resembling those of torticollis or cervical dystonia.[6]

In pediatric cases, cervical dystonia may manifest distinctively from its presentation in adults, posing diagnostic challenges owing to potential symptom overlap with other conditions or developmental concerns. Consequently, these children may encounter instances of bullying that can negatively affect their self-esteem and their capacity to participate in typical daily activities.

This case report describes the successful treatment of a patient presenting with Class II malocclusion and cervical dystonia using a Herbst appliance. (Fig. 1). Originating in the early 1900s through the work of Emil Herbst, it saw a resurgence in the late 1970s when it was reintroduced by Pancherz. The Herbst appliance is a telescopic mechanism that is placed on both sides of the jaw. It was attached to bands on the maxillary permanent first molars and mandibular permanent first premolars, maintaining a consistently anteriorly positioned mandible (Fig.1).[7] Studies have indicated that dentoskeletal alterations achieved through Herbst appliance treatment for Class II malocclusion are more pronounced during the prepubertal growth stage than during the post pubertal stage, primarily because of the greater growth potential that remains available for prepubertal patients.[8]

Fig. 1: .The Herbst appliance consists of custom-fitted metal crowns or bands attached to the upper and lower first permanent molars. These crowns are interconnected by a telescopic mechanism, often made of stainless steel rods or tubes, which promotes controlled advancement of the lower jaw (mandible) into a more forward position. Image courtesy of American Orthodonticsonly for the understanding purpose.

Case presentation

In our orthodontic practice, a 13-year-old patient (Fig. 2) sought treatment due to symptoms of cervical dystonia and headaches, along with a desire to correct their dental alignment. Following a comprehensive clinical assessment augmented by lateral cephalometric and panoramic x-rays (Fig. 3), it was evident that the patient presented with Class II malocclusion, characterized by a 95% deep bite, a 5.5 mm overjet, and a retruded mandible (Fig. 4). Additionally, the patient experienced continuous head movements and neck cracking, which posed challenges in their school environment owing to instances of bullying. Given the patient's age, it was deemed appropriate to recommend the use of a Herbst appliance to address the underlying skeletal irregularities, with a focus on enhancing patient compliance.

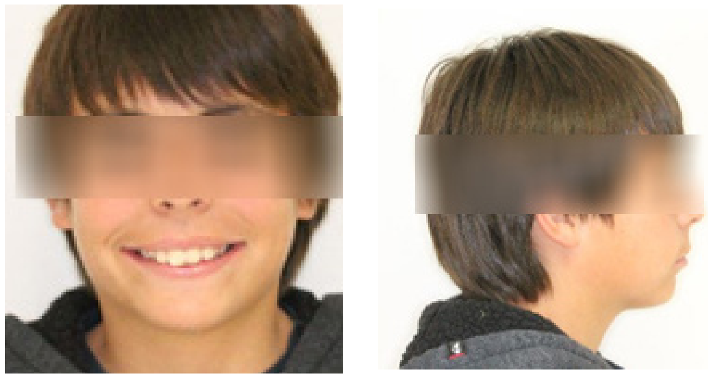


Fig. 2: .Initial facial and dental pictures showing class II malocclusion (frontal and profile).

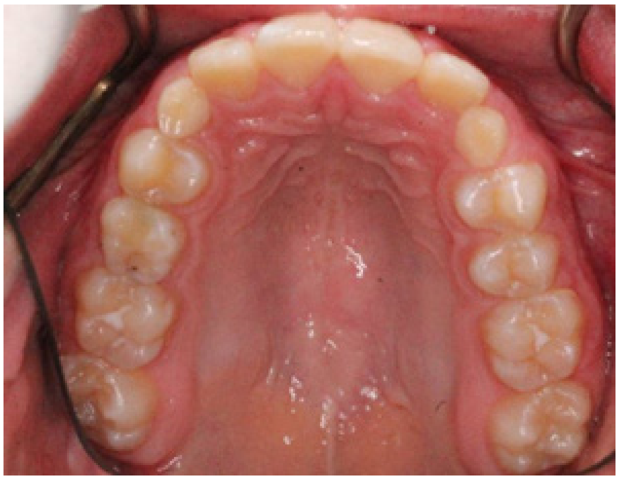
Fig. 3A: Panoramic radiograph

Fig. 3B: Lateral cephalogram radiograph

Fig. 3 .Initial facial and dental pictures showing class II malocclusion

All patient photos used with signed consent

4A .Right Buccal



4B .Upper Occlusal

4C .Lower Occlusal

4D .Center

Fig. 4 . Pretreatment intraoral photographs

Treatment procedure

Our laboratory received these impressions, facilitating the construction of a personalized Herbst appliance. The appliance was designed with fully enclosed bonded crowns affixed to the upper and lower first permanent molars. After the spacers were placed a few days before appliance delivery, the appliance was delivered. (Fig. 5). We placed an occlusal build-up with Bisco Light-Core composite on tooth 13 to stabilize the bite on the left side. Monthly adjustments were diligently made as necessary, enabling gradual advancement of the mandible and ensuring optimal treatment progress. After one year, the Herbst appliance was removed, and intraoral pictures and radiographs were taken. (Figs. 6,7,8,9) and braces were placed. We observed the patient monthly for one year, and the braces were removed (Figs.10, 11). New panoramic X-ray and Lateral Cephalometric images were obtained (Fig. 12), and the final pictures were taken (Fig.13)

Results: The Patient underwent a 24-month treatment utilizing a Herbst appliance and straight wire technique to correct their bite. This corrective procedure successfully alleviated cervical dystonia and neck cracking, significantly boosting the patient's confidence.[8]

5A: Right Buccal

Discussion and conclusion

This study aimed to evaluate the efficacy of the Herbst appliance in the treatment of a 12-year-old boy with cervical dystonia and class II malocclusion. Our findings demonstrate that the treatment approach successfully corrected the initial

5B: Upper Occlusal

5C: Center

5D: Lower Occlusal

Fig. 5: Intraoral images are taken of the patient after placing the Herbst appliance

6A: Upper Occlusal

6B: Lower Occlusal

Fig. 6C: Center

Figure 6: Intraoral images taken of the patient 6 months after placing the Herbst appliance

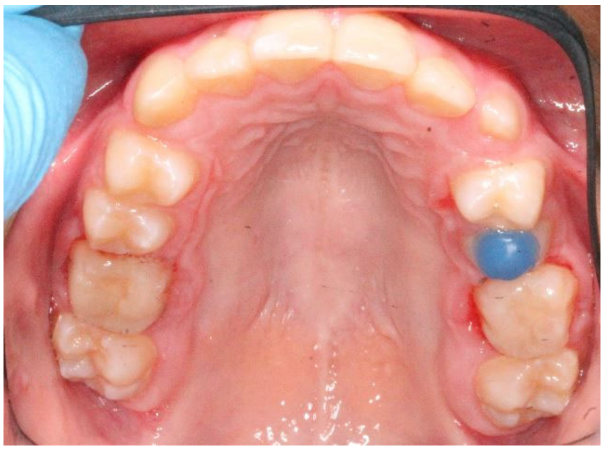
7A: **Profile**

7B: Frontal Smile

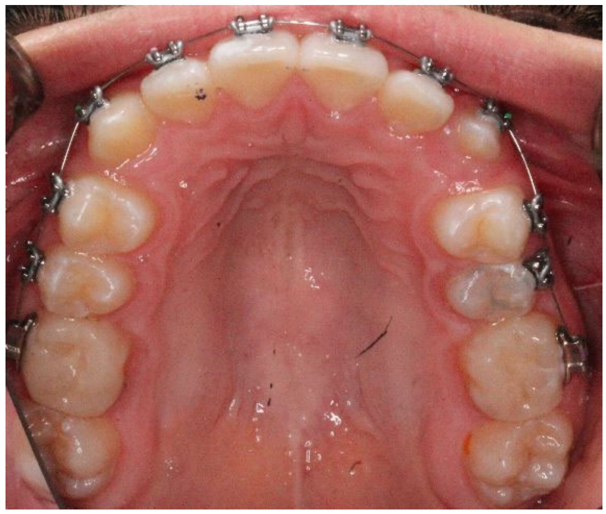
Fig. 7: Facial photographs taken 6 months after placing the Herbst

8A: Right Buccal

8B: Center



8C: Upper Occlusal



8C: Lower Occlusal

8C: Cephlametric Analysis

Fig. 8: **Intraoral images taken upon the removal of the appliance and moving onto the next phase and braces**

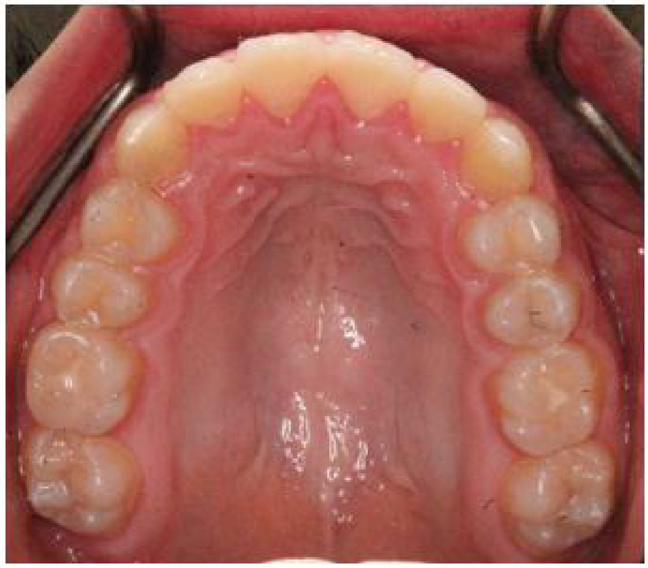
9A: Panoramic Radiograph

9B: Lateral Cephalogram Radiograph

Fig. 9: Radiographic images taken upon the removal of the appliance

Fig. 10: Facial images taken upon removal of the braces (profile and frontal smile).

11A: Center



11B: Upper Occlusal

11C: Right Buccal

11D: Lower Occlusal

Fig. 11: The final Intraoral images taken of the patient after one year of treatment

12A: Panoramic Radiograph

12B: Lateral Cephalogram Radiograph

Fig. 12: The final radiographic images taken of the patient after treatment

Fig. 13: The final facial images taken of the patient after one year of treatment

malocclusion, achieved class I occlusion, and eliminated cervical dystonia and the associated neck discomfort.

Two years after treatment completion, the patient remained asymptomatic, indicating the long-term effectiveness of the Herbst appliance. The positive outcomes of this treatment were well-received by both the patient and their parents, highlighting satisfaction with the overall treatment outcome.

However, it is important to acknowledge the challenges encountered in this study, particularly when ensuring patient hygiene. While efforts have been made to maintain good hygiene, additional measures should be implemented to improve this aspect of the treatment protocol. Additionally, some discomfort was reported in the cheek area, but the patient tolerated it well, suggesting an overall tolerability of the Herbst appliance.

Upon reviewing this case, it is evident that certain improvements could have been made. For instance, better alignment and midline correction could have been achieved by manipulating the Herbst appliance during the initial treatment stages.

Furthermore, obtaining a better alignment could have been facilitated by locating the lower second molar on the right side. This adjustment may have improved the overall treatment outcome, leading to a more favorable occlusal relationship.

To ensure the long-term stability of the corrected malocclusion, the patient was provided with a Hawley retainer for both the upper and lower arches. Lifetime use of these retainers is recommended to protect teeth from wear and tear, thereby maintaining the treatment outcome. Additionally, the inclusion of an anterior programmer in the Hawley retainer could have helped the patient by clenching or grinding at night.

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A Comparative Evaluation of Rate of En-Masse Retraction with and without Low-Intensity Laser Therapy – A Randomized Clinical Trial

by Dr. Rishika Arya, Dr. Wasundhara A. Bhad, Dr. Jyoti Manchanda, Dr. Santosh J. Chavan, Dr. Mohammed Niaz Ali A., and Dr. Ahmed Talha

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ABSTRACT

Introduction: Prolonged orthodontic treatment can harm tooth-supporting structures and reduce patient compliance. To expedite tooth movement, both surgical and non-surgical methods have been explored. Low-intensity laser therapy (LILT) is a promising non-surgical technique due to its safety and minimal invasiveness. This Randomized Controlled Trial (RCT) was designed to study LILT's effect on the rate of orthodontic tooth movement during en-masse retraction.

Materials and Methods: This RCT included 32 patients needing first premolar extractions for moderate crowding and protrusion. They were randomly assigned to either an experimental or control group. TAD-assisted en-masse retraction was performed, with the experimental group receiving laser application every 21 days. Data collection occurred at T0 (start of retraction), T1 (2 months), and T2 (end of retraction).

Results: In the control group, orthodontic tooth movement was 0.81 mm/month for the maxillary arch and 0.69 mm/month for the mandibular arch. In the experimental group, it was 0.99 mm/month and 0.93 mm/month, respectively. En-masse retraction took 155.7 days (5.12 months) for the maxillary arch and 152.3 days (5.01 months) for the mandibular arch in the experimental group, compared to 180.6 days (5.94 months) and 183.1 days (6.02 months) in the control group.

Conclusion: LILT increased the rate of orthodontic tooth movement by 22.2% in the maxillary arch and 34.7% in the mandibular arch, leading to reduction in total duration of treatment by 16% in the maxillary arch and 20.1% in the mandibular arch.

Keywords: Low-intensity laser therapy, en-masse retraction, accelerated orthodontics

Conflict of Interest: None

INTRODUCTION

Orthodontic treatment is widely known for its extended duration, with an average treatment duration of 19.9 months.[1] Prolonged treatment periods can harm tooth-supporting structures and may lead to a decline in patient compliance.[2] Various adjunctive methods can be used to expedite orthodontic tooth movement, broadly categorized as either surgical or non-surgical methods.[3]

Surgical methods carry risk of potential post-surgical complications such as pain, swelling,[4] loss of crestal bone, bone necrosis, edema, and gingival recession.[5,6]

On the other hand, non-surgical methods have gained popularity for their effectiveness in biologically accelerating tooth movement. These methods encompass various mechanical and physical approaches, such as low-intensity laser therapy (LILT), direct electric current, pulsed electromagnetic fields, and ultrasonic vibrations.[7–10]

Among these, LILT has emerged as a focal point in recent studies. LILT is characterized by its low energy output, ensuring that the treated area's temperature remains within the body's normal range.[11] With its safety and minimally invasive nature, LILT stands out as a promising technique for expediting orthodontic tooth movement.[8] The effect of LILT on the rate of OTM has been evaluated during canine retraction[7,8,12] and during leveling and alignment,[13] however, very limited literature is available on the effect of LILT on orthodontic tooth movement during en-masse retraction.

Hence, the aim of this Randomized Controlled Trial (RCT) was to assess the effectiveness of LILT in accelerating the rate of orthodontic tooth movement in patients undergoing treatment by first bicuspid extraction and en-masse retraction.

MATERIALS AND METHODS

Trial Design, Ethical Approval and Registry

Study design was a randomized controlled trial. The study design was approved by the Institutional Ethics Committee (Ref. no. IEC/05/54 dated on 25.04.2022) and consent from the participating subjects was obtained in advance. The trial was registered in the Clinical Trial Registry – India (Ref. no. CTRI/2022/06/055231).

*This article has been peer reviewed

Participants, Setting, and Eligibility Criteria

The study included patients aged 18-30 years with periodontally sound permanent dentition, presenting with dentoalveolar protrusion and moderate crowding, requiring first premolar extractions as a treatment plan. Since en-masse retraction was being evaluated, the study design involved two separate groups, i.e. experimental and control group. However, to avoid biological variation, patients were selected from the same ethnicity.

Patients with history of systemic illness and patients who had undergone previous orthodontic treatment were excluded.

Sample Size Calculation

The sample size of this study was calculated based on the study conducted by Lalnunpuii H et al,[14] considering a first-type error (α) level of 5% and second-type error (β) level of 20%. Determination of sample size was done by using OpenEpi Version 3 software and it yielded an approximate sample size of 28 samples. But, considering 10% dropouts, the final sample determined was 32 patients.

These patients were randomly allocated to two groups, experimental group (16 patients) i.e. patients undergoing LILT assisted en-retraction and control group (16 patients) i.e. patients undergoing en-masse retraction without LILT. Randomization was done using computer generated sequence. Allocation concealment to the patient was achieved by asking each patient to draw a sealed envelope containing an allocation.

Orthodontic Treatment Protocol

After thorough case analysis and treatment planning, first premolar extractions were done. Molar bands (0.180” x 0.006”) were customized and cemented with Glass Ionomer Cement (GC Gold Label). Pre-adjusted edgewise MBT brackets (ORTHO R Organizers, USA) of 0.022” slot were bonded with Transbond XT (3M, Unitech). Initial phase of alignment and leveling was initiated using 0.016-in, 0.016 x 0.022-in, 0.019 x 0.025-in heat-activated nickel-titanium archwires (G&H, Orthoforce, USA). At the end of alignment and leveling, a final working wire (0.019 x 0.025 in stainless steel) was inserted. After 21 days of 19x25-in SS wire placement, en-masse retraction was initiated. Incisors were consolidated by using 0.009-in steel ligature wires. Second premolars and first molars were also consolidated to make a single anchorage unit. Under local anesthesia, self-drilling mini-implants (S.K. Surgicals) measuring 1.5 x 8.0 mm were inserted in between the maxillary second premolar and 1st molar, and mandibular second premolar and 1st molar. A Nickel-titanium closed coil spring (G&H, Orthoforce, USA) was placed from the head of the micro implant to crimpable hook (Garmy) of the

Fig. 1: Laser Kit

All patient photos used with signed consent

Fig. 2: Laser Unit

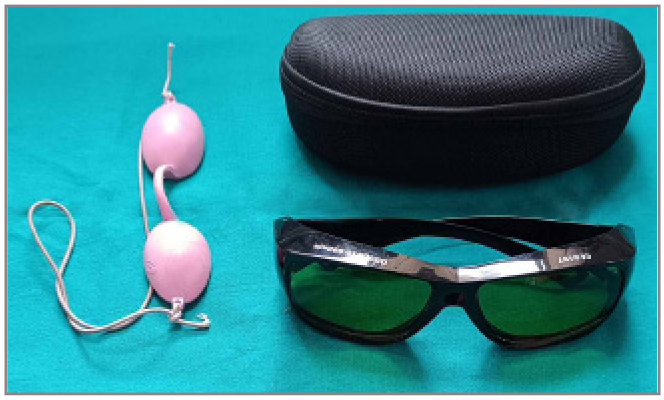

Fig. 3: Patient and operator safety goggles

Table 1: Laser parameters used in the study

Active medium	Gallium Aluminium Arsenide
Emission type	Continuous
Wavelength	980 nm
Power output	0.3W
Exposure time/point	3 seconds (total 10 points: 5 points buccally and palatally each) on all six anterior teeth from canine to canine
Total energy dose (Power*Time)	0.3*30 = 9J
Application	Direct contact
Sessions	On the day of commencement of retraction, then every 21st day until completion of retraction.

working wire. Length of Nickel-titanium closed coil spring chosen depending on the amount of extraction space to be closed, ensuring standardization of retraction force to 200 g using Dontrix gauge.

The low-intensity laser was applied in the experimental group using a semiconductor (GaAlAs) diode laser.

Low-Intensity Laser Therapy (Lilt) Protocol

The laser type used was a semiconductor (GaAlAs) diode laser (Model: DenLase Version: DenLase-SY-A. 1c, China Daheng Group, Inc) emitting infrared radiation with 980+/-10 nm wavelength operated according to the manufacturer’s recommendations. (Figure 1-3)

Laser parameters used in the study are specified in Table 1.

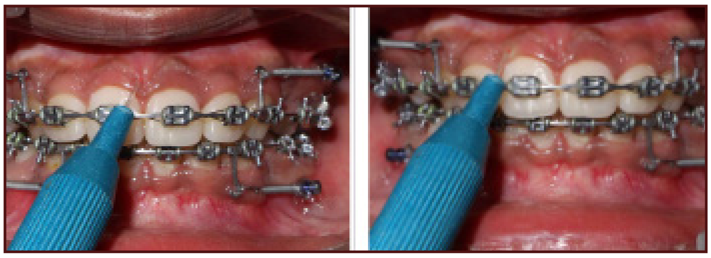

Fig. 4: Mesial and distal cervical point of irridiation (Buccal side)

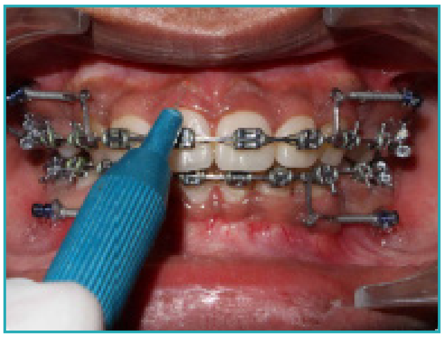

Fig. 5: Middle point of irradiation (Buccal side)

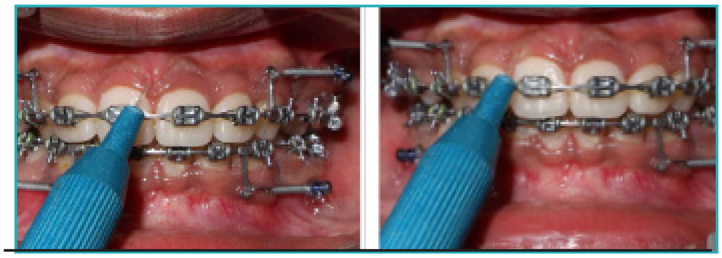

Fig. 6: Mesial and distal apical point of irradiation (Buccal side)

Fig. 7: Mesial and distal cervical point of irridiation (Palatal side)

Fig. 8: Middle point of irradiation (Palatal side)

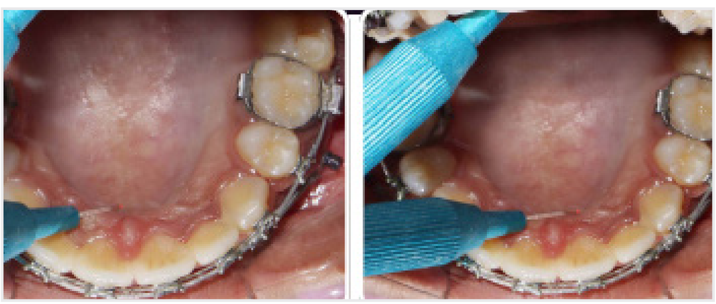

Fig. 9: Mesial and distal apical point of irradiation

Fig. 10: Measurement in maxillary models at T0 (commencement of en-masse retraction)

Fig. 11: Measurement in mandibular models at T0 (commencement of en-masse retraction)

Fig. 12: Measurement in maxillary models at T1 (2 months)

Fig. 13: Measurement in mandibular models at T1 (2 months).

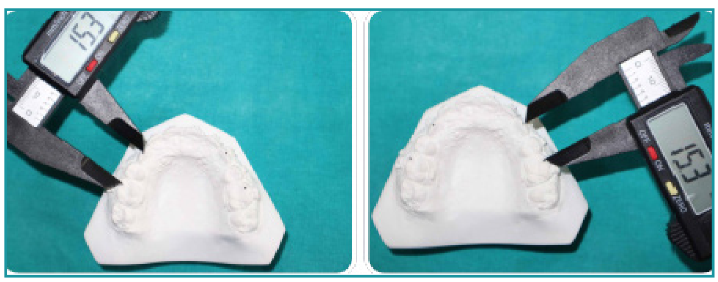

Fig. 14: Measurement in maxillary models at T2 (end of en-masse retraction)

Fig. 15: Measurement in mandibular models at T2 (end of en-masse retraction)

To ensure complete irradiation of the periodontium, irradiations were done buccally (Figure 4-6) and palatally (Figure 7-9) on all six anterior teeth from canine to canine at 5 points (2 irradiations on cervical third of root, 1 irradiation on middle third of root and 2 irradiations on apical third of root).

Measurement Of Orthodontic Tooth Movement (Otm):

Measurement of orthodontic tooth movement was done on progress models.

Three models were made for each patient at T0 (start of en-masse retraction), T1 (2 months) and T2 (end of en-masse retraction). (Figure 10-15)

Rate of orthodontic tooth movement was calculated as amount of orthodontic tooth movement/time period.

Statistical Analysis

The data on the distance between the cusp tip of the canine and the cusp tip of the mesiobuccal cusp of 1st molar for the control and experimental group was obtained at baseline (T0), after 2 months (T1) and at the end of en-masse retraction (T2) and entered in Microsoft excel sheet.

The data was analyzed using SPSS software v 23.0. The level of significance was kept at 5%. Data was subjected to normality assessment using the Shapiro-Wilk test. Since, the data was found to be normally distributed, parametric tests were applied. Results of the distance between the cusp tip of the canine and the cusp tip of the mesiobuccal cusp of the first molar in each group were presented using descriptive statistics. A comparison of displacement, rate of retraction, and duration of retraction from T0-T1, T0-T2, and T1-T2 between experimental and control groups was done using the independent t-test. Similarly, intragroup comparisons were also performed using the independent t-test.

RESULTS

The data on the distance between the cusp tip of the canine and the cusp tip of the mesiobuccal cusp of 1st molar for the control and experimental group was obtained at all time points were analyzed and central tendency was determined (mean and standard deviation).

Table 2: Descriptive details for the distance between the cusp tip of the canine and the cusp tip of the mesiobuccal cusp of the first molar in the experimental group

Interval	Side	Mean	SD	Minimum	Maximum
T0	UR	21.66	1.11	19.30	23.50
	UL	21.59	1.31	19.30	23.70
	LR	19.88	1.22	17.90	22.00
	LL	19.83	1.33	17.20	22.00
T1	UR	18.66	1.33	15.60	21.00
	UL	19.16	1.28	16.90	21.60
	LR	17.09	1.19	15.30	19.30
	LL	17.21	1.25	15.00	19.00
T2	UR	16.53	1.24	14.60	18.40
	UL	16.53	1.24	14.60	18.40
	LR	15.15	1.23	13.40	17.50
	LL	15.15	1.23	13.40	17.50

Table 3: Descriptive details for the distance between the cusp tip of the canine and the cusp tip of the mesiobuccal cusp of the first molar in the control group

Interval	Side	Mean	SD	Minimum	Maximum
T0	UR	20.79	2.38	17.10	25.20
	UL	20.78	2.10	17.10	24.10
	LR	19.23	2.26	15.50	22.20
	LL	19.68	2.14	17.00	23.70
T1	UR	18.78	2.30	15.20	23.00
	UL	18.72	2.00	15.30	21.90
	LR	17.35	2.05	14.60	20.20
	LL	17.51	2.13	14.70	21.50
T2	UR	16.29	1.47	14.10	19.30
	UL	15.57	3.05	5.50	19.30
	LR	15.30	1.19	13.50	17.10
	LL	15.30	1.19	13.50	17.10

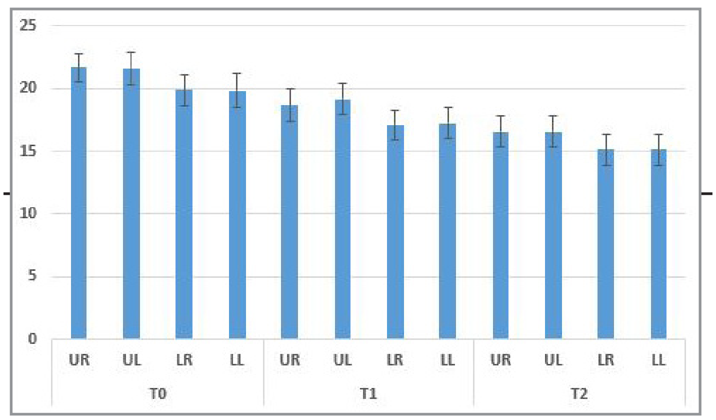

Fig. 16: Bar graph showing descriptive details for the distance between the cusp tip of the canine and the cusp tip of the mesiobuccal cusp of the first molar in the experimental group

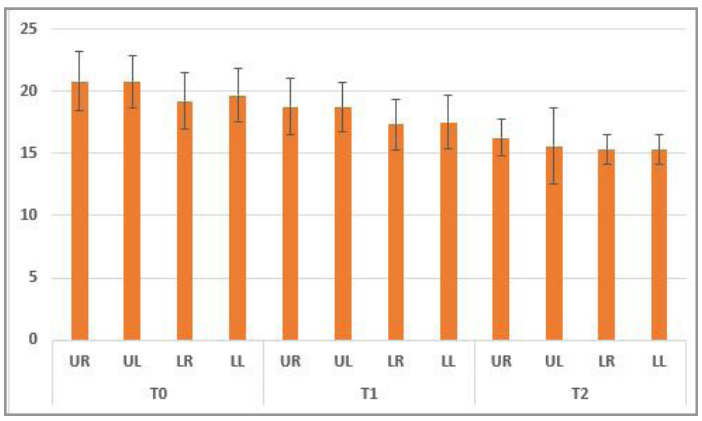

Fig. 17: Bar graph showing descriptive details for the distance between cusp tip of canine and cusp tip of the mesiobuccal cusp of the first molar for the control group

Table 4: Comparison of displacement from T0-T1, T0-T2, and T1-T2 between experimental and control groups

Interval	Side	Experimental		Control		Difference	p-value
		Mean	SD	Mean	SD		
T0-T1	UR	2.99	0.55	2.01	0.31	0.98	<0.001*
	UL	2.43	0.59	2.06	0.33	0.37	0.036*
	LR	2.79	0.60	1.88	0.48	0.91	<0.001*
	LL	2.63	0.65	2.17	0.62	0.46	0.052
T0-T2	UR	5.13	0.59	4.49	1.26	0.64	0.077
	UL	5.06	1.08	5.21	3.46	-0.15	0.875
	LR	4.73	0.79	3.93	1.41	0.80	0.055
	LL	4.68	1.31	4.38	1.67	0.30	0.568
T1-T2	UR	2.14	0.76	2.49	1.23	-0.35	0.339
	UL	2.63	1.15	3.15	3.41	-0.52	0.568
	LR	1.94	0.97	2.05	1.26	-0.11	0.791
	LL	2.06	1.32	2.21	1.56	-0.15	0.771

* Indicates a significant difference at p≤0.05

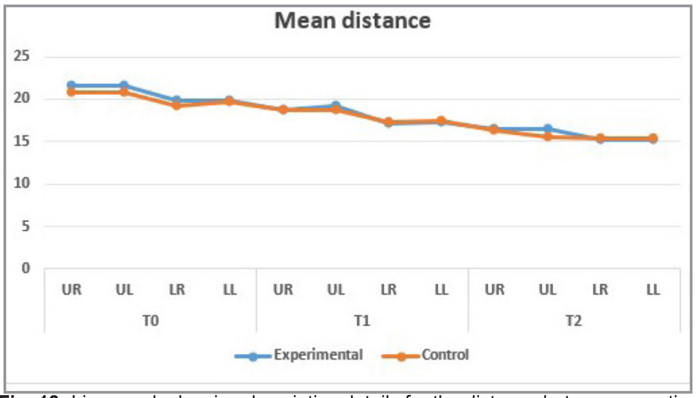

Fig. 18: Line graph showing descriptive details for the distance between cusp tip of canine and cusp tip of the mesiobuccal cusp of the first molar for the control group

Table 5: Comparison of rate of retraction from T0-T1, T0-T2, and T1-T2 between experimental and control group

Interval	Side	Experimental		Control		Difference	p-value
		Mean	SD	Mean	SD		
T0-T1	UR	1.50	0.27	1.00	0.16	0.50	<0.001*
	UL	1.22	0.30	1.03	0.17	0.19	0.036*
	LR	1.39	0.30	0.94	0.24	0.45	<0.001*
	LL	1.31	0.33	1.08	0.31	0.23	0.052
T1-T2	UR	0.69	0.26	0.63	0.31	0.06	0.534
	UL	0.85	0.39	0.79	0.83	0.06	0.793
	LR	0.65	0.32	0.51	0.31	0.14	0.230
	LL	0.68	0.43	0.55	0.39	0.13	0.371
T0-T2	UR	1.00	0.12	0.76	0.21	0.24	0.001*
	UL	0.99	0.21	0.87	0.56	0.12	0.444
	LR	0.94	0.16	0.65	0.24	0.31	<0.001*
	LL	0.93	0.26	0.73	0.28	0.20	0.042*

* Indicates a significant difference at p≤0.05

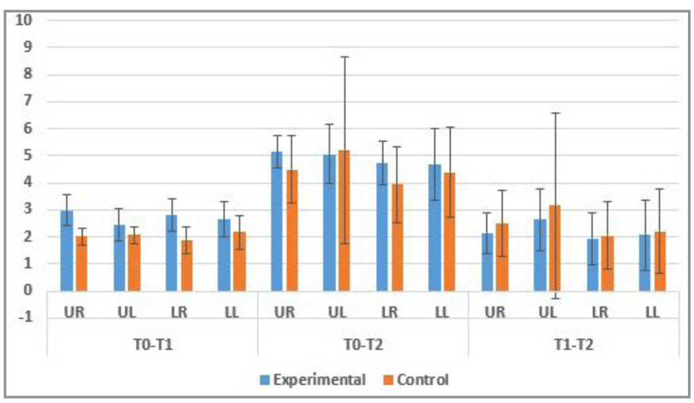

Fig. 19: Bar graph showing descriptive details for the distance between cusp tip of canine and cusp tip of the mesiobuccal cusp of the first molar for the control group

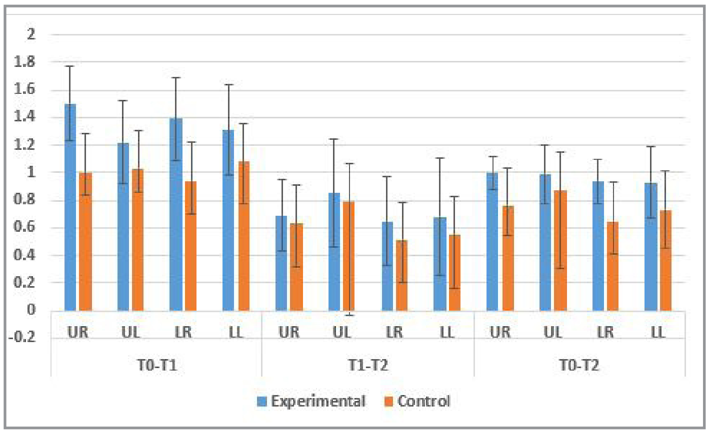

Fig. 20: Bar graph showing the comparison of the rate of retraction from T0-T1, T0-T2, and T1-T2 between experimental and control group

Table 2 and Figure 16 depicts descriptive statistics for the distance between the cusp tip of the canine and the cusp tip of the mesiobuccal cusp of the first molar in the experimental group.

Table 3 and Figure 17 depict descriptive statistics for the distance between the cusp tip of the canine and the cusp tip of the mesiobuccal cusp of the first molar in the control group. Figure 17 depicts comparison of mean distance for control and experimental groups at T0, T1, and T2 time.

The comparison of displacement between experimental and control groups (Table 4 and Figure 18) revealed that from T0 to T2 interval, the displacement was greater in the experimental group as compared to the control group; however, there was a non-significant difference.

The comparison of rate of retraction between experimental and control groups (Table 5 and Figure 19) revealed that from T0 to T2 interval, the rate of retraction was significantly greater in the experimental group as compared to the control group. As there was a difference in the rate of orthodontic tooth movement in patients undergoing en-masse retraction with LILT when compared with patients who did not receive any LILT, the Null Hypothesis of the study was rejected.

The comparison of duration of retraction (in months) from T0-T1, T1-T2 and T0-T2 between experimental and control group (Table VI and Graph VI) revealed that from T0 to T2 interval, the total duration of retraction in maxillary arch as well as mandibular arch was significantly lower in the experimental group arch as compared to the control group.

DISCUSSION

The duration of comprehensive fixed orthodontic treatment can vary widely, but according to the recent systematic review, the average duration of fixed orthodontic treatment was 19.9 months.[15]

There's a growing demand from patients for shorter treatment times. Possible interventions to accelerate orthodontic tooth movement can be categorized as surgical or non-surgical.[3]

The surgical methods encompass alveolar decortication, corticotomy, periodontal ligament distraction, and dentoalveolar distraction.[16] However, surgical approaches have the disadvantage of being invasive and carry the risk of injuries to the surrounding vital structures, infection, postoperative pain, and edema.[8]

Non-surgical techniques include low-intensity laser irradiation,[14] vibration,[17] pulsed electromagnetic fields,[10] electrical currents9, and pharmacological approaches.[18]

Over the past decade, numerous research endeavors have focused on exploring all these different modes to expedite orthodontic tooth movement. One such approach is low-intensity laser therapy (LILT). LILT has the advantage of being not only non-invasive but, clinically easily available as well,[2] thereby, attracting the attention of several researchers interested in exploring modalities of accelerated orthodontics.[7,8,12 14,19,20]

Thus, this study aimed to determine the clinical effectiveness of LILT in accelerating the rate of orthodontic tooth movement during en-masse retraction.

The study design was a randomized clinical trial wherein 32 patients (22 females and 10 males) in the age group of 18 to 30 years, presenting with dentoalveolar protrusion and moderate crowding, requiring first premolar extractions as their treatment plan, were included. Patient was sent for premolar extraction and strap was done and leveling and alignment was completed.

TADs (Temporary Anchorage Devices) were placed in between the second premolar and first molar of each quadrant. In the previous study by Lalnunpuii et al,[14] second molar banding and cross-arch stabilization was used to prevent anchorage loss during the retraction phase. However, in our study, placement of TADs ensured that absolutely no anchorage loss took place and only en-masse retraction was studied and not the forward movement of the first molar.

Progress models on which Orthodontic tooth movement was measured, were taken at 3 time points: before the commencement of en-masse retraction (T0), at 2 months (T1), and at the end of en-masse retraction (T2). A previous study by Doshi et al.[12] on the effect of LILT during canine retraction noted a decrease in the rate of orthodontic tooth movement in later time periods. Therefore, the current study evaluated the effect of LILT on orthodontic tooth movement over the entire duration of en-masse retraction.

Similar to a previous study by Arumughan et al.,[19] in all patients belonging to the experimental group, this laser regimen was applied every 21st day till en-masse retraction was complete as it coincides with normal recall visits.

Rate of orthodontic tooth movement at 2 months (T1) (Table 5 and Graph 20).

A mid-treatment progress model was made for each patient at 2 months (T1) to study LILT's effect on orthodontic tooth movement rate.

In the control group, after 2 months (60.8 days), the mean rate of orthodontic tooth movement was 1.01 mm/month for both the maxillary and mandibular arches. Conversely, in the experimental group, during the same period, the mean rate of orthodontic tooth movement was 1.36 mm/month for the maxillary arch and 1.35 mm/month for the mandibular arch. This indicates that the rate of tooth movement in the experimental group was approximately 1.34 times faster for the maxillary arch and 1.33 times faster for the mandibular arch compared to the control group i.e., there was a 34.6% increase in the rate of tooth movement for the maxillary arch and a 33.6% increase for the mandibular arch in the experimental group compared to the control group in the first 2 months after the commencement of en-masse retraction (T0-T1).

In a similar study by Arumughan et al.,[19] the rate of orthodontic tooth movement was evaluated only in the maxillary arch during en-masse retraction. Similar to our study, all six anterior teeth were irradiated in the experimental group after every 21 days. However, their laser parameters were different from our study, they used 810 nm GaAlAs diode laser with a power output of 0.1 W in a continuous wave mode. The progress model was made on the 84th day (2.7 months) after the commencement of en-masse retraction. Unlike our study, here, the distance between the contact points of the maxillary canine and the second premolar was measured to determine orthodontic tooth movement. They reported a 12.5% increase in the rate of orthodontic tooth movement in the experimental group compared to the control group.

Rate of orthodontic tooth movement at the end of en-masse retraction (T2) (Table 5 and Figure 20).

In the present study, progress records were also taken at the end of en-masse retraction to evaluate the effect of LILT on the rate of orthodontic tooth movement over the entire duration of en-masse retraction.

The present study reported that the mean rate of orthodontic tooth movement from T1 to T2, i.e. from 2 months after the commencement of en-masse retraction till the end of en-masse retraction in the experimental group was 0.77 mm/month and 0.84 mm/month for maxillary and mandibular arch respectively. However, in the control group, it was 0.71 mm/month and 0.53 mm/month for maxillary and mandibular arch respectively. This indicates that the rate of tooth movement in the experimental group was approximately 1.08 times faster for the maxillary arch and 1.58 times faster for the mandibular arch compared to the control group.

As discussed earlier, the highlight of the present study was that the effect of LILT on the rate of orthodontic tooth movement was evaluated over the entire duration of en-masse retraction (T0-T2).

So, the mean rate of orthodontic tooth movement over the entire duration of en-masse retraction in the control group was 0.81 mm/month and 0.69 mm/month for maxillary and mandibular arch respectively. However, in the experimental group, the mean rate of orthodontic tooth movement over the entire duration of en-masse retraction was 0.99 mm/month and 0.93 mm/month for maxillary and mandibular arch respectively. This indicates that the rate of tooth movement in the experimental group was approximately 1.22 times faster for the maxillary arch and 1.34 times faster for the mandibular arch compared to the control group. Therefore, for the T0-T2 interval, there was a 22.2% increase in the rate of tooth movement for the maxillary arch and a 34.7% increase for the mandibular arch in the experimental group compared to the control group.

A previous study by Lalnunpuii et al[14] reported similar findings with a 36.7% and 35.4% increase in the rate of orthodontic tooth movement was observed in the experimental group as compared to the control group for maxillary and mandibular arch respectively.

The effect of LILT on treatment duration (Table 6 and Figure 21)

On average, the en-masse retraction was completed in 155.7 days (5.12 months) and 152.3 days (5.01 months) in the maxillary and mandibular arch respectively in the experimental group. However, in the control group, it took 180.6 days (5.94 months) and 183.1 days (6.02 months) for en-masse retraction to be completed in the maxillary and mandibular arch respectively.

Table 6: Comparison of duration of retraction (in months) from T1-T2 and T0-T2 between experimental and control group(PHQ-15).

Interval	Arch	Experimental		Control		Difference	p-value
		Mean	SD	Mean	SD		
T1-T2	Max	3.12	0.23	3.94	0.28	-0.82	<0.001*
	Mand	3.01	0.19	4.02	0.16	-1.00	<0.001*
T0-T2	Max	5.12	0.23	5.94	0.28	-0.82	<0.001*
	Mand	5.01	0.19	6.02	0.16	-1.01	<0.001*

* Indicates a significant difference at $p \leq 0.05$

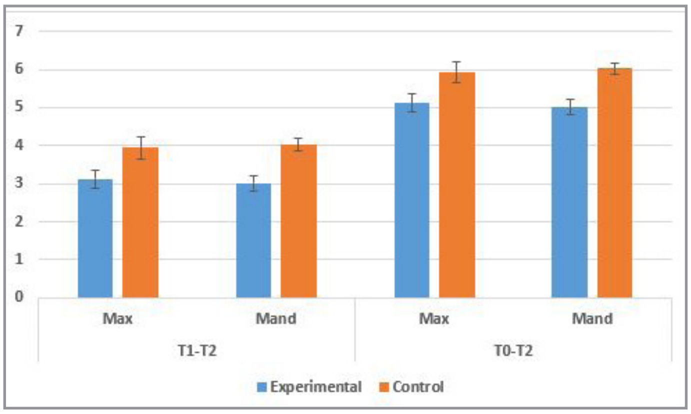

Fig. 21: Bar graph showing the comparison of duration of retraction (in months) from T1-T2 and T0-T2 between experimental and control group

Thus, on the application of low-intensity laser therapy (LILT), there was 16% and 20.1% reduction in total treatment time in the maxillary and mandibular arch respectively. A lesser increase in the rate of orthodontic tooth movement in the maxillary arch compared to the mandibular arch could be attributed to the greater distance between the periodontium and the irradiation site on the palatal side. As stated by Esnouf et al.,[12] energy delivered is reduced by 66% after being transmitted through 0.78 mm of skin tissue.

None of the previous studies[21,22] reported the effect of low-intensity laser therapy on treatment duration of en-masse retraction.

Limitation: Since en-masse retraction was being evaluated, the study design involved two separate groups, i.e. experimental and control group. This could have led to bias due to individual variability.

Scope for Future Research: Long-term studies with larger sample sizes are needed to assess the impact of LILT on the rate of orthodontic tooth movement throughout the entire duration of orthodontic treatment, to ascertain a noteworthy reduction in the overall treatment duration.

CONCLUSION

In the control group, orthodontic tooth movement was 0.81 mm/month for the maxillary arch and 0.69 mm/month for the mandibular arch. In the experimental group, it was 0.99 mm/month and 0.93 mm/month, respectively. En-masse retraction took 5.12 months for the maxillary arch and 5.01 months for the mandibular arch in the experimental group, compared to 5.94 months and 6.02 months in the control group. Therefore, LILT increased the rate of orthodontic tooth movement by 22.2% in the maxillary arch and 34.7% in the mandibular arch leading to reduction in duration of treatment by 16% in the maxillary arch and 20.1% in the mandibular arch.

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TIPS FROM THE EXPERIENCED

Storino Leash Revisited

By Dr. Adrian J. Palencar, MUDr, MAGD, IBO, FADI, FPFA, FICD

The author covered this topic in IAO Monthly Tip (April 2023). Storino Leash was just published then. Therefore, the author recently started experimenting with this technique. It takes quite a few trials to prove the efficacy of this protocol.

I am in treatment of 14 years old male, and I was amazed how efficient is Storino Leash. The following are the particulars:

1. Narrow arches
2. Hypodivergent (SN-GoM - 27°)
3. Severe Class II skeletal and dental (ANB 5.8 mm, Wits 7.5 mm)
4. Proclined maxillary incisors (U1 – SN 116°)
5. OB – 8.0 mm, OJ - 2.0 mm
6. The patient was biting his lower lip and he could not wrap his lips around the maxillary incisors.

All patient photos used with signed consent

Treatment:

1. Orofacial – myofunctional therapy
2. MX Hyrax
3. SWA, Storino Leash
4. Rick-a-nator, composite build ups and triangular elastics
5. Retention

Treatment as of today:

1. Maxillary Hyrax 5 months
2. SWA 10 months (7 months of Storino Leash included)

Prior to placement of Rick-a-nator the OB and OJ were reduced to 4.0 mm. It took the author only 15 months to achieve the last photograph's stage.

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Featured*

Relationship Between Vertical Facial Pattern and Dental Arch Form in Class II Division I Malocclusion

by Dr. Kurapati Krishna Teja, Dr. Mayuri Thomas, Dr. V. Deepti, Dr. Akshay Goje, Dr. Sonali Rathore, Dr. Vennela Gande

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Abstract

Background: This study investigates dental arch widths relative to vertical facial patterns in Class II Division I malocclusion, examining variations across horizontal, average, and vertical growth patterns.

Methods: A cohort of 120 subjects aged 8-30 years was categorized based on vertical growth patterns. Measurements from cephalograms and dental casts were subjected to statistical analyses including Kruskal-Wallis and Chi-Square tests ($p \le 0.05$).

Results: Significant differences in dental arch widths were observed among vertical growth patterns, with horizontal growth presenting wider arches compared to average and vertical growth patterns. Negative correlations were noted between SN-MP angle and arch widths, indicating narrower arches with increased SN-MP angles.

Conclusion: Vertical facial morphology significantly influences dental arch dimensions in Class II Division I malocclusion. Orthodontic treatment planning should consider these variations to achieve optimal and stable outcomes tailored to individual growth patterns.

Keywords: Dental arch form, Class II Division I malocclusion, Inter-molar and premolar width, Cephalometric analysis, Arch dimensions, SN-MP angle.

Conflict of Interest: None

Introduction

In orthodontic practice, achieving optimal dental arch form is crucial for treatment success and long-term stability. This goal is influenced by a complex interplay of genetic, functional, and environmental factors, particularly in relation to vertical growth patterns. Maintaining appropriate arch forms not only prevents relapse but also enhances overall dental health.

Recent advancements in orthodontic materials and techniques have facilitated faster alignment of dental arches. However, the challenge persists in matching available arch wires with patient-specific arch dimensions effectively. Understanding the impact of vertical facial morphology on dental arch dimensions is pivotal for accurate diagnosis and treatment planning. For instance, individuals with longer facial structures often exhibit narrower maxillary intermolar widths and reduced transverse dimensions, whereas those with shorter facial profiles tend to display larger cross-sectional measurements.[1]

Gender-specific variations in dental arch dimensions further underscore the complexity of orthodontic treatment. Studies by Wei (1970)[2] and Eroz et al. (2000)3 have documented significant differences in maxillary and mandibular inter-canine and intermolar widths across different populations and age groups, highlighting the need for personalized treatment approaches.

The stability of orthodontic outcomes, characterized by achieving and maintaining optimal occlusion, remains a primary concern. This study focuses on exploring the relationship between dental arch widths and vertical growth patterns in Class II Division I malocclusion. By elucidating these connections, the research aims to contribute valuable insights for refining

*This article has been peer reviewed

orthodontic interventions and improving treatment longevity.[4]

Materials and Methods

The study sample consisted of 120 subjects, both male and female, aged 8-30 years. Vertical facial patterns were categorized into three groups: horizontal growth pattern, average growth pattern, and vertical growth pattern (Figure 1). Pretreatment lateral cephalograms (Figure 2) and dental casts (Figure 3) were obtained for each subject. Measurements of inter-canine widths, intermolar widths, arch lengths of maxillary and mandibular casts, and arch perimeter were taken using digital calipers (Figure 4). Statistical analyses were performed using the Kruskal-Walli's test and Chi-Square test, with a significance level set at $p \leq 0.05$.

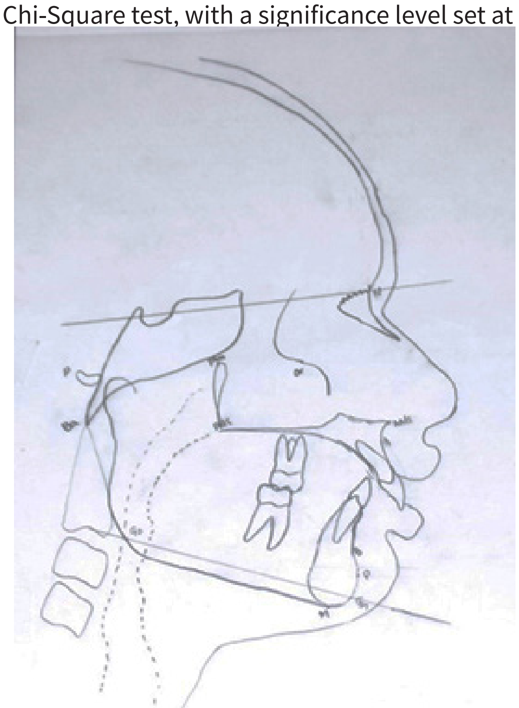

Fig. 1: Cephalometric tracing for hard tissue analysis

Fig. 2: Lateral cephalogram

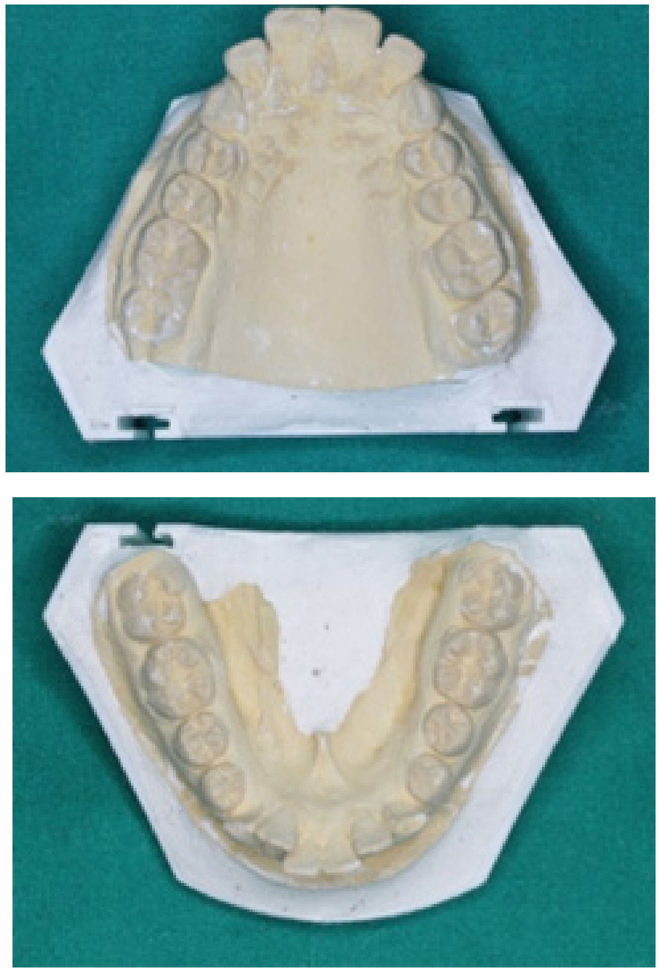

Fig. 3: Dental cast

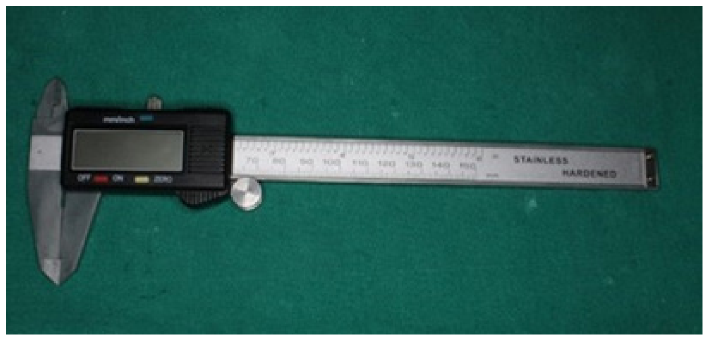

Fig. 4: Digital vernier calipar

Results:

The study revealed notable differences in dental arch widths across various vertical facial growth patterns. Subjects with a horizontal growth pattern consistently displayed the largest inter-premolar and inter-molar distances, with average maxillary inter-premolar and inter-molar distances of 37.51 mm and 47.72 mm, respectively (Table 1,1a,2,2a). Conversely, those with a vertical growth pattern exhibited the smallest measurements, averaging 33.86 mm for maxillary inter-premolar and 44.12 mm for maxillary inter-molar distances. These differences were statistically significant ($p < 0.001$). Significant negative correlations were found between the SN-MP angle and dental arch widths, indicating that as the SN-MP angle increased, the inter-premolar and inter-molar distances decreased (Table 3,3A,4). Landmark identification is greatly affected by operator experience, which might be as important as the tracing method itself. Because interoperator error has in general been found to be greater than intraoperator error, all measurements in this study were carried out by one examiner to minimize error.[5]

Discussion

Vertical Growth Patterns and Dental Arch Dimensions

The findings of this study confirm that individuals with different vertical growth patterns exhibit significant differences in their dental arch dimensions. Subjects with a horizontal growth pattern consistently displayed the largest inter-premolar and inter-molar distances. In contrast, those with a vertical growth pattern exhibited the smallest measurements. These differences were statistically significant, indicating a clear relationship between vertical facial growth and dental arch width.

Previous studies have reported similar findings, suggesting that vertical growth patterns can influence dental arch morphology. For instance, studies by Björk and Skieller (1983)[6] and Schudy (1964)[7] have shown that long-faced individuals tend to have narrower dental arches, while short-faced individuals have broader arches. The current study adds to this body of evidence by providing specific measurements of inter-premolar and inter-molar distances across different vertical growth patterns.

Implications for Orthodontic Treatment

Understanding the relationship between vertical facial morphology and dental arch dimensions has practical implications for orthodontic treatment planning. For example, individuals with a vertical growth pattern may require different treatment strategies compared to those with a horizontal growth pattern. Orthodontists need to consider these differences when selecting arch wires and designing treatment plans to ensure optimal outcomes.

One practical implication is the selection of arch wire shapes and sizes. For patients with a vertical growth pattern and narrower dental arches, orthodontists may need to use arch wires that promote

Table 1: Mean comparison of maxillary inter-premolar distance according to growth

Group	n	Mean	SD	Test statistic	P value
Horizontal growth pattern	40	37.5050	3.53211	25.535	**<0.001***
Average growth pattern	40	34.8470	2.48756		
Vertical growth pattern	40	33.8587	2.63808		

Kruskal Wallis test; p≤0.05 considered statistically significant

Table 1A: Pairwise comparison- post hoc analysis (Dunn's test)

Comparison between		P value
Horizontal growth pattern	Average growth pattern	**0.003***
	Vertical growth pattern	**<0.001***
Average growth pattern	Vertical growth pattern	0.308

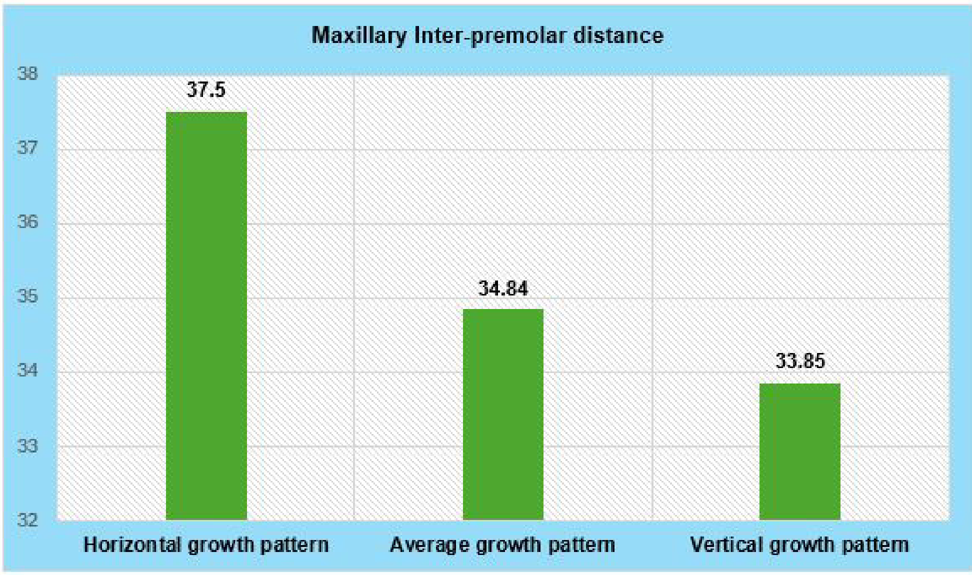

Fig. 5: Mean comparison of maxillary inter-premolar distance according to growth

Table 2: Mean comparison of maxillary inter-molar distance according to growth

Group	n	Mean	SD	Test statistic	P value
Horizontal growth pattern	40	37.5050	3.53211	25.535	**<0.001***
Average growth pattern	40	34.8470	2.48756		
Vertical growth pattern	40	33.8587	2.63808		

Kruskal Wallis test; p≤0.05 considered statistically significant

Table 2A: Pairwise comparison- post hoc analysis (Dunn's test)

Group	n	Mean	SD	Test statistic	P value
Horizontal growth pattern	40	37.5050	3.53211	25.535	**<0.001***
Average growth pattern	40	34.8470	2.48756		
Vertical growth pattern	40	33.8587	2.63808		

Kruskal Wallis test; p≤0.05 considered statistically significant

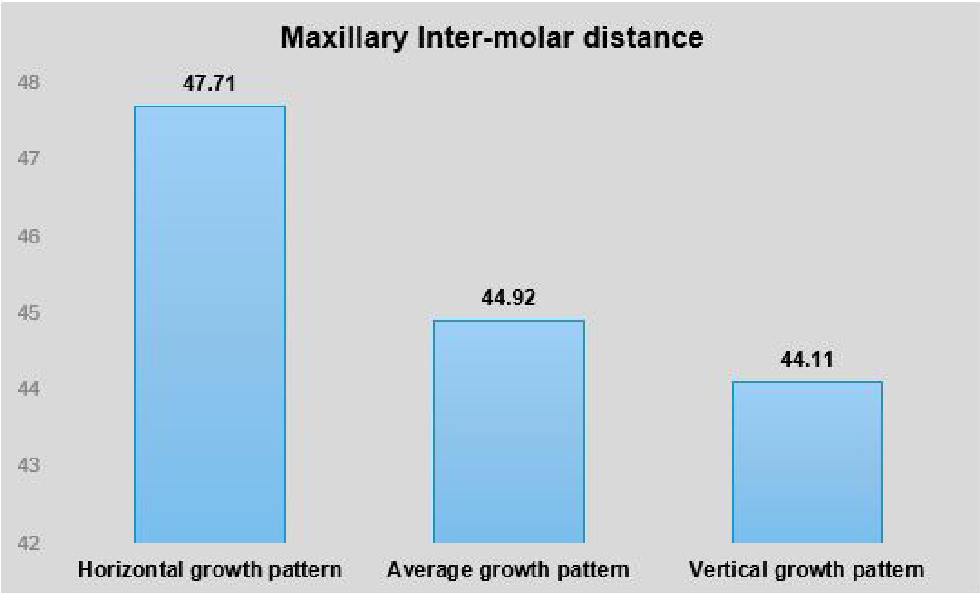

Fig. 6: Mean comparison of maxillary inter-premolar distance according to growth

Table 3: Mean comparison of maxillary inter-molar distance according to growth

Group	n	Mean	SD	Test statistic	P value
Horizontal growth pattern	40	37.5050	3.53211	25.535	**<0.001***
Average growth pattern	40	34.8470	2.48756		
Vertical growth pattern	40	33.8587	2.63808		

Kruskal Wallis test; p≤0.05 considered statistically significant

Table 3A: Pairwise comparison- post hoc analysis (Dunn's test)

Comparison between		P value
Horizontal growth pattern	Average growth pattern	**<0.001***
	Vertical growth pattern	**<0.001***
Average growth pattern	Vertical growth pattern	**<0.001***

transverse expansion to achieve a more favorable arch form8. Conversely, for patients with a horizontal growth pattern, maintaining the existing arch width might be more appropriate.

Stability and Relapse

The stability of orthodontic treatment outcomes is a critical concern for both orthodontists and patients. The current study's findings suggest that vertical facial growth patterns can influence post-treatment stability. Patients with a vertical growth pattern and narrower dental arches may be more prone to relapse, as their dental arches may not have the inherent stability seen in patients with broader arches.[4]

To mitigate the risk of relapse, orthodontists may consider using retention strategies that are tailored to the patient's vertical growth pattern. For instance, fixed retainers or long-term use of removable retainers may be necessary to maintain arch width and prevent relapse in patients with a vertical growth pattern. Additionally, addressing underlying skeletal discrepancies through orthognathic surgery or other means may enhance the stability of orthodontic outcomes in these patients.

Cephalometric Analysis and SN-MP Angle

The significant negative correlations between the SN-MP angle and dental arch widths further support the influence of vertical facial growth on dental arch morphology. The SN-MP angle is a commonly used cephalometric measurement to assess mandibular plane inclination and vertical growth pattern. The findings of this study indicate that as the SN-MP angle increases, indicating a more pronounced vertical growth pattern, the inter-premolar and inter-molar distances decrease.[9]

These correlations underscore the importance of comprehensive cephalometric analysis in orthodontic diagnosis and treatment planning. By evaluating the SN-MP angle and other cephalometric parameters, orthodontists can gain a better understanding of the patient's vertical growth pattern and its impact on dental arch dimensions. This information can guide the selection of appropriate treatment modalities and improve the predictability of treatment outcomes.

Gender Differences and Age Factors

While this study did not specifically analyze gender differences or age-related changes in dental arch dimensions, previous research has indicated that these factors can also influence arch morphology. For instance, males typically exhibit larger dental arch dimensions compared to females, and dental arch dimensions can change with age due to growth and development10.

Future research could further explore these aspects to provide a more comprehensive understanding of the factors influencing dental arch dimensions. Including a larger and more diverse sample could help to generalize the findings and enhance their applicability in clinical practice.

Conclusion:

This study underscores the importance of considering vertical facial morphology in orthodontic diagnosis and treatment planning. Significant differences in dental arch dimensions were observed across different vertical facial growth patterns, with horizontal growth patterns showing the largest arch widths and vertical patterns showing the smallest. Negative correlations between the SN-MP angle and dental arch widths further support that increased vertical facial dimensions are associated with narrower dental arches. These findings provide valuable insights for orthodontists in devising effective and stable treatment plans, tailored to individual growth patterns.

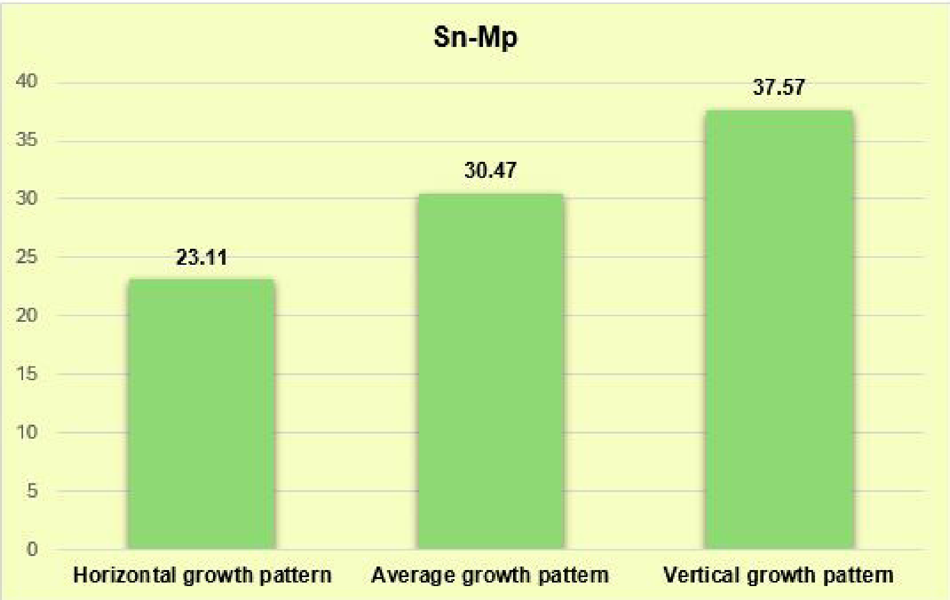

Fig. 6: Mean comparison of Sn-Mp according to the growth pattern

Table 4: Correlation of Sn-Mp with inter-premolar and inter-molar distance

parameters	Sn-Mp							
	Overall sample		Horizontal GP		Average GP		Vertical GP	
	r value	P value	r value	P value	r value	P value	r value	P value
Maxillary Inter-premolar distance	-0.436	**<0.000***	-0.011	0.948	0.144	0.377	-0.215	0.183
Maxillary Inter-molar distance	-0.422	**<0.000***	-0.179	0.270	-0.035	0.831	-0.262	0.102
Mandibular Inter-premolar distance	-0.303	**0.001***	-0.139	0.391	0.027	0.867	-0.245	0.127
Mandibular Inter-molar distance	-0.328	**<0.001***	-0.206	0.203	-0.033	0.839	-0.199	0.218

Spearman correlation test: $p \leq 0.05$ considered statistically significant.

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Treatment Effects of the Carriere Motion Appliance in Class II Malocclusion Patients Using Different Methods of Anchorage Control in the Mandible: A Randomized Clinical Trial

by Dr. Abdelshafy Ali Megahed Abdelshafy, Dr. Ibrahim Saad Abd El-Ghafar, Dr. Esmail Kamal Hewy Raslan and Prof. Dr. Saleh Anwar El-sayed Saleh

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Abstract:

Trial design: Parallel

Objective: Assessment of different anchorage methods with the Carriere motion appliance (CMA) to correct class II malocclusion (Cone beam study).

Materials and Methods: Twenty adolescents with class II molar relationship were treated with CMA and divided into two groups according to anchorage methods direct mini-screw group (DMG) and passive lingual arch group (PLG). Cone beam computed tomographic (CBCT) scans were taken before treatment (T0) and after distalization (T1). The treatment changes in measurements were calculated in each group, and the measurements were compared between them.

Results: In the PLG, there was a statistically significant anterior movement (2.03 ± 0.49 mm) as well as proclination of the lower incisor (3.70 ± 1.25), compared to a nonsignificant anterior movement (0.01 ± 0.02 mm) and proclination (0.11 ± 0.31) in the DMG. The amount of maxillary molar distalization was higher in the DMG (3.54 ± 1.47 mm) than in the PLG (2.62 ± 0.42 mm); however, the difference was statistically significant.

Conclusion: Direct miniscrew anchorage led to decreased anchorage loss in the mandibular molars and incisors, both in anterior movement and proclination.

Trial registration The ClinicalTrials.gov Protocol Registration and Results System (PRS) has this RCT registered as NCT05631353 on 21-11-2022.

Keywords: Carriere Motion Appliance, Class II malocclusion, Miniscrews, CBCT evaluation, Anchorage.

Conflict of Interest: None

Funding:The Science, Technology & Innovation Funding Authority (STDF) provides open-access funding in cooperation with The Egyptian Knowledge Bank (EKB).

Availability of data and materials: All the datasets used and analyzed during the current study are available from the corresponding author upon reasonable request.

Declarations: Ethical approval was obtained from the Research Ethical Committee at the Faculty of Dental Medicine for Boys, Al-Azhar University in Assuit, Egypt (AUAREC20220110-06). All patients were informed about the study and asked to sign informed consent forms, and all the cases in the research sample fulfilled the following inclusion and exclusion criteria: the patient eligibility criteria. In addition, this study was registered before its start at ClinicalTrials.gov with identifier number NCT05631353 on 21-11-2022.

Background:

Upper molar distalization is a commonly used treatment modality for correcting class II malocclusion in non-extraction cases.[1]

The orthodontic literature has carefully reviewed Class II correction appliances. Class II elastics effectively corrected Class II malocclusion.[2,3] Other frequently used Class II appliances include, but are not limited to, extraoral appliances such as headgear,[4-6] intramaxillary appliances,[7-9] and intermaxillary appliances.[2,10-14] However, most of these methods procline mandibular incisors.[3]

Since introducing the Class II Carriere Motion appliance (CMA), the orthodontic literature has mentioned many issues about treatment outcomes. The appliance was designed to be an intermaxillary, non-extraction, Class II corrector.[15] It consists of mold-injected, nickel-free stainless steel from the maxillary canine to the first molar. A hook attached to the canine pad provides elastic wear to the mandibular first molar, where anchorage is required. A ball-and-socket design on the molar pad permits tilting and rotation of the molar.[15]

A lingual arch, an Essix appliance, or mini-screws are anchorage methods that have been reported to prevent mandibular incisor protrusion during appliance activation.[16, 17]

Clinical studies[16, 20] and Case reports[18, 19] compared the treatment effects when two

*This article has been peer reviewed

different types of anchorage were used in the mandibular arch by full fixed orthodontic appliances or a lingual arch and reported that both methods led to the proclination of the lower incisors.

Further studies[21-24] assessed the CMA's treatment modifications using the Essix appliance as an anchor in the lower arch. They reported lower incisor proclination, significant mesial movement, and tipping of the first mandibular molar.

In one study, [16] the CMA was used with indirect miniscrew and Essix appliance as anchorage for class II elastics, and it reported little mesial movement, the tipping of the first mandibular molar, and lower incisor proclination with indirect miniscrews than Essix appliance. In another study, Ghozy et al. used an infrazygomatic miniscrew with CMA and found more significant distalization of the maxillary buccal segment than the Essix anchored one.[17]

Aim of Study: This study aimed to compare the 3D effects of direct miniscrew anchored vs. Passive lingual anchored CMA for distalization of the maxillary buccal segment.

Patients and Methods: This methodology was written according to CONSORT statement guidelines for randomized trials.

Trial Design: The study design was a randomized clinical trial, a parallel design in which participants were randomly assigned to an intervention or comparison group with a 1:1 allocation ratio and comparison group as follows:

a. Direct interdental Miniscrew Group (DMG): Interdental mini-screws in the lower arch were used for anchorage.
b. Passive Lingual appliance group (PLG): Passive lingual appliance in the lower arch was used for anchorage.

In addition, this study was registered before the start at ClinicalTrials.gov with identifier number NCT05631353 on 21-11-2022

Participants: Patients were recruited from the Outpatient Clinic at the Department of Orthodontics, Faculty of Dentistry, Al-Azhar University, Assiut branch, from January 2023 through January 2024.

Ethical approval was obtained from the Research Ethical Committee at the Faculty of Dental Medicine for Boys, Al-Azhar University in Assuit, Egypt (AUAREC20220110-06). All the parents of the enrolled patients signed the informed consent form as the patients were below the age of 17.

All patients were informed about the study and were asked to sign informed consent forms. All the cases of the research sample fulfilled the following inclusion and exclusion criteria.

Eligibility criteria: All the cases of the research sample fulfilled the following inclusion and exclusion criteria.

Inclusion Criteria of Patient Selection: -

- Adolescent patients aged 11–17 years.
- Unilateral or bilateral Class II molar relationship.
- Class II canine relationship.
- No history of previous orthodontic treatment.
- No malformed teeth, impacted teeth, and unerupted teeth.
- Good oral hygiene.
- No abnormal pressure habit.
- No periodontal diseases.
- No missing teeth in the maxillary arch.

The exclusion criteria included: -

- There is a need for extraction in the lower arch.
- Posterior crossbite.
- Presence of any craniofacial anomalies.
- Patients with syndromes.
- Uncooperative patients.

Intervention

The CMA was attached to the permanent upper canine and first molar, with the appropriate size chosen per the manufacturer's instructions. Participants were then randomly assigned to one of two groups. In the DMG, two miniscrews (MCTBIO, Yongin, Korea), 8 mm long and 1.6 mm in diameter, were inserted between the lower first and second premolar, one on each side. After miniscrew insertion, the cap with a hook was cemented on the miniscrew head with adhesive cement, as shown in Fig. 1.

Fig. 1A: Miniscrews and Caps Miniscrew Driver; 1B intervention

In the PLG, the first lower molar bands were fit, an alginate impression was taken for the lower arch with the bands in place, and a cast was poured to fabricate the passive lingual appliance. After fabrication, the passive lingual appliance was cemented on the lower arch with glass ionomer cement, as shown in Fig. 2.

Fig. 2: Passive lingual cementation using glass ionomer cement.

Class II elastics (Carriere motion 3D, oral elastic) were attached from the maxillary canine to the hook cemented on the lower miniscrew bilaterally for the miniscrew group and bands for the passive lingual appliance group. During the first month, 1/4-inch heavy elastics were used. In the following months, 3/16-inch heavy elastics were used. The patients were instructed to wear the elastics 24 hours per day, except during mealtimes, and to change them daily.

A follow-up session was scheduled every four weeks, and the appliance was removed in both groups after the patient reached a Class I relationship shown in Fig. 3 for DMG and Fig. 4 for PLG. For each patient, CBCT was obtained after distalization was completed. Afterward, fully fixed orthodontic appliances were bonded to all patients for leveling, alignment, and space closure to complete the orthodontic treatment.

The 3D full-face CBCT scanner (Sidexis 4 software from Dentsply Sirona 2) was used at two-time points for each patient. The first CBCT (T1) scan was obtained before treatment, and the second scan (T2) was obtained at the end of the distalization phase when the distalizer was removed.

The imaging acquisition parameters utilized included five mA, 120 kV, a field of view (FOV) measuring 13 cm in height by 16 cm in diameter, and exposure times of either 20 seconds or 40 seconds. Consistent scanning protocols were applied for each patient at T0 and T1, and the approved protocol did not require a supplementary CBCT scan after treatment.

The 3D analysis was performed on superimposition T1 and T2 using the two open-source 3D Slicer software version 4.10.2, and Romexis software version 5.3.4.39 used a growing tool in the software for manual segmentation tool layer by layer for layer tracing as shown in Fig. 5.

Several landmarks were used in CBCT analysis to evaluate the treatment outcome for class II patients with distalizers using the CMA protocol (Table 1). The same assessor and another observer analyzed pre- and post-CBCT images again to assess the intra- and interobserver reliability statistically.

Outcomes

The primary outcome was anchorage loss in the lower arch, while the secondary outcomes were the amount and type of distalization and the treatment duration.

Sample Size Calculation: This study would be an experimental, interventional, and randomized clinical trial, a convenience sampling technique used for patient selection.

Sample size calculation was performed using G* power 3.1.9.7. By selecting an alpha (α) level of 0.05 (5%), power=80%, and standard deviations (SD) of (2.2) and (4.00) calculated based on the results of the previous study (16) that recorded mandibular central incisor' torque variable (0.68 ± 2.22) and (5.30 ± 4.00) for Miniscrew and Essix appliances group respectively. The predicted sample size (n) was found to be 10 patients per group.

Randomization: Randomized selections were made for the total number of patients treated with Carriere Motion appliance and class II elastics. Randomization was done using an online Research Randomizer (Version 4.0) computer software. After sample randomization, these patients generated the random allocation sequence by the supervisors of this study. Also,

Fig. 3: Miniscrew anchorage group; A. Pre-treatment; B. Intervention; C. Post-distaization

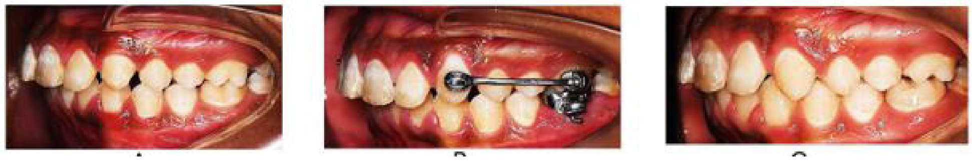

Fig. 4: Passive lingual anchorage group; A. Pre-treatment; B. Intervention; C. Post-distaization

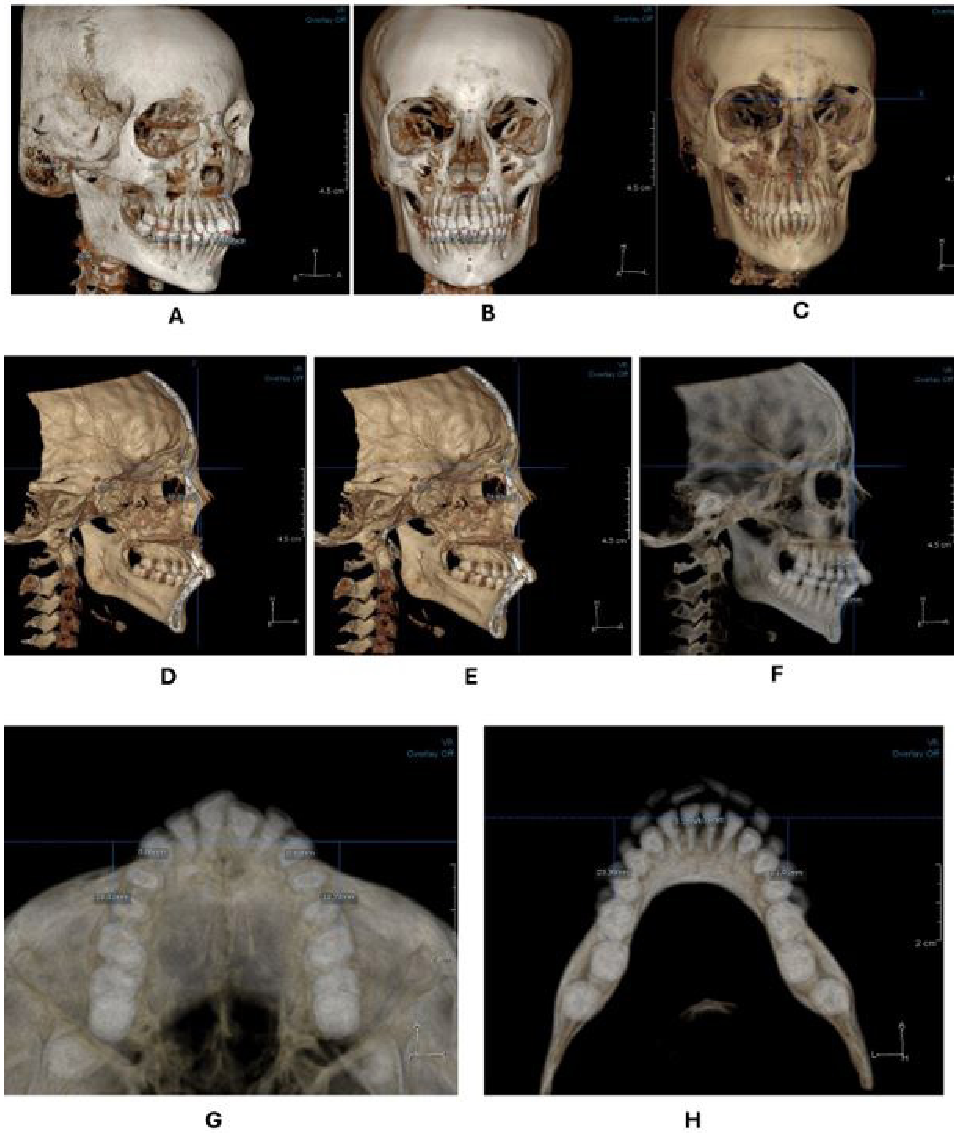

Fig. 5: DICOM 3d analysis view
A: Points placement on the Lateral view
B: Points placement on the Frontal view
C: Fused 3D view of Primary and Secondary datasets
D: SNA angle
E: SNB angle
F:AFH measurements
G:Bilateral maxillary canines, and 1st molars Anteroposterior distance measurement (U3 AP, U6 AP).
H: Bilateral mandibular central incisors, and 1st molarsAnteroposterior distance measurement (L1 AP, L6 AP).

participants were enrolled and assigned to interventions.

Blinding: The principal operator was only blinded during the bonding of the CMA. An external assessor measured the CBCT images for all patients blindly and independently.

Statistical Analysis: Statistical analyses were performed using Microsoft Excel (version 2019; Microsoft et al.) and IBM SPSS Statistics (version 25.0; IBM et al.). Intraclass correlation coefficients (ICCs) were used to assess the intraoperator and interoperator reliabilities, and the Bland-Altman method was used to determine random errors. Descriptive statistics are reported as mean and standard deviations. The Shapiro-Wilk test was used to test for normality, and Levene's test was used to assess the equality of variance. Independent t-tests were used to compare the mean values between the two groups, and paired t-tests were used to compare the mean values of the same group before and after treatment.

Results

Participant Timeline: Recruitment for this study began in January 2023 and continued until January 2024. Twenty patients were recruited and randomized 1:1 to either the miniscrew group (n=10) or the passive lingual appliance group (n=10). Distalization procedures were accomplished by April 2024 (Fig. 6).

Baseline data: As shown in Table 4, there was a statistically insignificant difference between the two groups regarding the male and female distribution inside the group and the mean age of patients.

Outcomes measurements: Treatment duration

As illustrated in Table 2, CMA corrected class II molar relation in the average duration of 6.1 ± 2.4 and 6.5 ± 2.7 in the DMG and PLG, respectively. The difference in distalization duration between the two groups was insignificant.

Only 2 of the 20 interdental mini-screws that were inserted failed. On the other hand, one of the ten passive lingual appliances debonded before completing phase 1 of the treatment and needed to be cemented again.

Skeletal and dental measurements: Tables 3 and 4 compare pre- and post-intervention data in DMG and PLG, respectively. Table 5 compares the changes

Table 1: All measurements and their respective abbreviations

Measurements	Abbreviation	Descriptions
Sella-Nasion-A angle	SNA	The angle between 3-point landmarks: S, N, and A point
Sella-Nasion-B angle	SNB	The angle between 3-point landmarks: S, N, and B point
ANB	ANB	The angle between 3-point landmarks: A, N, and B point
Anterior facial height	(AFH)	The vertical distance between N and Me
Lower facial height	(LFH)	The vertical distance between ANS and Me
Facial height ratio	ANS-Me/N-Me	The ratio of lower to total facial height
Mandibular central incisor		
Torque	(L1 TQ)	Measured as the angle between the long axis of mandibular central incisor and the mandibular plane from the sagittal view
Antero-posterior position	(L1 AP)	Measured as the horizontal distance from the edge of the mandibular central incisor to frontal plane from the sagittal view
Mandibular second molar		
Mesio-distal angulation	(L7 MD)	Measured as the angle between the mandibular second molar long axis and the mandibular plane from the sagittal view
Antero-posterior position	(L7 AP)	Measured as the perpendicular distance from mandibular second molar mesiobuccal cusp tip to frontal plane from the sagittal view
Vertical position	(L7 VER)	Measured as the perpendicular distance from mandibular second molar furcation point to mandibular plane from sagittal view
Maxillary canine		
Mesio-distal angulation	(U3 MD)	Measured as the angle between the long axis of maxillary canine and the maxillary plane from the sagittal view
Antero-posterior position	(U3 AP)	Measured as the horizontal distance from cusp tip of maxillary canines to frontal plane from the sagittal view
Vertical position	(U3 VER)	Measured as the perpendicular distance from center of maxillary canine to the maxillary plane from sagittal view
Maxillary first molar		
Mesio-distal angulation	(U6 MD)	Measured as the angle between the maxillary first molar long axis and the maxillary plane from the sagittal view
Antero-posterior position	(U6 AP)	Measured as the perpendicular distance from maxillary first molar mesio-buccal cusp tip to frontal plane from the sagittal view
Vertical position	(U6 VER)	Measured as the perpendicular distance from maxillary first molar furcation point to maxillary plane from sagittal view

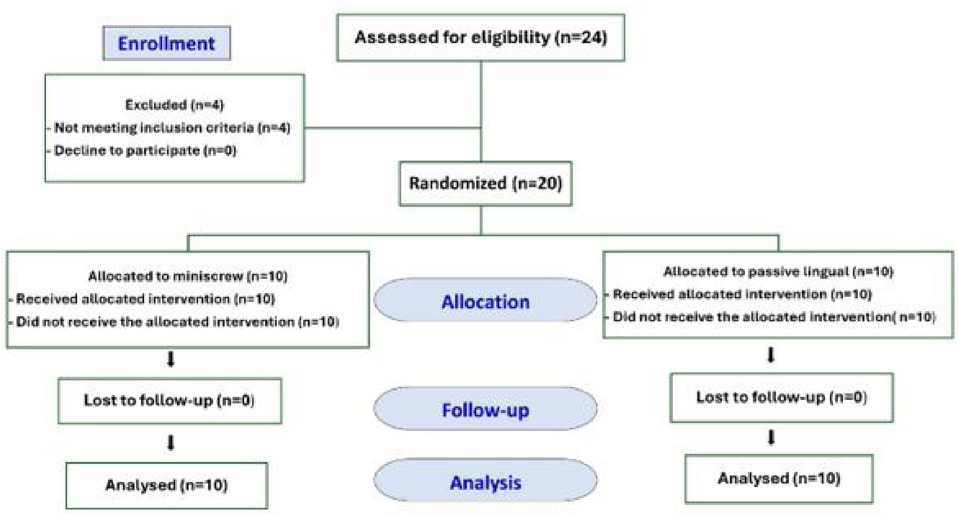

Fig. 6: The Consolidated Standards of Reporting Trials (CONSORT) participant flow diagram

Table 2: Clinical and Demographic data in DMG vs. PLG

Initial features	Mean		SD	Test of significance	
				χ^2	p-value
Gender	9 Female & 11 males			.582	.446*
Duration of distalization in months, mean (SD)				**t [20]**	**p-value**
Miniscrew Group	6.1		(2.4)	-0.463	.647\$
Passive lingual Group	6.5		(2.7)		
Age, years	14.7		1.2	-1.563	.129\$
Number of debonded CMAs, n (%)	0	1	2		
Miniscrew Group (n=10)	9(90%)	1(10%)	0		.838**
PLG(n=10)	8(80%)	1(10%)	1(10%)		
Failure of anchorage device	0 no failure		1(failure once)		
Miniscrew Group (n=10)	8(80%)		2(20%)		1.000***
PLG(n=10)	9(90%)		1(10%)		

Notes: The tests of significance are *chi-square test, **Fisher-Freeman-Halton Exact Test, ***Fisher's Exact test, and \$independent-samples t-test.

This table shows no statistically significant difference in age, sex, treatment duration, number of de-bonded CMAs, and failure of anchorage device between the two groups.

Table 3: Comparisons of pre-post data in DMG

Variables (Direct miniscrew group)	Pretreatment Mean	Pretreatment SD	Posttreatment Mean	Posttreatment SD	change Mean	change SD	p-value
SKELETAL MEASUREMENTS							
(SNA) angle	83.74	± .42	83.34	±.32	-.40	±.17	.000
(SNB) angle	78.29	±.35	78.46	±.27	.17	±.11	.001
(ANB) angle	5.45	±.47	5.30	±.43	-.15	±.05	.000
(LAFH) mm	61.1	± .42	61.1	± .42	0	± .42	.931
(PFH) mm	71.3	± 6.2	71.4	± 6.3	0.1	± 1	.743
DENTAL MEASUREMENTS							
Mandibular central incisor							
(L1 TQ)	101.50	±3.16	101.61	±3.17	.11	±.31	.288
(L1 AP)	67.21	±.96	67.23	±.97	.01	±.02	.070
Mandibular first molar							
(L6 AP)	32.40	±.82	32.42	±.82	.02	±.009	.000
(L6 MD)	81.37	±1.65	81.40	±1.64	.02	±.02	.115
(L6 VER)	18.05	±.89	18.01	±.85	-.03	±.06	.166
Maxillary canine							
(U3 AP)	64.66	±.60	60.91	±1.14	-3.74	±1.47	.000
(U3 MD)	76.42	±1.06	81.08	±1.30	4.66	±.84	.000
(U3 VER)	13.37	±.50	14.62	±.81	1.16	±.31	.000
Maxillary first molar							
(U6 AP)	45.16	±.46	42.61	±.72	-3.54	±.49	.000
(U6 MD)	84.89	±.97	81.40	±.88	-3.49	±.73	.000
(U6 VER)	12.23	±.68	11.43	±.44	-.79	±.39	.000
OTHER DENTAL MEASUREMENTS							
Overjet	6.63	±.92	5.70	±1.18	-.93	±.39	.000
Overbite	3.48	±.72	2.35	±.48	-1.12	±.53	.000
(U3 width tip)	29.04	±.92	31.43	±.90	2.38	±.43	.000
(U6 width tip)	50.08	±1.51	49.88	±1.1	-.19	±.39	.142

in the two groups.

Reliability testing: Intraclass correlation coefficient (ICC) was used for intra- and inter-observer absolute agreement in 16 participants. There was excellent intra- (0.985) and interobserver (0.981) absolute agreement.

Harms: Apart from the discomfort experienced by some patients who received the mini-screws, no substantial hazards were seen during the trial.

Discussion

CMA is used to distalize the entire posterior maxillary segment using Class II elastics and mandibular anchorage, converting the Class II molar relationship into a Class I relationship.[15] It has adverse effects on class II elastics, such as lower incisor proclination and extrusion of the mandibular molar.[21]

The null hypothesis was that miniscrews and a passive lingual appliance would not differ in anchorage control when treating class II molar patients with the CMA. The maxillary posterior segment can be distalized with miniscrew anchorage to eliminate the adverse effects of CMA with class II elastics.[16,17] No previous RCT evaluated CMA compared to direct miniscrew one inserted at the lower posterior alveolar bone. So, this RCT aimed to evaluate miniscrew anchored CMA for distalization of the maxillary buccal segment vs. conventionally anchored CMA.

CBCT was chosen due to a 3D imaging method; it enables evaluation of the three-dimensional effects of the CMA to overcome two-dimensional radiograph shortages of previous studies that used cephalometric radiographs to analyze the effects of CMA,[17,20,23,25,26] yet exposes the patients to a lower ionizing radiation level (compared to medical CT).[27]

Skeletal changes: Significant skeletal changes (SNA, SNB, ANB) during the treatment with CMA match those of other studies.[17,26,28] However, other studies[16,20,22,23] found insignificant skeletal changes. This is because of the more dentoalveolar effect of class II elastics due to the sample comprising postpubertal patients.[16,20,23] Also, a significant change was an increase in both groups' lower and posterior facial heights. This was due to the extrusion of the mandibular first molar in the passive lingual group and the distalization of the upper molars, leading to an increase in the mandibular plane angle.[25]

Maxillary canine movements: The amount of distal movement of the maxillary canine was found to be statistically significant in both groups. It was almost equal to the amount of distal movement of the molar.[16,17,20-22] However, the amount of distalization was much less than that of other skeletal anchorage distalizing appliances or conventional anchorage appliances.[29]

The distalization of the entire maxillary buccal segment by CMA means that there was no anchorage loss in the premolar area, unlike other distalizers that required retraction of the premolars and canines after molar distalization.[30, 31]

Maxillary molar movements: On average, with the CMA, distal movement of the maxillary first molars was 1.95 mm, approximately the same as previously reported by Sandifer et al.,[20] while only Class II elastics did not show any significant maxillary molar movements.[3]

It had been claimed that adding a ball-and-socket joint in the molar pad would lead to pure bodily distalization of the maxillary molar without distal tipping. However, in the current RCT, the maxillary molar distal tipping amount was statistically significant and similar in both groups. In the miniscrew group, the molar tipped (3.49), while the lingual appliance group tipped (3.82).[15] On the other hand, this degree of tipping was less than that produced by skeletal anchorage distalizing appliances (8.44) and conventional anchorage appliances (8.31).[29] This data did not correlate directly with the manufacturer's claim of ''distal movement of the canine along the alveolar ridge without tipping.''[15] The data showed tipping of the maxillary canine in both groups. Therefore, the ball-and-socket joint helped minimize molar tipping but did not completely prevent it.[16,17]

Mandibular molar movements: The mesial tipping, rotation, and extrusion amounts of lower molars significantly differed between the groups. In other studies, the passive lingual group tended to have more significant mesial movement and tipping of the mandibular first molar.[20, 23, 28]

Fouda et al.[16] used indirect anchorage through an SS wire to connect the miniscrew to the tooth, but there was little mesial movement and tipping to the second mandibular molar. There was no mesial movement or tipping as the elastics were loaded directly on the miniscrew, which matched with the infrazygomatic miniscrew study.[17]

Transferring the anchorage control from indirect to direct miniscrew anchorage eliminates horizontal and vertical components of the forces exerted by class II elastics on lower molars.

Mandibular incisors. The increase in mandibular central incisor movements significantly differed between the two groups. Data showed that the mandibular incisor moved more mesially in the passive lingual group, as noted in several studies.[20-23, 25,26] than the miniscrew group that showed no proclination of the lower incisor. This may suggest that, as an anchorage unit, a miniscrew is superior to the passive lingual arch to avoid anchorage loss, as reported in the Ghozy study.[17]

Overjet: It is typically observed in Class II malocclusions. From the data, although fixed appliances were not used on the anterior teeth, The overjet decreased significantly in both groups. This is due to the spontaneous distal movement of incisors into the space created after the distalization buccal segment in the direct miniscrew group[16,17] and the mandibular incisors proclination in the passive lingual group.[20-23, 25]

Limitations: The trial's patients and operator could not be blinded to the treatment modality with a small sample size. No treatment was finished during data collection, and the success of the CMA heavily depends on patient compliance with wearing elastics, which can vary significantly and impact the effectiveness of the treatment. Also, this study was limited to the first phase of treatment in which the CMA was used and did not involve observation of the patients during the second phase of treatment, which involved anterior segment retraction.

Generalizability: This study's generalizability might be constrained as it only involved one dental facility and one PhD candidate performing the treatments on only one ethnic group was investigated.

Conclusion:

- Direct Miniscrew anchored CMA resulted in a more significant distalization of the maxillary buccal segment than the lingual arch anchored one with no significant difference between them regarding the duration of distalization.
- Maxillary first molar and canine rotation with tipping were similar in both groups.
- Using miniscrews in the lower jaw stops class II elastics from negatively affecting the lower teeth and molars. It doesn't change the lower face height, suggesting that miniscrews can correct class II malocclusion by moving the upper teeth back without affecting the lower teeth.

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Article: "Successful Treatment of Class II Malocclusion in a Young Patient with Headache and Cervical Dystonia Using the Herbst Appliance: A Case Report"

Question: True or false, according to the authors; better alignment and midline correction could have been achieved by manipulating the Herbst appliance during the initial treatment stages.

A. True
B. False

Article: "A Comparative Evaluation of Rate of En-Masse Retraction with and without Low-Intensity Laser Therapy – A Randomized Clinical Trial"

Question: According to the author in Table 1; the Laser Parameter's Power Output is:

A. 0.1W
B. 0.03W
C. 0.3W
D. None of the above

Question: True or false, according to the author; recent systematic review, the average duration of fixed orthodontic treatment was 19.9 months

A. True
B. False

Article: "Relationship Between Vertical Facial Pattern and Dental Arch Form in Class II Division I Malocclusion"

Question: According to the authors; vertical facial patterns were categorized into which groups:

A. Horizontal growth pattern
B. Average growth pattern
C. Vertical growth pattern
D. All of the above

Article: Treatment Effects of the Carriere Motion Appliance in Class II Malocclusion Patients Using Different Methods of Anchorage Control in the Mandible: A Randomized Clinical Trial

Question: True or false, According to the authors; difference between the two groups regarding the male and female distribution inside the group and the mean age of patients was statistically significant?

A. True
B. False

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