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The Effect of Intrusive Forces on Root Resorption of Anterior Teeth in Class II Division 2 Deep Bite Cases Induced by Placement of Mini-Screw Implants and Intrusive Archwires. A Randomized Clinical Trial.

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Abstract
Introduction:The aim of this study was to investigate the effect of intrusive forces generated during the treatment of deep over-bite in Class II division 2 cases on root resorption, by using two different mechanics, mini-screw implants and intrusive archwire. Cone beam computed tomography (CBCT), was used in this study to determine the degree of root Resorption.
Design: This study was done according to the CONSORT Statement adaptations for orthodontic trials , the study design is a single center randomized clinical trial, parallel design where participants were randomly assigned to either interventional or comparison group with a 1:1 allocation ratio. Participants: Fourteen Class II Division 2, deep bite cases, age range from 15-25 years, and having deep-bite of more than 5 mm, were recruited from the Outpatient Clinic at the Department of Orthodontics, Faculty of Dentistry, Cairo University from March 2015 to March 2017.
Results:Mini-screw group showed statistically significantly higher mean root length than Archwire group. As regards root resorption, there was no statistically significant difference between mean root resorption values in the two groups.
Conclusion: Mini-screws showed higher mean root length decrease than archwire group. As regards root resorption, there was no statistically significant difference between mean root
resorption values in the two groups.
Keywords: *Mini-screws, Intrusive arch, Class II Division 2.*

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I. Introduction

Deep bite is a complex orthodontic problem that is encountered in many malocclusions, and can be considered a damaging form of Malocclusion as it may endanger the periodontal ligament, TMJ and palatal mucosa. A decrease in vertical skeletal growth, axial inclinations of the upper and lower anterior teeth, vertical positions of the anterior and posterior teeth, and loss of periodontal support are among the factors that contribute to deepening of the bite[1].

Class II division 2 malocclusion is a type of malocclusion that is always presented with severe deep bite, lingually inclined upper central and lower incisors, and labially flared maxillary lateral incisors. This malocclusion also tend to exhibit problems with the upper and lower occlusal planes, such as deep curves of Spee. The soft-tissue drape of the lips often conforms to the malocclusion, so that the lips may be redundant with a deep mento-labial sulcus[2].

Treatment of deep overbite can be achieved with various mechanics; extrusion of posterior teeth, intrusion of the incisors, or both. The treatment of choice depends on a variety of factors such as smile line, incisor display, and vertical dimension. Conventional methods of incisor intrusion usually involve appliances such as utility arches, 3-piece intrusion arches, or reverse curved arches. Labial tipping of the anterior teeth is commonly the outcome of these arches and gives the impression of deep-bite correction from the change in the vertical incisal edge positions. However, incisor protrusion is not the desired effect in patients with normal axial inclinations and in extraction patients who will need incisor retraction[3].

Correction of deep overbite in Class II division 2 malocclusion can be achieved with several mechanisms, one such mechanics is true intrusion of anterior teeth[1]. Deep overbite correction by intrusion of anterior teeth affords a number of advantages which includes simplifying control of the vertical dimension and allowing forward rotation of mandible to aid in Class II correction. It also aids in correction of a high gingival smile line.

The introduction of skeletal anchorage as a source of stationary anchorage to orthodontic forces has made most complex tooth movements simple. Because of their small dimensions, mini-screws offer the advantages of immediate loading, multiple placement sites, relatively simple placement and removal, placement in interdental areas where traditional implants cannot be placed, and minimal expenses for patients. Recently, the introduction of mini-implants into intrusion mechanics has been used as an alternative technique to conventional methods, which have side effects on anchorage segments such as narrowing of the buccal segment and elongation and distal tipping of the posterior teeth[4].

Intrusive mechanics is frequently related to the occurrence of apical root resorption. The concentration of orthodontic forces on the root, especially on the apex, can cause biological changes in the cementum and periodontal ligament, resulting in root resorption.Though the effectiveness of mini-implants in intrusion mechanics have been studied thoroughly, the effect on root resorption of the incisors is limited[5].

Detection of root resorption was usually done by means of periapical radiographs, panoramic radiographs, and scanning electron microscopy (SEM), but these methods are subject to magnification errors and unreliable reproducibility. Moreover, root resorption is a three-dimensional phenomenon, and conventional radiographs provide only two- dimensional representations. Therefore, a precise diagnostic method of imaging is needed to diagnose root resorption, which is possible only by three-dimensional volumetric evaluation. Recently, cone-beam computed tomography (CBCT), is wildly used for dental imaging in the field of root resorption research[5].

II. Materials and Methods

This study was done according to the *CONSORT Statement adaptations for orthodontic trials* throughout the materials and methods, results and discussion sections in order to produce high quality evidence with minimum bias. Figure (1)

Table 1 | CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts[43-45])	
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	
	2b	Specific objectives or hypotheses	
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	
Participants	4a	Eligibility criteria for participants	
	4b	Settings and locations where the data were collected	
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	
	6b	Any changes to trial outcomes after the trial commenced, with reasons	
Sample size	7a	How sample size was determined	
	7b	When applicable, explanation of any interim analyses and stopping guidelines	
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	
	13b	For each group, losses and exclusions after randomisation, together with reasons	
Recruitment	14a	Dates defining the periods of recruitment and follow-up	
	14b	Why the trial ended or was stopped	
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms[47])	
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	
Other information			
Registration	23	Registration number and name of trial registry	
Protocol	24	Where the full trial protocol can be accessed, if available	
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	

Figure (1)

2.1*Trial Design*: The study design is a single center randomized clinical trial, parallel design where participants were randomly assigned to either interventional or comparison group with a 1:1 allocation ratio. No changes to the methods after trial commencement occurred.

2.2 Participants: Patients were recruited from the Outpatient Clinic at the Department of Orthodontics, Faculty of Dentistry, Cairo University from March 2015 to March 2017. This study was approved by the Research Ethics committee, Faculty of Dentistry, Cairo University approved this study. All patients were informed about the study procedures.

Participants were further divided according to the following eligibility criteria :

Inclusion criteria:

- Class II Division 2, deep bite cases; more than 5 mm.
- Age range 15-25 years.
- The lower incisor edges occlude behind the cingulum of the upper incisors and the upper incisors are retroclined. (The British Standards Institute's classification of incisor relationship).
- Full cusp angle class II molar relation.
- No pervious orthodontic treatment
- Radiographs reveals no signs of root resorption •Patients should be free from any systemic diseases.
- No Sex Predilection.
- The Patient must have good oral hygiene and should comply to instructional motivation to provide a reasonable prognosis.

Exclusion criteria:

- Previous orthodontic treatment.
- Radiographs reveal presence of root resorption.
- Presence of any pathologic condition that may interfere with treatment.

2.3 Intervention: A strap up was done at the beginning, then allocation of the subjects was done at the day of placing the screws or the intrusive arch by using opaque sealed envelops, to randomly allocate the subjects, to avoid selection bias. Both the clinician and the patients were not blinded due to the nature of the clinical trial, but the clinician was not able to know the technique used till the day of the procedure.

2.4 *Case History and Clinical Examination:* This study protocol was approved by the Ethics committee of the faculty of dentistry, Cairo university, and a written consent was obtained from each patient. *Patient's Records:* For each patient the following records were taken prior to treatment and upon completion of the treatment period. *Photographs:* A set of 9 photographs were taken for every patient; 4 extra- oral photos and 5 intra-oral photos. Figure (2)

Figure (2)

Cone Beam Computed Tomography (CBCT): For each patient two CBCT scans were obtained; one pre-operative and another after completion of intrusion. CBCT images were acquired using a Next Generation i-CAT scanner (Imaging Sciences International, Inc., Hatfield, USA) Figure (3). After acquisition, data were exported and transferred in DICOM format and downloaded via a Compact Disk (CD) to a personal computer for analysis, where, Invivo Dental software (version 5.1; Anatomage, San Jose, CA, USA) was utilized. Figure (3)

Figure (3)

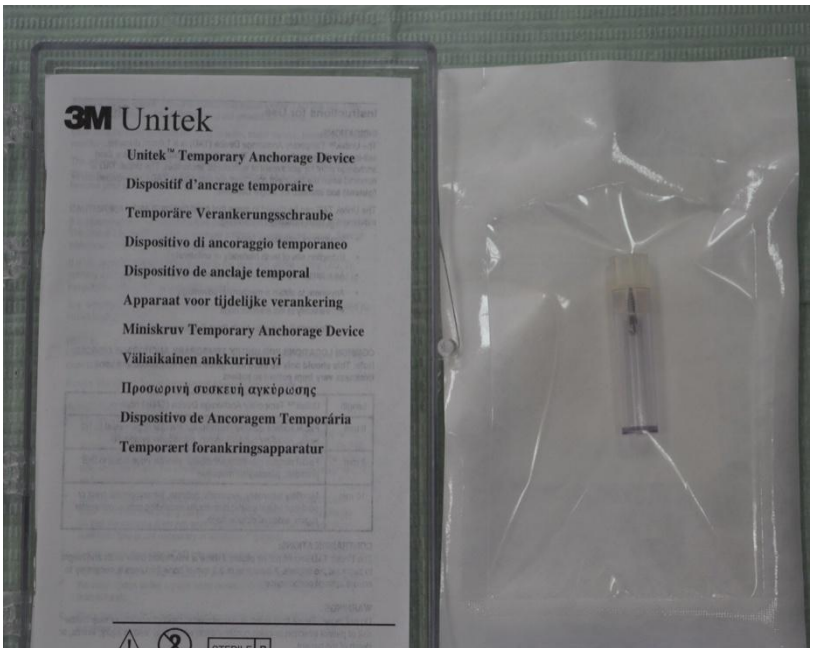
2.5 Mini-Screw group preparation: Before starting any intervention a bonding was done first, then allocation of the subjects was done at the day of placing the screws or the intrusive arch. Unfortunately, and due to the nature of the class II division 2 classic appearance, overlapped lateral incisors, some lateral incisor teeth were severely overlapped and tipped, with the central incisors, so laterals were bypassed, to avoid their effects on the nature of the case during leveling and alignment. Alignment aids in the paralleling of the roots to make the insertion of mini-screws more easy, to avoid any unwanted contact with the roots of the anterior teeth. The anterior teeth are then, ligated to act as a one unit during intrusion, then the anterior segment will receive, a rectangular heavy arch wire (17x25 St.st) to consolidate the anterior segment. Figure (4)

Figure(4)

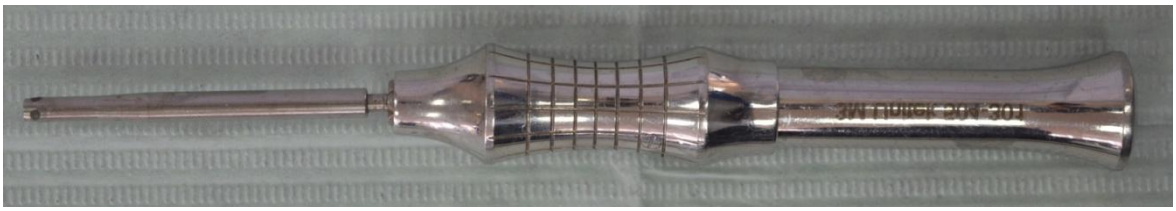
Subjects were ready for the screw insertion, all screws used in this study were (3M, Unitek)* with diameter 1.6 mm, length 6mm., self-drilling, were chosen due to the limited interradicular space in the anterior segment. Figure (5). Immediately prior to screw insertion the anterior region is disinfected with a cotton pellet soaked with Betadine(Povidone-iodine 10%). (3M Unitek)* Screw driver was used during all the trials, to insert all the mini-screws, Figure (6). Due to the great anatomical variations in the anterior region, some screws were not inserted on the same level, but standardization of the amount of the force applied was maintained by using same force gauge, (DentalMorelliLtda, Brasil,)* Figure (7), with force levels between 50-60 g.

(*3M, Unitek*)*: Manufacturer of the mini-screws

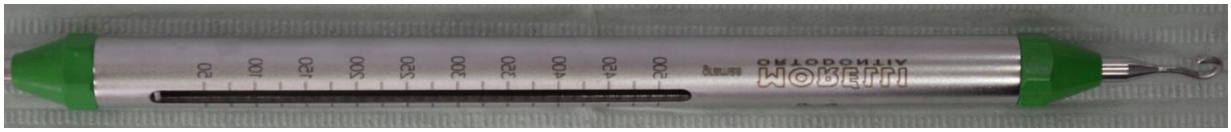
(*Dental MorelliLtda)*: Manufacturer of the force gauge.



Figure(5)



Figure(6)



Figure(7)

Screws were immediately loaded by elastomeric power chains (American orthodontics)* , forces were calculated by using a force gauge. After finishing the procedure, instructions were given to the patients to maintain the good oral hygiene to avoid any loosening in the screws, due to any periodontal inflammations. Patients were recruited every 3 weeks for 6 months for evaluation. Figure (8)

Figure (8)

(American orthodontics)* : Manufacturer of the elastomeric power chain.

2.6 Intrusive archwire group preparation: This group consisted of 7 patients who were randomly allocated to the intrusive arch group. Anterior teeth were leveled and aligned like the other group. After leveling teeth were consolidated with a heavy 17x25 St.st rectangular archwire. As previously mentioned not all teeth allowed for the leveling of the four anterior teeth, due to the decompensation of the original condition. Figures (9,10).

The anterior segment was then ligated together, as one unit. Unfortunately, due to the nature of the class II division 2, some laterals were bypassed, to avoid their effects on the leveling and alignment, moreover, it was impossible in practice to apply a rigid (large rectangular) stabilizing archwire onto incisors that were not level, because this arch would not be passive. The length of the wire is determined by the location of the moment bent into it. For ideal force activation, the bend should be 3-5mm mesial to the first molar auxiliary tube when the wire is inserted.

To produce higher force levels of 50-60g, which might be desirable in some patients, preformed 17x25 Nickel-titanium (Connecticut intrusion arch) archwires (Ortho Organizers, Inc.)* can be activated by placing moment bends in front of the molar tubes.

Figure (9).

(*Ortho Organizers, Inc*)* : Manufacturer of the *Connecticut intrusion arch*

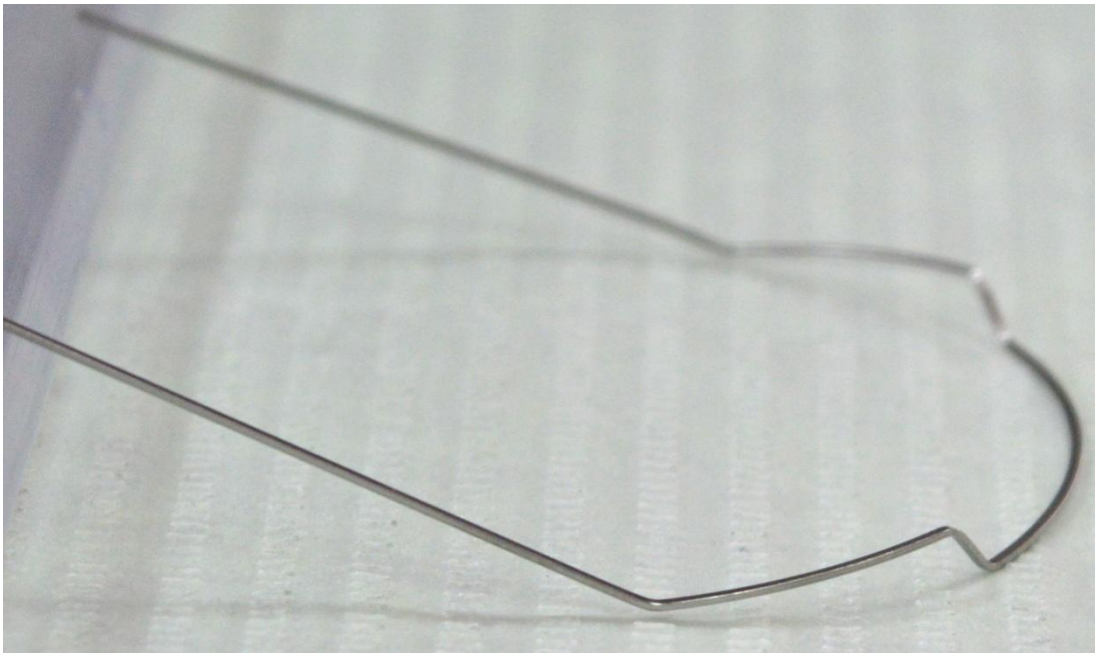


Figure (10). Nickel-titanium (Connecticut intrusion arch) archwire (Ortho Organizers, Inc.).

The bends can be increased or decreased to vary the magnitude of force, according to the objectives of the treatment plan. Then leveled and aligned teeth were consolidated with a heavy 17x25 St.st rectangular archwire, tied to the anterior portion of the intrusion arch. One of the multifunctional aspects of intrusion wires is that they can be used for flaring the incisors when needed. Because the upper central incisors are lingually inclined in Class II, division 2 patients, the intrusion arch should not initially be cinched distal to the molar tubes, so that the incisors can be flared prior to their intrusion .The wire can then be cinched back 2-3mm distal to the molar tubes for intrusion of the incisors. After finishing the procedure, instructions were given to the patients to maintain the good oral hygiene to avoid any loosening in the screws, due to any periodontal inflammations. Patients were recruited every 3 weeks for 6 months for evaluation.

2.7 Follow up period: The patients were asked to attend a follow up session every 3 weeks for 6 months, in order to check the following:

• Oral hygiene of the patient.

• Stability of the mini-screws.

• Re-activation of the delivered amount of force; in the mini-screw group, new elastomeric power chains were attached to the mini-screws, with checking the amount of force delivered with the force gauge to maintain standardization of the force throughout the study, on the other hand the intrusive archwire group were checked for the integrity of the V-bends to maintain the standardization of the amount of the delivered force.

One participant in the group of the mini-screw, showed failure of the 2 screws due to poor oral hygiene,which appeared as; screw mobility. Screws were removed, and left for two weeks for healing, then the previous procedures were repeated.

2.8Outcome: The primary outcome was is to measure the rate intrusion, and to see patient satisfaction during the treatment of deep over-bite cases,and the Secondary outcome, was to measure the amount of root resorption. There were no outcome changes after commencement of the trial.

III. Results

*Clinical findings: Intrusive arch group:*The intrusive arch was able to efficiently intrude the anterior segment (1.14mm) in a period of 6 months.

Mini-Screw Group: It was evident that the mini-screws were able to intrude the anterior teeth efficiently(1.29mm) in a period of 6 months.

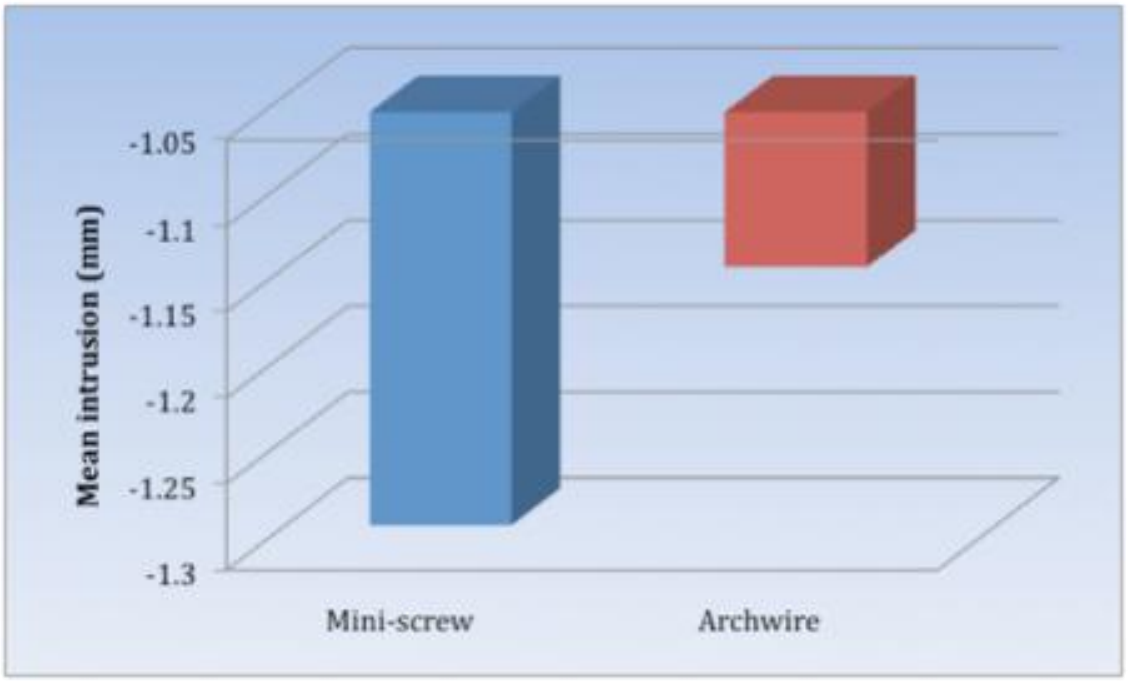
In comparison between the 2 groups there was no statistically significant difference between intrusion in the two groups either before treatment or after treatment. Also, there was no statistically significant difference between changes in intrusion values in the two groups.

Table (1): Mean, standard deviation (SD) values and results of repeated measures ANOVA and Mann-Whitney U tests for the comparison between intrusion and changes in intrusion values in the two groups

Time	Mini-screw		Archwire		*P*-value
	Mean	SD	Mean	SD	
Before treatment	14.36	1.16	14.09	2.23	0.605
After treatment	13.07	1.22	12.95	2.28	0.826
Change	-1.29	0.80	-1.14	0.80	0.354

**: Significant at P ≤ 0.05*

Table (1)



Figures (11) Bar chart representing mean change in intrusion values between the two groups

And concerning the amount of root resorption during intrusion it was revealed as follows, either before or after treatment; Mini-screw group showed statistically significantly higher mean root length than archwire group. As regards root resorption, there was no statistically significant difference between mean root resorption values in the two groups.

Table (2): Mean, standard deviation (SD) values and results of repeated measures ANOVA and Mann-Whitney U tests for the comparison between root length and root resorption values in the two groups

Time	Mini-screw		Archwire		*P*-value
	Mean	SD	Mean	SD	
Before treatment	14.09	2.19	12.73	1.58	0.019*
After treatment	13.16	2.10	12.01	1.61	0.042*
Change (Resorption)	-0.94	0.40	-0.72	0.75	0.113

**: Significant at P ≤ 0.05*

Table (2)

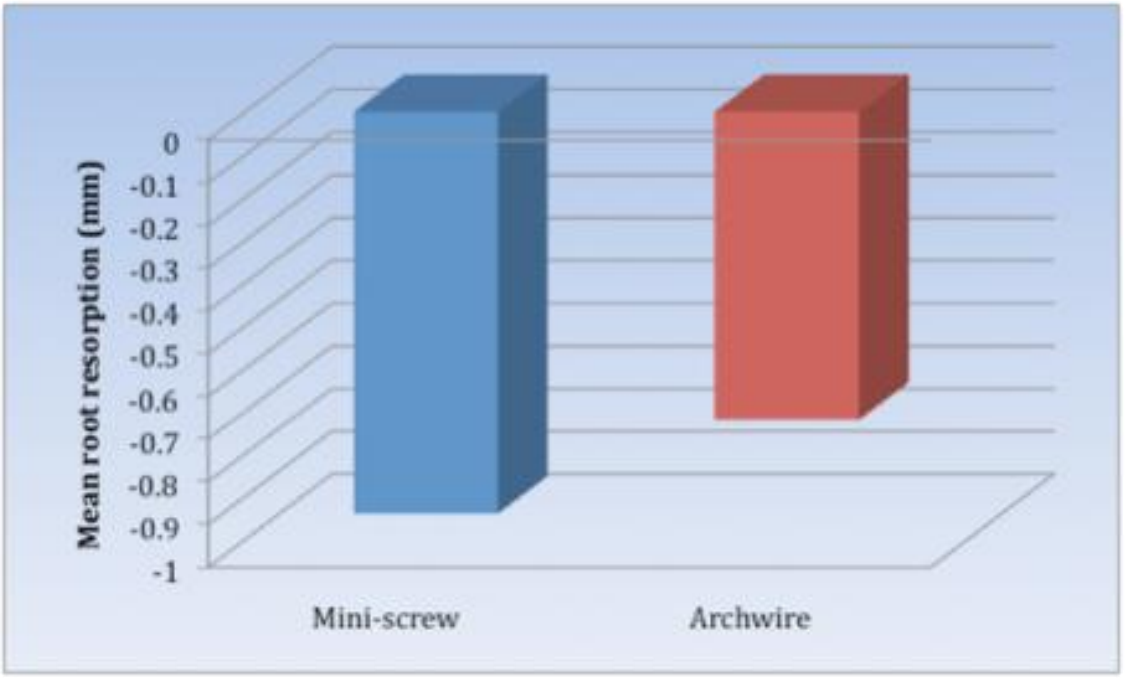


Figure (12) Bar chart representing mean root resorption values between the two groups

IV. Discussion

When reviewing the literature, many studies had addressed intrusion of anterior teeth in deep-bite patients, by comparing different intrusion modalities, either by using skeletal anchorage or by using intrusive arches. Semsik and Ttirkkahraman (2012)[4], Aydogdu and Ozsoy (2014)[6], Polat-Ozsoy et al. (2009)[1], Liou and Chang (2010)[7], Saxena et al(2010)[8],

Polat-Ozsoy et al(2011)[3], Al-falahi et al.(2012)[9] all addressed incisor intrusion only, and the efficiency of the intrusion modality used in deep-bite cases. However, the effect of intrusive forces on root apices has not gained the attention of researches except for few studies by Dermaut and De Munk(1986)[10], Baumrind et al. (1996)[11], McFadden et al. (1989)[12] ,Costopoulos et al.(1996)[13], Deguchi et al(2008)[14],Chiqueto et al(2008)[15]. Furthermore, the effect of intrusive forces on the root resorption was not studied before using three-dimensional cone beam computed tomography except for a single study by Aras and Tuncer (2016)[5]. Hence was the motive for carrying out the present study to compare the efficiency of conventional intrusive arches to skeletally supported intrusion of anterior teeth in class II division 2 cases as well as to study their effect on root resorption.

The current study design is a randomized clinical trial, in which the participants are assigned randomly to separate groups that compare different treatments. Neither the researchers nor the participants can choose which group to get enrolled into.Therefore, any differences in the results between both groups can be basically attributed to the intervention itself and not due to any kind of bias, rendering these type of studies the "gold standard" of the clinical research paradigm[16].

Due to the nature of the study, neither the patients nor the principal operator could be blinded. However, the principal operator carried out all the preparatory steps as well as the orthodontic strap-up for all of the patients enrolled into this study regardless of their groups and was only informed by their allocation at the day of insertion of either the mini-screws or the intrusive arch. therefore, the implementation of the allocation was carried out by a different personnel (MH) and hence alleviating any possibility of allocation bias. Sample size calculation in this study was done according to the results of

Dermaut and De Munck A (1986)[10] with a power of 95% regarding the difference in root length before and after intrusion, and the predicted sample size was a total of 14 cases i.e. 7 cases in each group. No sex predilection was carried out in this study as the growth factor was already precluded in the selection criteria so no effect of sex difference was expected to affect the results. In addition, due to the rarity of the Class II division 2 cases, gender type was not restricted.

The choice of the comparator in this study was the conventional intrusive arches which resemble the gold standard for intrusion of incisor, as mentioned by Burstone (1977)[17]. Conventional methods of incisor intrusion usually involve 2 x 4 appliances such as utility arches, 3-piece intrusion arches, or reverse curved arches [3]. The conventional intrusion mechanics with pre-formed nickel titanium Connecticut Intrusion Arch (CIA) were used in this study. Upon insertion, the V- bend lies just anterior to the molar brackets. For ideal force activation, the bend should be 3-5mm mesial to the first molar auxiliary tube when the wire is inserted.[2]

Unfortunately, the conventional intrusion archwires are not without demerits. Posterior segment extrusion and distal tipping are two of the mostly encountered problems during anterior segment intrusion. Therefore, introduction of skeletal anchorage into the field of orthodontics has definitely solved many of the anchorage loss and unwanted tooth movement problems. In this study the mini-screws were anteriorlyplaced between the upper laterals and canines. This was the same site chosen by Semsik and Ttirkkahraman (2012)[4], Polat-Ozsoy et al(2011)[3], Upadhyay et al (2008)[18] did in their studies. Upadhyay et al (2008)[18] explained placing the mini-screws between the upper lateral and canine for the availability of sufficient interdental bone, less soft tissue irritation and a larger anterior segment which required greater control. Moreover, the selection of the point of application of the intrusive force with respect to the center of resistance of the anterior segment was also an important consideration in the placement of the implants so that the nature of tooth movement that would occur could be predicted more accurately. The center of resistance of the six anterior teeth was estimated to be halfway the distance between the lateral incisors and canines. True intrusion without axial inclination change can only be obtained by directing the intrusive force through the center of resistance of the anterior teeth. Upadhyay et al (2008)[18] .In this study, leveling and alignment was not done prior to the application of the intrusive forces in either groups. This was mainly done to avoid reducing the overbite which would affect the results and would mask the intrusive effect of either techniques. This was in disagreement to the protocol followed by Polat- Ozsoy et al(2011)[3] and Aydogdu and Ozsoy (2014)[6] . However, in some of the cases the upper incisors experienced a greater degree of crowding due to overlapping of the upper lateral incisors. Therefore, it was found mandatory, in some of the cases to apply the intrusive force on the upper central incisors only and to bypass the lateral incisors. This was in accordance to the protocol followed by Semsik and Ttirkkahraman (2012)[4]

In the present study, the duration of the intrusion of the incisors for both, the conventional intrusive arch and the mini-screw groups was a period of 6 months.This was in accordance to Dermaut and De Munck A (1986)[10], Deguchi et al(2008)[14], who performed incisor intrusion during the same amount of time.

In this study, the method of the assessment of root resorption was done using CBCT, which was far more superior to the conventional periapical and panoramic radiographs in the assessment of root resorption, as stated by Dudic et al(2009)[19], and Sameshima and Asgarifar (2001)[20]. Root resorption is a volumetric loss to the root structure thus, it requires a 3-dimensional, quantitative tool for its assessment for obtaining precise and accurate results[5]. Moreover, studies by Baysal et al(2011)[21], Li et al(2013)[22], Akyalcin et al(2015)[23], and Aras and Tuncer (2016)[5], mentioned that CBCT is a highly efficient and reliable diagnostic method, that can be used in the assessment of root resorption, both linearly and volumetrically.

Summary and Conclusion: Deep bite is a complex orthodontic problem that is encountered in many malocclusions, and can be considered a damaging form of Malocclusion. Class II division 2 malocclusion is a type of malocclusion that is always presented with severe deep bite, lingually inclined upper central and lower incisors, and labially flared maxillary lateral incisors. This malocclusion also tends to exhibit problems with the upper and lower occlusal planes, such as deep curves of Spee. The introduction of skeletal anchorage as a source of stationary anchorage to orthodontic forces has made most complex tooth movements simple. Because of their small dimensions, mini-screws offer the advantages of immediate loading, multiple placement sites, relatively simple placement and removal, placement in interdental areas where traditional implants cannot be placed, and minimal expenses for patients. The aim of this study was to investigate the effect of intrusive forces generated during the treatment of deep over-bite in Class II division 2 cases on root resorption, by using two different mechanics, mini-screw implants and intrusive archwire. Cone beam computed tomography (CBCT), was used in this study to determine the degree of root Resorption.

From the results obtained from this study, the following was concluded; regarding intrusion of the anterior teeth and in comparison between the 2 groups there was no statistical significant difference in intrusion between the 2 groups after treatment. Concerning the amount of root resorption, mini-screws showed higher mean root length decrease than archwire group. As regards root resorption, there was no statistically significant difference between mean root resorption values in the two groups.

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