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YEDİTEPE UNIVERSITY
INSTUTE OF HEALTH SCIENCES

EXAMINATION OF THE EFFECTS OF SKELETAL-BORNE AND SOFT TISSUES-BORNE INTRAORAL MOLAR DISTALIZATION METHODS

PHD THESIS

Dt. Tarek ABIED

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APPROVAL

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APPROVAL
This thesis has been deemed by the jury in accordance with the relevant articles of Yeditepe University Graduate Education and Examinations Regulation and has been approved by Administrative Board of Institute with decision dated .... and numbered ....

Prof. Dr. Bayram YILMAZ
Director of Institute of Health Sciences

DECLARATION

I hereby declare that this thesis is my own work and that, to the best of my knowledge and belief, it contains no material previously published or written by another person nor material which has been accepted for the award of any other degree except where due acknowledgment has been made in the text.

01.03.2022

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TABLE of CONTENTS

LIST of TABLES

LIST of FIGURES

LIST of ABBREVIATIONS AND SYMBOLS.

°: Degrees

2D: two-dimensional

3D: three-dimensional

et al.: And others

Fig: Figure

ANB: A point Nasion B point angle (at Nasion)

ANS: Anterior Nasal Spine

Ba: Basion

N: Nasion

Po: Porion

PP – SN: Palatal Plane – Sella/Nasion angle

SNA: Sella Nasion A point angle (at Nasion)

SNB: Sella Nasion B point angle (at Nasion)

FH: Frankfort Horizontal

CBCT: Cone-Beam Computed Tomography

CT: Computed Tomography

MIMICS: Materialize Interactive Medical Image Control Systems

SD: Standard Deviation

mm: millimeter

ı : Left

X : X Reference Line

Y : Y Reference Line

/ : Angle

db : Tip Of Distobuccal Cusp

mb : Tip Of Mesiobuccal Cusp

dp :Tip Of Distopalatinal Cusp

gr : Gram

T0 : Before the Treatment

T1 : After the Treatment

ABSTRACT

Abied, T. (2022). Examination of The Effects of Skeletal-Born and Soft Tissues-Born Intraoral Molar Distalization Methods. Yeditepe University, Institute of Health Science, Department of Orthodontics, PhD Thesis, İstanbul.PhD Thesis. Istanbul. 2022.

The aim of our retrospective study is to evaluate the dental effects of the Palatally mini-screws assisted molar distalizer (study group) and comparing it with the soft tissues supported pendulum appliance (control group). 12 cases were collected from the archive of Orthodontic Department of Yeditepe University for each group. Cephalometric radiographs with metal guide and 3D models has been taken before and after the distalization process for each case were collected and evaluated. The mean age of the patients was 15.7 years old for both groups. There was no significantly difference with the average of the distalization period between both the control and the study groups. The upper molar distalization amount of the control group was significantly higher than the study group. Also The upper premolars and canine had a significant mesial shift in the control group while it had a significant distal shifting in the study group ($p<0.01$). The amount of the distal tipping of the upper first molar in the control group was significantly higher than the study group ($p<0.01$). Also the upper second and first premolars had a significantly mesial tilting in the control group while it had a significant distal tipping in the study group ($p<0.01$). Moreover, the upper first molar had a distobuccal rotation in the control group while it has shown mesiobuccal rotation in the study group ($p<0.01$). A significant labial tipping had been shown with the upper incisors in the control group ($p<0.01$), while unsignificant change in the study group ($p>0.05$).

Key Words: Class II malocclusion, Intraoral molar distalization, Pendulum appliance, mini-screws assisted molar distalizer

ABSTRACT (Turkish)

Abied, T. (2022). Kemik ve Diş Destekli Intraoral Molar Distalizasyon Yöntemlerinin Etkilerin Incelenmesi. Yeditepe Üniversitesi, Sağlık Bilimleri Enstitüsü, Ortodonti ABD., Doktora Tezi, Istanbul.

Retrospektif çalışmamızın amacı, Palatally mini vida destekli molar distalizerin (çalışma grubu) dental etkilerini değerlendirmek ve yumuşak doku destekli pendulum apareyi (kontrol grubu) ile karşılaştırmaktır. Yeditepe Üniversitesi Ortodonti Anabilim Dalı arşivinden her grup için 12 vaka toplandı. Her vaka için distalizasyon öncesi ve sonrası metal kılavuzlu sefalometrik radyografiler ve 3d modeller alınarak değerlendirildi. Hastaların ortalama yaşı her iki grup için de 15.7 idi. Hem kontrol hem de çalışma grupları arasında distalizasyon süresinin ortalaması ile anlamlı bir fark yoktu. Kontrol grubunun üst molar distalizasyon miktarı çalışma grubuna göre anlamlı derecede yüksekti. Ayrıca üst premolarlar ve köpek dişlerinde kontrol grubunda anlamlı bir mezial kayma varken, çalışma grubunda anlamlı distal kayma vardı ($p<0.01$). Kontrol grubunda üst birinci molar distal devrilme miktarı çalışma grubuna göre anlamlı derecede yüksekti ($p<0.01$). ayrıca üst ikinci ve birinci küçük azılarda kontrol grubunda önemli ölçüde mesial eğim bulunurken, çalışma grubunda önemli ölçüde distal devrilme vardı ($p<0.01$). Ayrıca kontrol grubunda üst birinci molar diş distobukkal rotasyona sahipken, çalışma grubunda mesiobukkal rotasyon gösterdi ($p<0.01$). kontrol grubunda üst kesici dişlerde önemli bir labiyal devrilme görülürken ($p<0.01$), çalışma grubunda anlamlı olmayan bir değişiklik ($p>0.05$).

Anahtar Kelimeler: Ağız-içi molar Distalizasyon aparey, pendulum aparey, mini-vida distekli molar distalizasyon, sınıf II malokluzyon.

1. INTRODUCTION AND AIMS

Class II malocclusion is the most common type of malocclusion in Europe and the Middle East[1].

Class II malocclusion characterized by forward position of the upper jaw and/or upper dentition or backward position of the lower jaw and/or lower dentition or combination of both forward of the upper jaw and backward of the lower jaw (1).

Correction of Class II malocclusion without extraction is a challenging case that requires maxillary molar distalization using intraoral or extraoral forces. For cases with minimal arch length discrepancy and a mild Class II molar relationship associated with a normal mandibular arch, molar distalization is a significant value (2).

Over the years, many types of molar distalizer have been developed; the most conventional method is to use head-gear, which can be used to restrict the maxillary forward growth (orthopedic) or to move molars backward (orthodontic) (4), However, the main disadvantage of head-gear is that it relies on patient cooperation, which makes the treatment result and duration unpredictable; it has also been reported that head-gear rejected by many patients because of aesthetic and social thoughts (3).

In order to overcome these difficulties and disadvantages, other types of intraoral distalizers and techniques have been developed, including magnets(5), elastic Ni-Ti coil springs (5,6), and pendulum (7).

The pendulum appliance has been proved successful in order of molar distalization. However, there are some disadvantages, including the laboratory time, anchorage loss, and mesial shifting of the anchor unit with incisors flaring. Moreover, clockwise rotation of the mandible results in an increase of the facial hight (8,9,10).

Many modifications have been made to the pendulum appliance in order to decrease the anchorage loss, including quad pendulum by Caprioglio et al. (11), Pendulum K, with an uprighting bend, toe-in bend, incorporation of a distal screw (12,13). The amount of anchorage loss decreased but not totally.

In order to solve that problem, many intraoral distalization appliances combined with bone-anchored screws have been developed, as by helping of these screws, molar distalization without incisors round-tripping can be achieved.

These screws can be placed in many places in the mouth; many studies showed that the screws placed in the alveolar bone could withstand the forces required for orthodontic teeth movement (14–17). But for the patients who have complete dentition, there is no available alveolar bone for inserting the screw. Therefore several studies have been made for other mini-screws placements sites such as zygomatic buttress, hard palate, symphysis, and mandibular retromolar area (18).

According to Gracco et al., both the anterior and posterior parts of the hard palate are considered as a safe area for inserting mini screws (19). Furthermore, the paramedian region has shown that the bone is 2mm thicker than the mid-sagittal and posterior region (20).

The mini-screws are easily inserted and removed at the palatal region under local anesthesia, and the force generated for molar distalization can be direct or indirect.

In this retrospective study, the main objective is to evaluate the efficiency and treatment outcome of direct molar distalization supported by palatal mini-screws.

2. LITERATURE REVIEW

2.1. The Class II Malocclusion

Class II malocclusion is considered as a main part of the orthodontic anomalies. It's generally described as dental, skeletal, and/or functional (21). According to Angle, he considered the upper first molar sagittal relationship as a reference to classify the malocclusion into three groups. He characterized the Class II malocclusions dentally as having a distal relationship of the mandibular teeth relative to the maxillary teeth of more than one-half of the width of the cusp (21), and he found that up to 27% of the cases have class II malocclusion (22).

2.2. Epidemiology of Class II Malocclusion

Class II malocclusion distribution exhibit different values among different area around the world. The class II malocclusion in America, according to the national health and nutrition examination survey, was about 10-15% in the mixed dentition which decrease gradually by age until it reaches 8-10% at the adult stage, probably because of jaw and bone growth and some individual having orthodontic treatment (23). Regarding the European population, the prevalence was about 15-20% has Class II malocclusion (24). For Latin American populations, the prevalence was 10% (25). And the same result was found in Arabic populations, which is 10% having class II malocclusion (26). For Turkish populations, the prevalence of Class II malocclusion has been found 28% (27) (Fig 2.2.1).

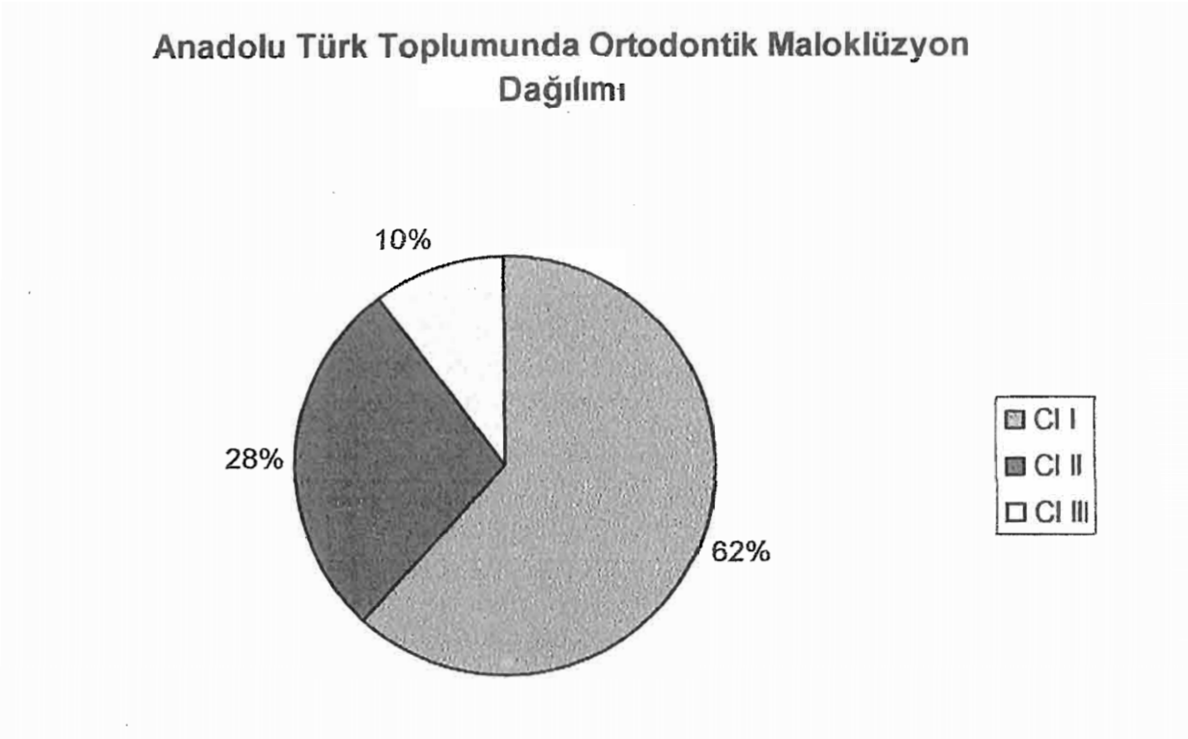

Figure 2.2.1: Orthodontic Malocclusion Distribution in Anatolian Turkish Society

2.3. Etiology of Class II Malocclusion

Many factors are considered to be affected factors for having Class II malocclusion, such as genetics, race, and family-related characters. Acquired habits tend to be repeated. For example, the hereditary traits which had been taken from one or both parents may produce the same characteristics in the siblings (21).

Also, there are some environmental factors such as early loss of deciduous teeth, which leads to the mesialization of the permanent molars, creating Class II molar relationship and impaction or vestibular erupting of permanent canine. Also, the thumb sucking habit, in which the finger moves the upper incisors forward, creating an imbalance in the occlusion resulting in Class II malocclusion. The same result could happen with tongue thrusting or lip sucking habits as well (21). According to McNamara, Class II malocclusion does not only develop from anteroposterior or vertical problems but also the transverse problems has a big effect on it (28).

2.4. Classification of Class II Malocclusion

Many studies show that Class II malocclusion does not appear from simple factors, but it is mostly related to skeletal and dentoalveolar components (29).

Angle classified the Class II malocclusion according to the position of upper incisors to two groups:

- Division I: The upper incisors angle increased, as well as increasing with the overjet
- Division II: The overjet increased but the incisors angle decreased (29)

Angle's classification generally depend on the dentoalveolar components. That's the reason many researchers think this classification is not sufficient for describing the malocclusion (30).

By developing of the cephalometric radiographs, the orthodontist starts to use it for the diagnosis of the cases to check both the upper and lower jaws and their relation with each other. Grabber and Vig by using cephalometric radiographs they classified the malocclusion as dental, skeletal, and combination of both dental and skeletal. For dental malocclusion, the relation between the upper and lower jaw is considered normal, but the relationship between the upper and lower teeth is abnormal. At the same time, the skeletal malocclusion, the relation between the upper and lower jaws are not normal (29).

Jarabak and Fizzle said that in Angle Classification, he did not mention the growth pattern of the face, so they made their own classification. For Class II malocclusion, they divided it into five groups (dental, skeletal, functional, dentoalveolar, skeletal-dentoalveolar) (31).

McNamara also gives attention to skeletal components while classifying the malocclusion. Moreover, he brought attention to the mandibular plane angle and lower facial height (28).

In 1980 Moyers et al. created a classification for the malocclusion. He divided the Class II malocclusion into two groups (horizontal and vertical); the horizontal groups divided into six groups, and he used the letters from A to F for the classification (A, B, C, D, E, and F). 4 groups from this classification (B, C, D, and E) have the characteristic of skeletal Class II malocclusion, F type has the least skeletal problems, the A-type described as Class II malocclusion but has a normal profile, the jaws have an ideal relationship and the lower incisors in their normal position while the upper incisors are protruded, making increasing in the overjet as well as overbite (32).

According to Bishara, in 1994, he published literature talking about Class II malocclusion. He said Class II malocclusion happened due to underlying skeletal irregularities and deformities; also, some people have normal skeletal relationships with the dental Class II relationship. And he divided this dental Class II malocclusion into two groups:

a- Maxillary dental protrusion:

When there are no skeletal irregularities are found in the cephalometric radiographs but the position of the pre-maxilla and increasing in the overjet, sometimes from poly-diastema in the maxillary arch. The lower dentition with the lower jaw is in a normal position.

b- Mesial movement of a maxillary permanent first molar:

Due to early extraction of an upper primary second molar or due to caries, the contact between the first permanent molar and the primary tooth will be lost, and the permanent molar will move mesially, creating a Class II molar relationship (33).

The treatment of skeletal or dental Class II malocclusion is related to many factors. For example, treatment of the growing patients has skeletal Class II malocclusion could be achieved by functional appliance, but mature patients with the same severity of Class II malocclusion would not be able to treat by the same appliance.

The growth pattern, severity of the malocclusion, soft tissue profile, and amount of crowding must be considered (34).

2.5. Class II Treatment Strategies

There are many methods and options for treating Class II malocclusion; the orthodontist has to check the skeletal and dental components and decide which treatment plan would be effective for the case. The treatment options include extra-oral appliance, expansion appliance, functional appliance, extraction, or maxillofacial surgery (28).

Over the past few years, non-extraction treatment has become more popular for the correction of Class II malocclusion (35).

Extraction treatment has negative side effects, as it results in narrowing of the dental arch, creating a dark buccal corridor while smiling as well as changing in the soft tissue profile(36).

Watson recommended six factors that have to be taken into consideration before extraction (37):

1- Hereditary factors versus environmental factors
2- Bone growth stimulation factors
3- Esthetic and facial harmony
4- Treatment plan suitability
5- Financial factors
6- Treatment aim

By the development of the new mechanics and equipments, most of the orthodontists tend to plan a non-extraction treatment for mild crowding cases (38). The ratio of non-extraction treatment decreased during the past few years from 60-80% to 30%, according to the study that O'Connor did in 1993 (39).

Sinclair also noted that with the development of distalization mechanics, more than 60% of the orthodontists start to prefer non-extraction over extraction treatment (40).

Molar distalization is one of the many methods to gain space.

Methods to gain space without extraction.

1- Incisors proclination
2- Arch expansion
3- Correction of rotations
4- Molar distalization
5- Stripping
6- Closing of the diastemas

If the Class II problem is related to the upper arch, then molar distalization could be one of the solutions (19,21,29,41).

2.6. Indications and Contraindications for the Molar Distalization

Protrusive maxillary dental arch, no indication for extraction, and mandibular molar couldn’t move mesially due to discrepancy of teeth/jaw relationship; maxillary molar distalization can be indicated (8,42).

Also, there are some features listed by Bowman as contraindications for molar distalization:

1- High mandibular angle
2- Protrusive profile
3- Anterior open bite
4- Severe crowding

2.7. Extra-oral Molar Distalization

Correction of jaw anomalies by using extra-oral force is a very conventional method. The first one who introduced this idea to the orthodontic field is Kingsley in 1875 (43).

Then they stopped using that extra-oral appliance for many years until 1962 Kloehn et al. created a foundation for an extra-oral appliance, which became so popular and one of the most important parts of orthodontics (44).

This extra-oral appliance can be used for the orthopedic purpose to restrict the forward growth of the maxilla or for the orthodontic purpose to distalize the upper molar and gain Class I molar relationship. This appliance is also named Head-gear (45).

Head-gear types are divided into three groups, depending on the anchor unit, the first one is cervical, which the anchor unit is the neck, second one is occipital or high pull head-gear which the anchor unit is the upper head, the third type is a combination of both first and second type (44). The cervical head-gear also known as Klohen head-gear type, as Dr.Klohen developed it, giving a force from behind of the neck, creating an extrusion and distal tipping movement of the first molar (46–48). This extrusion movement of the molar makes the mandible rotate downward and backward, resulting in an increase in gonial angle, change in condyle growth pattern and increase in lower facial height (49–53). Hence the cervical head-gear is creating a downward rotation of the mandible, so it's considered to be suitable for skeletal deep-bite cases (54).

When the first molar distalized by cervical head-gear, the second molar may block out and stay impacted 'as a result of distal tipping of the first molar' that's why Graber suggests using combined head-gear because combined head-gear take anchorage from both neck and upper head, so the intrusion force created by high-pull head-gear neglect the extrusion force created by cervical anchorage, and the distal crown tipping decreased as well (44,55).

The second type, known as occipital head-gear or high-pull head-gear, this type is recommended for the high angle growth pattern cases with protruded maxilla. It takes anchorage from the parietal area of the head, generating a distalizing and intrusion force to the upper molars. This movement makes the lower jaw rotate anteriorly (44,48,50,56,57).

The head-gear appliance is usually used by age below 16 because of its effect on the appearance of the patients. The patients between 14 and 16 has shown the least cooperation in the study made by Cureton et al. in 1993. Also Weiss et al., in their study, published in 1977, they claimed that the patients below 12 years old are more cooperative than older patients (58,59).

The head-gear has to be worn at least 16 hours per day for to be efficient in molar distalization. While to be able to change the maxillary growth, it has to be worn 12-14 hours per day for 18 months. So the main concern in this appliance is the patient's cooperation as the efficacy is totally related to it (60,61).

Doruk et al. added a timer on the back part of the head-gear and in order to check the appliance wearing time, the study started with 47 patients, and after two months it has been divided into two groups, first group who have been wearing the appliance more than 16 hours per day and the other group who wore it less than 16 hours per day. The second group had been informed about the timer at that stage. 4 months later, they found that the second group started to wear the appliance about 4.5-6 hours more than before (62).

Güray and Orhan made a very similar study. The patients were not informed in the first two months. After two months, they have been informed about the timer, and the result was a 26% increase in using the appliance (63).

As mentioned before, one of the disadvantages of the head-gear is molar tipping. To compensate this side effect, Cetlin and Ten Hoeve in 1983 suggested using head-gear in combination with intraoral appliance (211). The intraoral appliance that they used is a Hawley appliance with a finger spring on the mesial of the molars; by activating it about 1-1.5 mm, it generates 30gm force on the molar's crown. Together with the extra-oral force, it tends to give a parallel movement to the molars. Johnson et al. also used the same idea of intraoral appliance combined with extra oral head-gear. Their protocol was full-time intraoral appliance wearing and night time for the extraoral appliance. They got a result of a 6-8mm molar distalizaion within five months (64).

Aras et al. made a study on J-hook head-gear with a removable appliance to evaluate its effect. The patients were instructed to use the extraoral appliance for 11-12 hours per day and not to remove the intraoral appliance except during meals. The researchers reported an upper posterior mass distalization within five months without an increase in the overjet (65).

Ghosh and Nanda did a case study in 1996 on an 11 years old girl. They used extra oral head-gear in combination with an intraoral fixed nance appliance, and they applied a Niti open coil spring between the second premolar and first molar. They reported that molar distalization was achieved within four months, but also 2mm mesializaiton in the premolar (66).

In conclusion, extraoral appliance reported as a very successful method for molar distalization, but the main concern is the patient cooperation as it totally depends on the patient compliance, which tends to be problematic, increasing the treatment time and sometimes force the orthodontist to change the treatment plan from non-extraction to extraction option. This point forces the orthodontists to find other intraoral distalizer not dependent on the patient cooperation (67–72).

2.8. Intra-oral Molar Distalization

The first study on intra-oral distalizer was done by Blechman and Smiley on cats. They used a magnet to generate a force needed for moving the molar distally. This method has many advantages, such as not being related to the patient’s compliance, easy to activate, and minimal friction. This method received great attention from orthodontists, and many researches have been done upon it (73).

Gianelly et al. did a study on eight patients who have Class II malocclusion. They used an acrylic nance button as an anchorage and while distalizing the first molar with a magnet. They reported an 80% molar distalization within 2.5 months and 20% incisors protrusion, in other words, ‘’anchorage loss’’ (74).

Itoh et al. achieved a molar distalization on ten patients using magnets as a source of force and nance appliance as an anchorage. The activation period was every two weeks. They reported a 30-50% of anchorage loss (75).

Bondmark and Kurol, in their study on ten patients who have Class II malocclusion, they investigated the movement of the first molar by magnets, and acrylic nance button on premolars for anchorage, molar distalization of 4.2mm was achieved in a mean of 16.6 weeks along with 8.5 degrees distobuccal rotation, and 8 degrees distal tipping was noticed(76).

Upon using the magnets distalizer, its disadvantages start to appear. Despite the toxicity when it’s not well isolated, also it’s easy to break. Considered as a big appliance taking a large space in the mouth makes mucosa irritation, not being hygienic, and also it’s not cheap. So that’s why the researchers concentrate their studies on the open coil springs. Increasing the wire length provides a light and efficient force for the tooth movement (77).

Gianelly et al. achieved molar distalization between 1-1.5mm monthly by providing 100 grams force using a Niti open coil and activating it about 8-10mm. A nance acrylic button had been used for anchorage (69).

Pieringer et al. used an open coil spring on segmental archwires with a nance button for anchorage; also, they provided a force of 150-200 grams for distalization. They reported that 5-10mm of molar distalization with 8.5-22 degrees distal tipping in molars and 6 degrees labial tipping in upper incisors (78).

Erverdi et al. made a comparison between magnets technique and open coil spring technique; they performed distalization in 15 patients using magnets on one side and an open coil spring on the other side. The anchorage unit was a nance button. They got a conclusion that both techniques were working well for distalization, but open coil spring was easier due to the magnet technique needs activation every week, and it’s expensive (5).

Jones and White, in 1992 they developed a distalizer called Jones jig distalizer according to the name of the developer. It consists of a Niti coil spring bonded on thick segmental archwire taking the anchorage from the nance button. The activation process was every 4-5 months by compressing the coil 1-5mm providing distalization force 70-75 grams (79).

Gulati et al., in their study on the Jones Jig distalizer, reported 3.5 degrees distal molar tipping and 2.4 degrees distopalatal rotation with 2.8mm molar distalization, and they observed 2.6 degrees mesial tipping in premolars with 1.3 degrees increase in the mandibular angle, which was a result of molar extrusion. For that reason, the researchers advised applying distalization only in patients with normal mandibular plan angle (80).

Brickman et al. in 2000 applied Jones Jig distalizer on 72 patients with 70-75 grams force, and at the end of 6.3 months, they found 2.51mm and 1.79mm distalization on the first and second upper molars, respectively (81).

Patel et al. made a comparison between Jones Jig distalizer and Pendulum distalizer. They applied 100 grams of force for Jones Jig and 250 grams of force for the Pendulum. They concluded that Jones Jig appliance has more effect on second premolars as they found more mesialization and extrusion on second premolars in the patients who were treated by Jones Jig appliance (82).

Carano and Testa invented a new distalizer as an alternative mechanic to prevent rotation and tipping movement of the molars. They chose a nance button as an anchorage unit. They utilized Niti coils on a thick wire, from one side was embedded in the acrylic part of the nance appliance, and the other side was soldered to the palatal side of the molar band. Researches believed that they achieved a parallel movement for molar distalization (67).

Turk and Arici applied Distal Jet distalizer on two patients, the found intrusion and tipping in the first upper molars and extrusion in the first premolars (83).

Ngantung et al. performed molar distalization by using a Distal Jet distalizer on 33 patients. They got a Class I relationship within 6.7 months on average, with parallel tooth movement as the force vector was passing close from the center of resistance. They reported an anchorage loss as a side effect (84).

Bolla et al. also made a study on Distal Jet distalizer. They reported that the molar moved 3.2mm distally with 3.1 degrees of distal tipping. On the other hand, 3.1mm mesial movement of premolars and 0.6 degrees of incisor inclination as an anchorage loss (85).

The researchers noticed that using a Distal Jet distalizer, parallel movement can be achieved, but the anchorage loss in the anterior part was hard to prevent. For that reason, Fortini et al. in 1999 designed a new distalizer First-Class appliance in order to prevent the anchorage loss that is happening with the Distal Jet appliance. The appliance consists of two parts, labial part and palatal part, with a Niti spring between the first molar and the first premolar. Fortini et al. applied this appliance on 63 patients and they achieved 4.8mm distalization on average within 42 days (68).

Fortini et al. conducted another study by using the same distalizer First-Class appliance by applying this appliance on 17 patients. They reported that Class I relationship had been achieved within 2.4 months. The results showed 4mm distalization with distal tipping of 4.6 degrees and 1.2 degrees extrusion. As well as 2.2 degrees of mesial tipping along with 1.7mm mesial movement and 1 mm extrusion has been shown in second premolars. Also, 1.3mm protrusion and 2.6 degrees of proclination in anterior teeth have been reported as an anchorage loss (86).

Wilson and Wilson, in 1987, invented a 3D biometric distalization arch technique (BDA), and they named it 'the rapid molar distalization' it consists of 0.022-inch maxillary arch wire inserted passively in the slot, a hook on it for intermaxillary elastic and omega bending in the arch mesial to the molar. The distalization is done by an open coil spring placed between the molar tube and the omega bending. A lip bumper and utility arch are using in the lower arch for anchorage, while Class II elastics are used in purpose to prevent upper anterior protrusion (87).

Muse et al. conducted a study on 19 patients with Class II malocclusion. They applied Wilson Biometric Distalization Arch with Class II elastics and open coil springs for distalization and the used lingual arch with utility arches on the lower jaw for anchorage, as the anchorage had been taken from the lower jaw. At the end of 16 weeks of distalization, they observed 2.16 mm distalization in upper molars with 7.8 degrees of distal tipping. Because of anchorage loss, they also observed mesialization in the lower molars and 1.6 mm extrusion with 0.3 mm protrusion in the maxillary anterior teeth (72).

Tüçem et al. in their study on BDA, reported tipping in the molar, premolars, and canine as well as upper anterior proclination (88).

In 1995 Kalra developed the K-loop and introduced it to the field of orthodontics as a new intraoral distalizer, K-loop made of 2 loops from 0.017 x 0.025 TMA wire, bent as K letter extended gingivally between the second premolar and first molar, Nance appliance connected to the second premolars have been used to increase the anchorage. The segmental wire was inserted distally to the molar tube and mesially to the premolar bracket with a 20 degrees angle on each side in order to help to control the mesial and distal movement with the teeth are involved. The researcher reported 1mm premolar movement for each 4mm molar distalization (89).

Keleş and Sayınsu developed the 'intra-oral bodily distalizer' (IMBD), their aim of the study was to create a noncompliance dependent appliance providing molar distalization without distal tipping. The study had been done on 15 patients with an average age of 13.5 years. The appliance consists of an acrylic nance button covering the palatal area for the anchorage and distalization springs made of TMA wire are extending from the acrylic button to the molar bands. The distalization force was 230 grams on the each side. The molar uprighting has been accomplished with the help of second-order bendings. The researchers reported a parallel molar distal movement of 5.2mm along 7.5 months. On the other hand, they also reported a 4.3mm mesial movement in premolars and 4.7 degrees of upper incisor protrusion as a side effect or in other terms anchorage loss (70).

Keleş in 2001 introduced another bodily distalizer and called it Keleş Slider. The mechanics of Keleş Slider was 200 grams of force generated from Niti open coil between the acrylic button and molar tube, which is soldered 5mm gingival to the molar band to be close to the center of resistance of molar; the activation was done by a special type of stoppers. The researcher reported a 4.9mm distalization in 6.1 months without any dental tipping. The premolars showed 1.3mm mesial movement and 1.8mm incisor protrusion. The study was done on 15 patients who have unilateral Class II relationship (90).

Sayınsu et al. in their study on Keleş Slider, applied the appliance on 17 unilateral Class II patients, and they found that in average 0.48mm distalization monthly and 2.85mm in total. They reported 2mm mesialization and 2.03mm extrusion in the first premolars, 1.32mm protrusion, and 1.79 degrees of proclination in the anterior upper teeth, as well as extrusion 1.12mm (35).

Mavropoulos et al. used a Keleş Slider to treat 12 unilateral Class II patients, and their average age was 13.1 years. They applied 150 grams of distalization force. They observed 3.1mm distalization in molar while 2.1mm protrusion in anterior, as well as 6.1 degrees of mesial inclination in the premolar, which was used for anchorage. Also, they reported 1mm midline shift contralateral to the distalization side (91).

In the early 1960s, the Nickel-titanium alloy has been discovered, and they became of great interest in the orthodontic field. In 1978 Andreasen et al. were the first to use it in orthodontics. And Miura et al. were the first to use them for teeth aligning (92,93).

Locatelli et al. used a Niti wire for molar distalization, and they observed 1-2mm molar distalization monthly for cases where the second molar have not erupted yet; Nance Appliance has been used for additional anchorage. They reported that distalization was easier for the cases where the second molar has not erupted yet (94).

Giancotti and Cozza made a modification to the Locatelli System. They added neo-sentalloy archwire and also made 5mm activation range between second molar bands and second premolar brackets in purpose to distalize the second molars. Class II elastics have been used to prevent the mesial movement of second premolars, and lip bumper has been connected to the second molar as well. They reported that 80grams were enough for the first molar distalization after the distalization of the second molar (95).

Hilgers, in 1992 introduced the Pendulum appliance as a noncompliance molar distalization appliance. It consists of a modified nance appliance and 0.032 TMA springs extending from the acrylic button connected to the molar sheets palatally, applying a light constant distalizing force. Hilgers applied the appliance on 13 patients; the patients had been called in every three weeks for activation of the appliance. The springs have been activated up to 90 degrees, while 30% of the activation gets lost by inserting the spring into the palatal tubes. The noticed 5mm distalization in 3-4 months by adding approximately 230 grams of distalizing force to the molar. They stated that while distalizing upper molars with the Pendulum, the teeth going into crossbite. To overcome this side effect, Hilgers suggests adding expansion screws in the acrylic, and he called it ‘’pendex’’ appliance (96).

Ghosh et al. used pendulum appliance to treat 41 Class II malocclusion cases. The applied 230 grams distalization force by activating the spring 60-70 degrees. They reported 3.37mm distalization within 6.21 months in mean. Also, they reported 8.36 degrees distal tipping on the first molar. For the second molar, the result was 2.27mm distalization, 11.99 degrees of distal tipping, and 2.33mm of buccal tipping. They assumed that erupting of the second molar has no effect on the distalization process. And as an anchorage loss, the first premolar moved 2.55mm mesially, 1.29 degrees mesial tipping, and 1.7mm extrusion have been reported as well (97).

Elekdağ et al. in 2000 conducted a study on the Pendulum to evaluate the force effect on the molar distalization. The study done on two groups; for the first group, the spring has been activated by 60 degrees applying 150 grams force. And for the second group, the spring has been activated by 90 degrees applying 230 grams of force on molars. They stated that for the second group, the molar had been distalized faster, but the distal tipping and the anchorage loss was bigger than the first group (98).

The classic Pendulum showed a great result as a molar distalization noncompliance appliance, but the molar distal tipping point seems unavoidable. That’s why the researchers made some modifications to it, trying to move the molar bodily.

Byloff et al. made some changes to the spring connected from the acrylic pad to the molar palatally by adding 10-15 degrees uprighting bends on it. They noticed that decreasing in the molar distal tipping but leads to an increase in the anchorage loss (99).

Kinzinger et al. also made a modification to the classic Pendulum to achieve bodily molar distalization. They added a distal screw with bends on the helix also. The reported 0.67mm monthly distalization, 72.5% of the molar moved distally, and 27.5% of the premolars moved mesially. Also, they reported distal tipping and extrusion on molars and labial tipping on anterior teeth (100).

In another study for Kinzinger in 2002 also made a modification on pendulum appliance, the purpose of it was to distalize the second molar, they added a second helix connected palatally to the second molar. They activated the second helix to distalize the second molar at first; after 3 months, they started to activate the first helix to distalize the first molar. They reported a complete first and second molar distalization within 20 months (101).

Scuzzo et al. also made an adjustment to the classic Pendulum, and they called it M-Pendulum. They claimed that if the loops on the springs were directed posteriorly, it would prevent the distal tipping, and if any tipping happened, by activating the loops after distalization, it could correct it. The force that they used was 125grams. They reported a less distal tipping on molars but longer treatment time (102).

In general, TPA could be used to increase the anchorage, to correct the molar rotation or arch expansion. Haas et al., in 2000, used TPA for molar distalization by adding some modifications to it. They called the appliance 'The Goshgarian Transpalatal Bar'. It has two parts, passive and active. The passive part was inserted into the tube by 35degrees toward the part which need distalization. They reported a 32-48grams force making 2mm distalization within 5 months. They also reported increases in molar rotation and intermolar width, which are considered as unwanted side effects (103).

Küçükkeleş et al. used the hyrax screw for molar distalization by placing it perpendicular to the palatal suture, the anterior part of the hyrax screw was connected to the second premolars, and the posterior part of it was connected to the first molars. For the purpose of strengthening the anchorage, they used a lip bumper connected to the second premolars from the vestibular side. They reported 4.17mm molar distalization as well as 4.17mm premolar mesialization and 5.89degrees of proclination on the anterior teeth (54).

Greenfield created a new distalizer in 1995 and called it 'The Piston Appliance'. The Piston Appliance consists of two bands, one on the molar and the other on the second premolar, a nance button soldered to the second premolar palatally for anchorage, 0.36mm diameter tube soldered on the premolar labially and palatally, and a wire passing from this tube freely soldered on the molar band. The distalization force has been applied by open Niti springs on the wire and has been activated by a stopper soldered mesially to the spring. The researcher reported no molar tipping in molars (104).

Intra-oral appliances have many advantages comparing to the extra-oral ones. As it is esthetically acceptable, continuous force applying makes the treatment period shorter, no need for patient's compliance, and more comfortable. But also, their side effects were unavoidable. For example, the molar rotation, distal tipping, premolar mesialization and extrusion, and anterior protrusion leads to an increase in the overjet. Due to these issues, the researchers start to use the skeletal anchorage while distalization in order to decrease some of the side effects.

2.9. Skeletal Anchorage

In the previous intraoral molar distalization studies, the researchers found that there is almost always some loss in the anchorage while moving the molar distally. To overcome this side effect, the researchers started to give more attention to using skeletal anchorage by means of creating a reaction force with the same intensity and opposite direction against the distalization force with implants or mini-screws (15,67,85,96,105,106).

The rapid development of dental implants has led to their use in orthodontic anchoring. Oosthuizen et al. in 1973 made the first study to investigate skeletal anchorage on animals. Roberts et al. examined dental implants with continuous forces on, placed in animal's jaw, and concluded that stability was maintained throughout the process. They suggested using skeletal anchorage to solve the side effects of orthodontic tooth movement. Palatal implants were firstly used by Triaca et al. in 1992 as a skeletal anchorage in the orthodontic field. In the following years, this topic became more popular, and many researches have been done on it (107,108).

2.9.1 Factors Affecting The Mini Screw Stability

The biggest problem with mini-screws placed in order to provide skeletal anchorage is the stability of mini-screws. Partial osseointegration is needed for the stability of the mini-screws that's used in orthodontics (109,110).

The factors that affect the stability of the mini-screw are (111,112):

a- Factors related to the mini-screw
b- Factors related to the patient
c- Factors related to the manufacturing of the mini screw
d- Factors related to the loads on the mini screw

2.9.1.1. Factors Related to the Mini-screw

a- Biocompatibility

The materials used for the mini screw has to be bioactive and biocompatible. In addition, the mini-screws must be sufficiently durable as well as should not show unwanted ionic leakage and corrosion. Stainless steel and chromium cobalt alloys have been reported to have insufficient biocompatibility. Modern mini-screws are often made of titanium alloys because of their properties, such as the titanium is three times harder than stainless steel, and cobalt alloys have little response to heat or magnetic force and have high biocompatibility (113).

b- Mini-screw Diameter

The mini-screw diameter has a large effect on the stress distribution in the bone. The thickness of the mini-screw diameter is desirable for cortical bone support. It is inversely proportional between the thickness of the mini-screws and the failure rate due to fracture while inserting it. The small diameter of the mini-screw makes it easy to place it between the roots, but the reduction in the diameter significantly increases the torsional stress and, therefore, the risk of fracture. Researchers do not recommend using screws smaller than 1.3 mm in diameter, especially in the lower jaw, because the cortical bone is thick at that area (114,115).

c- Length of the Mini-screw

It was found that the length of the mini-screw had a significant effect on the stress distribution. Also, the groove design and screw diameter have been shown to have a significant effect on stress distribution. It has been shown that in areas with thick soft tissues such as palatal mucosa, long mini-screws are recommended since short screws can be easily removed. To get a good anchorage, the length of the screws has to be at least 5-6mm (116–119).

d- Mini-screw Design

Self-drilling mini-screws have been reported to have more contact with the bone than self-tapping. When the cortical bone is thin, self-tapping mini-screws can be used to insert it in the bone without drilling it by guide driller. If the guide driller has to be used, the hole must not exceed 85% of the mini-screw diameter to ensure proper stability (120,121).

e- Mini-screw Inserting Site

Selecting the appropriate mini-screw location is important to the success of the mini-screw. Five factors are important in determining the appropriate site for the placement of the mini-screw (112).

1- Methods and mechanics: When the mini-screws is inserted, the treatment target and the duration of the mini-screws are very important. Mechanics should be as simple as possible
2- Away from the frenulum, placing it in the area that contains attached gingiva: The mini-screw insertion area should contain sufficiently attached gingiva. This avoids patient discomfort, tissue growth, and micro-motion that causes mini-screw failure
3- Proper distance between the roots: Before the mini-screw insertion, the distance between the roots should be evaluated with the aid of periapical x-ray film or 3D cone-beam computed tomography. There must be a distance of at least 1-1.5 mm between the tooth root and the mini-screw
4- Away from the other anatomical structures: Other anatomical structures may interfere with the mini-screw placement. For example, inferior alveolar nerve, artery, vein, mental foramen, maxillary sinus, and nasal cavity.
5- Appropriate cortical bone thickness: Cortical bone thickness is the most important factor in the stability of the mini-screw. Areas with dense cortical bone should be preferred for good primary stability and long-term success.

f- Mini-screw Insertion Angle

The mini-screws are generally placed in the mucogingival joint. It is recommended that the mini-screw be inserted obliquely to retain more bone, thereby increasing the contact surface of the cortical bone (112).

2.9.1.2. Factors Related to the Patient

a- The General Condition of the Patient,

Metabolic disorders and radiation therapy affect the healing of bone tissue. Therefore, the general condition of the bone affects stability (112).

b- Bone Density,

Bone density is the determining factor for intra-bone anchorage. Factors such as age and genetics of the patient determine bone density. Initial stability after mini-screw placement is achieved by the presence of cortical bone (122).
Usually, mini-screw failures are more frequent in the maxilla than the mandible, and the reason is the large trabeculae and low bone density in the maxillary bone (123,124).

c- Soft Tissue Properties,

The soft tissue type, health, and thickness around the mini-screw affect the stability of the mini-screw. Mini-screws are placed in non-keratinized alveolar tissue have a higher failure rate than mini-screws are placed in the attached tissue. Therefore, it is recommended to place the mini-screws in the keratinized mucosa instead of the non-keratinized mucosa (125,126).

d- Local Stress Condition,

Stress from the environment can affect mini-screw stability. An example of local stress is the excessive force occurring during chewing between the mandibular first and second molars (112).

e- Oral Hygiene,

Chronic peri-implantitis can cause bone resorption and affect the stability of the mini-screw. However, there is no evidence that chronic inflammation is a direct risk factor for implant loss (112).

2.9.1.3. Factors Related to the Insertion Method

Primary stability is of great importance for mini-screw success, the experience of the practitioner, sterilization, whether or not the flap is lifted during the surgical procedure, self-tapping or self-drilling technique, the diameter of the drilling hole, cooling technique, punching speed and pressure, whether the hole is drilled only in the cortex or through the entire screw, the direction of placement is reported to affect the stability of the mini-screw (111,114,125,127–129).

In dental implant studies, atraumatic surgery has been reported to play a major role in implant success (130).

Two types of trauma occur during placement. During the placement of the bone, physical pressure occurs that can cause trauma to the adjacent bone. Particularly during self-drilling screws placement, the adjacent bone is affected by physical stress and shear motion. This cutting action causes micro-fracture of bone tissues, rupture of the endosteum or periosteum, and necrosis of the bone cells. Another trauma is caused by the heat generated during the placement (112).

2.9.1.4. Factors Related to the Loading Conditions

Factors related to loading conditions are duration, magnitude, timing, and direction of the loading force.

Till these days, there is no evidence of how much force the mini-screws can withstand (131).

Butcher et al. reported that the thick mandibular bone could withstand the force of 900 gr and over. There are studies reporting that the mini-screw remains stable under 300 gr and less force. This wide force range depends on the mini-screw material property, the design of the mini-screws, the diameter of the mini-screws, the length of the mini-screws, the placement site, bone density, and personal factors. However, the force applied to the mini-screws used for orthodontic purposes varies between 50-400 gr (126,132–134).

It is reported that there is no difference between the immediate loading mini-screws and the loading of mini-screws two weeks later. Clinically, good mini-screws can be loaded immediately after insertion (135).

Roberts et al. stated that they placed a force on the titanium implants placed in the rabbit femur for 10 weeks and that the implant had to have at least 10% bone contact in order to resist movements. In the same study, they found that an endosseous implant that they applied, penetrated a portion of the root of the mandibular canine tooth and the periodontal space. However, a normal histological improvement was observed in the periodontal ligament and cementum layer, and the implant remained stable (136).

Mannchen et al. presented two cases of correcting the Class II dental relationship using palatal implants as anchors for upper molar distalization. The implants used in the study were placed a few millimeters distal to the mid-palatal suture in the anterior palatine and posterior to the incisive foramen. Distalization was achieved in two months with the treatment, and upper incisors were slightly retracted and lingual tipping was performed (137).

Byloff et al. used the Pendulum appliance in conjunction with the Graz implant in the palate to prevent the side-effects that occur with the classic Pendulum during molar distalization. They reported achieving a molar distalization within 8 months without the mesial movement of premolars and anterior teeth by applying this appliance on 7 patients with 250grams force. Also, they reported an easy activation of the appliance as well as being operator friendly (138).

Kırcelli et al. also did the same modification on the Pendulum appliance as Byloff et al., but the only difference was the screws, they used 2x8mm instead of the Graz implant. At the 7 months, They reported 10.9 degrees distal tipping and 6.4mm distal movement of the first molar; also, they reported 5.4mm distal movement of second premolars due to not being engaged in the anchorage unit (139).

Karaman et al. used a modified Distal Jet Appliance in conjunction with mini-screws placed in the rugae area in the palate to treat a 11 years old patient who has a unilateral Class II relationship. They reported 5mm molar distalization without any anchorage loss within 4 months (15).

Keleş et al. applied a Keleş Slider supported with palatal mini-screws on a 17 years old patient with Class II Division 1. At the end of the 5^{th} month, they reported 4mm molar distalization without any anchorage loss, an increase in the overjet, or incisors tipping. Also, they reported a bodily movement as the force was passing near the center of resistance of the molar from the palate. Palatal implants were removed 3 months before the end of fixed treatment, and bone healing was achieved at the end of the first month without scar tissue (106).

Gelgor et al. applied distalization force on molar from the buccal side, taking anchorage indirectly from mini-screws placed in the palate. They used 2mm diameter and 14mm length screws inserted them in the palate; TPA was connecting the first premolars together, passing around the screws in the form of U shape and attached to it by composite. The force was applying by NiTi open coil generating 250grams. At the end of 5 months, the researchers reported 8.8degrees distal molar tipping and 4mm distal movement together with disto-palatal rotation. Anchorage loss was not significant in their cephalometric evaluation (14).

Park et al., in 2004 treated 2 cases with Class II malocclusion by molar distalization using mini-screws. In the first case, they inserted the screw between the first and second molar from the palate; in the second case, they inserted the screw between the second premolar and first molar from the buccal side. They stated that molar distalization with anchorage taking from mini-screws is an efficient way of distalization without anchorage loss (140,141).

Sugawara et al. in 2006, applied for a mini plate in the zygomatic buttress area on 25 patients, their ages were between 15-45 years old who completed their growth and development; they called this system as ‘skeletal anchorage system’ (SAS). Before distalization, they extracted the third molars bilaterally for 12 patients, and the second molar for the other 6 patients as the third molars were difficult to extract for that group. They reported a 3.78mm crown distalization of the first molar and 3.2mm distalization at the root level (17).

Kaan et al. 2007 used a modified Lokar Appliance supported with mini-screws on 20 patients. They soldered an activator tube buccally on the molar band to the Lokar Appliance in order to make the force pass as close to the center of resistance as possible. The distalization force was taken from NiTi open coil taking anchorage from mini screw placed between the first molar and second premolar buccally. After 10.8 months of distalization, they got a result of 3.28mm distal movement of the molar with 5.48 degrees of distal tipping. Distal tipping of the upper incisor was insignificant, with 0.93 degrees of distal tipping and a decrease in overjet values.

In contrast to issues occurring with mini-screws in terms of the narrow buccal inter-radicular area and the possibility of root damage while distalization, difficulties faced with the surgical procedure needed for zygomatic anchorage systems, other sites for skeletal anchorage was investigated as the palate. The cortical bone thickness in the palate being sufficient and away from structures as nerves, vessels and roots thought to be suitable for mini-screws in the palate. Several researchers started to investigate the palate as an anchorage site.

3. MATERIALS AND METHODS

3.1. Materials

In order to examine the dental effects of a mini-screw assisted method developed for molar distalization, a study group consisting of 12 individuals compared with a control group consisting of 12 individuals who had been used Pendulum distalizer to differentiate the effects of the appliance on molar movement, rotation, tipping, and anterior anchorage loss.

In this study, the record of 12 patients (8 girls and 4 boys) whose ages ranged from 12 to 17 years with a mean age of 15.7 years has been collected from the Archive of Orthodontic Department of the Faculty of Dentistry of Yeditepe University who had been treated by distalization appliance assisted by mini-screws in the palate. The patients were included in the study according to the following criteria:

- Class I or II skeletal relationship
- Low or normal angle skeletal relationship
- Not having an open bite
- Having both sides dental class II relationship
- Minor crowding in the lower dentition
- The first and second maxillary molars are not missing
- Upper third molar extracted or being at germ form
- Non-extraction cases
- Patients who completed the distalization period and all the records had been taken before and after the distalization.

The control group included in this study consisted of 12 individuals (9 girls and 3 boys) with the same including criteria. Their records were also collected from the archive of the Department of Orthodontics in the Faculty of Dentistry of Yeditepe University.

The distalization time range for the study group was 4-7 months with a mean of 5.7 months and for the control group, 5-7 months and two weeks with a mean of 6.1 months.

The Ethical Committee of the Institute of Health Sciences, Yeditepe University, approved this retrospective study.

3.2. Molar Distalization with Palatinal Mini-Screws Assisted

3.2.1. Background Information

The appliance consisted of two sheathed bands cemented on the upper first molars, two mini screws 14x2mm inserted at the third rouge area on the palate, a special fabricated cap covering the head of the screws cemented on it by glass ionomer cement, 1.2mm stainless steel wire passing throw the caps connected to the 1.32mm hole pipe soldered with stainless steel Z-tube which is inserted to the palatal sheath of the molar bands, and a NiTi open coil used for activation (Fig.3.2.1). The patients were called in every four weeks for controls, and the coil was being activated when needed by adding stainless steel stopper or flowable composite on the wire mesially (Fig.3.2.2). Distalization was completed in 4-7 months, depending on the case.

After the distalization had been completed, the appliance and screws were removed, and a Nance appliance had been inserted to preserve the position of the molars. The fixed orthodontic treatment has been continued for the final alignment of the arch.

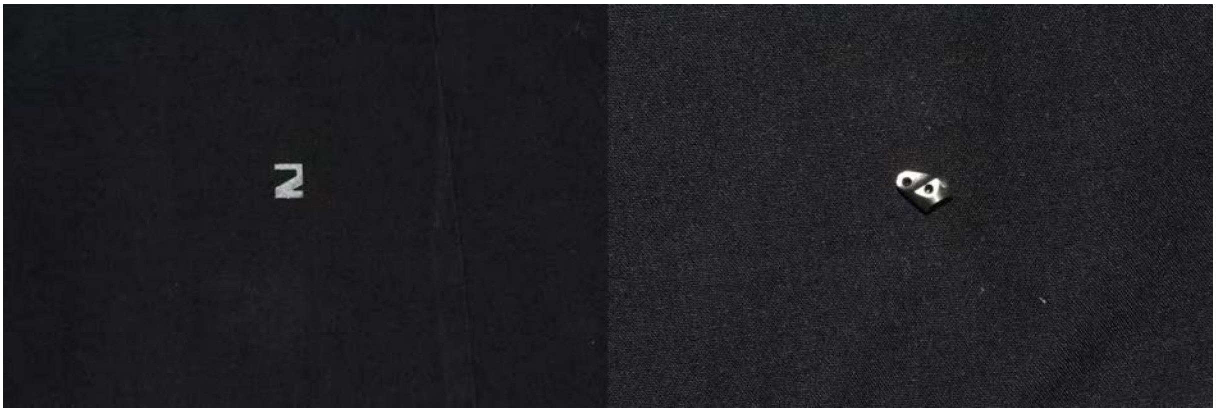

Figure 3.2.1.1. : Z-tube and Cap

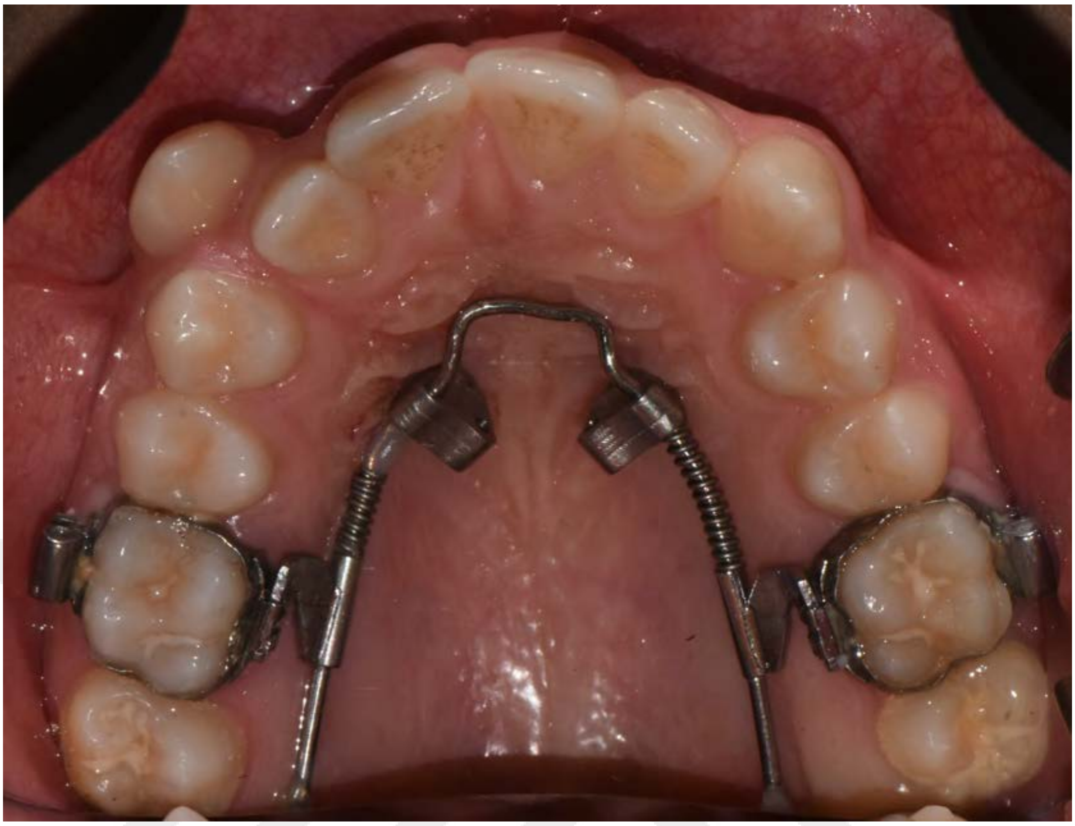

Figure 3.2.1.2. : Distalization mechanics

3.2.2. Placement of the Mini-screws

Two mini-screws 14x2mm were placed on the third rouge area in the palate for anchorage. After placing the mini-screws, the caps were temporarily fixed on the head of the mini screw by wax. Then a silicon impression had been taken with the molar bands and the caps.

3.2.3. Fabrication of the Appliance

The appliance had been fabricated at the laboratory of the Orthodontic Department of Yeditepe University. After taking the impression, the impression had poured by stone. Then 1.2 stainless steel wire had been designed to get an arch form. The wire has to pass from the holes of both the caps and the Z-tube. Also, it had to be long enough by distally in purpose to provide the sliding movement of the molar.

Figure 3.2.3.1: Fabrication of the appliance with adding face-mask hooks

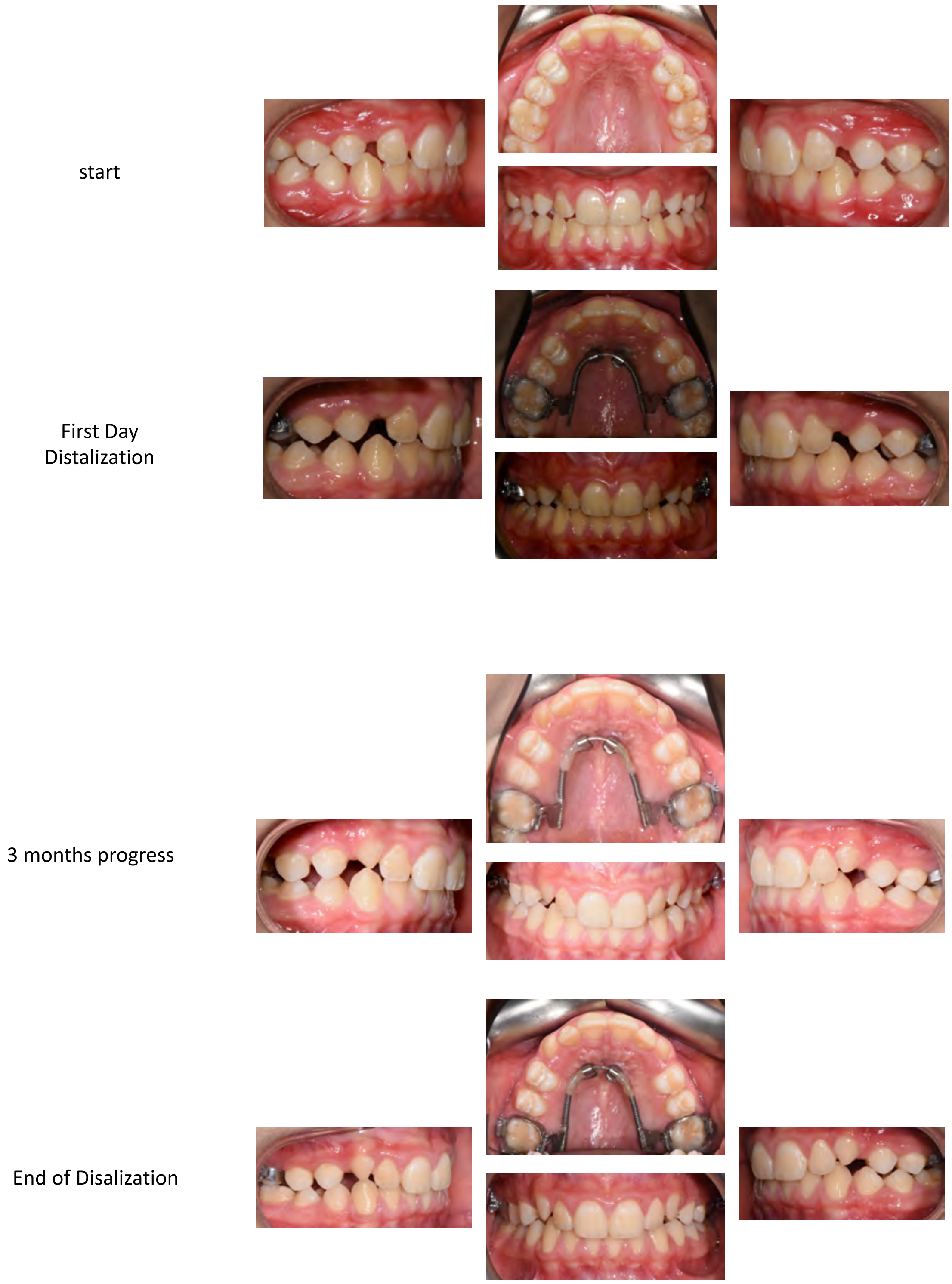

Figure 3.2.3.2.: Monthly Progress of a Bilateral Distalization Case

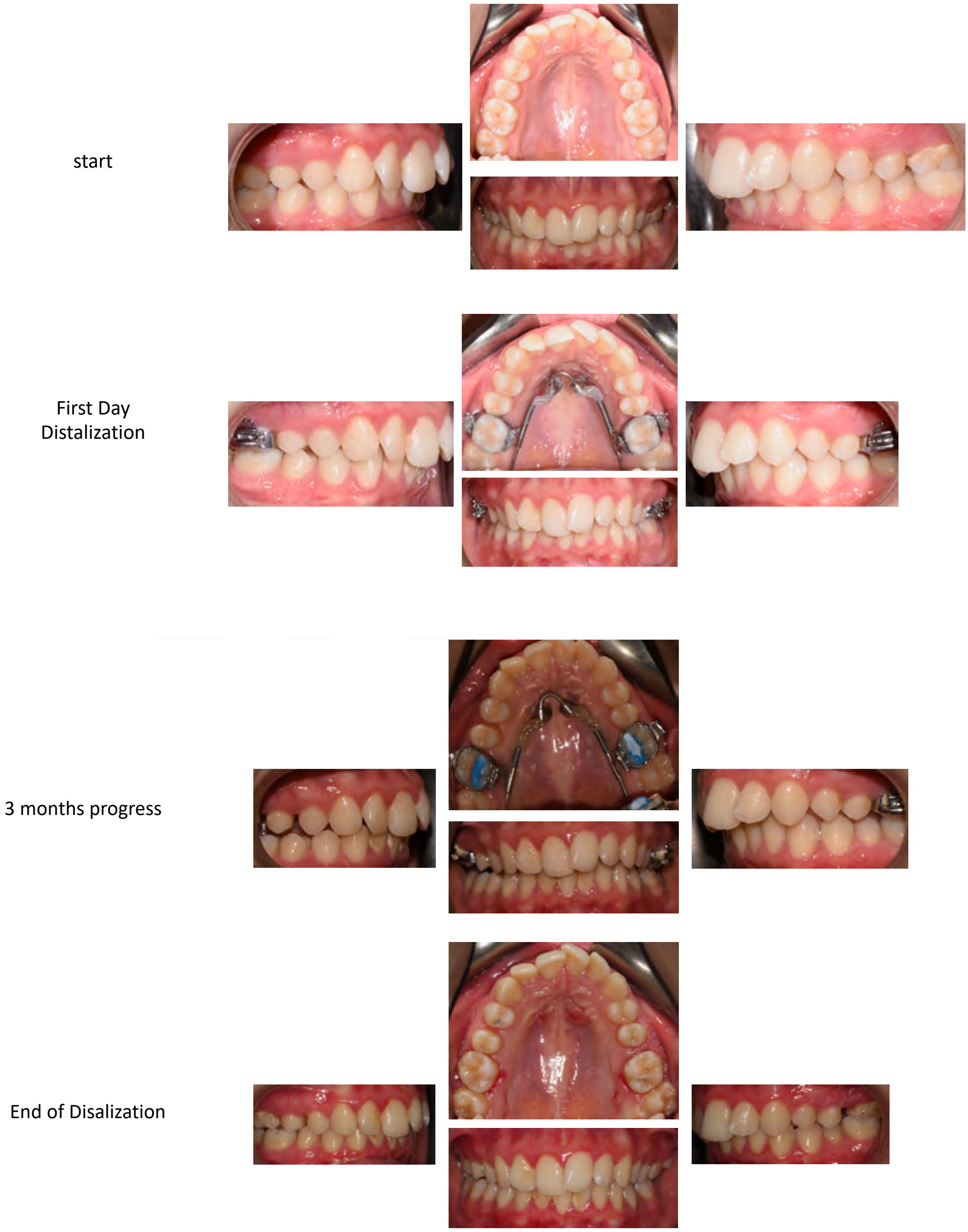

Figure 3.2.3.3.: Monthly Progress of an Another Bilateral Distalization Case

3.2. The Cephalometric Analysis

The changes that happened on the dental or soft tissues due to treatment were measured on lateral cephalometric radiographs, which were taken before and after the distalization.

3.3.1. Skeletal Points

1. S: Midpoint of Sella turcica
2. N: The most anterior intersected point of the nasofrontal suture
3. Po: The most superior point of meatus acusticus externus
4. Or: Most inferior point of the orbital cavity
5. Ba: The most posteroinferior point of the basillary part of the occipital bone.
6. ANS: The most anterior point of the maxillary part supporting the nose
7. PNS: The most posterior point of the hard palate.
8. A point: The most inner point of the alveolar process, between the ANS and the prosthion.
9. B point: The most inner point on the concavity between the pogonion mandibulary infra-dental point of the mandible.
10. Pg: The most anterior point of the mandible
11. Gn: The midpoint of menton and Pg.
12. Me: The most inferior point of the mandibular symphysis
13. Go: The most posterior and inferior point of the mandibular symphysis.

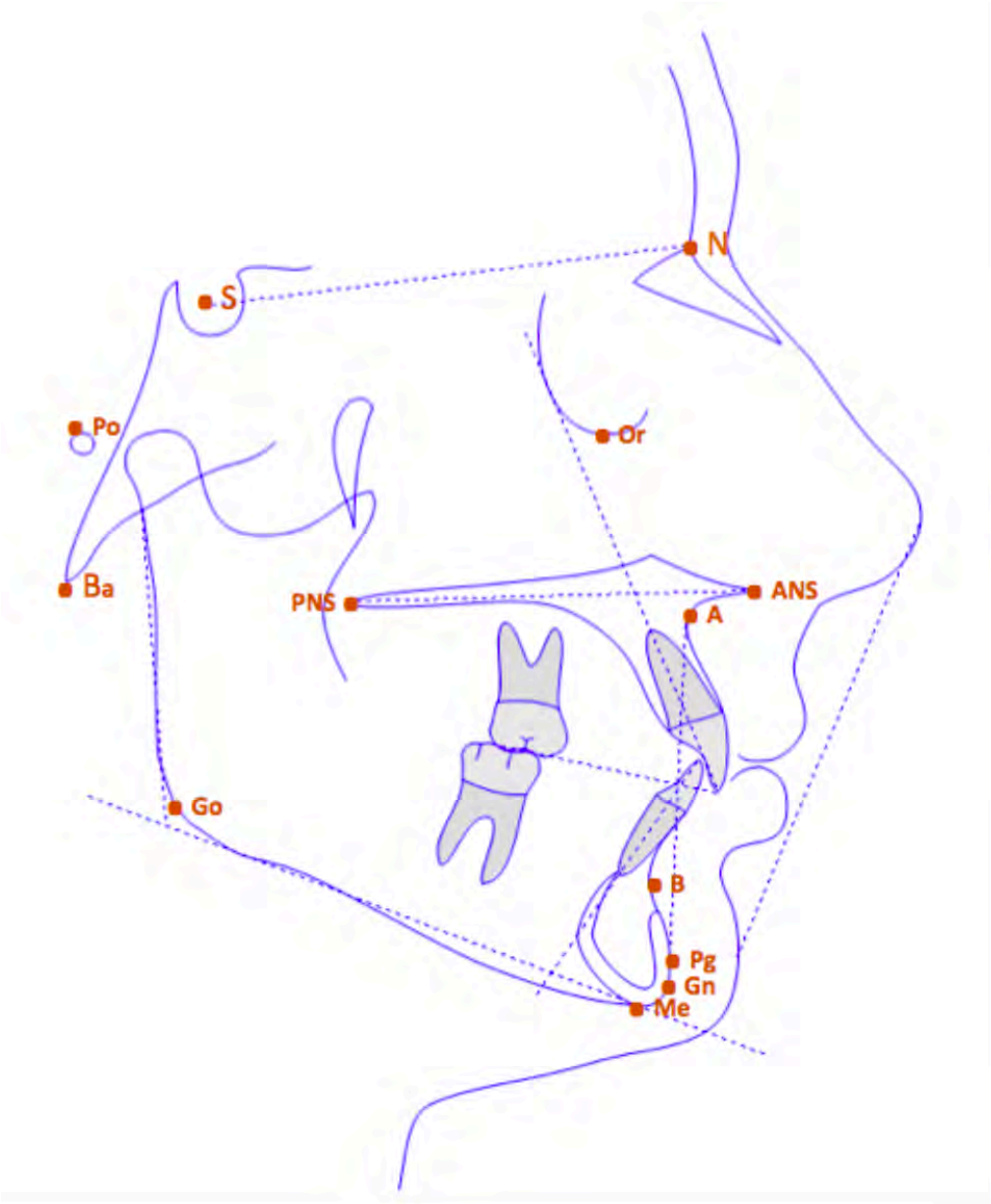

Figure 3.3.1. : Cephalometric Skeletal Points

3.3.2. Dental Points

1. U1i: The incisal edge of the upper central
2. U1a: The apex of the upper central
3. U4t: The cusp tip of the upper first premolar
4. U4a: The apex of the upper first premolar
5. U5t: The cusp tip of the upper second premolar
6. U5a: The apex of the upper second premolar
7. U6b: The bifurcation point of the upper first molar
8. U6bg: The buccal development groove of the upper first molar
9. U7b: The bifurcation point of the upper second molar
10. U7bg: The buccal development groove of the upper second molar.

3.3.3. Soft Tissue Points

1. Sn, subnasale: The intersection point of the nose with the upper lip.
2. Ls, labiale superior: The most superior anterior point of the upper lip.
3. Li labiale inferior: The most inferior and anterior point of the lower lip.
4. Pgs: Soft tissue pogonion, the most anterior point of the chain.

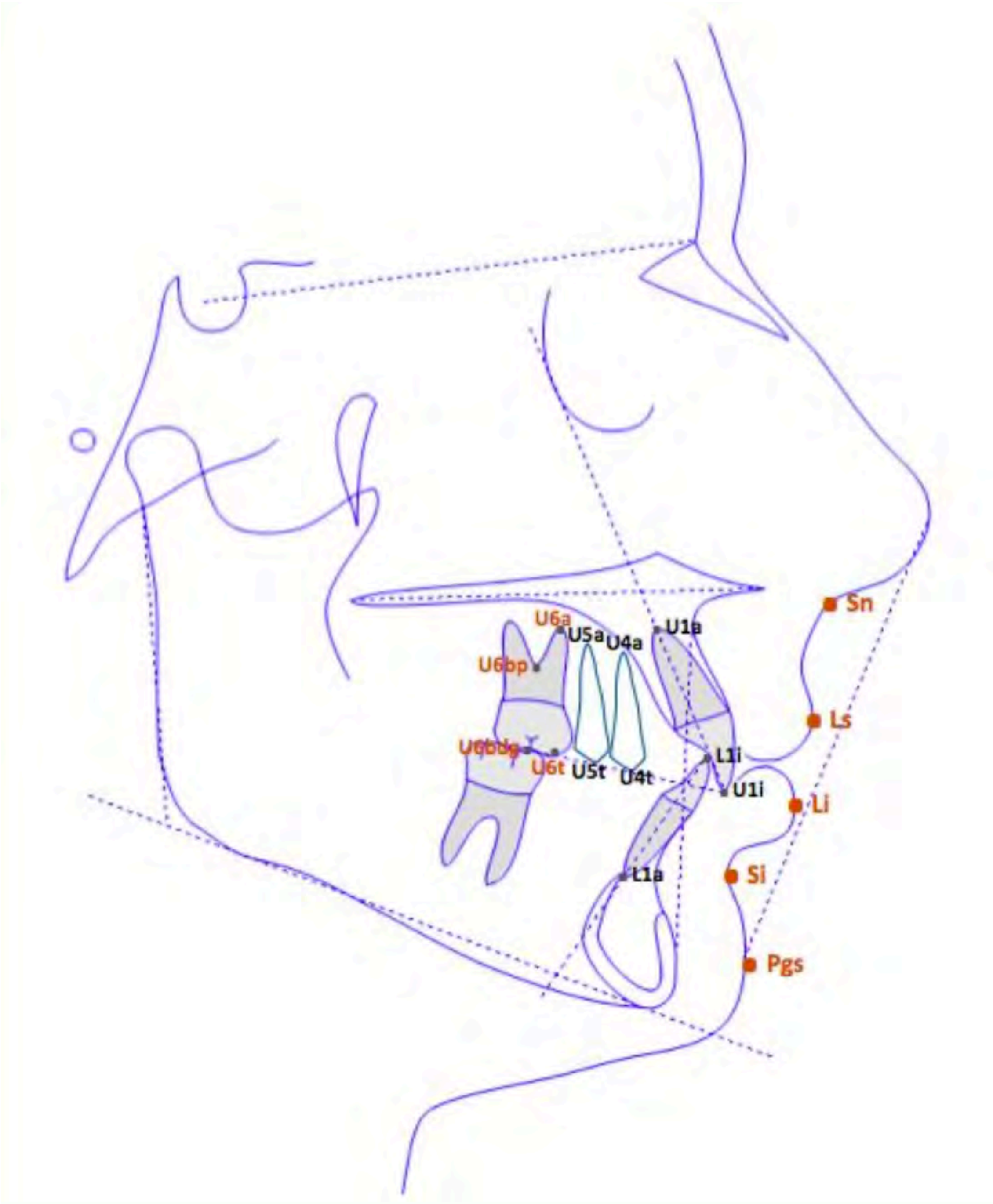

Figure 3.3.2. : Soft tissue and Dental points.

3.3.4. Reference planes

1. SN: The plane passing through Sella and Nasion
2. Palatal Plane (PP): The plane passing through the anterior nasal spine and posterior nasal spine
3. Occlusal Plane (OP): The plane passing through incisal edges of upper and lower incisor anteriorly and the buccal cusp of upper and lower molars posteriorly.
4. Mandibular Plane (MP): The plane passing through gonion and metal point

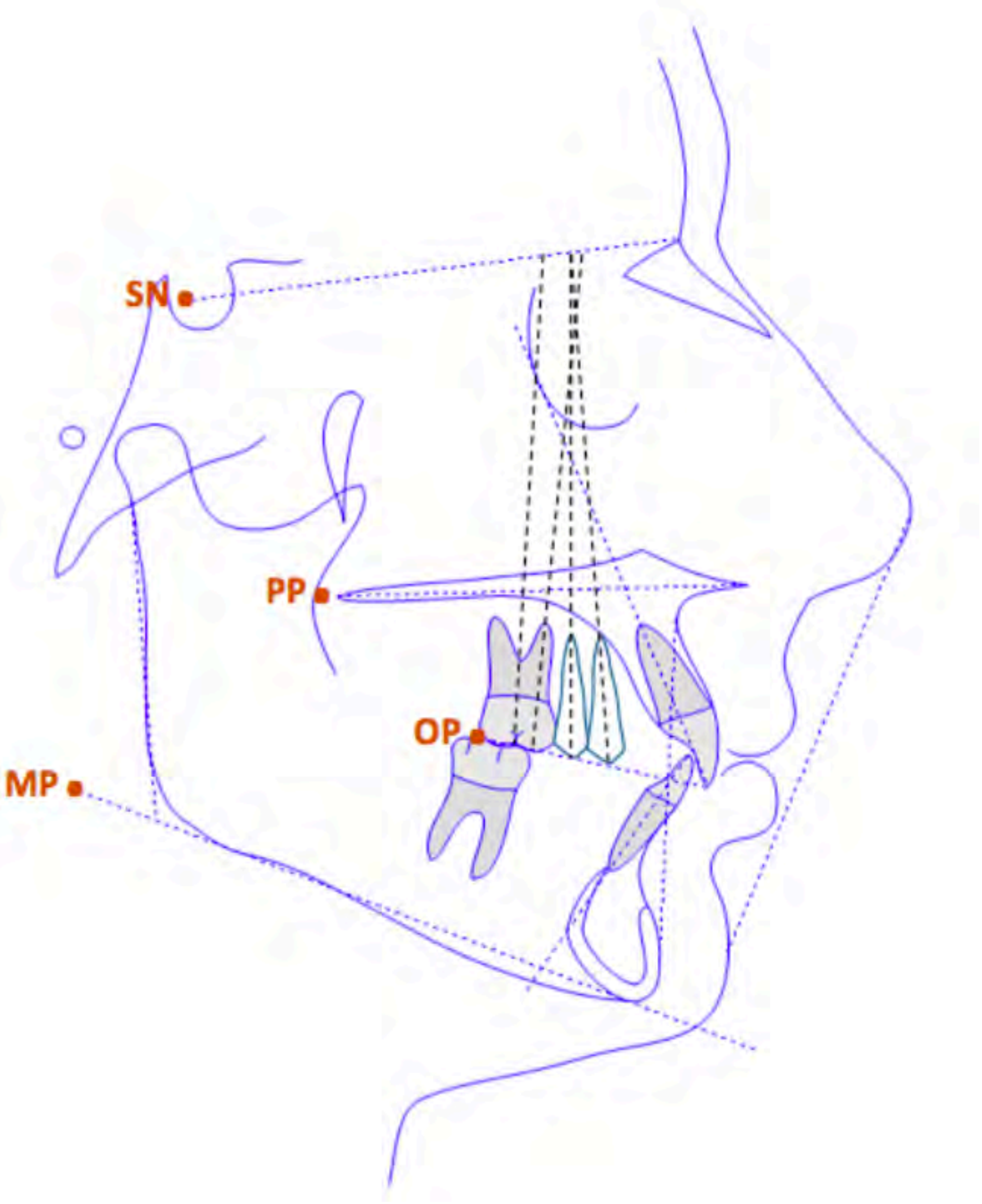

Figure 3.3.3. : Cephalometric reference planes.

3.3.5 Cephalometric Measurements Used In Study

1. U1^SN: The angle between upper central to the cranial base
2. U6^SN: The angle between the upper first molar to the cranial base
3. U4^SN: The angle between the upper first bicuspid to the cranial base
4. U5^SN: The angle between the upper second bicuspid to the cranial base
5. U7^SN: The angle between the upper second molar to the cranial base

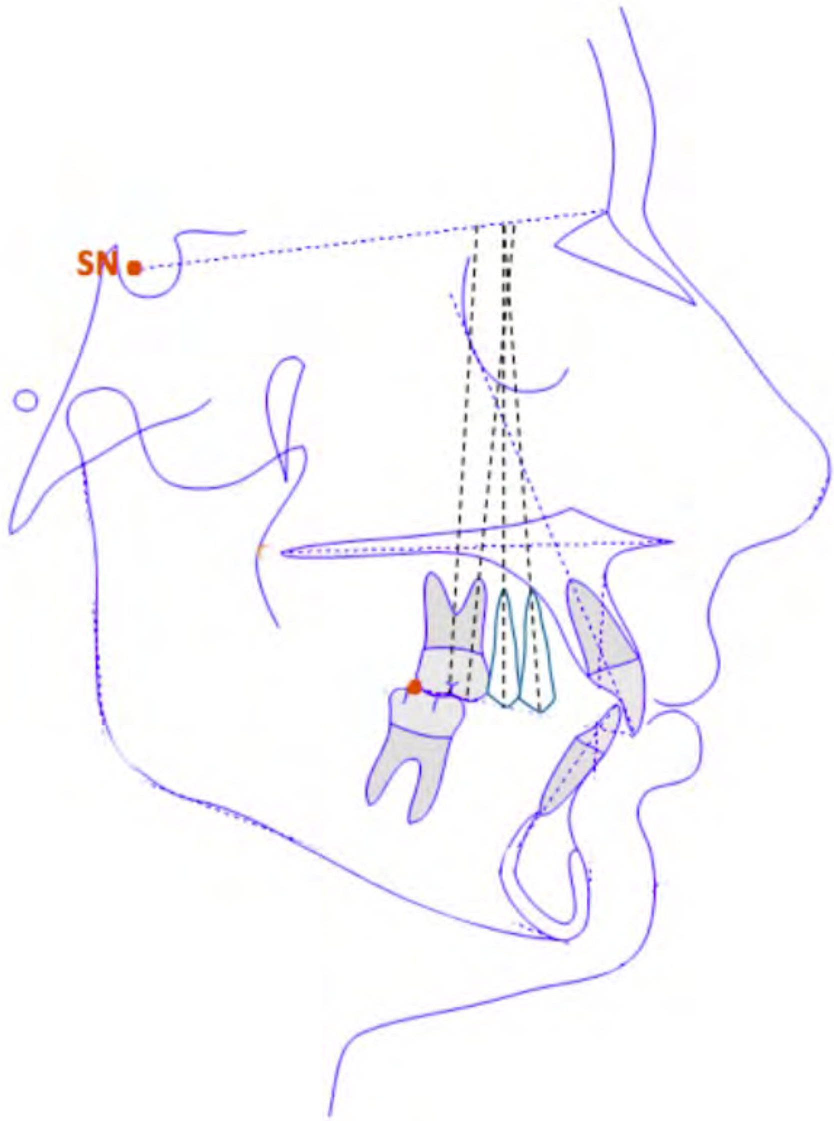

Figure 3.3.4. : Cephalometric Measurements Used In Study

3.5. Study Cast Analysis

Two plaster models had been prepared for each patient, one before the distalization and one after the distalization.
Each model had been scanned by the SIRONA device (ORTHOMODEL 2007) in order to get an STL format from each model. (Fig 3.5.1.)
The upper models of each case before and after the distalization had been transferred to MIMICS software version 16.0 (Materialise's Interactive Medical Image Control System) in purpose to get all the measurements.

The pre (T0) and after (T1) distalization digital models of the same case had been superimposed on three fixed points (incisive papilla, right and left second rouge area), taking into consideration the maxillary rouge area is a reliable reference anatomical site according to the study done by Hoggan and Sadowsky in 2001 (142). T0 & T1 were given different colors in purpose to get clear superimposed images. (Fig 3.5.2.)

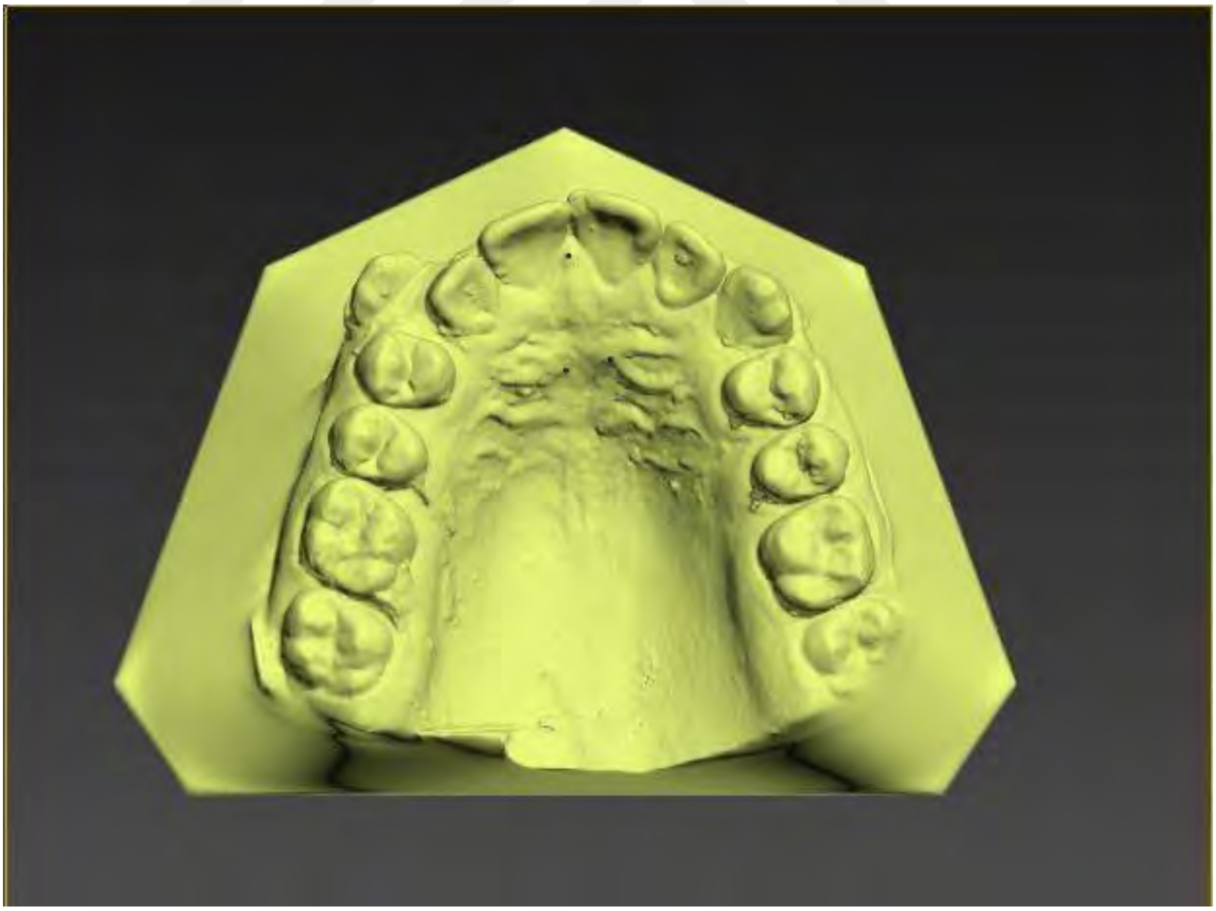

Figure 3.5.1. : STL format of the model

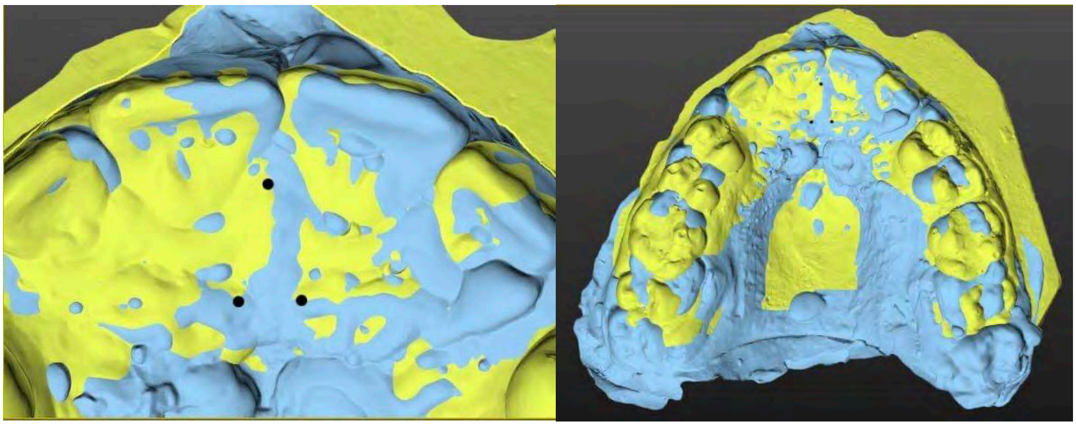

Figure 3.5.2. : Superimposition on three fixed points

In order to determine the possible amount of transversal and sagittal movement in the teeth before and after distalization, the plane passing through the mid-palatal suture was used as the “Y” reference plane, and the “X” reference planes obtained perpendicularly to the “Y” plane, passing through the incisive papilla point. (Fig 3.5.3.)

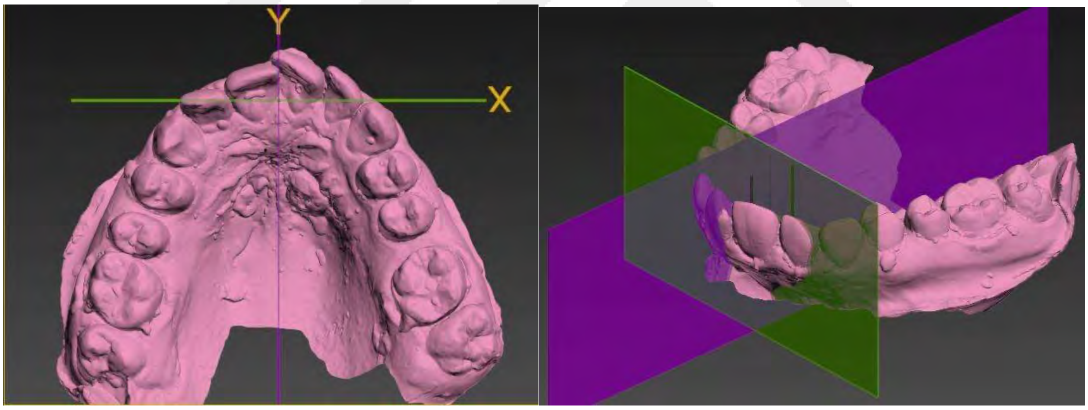

Fig 3.5.3. : X-Y reference planes

To calculate the amount of sagittal movement for the upper teeth, a perpendicular plane from “X” to the mesial cusp tip of the upper cuspid, first bicuspid, second bicuspid, the first molar and the second molar separately had been extended. This process was done on T0 and T1 digital models; then, by calculating the differences between the lengths of these lines on T0 and T1, the amount of movements was determined for each tooth examined. (Fig 3.5.4.)

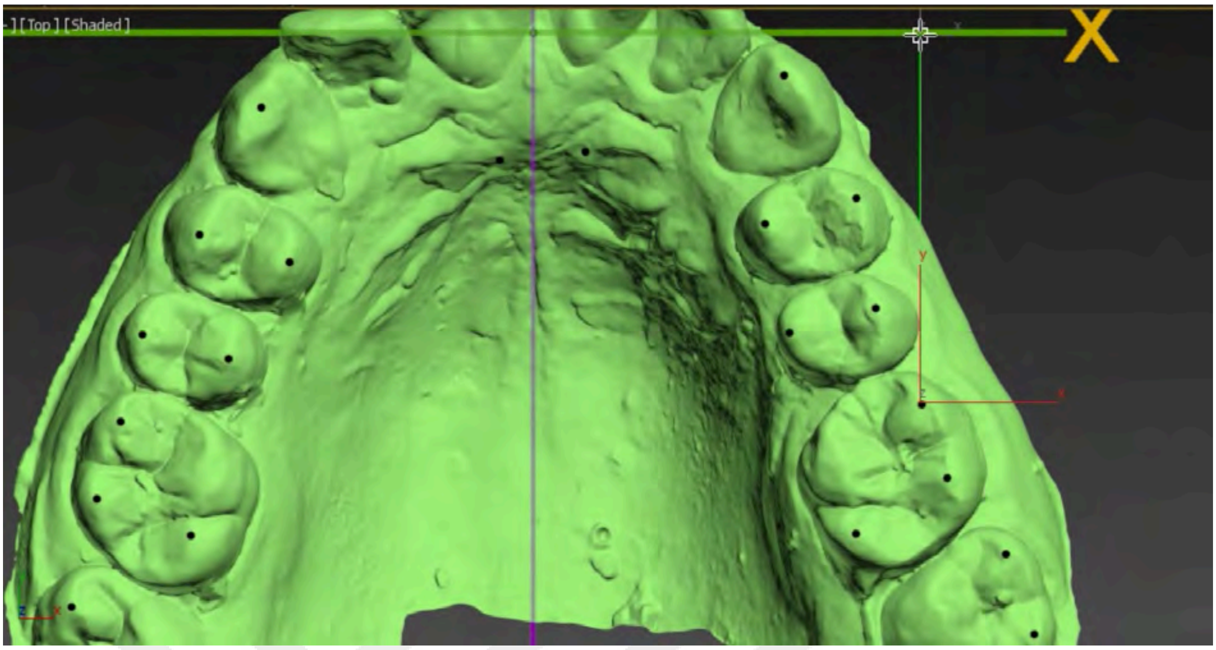

Figure 3.5.4. : Measuring the distance from upper first molar to X Plane

In order to determine the amount of rotation after distalization, two points had been registered for each posterior tooth in the upper arch, one point is the tip of the buccal cusp, and the other is the tip of the palatal cusp. A plane passing through these two points to the "Y" reference plane had been created. The angle between this plane and the "Y" plane had been measured twice, before and after the distalization. The difference between the angles of each tooth shows the amount of rotation. (Fig 3.5.5.)

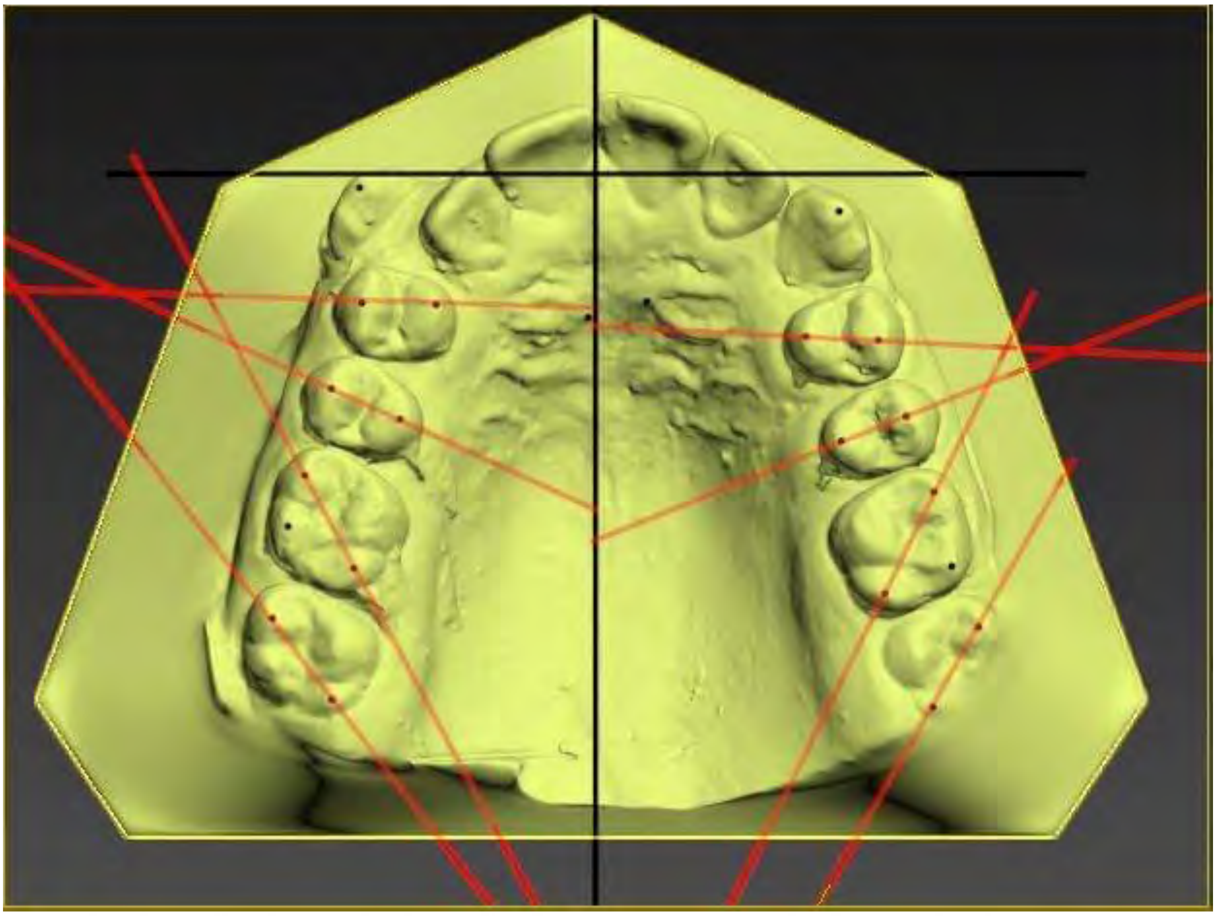

Figure 3.5.5. : Measuring the rotation from upper teeth to Y Plane

3.5.1. Points Used in the Study

1. 3: The tip of the upper right canine
2. 3’: The tip of the upper left canine
3. 4b: The tip of the buccal cusp of the first right premolar
4. 4p: The tip of the palatal cusp of the first right premolar
5. 4’b: The tip of the buccal cusp of the left first premolar
6. 4’p: The tip of the palatal cusp of the left first premolar
7. 5b: The tip of the buccal cusp of the second right premolar
8. 5p: The tip of the palatal cusp of the second right premolar
9. 5’b: The tip of the buccal cusp of the left second premolar
10. 5’p: The tip of the palatal cusp of the left second premolar
11. 6mb: The tip of the mesiobuccal cusp of the right first molar
12. 6db: The tip of the distobuccal cusp of the right first molar
13. 6dp: The tip of the distopalatal cusp of the right first molar
14. 6’mb: The tip of the mesiobuccal cusp of the left first molar
15. 6’db: The tip of the distobuccal cusp of the left first molar
16. 6’dp: The tip of the distopalatal cusp of the left first molar
17. 7mb: The tip of the mesiobuccal cusp of the right second molar
18. 7db: The tip of the distobuccal cusp of the right second molar
19. 7’mb: The tip of the mesiobuccal cusp of the left second molar

20. 7'db: The tip of the distobuccal cusp of the left second molar

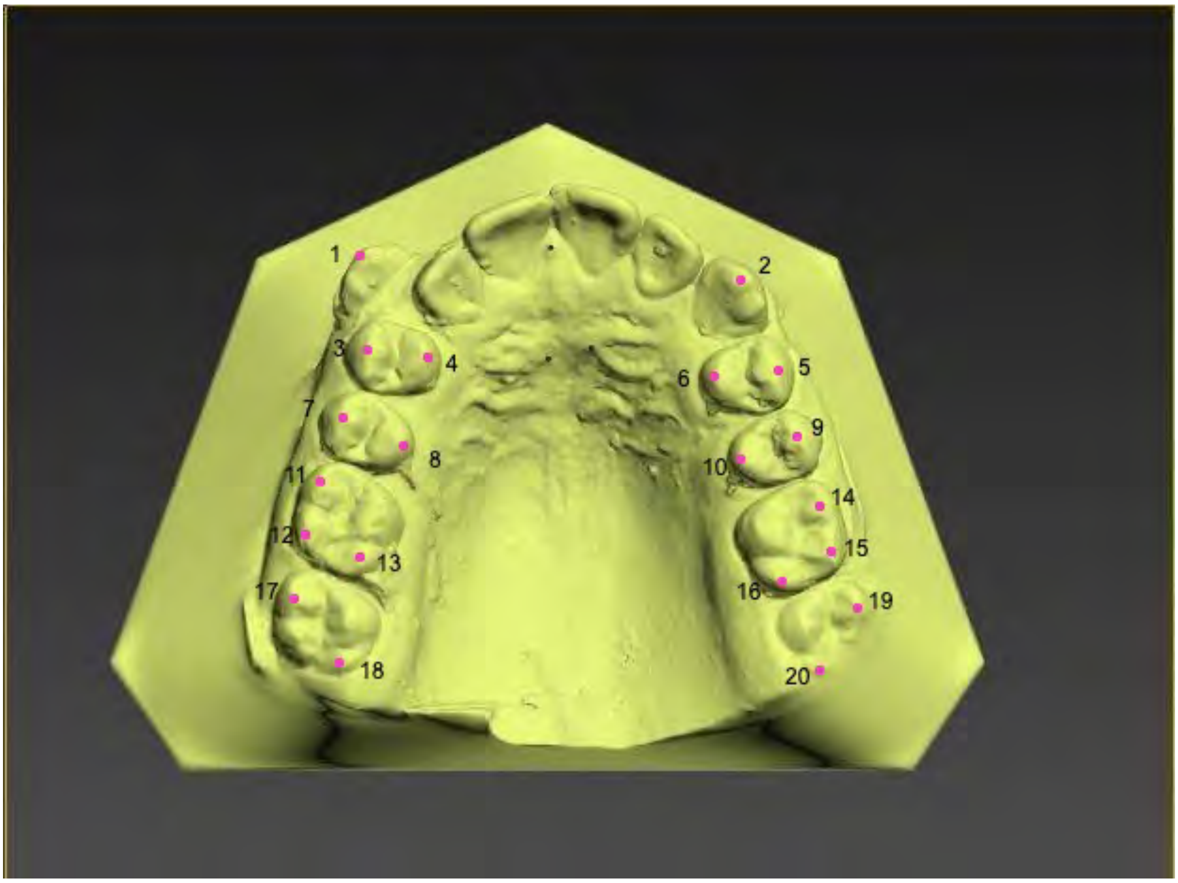

Figure 3.5.1.1 : Model points used in the study

3.5.2. Angles Used in the Study

1. 4/Y: The inner angle of the plane passing through buccal and palatal cusp tip of right first premolar with "Y" reference plane.
2. 4'/Y: The inner angle of the plane passing through buccal and palatal cusp tip of left the first premolar with "Y" reference plane.
3. 5/Y: The inner angle of the plane passing through buccal and palatal cusp tip of right second premolar with "Y" reference plane.
4. 5'/Y: The inner angle of the plane passing through buccal and palatal cusp tip of left second premolar with "Y" reference plane.
5. 6/Y: The inner angle of the plane passing through the mesiobuccal and distopalatal cusp tip of the right first molar with "Y" reference plane.
6. 6'/Y: The inner angle of the plane passing through mesiobuccal and distopalatal cusp tip of the left first molar with "Y" reference plane.
7. 7/Y: The inner angle of the plane passing through the mesiobuccal and distopalatal cusp tip of the right second molar with "Y" reference plane.
8. 7'/Y: The inner angle of the plane passing through mesiobuccal and distopalatal cusp tip of left second molar with "Y" reference plane.

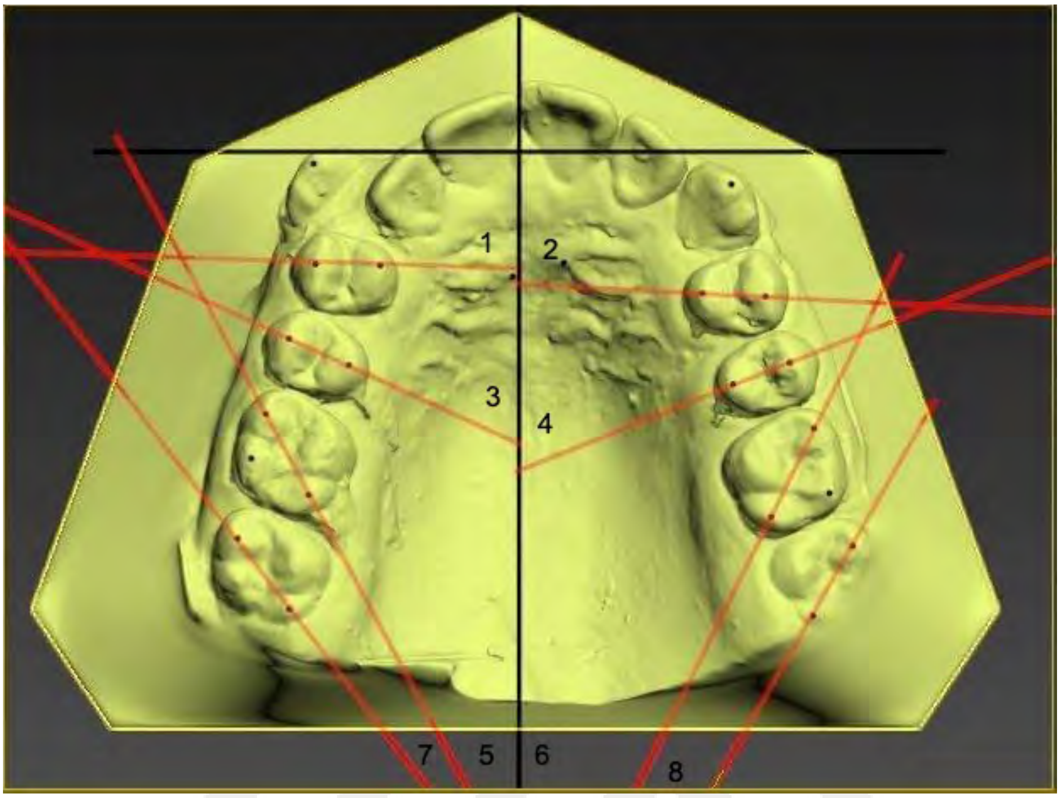

Figure 3.5.2.1. : Model angles used in the study

3.5.3. Linear Measurements Used in the Study

1. 3⊥X: Perpendicular plane from X plane to the tip of the right upper canine
2. 3'⊥X: Perpendicular plane from X plane to the tip of the left upper canine
3. 4⊥X: Perpendicular plane from X plane to the buccal cusp tip of the right first premolar
4. 4'⊥X: Perpendicular plane from X plane to the buccal cusp tip of the upper left first premolar
5. 5⊥X: Perpendicular plane from X plane to the buccal cusp tip of the upper right second premolar
6. 5'⊥X: Perpendicular plane from X plane to the buccal cusp tip of the upper left second premolar
7. 6⊥X: Perpendicular plane from X plane to the mesiobuccal cusp tip of the upper right first molar
8. 6'⊥X: Perpendicular plane from X plane to the mesiobuccal cusp tip of the upper left first molar
9. 7⊥X: Perpendicular plane from X plane to the mesiobuccal cusp tip of the upper right second molar
10. 7'⊥X: Perpendicular plane from X plane to the mesiobuccal cusp tip of the upper left second molar

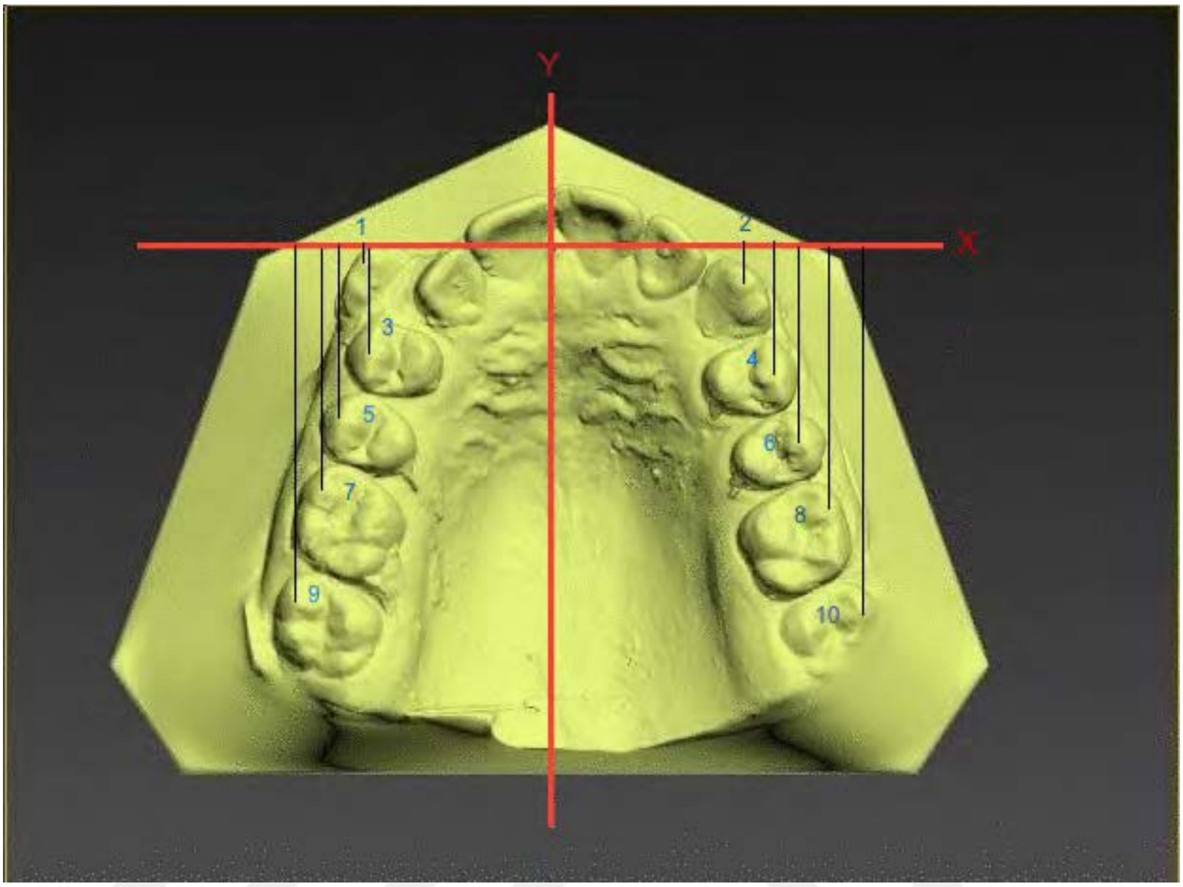

Figure 3.5.3.1 : Liner Measurements Used In The Study

4. STATISTICAL ANALYSIS

The statistical analysis in this study were performed by using the NCSS (Number Cruncher Statistical System) 2007 Statistical Software (Utah, USA) package program.

In the evaluation of the data, in addition to descriptive statistical methods (mean, standard deviation), the distribution of variables was examined with the Shapiro - Wilk normality test.

The paired t-test was used in the pre-treatment and post-treatment comparisons of the variables with a normal distribution.

The independent t-test had been used in the comparison of paired groups, Mann Whitney U test was used in the comparison, and chi-square test was used in the comparison of qualitative data.

The results were evaluated at the significance level of $p<0.05$.

While calculating the sample size of this study, the G*power program was used.

The sample size was found 7 subjects at least.

5. RESULTS

In this study conducted to examine the dental effects of the palatinal mini-screw supported appliance developed for bilateral molar distalization, the descriptive statistical data regarding the chronological age and gender of the study group consisting of 12 individuals and the control group consisting of 12 individuals using the pendulum apparatus is presented in the (Table 5.1.).

As seen in Table 5.1., the chronological average age of 24 individuals included in the study and control groups is 14 years and 10 months.

In the study group, it was observed that the distalization period varied between 6 months 2 weeks and 3 months 2 weeks and lasted in an average of 5 months and 3 weeks. In the control group, distalizaiton periods range from 7 months and 1 week to 5 months and 1 week, and the average is 5 months and 3 weeks.

The descriptive statistical information about the findings regarding the comparison of the means for the initial orthodontic model and cephalometric measurements in the application and control groups are presented in the Table 5.2..

The descriptive statistical information about the findings regarding the comparison of the means for the orthodontic model and cephalometric measurements after the distalization in the study and control groups are presented in the Table 5.3..

The descriptive statistical information about the orthodontic model and cephalometric measurements of the study group and the findings related to the intragroup comparison of the mean before and after the distalization is presented in the Table 5.4..

The descriptive statistical information about the orthodontic model and cephalometric measurements of the control group and the findings related to the intragroup comparison of the mean before and after the distalization is presented in the Table 5.5..

The descriptive statistical information about the findings regarding the comparison of the mean total distalization, rotation, and tipping movements for the orthodontic model and cephalometric measurements after the distalization in the study and control groups are presented in the Table 5.6..

3D Study Cast Pre-treatment Analysis

The difference between the pre-treatment $3{\perp}X$, $4{\perp}X$, $5{\perp}X$, $6^{mb}{\perp}X$, $6^{db}{\perp}X$, and $7{\perp}X$ distance measurement means of the study and control groups were not found to be statistically significant. $p>0,05$

The difference of the pre-treatment 4/Y, 6/Y, 7/Y angle measurement means of the study and control groups were not found to be statistically significant. $p>0.05$

The pre-treatment 5/Y angle measurement means of the Study Group were found to be statistically significantly lower than the control group. $p<0.05$

Cephalometric Pre-treatment Analysis

The pre-treatment U1/SN, U4/SN, U6/SN, U7/SN angles means of the study and control groups were not found to be statistically significant. $p>0.05$

The pre-treatment U5/SN angle means of the Study Group were found to be statistically significantly lower than the control group. $p<0.05$

Comparison of the Post-treatment 3D Cast Analysis of the Control and Study Groups

3>X mean measurement of the study group was found to be statistically significantly higher than the control group (p = 0.0001).

4>X mean measurement of the study group was found to be statistically significantly higher than the control group (p = 0.0001).

5>X mean measurement of the study group was found to be statistically significantly higher than the control group (p = 0.0001).

There was no statistically significant difference between the 3D Cast Analysis 6 mb> X measurement averages of the control and study groups (p = 0.441).

3D Cast Analysis 6 db> X mean measurement of the study group was found to be statistically significantly lower than the control group (p = 0.018).

There was no statistically significant difference between the 3D Cast Analysis 7> X measurement averages of the control and study groups (p = 0.305).

3D cast analysis of the post-treatment study group 4/Y angle averages were found to be statistically significantly lower than the control group (p = 0.001).

3D Cast Analysis 5/Y angle averages of the study group were found to be statistically significantly lower than the control group (p = 0.0001).

There was no statistically significant difference between the 3D Cast Analysis 6/Y angle averages of the control and study groups (p = 0.333).

There was no statistically significant difference between the 3D cast analysis 7/Y angle averages of the control and study groups (p = 0.333).

Comparison of the Post-treatment Cephalometric Analysis of Control and Study groups

The mean measurements of the cephalometric analysis U1 / SN of the post-treatment study group were found to be statistically significantly lower than the control group (p = 0.002).

The mean measurement of cephalometric analysis U4 / SN of the study group was found to be statistically significantly lower than the control group (p = 0.0001).

The mean measurement of cephalometric analysis U5 / SN of the study group was found to be statistically significantly lower than the control group ($p = 0.0001$).

The mean measurement of cephalometric analysis U6 / SN of the study group was found to be statistically significantly lower than the control group ($p = 0.005$).

There was no statistically significant difference between the cephalometric analysis U7 / SN measurement averages of the control and study groups ($p = 0.184$).

Comparison of the Pre and Post-treatment of 3D Study Cast Analysis for the Study Group

The mesiobuccal cusp of upper first molars' mean distance to the X plane was 23.78±2.80mm before the treatment and 27.64±2.79mm after the treatment, which was found statistically significant ($p<0.05$). According to the statistical analysis, the mean amount of distalization of the mesial and distal cusps of the upper first molars were 3.86±1.92mm and 3.57±1.91mm to X plane accordingly ($p<0.05$), this distalization accomplished with 1.10±0.70 degree mesiopalatinal rotation to Y plane ($p<0.05$).

The upper second molars' mean distance to the X plane was 35.13±3.38mm before the treatment and 38.56±3.94mm after the treatment, which was found statistically significant ($p<0.05$). According to the statistical analysis, the mean amount of distalization of the upper second molars was 3.43±2.31mm ($p<0.05$). This distalization accomplished non-significant with 2.09±3.85 degrees disto-palatinal rotation to Y plane ($p>0.05$).

The upper second premolars' mean distance to the X plane was 17.50±2.74mm before the treatment and 20.13±2.38mm after the treatment, which was found statistically significant ($p<0.05$). According to the statistical analysis, upper second premolars moved distally by distal drifting; the mean amount of distalization was 2.63±2.09mm ($p<0.05$). This distalization was accomplished with non-significant 1.17±3.92 degrees mesiopalatinal rotation to the Y plane ($p>0.05$).

The upper first premolars' mean distance to the X plane was 10.88±2.26mm before the treatment and 11.73±3.58mm after the treatment, which was not found statistically significant ($p>0.05$). According to the statistical analysis, upper first premolars moved distally by distal drifting; the mean amount of distalization was 1.60±1.88mm ($p>0.05$). This distalization was accomplished with non-significant 2.68±5.58 degrees mesiopalatinal rotation to the Y plane ($p>0.05$).

The upper canines' mean distance to the X plane was 2.88±1.94mm before the treatment and 3.93±1.54mm after the treatment, which was found statistically significant ($p<0.05$). According to the statistical analysis, upper canines moved distally by distal drifting, the mean amount of distalization was 1.06±1.46mm ($p<0.05$).

Comparison of the Pre and Post-treatment Cephalometric Analysis of the Study Group

The upper central's mean angulation to the SN plane was (97.08±5.65) before the treatment and (97.07±5.64) after the treatment, which was not found statistically significant ($p>0.05$). These results show that the upper centrals had tipped 0.02±0.06 degrees.

The upper first molars' mean angulation to the SN plane was 68.25±3.60 degrees before the treatment and 67.02±3.66 degrees after the treatment, which were found statistically significant ($p<0.05$). These results show the upper first molar had tipped 1.23±0.87 degrees distally.

The upper second molars' mean angulation to the SN plane was 61.64±4.76 degrees before the treatment and 58.95±4.74 degrees after the treatment, which were found statistically significant ($p<0.05$). These results show the upper first molar had tipped 2.69±0.64 degrees distally.

The upper second premolars' mean angulation to the SN plane was 71.75±5.17 degrees before the treatment and 67.49±8.23 degrees after the treatment, which was found statistically significant ($p<0.05$). These results show the upper first molar had tipped 5.93±1.60 degrees distally.

The upper first premolar's mean angulation to the SN plane was 79.08±6.08 degrees before the treatment and 76.07±4.79 degrees after the treatment, which was found statistically significant ($p<0.05$). These results show the upper first molar had tipped 2.93±1.45 degrees distally.

Comparison of the Pre and Post-treatment 3D Study Cast Analysis of the Control Group

The mesiobuccal cusp of upper first molars' mean distance to the X plane was 24.49±1.40mm before the treatment and 28.83±2.42mm after the treatment, which was found statistically significant ($p<0.05$). According to the statistical analysis, the mean amount of distalization of the mesial and distal cusps of the upper first molars were 4.34±1.16mm and 4.76±1.31mm to X plane accordingly ($p<0.05$), this distalization accomplished with 2.29±0.75 degree mesiopalatinal rotation to Y plane ($p<0.05$).

The upper second molars' mean distance to the X plane was 36.32±1.45mm before the treatment and 40.04±2.04mm after the treatment, which was found statistically significant ($p<0.05$). According to the statistical analysis, the mean amount of distalization of the upper second molars was 3.72±0.76mm ($p<0.05$). This distalization accomplished significant with 1.34±1.15 degrees mesiopalatinal rotation to Y plane ($p<0.05$).

The upper second premolars' mean distance to the X plane was 17.38±1.45mm before the treatment and 15.23±0.96mm after the treatment, which was found statistically significant ($p<0.05$). According to the statistical analysis, the mean amount of anchorage loss of the upper second premolars were 2.16±0.67mm. This mesialization movement accomplished with significant 6.05±1.97 degrees of disto-palatinal rotation to the Y plane ($p<0.05$).

The upper first premolars' mean distance to the X plane was 9.78±1.12mm before the treatment and 7.33±0.74mm after the treatment, which was found statistically significant ($p<0.05$). According to the statistical analysis, upper first premolars moved mesially by anchorage loss, the mean amount of mesialization were 2.46±0.71mm ($p>0.05$). This mesialization movement was accomplished with a significant 6.02±1.25 degrees distopalatinal rotation to the Y plane ($p<0.05$).

The upper canine's mean distance to the X plane was 3.63±0.75mm before the treatment and 0.48±0.88mm after the treatment, which was found statistically significant ($p<0.05$). According to the statistical analysis, upper canines moved mesially by anchorage loss, the mean amount of distalization were 3.05±0.78mm ($p<0.05$).

Comparison of the Pre and Post-treatment Cephalometric Analysis of the Control Group

The upper central's mean angulation to the SN plane was (96.67±2.99) before the treatment and (103.92±3.42) after the treatment, which was found statistically significant ($p<0.05$). These results show that the upper centrals had tipped 7.08±1.00 degrees mesially.

The upper first molars' mean angulation to the SN plane was 67.08±1.78 degrees before the treatment and 63.42±1.51 degrees after the treatment, which were found statistically significant ($p<0.05$). These results show the upper first molar had tipped 3.67±0.78 degrees distally.

The upper second molars' mean angulation to the SN plane was 60.70±0.82 degrees before the treatment and 56.80±1.32 degrees after the treatment, which were found statistically significant ($p<0.05$). These results show the upper first molar had tipped 3.70±0.95 degrees distally.

The upper second premolars' mean angulation to the SN plane was 77.25±1.76 degrees before the treatment and 81.92±1.83 degrees after the treatment, which were found statistically significant ($p<0.05$). These results show the upper first molar had tipped 4.67±0.98 degrees mesially.

The upper first premolars' mean angulation to the SN plane was 81.67±2.81 degrees before the treatment and 87.92±1.12 degrees after the treatment, which were found statistically significant ($p<0.05$). These results show the upper first molar had tipped 6.25±0.97 degrees mesially.

Comparison of the Total Distalization and Distolingual Rotation of the Control and Study Groups

Total distalization 3>X mean measurement of the study group was found to be statistically significantly higher than the control group ($p = 0.0001$).

Total distalization 4>X mean measurements of the study group were found to be statistically significantly higher than the control group ($p = 0.0001$).

Total distalization 5>X mean measurements of the study group were found to be statistically significantly higher than the control group ($p = 0.0001$).

There was no statistically significant difference between the mean of Total distalization 6 mb>X measurement of the control and study groups (p = 0.464).

Total distalization mean measurement of 6db>X of the study group was found to be statistically significantly higher than the control group (p = 0.024).

There was no statistically significant difference between the means of Total distalization 7>X measurements of the control and study groups (p = 0.448).

Total distolingual rotation 4 / Y angle averages of the study group were found to be statistically significantly lower than the control group in the model analysis (p = 0.005).

Total distolingual rotation 5 / Y angle averages of the study group were found to be statistically significantly lower than the control group in the model analysis (p = 0.001).

Total distolingual rotation 6 / Y angle averages of the study group were found to be statistically significantly higher than the control group in the model analysis (p = 0.001).

Total distolingual rotation 7 / Y angle averages of the study group were found to be statistically significantly higher than the control group in the model analysis (p = 0.041).

Comparison of the Total Distal Tipping of the Control and Study Groups

The mean of total distal tipping U1 / SN of the study group were found to be statistically significantly higher than the control group in cephalometric analysis (p = 0.0001).

The mean of total distal tipping U4 / SN of the study group were found to be statistically significantly higher than the control group in cephalometric analysis (p = 0.0001).

The mean of total distal tipping U5 / SN of the study group were found to be statistically significantly higher than the control group in cephalometric analysis (p = 0.0001).

The mean of total distal tipping U6 / SN of the study group were found to be statistically significantly lower than the control group in cephalometric analysis (p = 0.0001).

The mean of total distal tipping U5 / SN of the study group were found to be statistically significantly lower than the control group in cephalometric analysis (p = 0.014).

Table 5.1. : The statistical analysis of the chronologic age and the gender of both the study and control groups

		Control Group n:12		Study Group n:12		p
Age (month)		178.83±24.88		178.75±21.1		0.993*
	Male	3	%25	4	%33.33	
Gender	**Female**	9	%75	8	%66.67	0.653+

Table 5.2. : Model and cephalometric analysis of both groups before the treatment

		Pre-Treatment		
		Control Group n:12	**Study Group n:12**	**p***
	3>X	3.63±0.75	2.88±1.94	0.219
	4>X	9.78±1.12	10.88±2.26	0.148
	5>X	17.38±1.45	17.50±2.74	0.897
	6 mb>X	24.49±1.40	23.78±2.8	0.441
	6 db>X	30.54±1.56	28.78±3.05	0.093
Model Analysis	**7>X**	36.32±1.45	35.13±3.38	0.320
	4/Y	79.53±6.15	76.12±12.49	0.404
	5/Y	81.44±6.56	69.86±6.31	**0.0001**
	6/Y	31.97±3.54	28.99±3.91	0.063
Model Analysis	**7/Y**	33.28±1.17	32.12±6.10	0.571
	U1/SN	96.67±2.99	97.08±5.65	0.823
	U4/SN	81.67±2.81	79.08±6.08	0.195
	U5/SN	77.25±1.76	71.75±5.17	**0.002**
Cephalometric	**U6/SN**	67.08±1.78	68.25±3.60	0.325
Analysis	**U7/SN**	60.70±0.82	61.64±4.76	0.548

Table 5.3. : Model and cephalometric analysis of both groups after the treatment

		Post-Treatment		
		Kontrol Grubu n:12	**Çalışma Grubu n:12**	**p**
Model Analysis	**3>X**	0.48±0.88	3.93±1.54	**0.0001**
	4>X	7.33±0.74	11.73±3.58	**0.0001**
	5>X	15.23±0.96	20.13±2.38	**0.0001**
	6 mb>X	28.83±2.42	27.64±2.79	0.276
	6 db>X	35.32±2.77	32.38±2.88	**0.018**
	7>X	40.04±2.04	38.56±3.94	0.305
Model Analysis	**4/Y**	85.48±6.23	73.53±8.79	**0.001**
	5/Y	87.44±7.14	68.69±4.50	**0.0001**
	6/Y	29.68±4.16	27.94±4.45	0.333
	7/Y	31.50±1.24	34.00±8.75	0.383
Cephalometric Analysis	**U1/SN**	103.92±3.42	97.07±5.64	**0.002**
	U4/SN	87.92±3.12	76.07±4.79	**0.0001**
	U5/SN	81.92±1.83	67.49±8.23	**0.0001**
	U6/SN	63.42±1.51	67.02±3.66	**0.005**
	U7/SN	56.80±1.32	58.95±4.74	0.184

Table 5.4. : Model and cephalometric analysis of the study group after the treatment

		Study Group		
		Pre-Treatment	**Post-Treatment**	**p‡**
Model Analysis	**3>X**	2.88±1.94	3.93±1.54	**0.029**
	4>X	10.88±2.26	11.73±3.58	0.399
	5>X	17.50±2.74	20.13±2.38	**0.001**
	6 mb>X	23.78±2.80	27.64±2.79	**0.0001**
	6 db>X	28.78±3.05	32.38±2.88	**0.0001**
	7>X	35.13±3.38	38.56±3.94	**0.001**
Model Analysis	**4/Y**	76.12±12.49	73.53±8.79	0.147
	5/Y	69.86±6.31	68.69±4.50	0.325
	6/Y	28.99±3.91	27.94±4.45	**0.0001**
	7/Y	32.12±6.10	34.00±8.75	0.164
Cephalometric Analysis	**U1/SN**	97.08±5.65	97.07±5.64	0.339
	U4/SN	79.08±6.08	76.07±4.79	**0.0001**
	U5/SN	71.75±5.17	67.49±8.23	**0.043**
	U6/SN	68.25±3.60	67.02±3.66	**0.0001**
	U7/SN	61.64±4.76	58.95±4.74	**0.0001**

Table 5.5. : Model and cephalometric analysis of the control group after the treatment

		Control Group		
		Pre-Treatment	**Post-Treatment**	**p‡**
	3>X	3.63±0.75	0.48±0.88	**0.0001**
	4>X	9.78±1.12	7.33±0.74	**0.0001**
	5>X	17.38±1.45	15.23±0.96	**0.0001**
	6 mb>X	24.49±1.40	28.83±2.42	**0.0001**
	6 db>X	30.54±1.56	35.32±2.77	**0.0001**
Model Analysis	**7>X**	36.32±1.45	40.04±2.04	**0.0001**
	4/Y	79.53±6.15	85.48±6.23	**0.0001**
	5/Y	81.44±6.56	87.44±7.14	**0.0001**
	6/Y	29.68±4.16	31.97±3.54	**0.0001**
Model Analysis	**7/Y**	31.50±1.24	33.28±1.17	**0.0001**
	U1/SN	96.67±2.99	103.92±3.42	**0.0001**
	U4/SN	81.67±2.81	87.92±3.12	**0.0001**
	U5/SN	77.25±1.76	81.92±1.83	**0.0001**
Cephalometric	**U6/SN**	67.08±1.78	63.42±1.51	**0.0001**
Analysis	**U7/SN**	60.70±0.82	56.80±1.32	**0.0001**

Table 5.6. : Comparison of the model and cephalometric analysis between the study and control groups after the treatment

		Kontrol Grubu n:12	**Çalışma Grubu n:12**	**p‡**
	3>X	-3.05±0.78	1.06±1.46	**0.0001**
	4>X	-2.46±0.71	1.60±1.88	**0.0001**
	5>X	-2.16±0.67	2.63±2.09	**0.0001**
	6 mb>X	4.34±1.16	3.86±1.92	0.464
	6 db>X	4.76±1.31	3.57±1.91	**0.024**
Total distalization	**7>X**	3.72±0.76	3.43±2.31	0.448
	4/Y	6.02±1.25	-2.68±5.58	**0.005**
	5/Y	6.05±1.97	-1.17±3.92	**0.001**
Model Analysis Total distolingual rotation	**6/Y**	2.29±0.75	-1.10±0.70	**0.001**
	7/Y	1.34±1.15	2.09±3.85	**0.041**
	U1/SN	-7.08±1.00	0.02±0.06	**0.0001**
	U4/SN	-6.25±0.97	2.93±1.45	**0.0001**
	U5/SN	-4.67±0.98	5.93±1.60	**0.0001**
Cephalometric Analysis Total distal tipping	**U6/SN**	3.67±0.78	1.23±0.87	**0.0001**
	U7/SN	3.70±0.95	2.69±0.64	**0.014**

6. DISCUSSION

6.1. Discussion of the Aim of the Study

Since Class II malocclusion is the second most common type of orthodontic malocclusions in society, investigation of the diagnosis and treatment of this malocclusion has always been a priority among the orthodontists. Many new methods and techniques have been developed in the treatment of Class II malocclusions. Depending on whether the origin of malocclusion is skeletal or dental, treatment alternatives vary (143).

If the cause of the Class II malocclusion is dental, there are two treatment options, the first one is the extraction from one arch at least (144,145) and the second alternative is non-extraction treatment by using intermaxillary elastics or molar distalization (146,147).

Extraoral devices have been the most accepted distalization appliance for many years, but they are no longer considered aesthetic (148). At the same time, since they are removable, their effectiveness depend on the level of cooperation of the patient (4,149). Failure of the patient to comply with the treatment leads to prolonged treatment time, a conflict between the orthodontist, the patient and his family, and unwanted treatment results (70). At the same time, clinicians have tended to use intraoral molar distalization mechanics because extraoral appliances cause injuries inside and outside the mouth and damage the vertebrae (150,151).

Although intraoral molar distalization appliances offer an effective treatment option because they are independent of patient cooperation and they continuously apply force (70), they usually cause anchorage loss and undesirable side effects due to taking anchor from teeth and tissues. These side effects increase the crowding, protrusion of the upper incisors as well as increase in the overjet; also, it tilts the molars, premolars, and canines (70,82,105,152,153).

Mini screws and bone-supported intraoral molar distalization appliances have opened a brand new horizon in intraoral molar distalization appliances to obtain more predictable results at the end of the treatment and to shorten the total treatment time by means of preventing anchorage loss and reducing side effects (154–157).

The Pendulum appliance is the first one of the dental-tissue-supported intraoral molar distalization appliances (96). As it is easy to use, it has been considered as the most widely studied conventional appliance (148). It has been used in our study as the dental-tissue-supported appliance for the control group.

The other bone-supported intraoral molar distalization appliances used in our study were fabricated at the laboratory of Yeditepe University Dental Hospital.

In our study, the effects of dental tissue-supported Pendulum appliance and bone-supported intraoral molar distalization appliance on dental tissues were compared with cephalometric and model analysis evaluations.

6.2. Discussion of the Materials And Method of the Study

In our study, there is no statistically significant difference between the chronological averages age of the individuals in the control and study groups. The reason for this is that the individuals included in our study in both groups were selected from the patients who were in the growth and development period when the molar distalization appliances were used. In the previous studies, the researchers generally selected growing patients for their studies. In fact, in the meta-analysis study done by Grec et al. about the effects of intraoral molar distalization appliances, studies that constitute a sample group above the age of 18 were excluded (148).

In studies where molar distalization was performed with Pendulum appliance, Ghosh and Nanda (97) had 41 individuals whose mean age was 12 years 5 months ± 1 year 10 months, Byloff and Darendelis (158), whose mean age was 11 years 1-month ± 1 year 9 months, Byloff et al. (99). 20 individuals with a mean age of 13.11 ± 1.1 years, Bussick and McNamara (8), 13 individuals aged between 8 years 4 months and 16 years 5 months, Fuziy et al. (7). 31 individuals with an average age of 14.6 years. And Angelieri et al. (152) performed the study on 22 individuals with a mean age of 14.5 years. Chiu et al. (153) in their study comparing Pendulum and Distal Jet appliance, the mean age of 32 patients who underwent molar distalization with the Pendulum appliance was 12.5 years, while the mean age of 32 patients who underwent molar distalization with Distal Jet appliance was 12.3 years. Polat-Özsoy et al. (159) in their study comparing the Pendulum appliance and the bone-anchored Pendulum appliance (BAPA), the mean age of 17 patients who underwent molar distalization with the Pendulum appliance was 13.6 years , while the mean age of 22 patients who underwent molar distalization with BAPA was 13.6 years. Patel et al. (82) in their study comparing the Pendulum and Jones Jig appliance, the mean age of 20 patients who underwent molar distalization with the Pendulum appliance was 13.9 years, while the distal Jet appliance was the average age of 20 patients they included to the study was 13.2 years.

Wilmes and Drescher (154), in their study, achieved molar distalization by using Beneslider appliance; they included 12 individuals with an average age of 12.4 years and 6 individuals with a mean age of 35.3 years in their study. Nienkemper et al. (160) in their study, where they achieved the molar distalization with the Beneslider appliance, they divided the patients into three groups according to the eruption positions of the second molar teeth, and accordingly, 14 individuals with an average age of 11.5 in the first group, 23 individuals with an average age of 13.7 in the second group and 14 with an average age of 30.9 in the third group.

In our study, the mean age for both groups was 14.9 ± 2.07 years.

In our study, there is no statistically significant difference between the gender of the individuals in the control and study groups.

Ghosh and Nanda (97), Bussick and McNamara (8), reported that they did not consider the gender difference in their study of molar distalization with the Pendulum appliance. Önçağ et al. (16) conducted molar distalization with an osseointegrated mini implant-supported Pendulum appliance and a conventional Pendulum appliance and reported that they did not discriminate between gender. Runge et al. (161) they reported that growth and development would not affect the treatment result due to the short distalization time.

Bondemark et al. (162) in their study, where they completed molar distalization in 6 months with magnets and NiTi springs, they reported that the growth development factor could be ignored due to the short duration of treatment.

The inclusion criteria for our study included dental unilateral or bilateral Class II relationship, skeletal Class I or Class II relationship, normal or low angle growth pattern, minimal crowding in the lower teeth, and planned treatment without extraction, the third molar had been extracted or absent. It was paid attention that the patient had not used any other auxiliary distalization procedure (headgear, elastic, etc.) during the period of distalization with the appliance.

In studies where molar distalization was performed by using intraoral molar distalization appliances, an increase in the vertical direction with clockwise rotation was observed in the mandible, as the first molar teeth were overturned and extruded distally while moving distally (8,13,80,97,152,158,159). Bussick and McNamara (8) reported that the facial dimensions increased slightly during the treatment with the Pendulum appliance, especially in cases where the upper second molar tooth has erupted. Due to the extrusion of the molar teeth, there was an increase in the angle of the mandibular plane and the height of the lower anterior face, and a decrease in overbite was observed. Ghosh and Nanda (97) reported that in individuals with high mandibular plane angle(dolichocephaly), lower face height increased after molar distalization, and care should be taken in the treatment of these cases. Byloff and Darendeliler (158), Gulati et al. (80), Angelieri et al. (152), Kinzinger et al. (13), Polat-Özsoy et al. (159) reported that the angle of the mandibular plane increased due to the extrusion of the maxillary first molar teeth as a result of the molar distalization treatment. Therefore, in our study, intraoral molar distalization appliances were applied to patients with normal or low angle growth patterns.

The presence and location of the third molars have also been reported as one of the factors that should be considered when examining the dental effects of molar distalization (163). When the effect of the third molar tooth was examined in the treatment of intraoral molar distalization, it was reported that the first molar teeth were tipped more distally, and the duration of treatment was prolonged in the presence of third molars. However, after the third molars germectomy, it has been demonstrated that the first and second molars are pushed distally with an almost parallel movement (12). For this reason, the presence of third molars of all collected cases in our study, whose upper right and/or left third molar germs was detected by radiographs, was eliminated.

When molar distalization studies were investigated, the researchers used cephalometric radiographs ([5,7,8,12,14,16,17,35,82,84–86,97,152,154,159–161]), plaster models (12,85,97,164), model photocopies (5,70,165), model photos (162,166), three-dimensional modelling (154,167–174), and three-dimensional cephalometry techniques (175), to measure the dental and skeletal effects obtained as a result of distalization treatment.

During the distalization movement of the maxillary molar teeth, movement occurs in all three directions of space. Therefore, it can be thought that the most reliable measurement can be obtained from cone-beam computed tomography images. However, conical beam computed tomographs (45-558 µSv) still have a much higher radiation dose compared to lateral radiographs (1.1-3.4 µSv) (176). For this reason, measuring from cephalometric images obtained from cone-beam computed tomography creates ethical problems.

Limitations of lateral cephalometric radiographs are distortions and superimpositions on the right and left side of the image. In our study, in order to eliminate this problem, metal guides prepared in different forms were applied to the right and left teeth (70). In order to evaluate the movements of maxillary molar teeth in three directions of space, the tipping movement was evaluated with cephalometric radiographs, sagittal movement and rotations in the molar and premolar teeth were evaluated with 3D model photocopies.

In their study conducted in 2000, Keleş and Sayınsu (70) cemented temporary acrylic crowns with a metal guide with a thickness of 0.032" to the upper right-left first molar, upper right-left second premolar, and upper right central tooth in order to evaluate the dental changes that occur after molar distalization more reliably. Since these metal guides are inclined in different directions in the right and left teeth, the problem of superimposition in lateral cephalometric radiographs has been eliminated. Cephalometric radiographs were taken so that the metal guides in the temporary acrylic crowns of the patients did not undergo any deformation, so the cephalometric radiographs were taken before and after molar distalization. The reliability of the cephalometric analysis was increased by overlapping the metal guide images while comparing each other. In our study, a piece of 19x25 ss wire was cemented on the right molars and premolars on the transverse direction and for the left side on the vertical direction for both pre and post distalization cephalometric films in order to eliminate the superimposition that appears on 2D cephalometric.

Nalçacı et al., in their study in 2014 (172), compared the amount of molar distalization by measuring cephalometric radiographs, gypsum model photocopies, and three-dimensional models. He reported that there is no significant difference between the measurements made from three-dimensional models and model photocopies, and he concluded that 3D digital models are reliable to assess the results of upper molar distalization and can be considered a valid alternative to conventional measurement methods. For this reason, 3D digital models were preferred in our study.

In our study, the study group was selected from the archive in which the patients underwent molar distalization using a palatinal screw distalization appliance. The palatinal screw distalization appliance is a skeletal anchorage-supported distalization appliance that is anchored from two mini screws bilaterally placed in the anterior palatinal region. This appliance does not have any direct contact with any teeth other than the upper first molar teeth, and it is used to detect the spontaneous movements caused by molar distalization on the neighbouring teeth.

In order to provide skeletal anchorage in orthodontics, osseointegrated implants, onplants, mini-plates are anchorage units with very good stability and can be used safely. But, these systems that provide osteointegration are difficult to use routinely. Implants usually require osseointegration before orthodontic force is applied, the need for a lot of bone tissue in the area where it is placed, having anatomical limitations, placing and removing it with invasive procedures, requiring post-operative medication, being expensive and not being used in individuals younger than 16 years, restricts their use for orthodontic reasons (177). Onplants that require less bone thickness and shorter osseointegration time compared to intraosseous implants are also preferred systems for orthodontic anchoring (178,179). However, removal of the soft tissue after osseointegration and removal of the anterior implant with an osteotome after treatment may cause uneasiness in patients (180). The necessity of flap removal during the insertion and removal of mini-plates, pain, and swelling after the surgical procedure, increased risk of infection due to soft tissue irritation, and mucosal openings (dehiscence) around the mini-plate in some cases cause their preference to be limited (181,182).

In our clinic, the use of mini-screws was preferred due to the advantages such as requiring fewer surgical procedures compared to osseointegrated implants, onplants, and mini-plates, being easier to apply, not requiring an osseointegration process, not requiring post-operative medication, immediate force, and low cost (183). Moreover, their small size and ease of application, they can be easily placed in many different anatomical regions in the mouth, allowing the direction of the force to be adjusted ideally in accordance with the orthodontic movement (125).

In addition to all these advantages, as they cannot provide osseointegration like palatal implants or mini-plates, they provide retention by compressing the bone tissue by mechanical methods. In some studies, they reported some displacement of mini-screws had been encountered with the effect of orthodontic forces (184). But even if they do not provide stable anchorage as much as osseointegration systems, the superiority of anchorage support obtained from mini-screws compared to conventional anchorage systems has been proven by studies (185). Considering the factors affecting retentions, it has been reported that selection of the right size of the mini-screws, correct placement techniques, and ideal force applications successfully protect the anchorage during orthodontic movement (111). In the literature, there are studies that have achieved successful molar distalization with distalization appliance applications performed with mini screws (14,139,169), as well as studies reporting that mass distalization in the buccal segment is achieved with mini screw anchorage (140,141).

As mentioned before, the retention of the mini-screws is provided by primary stabilization. For the success of the primary stabilization, the thickness of the cortical bone in the area where the mini screw is applied, the dimensions of the mini screw (111), the angle of insertion (186), and the properties of the orthodontic force applied by taking the anchorage support from the mini screw are important factors (187).

Some studies evaluated the areas where mini-screws can be applied successfully regarding the palatinal region in terms of histomorphology and ease of access during application (188,189). Since there is no risk of damaging any anatomical structure such as blood vessels, nerve, or tooth roots in the median and paramedian areas, mini-screws can be easily applied in this areas (190,191). It has been reported that mini-screws is not recommended to be applied to the suture area and the paramedian area, considering that primary stability may decrease due to incomplete calcification in the suture in individuals who are still at the growing stage, and for the adults due to the interposition of the connective tissue between the screw and bone (192). Since the palatinal bone contains varying amounts of cortical bone and soft tissue thickness in different regions, researchers have carried out studies to determine the most suitable region for mini screw application (193–195). Studies have reported that bone thickness decreases from front to back and from the median palatinal suture laterally (193). It was found that the maximum bone thickness was found 2 mm lateral to the median suture, between the mesial contact point of the first premolar and the distal contact point of the second premolar tooth. In another study, it was reported that 6-9 mm posterior to the incisive foramen in the palatinal region and 3-6 mm lateral to the sagittal suture was the safest area for mini screw insertion (196). Another study indicates that the most suitable area for the application of skeletal anchoring elements is 4 mm posterior to the incisive foramen and 3 mm lateral to the median suture (195). It has been stated that the cortical bone thickness in this area is more than 1 mm and the palatinal mucosa thickness is thinner than 3.5 mm, so mini-screws of 6 mm length can be easily applied to the area, and the possibility of displacement of the applied mini-screws due to the effect of orthodontic forces is low. The density of the cancellous bone under the cortical bone also contributes to the retention of the anchorage units. In order to ensure the stabilization of the mini-screws until the end of the treatment, the importance of the quality of the cancellous bone in the applied area is emphasized in the studies (197). It has been reported that the area located 3 mm posterior and 1-5 mm lateral to the incisive foramen in the maxilla has a spongious bone density suitable for stabilization of the skeletal anchorage units (198). Based on all these findings, the mini-screws applied in our study were placed in the anterior palatinal region, one on each side 3-4 mm lateral to the suture palatinal media, 7-8 mm behind the incisive foramen, not touching the teeth and/or roots.

In studies using skeletal anchorage for the distalization of maxillary molar teeth, it was concluded that the use of a single mini screw failed against rotational forces, and stability would be better with the use of two mini screws (159). The palatinal screw distalization apparatus in our study group also includes a stable anchorage unit with two mini-screws.

There is a study indicated that the ideal region for skeletal anchorage in molar distalization is the palatinal region, but implants with a diameter of less than 2 mm are generally unstable and lost when used for the palatinal region (123). In addition, it is reported that the length of the functional part of the mini-screws to be used in the anterior palatinal region for sufficient retention should be at least 10mm and 8 mm away from the incisive foramen, taking into account the soft tissue thickness and bone height (192). Studies have shown that the length of the mini-screws to be applied in the palatinal region should be longer, considering the thick structure of the palatinal mucosa (117).

In our study, the size of mini-screws applied to the cases in the study group was 2mm diameter and 12mm length.

The mini-screws used for the cases of the study group were specially designed for the palatinal soft tissue thickness with a 5mm non-threaded part in the neck region. In studies evaluating the soft tissue covering the palatinal bone, it was reported that the soft tissue thickness increased from the median suture to the lateral and from the posterior to the anterior (195). For this reason, when choosing the mini-screws, it is taken into consideration that the soft tissue thickness in the area where we apply mini-screws is high. The part designed to be included in the soft tissue does not contain a thread, so the mini screw eliminates the risk of irritation in the soft tissue and ensures effective plaque control. The threaded 5mm part under the unscrewed neck is inserted into the bone. The amount of bone in the area chosen for mini screw application is important for the retention of the mini screw as well as for determining the size of the mini screw in order not to damage the surrounding tissues. The anterior palatinal region has a bone thickness of 4-8 mm, and it has been reported as the most suitable region with the highest bone height for mini screw application in the palatinal bone (192). It is recommended that the part of the mini-screws in the bone for the palatinal region should not exceed 6-8 mm in order to prevent the penetration of the mini screw into the surrounding tissues (199). For this reason, the fact that the mini screw used in our study contains a 7 mm threaded part provides maximum retention at safe limits. Studies conducted show that 5-6 mm compression into the bone is sufficient for stability (177).

Romanos et al., in their study, reported that immediate force loading on mini-screw has ossification effects positively around it and that mini-screws with force loading at the time of application have successful clinical results (200). With this information and due to the lack of osseointegration feature of the mini-screws, a few days after the mini-screws were applied, the force was loaded as soon as the laboratory procedures of the appliance were completed for our study group cases.

In another previous study, it was determined that 2 mm diameter and 11 mm long mini-screws applied to the palatinal bone resist the orthodontic force of 240-480 g without creating a fracture in the bone, although osseointegration does not occur (201). The palatinal screwed distalization apparatus in our study group was applied in a way that a 400 g force was transmitted to the mini-screws on each side. In a similar study that performed molar distalization with a mini screw, a 350 g force was applied, and a successful distalization was achieved (202).

Mechanics of intraoral molar distalization include Niti springs, Niti wires, magnets, or screws applied either from the palatinal or buccal side. Even if the results obtained with the buccal and palatinal applications are kindly similar, it has been reported that in the mechanics applied from the palatinal side, less molar distal tipping happens comparing to the buccal side mechanics due to the application of force closer to the center of resistance of the maxillary molars (163). If the force applied to the maxillary molar teeth during distalization from the coronal of the trifurcation area, that is, above the center of resistance of the tooth, a distal moment occurs to the molar teeth results of distal tipping (80,84). In order to eliminate this problem, the force vector can be passed through the center of resistance of the molar tooth, or it is necessary to apply a second force to create a moment in the opposite direction (70). For this reason, attention has been paid to the fact that the mini implant-supported intraoral molar distalization appliances in our study group are those that apply force from the palatinal region, and the force vectors are positioned so that they pass through the center of resistance of the maxillary molar teeth by using Z tubes in order to provide parallel movement. To prevent the molar distal tipping in the Pendulum appliance group, Byloff et al. recommended that 10 -15 degrees uprighting twist bending has to be applied to the helix arms entering the molar sheath, with this bending they reported in their study that the molar distal tipping decreased from 14.5 degrees to 6.07 degrees (99).

Hilgers reported that for molar distalization with the Pendulum appliance, the helix should be activated 60 degrees at the beginning of the treatment, and the helix should not be reactivated (96). Ghosh and Nanda (97) followed Hilgers' protocol by activating 60 -70 degrees, Joseph and Butchart (203) 90 degrees, Bussick and McNamara (8) 60 -90 degrees. Byloff and Darendeli (158) stated that the helix should be activated 45 degrees at the beginning and reactivated when necessary during distalization. In our control group, the protocol that was used was the same as Byloff and Darendelians, 45 degrees activation at the beginning of distalization, and checked them every 4-6 weeks and reactivated if the activation of the helix was necessary.

Until today, forces varying between 100g-500g have been applied to perform molar distalization in studies conducted with intraoral molar distalization appliances. Gianelly et al. (69) applied 100g of force with Niti springs, while Erverdi et al. (5) applied 225g with Niti springs and magnets, and Bondemark et al. (162) applied 225g of force with magnets. Keleş et al. (35) reported that they applied 200g of force with Niti springs in their study with Keleş Slider. For the Pendulum appliance, one of the appliances we used in our study when the helixes are 45 degrees activated, a force of 200-250 g is applied unilaterally (158). Some researchers have reported that the Pendulum appliance exerts a force of 230-250g, regardless of how many degrees the helixes are activated (7,82,152,159). Wilmes and Drescher (204) applied 240g of force in their study in 2008 in order to achieve molar distalization with the Benefit appliance. However, Nienkemper et al. (160), in their study in 2014, reported that for molar distalization, 240g of force should be applied in cases where the second molar teeth have not erupted, and 500g in cases with second molar teeth. In our thesis study, by activating the helixes 45 degrees in the control group, 230-250 g force was applied to the first molar teeth, 400g force by activating Niti springs in the study group.

In the studies, researchers continued the molar distalization until the molar teeth reach a superclass I or Class III relationship in order to prevent the loss of anchorage in the molars during the retraction of the premolar, canine, and incisor teeth after distalization (7,14,91,99,203,205). Gelgör et al. (14) reported that they overcorrected 2 mm more after molar teeth reached a Class I relationship. In our thesis study and control groups, the distalization procedures were continued until a superclass I relationship was achieved in the first molar teeth in order to avoid anchorage loss during fixed orthodontic treatment.

Niti springs must be activated at regular intervals in order for those who use Niti springs as a force element among the intraoral molar distalization apparatus to be able to apply the force continuously at the same intensity. Papadopoulos reported that molar distalization cases treated with AMDA appliance should be checked in every 4 weeks for oral hygiene, stabilization of mini implants, and reactivation of the springs (206). In the study in which Bussick and McNamara (8) performed molar distalization with the Pendulum appliance, they controlled the patients in every 3-4 weeks and reactivated the appliance when necessary. In studies of Ghosh and Nanda (97), Önçağ et al. and Polat-Özsoy et al. (159) performed molar distalization with the Pendulum appliance, they checked the patients once a month and reactivated the device when necessary. In our thesis study, oral hygiene and stability of the mini implants were checked by giving appointments to the patients in both groups in every 4 weeks, and reactivation of their appliances were made when necessary.

Byloff and Darendeliler (158), after distalizing the molars to superclass I relationship with the Pendulum appliance, they removed the distalization appliance and applied the Nance appliance to protect the anchorage on the same day. Angelieri et al. (152) after completing the molar distalization with the Pendulum appliance, they applied cervical headgear together with the Nance appliance on the same day. In our thesis study, after the molar distalization is completed with the Pendulum appliance or the palatinal mini screw-assisted distalizer, the appliances are removed from the mouth, and the Nance appliance is applied in the same session to prevent anchorage loss.

6.3. Discussion of the Results of the Study

In our study, the amount of the distalization of the first molar teeth was determined by 6 mb>X plane (mm) measurement. In both groups, a statistically significant distalization occurred in the first molar tooth.

Ghosh and Nanda (97), they performed molar distalization with the Pendulum appliance, they reported a statistically significant distalization of 3.37mm in the first molar teeth, Byloff and Darendeliler (158), they reported a statistically significant distalization of 3.39 ± 1.25mm in the first molar teeth, Bussick and McNamara (8), in their study they reported a statistically significant distalization in first molar teeth 5.7 ± 1.9mm, Chiu et al. (9) reported a statistically significant distalization of 6.1mm in first molar teeth, Fuziy et al. (7) reported a statistically significant distalization in first molar teeth of 4.6mm, Angelieri et al. (152) reported a statistically significant distalization of 2 mm in first molar teeth, Önçağ et al. (16) reported a statistically significant distalization of 5.03 mm in first molar teeth, Polat-Özsoy et al. (159) found a statistically significant distalization of 2.7 ± 1.7mm in the first molar teeth, and Patel et al. (82) found a 3.51mm distalization in the first molar teeth. Therefore, the molar distalization amount of the first molar teeth varies between 2mm and 6.1mm in studies where molar distalization was performed with the Pendulum appliance.

In our study, a statistically significant level of distalization was observed in the first molar teeth of 4.34 ± 1.16mm (6mb-X plane(mm); p: 0.0001; $p < 0.05$) in the Pendulum group in accordance with these findings (Table 5.5.). The amount of distalization we detected in the Pendulum group (control group) was also significantly higher than the study group in the comparison between groups ($p < 0.05$) (Table 5.6.). The high amount of distalization in the Pendulum group may be due to the severity of Class II malocclusion of the individuals in this group and the excessive amount of overcorrection compared to the mini implant-supported groups due to the concern of recurrence.

Wilmes and Dresher (154), who performed molar distalization with the Benefit appliance, found a statistically significant level of distalization of 4.6 ± 1.5 mm in the first molar teeth, and Nienkemper et al. (160) found a statistically significant result of distalization of 3.6 ± 1.9 mm in the first molar teeth. In our study, a statistically significant result of distalization was observed in the study group of 3.86 ± 1.92 mm (6mb-X plane (mm); p: 0.0001; $p < 0.05$) consistent with these findings (Table 5.4.).

In our study, a moderate level of molar distalization occurred in the mini implant-supported distalization appliance group, while a significantly higher amount of first molar distalization was observed in the Pendulum appliance group. However, the amount of distal tipping of molars in the Pendulum group is also significantly high, and there are studies reporting that almost all of the molar distalization cases show some amount of relapse after the end of the distalization stage. Darendeans (207-p563) reported that the total amount of distalization of the mean molars decreased from 2.92 ± 1.99 mm to 0.10 ± 2.31 mm at the end of the entire treatment. Angelieri et al. (152) reported that the molar teeth distalized by 2 mm with the Pendulum appliance showed a relapse of 2.1mm at the end of the treatment. Angelieri et al. suggested that the Class I molar relationship was preserved at the end of the entire treatment with the help of dental compensation and anterior sagittal development of the mandible after molar distalization. Therefore, we think that the decision to use the Pendulum appliance should be considered in terms of the risk of relapse and that this high molar distalization capability should not be deceptive, considering the side effect of distal tipping.

During molar distalization, the amount of distal tipping of the first molars is as important as the amount of distalization. In our study, the amount of tipping of the first molar teeth was determined by the U6/SN plane (°) measurement. At the end of the treatment, a statistically significant distal tipping was observed in the Pendulum (U6/SN (°); p: 0.0001; $p < 0.05$) (Table 5.5.). Distal tipping occurred at 3.76° ± 0.78° in the Pendulum group (Table 5.5).

Ghosh and Nanda (97) performed molar distalization with the Pendulum appliance; they reported a statistically significant distal tipping of 8.36° ± 8.37° in the first molar teeth. Byloff and Darendeli (158) also in their study of molar distalization with Pendulum appliance, they reported a statistically significant distal tipping of 14.5° ± 8.33° in the first molar teeth. Byloff et al. (99) in their study they gave a 15° bending to the distal arms of the appliance in order to decrease the distal tipping effect, they reported 6.07° ± 5.15° distal tipping in the first molar teeth. Bussick and McNamara (8) reported a statistically significant distal tipping in the first molar teeth; 10.6° ± 5.6°. Chiu et al. (153) reported a statistically significant distal tipping of 10.7° ± 5.5° in the first molar teeth. Fuziy et al. (7) reported a statistically significant distal tipping of 18.5° in the first molar teeth. Angelieri et al. (152) reported a statistically significant distal tipping of 9.4° in the first molar teeth, Önçağ et al. (16) reported a statistically significant distal tipping of 6° in the first molar teeth. Polat-Özsoy et al. (159) reported a statistically significant distal tipping of 5.3° ± 3.8° in first molar teeth, Patel et al. (82) found a statistically significant distal tipping of 10° ± 4.04° in the first molar teeth. Therefore, in the studies where molar distalization was performed with a Pendulum appliance, first molar teeth were tipped distally between 5.3° and 18.5° during molar distalization.

In our study, 3.76 ° ± 0.78 ° distal tipping showed in the molar distalization group with the Pendulum appliance (Table 5.5). In our study, a 15° bend was applied to the arms of the Pendulum appliances, where the helical arms enter the sheaths of the molar bands, in order to reduce the distal tipping, according to the recommendation of Byloff et al.

In mini implant-supported molar distalization systems, Wilmes and Drescher in their study they performed molar distalization with Benefit appliance, the reported a 1.9° ± 1.3° of distal tipping in the first molar teeth, Nienkemper et al. performed molar distalization with the Benefit appliance they reported a 1.6° ± 6.7° of distal tipping in the first molar teeth, Kook et al. performed distalization with a modified palatal anchorage system, they reported a 3.4° ± 5.8° of distal tipping in the first molar teeth, Kinzinger et al. in their study with two mini-implant supported Distal Jet appliance they reported a 3° of distal tipping in the first molar teeth. In our study, 1.23° ± 0.87° of distal tipping was observed in the first molar teeth in the group, which was performed by palatinal supported mini-screws molar distalizer, and this value was statistically significant (6/SN plane (°); p: 0.0001; $p > 0.05$) (Table 5.4.).

The biggest disadvantage of tooth-supported intraoral molar distalization appliances is the loss of anchorage, resulting in the mesialization of the anterior teeth. Due to the fact that mini implant-supported appliances do not receive anchorage from the anterior teeth, distalization is also observed in premolar teeth with the effect of transseptal fibers (208). In our study, the amount of mesialization or distalization in the second premolar and first premolar teeth was measured with a distance of 5>SN plane (mm), 4>SN plane (mm), respectively.

In our study, the distalization amounts of the second premolar teeth at the end of the treatment in the palatinal mini-screws assisted distalizer group was found statistically significant (5>SN plane (mm); p: 0.001; $p < 0.05$) (Table 5.4.). In the second premolar teeth, a distalization of 2.63 ± 2.09mm in the study group was observed (Table 5.4.).

Wilmes and Drescher (154) and Nienkemper et al. (160) in their studies on Benefit appliance they measured molar distalization only and did not report about the movements of the premolar teeth. Likewise, Papadopoulos (209), reported that premolar teeth distalized spontaneously, without providing information about the amount of distalization.

Ghosh and Nanda, performed molar distalization with Pendulum appliance, they found a statistically significant mesialization of 2.55 ± 1.9mm in the first premolar teeth, Byloff and Darendeliler, reported a 1.63 ± 1.37mm mesialization in the second premolar teeth, Byloff et al. reported a 2.22mm mesialization in the second premolar teeth, Bussick and McNamara, found a statistically significant mesialization of 1.8 ± 2 mm in the second premolar teeth, Chiu et al. found a statistically significant mesialization of 1.4 ± 1.9mm in the second premolar teeth, Fuziy et al. reported a statistically significant mesialization of 2.65mm in second premolar teeth, Angelieri et al. reported a statistically significant mesialization in second premolar teeth 3.6 mm, Önçağ et al. reported a 2,16mm mesialization in second premolar teeth, Polat-Özsoy et al. found a statistically significant mesialization of 2.3 ± 2.1 mm in second premolar teeth, Patel et al. found a 2.23 mm of mesialization in second premolar teeth. Therefore, in studies where molar distalization was performed with a Pendulum appliance, second premolar teeth were mesialized between 1.4 mm and 3.6 mm during the molar distalization. The amount of mesialization in the second premolar teeth in the Pendulum group in our study is compatible with the studies in the literature. In our study, a statistically insignificant mesialization of 2.16 ± 0.67mm was observed in the second premolar teeth in the Pendulum group ($p > 0.05$) (Table 5.5.). As a result, when comparing the differences in dental changes due to treatment between groups, the amount of mesialization in the Pendulum group is statistically significant compared to the amount of distalization in palatinal mini-screw assisted distalizer (Table 5.6.).

While the second premolar teeth distalized or mesialized, it shows some tipping in the same direction. In our study, the amount of tipping of the second premolar teeth was determined by the U5/SN plane (°) measurement. For the Pendulum group, it showed statistically significant 4.67° ± 0.89° mesial tipping of upper second premolars (p: 0.001; $p < 0.05$) (Table 5.5.). And the palatinal mini-screws assisted distalizer group showed statistically significant 5.93° ± 1.60° distal tipping of upper second premolars (p: 0.043; $p < 0.05$) (Table 5.4.). The ratio of the distal tipping for second premolar teeth in the palatinal mini-screws assisted distalizer group was significantly lower than the Pendulum group (Table 5.6.).

Polat-Özsoy et al. (159) measured the premolar tilting in their study on mini-screw supported Pendulum appliance, they reported 9.9° ± 5.2° of distal tipping in the second premolar teeth. Kırcelli et al. (168), also in their study on mini-implant-supported pendulum appliance, they reported distal tipping of 16.3° ± 6.5° in the second premolar teeth. And in the study of Escobar et al. (210) using a mini implant-supported Pendulum appliance, distal tipping of 8.62° ± 5.08° was reported in the second premolar teeth. However, these appliances are mini implant-supported molar distalization appliances, but since they work with the Pendulum appliance mechanism, the distalization force passes under the resistance center, and severe distal tipping in premolar teeth is predictable with the effect of severe distal tipping in the molar teeth. In our study, the amount of distal tipping in the first molar teeth in the mini-screws assisted molar distalizer group was found to be significantly lower; the reason is that with the help of Z-tubes, the force is passing very near to the center of resistance of molar teeth. Although the second premolar teeth showed much more distal tipping than molars teeth but less than the studies used mini-screw supported Pendulum appliance.

In our study, the upper anterior teeth angulation to the horizontal plane (SN plane) was determined by U1/SN plane. In the Pendulum group was found a statistically significant increase of 7.08° ± 1.00° (p: 0.0001; $p < 0.05$) (Table 5.5.). And for the palatally mini-screws assisted distalizer shows non-significant difference 0.02° ± 0.06° (p: 0.339; $p > 0.05$) (table 5.4.).

Since the Pendulum appliance has a design that is supported by anterior teeth, this result is within expectations. Ghosh and Nanda (97), who performed molar distalization with the Pendulum appliance, had a statistically significant increase of 2.4 ± 4.57 degrees in the U1-SN angle, Byloff and Darendeliler (158) also reported an increase of 0.92 ± 0.67 mm in incisors protrusion. Bussick and McNamara (8) reported a statistically significant increase of 3.6 ± 8.4 degrees in incisors angle to Frankfort horizontal plane. Chiu et al. (9) reported a statistically significant increase of 3.1 ± 4.1 degrees in incisor teeth angle to Frankfort horizontal plane. Angelieri et al. (152) reported a statistically significant increase of 4 degrees in the incisors angle to the palatal plane, Önçağ et al. (16) reported an increase in the U1-SN angle 2.03 degrees. Polat-Özsoy et al. (159) found an increase of 0.9 ± 2.4 degrees in the angle of incisors to the Frankfort horizontal plane. Patel et al. (82) reported a statistically significant increase of 3.11 degrees in the U1-SN angle. Therefore, in the studies where molar distalization was performed with the Pendulum appliance, the proclination of the incisor teeth was found between 0.9 to 3.6 degrees after the molar distalization. In our study, a statistically significant increase of 7.08° ± 1.00° was observed in the incisors for the Pendulum group ($p < 0.05$) (Table 5.5.). In the Pendulum group, the U1/SN plane angle, which means the proclination of the incisors, is statistically significantly higher than the palatally mini-screws assisted distalizer group in the comparison of the differences between the treatment-related dental changes (Table 5.6.). This situation reveals the anchorage loss in the Pendulum group. It is necessary to consider that this tooth-supported appliance will cause a round trip effect on the incisors during the retraction of the anterior teeth after molar distalization; this may cause root resorptions and an increase in the treatment time.

On the other hand, a non-significant difference was showed in the U1/SN plane angles for the palatally mini-screws assisted distalizer group used in our study (Table 5.4.). Nienkemper et al. (160) performed molar distalization with the Benefit appliance; they found 1.0 ± 7.5 degrees of retrusion in incisors. While Wilmes and Drescher (154) did not mention the effect of the Benefit appliance on incisors. Papadopoulos (209) in his case report with the AMDA appliance, he reported 6.8 degrees retrusion in the incisors. The information in the literatures, as well as the findings in our study, shows that the use of these mini screws-supported systems would be an advantage in the total treatment time, and it will be more suitable to protect the integrity of the roots of the incisor teeth.

In studies performed with intraoral molar distalization appliances, it was reported that after completion of the molar distalization, axial rotation occurs in the molar teeth because of the distalization force and the direction of this force (80,85,154).

In our study, the angle made by the molar teeth with the median plane to measure the rotation rate of the molars was determined by 6/Y plane. This angle increased by 2.29 ± 0.75 degrees in the Pendulum group, while it decreased by 1.10 ± 0.70 degrees in the palatally mini-screws assisted distalizer group. Among these findings, the increase in the

Pendulum group is statistically significant and indicates that the molar teeth performed mesiobuccal rotation, while the decrease in the palatally mini-screws assisted distalizer group is statistically significant and indicates that the molar teeth performed a distobuccal rotation.

In studies of molar distalization with Pendulum appliance, Kinzinger et al. reported a non-significant mesiobuccal rotation of 4.73 ± 5.26 degrees in upper molar teeth. Ghosh and Nanda reported a mesiobuccal rotation of the first molar teeth, but they did not report this in degrees. Although the mesiobuccal rotation observed in the Pendulum group in our study complies with the studies in the literature. This mesiobuccal rotation of the first molar teeth will cause both the reduction of the transversal width of the molar teeth. To correct this rotation during the fixed orthodontic treatment phase, prolong the total treatment time.

Wilmes and Drescher, in their study with the Benefit appliance, reported a distobuccal rotation of 3.4 ± 2.0 degrees after the molar distalization. In our study on palatally mini-screws assisted molar distalizer group, 1.10 ± 0.7 degrees distobuccal rotation was detected after the molar distalization.

7. CONCLUSION

In our study, the activities of Pendulum and palatially mini-screws assisted molar distalizer used to perform maxillary molar distalization were evaluated through cephalometric radiography and 3D study model records, and the following results were obtained:

1. Both palatally mini-screws assisted distalizer and pendulum distalizer were effective in distalization of the first molar. However the molar teeth in palatally mini-screws assisted distalizer group were distalized more parallel than the pendulum group.
2. There is no significant difference in the distalization time between both groups.
3. In both groups some molar tipping observed but in the palatally mini-screws assisted distalizer group the tipping amount was less than the pendulum group.
4. The second premolar teeth moved mesially in the Pendulum group, while it moved distally in the palatally mini-screws assisted distalizer group.
5. The second premolar teeth tipped mesially in the Pendulum group, while it tipped distally in the palatally mini-screws assisted distalizer group.
6. The incisors inclination angle increased in the pendulum group after the distalization while it did not changed in the palatally mini-screws assisted distalizer group.
7. The upper molar teeth show mesiobuccal rotation in the pendulum group while it shows distobuccal rotation in the palatally mini-screws assisted distalizer group

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9 APPENDICE

9.1. Ethical Approval

T.C. YEDİTEPE ÜNİVERSİTESİ

Sayı : 37068608-6100-15- 2176
Konu: Klinik Araştırmalar
Etik Kurul Başvurusu hk.

01/07/2021

İlgili Makama (Tarek Abied)

Yeditepe Üniversitesi Diş Hekimliği Fakültesi Ortodonti AD. Prof. Dr. Didem Nalbantgil'in proje koordinatörü olduğu, Dt. Tarek Abied'in sorumlu araştırmacı olduğu **"Kemik ve Diş Destekli İntraoral Molar Distalizasyon Yöntemlerinin Etkilerinin İncelenmesi"** isimli araştırma projesine ait Klinik Araştırmalar Etik Kurulu (KAEK) Başvuru Dosyası **(2225)** kayıtlı Numaralı KAEK Başvuru Dosyası, Yeditepe Üniversitesi Klinik Araştırmalar Etik Kurulu tarafından **30.06.2021** tarihli toplantıda incelenmiştir.

Kurul tarafından yapılan inceleme sonucu, yukarıdaki isim belirtilen çalışmanın yapılmasının etik ve bilimsel açıdan uygun olduğuna karar verilmiştir. **(KAEK Karar No: 1466)**

Prof. Dr. Turgay ÇELİK

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