E- ISSN: 2148-9505

TURKISH JOURNAL OF ORTHODONTICS

TJO

The Official Journal of Turkish Orthodontic Society

galenos Publishing House

Volume 37
Issue 02
June 2024

The Official Journal of Turkish Orthodontic Society

TURKISH JOURNAL OF ORTHODONTICS

TJO

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E-mail: info@galenos.com.tr/yayin@galenos.com.tr
Web: www.galenos.com.tr
Publisher Certificate Number: 14521

Printing Date: June 2024
E-ISSN: 2148-9505
International scientific journal published quarterly.

TURKISH JOURNAL OF ORTHODONTICS

The Official Journal of Turkish Orthodontic Society

Editorial Board

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The journal is published online.

Owner: Derya Germeç Çakan on behalf of the Turkish Orthodontic Society

Responsible Manager: Çağla Şar

Editor in Chief: Çağla Şar

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Original Articles

Review

TURKISH JOURNAL OF
ORTHODONTICS

DOI: 10.4274/TurkJOrthod.2023.2022.191

Original Article

Relationship Between Circummaxillary and Intramaxillary Suture Densities and Skeletal Effects of Rapid Maxillary Expansion

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Cite this article as: Başal E, Acar YB. Relationship Between Circummaxillary and Intramaxillary Suture Densities and Skeletal Effects of Rapid Maxillary Expansion. *Turk J Orthod.* 2024; 37(2): 72-78

Main Points

- Cervical vertebral stage can be a predictive parameter of bone density.
- The mean density of both midpalatal and circummaxillary sutures has a significant relationship with cervical vertebral stages.
- No significant correlation was found between the skeletal response and density measurements.

ABSTRACT

Objective: This retrospective clinical study aimed to evaluate the maturation of intramaxillary and circummaxillary suture systems and cervical vertebral maturation as predictors of the skeletal response achieved by rapid maxillary expansion (RME).

Methods: A Digital Imaging and Communication in Medicine dataset of 20 patients (mean age: 15.55 years) prior (T0) and after (T1: 3.5±0.5 months) to RME were retrieved from the archive and analyzed. Bone density values of midpalatal suture (MPS), zygomaticomaxillary suture (ZMS), zygomaticotemporal suture (ZTS), pterygopalatine suture (PPS), and transverse palatine suture (TPS) were measured. The cervical vertebral maturational stages (CVS) were examined. The linear distances between the most lateral points of the piriform apertures were measured as the anterior reference, and the medial margins of the greater palatine foramina on the axial slice were chosen as the posterior reference. The difference at T1-T0 was calculated as the skeletal response to RME at anterior and posterior skeletal references. Spearman's rho rank and Kruskal-Wallis tests were used.

Results: Mean density values of ZMS, PPS, ZTS, TPS, MPS-Anterior, and MPS-Posterior were 922.81, 807.44, 753.83, 640.77, 661.13, and 604.59 HU, respectively. Mean linear changes in anterior and posterior skeletal expansion were 2.93±1.78 and 1.93±2.52 mm. There was no significant relationship between maturation indicators and skeletal response. Significant relationships were found between CVS and MPS density and CVS and circummaxillary suture average density ($p \leq 0.05$).

Conclusion: Sutural density showed significant variations among CVSs. Although there was no correlation between skeletal response and density measurements, sutural density was found to be a promising indicator for future studies.

Keywords: Maxillary expansion, sutures, bone density

INTRODUCTION

Rapid maxillary expansion (RME) is a frequently used protocol for orthopedic opening of the midpalatal suture (MPS) for the correction of maxillary transverse deficiency in orthodontic practice. While treatment success can be obtained in young individuals by a skeletal response; in adults, treatment failure is attributed to increased rigidity of the facial skeleton and interlocking of the MPS.[1] The preferred method of treatment for individuals

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Received: December 19, 2022 **Accepted:** August 15, 2023 **Publication Date:** June 30, 2024

with complete bone development is the surgically assisted RME (SARME) protocol.[2] The choice of treatment is important in terms of reducing morbidity and preventing unnecessary surgical procedures. Whether the response to RME will be more dental or skeletal has conventionally been reported to be related to chronological age.[3] Additionally, other conventional methods such as hand-wrist radiographs, skeletal maturation assessment on cervical vertebral stages (CVS), or evaluation of the midpalatal sutural opening with occlusal radiography have been used to choose between treatment options.[4-7] While some studies support the treatment being in the prepubertal period, others have reported that orthopedic changes can be obtained in adults.[8-10] Likewise, cadaveric studies have shown that the developmental process of MPS has diversity among individuals, and detailed evaluation is essential.[11]

The articulations of the maxillary bone consist of transverse palatine suture (TPS), frontomaxillary suture, and zygomaticomaxillary suture (ZMS). The interdigitation and complexity of these sutures increase as development progresses, and may prevent the desired effects of orthopedic treatments.[12] In addition, previous studies have shown that all maxillary articulations, especially ZMS, zygomaticotemporal sutures (ZTS), and pterygopalatine sutures (PPS), cause resistance to RME.[5,13] Therefore, MPS and circummaxillary structures have been evaluated three dimensionally. Jang et al.[14] considered only MPS in their study, emphasizing that other resisting structures must be considered in RME. Angelieri et al.[15] proposed a visual five-stage classification of the morphological maturational stages of MPS and stated that it is possible to estimate the treatment results from stages. However, subsequent clinical studies on morphological stages did not find a significant relationship between these parameters.[16,17] Studies regarding the effects of MPS and circummaxillary rigidity on treatment results have conflicting results, and the relationship still needs to be investigated.[16,18] The aim of this retrospective clinical study was to evaluate intramaxillary and circummaxillary suture densities, CVSs, and their effect on skeletal expansion in a group of growing subjects who underwent RME.

METHODS

This retrospective study was approved by the Ethical Committee of Clinical Studies of Marmara University, Faculty of Dentistry (approval no.: 2019-281, date: 28.03.2019). The study sample comprised the computed tomography (CT) of 20 patients (mean age: 15.55; range: 13-17 years; eleven females, nine males) who had RME as part of their comprehensive orthodontic treatment in Marmara University, Department of Orthodontics between 2001 and 2004 years. CT data were retrieved from the clinical archive. Sample size calculation was performed using G*Power software (version 3.1.9.2, Heinrich-Heine-University Düsseldorf, Germany), considering the strong level of correlation between "MPS ratio" and "greater palatine foramina" parameters (r=-0.78) in a previous study by Grünheid et al.[16]. The calculation indicated that a minimum of 20 patients was required for a power of 0.80 and α level of 0.05 to obtain an effect size of 0.5. The inclusion criteria were as follows: permanent dentition, skeletal maxillary constriction with bilateral posterior crossbite, no systemic or periodontal diseases, no previous orthodontic treatment, and complete records. Expansion was performed using a bonded Hyrax expander activated at a rate of 0.5 mm/day and continued until the upper first molar palatal cusp tips aligned with the lower first molar buccal cusp tips.[19] The expander was kept for passive retention for 3 months. After removal of the expansion appliance, a transpalatal arch with arms extending to the premolars was placed to maintain further retention.

The CT images consisted of T0 (before treatment) and T1 (3.5±0.5 months after RME). T1 records were taken before placement of the transpalatal arch to avoid metal artifacts. CT volumes were obtained using the same spiral CT device (Siemens Sensation 40, Siemens Medical Solutions of Siemens, Erlangen, Germany) at 120 kV, 80-mAs, 12.6x12.6-cm field-of-view, 512x512-pixel matrix, 0.3-mm increment slices, and 0.4-mm voxel size. Digital Imaging and Communication in Medicine (DICOM) images were analyzed using Mimics v.20.0 (Materialize, Leuven, Belgium). The head position was verified by ensuring that the palatal plane was parallel to the true horizontal plane and the midsagittal plane was parallel to the midsagittal cursor line of the software in coronal and axial.

Density measurements:

1. ZMS: The midpoint of the suture was marked on the 3D model, and the density was measured in Hounsfield units (HU) in a 2x2-mm^2 area in the section on the sagittal plane (Figure 1a).

2. ZTS: The midpoint of the suture was marked on the 3D model, and density was measured in a 2x2-mm^2 area in the coronal and sagittal planes (Figure 1b).

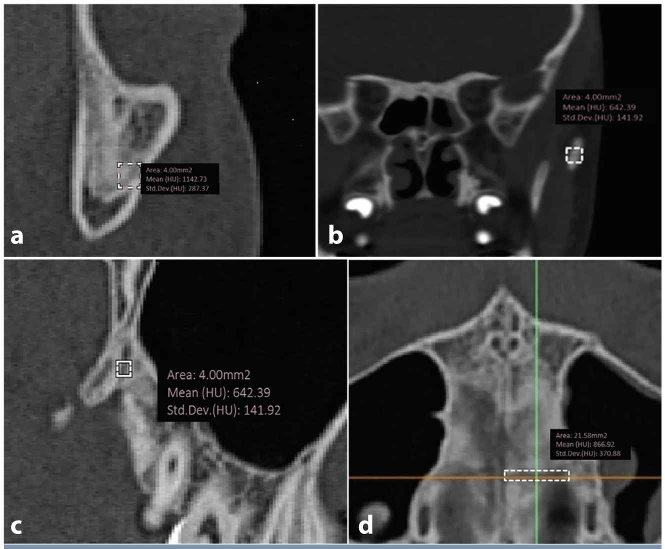

Figure 1. a) Density measurements of ZMS in sagittal view, b) Density measurements of ZTS in coronal view, c) Density measurements of PPS in sagittal view, d) Density measurements of TPS in axial view
ZMS, Zygomaticomaxillary suture; ZTS, Zygomaticotemporal sutures; PPS, Pterygopalatine sutures; TPS, Transverse palatine suture

3. PPS: The midpoint of the suture was marked on the 3D model, and density was measured in a 2x2-mm^2 area in the sagittal and axial planes (Figure 1c).

4. TPS: Density was measured in a rectangular area with a long edge along the suture and a short edge of 2 mm in the section where the TPS is most visible along the superoinferior thickness of the palate (Figure 1d). In patients with a deep palatal vault, it was not possible to visualize the entire suture lengthwise; therefore, the head orientation was arranged twice to visualize the right and left parts of the sutures in the axial section. Then, the two measurements were averaged.

Measurements of all circummaxillary sutures were made bilaterally, and the average value was named "Circummaxillary sutures' average density" (CSD).

5. MPS: Density was measured in 4x4-mm^2 areas at three different regions on an axial slice at the level of the palatal plane. MPS-Anterior (MPS-Ant) was measured distal to the incisive foramen. MPS-Middle was measured at the level of the line passing through the distal contacts of the left and right first premolars. MPS-Posterior (MPS-Post) was measured at the level of the first molars (Figure 2). The average of three measurements was recorded as (MPS-Ave).

For skeletal expansion, the most lateral points of the piriform aperture were selected as the anterior reference (Figure 3a). The medial margins of the greater palatine foramina were chosen as the posterior reference on the axial slice in the center of the hard palate (Figure 3b). The linear distance between these points was measured at T0 and T1, and the difference was accepted as the anterior and posterior skeletal response to RME.

CVS were evaluated on the lateral cephalogram extracted from the T0 DICOM volumes as described by Franchi et al.[6].

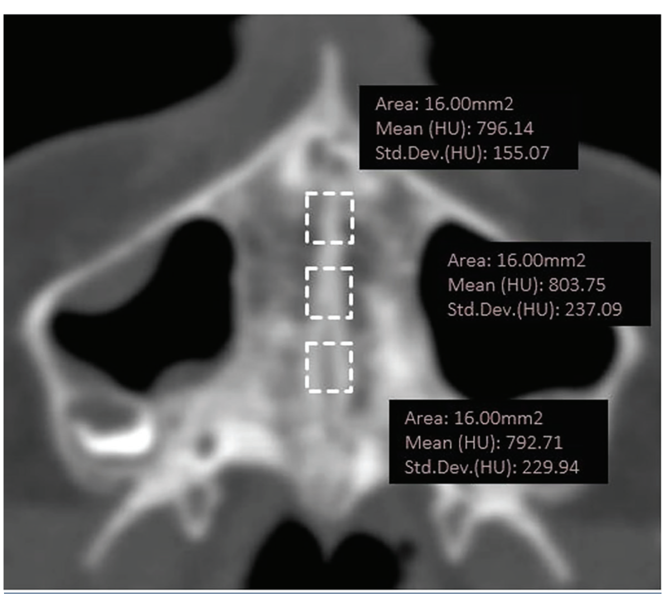

Figure 2. Density measurements of anterior, middle and posterior regions of MPS
MPS, Midpalatal suture

All measurements were made by one examiner, blind-tested during analysis with the help of random numeric identifiers, and repeated 3 months later.

Statistical Analysis

All statistical calculations were performed using SPSS 25.0 (IBM Corp, NY, USA). The conformity of the variables to the normal distribution was examined using Kolmogorov-Smirnov test. Intraexaminer agreement was assessed using the intraclass correlation coefficient (ICC) for continuous variables and the Kappa coefficient for categorical variables. Correlations between variables were assessed using the Spearman correlation coefficient. Variables that did not conform to normal distribution were compared with Kruskal-Wallis test.

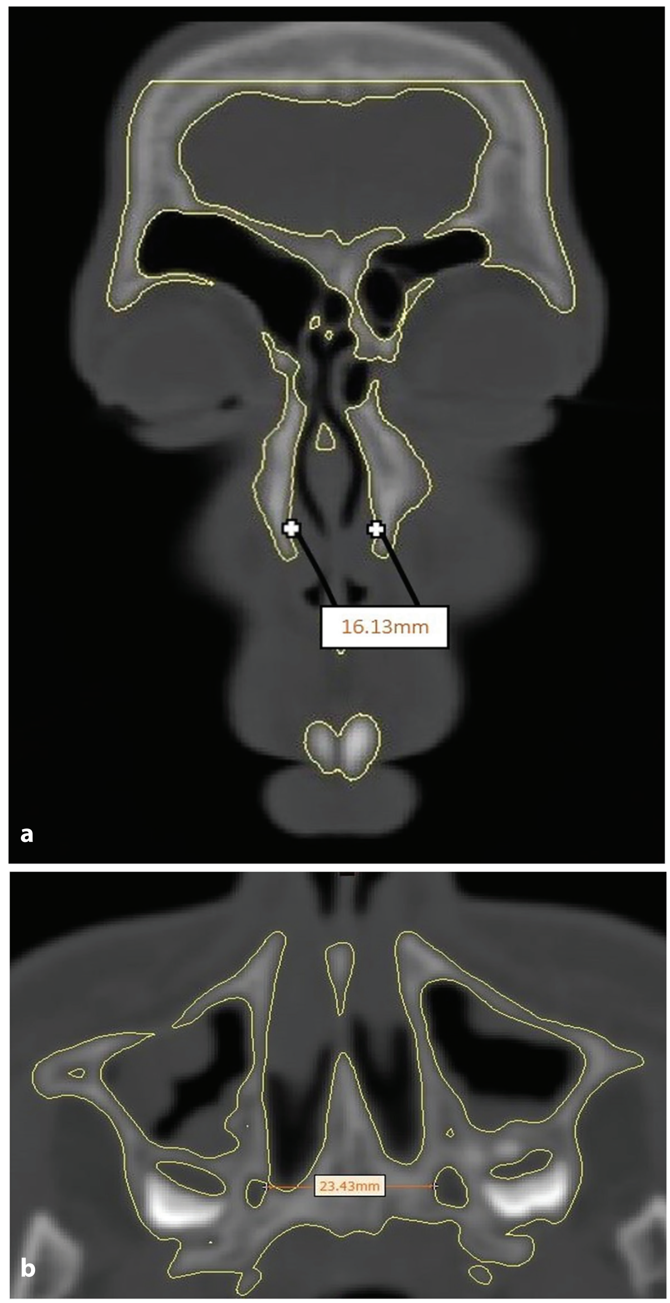

Figure 3. a) Anterior skeletal expansion measurements in coronal view, **b)** Posterior skeletal expansion measurements in coronal view

Then, Mann-Whitney U test with Bonferroni adjustment was performed as post-hoc test for pairwise comparison of significant variables. Statistical significance was determined at $p<0.05$.

RESULTS

Descriptive statistics of the study are shown in Table 1. There was no significant relationship between maturation indicators

Table 1. Descriptive statistics of the sample group

	T0		T1		Difference		p-value
	Mean	SD	Mean	SD	Mean	SD	
Anterior skeletal expansion (mm)	20.98	1.84	23.91	1.94	2.93	1.78	<0.001*
Posterior skeletal expansion (mm)	26.46	2.89	28.39	2.84	1.93	2.52	<0.001*
	Mean	SD					
MPS-Anterior (HU)	661.13	165.04					
MPS-Posterior (HU)	604.59	189.45					
ZMS (HU)	922.81	219.28					
PPS (HU)	807.44	144.92					
ZTS (HU)	753.83	190.64					
TPS (HU)	640.77	124.36					

*p<0.05
SD, Standard deviation; HU, hounsfield units; MPS, midpalatal suture; ZMS, zygomaticomaxillary suture; PPS, pterygopalatine suture; ZTS, zygomaticotemporal suture; TPS, transverse palatine suture

Table 2. Relationship between maturation indicators and skeletal response

		Anterior skeletal expansion (mm)			Posterior skeletal expansion (mm)		
Continuous variables		Correlation coefficient		p-value	Correlation coefficient		p-value
CSD (HU)		-0.089		NS	0.035		NS
ZMS (HU)		0.196		NS	0.165		NS
PPS (HU)		0.215		NS	0.018		NS
ZTS (HU)		-0.190		NS	-0.101		NS
TPS (HU)		0.406		NS	0.235		NS
MPS-Anterior (HU)		0.142		NS			
MPS-Posterior (HU)					-0.226		NS
Categorical variable		Mean	SD		Mean	SD	
Cervical vertebral maturation	CS3	2.42	1	p=0.037*	1.43	2.09	NS
	CS4	4.55	0.94		2.86	1.24	
	CS5	2.59	2.28		1.54	1.08	
	CS6	1.81	1.15		1.64	1.99	

*p<0.05
NS, not significant; SD, Standard deviation; HU, hounsfield units; CSD, circummaxillary sutures' average density; ZMS, zygomaticomaxillary suture density; PPS, pterygopalatine suture density; ZTS, zygomaticotemporal suture density; TPS, transverse palatine suture density; MPS, midpalatal suture density

Table 3. Relationship between intramaxillary and circummaxillary sutures' density values and cervical vertebral maturation

		MPS-Ave (HU)				CSD (HU)		
		Mean	SD	p-value		Mean	SD	p-value
Cervical vertebral maturation	3	525.86[a]	139.54	p=0.016*		625.65[x]	106.3	p=0.024*
	4	558.56[a,b]	130.67			661.88[x,y]	155.71	
	5	729.91[a,b]	17.01			804.93[x,y]	67.79	
	6	802.75[b]	138.02			869.22[y]	34.67	

*p<0.05
[a, b], Indicates the results of pairwise comparisons for MPS-Ave parameter. Different letters mean statistically significant differences; [x, y], Indicates the results of pairwise comparisons for CSD parameter. Different letters mean statistically significant differences
NS, not significant; SD, Standard deviation; HU, hounsfield units; CSD, circummaxillary sutures' average density; MPS-Ave, Average value of anterior, middle and posterior measurements for midpalatal suture density

(CSD, MPS-Ant, MPS-Post) and skeletal response (Table 2). CVS and anterior expansion amount showed a statistically significant correlation. When Mann-Whitney U test with Bonferroni adjustment was performed on the results of the pairwise comparisons, there was no statistically significant difference between the groups.

Kappa value had a mean value of 0.961 and ICC had a mean value of 0.909.

Significant differences were found between the mean values of both MPS-Ave and CSD in the CVS groups between CVS3 and CVS6 (p=0.049 and p=0.041 respectively) (Table 3). The mean values of density in CVS6 were found to be higher than those in CVS3.

DISCUSSION

In orthodontic practice, there is a lack of definitive guidelines concerning the choice between RME and SARME, despite the frequent use of RME. Previous studies have reported conflicting results regarding the relationship between maturation indicators and biological responses to RME. Researchers have emphasized the need to evaluate the maturation level of circummaxillary and midpalatal sutures,[13,20] which shows developmental diversity between postpubertal individuals.[10] However, the relationship between RME outcomes and resistance caused by articulations of the maxillary bone has not been adequately investigated, while studies have focused on MPS from various aspects. Therefore, the current study investigated the relationship between the skeletal effects of RME and circummaxillary and intramaxillary suture densities.

Cone-beam CT (CBCT) is a valid tool for 3D imaging in dentistry. However, the major limitation of studies investigating bone density on CBCT is the low standardization between scanners, which causes variability in the Hounsfield scale.[21] On the other hand, CT has superior reliability for bone mineral density quantification.[18] Comparative studies have confirmed the reliability and high accuracy of CT for quantitative and qualitative analyses as a valuable diagnostic supplement to subjective bone density evaluation.[22] The advantages of obtaining CT volumes in a short-term T0-T1 period were eliminating the influence of growth and the possible additional effects of post-expansion treatment procedures in the transverse dimension.

During measurements, to prevent any drawbacks that may result from head positioning, the measurements were verified on all planes and 3D masks, reference points with repeatability were preferred, and reference planes were created, thereby reducing the margin of error. Nonetheless, the scoring of these structures may be a possible limitation of our study due to anatomical factors.

The circummaxillary sutures, despite the thin nature of their structures, were visible in our sample group because of the superior reliability of the qualitative evaluation of CT. Standardized measurements were achieved by choosing a rectangular area in the middle of the sutures instead of volumetric density measurements, considering the 2D anatomy. For skeletal expansion measurements, anatomical points from the study by Grünheid et al.[16] were selected. The greater palatine foramen provides information about skeletal expansion in the posterior region of the hard palate, while the lateral margins of the piriform aperture are the region affected by the pyramidal effects of RME treatment. A common feature of these two regions is that they are easily identifiable and reproducible and are not be affected by the devices used in the treatment because they are not related to the dental structures.

Angelieri et al.[23] divided the stages of their classification into prepubertal (A-C) and postpubertal groups (D-E) and stated that while shifting from RME to SARME, it would be beneficial to perform detailed pretreatment evaluations for postpubertal individuals using 3D images. However, this conclusion was not tested clinically. In another study, the sample group who underwent RME was divided into two groups, as in Angelieri et al.[15], and compared the changes that occurred after RME on CBCT, but did not find a significant difference.[17] Grünheid et al.[16] used CBCT images and reported that there was no significant correlation between morphological stages, CVS, and skeletal response to RME. Grünheid et al.[16] also proposed an indirect parameter, "midpalatal suture density ratio" (MPSD-Ratio). MPSD-Ratio showed a significant negative correlation with the skeletal effects of RME, and they concluded that MPSD-Ratio can become a clinical predictor. However, in the following study on MPSD-Ratio with a larger sample, it was concluded that MPSD-Ratio is not an accurate predictor.[24] In this study, there was no significant relationship between sutural density and skeletal expansion, which is consistent with previous studies.

According to Korbmacher et al.[25] the bone density of MPS and fracture resistance, which increase with age, are the most reliable parameters regarding anatomical resistance to RME. Although density measurements of circummaxillary sutures have been reported as the contributory resistance regions that might affect the success of RME[13] and they showed bony displacement in response to RME,[26] CSD was not evaluated previously. Therefore, there have been no studies to compare the results of this study regarding CSD measurements. Acar et al.[18] measured volumetric bone density from various 3D segments of the maxillary bone in patients with RME. They found a highly significant correlation between the density of MPS, maxillary buttresses, and intermolar angle increase. However, they also concluded that they were not sufficient parameters to predict the prognosis.[18] Lee et al.[27] reported that Le Fort I corticotomy or PPS separation does not result in different results than separation of solely MPS during RME treatment. These results are consistent with our findings.

Study Limitations

In the current study, significant differences in both MPS and CSD values were observed between CVS3 and CVS6. The relationship between circummaxillary sutural density and CVS has not been previously investigated. On the other hand, the relationship between MPS density and CVS was evaluated in previous studies, and the results were consistent with our findings.[9,20] As bone maturation progresses, the negative effect of the increase in sutural density on the treatment response was also reported previously.[8] The idea of achieving sutural maturation from lateral cephalograms as a routine orthodontic record, which has a lower dose of exposure, is valuable. For this reason, a larger sample would favor the reliability of the results regarding the relationship between CVS and sutural density. In addition, this study was limited by several factors. CT can be considered an outdated imaging technique for dentistry due to its adverse effects and should only be limited to cases in which it is mandatory. The CT data used in this study were obtained almost 15 years ago for airway evaluation when CBCT was not commonly used. Its suitability for measuring density, examining very thin structures like the sutures, and thinner slice thickness makes it the modality of choice in this study because circummaxillary sutures are on extremely small scales and irregular.

CONCLUSION

Although no correlation was found between the skeletal response to RME and the circummaxillary and intramaxillary sutural densities, the significant difference between CVS3 and CVS6 in terms of MPS-Ave and CSD can be promising in a larger sample size with a wider age range. Within its limitations, this study confirms that CVS classification is a strong maturation predictor, showing a significant relationship with MPS-Ave and CSD.

Ethics Committee Approval: Ethical approval was obtained from the Ethics Committee of Marmara University Faculty of Dentistry (approval no.: 2019-281, date: 28.03.2019).

Informed Consent: The study was retrospective, so no written informed consent was obtained.

Authorship Contributions: Concept - Y.B.A.; Design - E.B.; Supervision - Y.B.A.; Materials - E.B.; Data Collection and/or Processing - E.B; Analysis and/or Interpretation - Y.B.A.; Literature Review - E.B.; Writing - E.B.; Critical Review - Y.B.A.

Declaration of Interests: The authors have no conflicts of interest to declare.

Funding: The authors declared that this study has received no financial support.

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DOI: 10.4274/TurkJOrthod.2023.2022.58

TURKISH JOURNAL OF ORTHODONTICS

Original Article

Inter-examiner Reliability of Two Methods for Scoring Post-Orthodontic White Spot Lesions from Digital Photographs

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Cite this article as: Papadimitriou A, Mortensen D, Sifakakis I, Salamara O, Twetman S, Gizani S. Inter-examiner Reliability of Two Methods for Scoring Post-orthodontic White Spot Lesions from Digital Photographs. *Turk J Orthod.* 2024; 37(2): 79-83

Main Points

- There was a moderate to strong positive relationship between the two systems, and the reliability ranged from moderate to excellent, depending on the examiner.
- For both scoring systems, the agreement concerning sound surfaces and the most severe lesions was high, whereas uncertainties occurred for the less severe white spot lesions (WSLs).
- It was practical to score WSLs in a standardized way from photographs.

ABSTRACT

Objective: To compare the reliability of two scoring systems for detecting white spot lesions (WSLs) from clinical photographs captured during debonding of fixed orthodontic appliances.

Methods: Digital images of 58 healthy adolescents (34 females and 24 males) were examined, depicting 384 buccal surfaces of maxillary incisors, canines, and first premolars. Three trained examiners (E1, E2 and E3) independently evaluated the fully anonymized photos in a randomized order using the Gorelick index (GI) and the modified International Caries Detection and Assessment System (ICDAS II). A 1-2-week interval separated the scorings. Spearman's rank correlation coefficient, Fisher's z-test, and the interclass correlation coefficient (ICC) were applied to compare the scoring methods and express examiner agreement.

Results: The two scoring systems showed a moderate to strong positive relationship, but inter-examiner variations were significant ($p<0.05$). We found moderate to good reliability (ICC 0.60 to 0.84) with the ICDAS II system and good to excellent values with the GI (ICC 0.72 to 0.94), depending on the examiner. The agreement concerning the sound surfaces and the most severe WSLs was perfect, whereas the scoring of the milder lesion stages appeared more uncertain.

Conclusion: A moderate to strong positive relationship was demonstrated between the two methods when scoring the presence and severity of WSLs from digital images. Significant inter-examiner variations affected reliability.

Keywords: Adolescents, caries index, white spot lesions, fixed appliances, orthodontics

*The authors Mortensen and Papadimitriou had equal distribution at the paper.

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Received: May 27, 2022 **Accepted:** June 04, 2023 **Publication Date:** June 30, 2024

INTRODUCTION

White spot lesions (WSLs), which are also known as enamel demineralization, are a common and unwanted side effect of treatment with fixed orthodontic appliances.[1,2] The build-up of a dental biofilm (plaque) adjacent to the devices affects oral hygiene and increases the risk of enamel mineral loss.[3] The prevalence of WSLs after orthodontic treatment varies from 2% to 96%, depending on the method and criteria for lesion detection and patients' compliance with recommended preventive measures.[4] The detection and scoring of WSLs rely on clinical visual methods and/or adjunctive technologies such as laser fluorescence, quantitative light-induced fluorescence, and impedance spectroscopy.[5-8] Because clinical scoring is inexpensive, visual inspection of clean, dry tooth surfaces remains the standard care in early lesion detection.[9,10] However, multicenter studies and unforeseen events, like the coronavirus disease-2019 pandemic, may impede access to clinical inspection by calibrated examiners. Thus, scoring WSLs from clinical digital photographs has emerged as a practical and timesaving option.[11,12] Common scoring systems in orthodontic care are Gorelick index (GI)[5] and the International Caries Detection and Assessment System (ICDAS II).[10] To the best of our knowledge, there is a lack of information on the utility of the abovementioned methods when scored from digital images. Therefore, the aim of the present study was to compare the reliability of the Gorelick and ICDAS II indices in scoring WSLs with the aid of clinical digital photographs captured immediately after removal of the fixed orthodontic appliances.

METHODS

Study Design

This retrospective study reevaluated clinical photos from participants in two earlier studies.[8,12] The pooled study group consisted of 58 healthy adolescents (34 females and 24 males) and included 384 buccal surfaces of maxillary incisors, canines, and first premolars. All patients received treatment with fixed orthodontic appliances at the School of Dentistry, National and Kapodistrian University of Athens. The patients were consecutively enrolled, and the inclusion criterion was at least two buccal WSLs at the time of debonding. The exclusion criteria were severe chronic diseases and regular use of xenogenic drugs. The patients and their parents provided written informed consent for the study, and the protocol was approved by the Ethics Committee of the Dental School, National and Kapodistrian University of Athens (approval no.: 409, date: 24.10.2016).

Clinical Procedures

After debonding, the remaining composite material on the buccal tooth surfaces was thoroughly removed with a slow rotating carbide bur, followed by polishing with a rubber cup and pumice paste. After drying with compressed air, three digital photographs (frontal, right, and left lateral) of each patient were obtained with a digital single-lens reflex camera (Nikon D7100 body with a Nikon AF-S VR Micro-NIKKOR 105 mm f/2.8G IF-ED lens) equipped with a polarized filter and a dual flash. One single investigator took all photographs to standardize the quality. The camera was angled around 20° perpendicular to the buccal tooth surfaces to minimize flash reflection. The photographs were then anonymized and provided with a specific research code. Three trained examiners (E1, E2 and E3) independently evaluated the photos in a randomized order using a high-definition screen in a darkened room. The first session included the assessment with the GI (Score 1= no visible white spot or surface demineralization; Score 2= WSL covered less than one-third of the tooth surface, no surface disruption; Score 3= WSL covered more than one-third of the surface, with roughened surface; and Score 4= visible cavitation).[5] After 1-2 weeks, the same three examiners reassessed the photos in a blinded manner with the merged ICDAS II index;[7,11] Score 0a= no visible signs of demineralization (ICDAS 0); Score 1a= enamel caries when viewed dry or wet (ICDAS 1 and 2); Score 2a= localized enamel breakdown or underlying dark shadow (ICDAS 3 and 4); Score 3a= dentin caries with visible cavity (ICDAS 5). Figure 1 depicts ICDAS II score 1a lesions, while Figure 2 showcases examples of ICDAS II score 2a lesions. The three examiners undertook a consensus-based training program with both methods before the original studies.

Statistical Analysis

Statistical analysis was performed using the Statistical Package for the Social Sciences (SPSS Inc, version 26.0, Chicago, IL, USA). We assumed that the four categories of the

Figure 1. Representative image of the ICDAS II score 1a lesions
ICDAS II, International Caries Detection and Assessment System

Figure 2. Representative image of the ICDAS II score 2a lesions
ICDAS II, International Caries Detection and Assessment System

scoring systems would correspond to each other. The normality of the distribution was checked before the parametric tests were applied. Spearman´s rank correlation coefficients for the two scoring methods were calculated, and the obtained coefficients were compared using Fisher's *z*-test. The difference between the paired proportions of sound surfaces vs. surfaces with WSL was tested for each examiner using the McNemar test. The distribution of scores within the classification systems was compared using chi-squared tests. The interclass correlation coefficient (ICC) was used to assess examiner agreements. P-values <0.05 were considered statistically significant.

RESULTS

This study included a total of 384 buccal sites from 58 patients. The mean age was 15 years, ranged from 13.1 to 17.1 years. Table 1A-C shows the cross-tabulation of the two scoring methods by the three examiners. The Spearman correlation coefficients for E1, E2, and E3 were 0.53, 0.80, and 0.61, respectively. This coefficient was significantly higher (p<0.05) for E2 than for E1 and E3. When dichotomized to sound surfaces vs. surfaces with WSL, only examiner E3 demonstrated a significant difference between the proportions obtained from the two methods (Table 2). Examiner E2 scored significantly higher WSL levels (p<0.05) with the modified ICDAS II system than the other two examiners, but no such differences were found with the GI. The ICC values are presented in Table 3. The values ranged from 0.60 to 0.84 with the ICDAS II system, indicating moderate to good reliability. The corresponding figures for the GI varied between 0.72 and 0.94, which suggested good to excellent reliability.

Table 1A-C. Cross-tabulation of the WSL scores registered by the three examiners (Table 1A for examiner E1, 1B for E2 and 1C for E3) with the modified ICDAS II index and the GI

Table 1A.						
	GI					
ICDAS II	**1**	**2**	**3**	**4**	**Total**	
0a	57	25	5	0	87	22.7%
1a	30	187	33	0	250	65.1%
2a	3	14	26	1	44	11.5%
3a	1	0	0	2	3	0.8%
Total	91	226	64	3	384	100.0%
	23.7%	58.9%	16.7%	0.8%	100.0%	
Table 1B.						
	GI					
ICDAS II	**1**	**2**	**3**	**4**	**Total**	
0a	50	0	0	0	50	13.0%
1a	0	274	46	0	320	83.3%
2a	0	0	8	3	11	2.9%
3a	0	0	0	3	3	0.8%
Total	50	274	54	6	384	100.0%
	13.0%	71.4%	14.1%	1.6%	100.0%	
Table 1C.						
	GI					
ICDASII	**1**	**2**	**3**	**4**	**Total**	
0a	61	17	0	0	78	20.3%
1a	33	202	34	0	269	70.1%
2a	1	17	17	1	36	9.4%
3a	0	0	0	1	1	0.3%
Total	95	236	51	2	384	100%
	24.7%	61.5%	13.3%	0.5%	100.0%	

WSL, white spot lesion, ICDAS II, International Caries Detection and Assessment System, GI, Gorelick index

DISCUSSION

This is the first study to compare the reliability of two scoring systems for the presence of WSLs immediately after the debonding of fixed orthodontic appliances. Instead of visual clinical inspection, three digital high-resolution images were evaluated in each patient to study the buccal surfaces of the maxillary incisors, canines, and first premolars. The examiners found scoring from photographs practical and time-saving because the assessments could be performed outside regular office hours and in a standardized mode. The scoring index developed by Gorelick et al.[5] was exclusively developed for orthodontic patients, while the ICDAS II index was an assessment system for coronal caries,[7] which was later adapted for orthodontic patients.[11] However, it should be noted that the two systems might not be directly comparable; the practical difference between these methods is that the former focuses on lesion extension (surface area) and the latter on lesion discrimination. However, the most advanced stages with both systems clearly denote cavitation.

The main findings of this study indicated moderate to excellent concordance between the two scoring systems, depending on the examiner. Although the agreement concerning the sound

Table 2. Difference between the paired proportions of sound surfaces vs. presence of WSL for the two scoring systems by examiner

Examiner	Difference, %	95% confidence interval	p-value
E1	1.04	-3.04 to 5.12	0.71*
E2	0.00	-0.72 to 0.72	1.00**
E3	4.43	0.81 to 8.05	0.02***

Statistical significance: *p<0.05, **p<0.01, ***p<0.001
WSL, white spot lesion

Table 3. ICC for the two WSL scoring methods and by examiner (E1, E2 and E3). ICC values between 0.5 and 0.75 indicate a moderate reliability, between 0.75 and 0.90 a good reliability, and values greater than 0.90 indicate an excellent reliability

	E1 vs. E2	E1 vs. E3	E2 vs. E3
ICDAS II	0.60	0.84	0.74
GI	0.74	0.94	0.72

ICC, interclass correlation coefficient, WSL, white spot lesion, ICDAS II, International Caries Detection and Assessment System, GI, Gorelick index surfaces and the most severe lesions was perfect, uncertainties occurred for the lower scores with both indices. For example, the prevalence of Gorelick score 2 varied between 59% and 71% among the examiners, and the values for ICDAS II score 1a ranged from 65% to 83%. Over time, however, this might not be a major problem because the prevalence of minor post-WSLs (GI Score 2) seems to drop by over 50% one year after debonding due to natural remineralization and secondary prevention.[1,13] However, inter-examiner variability may influence the estimated prevalence of post-orthodontic WSLs in clinical trials. In the present study population, the prevalence would have ranged from 75% to 87%, with no major differences between the scoring methods. This prevalence of WSLs was indeed higher than expected in an "average" population of orthodontic patients,[14,15] but was explained by the inclusion criteria, in which only patients with WSLs were enrolled.

The present study indicated that both scoring methods may be useful in the clinic, but it was not possible to argue in favor of one method over the other, due to a lack of formal validation.[16,17] Obviously, this was not within the scope of this project, as a validation study necessitates clinical access to patients and adherence to a predetermined standard. In clinical research, the use of digital images offers several advantages, such as the possibility of masking patients and enabling a random order of examination and reassessment of previously collected study groups. It also facilitates the performance of multicenter studies, which are often necessary to recruit a sample size with sufficient power. The impact of inter-examiner variability can also be limited by involving multiple independent examiners.

Study Limitations

To minimize the photographic shortcomings, a standardized exposure procedure was used, and the camera was equipped with a polarizing filter and angled to avoid flash reflections from the tooth surfaces, to mimic enamel demineralization. The three examiners went through a consensus-based training program before the evaluation sessions; however, it is possible that further education and experience could have improved the concordance. No dropouts of patients or images due to technical errors were present because this study was a reexamination of material from two previous trials. It is however important to note that the sample size was relatively small, and further research with a larger study population would provide more robust evidence for the reliability of the two methods. Another limitation of the study was the use of a slow rotating carbide bur to remove the remaining composite material after bracket removal, a procedure that undoubtedly affected the enamel surface and potentially influenced the subsequent scorings.

CONCLUSION

A moderate to strong positive relationship was found between the two methods for scoring the presence and severity of WSL development from clinical photographs, which were exposed immediately after debonding of fixed orthodontic appliances. Significant inter-examiner variations were obtained; however, the agreement-concerning the sound surfaces and the most severe WSLs was high. Clinicians involved in practice-based research might therefore undergo structured training to visually classify WSLs using any of the two scoring systems to improve the reliability and quality of the outcome measure.

Ethics

Ethics Committee Approval: The research protocol was submitted on 11/07/2016 and approved on 24/10/2016 by the Ethics Committee of the Dental School, National and Kapodistrian University of Athens, according to Helsinki's Declaration (approval no.: 409, date: 24.10.2016).

Informed Consent: The patients and their parents provided written informed consent for the study.

Author Contributions: Concept - I.S., S.T., S.G.; Design - I.S., S.T., S.G.; Supervision - I.S., S.T., S.G.; Materials - A.P., D.M., I.S., O.S.; Data Collection and/or Processing - A.P., D.M., O.S.; Analysis and/or Interpretation - D.M.; Literature Review - I.S., S.T. S.G.; Writing - A.P., D.M., S.T.; Critical Review - I.S., S.T. S.G.

Declaration of Interests: All authors declare that they have no conflict of interest.

Funding: This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

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TURKISH JOURNAL OF
ORTHODONTICS

DOI: 10.4274/TurkJOrthod.2023.2023.2

Original Article

Effects of Mask Usage During the COVID-19 Pandemic on Sign and Symptoms of Temporomandibular Joint Disorder: A Survey Study

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Cite this article as: Sunal Aktürk E, Aydın İ, Şeker ED. Effects of Mask Usage During the COVID-19 Pandemic on Sign and Symptoms of Temporomandibular Joint Disorder: A Survey Study. *Turk J Orthod.* 2024; 37(2): 84-90

Main Points

- During the use of N95 respirator masks, an increase in mouth breathing and mask-related parafunctional movements was observed.
- The increase in pain during the pandemic period in individuals who selected N95 respirators as their professional mask was higher than in those who used surgical masks.
- The increase in temporomandibular joints pain and muscle pain at rest during the pandemic period was higher in those who chose N95 respirators than in those who chose to wear a single surgical mask.

ABSTRACT

Objective: To evaluate possible temporomandibular disorders (TMD) symptoms that may occur due to mask use in dentists during the coronavirus disease-2019 pandemic period and identify potentially effective factors.

Methods: An online questionnaire consisting of three parts was sent to dentists and clinical dental students. The first part included questions regarding sociodemographic information. In the second part, questions were asked to evaluate stress levels, TMD symptoms, and treatment of TMD, if any, before (T0) and during the pandemic (T1). In the last part, professional mask choice, mask-related parafunctional movements, and breathing patterns while wearing a mask were evaluated.

Results: TMD symptoms and stress levels were significantly higher at T1. An increase in mouth breathing and mask-related parafunctional movements was reported during the use of N95 masks compared with daily life in dentists whose professional mask selection was an N95 respirator. The change in temporomandibular joints pain and muscle pain at rest between T0 and T1 was higher in those whose professional mask choice was N95 respirators than in those who chose to wear one surgical mask.

Conclusion: The increase in mouth breathing and mask-related parafunctional movements during the use of N95 respirators may increase TMD.

Keywords: COVID-19, N95 respirators, surgical mask, temporomandibular joint disorder

*Part of this research was presented as a poster at the 17th Turkish Orthodontic Society International Virtual Symposium, November 28-29, 2021. Preprint version of this manuscript was posted online on Researchsquare.

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Received: January 17, 2023 **Accepted:** August 03, 2023 **Publication Date:** June 30, 2024

INTRODUCTION

The novel Coronavirus disease-2019 (COVID-19) was first detected in Wuhan City, China, and the World Health Organization (WHO) China Country Office was informed of cases of pneumonia with unknown etiology on December 31 2019.[1] WHO announced COVID-19 to be a pandemic on March 11, 2020.[2]

Studies have shown that interpersonal transmission of the coronavirus causing COVID-19 (severe acute respiratory syndrome-coronavirus-2) occurs through respiratory droplets, contact, airborne, and fomite transmission; thus, governments have either recommended or made compulsory that facemasks be used in public areas.[3] Wearing facemasks in public areas was compulsory in Turkey between September 8, 2020, and April 27, 2022.[4] Researchers have reported that although standard surgical masks are sufficient during daily activities, FFP2 or more protective masks are necessary in occupations that involve exposure to respiratory droplets.[5]

An article titled "The Workers Who Face the Greatest Coronavirus Risk" was published by the New York Times in March 2020 with a chart demonstrating that dentists and other dental care workers who face the greatest risk of getting infected by the new coronavirus highlighted their frequency of exposure to the disease and physical proximity to others, in this case, patients.[6]

According to the report of the WHO science briefing in July 2020, transmission through aerosols has necessitated the use of filtering facepiece respirators, such as FFP2/N95 or FFP3/N99 respirators, during aerosol-generating procedures in the field of healthcare.[3] Additionally, it has been reported that healthcare workers should use personal protective equipment such as face shields/goggles, and gowns during these procedures.[7]

Ong et al.[8] noticed that the prolonged use of masks increased the prevalence of headaches, especially for individuals with a history of headaches; however, they also found that long-term mask use does not reduce the oxygen saturation level in the blood. In addition to headaches, other discomforts reported while wearing a mask include nasal bridge scarring,[9] facial itching,[9] rash/irritation,[10] and discomfort related to increased facial temperatures.[11] In the study conducted by Luximon et al.,[12] participants reported an increase in humidity, breathing difficulty, and overall discomfort while wearing facemasks, especially while wearing the N95 mask and in situations that required speaking.

The increase in the number of patients with temporomandibular disorder (TMD) who presented to our clinic during the pandemic period and the reporting that parafunctional habits such as clenching, mouth breathing, and keeping the mask in place or fixing it became more frequent among our colleagues, especially during the use of N95 respirators, led us to conduct this study. The aim of this study was to evaluate possible TMD symptoms that may occur due to mask use among dentists during the COVID-19 pandemic period and identify potentially effective factors.

METHODS

This study was approved by the Turkish Ministry of Health (2021-04-07T11_42_33) and the Bezmialem Vakıf University Non-Invasive Ethics Committee (approval no.: 2021/168, date: 29.04.2021). A questionnaire was created online through Google Forms (Google LLC, Mountain View, CA, USA) and sent to dentists and clinical dental students via e-mail, WhatsApp, and social media platforms (Instagram, Twitter). Dentists who were not working during the pandemic period and preclinical dental students were excluded from the study.

The questionnaire consisted of three parts. The first part included questions on demographic information, including age, sex, status, institution, and weekly working hours. In the second part, questions were asked to evaluate stress levels and TMD symptoms (limitation of mouth opening, temporomandibular joints (TMJ) and masticatory muscle pain at rest and function, alteration during function, TMJ sounds, jaw locking, or luxation), and treatment of TMD if any of individuals for before (T0) and during the COVID-19 pandemic period (T1). Individuals were requested to score their stress levels, pain levels, and levels of limitation of mouth opening on a visual analog scale of 0 (none) to 10 (high). In the last part, professional mask choice, mask-related parafunctional jaw movements (lateral or protrusive positioning of the mandible, grinding, repetitive mouth opening and closing, involuntary mouth opening), and breathing pattern while wearing a mask were evaluated. The last two criteria were also questioned regarding mask usage in their routine lives. A sample of the questionnaire is included in Appendix 1. The data were collected from May 25 to August 15, 2021.

Statistical Analysis

A total of 554 individuals filled out the questionnaire. Fifty-nine of them stated that they were not actively working; thus, these individuals were excluded from the analyses, and the statistical analyses were conducted on the data collected from 505 individuals.

The analyses were performed using IBM SPSS Statistics software (version 22.0; IBM Corp., Armonk, NY). The data are expressed as mean and standard deviation or frequency with percentage values for the variables. Data normality was assessed using the Shapiro-Wilk test. Comparison of limitation of mouth opening, TMJ, and masticatory muscle pain during rest and function in different periods (T0: before the COVID-19 pandemic, T1: during the pandemic) was performed using the Wilcoxon Signed-Rank test. Changes in terms of TMD symptoms between the periods (ΔT0/T1) in the groups formed according to their mask preferences while performing dental procedures (Group 1: one surgical mask, Group 2: two surgical masks, Group 3: N95/FFP2 or N95/FFP2 + surgical mask) were analyzed using the Kruskal-Wallis test. The Bonferroni post-hoc test was used to determine the source of the differences that were found to be significant.

McNemar's test was used to compare breathing patterns and parafunctional movements (keeping mouth open, teeth clenching, lateral or protrusive movement of the mandible, opening and closing the mouth repeatedly to adjust the mask) while performing dental procedures and in daily life between the groups. Spearman's rank correlation coefficient was used to examine the correlation between weekly working hours and TMD symptoms. The level of statistical significance was accepted as p<0.05.

RESULTS

The distributions of the participants' demographic characteristics, including age, sex, status, institution, weekly working hours, and professional mask choice, are given in Table 1. The results of the comparison of TMD symptoms, including limitation of mouth opening, TMD and masticatory muscle pain during rest and function, and stress levels between T0 and T1, are shown in Table 2. All these symptoms and stress levels were found to be significantly higher at T1 than at T0 (p<0.001).

While the number of participants reporting no alteration in function decreased during the COVID-19 pandemic period, an increase was observed in the number of individuals who reported functional alterations (TMJ sounds, locking, or luxation). Furthermore, the number of participants with painless function decreased, and those who experienced pain during one or more movements (opening or closing the mouth, lateral or protrusive movement of the mandible) increased from T0 to T1. While 52 of the participants reported that they had received treatment for TMD (painkillers, anti-inflammatory drugs, muscle relaxants, oral splints, physical therapy, TMJ surgery, or Botox injections) before the pandemic, 53 participants reported that they had received treatment during the pandemic period (Table 3). Among the participants who received treatment for TMD during the pandemic, 29 individuals started treatment during the pandemic period without having received any prior treatment, whereas 24 individuals had received treatment before the pandemic and continued their treatment during the pandemic period.

Changes in TMD symptoms between the periods (ΔT0/T1) in the groups formed according to mask preferences while performing dental procedures are demonstrated in Table 4. The results revealed a statistically significant difference in the change in TMJ pain at rest (p=0.01) and masticatory muscle pain at rest (p=0.008) only between Group 1 and Group 3. The results of the comparison of breathing patterns and parafunctional activities while performing dental procedures and in daily life within the groups are shown in Table 5. Statistically significant differences in breathing patterns and the presence of parafunctional activities were detected only in Group 3 (p<0.001). No correlation was found between working hours and TMD symptoms (p<0.05).

Table 1. Socio-demographic characteristics of the participants (n=505)

Age (years)	n	Percentage
20-25	175	34.7%
25-30	141	27.9%
30-40	86	17%
40-50	46	9.1%
50-60	37	7.3%
60+	20	4%
Gender		
Female	346	68.5%
Male	159	31.5%
Type of institution		
Governmental oral and dental health center	47	9.3%
Private dental office	103	20.4%
Private dental polyclinic/hospital	114	22.6%
University	241	47.7%
Profession		
Clinical dental student	139	27.5%
Postgraduate student	71	14.1%
Dentist	194	38.4%
Dental specialist	101	20%
Weekly working time		
<10 hours	100	29.8%
10-20 hours	89	17.6%
20-30 hours	63	12.5%
30-40 hours	123	24.4%
40< hours	130	25.7%
Professional mask choice		
One surgical mask	44	8.7%
Two surgical masks	80	15.8%
N95/FFP2 or N95/FFP2 + surgical mask	381	75.5%

Table 2. Comparison of TMD symptoms and stress levels between T0 and T1

	T0		T1		
	Mean	SD	Mean	SD	p-value
Limitation of mouth opening	0.37	0.81	0.64	1.05	**<0.001*** **
TMJ pain at rest	0.77	1.45	1.21	1.83	**<0.001*** **
TMJ pain in function	0.76	1.31	1.36	2.00	**<0.001*** **
Muscle pain at rest	0.87	1.46	1.49	2.07	**<0.001*** **
Muscle pain in function	0.96	1.56	1.62	2.24	**<0.001*** **
Stress level	4.30	2.22	6.03	2.32	**<0.001*** **

***p<0.001
TMD, temporomandibular disorder; TMJ, temporomandibular joints

Table 3. Distribution and frequency of the treatment of TMD, functional alterations, and pain status in T0 and T1

		T0		T1	
		n	%	n	%
Functional alterations	Normal function	386	76.4%	348	68.9%
	TMJ sounds (clicking or crepitus)	119	23.6%	150	29.7%
	Jaw locking or luxation	0	0%	7	1.4%
Pain during function	Painless function	462	91.5%	404	80%
	Pain during one movement*	36	7.1%	76	15%
	Pain during at least 2 movements*	7	1.4%	25	5%
Treatment of TMD	Presence	52	10.3%	53	10.5%
	Absence	453	89.7%	452	89.5%

*Opening the mouth, closing the mouth, lateral or protrusive movements of the mandible
TMD, temporomandibular disorder; TMJ, temporomandibular joints

DISCUSSION

Temporomandibular disorders are multifactorial conditions affecting both soft or hard tissues. Trauma,[13] emotional state,[14,15] malocclusion[16,17] and oral parafunctions[18,19] can be counted among the known etiological factors for TMD. Oral, masticatory, and facial behaviors that do not serve any functional purpose are generally referred to as oral parafunctions.[20] These behaviors are usually harmless; however, when their frequency or the forces induced by them exceed physiological tolerance, they can cause harmful effects on joints and muscles. Commonly reported oral parafunctions include teeth clenching and grinding, nail biting, and gum chewing.[21,22] The aim of this study was to evaluate possible TMD symptoms that may occur due to mask use among dentists during the COVID-19 pandemic and to identify potentially effective factors, including parafunctional movements associated with mask preference.

TMD presents with bilateral or unilateral symptoms such as muscle pain, headaches, TMJ sounds, jaw locking or luxation, tinnitus, and restricted mouth opening.[23,24] Some conditions, such as toothaches, earaches, maxillary sinusitis,

Table 4. Intergroup comparison of the change in TMD symptoms between the periods (ΔT0-T1)

(ΔT0-T1)	Group 1 (n=44)		Group 2 (n=80)		Group 3 (n=381)				
	Mean	SD	Mean	SD	Mean	SD	p-value	Post-hoc p-value	
ΔLimitation of mouth opening	0.06	1.06	0.2	0.8	0.3	0.9	0.19		
ΔTMJ pain at rest	-0.02	1.48	0.27	0.01	0.52	1.35	**0.01****	Group 1-3	**0.02***
ΔTMJ pain in function	0.34	2.03	0.46	1.01	0.65	1.47	0.23		
ΔMuscle pain at rest	0.04	0.65	0.32	0.91	0.74	1.61	**0.008****	Group 1-3	**0.04***
ΔMuscle pain in function	0.18	2.03	0.47	1.00	0.76	1.50	0.05		

*p<0.05; **p<0.01
T0, before the pandemic; T1, during the pandemic; TMJ, temporomandibular joints; SD, standard deviaiton

Table 5. Intragroup comparison of breathing patterns and parafunctional movements while performing dental procedures and in daily life

			Daily life		Performing dental procedure		
			n	%	n	%	p-value
Group 1 (n=44)	**Breathing pattern**	Nasal breath	21	48%	20	45%	0.51
		Mouth breath	4	9%	3	7%	
		Nasal and mouth breath	19	43%	21	48%	
	Parafunctional movement	Presence	29	66%	29	66%	1
		Absence	15	34%	15	34%	
Group 2 (n=80)	**Breathing pattern**	Nasal breath	37	46%	39	49%	0.47
		Mouth breath	12	15%	13	16%	
		Nasal and mouth breath	31	39%	28	35%	
	Parafunctional movement	Presence	50	63%	55	69%	0.33
		Absence	30	38%	25	31%	
Group 3 (n=381)	**Breathing pattern**	Nasal breath	195	51%	145	38%	**<0.001*****
		Mouth breath	25	7%	55	14%	**<0.001*****
		Nasal and mouth breath	161	42%	181	48%	**0.03***
	Parafunctional movement	Presence	234	61%	297	78%	**<0.001*****
		Absence	147	39%	84	22%	

*p<0.05; ***p<0.001

carcinomas, neuralgias, salivary gland diseases, acromegaly, Eagle syndrome, migraine, and high blood pressure, mimic the symptoms of TMD.[25] This study excluded clinical examinations and was based on the self-reports of the participants. To prevent confusion of TMD symptoms with the other conditions mentioned above, the questionnaire was administered only to dentists and clinical dental students. The participants were asked to evaluate their TMD signs and symptoms in one specific period (before and during the COVID-19 pandemic period).

The participants in this study reported an increase in TMD symptoms during the pandemic compared with those before the pandemic. Etiological factors such as professional mask preferences, duration of mask use, parafunctional habits that could be formed due to wearing a mask, and stress were investigated in this study.

Of the participants, 75.5% reported that their choice of professional mask was N95/FFP2 or N95/FFP2 + surgical mask, 15.8% chose to wear two surgical masks on top of each other, and 8.7% preferred one surgical mask. In the comparison of the TMD symptoms among the groups created according to their professional mask choices, there was no significant difference in terms of the limitation of mouth opening or TMJ and masticatory muscle pain at function. However, the difference in the change of TMJ pain and masticatory muscle pain at rest was higher in Group 3 than in Group 1.

The participants in Group 3 stated that their mouth breathing and mask-related parafunctional movements (lateral or protrusive positioning of the mandible, grinding, repetitive mouth opening and closing, involuntary mouth opening) increased compared with daily life during the use of N95 masks. Neither of the other groups reported a significant difference. This result also indicated the impact of FFP2/N95 use on breathing patterns and parafunction, which may explain the increase in TMJ and masticatory muscle pain at rest during the pandemic period among individuals who preferred N95 respirators as their mask preference (Group 3) compared with those who preferred one surgical mask (Group 1). Supporting the findings of this study, there are studies reporting a significant relationship between parafunctional habits, mouth breathing, and TMD.[26,27] Kojima et al.[28] reported that involuntary mouth opening, like bruxism, may play a role in the development of TMDs. Scheid et al.[24] reported that the sustained use of masks increased the prevalence of headaches in individuals with a history of headaches but also noticed that long-term mask usage does not reduce oxygen saturation levels in the blood. This finding led to the suspicion of other causes of headaches that could be related to mask use. The increasing number of patients who consulted our clinic with TMJ complaints during the COVID-19 pandemic and our colleagues reporting the adoption of parafunctional behaviors during mask use prompted the need to investigate the effects of facemask use on TMJ.

The present study explored the possible effects of prolonged mask usage on TMD during the COVID-19 pandemic. To evaluate the relationship between professional mask-wearing duration and TMD signs and symptoms, the participants were asked about their weekly working hours. No significant correlation was found between weekly working hours and TMD symptoms. Although the weekly working hours of the participants were expected to provide information about the duration of their professional mask usage, this period may not completely reflect the time worked with the mask or long-term use of masks in daily life, which may explain the lack of correlation.

The association between depression and stress and different physical symptoms of TMD is widely acknowledged.[14,15] A study on patients with TMD revealed that increased stress levels during the pandemic led to an increase in parafunctional habits (awake and sleep bruxism, clenching) and sleeping disorders (variation in the quality and duration of sleep, fatigue).[29] A recent meta-analysis of 13 studies showed that depression, anxiety, and insomnia were highly prevalent among healthcare professionals.[30] Considering this information, it should be noted that stress is a significant factor for TMD. According to the self-reports of the participants in this study, their stress levels increased during the pandemic compared with pre-pandemic period.

Study Limitations

Although the purpose of this study was to investigate the effects of mask usage on TMD, a limitation of our study is that the etiology of TMD is multifactorial, and one factor cannot be evaluated alone. Another limitation is that the TMD symptom data in this study were not based on clinical examinations, but were recorded according to the self-reports of the participants. Additionally, information about the pre-pandemic period was collected during the pandemic period.

CONCLUSION

The results of this study indicated that an increase in TMD was observed in dentists during the pandemic period. The degree of change in TMJ pain and masticatory muscle pain at rest between the periods (ΔT0/T1) was higher in participants whose professional mask choice was N95 respirator or an N95 respirator with a surgical mask cover than in those who chose to wear a surgical mask. An increase in mouth breathing and mask-related parafunctional movements was reported during the use of N95 respirator masks compared with daily life in dentists who selected N95 respirators as their professional masks.

Ethics

Ethics Committee Approval: This study was approved by the Turkish Ministry of Health (2021-04-07T11_42_33) and the Bezmialem Vakıf University Non-Invasive Ethics Committee (approval no.: 2021/168, date: 29.04.2021).

Informed Consent: A survey study.

Author Contributions: Concept - E.S.A., İ.A., E.D.Ş.; Design - E.S.A., İ.A., E.D.Ş.; Data Collection and/or Processing - E.S.A., İ.A., E.D.Ş.; Analysis and/or Interpretation - E.S.A., E.D.Ş.; Literature Review - E.S.A., İ.A.; Writing - E.S.A., İ.A.

Declaration of Interest: The authors have no conflicts of interest to declare.

Funding: The authors declare that this study has received no financial support.

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Appendix 1. The samples of the questionnaire used in this study

Questions asked to assess temporomandibular joint (TMJ) and stress level both before and during the pandemic	
Questions	**Answers**
- Your level of limitation in mouth opening before/during the pandemic (Pandemiden önce/pandemi döneminde ağız açmadaki kısıtlılık seviyeniz)	(Normal range) 0-1-2-3-4-5-6-7-8-9-10 (Severely restricted movement)
- Pain in your TMJ at rest before/during the pandemic (Pandemiden önce/pandemi döneminde istirahat halindeyken temporomandibular ekleminizdeki (TME) ağrı)	(None) 0-1-2-3-4-5-6-7-8-9-10 (Very severe and constant pain)
- Pain in your TMJ during function (opening, closing, protrusion or lateral movements) before/during the pandemic (Pandemiden önce/pandemi döneminde fonksiyon sırasında ekleminizdeki ağrı)	(None) 0-1-2-3-4-5-6-7-8-9-10 (Very severe and constant pain)
- Pain in your masticatory muscles at rest before/during the pandemic (Pandemiden önce/pandemi döneminde istirahat halinde çiğneme kaslarınızdaki ağrı)	(None) 0-1-2-3-4-5-6-7-8-9-10 (Very severe and constant pain)
- Pain in your masticatory muscles at function (opening, closing, protrusion or lateral movements) before/during the pandemic (Pandemiden önce/pandemi döneminde fonksiyon sırasında çiğneme kaslarınızdaki ağrı)	(None) 0-1-2-3-4-5-6-7-8-9-10 (Very severe and constant pain)
- Change in the normal function of TMJ while opening and closing the mouth before/during the pandemic (Pandemiden önce/pandemi döneminde ağız açma - kapama sırasında TME'nin normal fonksiyonundaki değişim) - Please tick only one option.	○ Sounds in TMJ area (clicking or crepitus), Shift in function ○ Jaw locking or luxation ○ Normal function
- Pain in TMJ during opening, closing, protrusion, and lateral excursion of the mandible before/during the pandemic (Pandemiden önce/pandemi döneminde mandibulanın açma, kapama, protruzyon ve lateral hareketleri sırasında TME'de ağrı) - Please tick only one option.	○ Pain during any one of the movements of mandible ○ Pain during at least two of the movements of mandible ○ Painless movement
- What treatment(s) did you receive for temporomandibular joint dysfunction (TMD) before/during the pandemic? (Pandemiden önce/pandemi döneminde TMD sebebiyle hangi tedavi/tedavileri gördünüz?) - Please tick one or multiple option.	○ Medication ○ TMJ splint ○ Botox ○ Physical therapy ○ TMJ surgery ○ None ○ Other:
-Your stress level before/during the pandemic (Pandemiden önceki/pandemi dönemindeki stress seviyeniz)	(None) 0-1-2-3-4-5-6-7-8-9-10 (Very high stress)
Questions about mask usage during the pandemic (after March 2020).	
- How many hours do you work in a week on average? (Haftada ortalama kaç saat çalışıyorsunuz?) - Please tick only one option.	○ I am not working. ○ 20-30 hours ○ Less than 10 hours. ○ 30-40 hours ○ 10-20 hours. ○ More than 40 hours
- How many days a week do you work? (Haftada kaç gün çalışıyorsunuz?)	I am not working-1 day-2 days-3 days-4 days-5 days-6 days -7 days
- Which of the following masks do you use while practicing your profession? (Hasta baktığınız sırada aşağıdaki maskelerden hangisini kullanıyorsunuz?) - Please tick only one option.	○ One surgical mask ○ Double surgical mask ○ Respirator only (N95/FFP2, FFP3, etc.) ○ Both surgical mask and a respirator ○ I do not use a mask
- How would you evaluate the adaptation of the mask you use with your face? (Kullandığınız maskenin yüzünüzle uyumunu nasıl değerlendiriyorsunuz?) - Please tick only one option.	○ It is perfect, it adapts very well. ○ It is big, there is an adaptation problem. ○ It is small, there is an adaptation problem.
- Which of the following(s) are you doing when practicing your profession while wearing a mask? (Hasta baktığınız sırada maske takılıyken aşağıdakilerden hangisini/hangilerini yapıyorsunuz?) - Please tick one or multiple option.	○ I involuntarily keep my mouth open. ○ I involuntarily grit my teeth. ○ I involuntarily position my jaw to the right, left or front. ○ I open and close my mouth to adapt the mask to my face. ○ None
- How do you breathe when performing your profession while wearing a mask? (Hasta baktığınız sırada maske takılıyken nasıl solunum yapıyorsunuz?) - Please tick only one option.	○ I am breathing from my mouth. ○ I am breathing from my nose. ○ I am breathing from both my nose mouth.
- What are the difficulties you encounter while working with the mask? (Maske ile çalışırken karşılaştığınız zorluklar nelerdir?) - Please tick one or multiple option.	○ My mask is slipping up/down. ○ My mask is slipping to the right/left. ○ My glasses/face shield are fogging up. ○ I have trouble breathing. ○ Other:
- Which of the following(s) are you doing when wearing a surgical mask in daily life? (Gündelik hayatta cerrahi maske takılıyken aşağıdakilerden hangisini/hangilerini yapıyorsunuz?) - Please tick one or multiple option.	○ I involuntarily keep my mouth open. ○ I involuntarily grit my teeth. ○ I involuntarily position my jaw to the right, left or front. ○ I open and close my mouth to adapt the mask to my face. ○ None
- How do you breathe while wearing a surgical mask in daily life? (Gündelik hayatta cerrahi maske takarken nasıl solunum yapıyorsunuz?) - Please tick only one option.	○ I am breathing from my mouth. ○ I am breathing from my nose. ○ I am breathing from both my nose mouth.

DOI: 10.4274/TurkJOrthod.2023.2022.176

TURKISH JOURNAL OF
ORTHODONTICS

Original Article

Investigation of the Mechanical Properties of Thermoplastic Materials Influenced by Different Chemicals

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Cite this article as: : Asefi S, Nejatifard M, Kayyal S, Shahabi S. Investigation of the Mechanical Properties of Thermoplastic Materials Influenced by Different Chemicals. *Turk J Orthod.* 2024; 37(2): 91-97

Main Points

- Chemical solutions do not significantly affect the aligners performance or chemical composition.
- Orange juice and Cola should be avoided because of their cariogenic capability and not because of adverse effects on aligner performance.
- Chlorhexidine mouthwash can be used during clear aligner treatment without side effects.

ABSTRACT

Objective: The quality of orthodontic forces in aligners is mainly influenced by their mechanical properties. At present, there is insufficient information on how environmental factors affect the mechanical function of aligners, and studies have shown that patients do not pay enough attention to removing aligners while eating and drinking. Therefore, in this study, we investigated the effect of different chemicals on the mechanical properties of thermoplastic materials.

Methods: In this study, 175 thermoplastic samples from Easy-Vac gasket (3A Medes, Korea) were prepared, and their chemical composition, tensile strength, and hardness before and after exposure to solutions of orange juice, Cola, chlorhexidine mouthwash, and distilled water were measured. One-Way analysis of variance (ANOVA), Tamhane's test, and Tukey's test were used for statistical analysis.

Results: The tensile strength of the sheets increased with continuous exposure to orange juice and chlorhexidine mouthwash, and their hardness decreased with continuous exposure to carbonated beverages. There was no change in the chemical composition of the samples after exposure to different chemicals.

Conclusion: Although these changes are statistically significant, they do not have a significant effect on the result of aligner performance. Therefore, the only concern is the cariogenicity of orange juice and Cola during treatment with aligners and the administration of chlorhexidine mouthwash.

Keywords: Tensile strength, hardness, fourier transform infrared spectroscopy, clear aligner, chlorhexidine, solutions, dentistry, orthodontics

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Received: December 25, 2022 **Accepted:** April 27, 2023 **Publication Date:** June 30, 2024

INTRODUCTION

The appearance of orthodontic appliances plays a vital role in patient acceptance of treatment and satisfaction.[1,2] Many patients do not accept the metallic appearance of fixed orthodontic treatment and seek another alternative treatments to have a beautiful smile. Recent surveys have shown that only 33% of people who need orthodontic treatment are willing to undergo treatment using brackets.[3,4] Clear aligners are preferred by adults because of their aesthetics and comfort compared to fixed orthodontic treatment[5], as well as their mobility, convenience of hygiene, reduced chair time and longer intervals between visits to the orthodontists.[1,6]

Unlike traditional instruments, the quality of orthodontic forces in clear aligners is more influenced by the mechanical properties created during manufacturing.[7-9] Thermoplastic materials have a viscoelastic and changeable nature, making them prone to stress relaxation. Previous laboratory studies have shown a rapid decrease in these appliances' force productivity due to stress relaxation. Ideal properties of aligners include biocompatibility, translucency, good elasticity, strength, and stability in the oral environment.[10] Research has shown that the treatment outcome is strongly related to the physical properties of the aligners. Clear aligners with higher hardness, used for two weeks of activity time, have shown the best results in improving tooth alignment and smoothing.[11]

In addition to the initial mechanical properties, oral environmental conditions over time may affect the properties of materials, such as reduced force-bearing capacity and the effectiveness of treatment.[8,12] Despite the high level of precision during manufacture, the original shape and composition of the aligners in the mouth do not remain stable during use and change slowly. Although these materials are biocompatible, they are not inert. They are affected by various factors such as the consumption of food and coloring beverages, mouthwashes, organic and inorganic liquids, heat, moisture, long-term contact with salivary enzymes, inhaled gases, trauma from swallowing, speaking, and bruxism.[13,14]

Despite the significant impact of the physical properties of aligners on treatment success, there is currently insufficient information on how environmental factors affect the mechanical performance of aligners.[12,15] To prevent mechanical damage to the aligners, patients are advised to avoid eating and drinking while using the aligners. However, studies show that patients' compliance with removing orthodontic appliances is insufficient[16,17], which is often a concern for orthodontists.

There have been advanced developments in digital treatment planning by recent software and 3D printers, making clear aligner therapy easily accessible to clinicians and laboratories. The patent for this technology was originally held by Align technology, but today, it is available to others. Therefore, local laboratories can also use digital software and 3D printers to simulate treatment stages. However, they still need to use commercial thermoplastic materials to fabricate clear aligners. Previous studies have usually evaluated well-known aligners like Invisalign, whereas there is insufficient evidence about other commercial thermoplastic materials.[14,15,18,19] The manufacturer's information may be the only data available for clinicians or laboratories who want to use these thermoplastic materials as clear aligners.

To provide evidence to patients and orthodontists about clinical considerations and instructions for use, as well as inform manufacturers to improve the quality of their products and eliminate scientific shortcomings related to clear aligners, this study aimed to evaluate the mechanical properties and chemical composition of clear aligners after exposure to various chemical liquids *in vitro*. The null hypothesis was that there would be no change in the tensile strength, hardness, and chemical composition of aligners under different chemicals.

METHODS

According to the results of the study by Schuster et al.[20], considering α=0.05 and β=0.2, an average standard deviation of 20 MPa, and an effect size of 0.46 using the One-Way ANOVA power analysis option of PASS 11 software (NCSS LLC, Utah, USA), the minimum sample size for each of the five study groups was estimated to be 13 samples for the tensile strength and hardness test and 5 samples for the Attenuated Total Reflectance- Fourier test Transform InfraRed (ATR-FTIR) test.

The research's executive protocol was reviewed and approved by the Institutional Research Ethics Committee, School of Dentistry-Tehran University of Medical Sciences (approval no.: IR.TUMS.DENTISTRY.REC.1398.089, date: 31.07.2019).

Thermoplastic sheets specifically for making aligners (Easy-Vac gasket, 3A Medes, Korea) with the same thickness were vacuum-formed in the laboratory using a vacuum form Easy-Vac machine (3A Medes, Korea) with a thickness of 0.75 mm on a glass plate with dimensions of 8×8 cm. In this experiment, five groups of 35 samples (each group included 15 samples in the form of an hourglass for the tensile strength test, 15 samples in the form of a square for the hardness test, and 5 samples in the form of a square for the ATR-FTIR test) were used.

Four of the five experimental groups were randomly placed in each of the following four vessels for 22 hours a day; 2 hours were considered for eating, drinking, or hygiene time over 14 days in an incubator at 37 °C (totaling 308 hours) to replicate conditions similar to oral conditions. The exposure time to chemical solutions may be longer than real conditions. Still, there is no consensus among experts on the exact exposure time since each patient has individual behavior in following the clinician's orders. Additionally, we wanted to detect influences under the most severe conditions, which may be identified by measurements

Container 1: Contains 100 mL of industrial orange juice (SunStar, Zarrin Jam Marina manufacturer, Kashan, Iran)

Container 2: Contains 100 mL Cola (Coca-Cola, Khoshgvar Company, Semnan, Iran)

Container 3: Contains 100 mL chlorhexidine mouthwash (chlorhexidine najo, Iran Najo company, Tehran, Iran)

Container 4: Contains 100 mL of distilled water (Zalal Teb Shimi Company, Karaj, Iran)

Container 5: Specimens were placed in a dry container and considered the control group.

The samples were removed from the solutions twice a day, washed under running water each time, and dried with a rapid flow of air. They were kept out of the solution for 1 hour and returned to the solution. This process simulated the removal of the aligners from the mouth while eating and performing health care.To measure the tensile strength, samples (75 mm long and 10 mm wide) were designed on both sides using SolidWorks software according to ISO 527-2-1BA and cut using a CO_2 laser cutting machine (Figure 1), and 75 specimens were prepared. The specimens were randomly divided into five groups of 15.

After storage in each group's solution, the tensile force was applied to samples with the same thickness and hourglass shape at a constant speed of 5 mm/min while they were held at the same distance by the clamps of the universal testing machine (Zwick/Roell Z050, Germany). The samples torn in the middle area were considered acceptable, and the force applied to each sample was calculated in newtons. The increase in the length of each sample at the time of tearing was also calculated by measuring the length of each sample before and after tearing using a caliper with a reading accuracy of 0.01 mm. Samples that did not rupture in the middle region were excluded from the experiment and retested.

To evaluate the chemical composition, 25 samples were prepared in a square shape with dimensions of 1×1 cm and were randomly divided into five groups of five. After storing each group's solution, the groups were placed in an ATR-FTIR device (Nicolet 10, Thermo Scientific, USA) to study their chemical composition. In this device, the infrared light spectrum is irradiated on the specimens. Subsequently, this device calculates the absorption or emission spectrum of the infrared radiation that crosses through or reflects the specimens.

To measure microhardness, 75 samples were made in a square shape with dimensions of 1×1 cm and were randomly divided into five groups of 15. Fifteen samples from each group were subjected to the Vickers microhardness test (Bareisis, Germany). Each specimen was exposed to the diamond sink of the machine with an internal angle of 136°. Force was applied to each specimen at least three points, at a distance of 50 μm from each other and the edges of the specimen. The applied force was 10 mN, which was applied for 10 s, held for 1 s on the sample surface, and then removed for 10 s. The hardness of the sample was measured by calculating the diameters of the square impressions left on the sample under a microscope and reported with the Vickers hardness number (VHN). The mean numerical value obtained from the three indents was reported as the hardness number.[21] To reduce errors, all measurements were performed under the same conditions by a person blinded to the groups.

Statistical Analysis

Statistical analyses were performed using SPSS software version 22 (IBM, USA). A One-Way ANOVA test was used to evaluate the significant differences in the tensile strength and hardness test measurements. A significant level for p-value was considered to be 0.05. Levene's test was used to determine data normality.

Then, Tamhane's test was used to compare tensile strength between different study groups. Moreover, to measure the significant difference between the hardness tests groups pairwise, the Tukey Honest Significant Difference test was used because the data scatter was not significantly different from each other ($p=0.31$).

The ATR-FTIR test, which was used to evaluate the chemical composition, did not require specific statistical analysis because of the similar chemical composition of all samples.

RESULTS

The tensile strength comparisons between the groups distilled water, Cola, and dry groups, respectively are presented in Table 1 and Figure 2. One-Way ANOVA showed a significant difference in tensile strength between the groups ($p=0.021$). Chlorhexidine and orange juice have significantly higher tensile strength than the dry group ($p<0.05$), whereas this difference was insignificant in the other groups.

According to the FTIR results, which showed the number of molecular changes in the studied substance upon contact

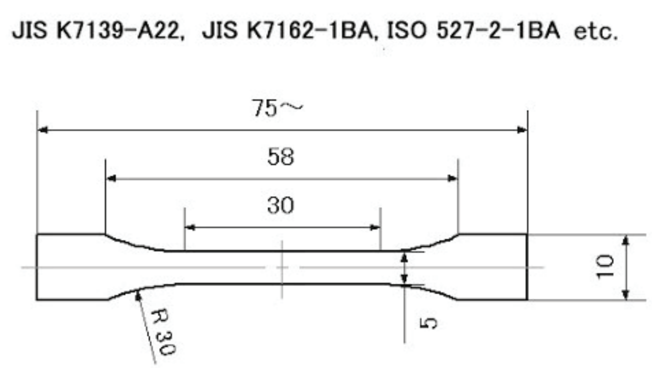

Figure 1. Standard shape of tensile strength specimens (measures are in mm scale)

with the mentioned chemicals, all groups showed the same peaks. The sum of the peaks indicates the characteristics of the following clauses:

OH (3380 cm^{-1}), NH (3313 cm^{-1}), aromatic C-H (3047, 1605, 1597, 812, 766 cm^{-1}), CH (2928, 2853, 1413, 915 cm^{-1}), C=O (1728, 1308 cm^{-1}), amide I (C=O of NCO, 1698 cm^{-1}), amide II (NH and C=O of NCO, 1518 cm^{-1}), C-O (1214, 1205 cm^{-1}), and C-O-C (1100-1060 cm^{-1}).

The total of these clauses indicates the urethane-based structure of the material under study. In fact, the observed molecular formula is a polyurethane thermoplastic material, which remained unchanged during contact with the mentioned materials.

The mean hardness was highest in the dry group, approximately 11.85 Newtons, followed by distilled water, orange juice, chlorhexidine, and Cola (Figure 3 and Table 2). One-Way ANOVA revealed a significant difference between the groups (p<0.001).

In the post hoc analysis, all groups were compared with the dry group. The Cola group showed a significant difference in hardness compared to the dry group (p<0.001), but this difference was not significant in the other groups.

DISCUSSION

Clear aligners should have certain physical characteristics to ensure clinical performance. Ideally, a thermoplastic aligner should have an acceptable tensile strength to apply the required force within the appropriate elastic range during the treatment period and high hardness to provide sufficient resistance against teeth and oral tissues, thereby preventing thinning and deformation.[19] As the aligner's hardness decreases, cracks may appear on the appliance surface, which can affect its performance during the treatment period.[22] Therefore, factors such as the manufacturing temperature of aligners[7,23], the temperature of foods or drinks consumed while using the appliance, and intraoral temperature can all affect the aligner's hardness.[2]

Despite the significant impact of the physical properties of aligners on treatment success, there is currently insufficient information on how environmental factors affect the mechanical performance of aligners.[12,15] Most existing studies have examined the effect of intraoral aging on the mechanical properties of aligners. Therefore, the findings of this study are novel and of great importance in the production of aligner sheets and recommendations for orthodontic treatment. In addition, it serves as a valuable guide for researchers to conduct more extensive studies in this field.

This study tested the accuracy of the tensile strength, hardness, and chemical composition of the Easy-Vac gasket thermoplastic

Table 1. Comparison of tensile strength of each experimental group by One-Way ANOVA test (p<0.05); Tamhane's test is used to compare groups pairwise

	Groups	Mean (n) ± Standard deviation
Tensile strength	Orange juice	53.41$^{\beta}$±7.69
	Cola	48.42±6.35
	Chlorhexidine	54.65$^{\alpha}$±7.46
	Distilled water	51.96±11.44
	Dry	46.12$^{\alpha,\beta}$±4.56

Symbols ($^{\alpha,\beta}$) shows significant difference between groups

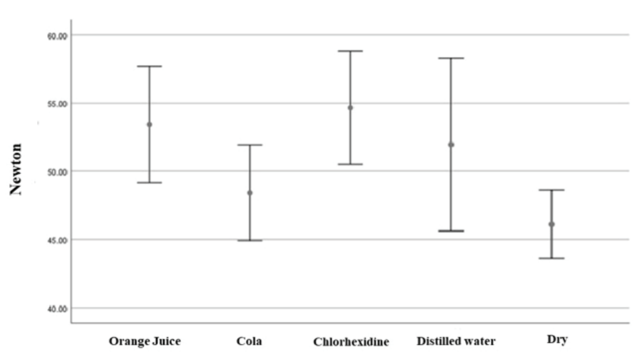

Figure 2. Tensile strength of each experimental group

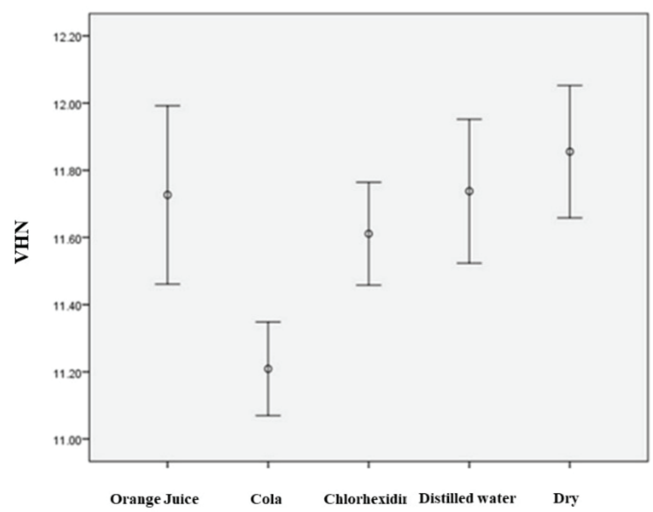

Figure 3. Hardness of each experimental group

Table 2. Comparison of hardness of each experimental group by One-Way ANOVA test (p<0.05); Tukey HSD test is used to compare groups pairwise

	Groups	Mean (VHN) ± Standard deviation
Hardness	Orange juice	11.72±0.47
	Cola	11.20$^{\alpha}$±0.25
	Chlorhexidine	11.61±0.27
	Distilled water	11.73±0.38
	Dry	11.85$^{\alpha}$±0.35

Symbol ($^{\alpha}$) shows significant difference between groups
VHN, Vickers hardness number; HSD, Honest significant difference

sheet after exposure to carbonated beverages, orange juice, chlorhexidine mouthwash, and distilled water. The reason for not using artificial saliva as a group is the possibility of the effect of chemical compounds of artificial saliva on different properties of aligners because the composition of artificial saliva is not the same as that of natural saliva and can have harmful effects on the properties studied in this study. Additionally, dry specimens were considered a control group. After all, their mechanical properties are the most reliable data in the *in vitro* study. They can be used in future studies as basic information for clinical evaluation or study design. Simulation of the oral environment cannot be achieved reliably in an *in vitro* study design. It may come to mind that a group immersed in distilled water or artificial saliva should be considered a control group; however, the composition of these solutions is completely different from that of an oral fluid with enzymes, microorganisms, and fluctuations in temperature or PH. Thus, we considered dry specimens a reliable control group in the *in vitro* study design.

In this study, the tensile strength of specimens exposed to chlorhexidine mouthwash and orange juice increased, whereas that of samples exposed to Cola and distilled water did not change.

In the results of Ryokawa et al.'s[24] study, tensile yield stress decreased in all eight thermoplastic products under the *in vitro* condition. Factors affecting these properties include changes in temperature and saliva and intraoral aging. Gould et al.[25] examined the physical properties of mouth guards at 23 °C and 37 °C (mouth temperature). Hardness, water absorption, and tensile strength levels were examined according to mouthguard standards in five common market brands (Essix™ Resin, Erkoflex™, ProForm™-regular, Proform™-laminate, and PolyShok™). The results showed that the tensile strength decreased with increasing temperature. Temperature was the influencing factor on these properties. Ihssen[12] confirmed the Ryokawa[24] and Gould[25] test results for temperature change and intraoral aging on tensile strength.

These studies show that intraoral aging can decrease tensile strength in clear aligners, which contrasts with the results observed in the chlorhexidine and orange juice groups, where tensile strength increased. This study result is consistent with Ahn's[26] study, which revealed that intraoral aging increases the ultimate tensile strength of polyethylene terephthalate glycol (PETG) vacuum retainers. Although this increase was statistically significant, it is not enough to affect the performance of clear aligners; therefore, its impact can be ignored.

The results of the FTIR test showed that the structure of the studied thermoplastic material was based on polyurethane, and its molecular formula did not change after being placed in chemical solutions. Gerard Bradley et al.'s[14] study compared the effect of intraoral aging on the mechanical and chemical properties of Align Technology brand aligners used by the patient for 44 days with unused aligners from the same brand as control. The results showed no change in the chemical composition of the aligners before and after consumption. Other studies[17,27] have confirmed this result. Ahn[26] also implied that intraoral aging does not change the biochemical composition of PETG vacuum retainers. These studies are consistent with our study. This means that environmental factors do not affect the chemical composition of clear aligners, either *in vivo* or *in vitro*.

In our study, the hardness test results showed that the hardness of the samples exposed to carbonated beverages decreased, but the hardness of the samples in solutions of orange juice, chlorhexidine, and distilled water did not change. Condo' et al.[16] revealed that the crystal structure of aligners changes due to the heat of the mouth and the application of orthodontic forces, which increases the hardness and hyperplasticity after use. Gould et al.[25] showed that the degree of hardness decreased with increasing temperature from 23 °C to 37 °C (oral temperature). These results were also confirmed by Gerard Bradley et al.'s[14] study.

Although the hardness test results in our study in the carbonated beverage group were statistically significant, it is not enough to affect the performance of clear aligners, so their effect can be ignored. Chlorhexidine mouthwash and orange juice also did not affect the hardness of the aligner.

In summary, the results of our study showed that the tensile strength, hardness, and chemical composition of clear aligners could be influenced by different chemicals; however, these changes are negligible. The implications of future research are conspicuously felt. This report evaluated the tensile strength, ATR, and hardness. Future studies are needed to test other important characteristics such as flexural strength[28], fatigue[29], roughness[30], and color stability[31] to complete the knowledge about these thermoplastic materials.

Study Limitations

Our study has limitations, such as evaluating only one thermoplastic material, and being conducted under *in vitro* conditions. It is suggested to investigate other thermoplastic materials and different commercial products and design future studies to stimulate the oral environment or conduct studies *in vivo* conditions.

CONCLUSION

Beverages consumed by patients do not change the chemical composition of the thermoplastic sheets, but they do alter the tensile strength and hardness of the sheets. Although these changes are statistically significant, they are too negligible to cause problems in the treatment process. Therefore, the only concern is the cariogenicity of these drinks (orange juice and carbonated beverages) during treatment with aligners.

Chlorhexidine mouthwash is also safe during the treatment process.

Ethics

Ethics Committee Approval: The research's executive protocol was reviewed and approved by the Institutional Research Ethics Committee, School of Dentistry-Tehran University of Medical Sciences (approval no.: IR.TUMS.DENTISTRY.REC.1398.089, date: 31.07.2019).

Informed Consent: This study was designed as an experimental *in vitro* study, therefore informed consent is not involved for this study.

Author Contributions: Concept - S.A., S.S., Design - S.A., S.S., Supervision - S.A., Materials - S.K., Data Collection and/or Processing - S.K., Analysis and/or Interpretation - S.A., M.N., S.K., Writing - S.A., M.N., Critical Review - S.A.

Conflict of Interest: The authors have no conflicts of interest to declare.

Financial Disclosure: The authors declare that this study has received no financial support.

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TURKISH JOURNAL OF
ORTHODONTICS

DOI: 10.4274/TurkJOrthod.2023.2022.189

Original Article

Investigation of Different Miniscrew Head Designs by Finite Element Analysis

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Cite this article as: Çıklaçandır S, Kara GG, İşler Y. Investigation of Different Miniscrew Head Designs by Finite Element Analysis. *Turk J Orthod.* 2024; 37(2): 98-103

Main Points

- The bracket head was calculated to be the best design with the lowest stress distribution.
- The highest stress value was obtained in the button head design.

ABSTRACT

Objective: To determine the optimum miniscrew head design in orthodontic treatments for primary stability and compare stress distribution on a representative bone structure.

Methods: Miniscrews with cross heads, mushroom-shaped heads, button heads, bracket heads, and through-hole heads were compared using finite element analysis. Miniscrews, whose three-dimensional drawings were completed using the SolidWorks computer-aided software package, were inserted in the bone block. Orthodontic force was applied to the head, and stress distributions, strains, and total deformations were investigated.

Results: The lowest von Mises stress of 5.67 MPa was obtained using the bracket head. On the other hand, the highest von Mises stress of 22.4 MPa was found with the button head. Through mesh convergence analysis, the most appropriate mesh size was determined to be 0.5 mm; approximately 230,000 elements were formed for each model.

Conclusion: Because the need for low stress is substantial for the primary stability of the miniscrew, this study demonstrated that the bracket head miniscrew is the optimal head design. In addition, it is posited that the success rate of orthodontic anchorage treatments will increase when bracket head miniscrews are used.

Keywords: Miniscrew, temporary anchorage, orthodontic treatment, finite element analysis

INTRODUCTION

The use of miniscrews for anchorage control during tooth movement in dentistry applications has been increasing in recent years due to their many advantages.[1] Because miniscrews can be placed in various locations in the mouth, anchorage areas are increased.[2] The recovery period is faster compared to traditional methods; in addition, surgical procedures are easy, and the application is simpler. Undesired tooth movements are prevented because force is not applied directly to the teeth. Finally, increased patient comfort, minimized risk of infection, and low material and application costs, combined with above points, demonstrate the many advantages of using miniscrews.[3] However, some complications may be encountered during treatment, such as fracture during insertion, removal of the miniscrew, penetration into the sinus cavities, risk of inflammation, embedding, pain, bleeding, and allergic reactions.[4] Overall, more research is needed to shed light on the effects of miniscrews, which are now a popular application.[5]

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Received: December 16, 2022 **Accepted:** April 13, 2023 **Publication Date:** June 30, 2024

The stability of the miniscrew and the success of treatment are directly related to the properties of the specific type of miniscrew used.[6] The success rate in miniscrew applications is relatively high. According to a 2011 study, a high success rate of 87.7% was reported in miniscrew applications.[7] In contrast, treatment failures have been observed and attributed to issues with application and miniscrew or tissue properties. Miniscrew designs are of great importance for primary stability.[8]

Miniscrews made of titanium or stainless steel are available in many designs and sizes. The implant industry makes its production decisions after considering many factors in terms of design, such as length, thread dimensions and shapes, pitch width and depth, outer-inner diameter, neck length, shape, and tip and head design.[9,10] Studies have assessed miniscrews from a range of perspectives. The finite element method has been used to calculate stress distribution, deformation, and strain.[11]

In previous studies, Finite Element Analysis (FEA) of the miniscrew was generally performed by simplifying the bone structure. The cortical and cancellous bone structure was designed as a cube, a miniscrew was inserted, and different properties were compared. Ye et al. [12] investigated the thread depth and thread pitch of miniscrews on a bone block, simulating seven different models by changing the thread depth and pitch. In another comprehensive study, the properties of miniscrews placed in the bone block, including cortex thickness, force direction, and size, length, and diameter of the miniscrew, were analyzed.[13] In 2014, Perillo et al.[14] compared the insertion angle and the forces applied to the miniscrew head on the bone block. Although there is FEA research evaluating the different properties of miniscrews, the comparison of miniscrew head designs remains unclear. Therefore, in this study, different head designs on the bone block were created in accordance with the original dimensions and compared using FEA.

METHODS

Miniscrew models and bone blocks were created using SolidWorks (v.2016, SolidWorks Corp., Waltham, MA, USA). Five different miniscrew head designs-cross head, mushroom head, button head, bracket head, and through-hole or circle head-were drawn in their actual dimensions (see Figure 1[15-17]). All miniscrew models were cylindrical, with dimensions of 8 mm in length and 1.6 mm in length and diameter, respectively. To simplify the model, threads were not added to the screws. The bone block was formed from two parts, representing the cortical and cancellous structures. The problem was simplified by reconstructing the bone block as a rectangular in dimension of 20x20x2 (WxDxH) for cortical bone and 20x20x13 (WxDxH) for cancellous bone.[13] Miniscrews were placed in the middle of the block at a 90° angle. The miniscrew cavity on the bone block was created by assembling the miniscrew models and bone blocks. The SolidWorks simulation tool was used to perform the static analysis. The contact between the screw and the cortical and cancellous bones was defined as fully bonded.[18] All materials were assumed to be linearly elastic, homogeneous, and isotropic.[13] The material properties are shown in Table 1 and are assigned to the respective models.[19-21] Mesh convergence analysis was performed, and the optimum mesh size was determined to be 0.5 mm (Figure 1h).

As boundary conditions, fixed supports were determined in the bone block from all directions except the upper surface (Figure 1g). To create orthodontic force, a horizontal force of 2 N (≈200 gf) was applied to the head of the miniscrew, according to the literature.[19] After determining the boundary conditions, the von Mises stress, equivalent strain, and total deformation were calculated using the simulation tool for each model. The Von Mises value is a calculation method used to determine whether the model has undergone plastic deformation or fracture under any loading condition. This value, which is generally used for isotropic and ductile metal materials, is the most crucial parameter to consider in designs.[22] Strain is a type of deformation that shows the dimensional or shape change that occurs due to the force applied to the object. The deformation of an object under the influence of internal and external forces or a change from its original shape is called total deformation.[23]

RESULTS

The values calculated from the analysis of the miniscrews are shown in Table 2. The highest stress was observed in the button

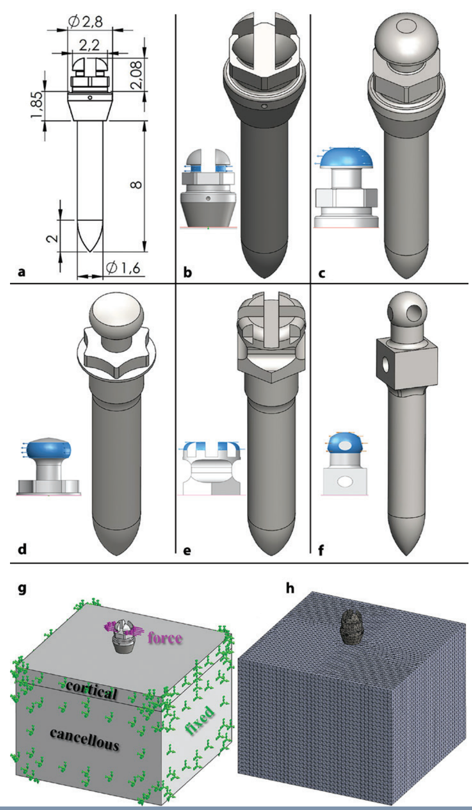

Figure 1. Drawing and FEA properties; **a)** Miniscrew dimensions, **b)** Cross head, **c)** Mushroom head, **d)** Button head, **e)** Bracket head, **f)** Through-hole head, **g)** Definition of boundary conditions, **h)** Meshing

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head miniscrew, whereas the lowest stress was observed in the bracket head miniscrew. The cross head and mushroom head results were similar; however, the through-hole head type had slightly less stress. The stress distributions of the miniscrews are shown in Figure 2. In the cross head and through-hole head miniscrews, stress was distributed to the thread parts, whereas stress occurred mainly on the collar and head parts in the mushroom head, button head, and bracket head. The highest stress values in the mushroom and button heads were observed in the neck region, while the highest stress in the bracket head occurred in the head region.

The stress distribution in the bone block, with the miniscrew hidden is shown in Figure 3. It was observed that more stress occurred on the bone block with the button head compared with the other models. In all models, stress was induced in the upper 2 cm of the bone block, and the highest stress was at the top surface and the intersection with the miniscrew. The maximum von Mises stresses on the bone block were calculated as 4.25 MPa for the cross head, 2.47 MPa for the mushroom head, 3.99 MPa for the button head, 2.49 MPa for the bracket head, and 5.80 MPa for the through-hole head. Deformed models are shown in Figure 4 with a scale factor of approximately 1500. The highest displacement was calculated for the through-hole head, while the lowest was observed for the bracket head. There was little difference between the button head and mushroom head miniscrews according to total deformation. The lowest strain was observed in the bracket head, as with the total deformation. On the other hand, the highest strain was calculated in the cross head miniscrew. In the button head and through-hole head, strain values were determined to be almost the same. The strain results of the models are shown in Figure 5. Mesh convergence analysis was performed by changing the mesh size from 2 mm to 0.5 mm. The results of the mesh convergence analysis for the mushroom head miniscrew are shown in Figure 6. All analyses took less than a minute because the model converged without exceeding the 0.5-mm mesh size and a powerful workstation computer was used. Accordingly, with approximately 239 thousand elements in the 0.5-mm mesh size, the allowable change was decreased below 5%, and iteration was stopped. In addition, because of the analysis performed on all models, there were approximately 230,000 elements in the 0.5 mm mesh size. The node and element numbers of all models are shown in Table 2.

DISCUSSION

Stress distributions were concentrated on the miniscrew shanks in cross-head and through-head designs, likely due to the different collar designs. It was concluded that collar and neck designs are essential, and their differences directly affect the results. For example, in the button design, the highest stress was observed at the neck due to the smaller diameter design. Therefore, it was determined that there is an inverse relationship between the diameter of the neck and von Mises stress. The lowest neck diameter was 1 mm for the button head, 1.3 mm for the mushroom head, 2.2 mm for the cross head, 2.83 mm for the through-hole head, and 2.6 mm for the bracket. One of the reasons why the bracket design has lower stress than the others is its high neck diameter, and the other is the hexagonal collar design. In addition, the results of von Mises stress in the cross head, mushroom head, and button head, which have a cylindrical neck design, are higher than those of the through-hole, which is the cube design, and the bracket, which is the hexagonal design. Furthermore, although the cross head and bracket head designs are close to each other, the hexagonal neck design reduces the stress value. In the bracket head design, the stress distribution was spread to the miniscrew head and could not extend to the miniscrew tip. In this design, the lowest von Mises stress was calculated as 2.49 MPa in the bone block. Another design with a low von Mises stress value in the bone block is the mushroom head with a stress of 2.47 MPa.

Table 1. Material properties

Models	Miniscrew	Cortical bone	Cancellous bone
Elastic modulus (MPa)	114000	14700	1500
Poisson's ratio	0.34	0.3	0.3

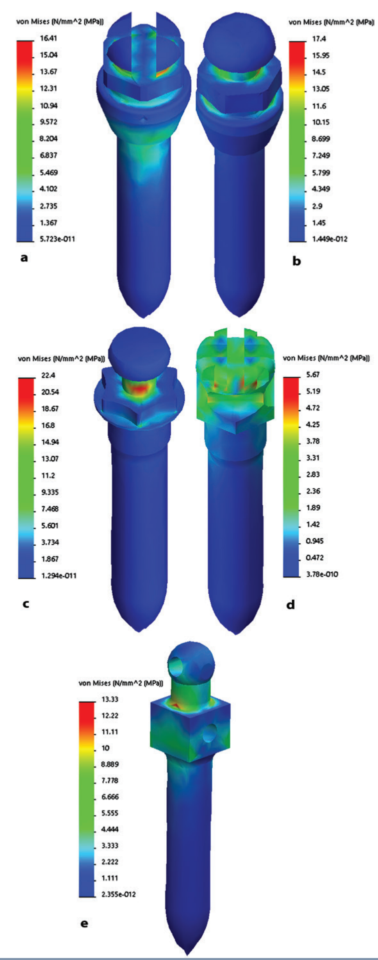

Figure 2. Stress distributions of miniscrew head types isolated from bone block; **a)** Cross head, **b)** Mushroom head, **c)** Button head, **d)** Bracket head, **e)** Through-hole head

The neck and collar parts have the highest design with a total length of 4.75 mm, preventing the spread of stress to the miniscrew tip. The second-highest length after the mushroom head is the bracket head, with 4.07 mm. In these two designs, the total length of the neck and collar is higher than that of the others, intensifying the stress on the miniscrew head. Furthermore, in cross and bracket head designs, the load is distributed evenly on the surfaces by dividing it into four.

However, the effect of this parameter on stress was limited because both stress values were quite far from each other. On the other hand, the load is applied along a cylindrical surface in other head designs. In these models, the results are close to each other, but because many variables differ, it cannot be concluded that only this parameter affects stress.

However, the applied force to different surfaces caused a change in the region where the stress is concentrated; as a result, the stress in the cross and bracket head designs was concentrated at the corner points and finer trims, which may cause the cross and bracket head designs to become more fragile. Another critical parameter is the distance between the applied load and the bone surface. These distances are 2.81 mm for the cross head, 2.6 mm for the mushroom head, 1.5 mm for the button head, 1.81 mm for the bracket head, and 2.15 mm for the through-hole head. On the other hand, according to Table 2, the order of maximum stress values is from largest to smallest as follows; button head, mushroom head, cross head, through-hole head, and bracket head. Although the button head had the lowest distance, it produced the highest stress. Conversely, the cross head had the highest distance, and the average stress value was calculated. Therefore, it cannot be assumed that there is a linear or inverse relationship between the distance of the applied load to the bone surface and the stress results. However, this variable demonstrated that it affected the analysis results.

It started with approximately 20,000 elements in all models and ended with approximately 230,000 elements. These values are high compared to those of other studies and increase the computational time.[19] However, a small element size is necessary to converge the results and to reduce the effect of the mesh size change to less than 5%. When the mesh convergence analysis was completed, von Mises stresses similar to those in previous studies were confirmed. For example, Liu et al.[13] calculated von

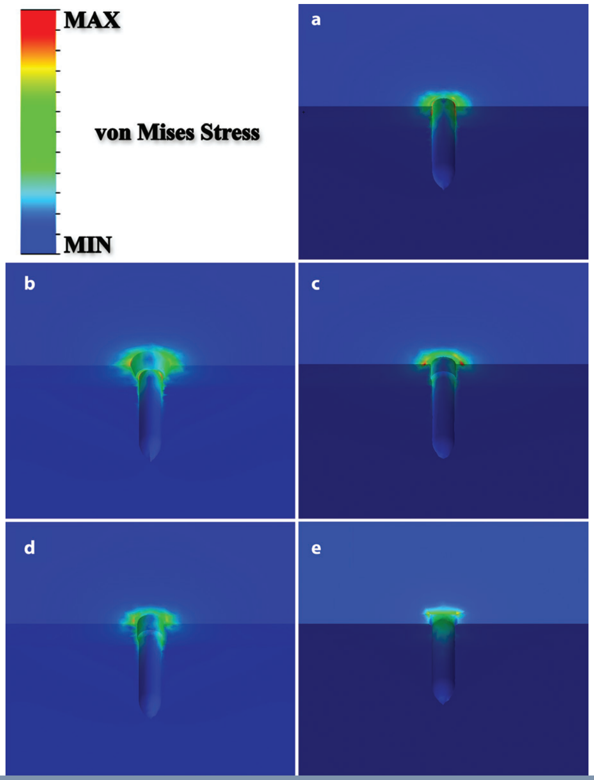

Figure 3. Von Mises stress distributions of the miniscrew cavity; **a)** Cross head, **b)** Mushroom head, **c)** Button head, d) Bracket head, **e)** Through-hole head

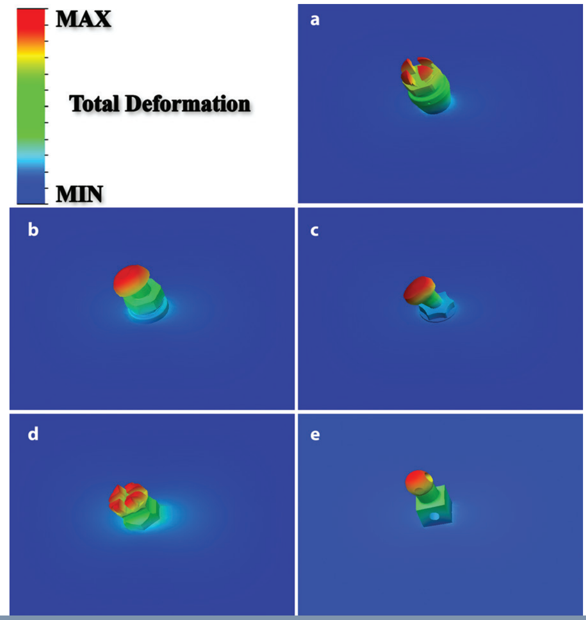

Figure 4. Total deformations of miniscrew head types; **a)** Cross head, **b)** Mushroom head, **c)** Button head, **d)** Bracket head, **e)** Through-hole head

Table 2. Analysis results and mesh details for each model

Miniscrew head designs	Cross	Mushroom	Button	Bracket	Through-hole
Von mises stress (MPa)	16.41	17.40	22.40	5.67	13.66
Total deformation (mm)	1.02E-03	7.80E-04	8.03E-04	4.26E-04	1.23E-03
Strain	1.66E-04	1.36E-04	1.45E-04	9.87E-05	1.45E-04
Total nodes	327361	334906	332820	331841	317955
Total elements	233030	238958	237563	236811	226359

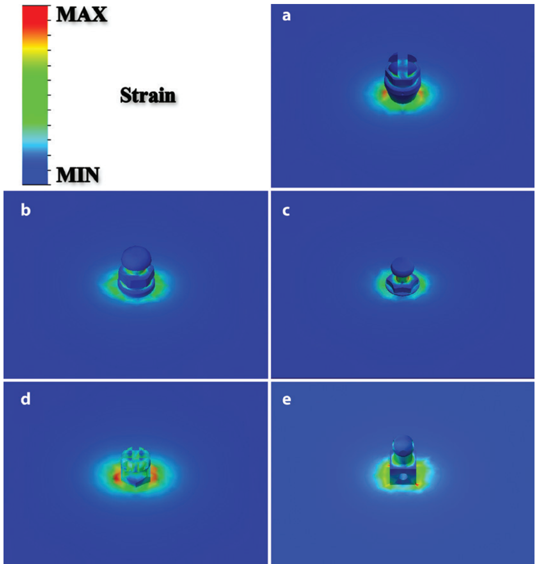

Figure 5. Equivalent strain results of miniscrew head types; **a)** Cross head, b**)** Mushroom head, **c)** Button head, **d)** Bracket head, **e)** Through-hole head

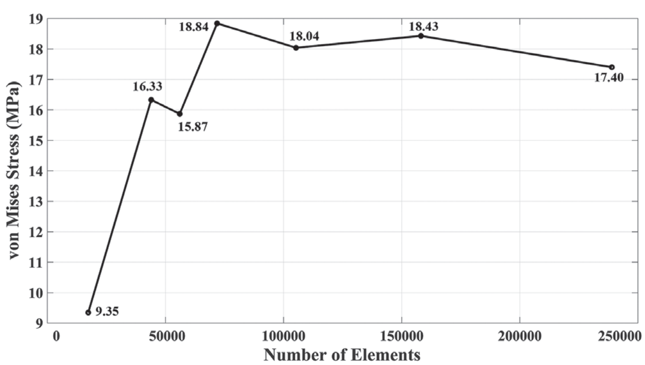

Figure 6. Mesh convergence analysis result for von Mises stress

Mises stress as approximately 15 MPa by applying a 2 N force to the miniscrew head at a 90º insertion angle. This value is almost the same as the stress value obtained from our cross-head, mushroom-head, and through-hole head designs. Similarly, while they calculated the total deformation as 3 µm, our study determined approximately 1 µm of total deformation in the cross-head and through-hole head designs.

In the study of Perillo et al.,[14] von Mises stress was calculated as 5.6 MPa in the bone block when they inserted the miniscrew perpendicularly and applied a 2 N force to the miniscrew head at a force direction of 0º. Our simulation calculated the highest von Mises stress value observed in the bone block as 5.8 MPa. Although the FEA software used in both studies differed, very similar results were observed. In a study by Ye et al.[12] comparing thread properties, the von Mises stresses were between 9 and 20 MPa with designs similar to our cross head design. Correspondingly, in our study, the von Mises stress value was 16.41 MPa in the cross head. Overall, the results of our study are very confirmatory for the validation stage of our models, as we obtained results close to those of previous studies.

Study Limitations

There are some limitations to this study. First, the bone structure is not homogeneous and has anisotropic properties that vary throughout. Solving such a complex problem is tricky and requires more running time in FEA. In addition, computed tomography scans of the maxilla or mandible are required to determine the material properties with image processing. Therefore, the bone structure was simplified by using a bone block with defined cortical and cancellous material properties. Although the cortical thickness varies in the literature, it was averaged at 2 mm.[13] The effect of bone density on the results is not the focus of this study. In addition, this is not a disadvantage because the same bone block is used in all models. Another limitation is that the thread design was not included in the models to avoid problems in the contact regions and ensure mesh convergence. Because contact meshes in the cavity of the bone block with the miniscrew threads are sometimes not detected, the analysis cannot be performed. This omission does not cause a disadvantage because other dimensions remained consistent across all models, except for the head designs. This study did not investigate the effects of insertion angle, miniscrew dimensions, force direction, and bone properties constant, as these parameters are well-studied in the existing literature. Instead, the focus was on comparing different miniscrew head designs available in the market without modifying their original dimensions and shapes. Future studies could benefit from investigating each of these parameters in detail to develop more stable miniscrews.

CONCLUSION

As a result of the analysis, the lowest stress was obtained in the bracket head, while the highest stress was calculated in the button head. Stress occurred mainly in the collar and head parts in the mushroom head, button head, and bracket head. Consequently, it is concluded that bracket head designs will increase the success ratio in miniscrew treatments. This study was limited to five different miniscrew head designs. In future studies, it is desired to include different head designs and make the model more complex.

Ethics

Ethics Committee Approval: The ethics committee of İzmir Katip Çelebi University decided that this study did not require ethical approval (approval no.: 0488, date: November 18, 2021).

Informed Consent: Not applicable.

Author Contributions: Concept - S.Ç., G.G.K.; Design - S.Ç.; Supervision - Y.İ.; Data Collection and/or Processing - S.Ç., G.G.K.; Analysis and/or Interpretation - S.Ç., G.G.K.; Literature Review - S.Ç., G.G.K.; Writing - S.Ç., G.G.K., Y.İ.

Declaration of Interests: All authors declare that they have no conflict of interest.

Funding: This study was supported by İzmir Katip Çelebi University Scientific Research Council Agency as project number 2023-TDR-FEBE-0005 for Samet Ciklacandir's doctoral thesis studies.

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TURKISH JOURNAL OF
ORTHODONTICS

DOI: 10.4274/TurkJOrthod.2023.2023.14

Original Article

Assessment of Bone Thickness at the Infra Zygomatic Crest Region for Various Orthodontic Miniscrew Implant (OMSI) Insertion Angles: A Cone-Beam Computed Tomographic Study

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Cite this article as: Sharan J, Bajoria A, Jena AK, Sinha P, Shivakumar A, Kamal VK, Marya A. Assessment of Bone Thickness at the Infra Zygomatic Crest Region for Various Orthodontic Miniscrew Implant (OMSI) Insertion Angles: A Cone-Beam Computed Tomographic Study. *Turk J Orthod.* 2024; 37(2): 104-111

Main Points

- Cone-beam computed tomography assessment provided an optimal clinical parameter for safe placement of the miniscrew at the infrazygomatic crest (IZC) bone.
- The bone thickness of the IZC ranged from 4.39 mm to 9 mm along the distobuccal root of the permanent first molar
- Adequate bone thickness (6 mm to 9 mm) at the IZC was found with a probable miniscrew insertion angle of 55°-75°.
- The best possible position for orthodontic miniscrew implantation was 13.69-16 mm from the maxillary occlusal plane along the distobuccal root of the permanent first molar.

ABSTRACT

Objective: To evaluate the infrazygomatic crest (IZC) bone and develop guidelines for the optimum placement of orthodontic miniscrew implants (OMSIs) along the distobuccal root of the permanent maxillary first molar.

Methods: Bone thickness of the IZC region of 50 young adults (25 males and 25 females) aged 18-30 years were evaluated using cone-beam computed tomography images. The infrazygomatic bone thickness along the distobuccal root of the permanent maxillary first molar was assessed at various insertion angles (40° to 75° i.r.t the maxillary occlusal plane) with an increment of 5°. Student's t-test was used to compare the IZC bone thickness and height at the orthodontic miniscrew insertion site for males and females on the right and left sides.

Results: The bone thickness of the IZC region above the distobuccal root of the permanent maxillary first molar was estimated between 4.39±0.25 mm and 9.03±0.45 mm for insertion angles from 40° to 75° to the maxillary occlusal plane. The corresponding OMSI insertion heights were 17.71±0.61 mm to 13.69±0.75 mm, respectively, above the maxillary occlusal plane. There were statistically significant gender and side-wise variations in bone thickness at the IZC area and insertion height.

Conclusion: The safe position for OMSI placement at the IZC was 13.69-16 mm from the maxillary occlusal plane with an insertion angle between 55° and 75°. These parameters provide the optimum placement of OMSIs along the distobuccal root of the permanent maxillary first molar.

Keywords: Bone thickness, cone-beam computed tomography, infrazygomatic crest, orthodontic miniscrew implant

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Received: February 03, 2023 **Accepted:** July 28, 2023 **Publication Date:** June 30, 2024

INTRODUCTION

Maintaining anchorage has always been a key component of the success of comprehensive orthodontic treatment.[1] Orthodontic miniscrew implants (OMSIs) are considered effective anchorage support in the orthodontic armamentarium.[2,3] Several advantageous aspects of OMSIs, such as their small size, relatively uncomplicated surgical procedure, ease of placement, patient cooperation, possibility of immediate loading, and availability of multiple sites in the maxilla and mandible, have made them a promising tool in orthodontics.[4-9] In routine orthodontic practice, inter-radicular sites are used for OMSI placement, but their placement requires careful evaluation due to limited inter-radicular bone width.[10] This increases the risk of root injury when OMSI is placed in the inter-radicular area.[11-13] In addition, it has been observed that OMSI in the inter-radicular area can limit the extent of orthodontic tooth movement, whereas this is not the case with extra-radicular placement.[14] This has led clinicians to consider other favorable alternative OMSI placement sites, such as the infrazygomatic crest (IZC), mandibular buccal shelf, and hard palate.

The IZC of the maxilla is one of the most commonly used extraradicular sites for OMSI placement. It is also considered as an anatomically reinforced bone, with the cortical bone layer thickening along the maxilla from the zygoma to the molar.[15,16] The advantage of using IZC is that it is distant from the roots and has a higher bone density than the interradicular region. This could be a critical factor in the primary stability of OMSI. For various orthodontic tooth movements, such as en-masse retraction of anterior teeth, retraction of canines, group distalization of maxillary molars, and intrusion of the maxilla teeth, the OMSI at the IZC serves as absolute anchorage support.[15]

IZC consists of the cortical bone at the zygomatic process of the maxilla. It is a bony structure that appears as a ridge and is located between the zygomatic process of the maxilla and the alveolar ridge. The apex of the mesial root of the maxillary permanent first molar normally bounded the zygomatic crest distally and inferiorly, while the medial portion of the maxillary sinus and the protruding zygomatic process bounded it superiorly (Figure 1).[16,17] The height and thickness of the IZC vary with age, i.e., in young patients, the maximum thickness of the IZC is located between the maxillary deciduous second molar and permanent first molar; while in adult patients, it is located above the permanent maxillary first molar.[18] The primary stability of OMSI is essential for its success, which depends on bone thickness. Therefore, proper positioning of the OMSI at the appropriate IZC area is crucial. Earlier studies on the subject reported safe placement of IZC screw bilaterally at approximately 11 mm from the maxillary alveolar crest

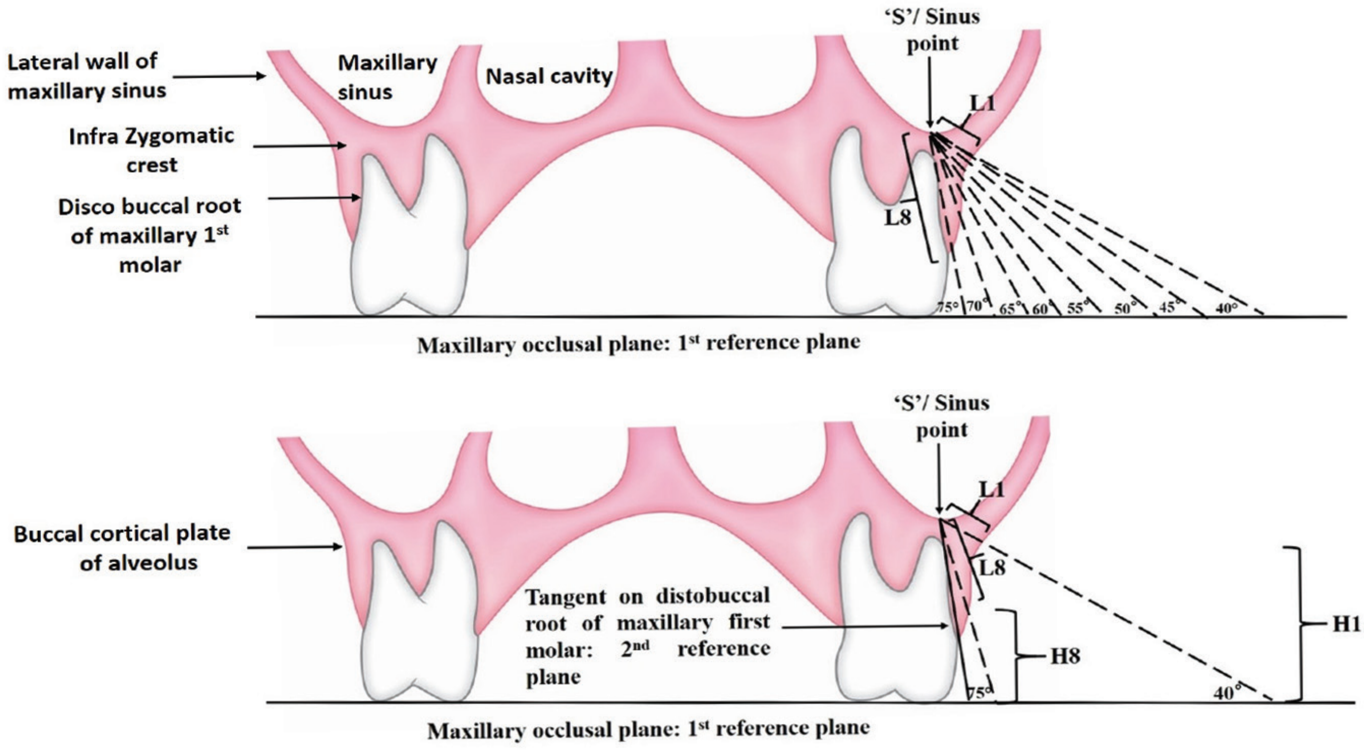

Figure 1. Illustration of the infra zygomatic crest region and reference planes used for the linear measurements
(H: Vertical height of the OMSI insertion from the maxillary occlusal plane at insertion angle, i.e., H1 at 40 40°; H2 at 45°, H3 at 50°, H4 at 55°, H5 at 60°, H6 at 65°, H7 at 70°, and H8 at 75°. L: IZC bone thickness for OMSI insertion angle at various angulation, i.e., L1 at 40 40°; L2 at 45°, L3 at 50°, L4 at 55°, L5 at 60°, L6 at 65°, L7 at 70°, and L8 at 75°)
OMSI, orthodontic miniscrew implant

between the first and second molars.[19] In another investigation, Song et al.[20] concluded that the optimal insertion heights and angles were 12-18 mm from the occlusal plane and 40-70°, respectively, for mini-implant placement in the IZC. The dimension of the OMSI routinely used in the IZC region was in the range of 10-14 mm in length 10-14 mm long, and had a minimum diameter of 2 mm.[20] Most studies have used the mesiobuccal root of the maxillary permanent first molar as a reference plane to assess an accurate site for the placement of OMSI.[16,21] However, the morphological variations of the mesiobuccal root of the permanent maxillary first molar are greater than those of the distobuccal root.[22]

Therefore, the aim of the present study was to evaluate bone thickness in the IZC area using cone beam computed tomography images and develop a guideline for the optimum placement of OMSIs along the distobuccal root of the permanent maxillary first molar. The hypotheses were as follows: 1) the IZC bone thickness increases with an increase in the probable angle of insertion and the height of insertion in relation to the maxillary occlusal plane, and 2) the IZC bone thickness is greater in males than in females.

METHODS

The current cross-sectional study was based on pre-orthodontic cone-beam computed tomography (CBCT) scans of patients who presented to the department for orthodontics. This study was approved by the Institutional Ethics Committee of the All India Institute of Medical Sciences, Bhubaneswar (T/IM-NF/Dentistry/120/137). A sample size of 33 was calculated on the basis of a significance level of α of 0.01, a power of 80%, and an effective size of 0.85, as considered in previous studies.[23-25]

The initial sample selection included CBCT scans with limited field of view from 114 patients aged 18-30 years. These scans were obtained from the archives of the Unit of Orthodontics and Dentofacial Orthopedics, Department of Dentistry, All India Institute of Medical Sciences, Bhubaneswar. All CBCT images were acquired using a NewTom scanner (NewTom, Imola, Italy) with an operating voltage potential of 80 kV, a constant voltage wave shape of 4-8 mA, an irradiation time of 13 s, and a field of view of 11 cm, 13 cm.

The inclusion criteria included CBCT scans of subjects aged 18 years with a full complement of teeth and no previous orthodontic and/or orthognathic surgical treatment. The exclusion criteria included CBCT scans with a substandard visible IZC region and those from subjects with pathological conditions including facial trauma, congenital anomalies and syndromes, and bone pathologic conditions. A total of 64 CBCT scans were excluded, and the final sample consisted of CBCT scans from 50 orthodontic patients (25 males and 25 females) with a mean age of 21.58±2.59 years. All measurements on the CBCT images were performed according to the recommendations of Liou et al.[16]. The thickness of the bone at the IZC was measured along the distobuccal root tip of the permanent maxillary first molar. CBCT images with visible IZC bone thickness, distobuccal root tip, and permanent maxillary first molar surface were selected and oriented in all CBCT sections. Multiplanar reformatting of the obtained data and the region of interest were measured using NewTom NNT analysis software. After orienting the CBCT images as suggested by Azevedo et al.,[26] two reference planes were constructed. The first reference plane was constructed horizontally, connecting the mesiobuccal cusps of the permanent maxillary first molars on the left and right sides. This is referred to as the maxillary occlusal plane (Figure 1). At the same time, a second reference plane was constructed by drawing a tangent to the buccal surface of the first molar's distobuccal root. This second plane touched the floor of the maxillary sinus at the sinus point, or "S" point (Figure 1).

From the "S" point, incremental planes were drawn with incremental angulations of 5° between 40° and 75° on the maxillary occlusal plane (Figures 1 and 2). The thickness of the IZC bone, i.e. ,"L" for each incremental plane, was defined as the distance between the plane contacting the IZC bone and the S point. Therefore, 8 IZC bone thicknesses (i.e., L1 to L8) were derived for all subjects for probable insertion angles ranging from 40° to 75°. In addition, the height from the first reference plane (i.e., maxillary occlusal plane) to the probable insertion site at different insertion angles (i.e., 40° to 75°) was plotted on the CBCT images. These heights were derived by drawing a perpendicular line from the probable insertion points on the IZC bone (i.e., 40° to 75°) to the maxillary occlusal plane. Thus, a total of eight vertical heights (H1 to H8) were derived for each insertion angle.

Statistical Analysis

STATA software (StateCorp LLC, Texas, USA) version 20.0 for the window was used for all data analysis. Sidewise (right vs left) OMSI insertion site bone thickness (in mm) and OMSI insertion site bone height from the maxillary occlusal plane at various angulations were statistically computed using descriptive statistics. The normality of a continuous variable was examined using the Shapiro-Wilk test. Student's t-test was used to compare the IZC thickness (L1 to L8) and height (H1 to H8) at OMSI insertion sites for males and females on the right and left sides. A p-value of <0.05 was considered as the level of significance.

RESULTS

The thickness of the bone at the IZC varied at different insertion sites for OMSI. It was observed that the greater the angle of insertion of the OMSI, the thicker the IZC bone was (Figures 1 and 2). The No statistically significant differences were observed between the right and left sides in terms of IZC bone thickness at different OMSI insertion angles (Table 1). However, the IZC bone thickness on the right side at OMSI insertion angles of 40°, 45°, 50°, 55°, 60°, and 75° (i.e., L1, L2, L3, L4, L5, and L8) was statistically significant in both male and female subjects

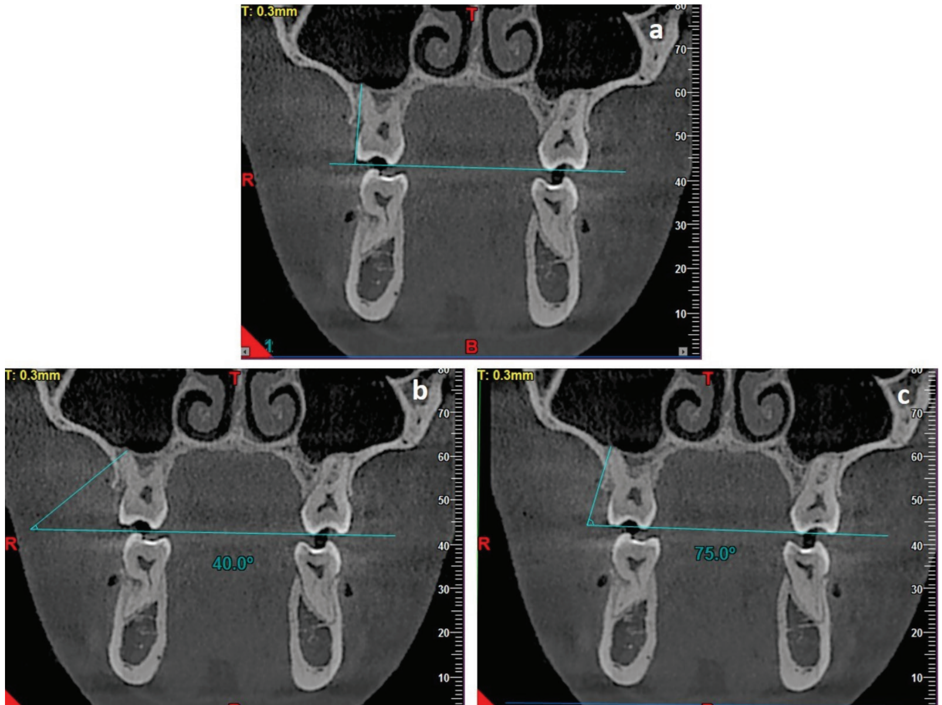

Figure 2. Multi-planar reconstructed CBCT images depicting the coronal sections of 0.3 mm thickness with reference plane contacting the mesio-buccal cusps of maxillary first molars. **a)** The orientation of the CBCT images according to the predefined reference planes for analyzing different linear measurements. **b)** the linear measurement of the infra zygomatic crest at 40 degrees from the reference plane. **c)** the linear measurement of the infra zygomatic crest at 75 degrees from the reference plane

CBCT, cone-beam computed tomography

Table 1. Comparison of OMSI insertion site bone thickness (in mm) at various angulations among males and females at the IZC region

IZC bone thickness at OMSI insertion angulations	Male		Female		Comparison (p-value)			
	Right side (MRTT) Mean±SD (n=25)	Left side (MLTT) Mean±SD (n=25)	Right side (FRTT) Mean±SD (n=25)	Left side (FLTT) Mean±SD (n=25)	MRTT vs. MLTT	FRTT vs. FLTT	MRTT vs. FRTT	MLTT vs. FLTT
40° (L1)	4.46±0.26	4.41±0.28	4.29±0.28	4.40±0.25	0.563	0.106	0.017*	0.531
45° (L2)	5.11±0.39	5.04±0.45	4.70±0.32	4.76±0.49	0.571	0.588	0.002**	0.982
50° (L3)	5.48±0.35	5.58±0.46	5.18±0.26	5.12±2.08	0.373	0.472	0.001**	0.763
55° (L4)	5.83±0.37	5.85±0.33	5.38±0.28	5.36±0.28	0.811	0.763	0.001**	0.861
60° (L5)	6.26±0.43	6.28±0.39	5.84±0.23	5.86±0.32	0.801	0.879	0.001**	0.806
65° (L6)	6.63±0.34	6.52±0.32	6.68±0.42	6.57±0.38	0.279	0.364	0.663	0.159
70° (L7)	7.83±0.39	7.88±0.33	7.79±0.26	7.76±0.32	0.617	0.700	0.644	0.880
75° (L8)	9.16±0.37	9.29±0.41	8.84±0.41	8.82±0.41	0.249	0.811	0.005**	0.577

*p<0.05, **p<0.01

MRTT, male right side thickness (in mm); MLTT, male left side thickness (in mm); FRTT, female right side thickness (in mm); FLTT, female left side thickness (in mm), OMSI, orthodontic miniscrew implant; IZC, infrazygomatic crest; SD, standard deviation

(Table 1).

The sidewise comparison (i.e. right vs. left) for all subjects regardless of gender revealed no statistically significant difference in the IZC bone thickness at different insertion angles (Table 2). The IZC bone thicknesses on the right and left sides were combined for all subjects, and the mean thickness was derived (Table 2). The mean bone thickness of the combined sample (i.e., right + left) ranged from 4.39±0.25 mm (L1) to 9.03±0.45 mm (L8) for OMSI insertion angles from 40° to 75°. The combined mean IZC bone thickness of the subjects was close to or above 6 mm at insertion angles of 55°-75°, i.e., L4-L8 (Table 2).

The height of OMSI placement from the maxillary occlusal plane (first reference plane) at different insertion angles showed remarkable variations (Figure 1). However, a general trend was observed for the placement height and OMSI insertion angle, i.e., the placement height decreased with increasing OMSI insertion angle (Table 3). A statistically significant difference ($p<0.05$) in insertion height was observed for the right and left sides of the male subjects at insertion angles of 60° (H5) and 70° (H7). Further comparison between the female right-side insertion height and the female left-side insertion height revealed that the difference in the mean insertion height was statistically significant at insertion angles of 50°, 65°, and 70°, i.e., H3, H6, and H8, respectively (Table 3). Similarly, a trend was observed for right-side height in males and right-side height in females at insertion angles of 40°, 60°, and 75° (Table 3).

Overall, sidewise comparisons (right vs. left) for OMSI insertion height for male and female subjects revealed a statistically significant difference when the male subjects' right side was compared with the female subjects' right side at insertion angles of 40°, 60°, 70°, and 75°, i.e., H1, H5, H7, and H8 (Table 3). A similar trend was observed when the height of the left side of male subjects was compared with the height of the left side of female subjects (Table 3). A sidewise comparison (right vs. left) was performed for all subjects for the insertion heights at different OMSI insertion angles. The insertion height was statistically significant at OMSI insertion angles of 50° and 70°, i.e., H3 and H7, respectively (Table 4).

DISCUSSION

Our study followed the observations of Ahmed et al.[22] in selecting the second reference plane. They observed that 78% of the mesiobuccal roots of the permanent maxillary first molar had a distal curvature and 1% had an S-shaped root. In contrast, for the distobuccal root, the mesial and distal curvatures were 19% and 17%, respectively, which is much less than the mesial

Table 2. Sidewise (right vs. left) comparison of probable OMSI insertion site thickness (in mm) at various angulations among all subjects

IZC bone thickness at OMSI insertion angulations	Right side Mean±SD (n=50)	Left side Mean±SD (n=50)	p-value	Combined (Rt+Lt) thickness at IZC region Mean±SD (n=100)
40° (L1)	4.37±0.25	4.41±0.26	0.531	4.39±0.25
45° (L2)	4.91±0.41	4.90±0.49	0.982	4.91±0.45
50° (L3)	5.33±0.34	5.36±0.44	0.763	5.34±0.40
55° (L4)	5.60±0.39	5.60±0.40	0.960	5.60±0.40
60° (L5)	6.05±0.40	6.07±0.41	0.806	6.06±0.41
65° (L6)	6.65±0.38	6.55±0.35	0.159	6.60±0.41
70° (L7)	7.81±0.33	7.82±0.33	0.880	7.82±0.33
75° (L8)	9.01±0.42	9.06±0.47	0.577	9.03±0.45

OMSI, orthodontic miniscrew implant; IZC, infrazygomatic crest; SD, standard deviation

Table 3. Comparison of probable OMSI insertion site bone height (in mm) from the maxillaryocclusal plane at various angulations among males and females at the IZC region

Bone height at IZC region for OMSI insertion angles	Male		Female		Comparison (p-value)			
	Right side (MRTH) Mean±SD n=25	Left side (MLTH) Mean±SD n=25	Right side (FRTH) Mean±SD n=25	Left side (FLTH) Mean±SD n=25	MRTH Vs. MLTH	FRTH Vs. FLTH	MRTH Vs. FRTH	MLTH Vs. FLTH
40° (H1)	18.02±0.64	17.94±0.62	17.50±0.64	17.37±0.50	0.623	0.323	0.001**	0.000***
45° (H2)	17.24±0.28	17.03±0.58	16.95±0.79	16.96±0.40	0.298	0.935	0.082	0.613
50° (H3)	16.59±0.60	16.30±0.70	16.65±0.27	16.40±0.57	0.129	0.042*	0.652	0.636
55° (H4)	16.28±0.59	15.96±0.72	16.09±0.23	16.06±0.35	0.096	0.739	0.136	0.551
60° (H5)	15.88±0.55	15.28±0.51	15.51±0.31	15.49±0.37	0.024*	0.836	0.004**	0.401
65° (H6)	15.12±0.34	15.06±0.54	15.09±0.27	14.83±0.26	0.853	0.001**	0.933	0.065
70° (H7)	14.92±0.51	14.60±0.51	14.11±0.46	13.86±0.34	0.028*	0.034*	0.000***	0.000***
75° (H8)	14.38±0.51	14.16±0.53	13.17±0.39	13.04±0.44	0.148	0.267	0.000***	0.000***

*p<0.05, **p<0.01, ***p<0.001
MRTH, male right side height; MLTH, male left side height; FRTH, female right side height; FLTH, female left side height; OMSI, orthodontic miniscrew implant; IZC, infrazygomatic crest; SD, standard deviation

Table 4. Sidewise (right vs. left) comparison of probable OMSI insertion site height (in mm) from the maxillary occlusal plane at various angulations among all subjects

Bone height at IZC region for OMSI insertion angles	Right side Mean±SD (n=50)	Left side Mean±SD (n=50)	p-value	Combined (Rt+Lt) height of OMSI insertion at IZC region (n=100)
40° (H1)	17.76±0.60	17.65±0.63	0.372	17.71±0.61
45° (H2)	17.09±0.56	16.99±0.50	0.378	17.04±0.53
50° (H3)	16.22±0.46	16.34±0.65	0.016*	16.28±0.56
55° (H4)	16.18±0.45	16.01±0.56	0.096	16.10±0.52
60° (H5)	15.70±0.48	15.39±0.87	0.300	15.54±0.71
65° (H6)	15.10±0.54	14.95±0.44	0.307	15.03±0.71
70° (H7)	14.51±0.63	14.23±0.57	0.020*	14.37±0.62
75° (H8)	13.77±0.76	13.60±0.74	0.248	13.69±0.75

*p<0.05
OMSI, orthodontic miniscrew implant; IZC, infrazygomatic crest; SD, standard deviation

root curvature. The curvature of the root tip causes problems when drawing the tangent along the root surfaces because the root tip is oriented in one plane and the tangent at the root surface is oriented in another plane. Previous studies have used the mesiobuccal root of the permanent maxillary first molar to construct the second reference plane.[16,21] More recent studies are optimistic about using the distobuccal root of the permanent maxillary first molar to avoid errors in drawing the tangent along its surface compared with the mesiobuccal root.[25,27]

The present study revealed a variation in IZC bone thickness from 4.39 mm to 9.03 mm with a proposed OMSI insertion angle of 40° to 75° in relation to the maxillary occlusal plane. The corresponding OMSI insertion heights ranged from 17.71 to 13.69 mm above the maxillary occlusal plane (i.e., the first reference plane). Our findings were consistent with the results of the studies of Liou et al.[16] and Baumgaertel et al.[21], who pointed out that anatomically, the IZC has two cortical plates (i.e., a vestibular and a lateral wall of the maxillary sinus). This works in favor of the IZC because it allows bicortical engagement of the OMSI, thus enhancing primary stability.[16,28] The greater thickness of the IZC allows better contact between the OMSI and bone, which enhances the primary stability of the OMSI.

Many previous studies have shown ethnic differences in bone thickness, which could be of great importance in selecting the appropriate dimensions (length and thickness) of OMSI for a particular patient.[16,18,27] The proposed OMSI insertion angle and position of 40° is technically simpler and reduces the incidence of OMSI slippage and root injury.[16,21] However, this angulation and position could result in a lower OMSI-bone contact depth and may carry a higher risk of alveolar/buccal mucosa irritation. On the other hand, the proposed OMSI insertion angle and position at 75° is technically challenging because of the actual insertion angle between the OMSI and the IZC.[16,21] This position poses a higher risk of slippage of the OMSI and bone stripping. In addition, at this insertion angle, a slight deviation in the insertion of the OMSI could increase the risk of root injury. Another complication of high OMSI insertion angles is the emergence of its thread after placement in the IZC region in the alveolar mucosa. This could result in soft tissue inflammation, overgrowth, and, in rare cases, infection around the OMSI. Studies have shown that these problems can be prevented and minimized if OMSI is placed at the keratinized gingiva or at the mucogingival junction.[2,29-32]

This study demonstrated that the proposed angle of insertion should be greater than 55°. The insertion height should be less than 15.59 mm above the occlusal plane; so that the OMSI-bone contact will be maintained at a thickness of not less than 6 mm. This finding is in agreement with Baumgaertel and Hans[21] who pointed out that insertion of an OMSI of 6 mm or more in the IZC region has a higher probability of penetrating the Schneiderian membrane lining.[19] In addition, several researchers have observed that a 6-mm OMSI bone contact is sufficient for the OMSI to be stable during orthodontic loading in adult patients.[33,34]

Optimal angulation and position of the OMSI in the IZC region are critical for minimizing damage or perforation of the maxillary sinus.[35,36] Anatomical variations, such as the reverse fold and the presence of septa, must be considered and checked along with bone thickness before placing the OMSI.[37] The best site for OMSI insertion was 14.50-16 mm in relation to the probable insertion angle of 55°-75° with reference to the maxillary occlusal plane along the distobuccal root surface of the permanent maxillary first molar. Similar observations were reported by Song et al.[20] They concluded that the optimal insertion heights and angles were 12-18 mm from the occlusal plane and 40-70°, respectively, for mini-implant placement in the IZC in relation to the distal root of 1st permanent maxillary molar.

The dimension of the OMSI routinely used in the IZC region is 10-14 mm long and has a minimum diameter of 2 mm. The present study demonstrated that OMSI with the above dimensions could be used safely, and the likelihood of damage or perforation of the maxillary sinus is very low. In addition, our study found that the optimal OMSI insertion zone in the IZC region was 16.10-13.69 mm above the maxillary occlusal with an insertion angle of 55°-75°. Our findings are in agreement with Tavares et al. observation, who believed that the best bone availability between 1st and 2nd maxillaries is seen between 1st and 2nd molars in the IZC for inserting the extra-alveolar bone miniscrew at a distance of 4 mm from the CEJ at an insertion angle of 60° for all individuals.[37] Arango et al.[38] reported a similar observation and pointed out that the IZC bone thickness distal to the maxillary permanent first molar was larger at 55°, 65°, and 70° in men. Recently, Wilmes et al.[39] used a novel CAD-CAM fabricated approach for positioning the OMSI on the palatal aspect. This approach facilitates precise and safe positioning and insertion of the OMSI. A similar approach can be considered and used for the predictable placement of OMSI in the IZC region. The hypotheses proposed in this study appear to be relevant and true. Furthermore, the parameters of our study provide good guidelines to clinicians for the safe placement of OMSI in the IZC region. The final positioning of the OMSI depends on the clinical judgment of the orthodontist, who consider certain anatomic variations in some individuals.

Study Limitations

The limitation associated with our study is the morphological variations in the roots of the maxillary first permanent molar. The data should be used with caution, in cases where the distobuccal root exhibits anatomic variation. Clinical judgment for placement of OMSI should be based on the extent of anatomic variation of the distobuccal root and adjacent structures.

CONCLUSION

• The thickness of the IZC bone ranged from 4.39 mm to 9.0 mm at a probable insertion angle of 40° to 75°, which corresponded to a height of 13.60 mm to 17.65 mm in relation to the maxillary occlusal plane along the distobuccal root surface of the permanent maxillary first molar.

• From OMSI insertion angles of 55° to 75°, bone thickness in the IZC region corresponded to 6 and 9 mm. Furthermore, the same corresponds to an insertion height of 16-14.50 mm from the maxillary occlusal plane.

• There was no statistically significant change in IZC bone thickness between males and females.

• CAD-CAM technology could be facilitated to improve the safe placement of IZC implants.

Acknowledgment

The authors would like to acknowledge Dr. Abhishek Gosh for his help in revising the manuscript.

Ethics

Ethics Committee Approval: This study was approved by the Institutional Ethics Committee of All India Institute of Medical Sciences, Bhubaneswar (T/IM-NF/Dentistry/120/137).

Informed Consent: Written informed consent was obtained from each patient for comprehensive orthodontic treatment and to use their records for various academic and research activities.

Author Contributions: Concept - J.S.; Design - J.S., A.B.; Supervision - J.S., A.K.J.; Materials - J.S., A.B.; Data Collection and/or Processing - J.S., A.B., V.K.K., P.S.; Analysis and/or Interpretation - J.S., A.B., V.K.K., A.S. A.M.; Literature Review - J.S., A.M., A.S.; Writing - J.S., A.M., A.K.J., V.K.K; Critical Review - A.K.J., A.S.

Declaration of Interests: All authors declare that they have no conflict of interest.

Funding: This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

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TURKISH JOURNAL OF ORTHODONTICS

DOI: 10.4274/TurkJOrthod.2023.2023.78

Original Article

Assessment of Changes in Behavior and Quality of Life after Monobloc Treatment in Children with Obstructive Sleep Apnea or Primary Snoring

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Cite this article as: Çapan E, Kılıçoğlu H, Uzunçıbuk H. Assessment of Changes in Behavior and Quality of Life after Monobloc Treatment in Children with Obstructive Sleep Apnea or Primary Snoring. *Turk J Orthod.* 2024; 37(2): 112-121

Main Points

- All sleep-disordered breathing problems have harmful behavioral and neurocognitive effects on children and lower their quality of life.
- The use of a monobloc appliance in children with primary snoring and obstructive sleep apnea reduced the symptoms of sleep-breathing disorders and improved their quality of life.

ABSTRACT

Objective: The aim of this study was to examine the quality of life and behavioral disorders in children with obstructive sleep apnea (OSA) or primary snoring, as well as how these problems changed after monobloc treatment.

Methods: Fourteen children with primary snoring and 16 children with OSA who had skeletal class II malocclusion due to mandibular retrognathia were treated with monobloc appliances. To investigate the relationship between behavioral disorders and quality of life, parents were asked to complete four questionnaires: attention deficit and hyperactivity disorder (ADHD) scale, strength and difficulties questionnaire (SDQ), pediatric sleep questionnaire (PSQ), and Pittsburgh sleep quality scale (PSQS). Mann-Whitney U and Wilcoxon signed-rank tests were used to evaluate the data.

Results: According to the results of the PSQ and PSQS, an increase in sleep quality was observed after monobloc treatment. The decrease in the total ADHD score at the end of the treatment was found to be statistically significant in both the OSA ($p<0.01$) and snoring ($p<0.01$) groups. According to the SDQ scores, the increase in the social behavior score and the decrease in the peer bullying score in the snoring group were statistically significant ($p<0.05$).

Conclusion: The use of a monobloc appliance in pediatric patients exhibiting primary snoring and OSA resulted in a notable reduction in sleep-breathing disorder symptoms and a notable enhancement in their overall quality of life. Based on the analyses of the questionnaires, it was concluded that the increase in sleep quality improved the pediatric patients' quality of life after orthodontic treatment with orthodontic monobloc appliances.

Keywords: Pediatric OSA, questionnaire, monobloc, polysomnography, quality of life

INTRODUCTION

The sleep-disordered respiratory spectrum includes primary snoring, upper airway resistance syndrome, obstructive hypoventilation, and obstructive apnea. Obstructive sleep apnea (OSA) is considered the most serious form on the spectrum.[1] Worldwide, 9-38% of the adult population and 2-5% of the pediatric population suffer from OSA.[2]

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Received: June 01, 2023 **Accepted:** September 04, 2023 **Publication Date:** June 30, 2024

Untreated OSA in children can lead to enuresis, abnormal growth, learning disabilities, behavioral problems, cardiovascular complications, and even death.[3,4] In addition to nighttime symptoms such as snoring, sleeping in abnormal postures, night sweats, and bedwetting, children with OSA may also exhibit daytime symptoms like aggression, hyperactivity, attention deficit, learning difficulties, a morning headache, and anxiety.[5,6] Snoring, the mildest form of sleep disorder, is no longer considered harmless. Numerous investigations have demonstrated a correlation between snoring and behavioral daytime and nighttime symptoms.[1,7,8] All sleep-disordered breathing problems, including primary snoring, have harmful behavioral and neurocognitive effects on children and lower their quality of life.[7,9] Several questionnaires, such as the Strength and Difficulties Questionnaire (SDQ) and the Attention Deficit and Hyperactivity Disorder (ADHD) scale, are also used to measure the changes in behavior and brain function caused by treating sleep disorders, as well as the changes in sleep quality that affect the quality of life.[10,11]

Presently, polysomnography (PSG) is the gold standard diagnostic tool for identifying OSA in pediatric patients.[12] PSG is the recording of neurophysiological, respiratory, cardiovascular, and other physical and physiological data during sleep in a sleep laboratory, usually for the whole night, at specific times, simultaneously, and continuously. With PSG, in addition to sleep stages, several physiological characteristics, organ functioning, and interactions throughout sleep and wakefulness can be analyzed in detail.[13] Despite its effectiveness, PSG has a variety of disadvantages that restrict its overall utility. PSG has limited efficacy for diagnosing pediatric OSA due to its high cost, inconvenient nature, and lack of availability in underprivileged locations.[12] These constraints have prompted clinicians to use affordable and accessible diagnostic questionnaires an aid to PSG.[12,14]

The primary cause of sleep disorders is a narrowed upper airway. Several procedures, such as adenoidectomy and tonsillectomy, continuous positive airway pressure, rapid maxillary expansion (RPE), mandibular distraction or advancement, anti-inflammatory therapy, and weight loss, are used individually or in combination as treatments for sleep disorders. Several studies have demonstrated that RPE and monobloc appliances, two orthodontic treatment methods, are effective for treating sleep-disordered breathing in children.[15-17] The aim of this study was to examine the effects of orthodontic treatment with a monobloc appliance on the quality of life and behavioral disorders in children diagnosed with OSA or primary snoring with skeletal class II malocclusion due to mandibular retrognathia.

METHODS

This research was conducted in compliance with the Declaration of Helsinki, and the protocol was authorized by the İstanbul University, İstanbul Faculty of Medicine Clinical Research Ethics Committee, İstanbul, Turkey (approval no.: 2012/516-1010, date: March 09, 2012). All patients and their parents provided written consent to participate.

Patient Selection and Profile Determination

The anamnesis form for children with OSA may include questions related to the symptoms and risk factors associated with OSA. The pediatric sleep questionnaire (PSQ) is a commonly used tool to identify children at increased risk of OSA. It assesses symptoms such as snoring, observed apnea, daytime sleepiness, and inattentiveness.[18] Other relevant questions may include inquiries about the presence of craniofacial disorders, cerebral palsy, epilepsy, and other developmental disabilities, as these conditions are associated with a higher risk of OSA in children.[18,19] In addition, questions about the severity of OSA, such as the frequency and duration of apnea events during sleep, may be included.[20] The anamnesis form should also consider the potential impact of OSA on cardiovascular, neurocognitive, and metabolic systems. The anamnesis form gathers information that helps in the identification, assessment, and management of OSA in children.[21] The anamnesis form used in the present study was developed with consideration for this information. In addition to the questions presented in the anamnesis form, an assessment of risk factors for sleep and breathing disorders was conducted. The parents' snoring, smoking, asthma, hay fever, bruxism, and mouth or nose breathing were evaluated.

A cohort of 50 individuals, ranging in age from 8 to 14 years, who needed treatment at the department of orthodontics and presented with complaints of snoring, were subsequently directed to the sleep laboratory. Thirteen patients were excluded from the study following a polysomnographic examination because of the absence of a diagnosis of OSA or primary snoring. Four participants were excluded from the study due to having body mass index (BMI) measurements exceeding 85%. Cephalometric radiographs were assessed, and three patients who did not exhibit skeletal Class II anomalies (ANB<4°) were excluded from the study. Finally, 16 patients (mean age 11.25±1.23), 9 girls and 7 boys, with an apnea-hypopnea index (AHI) of 1 or greater constituted the OSA group, and 14 patients (mean age 10.97±1.51), 4 girls and 10 boys, with an AHI less than 1 constituted the primary snoring group.

BMI is a metric used to assess obesity on a personal level, considering an individual's height (kg/m^2). The BMI is classified as exceeding 19 within the age range of 1-2, exceeding 18 within the age range of 2-6, exceeding 21 within the age range of 6-10, and exceeding 26, indicating probable obesity within the age range of 10-18. The assessment of BMI in children can be conducted using BMI percentile curves that have been developed based on age and gender. Based on the provided information, children whose BMI falls within the range of >85% are categorized as overweight, while those whose BMI falls within the range of >90% are classified as obese. Obesity has been identified as a significant risk factor for the development of OSA. An increase of 1 kg/m^2 in BMI is associated with a 12% increase in the likelihood of developing OSA.[22]

Brodsky, Friedman, and adenoid scoring were performed by examining all the cases to be included in the study in the otolaryngology department. In the physical examination, the presence and degree of tonsillar hypertrophy were determined between grades I and IV using the Brodsky classification. According to the Friedman Tongue Position Scoring System, the patient's mouth was opened without protruding his tongue, and the tongue, soft palate, uvula, and tonsils were evaluated. According to the appearance of the soft palate, the patient was given a score of 1-4.

The assessment of adenoid size was performed using nasal endoscopy, with scores ranging from 0 to 4 based on the degree of adenoidal obstruction in the airway. The scoring system assigns a value of 0 when there is no obstruction of the airway, a value of 1 when the closure is less than 25%, a value of 2 when the closure falls within the range of 25-50%, a value of 3 when the closure falls within the range of 50-75%, and a value of 4 when the closure exceeds 75%.

These scorings were evaluated alongside the clinical examination, and the patients who required tonsillectomy and/or adenoidectomy were identified. Adenotonsillectomy was performed on a patient with OSA, which was deemed necessary. The patient, who was re-evaluated 8 weeks after the operation, was found to have an AHI below 1 according to PSG, but habitual snoring continued. Therefore, she was included in the study in the primary snoring group.

The inclusion criteria were as follows:

• Patients who presented to the orthodontic department with complaints of snoring,

• Patients with skeletal Cl II anomalies due to mandibular retrognathia (SNB<78°, ANB>4°),

• Patients with primary snoring or OSA confirmed by PSG,

• Patients with no systemic diseases,

The exclusion criteria were as follows:

• Patients with congenital or dental abnormalities (e.g., cleft lip & palate),

• Patients with systemic disorders (e.g., chronic cardiorespiratory or neuromuscular disease, chromosomal syndrome),

• Overweight patients (BMI>85%).

Treatment Procedure

Lateral cephalometric radiographs were obtained using a digital X-ray device (Sirona Orthophos XG Plus DS/Ceph, Bensheim, Germany) and were analyzed with NemoCeph Software (Nemotec, NemoCeph Software, Madrid, Spain). Although upper airway surgeries are the primary treatment method and option for OSA, the efficacy exhibits considerable variability, and their impact on loop gain may vary depending on the initial severity of OSA. Therefore, orthodontic treatment was prompted by a comprehensive assessment of the patients' scores and their specific orthodontic treatment requirements.

The design and construction of a monobloc appliance may vary depending on the individual patient's needs and the orthodontist's treatment plan. In the present study, all the appliances were custom-made using dental impressions and acrylic material, which is biocompatible and safe for intraoral use, by the same orthodontic technician. During the occlusion recording process for the monobloc appliance, participants were instructed to advance their mandible forward until the overjet reached an approximate measurement of 2 mm through the vertical opening and, subsequently, to gradually bite into the recording wax by increasing 3-4 mm vertically on the freeway space. Efforts were made to establish a Class I relationship between the canines and molars in the sagittal plane and to achieve proper alignment of the upper and lower dental midlines to prevent midline discrepancy.

In cases where a lateral crossbite occurs upon the advancement of the mandible, the necessary degree of expansion is achieved through the use of an expansion screw. Therefore, a transversal Hyrax expansion screw (Leone Orthodontics, Firenze, Italy) was added to the monobloc appliance. The patients were instructed to turn the screw twice a week by applying the slow expansion protocol (0.25 mm per turn). The participants were instructed to wear the appliance for a minimum of 17 hours per day. To correct the high angle and dolichocephalic structure determined by clinical examination and cephalometric analysis, the patients were given an occipital headgear for nighttime use only with a monobloc appliance (Figure 1). The mean duration of treatment was 7.86±1.17 months for the primary snoring group and 8.06±1.29 months for the OSA group.

For all patients, PSG records, anamnesis forms, orthodontic materials, otolaryngological examinations, and scoring adenoids and tonsils with the Brodsky and Friedman scales, and BMI measurements were performed. Their parents were asked to fill out four questionnaires that assessed children's sleep quality and behaviors. After dental Class I relationships were established in all patients, questionnaires and PSG records were repeated (Figure 2).

Polysomnographic Assessment

This study included performing PSG studies in the sleep laboratory of İstanbul University, İstanbul Faculty of Medicine, Department of Chest Diseases, under the guidance of a skilled sleep specialist. The PSG studies were conducted during the patients' natural sleep. The participants were transported to the designated room 90 minutes before their habitual sleep period, affording them an opportunity to acclimate to their surroundings. Following the provision of information to the patient and their parents regarding the procedure and the subsequent connection of electrodes, electrode bonding was initiated.

The ALICE 5 (Pennsylvania, US) device was used to perform PSG. PSG used two-channel EEG (C3-A2, O1-A2, Electroencephalogram), a two-channel electrooculogram, a two-channel submental electromyogram (EMG), an oronasal flow meter, a finger pulse oximeter, a tracheal microphone, a body condition detector, a two-channel thoraco-abdominal motion belt, two-channel tibial EMGs, and one electrocardiogram. The device collects data on brain activity, eye movements, muscle tone, respiratory patterns, and other relevant parameters. The American Academy of Sleep Medicine's updated guideline was used to define diagnostic criteria and staging for sleep disorders in children. According to this:

Figure 1. The monobloc appliance used in the orthodontic treatment

Obstructive apnea: A 90% or greater reduction in airflow or signal detected by an oro-nasal thermistor, non-invasive ventilation device, and other types of sensors while continuing respiratory effort as determined by chest and abdominal movements during at least two respiratory cycles.

Central apnea: The presence of one of the three criteria listed below in a patient with a decrease of more than 90% in airflow determined by sensors and no respiratory effort detected.

1. The occurrence lasted at least 20 s.

2. Persistent for at least two respiratory cycles and accompanied by awakening or ≥3% oxygen desaturation.

3. Continuation of at least two respiratory cycles in children younger than one year of age, heart rate below 50 beats/min for more than five seconds, and heart rate below 60 beats/min for more than 15 seconds.

Hypopnea: A decrease in airflow of at least 30%, persisting for at least two respiratory cycles, and accompanied by awakening or ≥3% oxygen desaturation.

Hypoventilation: The pCO_2 level, measured by arterial or other methods, is above 50 mmHg, which is more than 25% of the total sleep time.

Awakening associated with respiratory effort: Situations where increased respiratory effort during at least two respiratory cycles, flattening of the inspiratory part on nasal pressure measurement or non-invasive ventilation device, snoring, pCO_2 elevation, or awakening is observed, but the event does not meet the criteria for apnea and hypopnea.[2]

A calculation was performed to determine the index of obstructive events, specifically obstructive apnea and

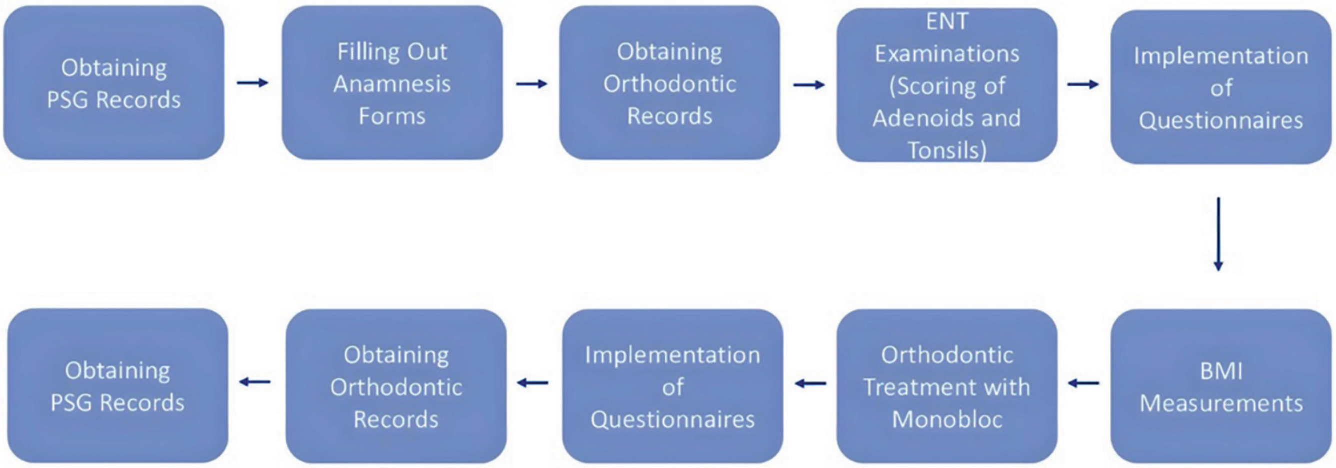

Figure 2. Flow-chart of the study
PSG, polysomnography; BMI, body mass index; ENT,

obstructive hypopnea, per hour. A positive PSG result was obtained when the AHI exceeded one per hour, leading to a diagnosis of sleep-disordered breathing. Mixed apneas were classified and recorded as obstructive. The evaluation excluded records with a duration of 5 hours.

Administration of Surveys

The 0-3 ADHD scale score is determined by evaluating the child's focus on schoolwork and activities, movements in their social environment, and the frequency and manner of speaking with other people. The SDQ is a descriptive tool that evaluates a child's social behavior, attention deficit and hyperactivity, emotional and behavioral problems, and exposure to peer bullying. The PSQ is a diagnostic and follow-up instrument used to detect the child's breathing difficulty, frequency of snoring, mouth breathing during sleep, growth stagnation, and daytime social environment distraction. The Pittsburgh Sleep Quality Scale (PSQS) evaluates a person's sleep pattern over the past month by asking, "What time did you go to bed?", "How long have you been sleeping?", "When did you awaken in the morning?", "Did you wake up during sleep?", "Have you had trouble breathing?".

Statistical Analysis

The IBM SPSS Statistics 22 program was used for statistical analysis. To determine the sample size, a power analysis was performed assuming 80% power and α=0.05 using a two-tailed t-test. While evaluating the study data, in addition to descriptive statistics (mean, standard deviation), one-way analysis of variance was used for intergroup comparisons of normally distributed parameters. The Mann-Whitney U test was used to compare parameters between two groups, and the paired sample t-test was used for within-group comparisons of normally distributed parameters. The Wilcoxon test was used to compare non-normally distributed parameters within groups. The significance level was set at $p<0.05$. The chi-square test was used for comparison of qualitative data, and Cronbach's alpha coefficient was used to determine the reliability of the surveys.

RESULTS

The evaluation of the qualitative and quantitative characteristics of the groups revealed the following findings: The mean treatment duration for the OSA group was 8.06±1.29 months, while for the primary snoring group, it was 7.86±1.17 months, with a p-value of 0.752. The mean age at T1 was 11.25±1.23 years for the OSA group and 10.97±1.51 years for the primary snoring group, resulting in a p-value of 0.587. At T2, the mean age for the OSA group was 11.64±1.49 years, compared to 11.91±1.20 years for the primary snoring group, with a p-value of 0.629. Regarding gender distribution, 43.80% of the OSA group were male, and 56.20% were female, whereas in the primary snoring group, 71.40% were male, and 28.60% were female. The gender distribution analysis yielded a p-value of 0.135, based on the chi-square distribution. There was no statistically significant difference between the groups in terms of treatment duration, age at T1 and T2, and gender ($p>0.05$).

When the hand-wrist developmental periods of the patients included in the study were examined, it was observed that 6 children in the OSA group were in the PP2, 5 children in the MP3=period, and 5 children in the MP3cap period. In the snoring group, 6 children were in the PP2 period, 5 children in the MP3=period, 2 children in the MP3cap period, and 1 child in the DP3u period (Table 1).

The prevalence of the risk factors for sleep breathing disorders is presented in Table 1. The prevalence of snoring among mothers in the OSA group was 43.75%, whereas fathers exhibited a snoring prevalence of 62.5%. In addition, 31.25% of

Table 1. Hand-wrist development periods of the patients at T1 and prevalence of the risk factors for sleep breathing disorders

	OSA (n=16)			Primary snoring (n=14)		
	Female		Male	Female	Male	
PP2=	2		4	0	6	
MP3=	4		1	0	5	
MP3cap	3		2	2	0	
DP3u	0		0	1	0	
Mother's snoring	43.75%			35.71%		
Father's snoring	62.50%			71.42%		
Mother's smoking	31.25 %			21.42%		
Father's smoking	62.50%			50%		
Smoking individuals except parents	12.50%			0%		
Asthma	0%			0%		
Hay fever	0%			0%		
Bruxism	68.75%			35.71%		
Respiration	Nose	Mouth	Both	Nose	Mouth	Both
	0%	12.5%	87.5%	0%	14.28%	85.72%

OSA, obstructive sleep apnea

the mothers and whereas 62.5% of the fathers were smokers, and 12.5% of the parents smoked within their household. Neither asthma nor hay fever was present in any child. The prevalence of bruxism among children was 68.75%, with 12.5% of the children exclusively relying on mouth breathing, and the remaining 87.5% engaged in both nasal and mouth respiration.

In the snoring group, the prevalence of snoring was observed to be 35.71% in mothers and 71.42% in fathers. Snoring was reported to be present in 21.42% of mothers and 50% of fathers. Neither asthma nor hay fever was present in any child. The prevalence rate of bruxism was 35.71% in children. According to the data, 14.28% of the children exclusively engaged in mouth breathing, whereas the remaining 85.72% engaged in both nasal and mouth breathing.

The evaluation of the PSG findings is presented in Table 2. The decrease in stage 1 at the end of the treatment was found to be statistically significant during the T1-T2 period ($p=0.034$, $p<0.05$). A statistically significant decrease in the AHI was observed ($p=0.020$, $p<0.05$). The ADHD scale reliability analysis is presented in Table 3, and the evaluation of scores is presented in Table 4. The mean attention deficit scores of the snoring group at the beginning (T1) and at the end of the treatment (T2) were significantly higher than those of the OSA group ($p_1=0.030$; $p_2=0.007$; $p<0.05$; $p<0.01$). Furthermore, the decrease in attention deficit score at the end of the treatment was found to be statistically significant in both the OSA ($p=0.002$, $p<0.01$) and snoring ($p=0.001$, $p<0.01$) groups. The decrease in the hyperactivity score at the end of the treatment was found to be statistically significant in both the OSA ($p=0.008$, $p<0.01$) and snoring ($p=0.011$, $p<0.05$) groups. However, the decrease in the impulsivity score at the end of the treatment was found to be statistically significant only in the OSA group ($p=0.004$, $p<0.01$).

The mean total ADHD score at the end of the treatment (T2) for the snoring group was found to be significantly higher than that for the OSA group ($p_2=0.035$; $p<0.05$). The decrease in the total ADHD score at the end of the treatment was found to be statistically significant in both the OSA ($p=0.001$, $p<0.01$) and snoring ($p=0.004$, $p<0.01$) groups.

The Strengths and Difficulties Score's reliability analysis is presented in Table 3, and the evaluation of scores is presented in Table 5. In the intragroup evaluations, the increase in the social behavior score ($p=0.027$, $p<0.05$) and the decrease in the peer bullying score ($p=0.042$, $p<0.05$) in the snoring group were statistically significant.

Evaluations of the PSQ score's reliability analysis are presented in Table 3. The evaluation of the PSQ scores and PSQS scores are presented in Table 6.

The decrease in the snoring, sleepiness, behavior problems, and total score at the end of the treatment was statistically significant in the OSA ($p=0.001$, $p=0.042$, $p=0.050$, $p=0.001$ respectively) and snoring groups ($p=0.001$, $p=0.024$, $p=0.032$, $p=0.001$, respectively) within the groups.

A statistically significant decrease was observed in the PSQS score at the end of the treatment in the OSA ($p=0.005$, $p<0.01$) and snoring groups ($p=0.006$, $p<0.01$).

DISCUSSION

Inadequate sleep quality negatively affects emotional stability, cognitive performance, and physical growth. PSG is the gold standard for diagnosing OSA; however, due to the lack of sleep laboratories, other assessment tools are necessary. Questionnaire applications are one of the most prevalent approaches for assessing sleep and breathing disorders.[12]

In reliability calculations, a value between 0.00 and 0.25 represents little or no reliability, between 0.025 and 0.50 represents acceptable reliability, between 0.50 and 0.75

Table 2. Evaluation of the PSG findings

PSG	T1	T2	
	Mean±SD	Mean±SD	p-value
Stage 1 (%)	0.71±0.46	0.44±0.41	**0.034***
Stage 2 (%)	60.63±14.60	56.05±15.10	0.435
Stage 3-4 (%)	33.45±15.24	34.04±16.25	0.925
REM (%)	5.21±4.87	5.09±3.88	0.912
AHI	3.03±3.77	0.54±0.46	**0.020***
Mean saturation (%)	97.44±0.89	97.50±0.89	0.751
Minimum saturation (%)	85.88±16.37	91.56±3.35	0.142
Sleep activity (%)	85.7±8.37	88.8±8.4	0.133
Arousal index	10.8±7.16	13.34±5.49	0.386
ODI	2.26±1.58	1.38±0.89	0.116

[1]Paired samples t-test, *p<0.05
T1, beginning of the treatment; T2, end of the treatment; PSG, polysomnography; SD, standard deviation; REM, rapid eye movement; ODI, oxygen desaturation index; AHI, apnea-hypopnea index

Table 3. Attention deficit and hyperactivity disorder (ADHD) scale, strengths and difficulties questionnaire, and pediatric sleep questionnaire score's reliability analysis

	T1	T2
Total ADHD	0.936	0.912
Attention deficit	0.927	0.889
Hyperactivity	0.848	0.836
Impulsivity	0.881	0.832
Total difficulty points	0.653	0.752
Social behavior	0.473	0.673
Attention deficit /hyperactivity	0.733	0.732
Emotional issues	0.593	0.715
Behavior issues	0.416	0.197
Peer bullying	0.368	0.278
Snoring	0.543	0.435
Sleepiness	0.682	0.632
Behavior problems	0.845	0.741
Total	0.691	0.720

Table 4. Evaluations of attention deficit and hyperactivity disorder (ADHD) scale scores

		OSA	Snoring	
		Mean±SD (median)	Mean±SD (median)	p-value
Attention deficit	[1]T1	0.83±0.56 (0.80)	1.47±0.80 (1.40)	**0.030***
	[1]T2	0.47±0.41 (0.40)	0.96±0.59 (0.80)	**0.007****
	[1]T1-T2	-0.37±0.43 (-0.30)	-0.51±0.53 (-0.30)	0.502
	[2]p	**0.002****	**0.001****	
Hyperactivity	[1]T1	1.07±0.74 (1.10)	1.35±0.81 (1.40)	0.297
	[1]T2	0.72±0.60 (0.80)	1.02±0.74 (0.80)	0.276
	[1]T1-T2	-0.35±0.45 (-0.30)	-0.32±0.38 (-0.20)	0.866
	[2]p	**0.008****	**0.011***	
Impulsivity	[1]T1	1.36±0.90 (1.10)	1.49±0.90 (1.60)	0.629
	[1]T2	0.93±0.70 (0.60)	1.17±0.69 (1.20)	0.268
	[1]T1-T2	-0.44±0.50 (-0.40)	-0.31±0.55 (-0.30)	0.628
	[2]p	**0.004****	0.059	
Total ADHD	[1]T1	1.04±0.58 (0.90)	1.44±0.70 (1.60)	0.124
	[1]T2	0.66±0.46 (0.50)	1.03±0.50 (0.90)	**0.035***
	[1]T1-T2	-0.38±0.36 (-0.30)	-0.40±0.39 (-0.40)	0.917
	[2]p	**0.001****	**0.004****	

[1]Mann-Whitney U test, [2]Wilcoxon signed-rank test, *$p<0.05$ **$p<0.01$
T1, beginning of the treatment; T2, end of the treatment; OSA, obstructive sleep apnea; SD, standard deviation

Table 5. Evaluation of strengths and difficulties questionnaire scores

		OSA	Snoring	
		Mean±SD (median)	Mean±SD (median)	p-value
Social behavior	[1]T1	7.81±1.80 (8)	7.29±1.98 (7.50)	0.447
	[1]T2	8.25±1.84 (8)	8.43±1.60 (9)	0.715
	[1]T1-T2	0.44±1.46 (0)	1.14±1.70 (0.50)	0.275
	[2]p	0.226	**0.027***	
Attention deficit/ hyperactivity	[1]T1	5.25±2.79 (5)	6.36±2.71 (6.50)	0.257
	[1]T2	4.75±2.59 (4.50)	5.64±2.27 (6.50)	0.240
	[1]T1-T2	-0.50±2.03 (-1)	-0.71±2.13 (-1)	0.801
	[2]p	0.340	0.210	
Emotional issues	[1]T1	4.69±2.52 (5)	4.93±2.20 (5)	0.900
	[1]T2	3.50±2.73 (3.50)	4.21±2.64 (4.50)	0.463
	[1]T1-T2	-1.19±2.34 (-1.50)	-0.71±1.68 (-1)	0.459
	[2]p	0.063	0.154	
Behavior issues	[1]T1	3.25±2.08 (3)	3.14±1.41 (3)	0.800
	[1]T2	3.13±1.67 (3)	3.07±1.49 (3)	0.882
	[1]T1-T2	-0.13±1.20 (0)	-0.07±1.82 (0.50)	0.593
	[2]p	0.658	0.964	
Peer bullying	[1]T1	2.13±2.16 (2)	3±1.52 (2)	0.091
	[1]T2	1.88±1.82 (1.50)	1.93±1.49 (2)	0.749
	[1]T1-T2	-0.25±2.32 (0)	-1.07±1.69 (-1)	0.408
	[2]p	0.715	**0.042***	
Total difficulty points	[1]T1	23.13±6.91 (25)	24.71±4.51 (25.50)	0.723
	[1]T2	21.50±7.02 (21.50)	23.29±5.47 (23)	0.439
	[1]T1-T2	-1.63±5.07 (-1)	-1.43±3.78 (-1.50)	0.933
	[2]p	0.221	0.247	

[1]Mann-Whitney U test, [2]Wilcoxon signed-rank test, *$p<0.05$
T1, beginning of the treatment; T2, end of the treatment; OSA, obstructive sleep apnea; SD, standard deviation

Table 6. Evaluations of pediatric sleep questionnaire scores and Pittsburgh sleep quality scale scores

		OSA	Snoring	
		Mean±SD (median)	Mean±SD (median)	p-value
Snoring	[1]T1	0.58±0.34 (0.60)	0.73±0.26 (0.70)	0.230
	[1]T2	0.05±0.14 (0)	0.07±0.15 (0)	0.543
	[1]T1-T2	-0.53±0.32 (-0.50)	-0.66±0.30 (-0.60)	0.316
	[2]p	**0.001****	**0.001****	
Sleepiness	[1]T1	0.48±0.35 (0.60)	0.31±0.27 (0.30)	0.155
	[1]T2	0.27±0.31 (0.30)	0.11±0.16 (0)	0.122
	[1]T1-T2	-0.21±0.35 (-0.30)	-0.20±0.31 (-0.10)	0.966
	[2]p	**0.042****	**0.024***	
Behavior problems	[1]T1	0.54±0.34 (0.50)	0.67±0.34 (0.80)	0.264
	[1]T2	0.43±0.34 (0.40)	0.51±0.34 (0.50)	0.516
	[1]T1-T2	-0.11±0.20 (-0.10)	-0.16±0.32 (-0.20)	0.474
	[2]p	**0.050****	**0.032***	
Total	[1]T1	0.48±0.18 (0.50)	0.52±0.16 (0.50)	0.868
	[1]T2	0.25±0.16 (0.20)	0.24±0.12 (0.30)	0.868
	[1]T1-T2	-0.23±0.11 (-0.30)	-0.27±0.15 (-0.30)	0.262
	[2]p	**0.001****	**0.001****	
PSQS	[1]T1	5.88±3.01 (6)	4.57±2.47 (4.50)	0.233
	[1]T2	3.69±2.36 (3.50)	2.57±1.74 (20)	0.151
	[1]T1-T2	-2.19±2.40 (-1.50)	-2±1.80 (-2.50)	0.916
	[2]p	**0.005****	**0.006****	

[1]Mann-Whitney U test, [2]Wilcoxon signed-rank test, *p<0.05 **p<0.01
T1, beginning of the treatment; T2, end of the treatment; OSA, obstructive sleep apnea; SD, standard deviation; PSQS, Pittsburgh sleep quality scale

represents moderate-good reliability, and above 0.75 represents excellent reliability.[23-25] In the present study, the total scores of all questionnaires were above 0.65. Considering the total scores, the highest value was found in the ADHD questionnaire (T1: 0.936, T2: 0.912), whereas the lowest value was found in the SDQ (T1: 0.653, T2: 0.752).

The PSQ can be used to determine the risk of OSA and to detect and monitor daytime symptoms that may result from a sleep breathing disorder. A value above 0.33 in the total score indicates that the patient is in the risk group.[26] We believe that the reason for the high total score in both groups is that the questionnaire evaluates not only nighttime symptoms like PSG but also daytime symptoms like sleepiness and behavioral disorder. In this study, the decrease in all scores indicates a significant improvement in nighttime and daytime symptoms caused by sleep-disordered breathing.

If the overall PSQS score is 5 or below, it indicates good sleep quality, whereas a score of 6 or more indicates poor sleep quality.[25] In the present study, it was observed that the sleep quality at the beginning of treatment in both treatment groups was not particularly poor but improved with treatment.

Even though the severity of OSA makes it likely that the results of the ADHD questionnaire will show more severe subjective findings, the results of the present study show that primary snoring and OSA have the same effects on sleep and daily life. Wise et al.[27] reported that current PSQs are not sufficient to differentiate primary snoring from OSA. According to Kaemingk et al.,[28] issues with learning and memory are more prevalent when the AHI is greater than 5. We also believe that the low AHI may have contributed to the observed similarities between the OSA and snoring groups.

Urschitz et al.[29] examined hyperactivity and academic achievement in school-aged children with primary snoring, upper airway resistance syndrome, and OSA. They found that primary snoring is a complex condition with neurocognitive disorders similar to upper airway resistance syndrome and OSA.[29]

Arman et al.[30] found that the prevalence of snoring was 7% and that it was more prevalent in boys. Children who snore are more likely to experience nocturnal symptoms such as restless sleep, breathing difficulties during sleep, increased parental anxiety, nightmares, and bedwetting, as well as daytime symptoms such as daytime sleepiness and hyperactivity.[30] Mitchell and Kelly[7] found that sleep-related respiratory disorders severely impact the quality of life by producing behavioral and neurocognitive problems through a systematic review of 33 studies using different questionnaires. They noted that after having an adenotonsillectomy, patients experienced improvements in their problems and quality of life.[31]

In the Villa et al.[32] study, the parents of nine children in the control group and 14 children with OSA were asked to fill out a modified version of the Brouillette questionnaire before monobloc therapy and again six months later. Cozza et al.[33] applied the Italian version of the Epworth Sleepiness Scale, which is used to detect excessive daytime sleepiness, to 20 patients with OSA treated with a modified monobloc. In both studies, it was determined that there was an improvement in the daytime and nighttime symptoms.

With OSA, sleep quality deteriorates due to 200-300 microarousals every night, which significantly impacts drowsiness, increased body movements during night sleep, and alertness and attention functions the following day.[34] Nieminen et al.[34] suggested that the aforementioned micro-awakening attacks may adversely affect insulin-like growth factor-I (IGF-I) levels and the distribution of IGF-binding protein 3, which plays an important role in the cellular development of the prefrontal cortex. Hypoxia, which can be observed intermittently at night during sleep, can have a negative effect on executive functions, especially in the prefrontal cortex.[35,36]

In the chronic snoring group, Arman et al.[30] observed that learning difficulties and decreases in academic performance occurred more frequently. In addition to difficulties in regulating behaviors, emotions, and attention, it has been reported by their families that children had difficulty with executive functions such as decreasing their capacity to adapt to changing situations during the day, starting, maintaining, and planning their homework.[6]

It is recommended that clinicians be careful and initiate an appropriate consultation network in cases where complaints of sleep-disordered breathing and behavioral, cognitive, and academic impairments coexist. Improvement after adenotonsillectomy or orthodontic treatment can positively affect not only sleep and respiratory functions but also behavior and quality of life.

CONCLUSION

This research resulted in the following conclusions:

• Behavioral and emotional problems such as hyperactivity, agitation, and lack of attention, as well as the connection between cognitive skills and sleep-breathing disorders, are increasingly recognized.

• Parameters showed improvement in children's social behavior, peer relations, and sleep quality at the end of the treatment.

• The use of a monobloc appliance in children with primary snoring and OSA reduced the symptoms of sleep-breathing disorders and improved their quality of life.

Acknowledgment

We would like to thank Prof. Dr. Esen Kıyan who helped in allowing the use of sleep lab and Prof. Dr. Ayşe Arman, Prof. Dr. Murat Yener, Assoc. Prof. Yetkin Zeki Yılmaz who helped with the identification and preparation of surveys and in furthering the study.

Ethics

Ethics Committee Approval: This research was conducted in compliance with the Declaration of Helsinki, and the protocol was authorized by the İstanbul University, İstanbul Faculty of Medicine Clinical Research Ethics Committee, İstanbul, Turkey (approval no.: 2012/516-1010, date: March 09, 2012).

Informed Consent: All patients and their parents provided written consent to participate.

Author Contributions: Concept - E.Ç., H.K.; Design - E.Ç., H.K.; Data Collection and/or Processing - E.Ç.; Analysis and/or Interpretation - H.K.; Writing - E.Ç., H.U.; Critical Review - H.K.

Declaration of Interests: The authors declare no conflict of interest.

Funding: This research received no external funding.

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TURKISH JOURNAL OF
ORTHODONTICS

DOI: 10.4274/TurkJOrthod.2023.2022.172

Original Article

Effect of Aligning Forces by Two Preadjusted Edgewise Techniques on a Buccally Positioned Maxillary Canine at Varying Vertical Displacements: A Finite Element Study

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Cite this article as: Mathew S, Batra P, Arora N, Kumar Singh A, Kannan S, Talwar A. Effect of Aligning Forces by Two Preadjusted Edgewise Techniques on a Buccally Positioned Maxillary Canine at Varying Vertical Displacements: A Finite Element Study. *Turk J Orthod.* 2024; 37(2): 122-129

Main Points

- The most optimal displacement for engaging a vertically displaced canine in continuous mechanics is up to 4 mm from the occlusal plane.
- The piggyback method is more efficient with less counter effects on adjacent teeth compared to the continuous archwire.
- Maximum occlusal movement was observed at a 2 mm vertical displacement, which decreased progressively as the vertical displacement increased.

ABSTRACT

Objective: To evaluate the effect of continuous arch and piggyback mechanics in a straight wire appliance (SWA) for the alignment of buccal and variably vertically positioned maxillary canines.

Methods: A three-dimensional finite element model with near-normal occlusion and buccal and vertically displaced maxillary canines was used. Two groups were created to simulate two commonly used SWAs techniques, continuous archwire (Group 1) and piggyback models (Group 2). Each group had three subgroups with varying vertical displacement of the canine from 2 to 6 mm from the occlusal plane. The displacement and stress distribution were noted in each group.

Results: As the vertical displacement increased in Group 1, the concentration of von Mises stress increased progressively at the incisal third (0.36, 0.41 and 0.44 MPa) at 2, 4, and 6 mm, respectively, with decreased maximum occlusal movement in the vertical plane with respect to the canine. Group 2 exhibited a similar pattern but greater occlusal movement of the canine compared with Group 1.

Conclusion: A vertical displacement of 4 mm is the optimal level at which continuous arch mechanics should be considered. For displacements beyond 4 mm, the piggyback wire technique is a suitable alternative.

Keywords: Biomechanics, canine impaction, evidence-based practice, finite element analysis (FEM), force

INTRODUCTION

Ectopic, or vertically displaced teeth are one of the most commonly encountered orthodontic problems. This vertical displacement can occur in both anterior and posterior teeth; the most commonly occurring vertical displacement is in the permanent maxillary canine, with 1-2% prevalence in the general population.[1,2] The

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Received: November 29, 2022 **Accepted:** April 27, 2023 **Publication Date:** June 30, 2024

prevalence rate of ectopic eruptions in the Indian population was reported to be 5.5%.[3] Orthodontic tooth movement is a biological reaction of periodontal tissue to orthodontic force. The force applied to the teeth must be precisely controlled to generate the desired outcome.[4] A multibracket appliance with a continuous archwire produces a complex force system that is statically indeterminate.[5] The use of the continuous archwire technique for highly displaced canines may cause harmful or unwanted movement in the adjacent reactionary units. The adjacent teeth may intrude, they may tip, an occlusal cant may develop, there may be a lateral open bite, and the patient's arch form may distort due to these detrimental effects.[6,7] The piggyback technique, or a nickel titanium (NiTi) overlay serves as an alternative to the continuous archwire method. The piggyback technique utilizes a rigid base archwire, which is usually a high-tensile stainless steel wire, and NiTi overlay wire.[6] Orthodontic research can use finite element analysis (FEA) as a powerful tool to overcome clinical limitations in *in vivo* studies and investigate the displacement pattern and stress distribution. It is particularly suited to analyzing the complex force system produced by multibrackets and continuous archwire systems.[7-10] There are lacunae in the existing literature comparing the efficiency of the two methods and the optimal level of displacement of the vertically positioned canine when continuous arch mechanics should be considered efficient treatment mechanics. Therefore, the purpose of the present study was to compare the biomechanical characteristics of two different clinical techniques for correcting a vertically displaced canine, as well as to evaluate the displacement and stress pattern generated at different levels of vertical displacement.

METHODS

The finite element model (FEM) was constructed using cone-beam computed tomography (CBCT) (digital imaging and communications in medicine) images of a 25-year-old patient with a near-normal occlusion with a vertically displaced maxillary canine from the archives of the Oral Medicine and Radiology Department, Manav Rachna Dental College, and exported to create a three-dimensional FEA model of the maxillary arch. CBCT details: 90 kVp, 12 mA, exposure time of 29 s, slice thickness of 0.3 mm, and FOV of 16x8 cm. Manav Rachna Dental College institutional ethical approval (ref. no.: MRDC/IEC/2019/525, date: December 26, 2019) was obtained before starting the study.

Construction of the Model and Preprocessing

Volumetric data from the CBCT files was used to create a virtual model consisting of the maxillary bone and teeth. The boundaries of the maxilla were differentiated in each CBCT slice, and the geometries of the cortical and cancellous bone were segmented from the scan using image processing software (MIMICS, Version 21.0, Materialize, Leuven, Belgium). Further segmentation of each tooth was performed individually. The periodontal ligament (PDL) was modeled as uniformly thick at 0.25 mm around the teeth, with a cortical bone thickness of 1 mm around the alveolar process, and the remaining volume as cancellous bone following the tooth contour 1.0 mm below the cementoenamel junction (CEJ). MBT brackets (low profile Victory series) with 0.022" x 0.028" slots along with 0.012-inch NiTi and 0.018 stainless steel archwire beam elements (straight ovoid archforms) were geometrically modeled in HyperMesh (version 13.0, Altair Engineering Inc., Michigan, USA). Validation of the model was further carried out to evaluate element qualities like warpage, aspect ratio, and local re-meshing to improve the overall mesh quality of the model. The right maxillary canine was displaced buccally and vertically at heights of 2, 4, and 6 mm from the occlusal plane to simulate a buccally erupted ectopic canine.

The teeth, alveolar bone, PDL, brackets, and archwire were assumed to be isotropic and homogeneous linear elastic bodies, and Young's modulus and Poisson's ratio were determined for each component based on available literature (Table 1).[11-13] The alveolar bone was constrained at the nasal floor side in all directions, and each tooth was displaced within the periodontal space and made contact with adjacent teeth at contact points as individual elements. The boundary conditions were applied at maxillary sinus floor (Figures 1, 2).

Two clinical simulations were modeled in the FEM: Group 1 (modeled with a single 0.012" NiTi continuous straight ovoid

Table 1. Material properties used for modelling the structures

Material	Young's modulus (MPa)	Poisson's ratio
Teeth	4.0×10^4	0.3
PDL	5.0×10^{-2}	0.45
Cortical bone	1.4×10^4	0.26
Cancellous bone	1.37×10^3	0.3
Stainless steel	2.0×10^5	0.3
Nickel titanium	1.2×10^5	0.3

PDL, periodontal ligament

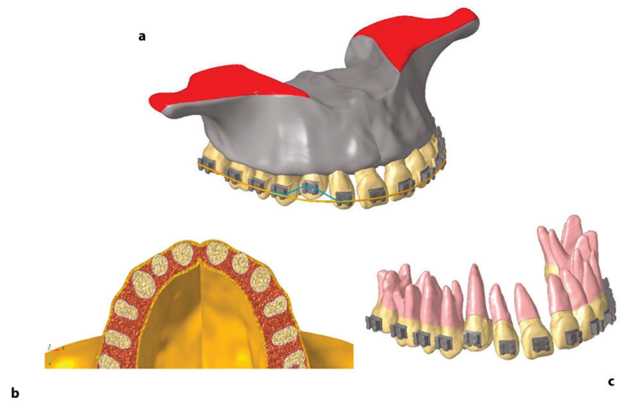

Figure 1. a) Boundary condition placed on the floor of the maxillary sinus (represented in red color) **b)** Segregation of the different parts of the model. Golden yellow=cortical bone. Dark brown=Medullary bone. Violet=PDL. Ivory=Teeth **c)** Finite element model including tooth, PDL, and bracket
PDL, periodontal ligament

form archwire) and Group 2 (modeled with a 0.018" SS straight ovoid form base wire with straight 0.012" NiTi in piggyback). In both groups, the wires were modeled in straight ovoid arch form and displaced in the region of the maxillary canine to engage in the bracket of the ectopically positioned canine (Figure 2). Hence, six models simulating varying heights of the maxillary canine (2 mm, 4 mm, and 6 mm from the occlusal plane) with two techniques were analyzed. Von Mises stress and normal stress were evaluated with varying amounts of deflection in the NiTi arch wire. Various simulations at three displacements (2 mm, 4 mm, and 6 mm) generated forces in the range of 80-100 gm.

A mesh convergence test was performed to understand the response for different mesh sizes, and the total number of elements was kept at 34, 65 and 350 (Figure 3). The mesh element was taken from test run 4, as from this point the tested parameter showed convergence. A standard coordinate system was constructed with the X-axis representing the buccolingual direction, the Y-axis representing the anteroposterior direction, and the Z-axis representing the occlusogingival direction. The buccal, anterior, and occlusal directions were defined as negative values (-x, -y, and -z directions), respectively. The displacement of the coronal tips (midpoints of the incisal edges of the lateral incisors, cusp tip of the canine, buccal cusp tips of the premolars, root apices, and mesial and distal contact points of the teeth involved) was calculated. Initial tooth displacement on each tooth was recorded at 4 points (mesial, distal, incisal, and root apex) to simulate orthodontic tooth movement based on the postulation that initial tooth displacement is a forecaster of long-term orthodontic movement.[14]

Statistical Analysis

The input models were processed, and the FEA solver calculated the results for the FEM. The amount of displacement, stress, and strain developed was recorded as the output. The finite element solver used to perform the simulation was OptiStruct version 2020 (Altair Engineering Inc, Troy, Michigan, United States).

RESULTS

The amount of stress and displacement of the maxillary canine and adjacent teeth (premolar and lateral incisor) and PDL in Groups 1 and 2 were analyzed and tabulated (Table 2, Figures 4 and 5). The maximum von Mises stress in the PDL (0.0204 MPa) was recorded at 2 mm displacement, which decreased as the displacement height increased (0.008 MPa at 6 mm displacement). A similar reduction in stress was also noted in the stress pattern on the teeth (lateral incisors, canines, and 1st premolars) in both groups, with Group 2 showing significantly

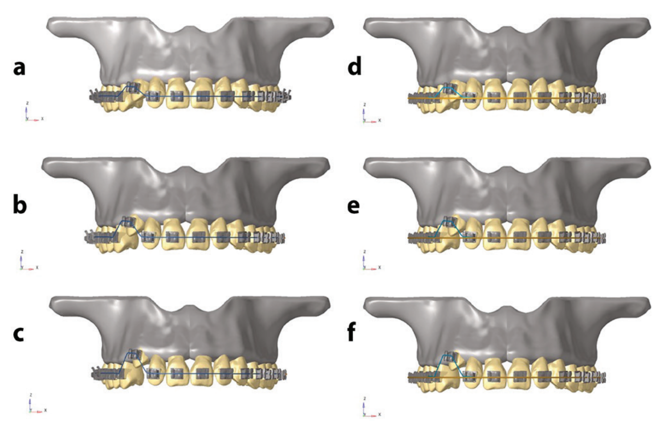

Figure 2. a-c) FEM models for different vertical displacements of maxillary canine Group 1 (Continuous arch wire technique) with 2 mm, 4 mm and 6 mm displacement; **d-f)** Group 2 (with 0.018" SS base wire and 0.012" NiTi piggyback or overlay) with 2, 4, and 6 mm displacements
FEM, finite element model; NiTi, nickel titanium

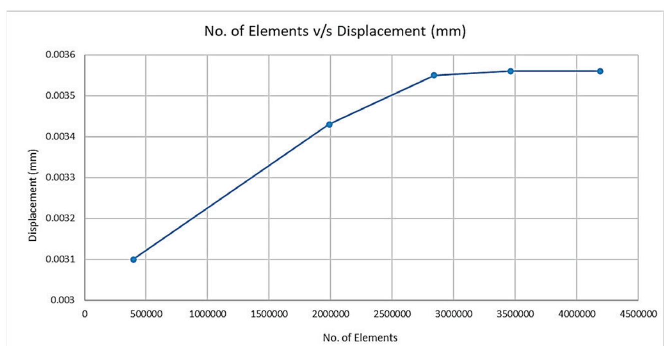

Figure 3. Number of nodes and displacement used during the mesh convergence test

Table 2. Maximum stress values on PDL and teeth (MPa)

	Height of displacement	PDL		Teeth		
		Maximum tension stress	Maximum compressive stress	Lateral incisors	Canine	First premolar
Group 1	2 mm	0.02043	0.01106	0.1169	0.3042	0.1221
	4 mm	0.01042	0.00967	0.0944	0.3615	0.1689
	6 mm	0.00841	0.00823	0.0476	0.4356	0.0816
Group 2	2 mm	0.02035	0.01108	0.1004	0.2984	0.1083
	4 mm	0.01050	0.00898	0.0326	0.4487	0.0796
	6 mm	0.00843	0.00814	0.0479	0.4278	0.0812

Group 1 (modeled with a single 0.012" NiTi continuous straight ovoid form archwire) and Group 2 (modeled with a 0.018" SS straight ovoid form base wire with straight 0.012" NiTi in piggyback)
PDL, periodontal ligament

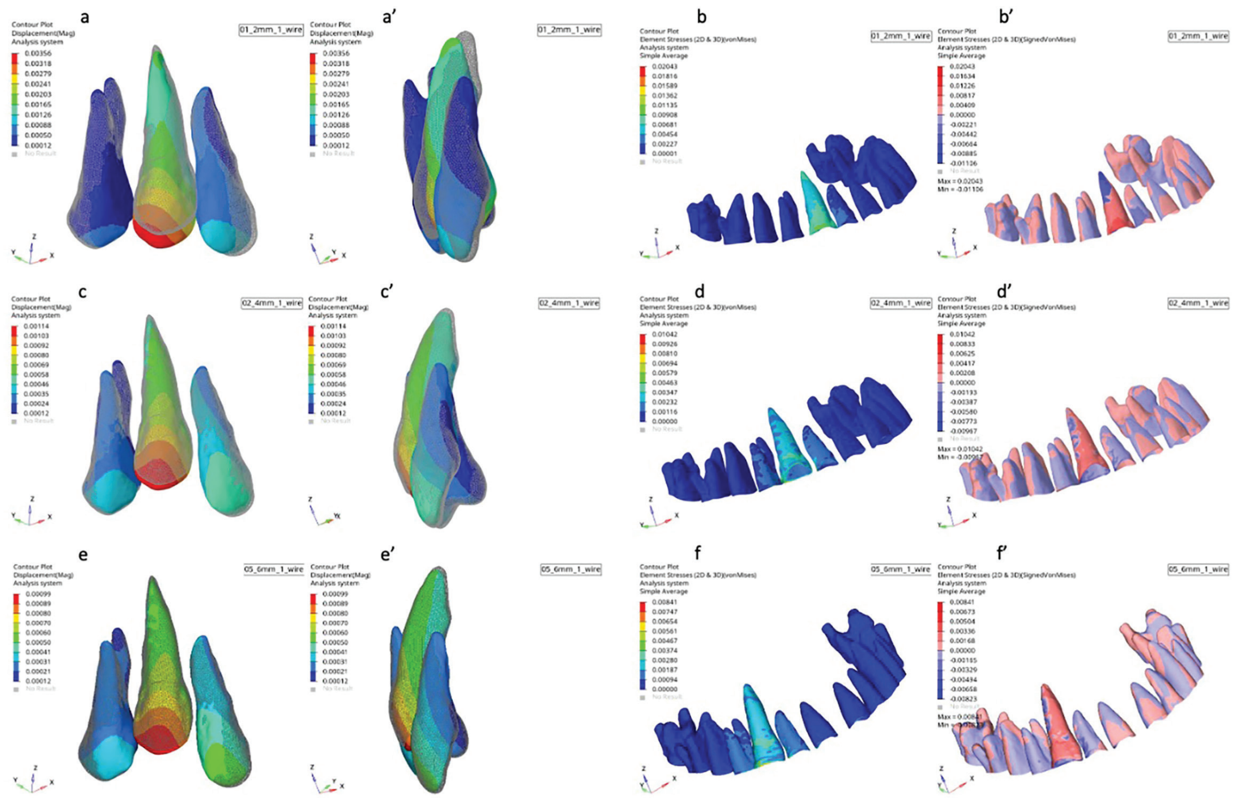

Figure 4. Representation of the total displacement and von Mises stress produced on teeth and PDL in Group 1 at; a, a', b, b') 2 mm displacement height of the canine; c, c', d, d') 4 mm displacement height of the canine; e, e', f, f') 6 mm displacement height of the canine
PDL, periodontal ligament

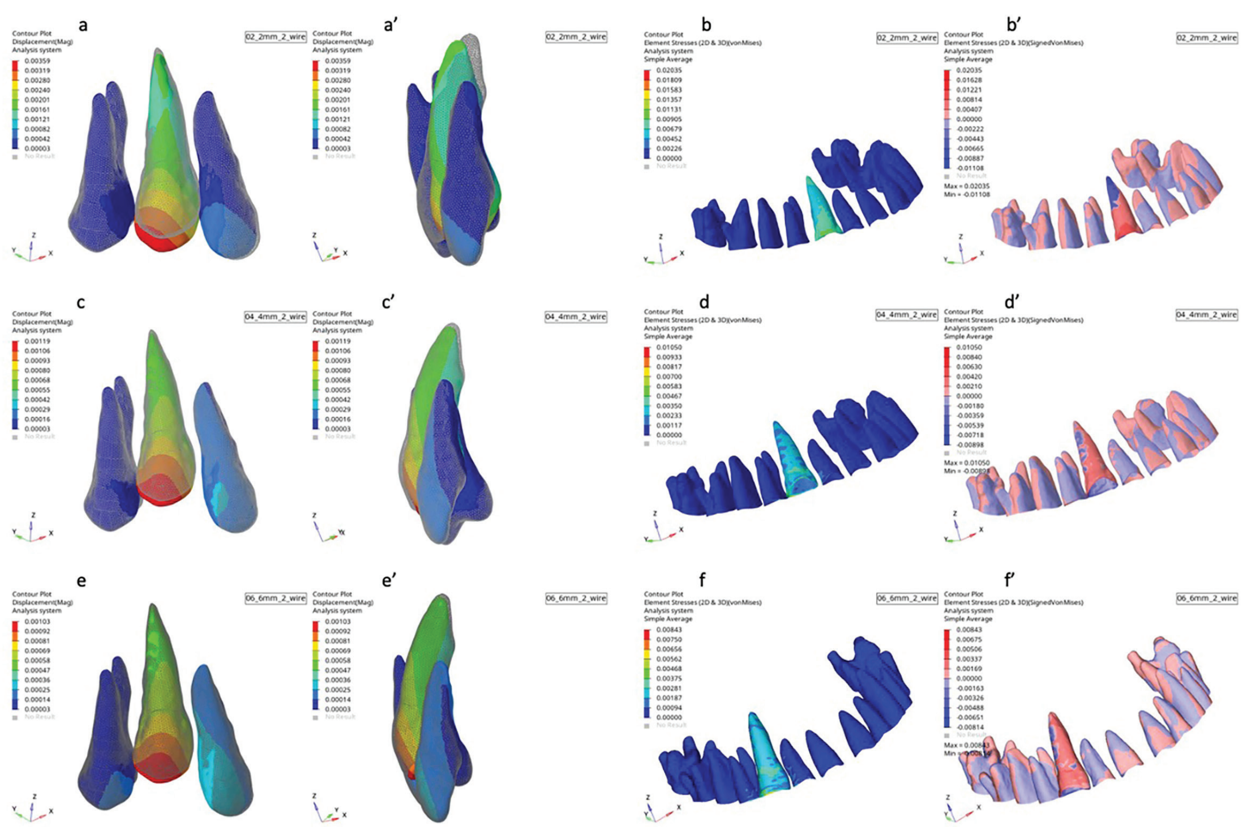

Figure 5. Representation of the total displacement and von Mises stress produced on teeth and pdl in Group 2 at; a, a', b, b') 2 mm displacement height of the canine; c, c', d, d') 4 mm displacement height of the canine e, e', f, f') 6 mm displacement height of the canine

Table 3. Displacement of teeth (lateral incisors, canine and 1st premolars) along the X, Y, and Z axis

	Height of displacement	Lateral incisor				Canine				First premolar			
		Mesial point	Distal point	Incisal point	Root apex	Mesial point	Distal point	Incisal point	Root apex	Mesial point	Distal point	Incisal point	Root apex
Along Z-axis (Occluso-gingival direction) (in mm)													
Group 1	2 mm	0.00019	0.00042	0.00032	0.00021	-0.00166	-0.00196	-0.00276	-0.00005	0.00030	0.00013	0.00029	0.00013
	4 mm	0.00027	0.00024	0.00032	0.00016	-0.00058	-0.00070	-0.00101	-0.00025	0.00027	0.00016	0.00031	0.00015
	6 mm	0.00020	0.00023	0.00027	0.00018	-0.00056	-0.00067	-0.00088	-0.00022	0.00027	0.00015	0.00029	0.00015
Group 2	2 mm	0.00002	0.00012	0.00007	0.00007	-0.00167	-0.00198	-0.00278	-0.00005	0.00012	0.00004	0.00011	0.00005
	4 mm	0.00008	0.00003	0.00008	0.00005	-0.0006	-0.00072	-0.00104	-0.00025	0.00011	0.00005	0.00012	0.00006
	6 mm	0.00004	0.00003	0.00005	0.00006	-0.00058	-0.00069	-0.00091	-0.00023	0.00011	0.00005	0.00011	0.00006
Along X-axis (Bucco-lingual direction) (in mm)													
Group 1	2 mm	-0.0006	-0.00051	-0.0009	0.0004	0.00026	0.00122	0.00138	-0.0011	0.00016	0.00010	0.00011	0.00006
	4 mm	-0.0003	-0.00014	-0.0004	0.00014	-0.00013	0.00013	0.00028	-0.0003	0.00004	-0.00008	-0.00005	0.00009
	6 mm	-0.0003	-0.00014	-0.0004	0.00015	-0.00005	0.00018	0.00021	-0.0003	0.00005	-0.00004	-0.00001	0.00008
Group 2	2 mm	-0.0003	-0.00022	-0.0004	0.00022	0.00027	0.00123	0.0014	-0.0011	0.00012	0.00003	0.0001	0.00004
	4 mm	-0.0001	-0.00002	-0.0002	0.00007	-0.00011	0.00015	0.00031	-0.0003	0.00006	0.00001	0.00003	0.00005
	6 mm	-0.0001	-0.00001	-0.0002	0.00007	-0.00004	0.00019	0.00023	-0.0003	0.00007	0.00002	0.00005	0.00005
Along Y-axis (Antero-posterior direction) (in mm)													
Group 1	2 mm	0.00015	0.00051	0.00028	-0.00028	0.00004	0.00006	0.00158	-0.0013	-0.00013	-0.0003	-0.00045	0.00026
	4 mm	0.00004	0.00031	0.00003	-0.00022	0.00009	0.00006	0.00046	-0.0004	-0.00007	-0.00017	-0.00031	0.00013
	6 mm	0.00007	0.00036	0.00016	-0.00021	0.00011	0.00012	0.00036	-0.0004	-0.00007	-0.00014	-0.00028	0.00013
Group 2	2 mm	0.00016	0.00039	0.00027	-0.00017	0.00005	0.00009	0.00160	-0.0013	-0.00001	-0.00011	-0.00017	0.00016
	4 mm	0.00004	0.00027	0.00012	-0.00013	0.00010	0.00012	0.00048	-0.0004	0.00002	-0.00004	-0.00010	0.00008
	6 mm	0.00001	0.00029	0.00019	-0.00013	0.00013	0.00014	0.00038	-0.0004	0.00001	-0.00003	-0.00009	0.00008

Group 1 (modeled with a single 0.012" NiTi continuous straight ovoid form archwire) and Group 2 (modeled with a 0.018" SS straight ovoid form base wire with straight 0.012" NiTi in piggyback)

reduced stresses on both adjacent teeth at 4 mm displacement (0.032 and 0.079 MPa on the lateral incisor and 1st premolar).

Directional changes along the occlusogingival direction (Z-axis) showed extrusion of the maxillary canine, with the maximum extrusive movement of the incisal point observed at a vertical height of 2 mm in both groups. However, Group 2 exhibited larger occlusal displacement of the canine at all three levels of vertical displacement. The total amount of extrusion of the maxillary canine decreased as the vertical height increased from 2 mm to 6 mm. Similarly, the reactionary forces acting on the lateral incisors and first premolar resulted in intrusive action on both teeth. There was a relative distal tipping of the lateral incisors, with more intrusive movement of the distal point compared with the mesial point. This discrepancy was greater in Group 1. A similar pattern was observed in the maxillary first premolar, showing a mesial tipping movement with more intrusive movement on the mesial point as compared to the distal point, with the relative difference being greater in Group 1. A summary of the movement along the Z-axis (occlusogingival direction) is shown in Table 3.

In the anteroposterior plane (Y-axis), the adjacent maxillary lateral incisor and first premolar in both groups showed distal and mesial movement of the crown. Among the different vertical displacements, the 4 mm model showed the least amount of reactionary forces, with the maximum effect observed with the 6 mm model in both groups. Similarly, Group 2 showed decreased reactionary forces on the adjacent teeth in all three models (2 mm, 4 mm, and 6 mm) compared with Group 1. The ectopically positioned canine showed uniform extrusive movement of the teeth in both groups (Table 3).

In the buccolingual direction (X-axis), the incisal tip of the canine showed palatal crown movement with buccal root movement of the root apex in both models. Similarly, the lateral incisor and premolar reported similar movements with the maximum displacement being 2 mm. A summary of the maximum values observed in the two groups is presented in Table 3.

The stress patterns observed on the canine and adjacent teeth in the continuous archwire technique (Group 1) increased proportionally with vertical displacement. The highest stress concentration on the canine was on the incisal third of the crown at 2 mm (0.36 MPa) which progressively increased toward the middle third of the crown (0.41 and 0.44 MPa) at 4 mm and 6 mm, respectively. The lateral incisor showed the least stress concentration at 2 mm of displacement at the distal surface of the incisal third (0.11 MPa) of the crown, which progressively increased until the distal surface of the cervical third of the root at 6 mm of displacement (0.18 MPa). The first premolar also showed a similar pattern, increaseing from the mesial surface of the incisal third of the crown at 2 mm (0.09 MPa) to the middle third (0.18 MPa) at 6 mm displacement. The maximum stress observed for the lateral incisor and first premolar was in the 4 mm displacement model, 0.20 MPa and 0.19 MPa. Table 2 summarizes the maximum von mises stress on the teeth (lateral incisor, canine and premolar). Both the piggyback technique and the continuous archwire technique displayed similar stress patterns on all teeth. Tensile and compressive stresses were concentrated on the PDL near the CEJ and apices of the lateral incisor, canine, and first premolar as vertical displacement accompanied tipping movements. The maximum tensile and compressive stresses generally followed the vertical displacement (Figures 4 and 5).

DISCUSSION

A vertically displaced canine is a common orthodontic problem due to its timing of eruption in the arch, reduced arch perimeter, and over-retained deciduous teeth.[2,15] The present study investigates the optimal modality and level of vertical displacement at which an ectopically positioned canine should be engaged in straight wire mechanics with minimum counter effects on adjacent teeth. The engagement of a continuous arch wire on vertically displaced canines results in intrusive and tipping forces on adjacent teeth. It can also result in canting of the occlusal plane due to the indeterminate nature of the forces.[16] Nanda et al.[17] described that full arch engagement of a highly displaced canine without a lacebark can lead to flaring of incisors (rowboat effect) and extrusion of the anterior teeth. The piggyback technique is often used to address this problem, aligning the displaced canine with a flexible wire while a rigid archwire supports the other teeth from these unwanted forces.[6]

In the present model, vertical forces (80-100 gms) on the ectopically placed maxillary canine were simulated by the deflection of a straight ovoid NiTi wire. The force magnitude was verified in accordance with by Theodorou et al.'s[18] systematic review, which recommends a force magnitude between 50 and 100 g for optimal orthodontic tooth movement with minimal adverse effects.The canine displacement in the piggyback model provided a marginally larger extrusive movement on the canine. However, extrusive forces decreased as the height of the canine displacement increased, with the largest displacement observed at 2 mm in both groups (Table 3). Previous studies by Kim et al.,[11] and Bacetti et al.,[19], have shown similar results. This decrease in the canine displacement with increased height can be attributed to binding at the bracket-wire interface due to increased deflection of the flexible wire. This indicates that the available force is not proportional to the vertical displacement of the canine.

Furthermore, the continuous archwire model showed variations in the amount of intrusion in adjacent teeth at different heights (Table 3). The largest intrusion effect in the lateral incisor was seen in the 2 mm model, followed by the 6 mm model, with the least intrusion in the 4 mm model. For the first premolar, the 2 mm model produced the least amount of intrusion, while the 4 mm and 6 mm displacement models produced similar amounts of intrusion. These results were contrary to Kim's[11] findings, which showed a steady increase in intrusion of adjacent teeth with vertical displacement. This difference could be due to the incorporation of the buccal inclination of the canine. The lateral incisor showed a greater intrusive effect than the first premolar at all three heights of displacement, which concurs with the results of Kim[11] and Wu[12] , correlating with differences in the root surface area of the lateral incisor and first premolar. In the piggyback group, a similar pattern of intrusion effect on the adjacent teeth was observed, but the amount of intrusion was significantly lower than in the continuous archwire group (Table 3).

In the antero-posterior direction (Y-axis), both the techniques showed a similar pattern. The continuous archwire technique exhibited the highest reactionary moments at the 2 mm displacement model, followed by the 6 and 4 mm models, with the lateral incisor and first premolars tipping toward the vertically displaced canine (Table 3). Kim et al.,[11] Wu et al.[12] and Fok et al.,[20], reported similar results, concluding that reactionary forces from vertically displaced canines caused distal tipping of the lateral incisors and anterior tipping of the first premolar. However, Kim et al.[11] further reported that increased vertical displacement of the canine led to increased reactionary forces on the adjacent teeth, which contrastd with the present study's findings. This variation may be due to the differences in parameters, because the height of canine displacement was measured only up to 3 mm. The Piggyback group showed reduced reactionary moments in the adjacent teeth compared with the continuous archwire model. The canine showed equal displacement of the mesial and distal points at all levels of displacement, suggesting a uniform extrusive tendency.

In the buccolingual direction (X-axis), Group 1 displayed uncontrolled tipping in both the canine and adjacent teeth. Fok et al.[20] reported a buccal force acting on the entire segment of the continuous arch when engaged on a highly displaced canine. The lateral incisor reported the greatest amount of uncontrolled tipping with palatal root movement at 2 mm, followed by 6 mm and the least in the 4 mm displacement model. The first premolar showed the highest amount of tipping at 4 mm, followed by 6 mm and the least at 2 mm (Table 3). Similar movement was observed in the first premolar but with comparatively less displacement than in the lateral. This uncontrolled tipping could result in a lateral open bite, a common side effect reported when engaging a continuous archwire in highly displaced canines.[6,7] In Group 2, the canine reported a similar pattern of uncontrolled tipping as in Group 1 model, but the amount of palatal root movement in the adjacent teeth was significantly reduced. The lateral incisor experienced half the amount of palatal root movement when compared with Group 1, with 2 mm showing the highest amount, followed by both the 4 mm and 6 mm models. The first premolar also showed less palatal root movement, with 2 mm having the least and both 4 mm and 6 mm reporting similar amounts.

Evaluating the stress pattern on individual teeth in both groups, the maximum von Mises stress in the PDL decreased as the displacement height increased. This result is accurate as the displacement also decreased with increased height. Similar reductions in maximum von Mises stress were observed in the PDL of both groups, with Group 2 showing significantly reduced stress on both adjacent teeth. Individual compressive and tensile stresses produced by the canine and adjacent teeth were also measured. The canines experienced generalized tensile stress, except for the buccal surface at the apical third, which experienced increased compressive stress due to the buccal root movement in both groups. Wilson et al.[21] reported a similar finding with extrusive forceapplied to the canine. Rudolph[13] and Penedo[22] found that compressive stress on the adjacent teeth was similar to that observed in this study, with compressive stress at the root surface and localized tensile stress on the buccal surface of the apical third of the PDL, suggesting palatal root movement.

The present study concluded that the continuous archwire does not have harmful effects on adjacent teeth as long as the vertical displacement is within 2 mm. The piggyback technique serves as an alternative with reduced reactionary effects and should be used for vertical displacements up to 4 mm. For displacements greater than 4 mm, alternative methods of extrusion, such as segment mechanics and vertical elastics, should be explored with further finite element studies.

Study Limitations

The study had a few limitations, including approximation in the material behaviors and geometry of the tissue like PDL, which was modeled as linear elastic with uniform thickness. Clinically, the PDL exhibits nonlinear, anisotropic, viscoelastic properties with an hourglass shape structure, which may affect the stress value and distribution patterns.

CONCLUSION

This study derived the following conclusions:

• The vertical forces generated for the extrusion of vertically displaced canines are transferred to adjacent teeth as reactionary forces, causing distal tipping of the lateral incisors and mesial tipping of the first premolars.

• The optimal level of engagement of a vertically displaced canine with continuous arch mechanics is at a vertical displacement of 4 mm.

• Piggyback mechanics serves as a superior treatment modality with significantly reduced counter effects on adjacent teeth during the extrusion of vertically displaced canines.

• Less tooth movement of the canine is observed in continuous arch mechanics when the vertical displacement exceeds 4 mm.

Ethics

Ethics Committee Approval: Manav Rachna Dental College institutional ethical clearance (ref. no: MRDC/IEC/2019/525, date: 26.12.2019) was obtained before starting the study.

Informed Consent: Written informed consent was obtained from the patient who agreed to take part in the study.

Author Contributions: Concept - S.K., Design - P.B., S.K., A.T., Supervision - P.B., N.A., A.K.S., A.T., Fundings - S.M., Data Collection and/or Processing - S.M., N.A., Analysis and/or Interpretation - A.T., Literature Review - S.M., P.B., N.A., A.K.S., Writing - S.M., N.A., A.K.S., Critical Review - P.B., A.T.

Conflict of Interest: The authors have no conflicts of interest to declare.

Financial Disclosure: The authors declare that this study has received no financial support.

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TURKISH JOURNAL OF ORTHODONTICS

DOI: 10.4274/TurkJOrthod.2024.2024.4

Review

Clear Aligner Therapy Concerns: Addressing Discrepancies Between Digitally Anticipated Outcomes and Clinical Ground Realities

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Cite this article as: Bichu YM, Weir T, Zou B, Adel S, Vaid NR. Clear Aligner Therapy Concerns: Addressing Discrepancies Between Digitally Anticipated Outcomes and Clinical Ground Realities. *Turk J Orthod.* 2024; 37(2): 130-139

Main Points

- The discrepancies between the digitally prescribed and clinically achieved outcomes are comprehensively reviewed.
- Achieving predictability, efficacy, and efficiency requires a multifaceted approach.
- More robust researches are needed to bridge this gap.

ABSTRACT

Expeditious strides in the fields of biomaterials, computer-aided design, and manufacturing have catapulted clear aligner therapy (CAT) to become a comprehensive orthodontic treatment modality. The efficiency of achieving planned tooth movement with clear aligners is a significant consideration while setting up the final treatment goals, as well as calculating treatment times and costs based on the available evidence. Contemporary research outcomes confirm that one of the most commonly reported clinical concerns with CAT is the discrepancy between the prescribed outcome in the digital treatment plan and the clinically achieved outcome from a given series of aligners. Inaccurate prediction of tooth movements may not only lead to a prolonged duration of aligner treatment with an additional need for refinement strategies; but it may also cause other concerns, such as patient burnout and increased potential for relapse. The authors of this paper have elucidated some of the critical elements that may help address this discrepancy between digitally prescribed and clinical outcomes based on an evidence-based approach with regard to the predictability and accuracy of CAT. A strong diagnostic acumen, judicious case selection, solid biomechanical understanding of various types of orthodontic tooth movements, a research framework that keeps pace with technological and material developments and provides evidence-based knowledge of the limitations of CAT; and above all, the ability of the clinician to continually innovate as per different clinical scenarios, all contribute to attaining treatment predictability, efficacy, and efficiency with CAT.

Keywords: Clear aligners, predictability, efficacy, efficiency, treatment outcomes

INTRODUCTION

Expeditious strides in the fields of biomaterials, computer-aided design, and manufacturing have catapulted clear aligner therapy (CAT) into becoming a comprehensive orthodontic treatment modality. Clear aligners have witnessed an unprecedented demand over the last decade, possibly due to aggressive marketing by commercial clear aligner manufacturers and the widespread utilization of social media channels.[1] A recent market analysis

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Received: January 07, 2024 **Accepted:** April 15, 2024 **Publication Date:** June 30, 2024

report[2] revealed that the global clear aligner market size has surged to USD 5.13 Billion in 2023, and a survey conducted across North America reflected the sentiment that more orthodontists in the younger generations believe that clear aligners will be the main technique to treat malocclusions.[3]

The efficiency of achieving planned tooth movement with clear aligners is a significant consideration while setting up the final treatment goals, as well as when calculating treatment times and costs based on the available evidence. Compromised treatment outcomes after aligner use might be related to the inherent inability of the appliance to achieve the anticipated amount of tooth movement at the beginning of the treatment because this is prescheduled through prediction models or company-driven prediction software.[4]

Studies have identified specific tooth movements that are difficult to predictably attain in clinical settings, which relate to both the type of tooth being moved and the direction of tooth movement.[5,6] Inaccurate prediction of tooth movements may not only lead to a prolonged duration of aligner treatment but may also cause other concerns, such as patient burnout and increased potential for relapse.

A recent overview of systematic reviews (SRs) and meta-analyses examining the predictability and clinical effectiveness of clear aligners compared with fixed appliances (FAs) has indicated that the current evidence on this matter is of low quality. While CAT can be used for treating complex malocclusions, it tends to produce less precise outcomes than FAs.[7] Additionally, another SR, which evaluated the available evidence on the effectiveness and efficiency of CAT in complex cases involving premolar extractions compared with FAs, also suggested that FAs hold the advantage of achieving superior buccolingual inclination and occlusal contacts within a shorter treatment duration.[8] It is important to note that while previous studies, including the current paper, use “clear aligner therapy” or “CAT” as a broad term, the individual studies within the referenced SRs primarily focused on the Invisalign system. The exception is the study by Zhang et al.,[9] who evaluated custom aligners produced in a university laboratory; Lombardo et al.,[10] who investigated F22 clear aligners, and Tepedino et al.,[11] who studied Nuvola systems, Jaber et al.,[12] who compared in-house clear aligners with FAs. Although these other types of aligners may impact the presented results, the findings and subsequent discussion can generally be applied to the commercial brand Invisalign, with the terms “clear aligners” or “CAT” used interchangeably. The significant implications of this overview, which summarizes contemporary evidence on the predictability and effectiveness of CAT, are outlined below.

Contemporary CAT Research Outcomes: An Overview

Predicted versus Achieved Results for Different Types of Tooth Movement

The assessment of Computer-Aided Tooth movement (CAT) involves comparing predicted and actual tooth movements, typically expressed as a percentage or numerical measurement (in mm or °). This has led to numerous studies aiming to evaluate CAT’s reliability. Most systematic reviews [13-17] included in analyses have shown low-quality evidence, except for one by Rossini et al.,[18] which was deemed moderate and focused on CAT’s efficacy in controlling orthodontic tooth movement. Conflicting results regarding CAT predictability stem from varying software capabilities, tooth types, study methodologies, and outcome reporting (Table 1).

CAT appears relatively reliable for horizontal movements[13-15] but less so for rotations, particularly in canines and premolars, due to anatomical constraints.[13-15,17,18] Even with Invisalign attachments, canine accuracy may be compromised because the curved anatomical surface of the canine could reduce the dynamics of the attachment grip.[17] Interproximal reduction (IPR) of enamel and derotation direction also influence efficacy, with mesial movements being more predictable.[14,19] Torque control, especially in arch expansion and anterior teeth, remains challenging.[13,15] Invisalign’s G8 enhancements improve posterior arch expansion and torque control,[20] however, further research is still needed.

Limited torque control for anterior teeth has also been observed.[13-16] CAT may produce clinically acceptable outcomes for minor buccolingual inclination of upper and lower incisors, albeit with a low level of evidence.[15] For extraction cases with Invisalign, power ridges and attachments on central incisors

Table 1. Summary of data synthesis from systematic reviews - predictability and/or accuracy (predicted versus achieved outcomes)

Treatment outcome	Summary of data synthesis from included systematic reviews
Predictability and/or accuracy (predicted vs achieved)	1. Teeth inclinations and occlusal contacts among limitations of Invisalign, when accuracy of planned movements achieved with aligners is concerned (Papadimitriou et al.,[13] 2018). 2. Expression of programmed movement is not fully accomplished with Invisalign (Galan-Lopez et al.,[14] 2019). 3. Most tooth movements with CAT not predictable enough except for minor horizontal movements. Predictability of minor extrusion of anteriors has increased compared to conclusions of previous SRs (Robertson et al.,[15] 2020). 4. Accuracy of movements for upper incisors ranges from 18.3% to 85%. For upper centrals: horizontal movements (especially rotation) most predictable and vertical movements less predictable. For upper laterals, horizontal movements (especially labiolingual tipping) most predictable and vertical movements less predictable (Collard et al.,[16] 2020). 5. Comparison between software-predicted and actual rotational movements showed low percentage accuracy for anteriors and premolars. Prediction of rotational movements with CAT not accurate, especially for canines. Selection of patients and malocclusions for CAT remains challenging (Koletsi et al.,[17] 2021).

CAT, clear aligner therapy; SRs, systematic reviews were recommended, especially in adults, because incisor torque loss was more obvious in adults than in adolescents when the same predicted incisor torque was prescribed.[6]

Vertical movements pose greater challenges,[14-16,18,21] with maxillary anterior tooth extrusion being the least accurate.[18,22] Novel attachments may improve outcomes, with extrusion showing greater predictability than intrusion, particularly in anterior open bite cases.[13] Maxillary incisors may undergo unintended extrusion, whereas posterior teeth may be apically placed.[15] This could explain why the absence of occlusal contacts and posterior open bites are commonly observed during CAT. G8 enhancements target deep bite correction, suggesting potential benefits from pre-intrusion spacing for lower incisors.[20]

Overall, while CAT shows promise for certain movements, further research is crucial to enhance its efficacy and predictability, especially in complex cases.[8]

Effectiveness of CAT versus FAs

The summary of the clinical efficacy and effectiveness of CAT (Tables 2 and 3), primarily in contrast with traditional FAs, was drawn from evidence compiled from nine SRs[8,13-15,18,22-25] ranging from low to moderate quality.[7] The clinical effectiveness of clear aligners varied across these SRs due to diverse factors, including differences in study designs. It is important to note that treatment outcomes may not solely hinge on the appliance but also on unexplored patient and clinician factors.[26]

Table 2. Summary of data synthesis from systematic reviews - Effectiveness or efficacy of CAT versus FA

Effectiveness or efficacy of CAT vs FA	1. Low to moderate level evidence exists regarding efficiency of CAT for certain movements. Whole array of malocclusions to be efficiently treated with CAT has not been covered by included studies. CAT may produce clinically acceptable outcomes comparable to FA for minor buccolingual inclination of upper and lower incisors. Treatment time required to achieve results comparable to FA has not been investigated yet (Robertson et al.,[15] 2020). 2. Orthodontic treatment with CAT is associated with worse treatment outcomes compared to FA in adult patients. Current evidence does not support clinical use of aligners as a treatment modality equally effective to gold standard of braces. No significant differences seen for treatment duration. Treatment duration not defined by appliance alone, and patient or treatment-related factors might come into play (Papageorgiou et al.,[25] 2020). 3. CAT had an advantage in segmented movement of teeth and shortening treatment duration. Braces were more effective in achieving great improvement, producing adequate occlusal contacts, controlling teeth torque, and increasing transverse width and retention than aligners (Ke et al.,[24] 2019). 4. Vertical movement and derotation are difficult movements to accomplish with aligners. IPR is recommended, especially in canines and in cases of crowding. There is better root control with fixed appliances. Buccolingual inclination and occlusal contacts are worse with Invisalign. Although it is possible to treat complex malocclusions with plastic systems, results are less accurate than those achieved with FA (Galan-Lopez et al.,[14] 2019). 5. Clear aligners: a. are effective in correcting dental crowding; b. present limitations regarding intrusion and extrusion of teeth, and in not promoting proper occlusal contact; c. Higher recurrence of crowding observed with Invisalign compared to FA; d. Little difference in treatment duration compared to braces (Pithon et al.,[22] 2019). 6. Invisalign might treat mild non-extraction cases faster but requires more time than FA for more complex cases. Invisalign can safely straighten dental arches in terms of levelling and derotating teeth (except for canines and premolars, where a small inadequacy was reported). Crown tipping can be easily performed. Teeth inclinations and occlusal contacts seem limitations of Invisalign (Papadimitriou et al.,[13] 2018). 7. Both CAT and FAs are effective in the orthodontic treatment of premolar extraction-based cases. FAs have the advantage of achieving better buccolingual inclination and occlusal contacts in a shorter treatment duration (Jaber et al.,[8] 2023).

CAT, clear aligner therapy; FA, fixed appliance; IPR, interproximal reduction

Table 3. Summary of data synthesis from systematic reviews - effectiveness or efficacy of CAT- the role of attachments and auxiliaries

Effectiveness or efficacy of CAT- the role of attachments and auxiliaries	1. Anterior root torque can be improved by using auxiliaries, such as power ridges and attachments. However, these may still be insufficient to ensure the right root control. 2. Posterior anchorage seems important to ensure greater control during anterior teeth retraction, which can be improved by adding attachments on greater number of teeth (from canine to second molar). Optimized and rectangular horizontal attachments have shown best results. 3. Evidence of influence of attachments on intrusion and extrusion is lacking, although attachments seem to improve intrusion. 4. Conflicting results about ability of attachments to improve rotational control. Majority of studies showed positive influence of attachments on derotation, although not statistically significant. Using two attachments on buccal and palatal sides or adding attachments on adjacent teeth may not improve rotation. Larger attachments with sharper edges showed better outcomes. 5. Use of attachments could increase molar mesiodistal movement efficacy; however, this improvement may not be clinically significant. 6. No clinical studies evaluated posterior buccolingual tipping/expansion. 7. Further clinical studies necessary to confirm above findings and increase knowledge about influence of attachments on different types of movement. (1-7 from Nucera et al.,[23] 2022). 8. CAT is not based on aligners alone and requires use of auxiliaries (attachments, interarch elastics, IPR, altered aligner geometries) to improve predictability. (Rossini et al.,[18] 2015).

CAT, clear aligner therapy; IPR, interproximal reduction

CAT demonstrates effectiveness in aligning and straightening dental arches, particularly beneficial for mild to moderate crowding in non-growing patients compared with FAs.[15,18,22] However, if crowding exceeds 6 mm, the incisors may tend to procline and protrude after alignment with CAT.[14] The ability of CAT to modify intercanine, interpremolar, and intermolar widths is comparable to that of FAs and aids in resolving crowding.[14,22] However, arch expansion through bodily tooth movements remains a limitation according to some SRs.[13,14,24] In addition, CAT is noted to have an advantage in treating segmented tooth movements.[24]

Current evidence, ranging from low to moderate certainty, suggests that CAT may yield inferior treatment outcomes compared with FAs, particularly in larger anteroposterior/vertical corrections and achieving adequate occlusal contact.[8,13,14,18,22,24,25] However, because of limited evidence and small sample sizes, definitive conclusions on CAT's superiority or inferiority to FAs are elusive.[23] CAT has been observed to produce acceptable outcomes similar to FAs for minor buccolingual inclination of upper and lower incisors, albeit with limited evidence.[15]

Treatment duration comparisons between CAT and FAs have yielded mixed results over the years. Some SRs suggest a shorter treatment duration with CAT for mild-to-moderate cases, especially for non-extraction treatments and segmented movements.[13,23] However, inconsistencies exist, possibly due to CAT's evolving role in treating complex cases[8] and variations in patient-related factors. The scarcity of randomized controlled clinical trials (RCTs) comparing treatment times between CAT and FAs underscores the need for further investigation in this area.[15]

Limitations of Current Studies and Unavailability of Robust Research Outcomes

The overview[7] evaluated the quality of the individual SRs using the AMSTAR-2 quality assessment tool[27] and found the level of evidence to be variable. Three out of 18 (16.66%) SRs were considered to have moderate-quality evidence, eight out of 18 (44.44%) were considered to have low-quality evidence, and seven out of 18 (38.88%) were considered to have critically low-quality evidence. Thus, none of the SRs included in the mentioned overview were evaluated to provide a high level of evidence as per the AMSTAR-2 assessment tool. A recent SR was classified as having low-quality evidence because it incorporated a retracted RCT[28] among the six trials it synthesized.[8]

The number of prospective RCTs included in individual SRs was minimal, with most studies being retrospective, non-randomized, cross-sectional, or observational in design. Furthermore, the included studies could be influenced by different types of bias, such as those arising from the absence of randomization and/or concealment of allocation (selection bias); or due to the lack of blinding protocols (detection bias), and lack of standardization of treatment protocols (performance bias). In addition, several confounding factors were not considered in the included studies, such as the severity of the malocclusion, the commercial brand of the clear aligner, the specifics of the clear aligner material, patient's compliance with aligners, the total number of aligners, the use of additional or refinement aligners, and protocol for aligner change. These factors could generate bias due to the absence of standardization. Furthermore, the elevated laboratory costs associated with the fabrication of commercially available clear aligners may pose an impediment to research. Finally, rapid advances in the field of aligner materials and prediction software may prevent a direct comparison between older studies and the most recent ones.

In addition to the above general variables, data regarding the efficacy of specific features of Invisalign, such as the effects of various geometries of bonded attachments, and aligner alterations, such as power ridges and pressure points, are still lacking, despite these features having been a part of Invisalign for many years. Similarly, the possibility of using variable modulus aligners in CAT is poorly studied.

In summary, different aligner brands and materials, movement protocols, wear regimens, attachment prescriptions, and altered aligner geometries make concise analysis of generic CAT challenging for researchers. This combined with the rapid evolution of CAT means that clinicians often have to rely on inadequate or out-of-date data when making the decision to use CAT for the treatment of their patients. The need for well-designed individual clinical trials for mapping the robust evidence on CAT cannot be overemphasized.

Ground Realities of Cat Clinical Performance

This review has endeavored to focus on studies that highlight the clinical performance of aligners and evaluate the achieved outcomes relative to either FA norms or CAT digitally prescribed norms, other than the previously discussed SRs or RCTs.

Orthodontists' Perceptions of the CAT

In a recent survey of orthodontists in Australia,[29] respondents indicated particular concerns regarding the finishing of CAT cases, specifically movements that included root torque, bite opening, extrusion, and rotations. Although several SRs have been conducted and provided detailed information regarding the clinical efficacy of CAT;[13,15,18,25] unfortunately, both the rapid evolution of CAT and the plethora of more recently published studies providing increasing data demonstrate that these existing SRs lack breadth and tend to be outdated.

Occlusal Outcomes

Studies report an overall loss of posterior contact from both initial numbers of contact and those predicted, while Bowman et al.[30] highlighted a significantly greater loss of contact from the maxillary buccal occlusal surfaces than from the palatal occlusal surfaces for cases of mild-to-moderate malocclusion treatment.

Deep Bite

Research into deep bite correction using CAT has provided some most clear outcomes. In non-growing subjects, Invisalign has been routinely reported as clinically achieving 39-52% of the digitally predicted bite opening.[31-36] Possible explanations for this shortfall include a posterior bite-block effect of aligners and an inability to adequately direct apically directed intrusive forces, along with a reported shortfall in the ability to extrude posterior teeth. The only strategy for bite opening that offers moderate predictability is relative intrusion by the proclination of incisors.[37]

Open Bite

The treatment of open bite has been promoted as a strength of CAT; on the other hand, claims of relatively good predictability. Although several case reports and retrospective studies have demonstrated successful management of mild anterior open bites with CAT, primarily by incisor extrusion,[38-41] maxillary central incisor extrusion efficacy with CAT was reported by Haouili et al.[19] as 56% in a non-AOB sample, with similar efficacy for the mandibular central incisor.

Rotational Corrections

While several studies have reported shortfalls in the achieved versus predicted outcomes for rotational movements, the need to examine large samples and the requirement to separate rotational movements from other movements make a definitive assessment of predictability difficult. Haouili et al.[19] reported an overall rotational efficacy of 56% for all rotations. Studies on samples limited to individual specific tooth rotations have shown efficacy in the order of 75% for upper central incisors and lower canines. An interesting finding is that teeth are sometimes reported to rotate in a direction opposite to that intended.[42,43]

Labiolingual Crown Inclination and Torque

Although research is sparse, the conclusions of most studies indicate a shortfall in clinically achieved torque or labial crown inclination relative to that prescribed. The prescribed lingual crown tip is much more predictable than the prescribed labial crown tip in both arches and may frequently be overexpressed. Tooth movement in directions opposite to those prescribed has also been reported.[44,45]

Transverse Dental Expansion

Maxillary transverse expansion is one of the most comprehensively studied movements for CAT.[30,46-48] Shortfalls in achieved expansion versus predicted outcomes in the order of 70-80% are common findings, with efficacy declining from the canines to the more posterior teeth. Lower arch expansion is less well studied, although it appears to be slightly more predictable. Transverse expansion is routinely reported as a tipping movement rather than bodily translation.

Mesiodistal Root Tip

Studies of prescribed mesiodistal root uprighting using CAT are very rare. Two studies related to specific tooth types have found efficacy of 35% (lower incisors)[49] and 70% (upper central incisors)[41] in non-extraction treatments. Unprescribed crown tipping after premolar extraction has been reported in several studies.[6,50,51]

Addressing Discrepancy Between Anticipated Outcomes and Clinical Reality

Contemporary evidence highlights that one of the most commonly reported clinical concerns with CAT is the discrepancy between the prescribed outcome in the digital treatment plan and the clinically achieved outcome from a given series of aligners.[13,15,18,25] The current paper elucidates some of the critical elements that may help narrow the gap

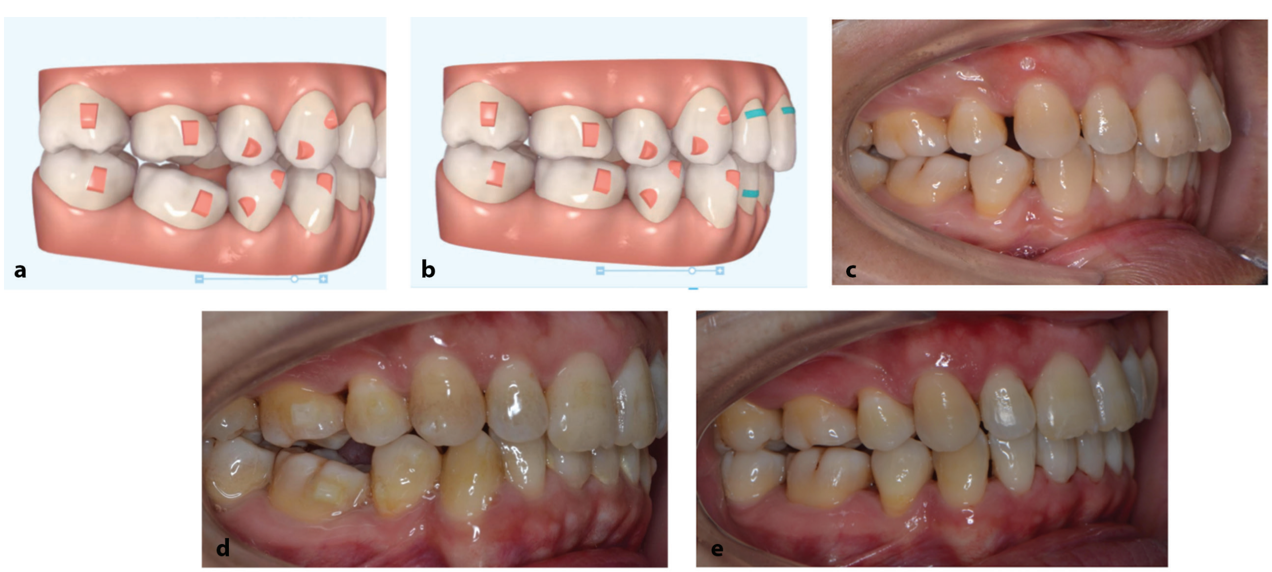


Figure 1. The discrepancy between anticipated digital outcomes and ground clinical realities, which warrants the need for refinement strategies to eventually achieve desired tooth movement. **a)** Anticipated digital outcome; **b)** Clinical ground reality; **c)** Pre-treatment photo; **d)** Molar dumping due to inappropriate biomechanical control and attachment design; **e)** Desired result post-refinement strategies

between digitally prescribed and clinical outcomes based on an evidence-based approach with regard to the predictability/accuracy of CAT. Figure 1 illustrates the discrepancy between anticipated digital outcomes and ground clinical realities, along with the need for refinement strategies to eventually achieve desired tooth movement.

Case Selection

Once a case has been adequately diagnosed, the suitability of a given case for an acceptable response to proposed orthodontic mechanotherapy is one of the most important elements to consider if treatment is to be timely and successful. All appliance systems have strengths and weaknesses, as do our clinical decisions regarding whether to extract or not, and patient biology adds a further level of discrimination. If we assume that a competent level of diagnosis and case selection is attained, our focus then shifts to the ability of our chosen mechanotherapy to achieve the desired treatment goals. As CAT is a relatively recent treatment modality, our knowledge of the strengths and weaknesses of CAT and the strategies we need to employ to overcome its weaknesses is far less complete than our knowledge of FA therapy.

Two simple considerations that apply to even basic CAT are: first, for treating mild-to-moderate crowding, evidence exists that the best results are likely to come if a) IPR is not relied upon as the primary means of space gain, as IPR is commonly underdone by approximately 50%;[52,53] b) Transverse dental expansion is either minimized or avoided, as it is commonly underexpressed in the maxilla in particular, is unstable in retention, and appears to lead to poor occlusal outcomes, including posterior open bites.[29,46-48,54] Thus, it would seem reasonable to avoid, wherever possible, both IPR and posterior expansion for the best clinical outcomes. Second, CAT tends to fail to achieve the prescribed labial crown torque to a significant degree.[43,44] This may leave the incisors visually more upright and more prone to incisor interference and posterior open bites.

Variable Modulus Aligners

Variable modulus archwire are regularly utilized in FA treatment. There is some evidence that variable modulus aligners may offer improved outcomes, with softer aligners providing improved alignment (analogous to the use of nickel-titanium archwires in fixed orthodontics) and harder aligners providing superior outcomes for bite opening,[32,33] torque,[48] and posterior intrusion.[48] Some commercial manufacturers offer variable modulus aligners, including 3M, Angel Align, and CA Clear Aligner.

Time-sensitive Aligner Change Regimes

Employing a "one-size fits-all" approach to aligner change regimens is contrary to biology. Different patients and different movements are likely to require different amounts of time. Some evidence exists that a 1-week aligner change protocol is as effective as a 2-week change for lower canine rotation, but that a 2-week aligner change is more effective for bite opening[33] and bite closing.[42] With FAs, archwire are changed as and when the desired movement has been expressed. Remote monitoring apps such as Dental Monitoring may offer a solution, particularly when monitoring alignment; however, the accuracy of these apps in determining the satisfactory progress of labiolingual root torque, bite opening, and mesiodistal root tip is yet to be proven.

Overcorrection

The overcorrection feature offered by Invisalign for desired tooth movements that are routinely known to be underexpressed is yet another facet for bridging the gap between the digital and clinical realities of clear aligner treatment. For overcorrection to be successful, it is essential to know the routine shortfalls expected of the tooth movement;[19,31,34,38,41-49] whether these movements reliably express shortfalls or whether they may express movements opposite to that prescribed;[42,43,49] and finally the appropriate timing of the overcorrections. For example, transverse expansion overcorrection is probably best placed at the end of the aligner treatment, while bite opening is necessary to permit incisor retraction and needs to be corrected early in such cases.

Attachments, Altered Aligner Geometries and Force Application to Teeth

Bonded resin attachments and altered aligner geometries are considered necessary by Invisalign to enhance the ability of Invisalign aligners to deliver appropriately directed forces to achieve desired tooth movement. However, despite the use of Invisalign attachments for more than two decades, our knowledge of the efficacy of the various proposed attachment types is limited. Evidence exists that the difference between the standard conventional attachments and the optimized attachments (the proprietary attachments from Align) is not clinically significant, at least for some tooth movements. It may also be inferred that in adults, bite ramps are ineffective at opening deep bites.[32,35,36] The clinical efficacy of Invisalign power ridges for palatal root torque is unproven even more than a decade after their introduction.

Biomechanical Considerations

Upadhyay and Arqub[55] presented the efficiency of aligners (in %) for different types of orthodontic tooth movement graphically to depict the consensus from the available literature on how good aligners actually are at moving teeth. Tipping has been demonstrated to be the most predictable tooth movement, whereas root movement or torquing was shown to be the least predictable movement, with recent literature demonstrating the mean efficiency of aligners to be around 50%. They have also succinctly summarized how achieving orthodontic tooth movement with CAT is more complex than it is with FAs, and this can be attributed to the absence of specific points of force application, variations in tooth anatomy, properties of aligner materials, mismatch between aligner and dentition geometries, slipping motions between contact shapes, and other biomechanical factors.[56] Accurate treatment prediction has long been a challenge not only for orthodontists but also for the plethora of prediction algorithms employed by multiple commercial aligner manufacturers. A practical solution for improving predictability and optimizing treatment duration is the addition of a predictable and customized adjunct to clear aligners.

Incorporation of Clinical Adjuncts into CAT

Clear aligner systems are biomechanically inadequate for achieving complex orthodontic movements on the basis of aligner use alone. The incorporation of adjuncts such as composite attachments, IPR, power ridges, auxiliary anchorage devices such as brackets, buttons, mini-screws (or similar temporary skeletal anchorage devices), and intraoral elastics, especially in scenarios such as mesialization, distalization, expansion, and/or extrusion, can help improve the predictability of CAT. Vaid et al.[57] inspired by the "Golden Circle Model", addressed questions such as the "Why, How and What" of adjuncts used in combination with CAT and have elucidated an "inside out" approach (from Why to What) to present the rationale, stepwise clinical workflow, and advantages of these adjuncts. An astute clinician who wishes to expand the repertoire of malocclusions that can be successfully managed by CAT should plan the inclusion of such adjunct appliances in their aligner treatment planning. This may help reduce the overall treatment duration and provide more predictable treatment results than those attained with clear aligners alone.

Robust Research Framework for Consistent Clinical Outcomes

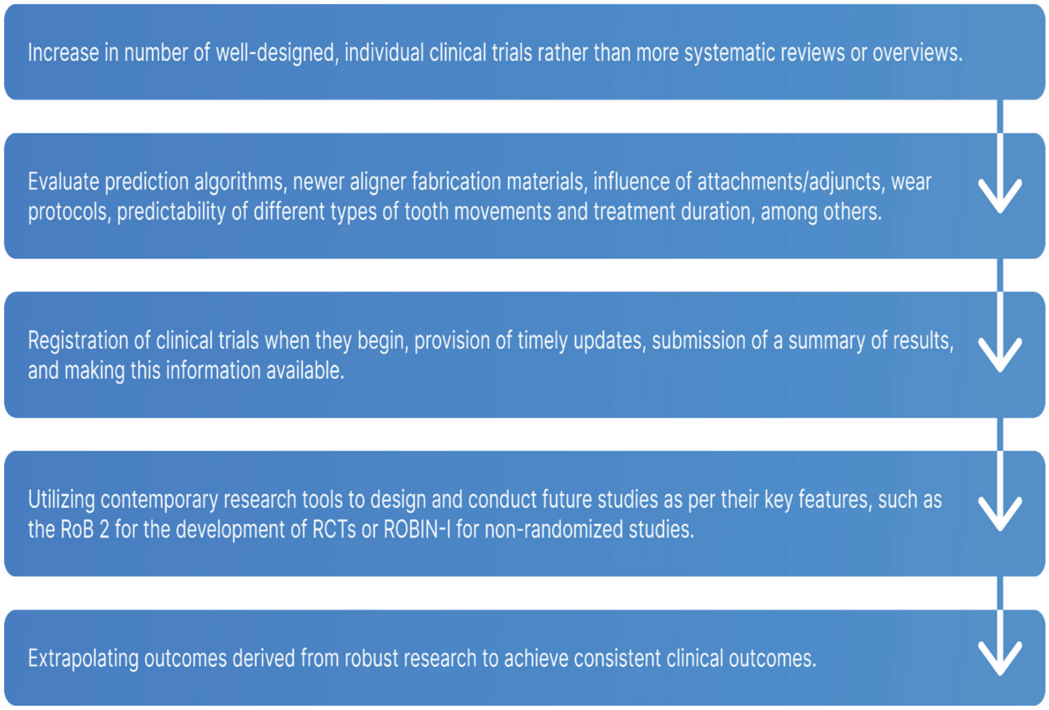
Technological advancements and their integration into any profession are essential. As clinicians we must leverage these advancements to enhance patient outcomes and shape the future of clear aligner applications in orthodontics.[58] Well-designed, individual clinical trials that thoroughly evaluate but are not limited to prediction algorithms, newer aligner fabrication materials, attachments/adjuncts, wear protocols, predictability of different types of tooth movement, and treatment duration are imperative to provide robust evidence and answer questions arising from the broad range of malocclusions that CAT is currently used to treat and to address the discrepancy between the digital and clinical reality.

Over the last two decades, research tools have considerably evolved to assess the quality of individual SRs included within an overview of SRs as well as the quality of individual clinical trials included within a single SR. These tools and methods clearly assist in categorizing the evidence obtained from individual studies, ranging from high to critically low, and inform the clinician about he degree of confidence in the information provided by a specific study. Another way of using these research tools is to plan and conduct future studies as per the key features outlined by the evidence evaluation tools, which may help in the development of a more robust research framework for the evaluation of multiple attributes of CAT and eventually lead to more consistent clinical outcomes. The current paper summarizes some of the defining steps for conducting robust studies on CAT and elucidates the essentials of some of the tools of evaluation of the evidence below.

Registration of clinical trials when they begin, provision of timely updates, submission of a summary of results, and making this information publicly available serve several purposes and benefit varied segments of the population. A results database likewise helps provide a public record of basic study results in a standardized format, promotes the fulfillment of ethical obligations toward the participants and the overall contribution of research results to medical knowledge, reduces publication and outcome reporting biases, and facilitates SRs and other analyses of the research literature.

RCTs constitute the gold standard for gleaning information on healthcare interventions. In 2019, Sterne et al.[59] developed and piloted a revised tool for assessing the risk of bias in randomized trials (RoB-2), which allows researchers to assess the risk of bias in five distinct domains. Although the role of non-randomized studies of the effects of interventions (NRSI) in determining treatment decisions remains controversial, NRSI continues to constitute an integral component of the evaluation of multiple disciplines in the field of healthcare.[60] Sterne et al.[61] (2016) described the development of ROBINS-I ("Risk of Bias in Non-randomized Studies of Interventions"), which evaluates the risk of bias in estimates of the effectiveness or safety (benefit or harm) of interventions from studies that did not use randomization to allocate interventions. Shea et al.[27] In 2017, AMSTAR 2 was devised as a critical appraisal tool to evaluate SRs that include randomized or non-randomized studies of healthcare interventions, or both. A thorough understanding of the various research tools at our disposal and the planning and subsequential conduct of clinical trials on CAT based on key fundamentals outlined by these tools will help clinical research teams design, conduct, and report the findings of clinical trials to achieve the most reliable findings possible that will eventually improve the predictability, efficacy, and effectiveness of CAT. Figure 2 outlines suggested guidelines for the development of a robust research framework for CAT studies to achieve consistent clinical outcomes.

Figure 2. Suggested guidelines for the development of a robust research framework for CAT studies to achieve consistent clinical outcomes



CAT, clear aligner therapy; RCT, randomized controlled clinical trial

CONCLUSION

Clear aligners represent one of the most significant advancements in orthodontics, exerting a growing influence in the orthodontic market. What began as an alternative appliance two decades ago has evolved into a comprehensive treatment solution.[57,58,62] The data collected from millions of patients over the past 20 years underscores the inadequacy of relying solely on a series of plastic aligners to address the diverse range of malocclusions routinely encountered in our specialty. Despite remarkable advancements in software, manufacturing, prediction algorithms, and materials, clear aligners alone are insufficient.[57,63-65]

Achieving predictability, efficacy, and efficiency with CAT requires a multifaceted approach. Strong diagnostic skills, careful case selection, a thorough understanding of biomechanics, ongoing research to keep pace with technological advancements, and a keen awareness of CAT's limitations are essential. Moreover, clinician innovation tailored to individual clinical scenarios is paramount.[55,57,66] These factors collectively contribute to bridging the gap between digitally anticipated outcomes and the clinical reality associated with CAT.

Ethics

Author Contributions: Concept – B.Z., Y.M.B., S.A., N.R.V.; Design – T.W., B.Z., S.A., N.R.V.; Data Collection and/or Processing – Y.M.B., T.W., B.Z.; Analysis and/or Interpretation – T.W., B.Z., S.A., N.R.V.; Literature Review – Y.M.B., T.W., B.Z.; Writing – Y.M.B., T.W., B.Z.; Critical Review – B.Z., S.A., N.R.V..

Declaration of Interests: The authors have no conflicts of interest to declare.

Funding: The authors declare that this study has received no financial support.

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