Mini-Implant Application for Molar Distalization and Extrusion

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ชื่อวิทยานิพนธ์ การประยุกต์ใช้หมุดปลูกฝังขนาดเล็กเคลื่อนฟันกรามถอยหลังและลงล่าง

ผู้เขียน นางสาวจินตรัตน์ แจ้งศรีสุข

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บทคัดย่อ

การเคลื่อนฟันกรามบนถอยหลังเป็นวิธีแก้ไขการสบฟันแบบที่สองให้ได้การสบฟันปกติ การใช้ cervical pull headgear ต้องอาศัยความร่วมมือของผู้ป่วยเป็นสำคัญ เครื่องมือภายในช่องปากที่ใช้เคลื่อนฟันกรามบนถอยหลังอาจมีผลให้สูญเสียฟันหลักยึด ดังนั้นการใช้หมุดปลูกฝังขนาดเล็กเป็นหลักยึดแทน cervical pull headgear จึงน่าสนใจ **วัตถุประสงค์** เพื่อศึกษาผลของการใช้หมุดปลูกฝังขนาดเล็กเป็นหลักยึดในการเคลื่อนฟันกรามบนซี่ที่หนึ่งไปทางด้านหลังและลงล่างในผู้ป่วยที่มีการสบฟันผิดปกติประเภทที่ 2 ร่วมกับมีการสบฟันลึก **วัสดุและวิธีการ** ผู้ป่วย 14 ราย เป็นผู้ชาย 4 คนและผู้หญิง 10 คนได้รับการรักษาด้วยการเคลื่อนฟันกรามบนถอยหลังและลงล่าง โดยผู้ป่วยมีลักษณะการสบฟันแบบที่สองร่วมกับมีฟันบนยื่นและฟันสบลึก ผู้ป่วยที่ปฏิเสธการใช้ cervical headgear ได้รับการแนะนำให้ใช้หมุดปลูกฝังขนาดเล็กเป็นหลักยึดร่วมกับ “extruded sectional arch wire” ที่ออกแบบพิเศษ หมุดปลูกฝังขนาดเล็กมีขนาดเส้นผ่านศูนย์กลาง 1.3 มิลลิเมตร และมีความยาว 8 มิลลิเมตรถูกฝังระหว่างรากฟันกรามซี่ที่หนึ่งและฟันกรามน้อยซี่ที่สองด้านแก้มทั้งซ้ายและขวา ด้านหนึ่งของลวดเหล็กกล้าไร้สนิมเส้นผ่านศูนย์กลาง 1 มิลลิเมตรถูกดัดเป็นตัวยูใส่ไว้ที่ด้านหน้าท่อสำหรับเฮดเกียร์ของฟันกรามบนซี่ที่หนึ่ง และอีกด้านหนึ่งที่มีลักษณะเป็นตะขออยู่บริเวณช่องปากส่วนนอกเหนือและหน้าต่อหมุดปลูกฝังขนาดเล็ก การเคลื่อนฟันกรามบนซี่ที่หนึ่งใช้แรงขนาด 250 กรัมดึงจากตะขอไปที่หมุดปลูกฝังขนาดเล็ก ลักษณะแนวแรงชี้ไปทางด้านหลังและลงล่าง ภาพรังสีด้านข้างก่อนและหลังการเคลื่อนฟันใช้เปรียบเทียบในการเคลื่อนฟันกรามบนซี่ที่หนึ่ง **ผลการทดลอง** ผู้ป่วยมีอายุเฉลี่ย 13.13 ± 1.19 ปี อยู่ในช่วง 11 - 15 ปี ฟันกรามบนซี่ที่หนึ่งถูกเคลื่อนเป็นระยะเวลา 3.82 ± 1.30 เดือนอยู่ในช่วง 2 – 6 เดือนจนมีการสบฟันเกินกว่าปกติ 2 มิลลิเมตร ฟันกรามบนซี่ที่หนึ่งถูกเคลื่อนอย่างมีนัยสำคัญทางสถิติถอยหลัง 6.17 ± 2.59 มิลลิเมตร และลงล่าง 1.32 ± 0.61 มิลลิเมตร และตัวฟันกรามบนซี่ที่หนึ่งเอียงไปทางด้านหลังเพิ่มขึ้น 18.71 ± 6.79 องศาอย่างมีนัยสำคัญทางสถิติ อัตราในการเคลื่อนฟันกรามซี่ที่หนึ่งถอยหลังและลงล่างคือ 1.70 ± 0.57 และ 0.39 ± 0.24 มิลลิเมตรต่อเดือนตามลำดับ **สรุป** ฟันกรามบนซี่ที่หนึ่งสามารถเคลื่อนถอยหลังและลงล่างจนได้การสบฟันแบบที่ 1 ได้ด้วยการใช้หมุดปลูกฝังขนาดเล็กและ extruded sectional arch wire ในระยะเวลาสั้น

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ABSTRACT

The molar distalization has been regularly used to correct Class II dental relation to Class I occlusion. The cervical pull headgear always needs patient's compliance which is a key for success of treatment. The effectiveness of the conventional intra-oral appliance does not move the maxillary molar distally only, but also the anchorage was loss. Improvements in implants have made their use possible as anchorage in orthodontic patients. So that the mini-implant is an anchorage of interest to move the molar substituted the cervical pull headgear. **Objectives**: To design a new appliance in conjunction with mini-implant to distalize and to extrude the first molar in class II deep bite patients. **Materials and methods**: Fourteen patients (4 male and 10 female) with a Class II molar relationship with large overjet and deepbite were selected and planned for correction by the maxillary molar distalization and extrusion. The patients declined the cervical headgear application. Mini-implants as anchorage together with a special design sectional wire developed at Prince of Songkla University were introduced to the patients. The 1.3-mm diameter and 8-mm length mini-implants were placed bilaterally and buccally between the roots of the upper second premolars and the first molars. A 1 mm stainless steel wire, placed in the headgear tube of the upper first molars on each side, was bended as a molar stop and extended to the vestibule to form a hook, positioned anteriorly and superiorly to the implants. A force of 250 gm, applied between the implant and the hook of the bended wire, was directed distally and occlusally for molar movement. The lateral cephlometric films were measured to compare the difference between before and after the maxillary molar distalization, using the Wilcoxon signed – rank test. **Results**: The mean age at the start of treatment was 13.13 ± 1.19 years, range from 11 to 15 years. The first molars were successfully distalized into an over corrected 2 mm Class I occlusion for 3.82 ± 1.30 months, range from 2 to 6 months. The maxillary molars were statistically significant having moved 6.18 ± 2.59 mm distally and 1.32 ± 0.61 mm occlusally. Also the maxillary molars were statistically significant having tipped distally at an average of 18.71 ± 6.79 degree. The rate of maxillary molar distalization and extrusion were 1.70 ± 0.57 mm per month and 0.39 ± 0.24 mm per month, respectively. **Conclusion**: Molar distalization and extrusion were achieved in Class II patient with hypodivergent facial pattern by mini-implant anchorage with an extruded sectional arch wire in a short time.

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Jintarat Chaengsrisuk

CONTENTS

LIST OF TABLES

LISTS OF DIAGRAMS/ FIGURES

LISTS OF ABBREVIATIONS AND SYMBOLS

CEJ	=	cementoenamel junction
cm	=	centimeter
cNmm	=	centinewton-millimeter
et al	=	and others
ESAW	=	extruded sectional arch wire
Fig.	=	Figure
g	=	gram
mm	=	millimeter
NiTi	=	nickel titanium
PP	=	palatal plane
ptm	=	the most superoposterior point on the outline of pterygomaxillary fissure
SD	=	standard deviation
T1	=	time before molar distalization
T2	=	time after molar distalization
$\underline{6}$	=	the maxillary first molar
/	=	per
%	=	percent
”	=	inch(es)

CHAPTER 1

INTRODUCTION

Background and rationale

The molar distalization has been commonly used to correct Class II dental relation to Class I occlusion. In the past, extra-oral appliance was commonly used but the patient's compliance is the major factor to obtain successful results. Beginning in the 1980s, non-compliance intra-oral appliances have been wildly used such as repelling magnets[1, 2], open coil springs[3-6], and pendulum[7, 8]. These intra-oral appliances do not move only the maxillary molar distally, but also the premolars and the anterior teeth which are the anchorage to move mesially and the overjet is increased eventually.

Mini-implant as intra-oral anchorage without patient compliance has been developed since 1983. Creekmore and Eklund[9] were the first orthodontist to apply a small screw for reposition the anterior teeth. Interestingly, the mini-implant could be loaded force immediately.[10, 11] The mini-implant has been used in the case of Class II malocclusions combined the other appliances for preventing the loss of anchorage.[12] For example, it was used as absolute anchorage by installed at palate or the maxillary interradicular bone for distalization and intrusion of molars.[13, 14] Unfortunately, mini-implants have never been applied for distalization and extrusion of the molars.

The correction of Class II malocclusion with cervical pull headgear needs patient's compliance which is a limitation for the success of the treatment. The use of mini-implant to distalize and to extrude the molars as cervical headgear is of interest to study.

Review of Literatures

Conventional molar distalization is not always indicated for Class II correction. It is contraindicated in open-bite patients and in the presence of a protrusive facial profile. In open-bite patients molar distalization would determine a clockwise mandibular rotation, thus increasing the lower face height and worsening the facial appearance. In the case of protrusive facial profile, the anterior anchorage loss, which occurs during molar distalization, would be worsen the inclination of the front teeth and, consequently, the profile itself. Molar distalization is recommended for the correction of Class II malocclusions in deep-bite patients and in the presence of a concave or normal facial profile.

Non-extraction treatment of Class II malocclusion frequently requires upper molar distalization into a final Class I relationship. To achieve this, a variety of treatment modalities have been suggested. For more than 100 years the most common procedure has been the headgear applied to upper molars, and its performance has been reliable. Unfortunately, headgear requires patient compliance to be effective. Often, the patient is not willing to wear the headgear for the recommended 12–14 hours per day.[15]

The cervical pull headgear and the patient compliance

Klein[16] investigated the movement of molars in the 24 patients, age range from 7 to 10 years, treated by cervical headgear. The average time for Class II division 1 correction was 17 months, range 6 to 33 months. During treatment the upper molar tipped distally for an average of 1.2 degree. In the average, distal movement was 1 mm. As much as 3 mm distal movement was recorded. There was no the upper molar reported moving forward. In vertical, the average cases demonstrated 2.3 mm of elongation, range 0 to 3.5 mm.

Gadini *et al*[17] evaluated maxillary basal bone, dentoalveolar, and dental changes in Class II Division 1 patients, age from 7.5 to 13.5 years, treated to normal occlusion by using cervical headgear and edgewise appliances ranged and compared to untreated group. However, maxillary basal bone changes were not significantly different between the treated and untreated groups. Distal dental relocation was more significant in the apex of the maxillary molars (0.47 mm/year) and gradually decreased in the center of resistance (0.34 mm/year) and in the molar cusp (0.25 mm/year). Vertically, none of the skeletal (0.67 mm/year) or dental (1.19 mm/year) changes was significant.

Taner *et al*[18] evaluated the effects of cervical headgear on the maxillary first molar, second molar, first premolar, and upper incisors. The mean amount of first molar distalization was 3.15 ± 1.94 mm. The second molars were also distalized to a mean amount of 2.27 ± 1.33 mm. The mean treatment time for distalization was 11.38 ± 3.18 months. During distalization, the maxillary molars were tipped distally for average 6.69 degree. Maxillary molars were extruded for average 1.42 mm.

Cole[19] evaluated twenty patients were supplied with electronic timing headgears that enabled to compare their reported hours of headgear use with electronically measured actual usage. Compliance levels varied from a low of 5.6% to a high of 107.7% with a mean of 74.5% and a standard deviation (SD) of 30.3. This showed that one third of patient that recommended to use headgear had compliance level lower than 50%.

Doruk *et al*[20] and Agar *et al*[21] used cervical pull headgear to correct the malocclusion. An electronic module timer was attached to the neckstrap to evaluate the number of hours the patients wore the headgear. The result showed that more than one half of patients wore headgear less than recommend and 20-30% of un-compliance patients were not better after monitoring process.

Egolf *et al*[22] evaluated factors related to compliance with the wearing of headgear and intraoral elastics by a questionnaire in 100 university clinic orthodontic patients. The result showed that headgear was rejected by many patients because of esthetic and social concerns. And major factors related to patient compliance wear are personality type, pain, interference with oral activities, health awareness, and self-consciousness about the oral condition.

Cureton *et al*[23] determined the role of the headgear calendar and its relationship to headgear compliance. Headgear timers were used covertly to monitor actual headgear wear of 28 patients for three consecutive orthodontic appointments. Fourteen patients were asked to monitor their daily headgear wear by using a headgear calendar. The other 14 patients did not use a calendar. The results show that patients who monitor their headgear wear with a headgear calendar are more compliant than those patients who do not (7.9 hours compared with 5.3 hours).

The intra-oral appliance for molar distalization

The use of an extra-oral appliance, the headgear, needs the patient compliance to wear. The difficulties of a headgear wear and the factor depended on patient cooperation stimulated many investigators to develop new intraoral devices and techniques for distal movement of molars.

Oztuk *et al*[6] used 250 g NiTi coil spring with a modified Nance's appliance in the late mixed or permanent dentition stage to correct Class II malocclusion. The results were that the mean maxillary first molar distalization was 5.44 mm (right) and 3.75 mm (left), with a mesial tipping of 11.56 degrees (right) and 11.34 degree (left), and the anchorage loss occurred as defined by mesial movement of the first premolars and proclination of the central incisors.

Mavropoulos *et al*[5] analyzed the maxillary molar movement in the patients (mean age 13.2 years) treated with a modification of the Jones jig appliance, which consisted of a modified Nance button as anchorage and an active unit. The average maxillary first molar distal movement was 2.8 mm. An anchorage loss was expressed by a 1.9-mm proclination of the central incisors.

Bolla *et al*[3] evaluated the nature of maxillary molar movement with the distal jet alone, to determine the extent of mesial movement of the anchorage unit. They found that the crowns of the maxillary first molars were distalized for an average of 3.2 mm and tipped distally an average of 3.18 degree. An anchorage loss was measured at the first premolars for averaged 1.3 mm and maxillary incisors were proclined an average of 0.68 degree.

Gulati *et al*[4] evaluated dental and skeletal changes after intraoral molar distalization with a sectional jig assembly. The first molars were moved for average 2.78 mm, at the rate of 0.86 mm/month. And there were increase in the overjet and mesial tipping of second premolar.

Ghosh and Nanda[8] used the pendulum appliance to move the maxillary first molars. The teeth were moved distally for the mean of 3.37 mm with a distal tipping of 8.36 degree. The mean reciprocal mesial movement of the first premolar was 2.55 mm with a mesial tipping of 1.29 degree.

Chiu *et al*[7] compared the pendulum and the distal jet. They found that the pendulum distalized the maxillary molars 6.1 mm more than distal jet 2.8 mm. The premolars and the incisors were moved anteriorly 1.4 mm, 1.1 mm in pendulum and 2.6 mm, 3.7 mm in distal jet.

Itoh *et al*[2] distalize molar with the repelling magnets. Molar distalization averaged 2.1 mm and distal tipping 7.4 degree. Labial movement of the anterior teeth averaged 1.2 mm and labial tipping 3 degree.

Bondemark *et al*[24] evaluated two force systems, repelling rare earth magnets and superelastic nickel-titanium coils, with respect to the clinical and the dentofacial treatment effects of the simultaneous distal movement of maxillary first and second molars in subjects with Class II malocclusion and deep overbite. The magnets and the supercoils moved the molar distally by mean 2.2 mm and 3.2 mm for 6 months, respectively. The decrease of the overbite was average 3.6 mm.

The most past study showed that the intra-oral appliance for molar distalization may cause anchorage loss characterized by the mesial movement or tipping of premolars or anterior teeth and the increase of the overjet. It may increase treatment time to move the teeth back and to create Class I occlusion.

The mini-implant anchorage

Improvements in implants have made their use possible as anchorage in orthodontic patients. A mini-implant for orthodontic anchorage should be small enough to place in any areas of alveolar bone, even apical bone. The surgical procedure should be easy enough for an orthodontist to perform and minor enough for rapid healing. The implant should be easily removable after finishing orthodontic treatment.

In 1983, Creekmore and Eklund[9] used a surgical vitallium bone screw inserted below anterior nasal spine in a 25-year-old female patient with a Class I molar relationship and a very deep overbite. Ten days after the screw was placed, a light elastic thread was tied from the head of the screw to the archwire. The result showed that the maxillary central incisors were elevated approximately 6 mm and torqued lingually about 25 degrees. The bone screw did not move during treatment and was not mobile at the time it was removed.

In 1997, Kanomi[25] was treated a 44-year-old male patient with severe curve of Spee and deep bite. The treatment plan was intrusion of the mandibular incisors. A mini-bone screw was implanted in the alveolar bone between the root apices of the mandibular central incisors. After four months, the mandibular incisors had been intruded 6 mm. Neither root resorption nor periodontal pathology was evident. The patient was satisfied with the overbite reduction without reported.

For molar distalization, the mini-implant was applied for direct and indirect anchorage. Kircelli[26] used modified pendulum appliance with mini-implant in the palatal region for an average of 6.4 mm molar distalizantion with 10.98 mm distal tipping. Also, the maxillary second premolar and first premolar were moved distally for an average of 5.4 $\pm$ 1.3 mm and 3.8 $\pm$ 1.1 mm, respectively.

Gelgor[27] was used intraosseous screw at palate to support anchorage unit for molar distalization with 250 g NiTi open coil spring between the first premolar and molar. For 4.6 months, the upper first molars were tipped 8.88 degree and moved 3.9 mm distally on average.

Keles[13] used the paramedian palatal implant instead of a Nance button for molar distalization with NiTi coil spring (the Keles slider appliance). The result showed that the molars were distalized bodily in 5 months, and no anchorage loss was observed.

Park[14] used a mini-implant which placed between first molars and second premolars buccally for distalized posterior teeth and canines with NiTi coil spring. The first molars were distalized on average of 1.64 mm. Moreover, in another study, Park[28] used a maxillary mini-implants placed between second premolar and first molar to provide anchorage for intruding the posterior teeth and retracting the anterior teeth, simultaneously.

Buchter *et al*[10]and Kim *et al*[29] evaluated the stability of the mini-implant during loading force. The results showed that an immediate loading of mini-implants in the minipig can be performed without loss of stability when the load-related biomechanics do not exceed 900 cNmm.[10] Furthermore, the drill-free mini-implants, which were loaded a force of 200 to 300 g with nickel-titanium coil springs after 1 week after insertion, were stable when twelve weeks ago.[29] And Ohashi[30] presented that the loading protocols for mini-implants involved immediate loading or a waiting period of 2 weeks to apply forces.

Success rate of the mini-implants were associated with inflammation around them and did not depend on the clinical variables of the mini-implant factors (type, diameter, and length), local host factors (occlusogingival positioning), general host factors (age, sex) and management factors (angle of placement, onset and method of force application, ligature wire extension, exposure of screw head, and oral hygiene).[11]

Objective

The purpose of this investigation is to design a new appliance in conjunction with mini-implant to distalize and to extrude the first molar in Class II deep bite patients.

Hypothesis

The first permanent molar can move distally and occlusally by mini-implant anchorage.

Significance of the study

The mini-implant anchorage will be another option for correcting the Class II deep bite without compliance.

The limitations of the study

The study can be applied to the patients after the eruption of permanent upper second premolars. This approach cannot deliver for adult patients because there is no growth to compensate the mandibular rotation from the molar extrusion.

CHAPTER 2

RESEARCH METHODOLOGY

Sample

Samples were selected from patients received treatment at the postgraduate orthodontic clinic, Prince of Songkla University. The criteria for subject selection included:

- Patients younger than 16 years-old having the permanent upper second premolars in the oral cavity.
- The occlusion was Class II malocclusion with a deep bite.
- Short lower anterior facial height with hypodivergence mandibular rotation.
- They never had either orthodontic or orthopedic treatment.
- They have no systemic, mental, behavioral, bleeding, and craniofacial disorders.
- The details of the study was explained to the patients. Inform and consent was signed by the patients before the study started.

Materials and methods

The transpalatal arch was placed on the upper permanent first molars before the brackets were bonded. At the second premolars, brackets were angulated by rotating the distal wing toward the occlusal plane for leveling and tipping the roots mesially to create spaces between the root of first molars and second premolars for mini-implant placement (Fig. 1).

Fig. 1 Transpalatal arch bar (left) and bracket bonding at second premolar (right)

When there were enough spaces (at least 5.5 mm) between the roots of first molars and second premolars, the bite wing films were taken to confirm the space and to locate the position by using the guided wire as shown in Fig 2. Then the mini-implants (1.3 mm in diameter and 8 mm in length) were installed buccally between the teeth. After that the lateral cephalogram was taken before molar distalization (T1).

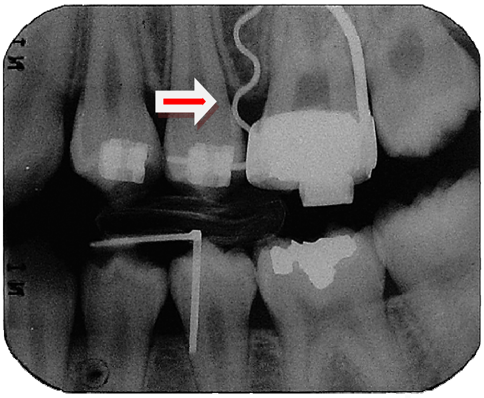

Fig. 2 The guided wire in the bite wing film to facilitate the mini-implant placement

The next visit, the 1-mm-diameter stainless steel wire was bended as shown in Fig 3. One end with bended stop was placed in the headgear tube of the first molar. Another end with bended hook was located anteriorly and superiorly from the mini-implant. It was called "extruded sectional arch wire" (ESAW). The wire was fixed by ligating the stop with the hook of the first molar for stabilization.

A force of approximately 250 g was applied from the hook of the ESAW to the mini-implant. The force vectors were inferior and posterior for molar distalization and extrusion.

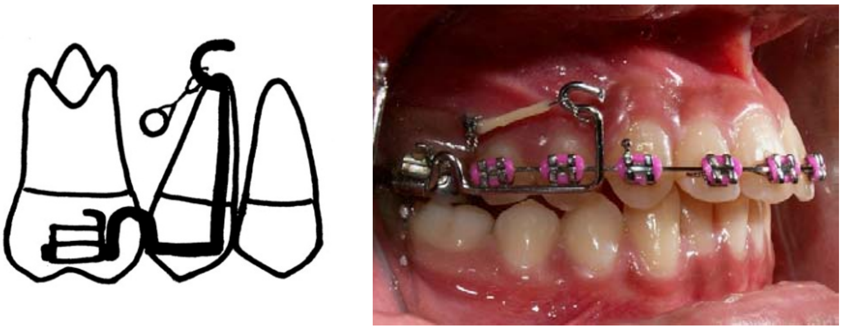

Fig. 3 Force was applied from the hook of ESAW to mini-implant anchorage

The force was measured and activated to maintain the force level of 250 g every month. And if the distance from the hook of the ESAW to mini-implant was too short to generate appropriate force, the ESAW was adjusted at the molar stop and the arm to keep the hook anterior and superior enough for 250g force application. When 2-mm Class III molar relationship was obtained as overcorrection, the lateral cephalogram was taken for post molar distalization records (T2).

Cephalometric variables and analysis

The films taken at T1 and T2 had wire guiding markers which are 0.018” x 0.022” stainless steel wire bended a right angle and the end of the wires were bent either anteriorly or posteriorly (Fig 4). Wire markers were inserted in the buccal tube of the first molars to identify the left and right sides.

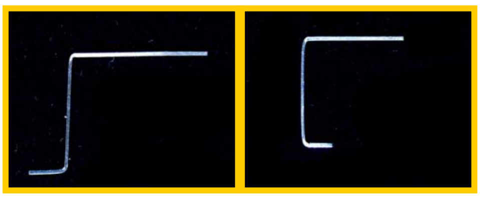

Fig. 4 The wire guiding markers

The cephalograms were traced with one investigator on separate occasions and repeated four weeks later for evaluation of errors in method. From the tracing, variables measured in distances and angles were indicated the movement of the first molars vertically and horizontally. The reference lines and the variables used for measurement as follow (Fig 5):

- PP line: the palatal plane.

- PP-ptm line: line perpendicular to PP that passes through the ptm.
- 6-PP (degree): the angle of intersection of the long axis of the upper first molar and PP line.
- 6-PP (mm): the distance from the PP line to the lowest of the upper first molar.
- 6-to-PP-ptm (mm): the distance form the PP-ptm line to the mesiobuccal cusp of the upper first molar.

The measurements at T1 and T2 were compared to explain the effects of the force applied to the first molars via ESAW by mini-implant anchorage.

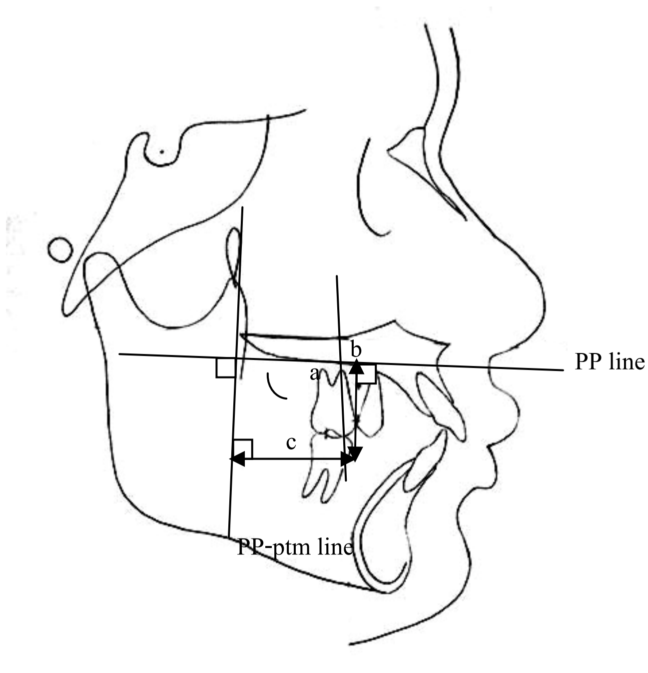

Fig. 5 The references and the variables were used for measurement of molar movement: a is 6-PP (degree), b is 6-PP (mm), and c is 6-to-PP-ptm (mm)

Statistic analysis

Ten cephalograms of 10 patients were randomly chosen and measured to calculate the accidental errors using Dahlberg's formula as follow:

$$S_x = \sqrt{\frac{\sum D^2}{2N}}$$

Where: S_x = the error of the measurement

D = the difference in measurements of cephalometric values on two different occasions

N = the number of double measurements

Statistical analysis was performed using SPSS software, and the results of the measurements were shown as means $\pm$ standard deviations. The differences between the T1 and T2 measurements were evaluated with a Wilcoxon signed – rank test and α less than or equal to 0.05 was considered as statistically significant.

CHAPTER 3

RESULTS

In this study, there were 14 patients, 4 male and 10 female participated and finished the investigation. The mean age at the start of treatment was 13.13 ± 1.19 years, range from 11 to 15 years. The first molars were successfully distalized into an over corrected 2 mm Class I occlusion by mini-implant anchorage at the end of the study. Distalization time was 3.82 ± 1.30 months, ranging from 2 to 6 months. An example of the distalization is presented in Fig. 6.

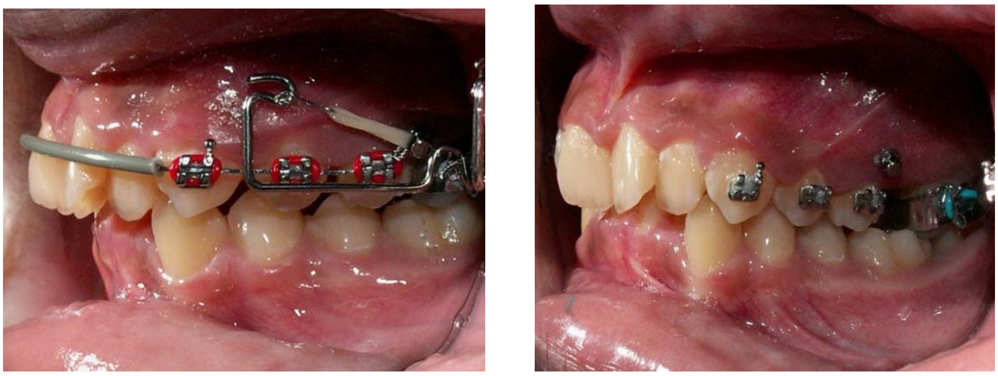

Fig. 6 The intra-oral photographs before (right) and after (left) molar distalization

Method error study

The three measurements were re-evaluated four weeks apart and calculated to determine intra-examiner error. No significant mean differences between the two series of records were found. The measurement error was 0.32, ranging from 0 to 0.50 mm for linear measurement, 6-PP and 6-to-PP-ptm. In the angular measurement (6-PP), the error was 0.28 degrees with a range from 0 to 1 degree.

Cephalometric analysis

The descriptive statistics, including the means and standard deviations before and after molar distalization, as measured from the cephalometric radiographs, are summarized in table 1, 2.

For the average treatment time of 3.82 months, the mean amount of maxillary molar distalization was 6.18 ± 2.59 mm measured at the mesial buccal cusp tip (6-to-PP-ptm). The maxillary molars were extruded 1.32 ± 0.61 mm from the palatal plane. The maxillary molars were tipped distally at an average of 18.71 ± 6.79 degrees (6-PP). The rate of maxillary molar distalization and extrusion were 1.70 ± 0.57 mm per month and 0.39 ± 0.24 mm per month, respectively.

There was a statistically significant difference (P = 0.001) between the position of the maxillary first molars at initial and after destalization stages. The teeth were distalized and extruded. At right and left sides, the movement of the molars was statistic significant difference before and after distalization. The molars were distalized 6.14 ± 2.54 mm and 6.12 ± 2.72 mm in right and left sides, respectively, and extruded 1.32 ± 0.64 mm in both sides (Table 3, 4). In comparison, Left and right sides were not statistic significant difference (Table 5).

From maxillary superimposition, the maxillary molars were moved mostly at the crown, whereas the apical was moved minimally. In addition, the maxillary premolars and canines were distalized naturally, and the maxillary incisors displayed palatal tipping during distalization of the maxillary molars with the mini-implant anchorage. There was no appliance connected between premolars and molars. All maxillary teeth showed extrusion during distalization (Fig. 7).

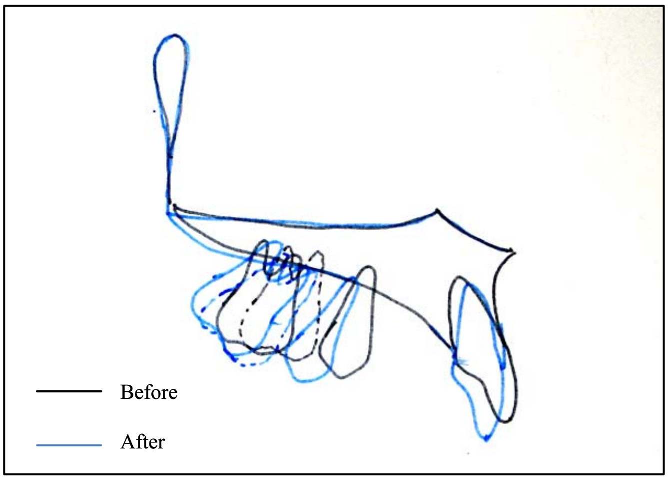

Fig. 7 The superimposition of the maxilla between before and after molar distalization

Table 1 The measurements of each patients

Patient	Sex	Age	Treatment time (months)	Before			After		
				6-PP (mm)	6 to PP-ptm (mm)	6-PP (degree)	6-PP (mm)	6 to PP-ptm (mm)	6-PP (degree)
1	male	13	5.5	21.00	25.00	83.00	23.00	16.00	59.00
2	male	12	5.0	19.50	24.00	82.00	21.50	13.00	48.00
3	male	12	3.0	19.50	24.50	82.00	20.00	19.00	69.00
4	female	13	3.0	22.00	28.00	78.00	23.00	18.50	53.00
5	female	15	4.0	22.50	29.50	88.00	23.50	23.50	63.00
6	female	11	5.0	21.50	23.00	69.00	23.00	18.00	56.00
7	female	12	2.0	18.00	21.00	71.00	20.00	18.00	61.00
8	female	14	5.5	24.00	34.00	89.00	26.00	25.00	68.00
9	female	12	3.5	22.00	25.00	79.00	23.50	21.00	66.00
10	female	14	2.8	23.50	26.00	80.00	24.50	19.00	63.00
11	male	13	2.8	21.50	33.00	81.00	22.50	29.00	67.00
12	female	14	4.2	26.00	31.00	85.00	26.50	24.50	62.00
13	female	14	2.5	21.00	29.00	86.00	23.00	26.00	73.00
14	female	13	2.5	21.00	25.50	84.00	21.50	21.50	67.00
Mean ± SD		13.13 ± 1.19	3.82 ± 1.30	21.64 ± 2.01	27.04 ± 3.83	81.21 ± 5.72	22.96 ± 1.89	20.86 ± 4.34	62.50 ± 6.76

Table 2 Descriptive statistics of cephalometric measurements at before and after molar distalization

Measurements	Before (T1)		After (T2)		T2-T1		Significance
	Mean	SD	Mean	SD	Mean	SD	
6-PP (mm)	21.64	2.01	22.96	1.89	1.32	0.61	.001
6 to PP-ptm (mm)	27.04	3.83	20.86	4.34	-6.18	2.59	.001
6-PP (degree)	81.21	5.72	62.50	6.76	-18.71	6.79	.001

Table 3 The measurements of right side

Patient	Before (T1)			After (T2)			T2 - T1		
	6-PP (mm)	6 to PP-ptm (mm)	6-PP (degree)	6-PP (mm)	6 to PP-ptm (mm)	6-PP (degree)	6-PP (mm)	6 to PP-ptm (mm)	6-PP (degree)
1	21.00	26.00	83.00	23.00	17.00	59.00	2.00	-9.00	-24.00
2	20.00	25.00	82.00	22.00	14.00	48.00	2.00	-11.00	-34.00
3	20.00	27.00	82.00	20.50	22.00	69.00	0.50	-5.00	-13.00
4	22.00	29.00	78.00	23.00	20.00	53.00	1.00	-9.00	-25.00
5	23.00	29.00	88.00	24.00	24.00	63.00	1.00	-5.00	-25.00
6	22.00	24.00	69.00	24.00	19.00	56.00	2.00	-5.00	-13.00
7	18.00	22.00	71.00	20.00	19.00	61.00	2.00	-3.00	-10.00
8	24.00	34.00	89.00	26.00	25.00	68.00	2.00	-9.00	-21.00
9	23.00	26.00	79.00	24.00	22.00	66.00	1.00	-4.00	-13.00
10	24.00	28.00	80.00	25.00	21.00	63.00	1.00	-7.00	-17.00
11	22.00	35.00	81.00	23.00	30.00	67.00	1.00	-5.00	-14.00
12	27.00	33.00	85.00	27.50	26.00	62.00	0.50	-7.00	-23.00
13	22.00	33.00	86.00	24.00	30.00	73.00	2.00	-3.00	-13.00
14	21.00	27.00	84.00	21.50	23.00	67.00	0.50	-4.00	-17.00

Table 4 The measurements of left side

Patient	Before (T1)			After (T2)			T2 - T1		
	6-PP (mm)	6 to PP-ptm (mm)	6-PP (degree)	6-PP (mm)	6 to PP-ptm (mm)	6-PP (degree)	6-PP (mm)	6 to PP-ptm (mm)	6-PP (degree)
1	21.00	24.00	81.00	23.00	15.00	57.00	2.00	-9.00	-24.00
2	19.00	23.00	82.00	21.00	12.00	48.00	2.00	-11.00	-34.00
3	19.00	22.00	83.00	19.50	16.00	70.00	0.50	-6.00	-13.00
4	22.00	27.00	78.00	23.00	17.00	53.00	1.00	-10.00	-25.00
5	22.00	30.00	88.00	23.00	23.00	63.00	1.00	-7.00	-25.00
6	21.00	22.00	68.00	22.00	17.00	55.00	1.00	-5.00	-13.00
7	18.00	20.00	70.00	20.00	17.00	60.00	2.00	-3.00	-10.00
8	24.00	34.00	89.00	26.00	25.00	68.00	2.00	-9.00	-21.00
9	21.00	24.00	79.00	23.00	20.00	66.00	2.00	-4.00	-13.00
10	23.00	24.00	80.00	24.00	17.00	63.00	1.00	-7.00	-17.00
11	21.00	31.00	82.00	22.00	28.00	68.00	1.00	-3.00	-14.00
12	25.00	29.00	84.00	25.50	23.00	61.00	0.50	-6.00	-23.00
13	20.00	25.00	86.00	22.00	22.00	73.00	2.00	-3.00	-13.00
14	21.00	24.00	85.00	21.50	20.00	68.00	0.50	-4.00	-17.00

Table 5 The means of measurement in left and right sides

		6-PP (mm)		6 to PP-ptm (mm)		6-PP (degree)	
		Mean	SD	Mean	SD	Mean	SD
Right	T1	22.07	2.16	28.43	3.98	81.21	5.73
	T2	23.39	2.03	22.28	4.55	62.50	62.50
	T2 –T1	1.32*	0.64	-6.14*	2.54	18.71*	6.79
Left	T1	21.21	1.93	25.64	3.99	81.07	6.03
	T2	22.53	1.83	19.43	4.36	62.36	7.15
	T2 –T1	1.32*	0.64	-6.21*	2.72	18.71*	6.79

* $p = 0.001$

Appliance design

The maxillary first molars were distalized and extruded with mini-implant anchorage and extruded sectional arch wire (ESAW). ESAWs (Fig. 8) were constructed in the following way:

1. A molar end was placed in the headgear tube of the molar band.
2. A molar stop was used to transfer force to the molar, to adjust for moving the hook of the ESAW to the same location after the molar movement at the next visit, and to ligate to the a hook of the molar band for preventing the rotation of ESAW.
3. The arm was bent in a horizontal and vertical part. The ratio of the horizontal and vertical part of the ESAW related to the mini-implant was approximately 2:1.
4. A hook was located anteriorly and superiorly in relation to the mini-implant for applying distalized and extruded force.

A force vector was angulated to horizontal plane 30 degree. When 250-g force was separated to vertical and horizontal vector, force was 216 g in horizontal and 125 g in vertical. (Fig. 9)

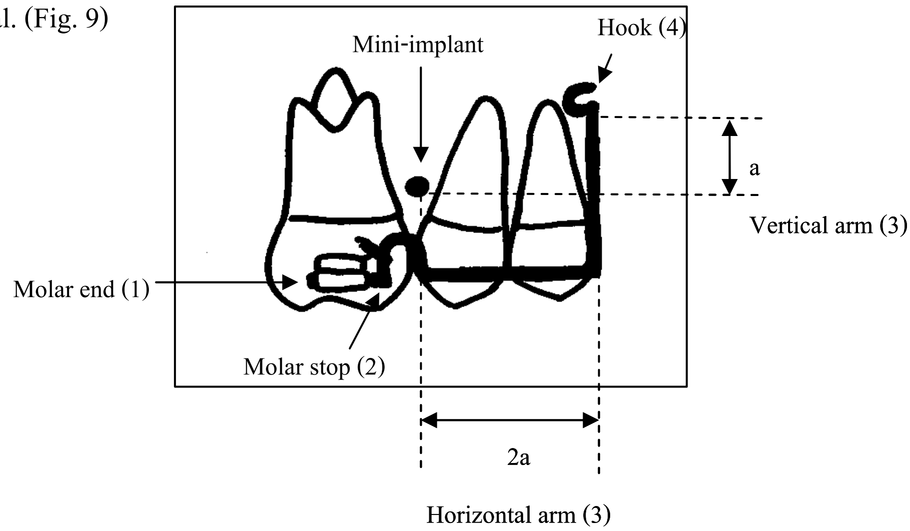

Fig 8. Diagram of extruded sectional arch wire (ESAW) related to mini-implant

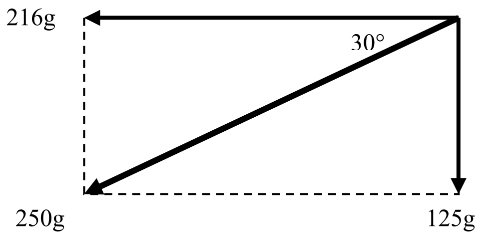

Fig 9. Separated force in horizontal and vertical vector

Clinical Observations

The insertion of the mini-implant was quick and simple. But two patients were excluded because of the failure of the mini-implants before and initial molar movement. (Fig. 8) In one case, the mini-implants were placed for 3 times but the mini-implants were displaced and mobility during initial force application. In another case, the mini-implants were not stable after the placement and dislodged after force application. Soft-tissue inflammation problems around the mini-implants were noted in two cases and suspected as the cause of failure.

However the maxillary first molars were overcorrected by the mini-implant anchorage, the extruded sectional arch wire, in some case, exhibited a problem during the treatment. Two failed mini-implants were on the left of 2 patients from 14 patients. The distalization of the teeth was continued by unilateral force application on right side until the overcorrection was done. No problem of the molar was rotation.

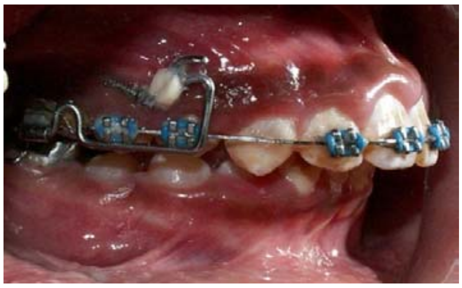

Fig. 10 The two case that loss of the mini-implants were excluded

Two cases presented palatal ulcer related to the palatal arch with loop. When the molar were distalized for a few months, the palatal arch was tipping and impinged into the palatal mucosa. (Fig. 9) In one case, the patient complained about pain but another case was no pain. New palatal arches without loops were replaced.

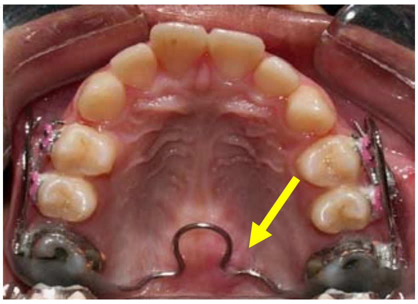

Fig. 11 The palatal arch was pressed into the mucosa

In 2 cases, the extruded maxillary first molars had first degree mobility indicated traumatic from occlusion. The molars were intruded during biting. Therefore, the bite was raised with composite on the occlusal surface of the maxillary premolars during molar distalization. (Fig. 10)

Fig. 12 The raised occlusion with composite

CHAPTER 4

DISCUSSION

The use of mini-implants has become an alternative mode of treatment in orthodontics over the last two decades. The esthetic and social concerns of the use of headgear wear for molar distalization and the anchorage loss that occurs with the application of intraoral molar distalization mechanics stimulated many investigators to use mini-implants for anchorage.

The objective in this study was to design a new appliance in conjunction with mini-implant to distalize and to extrude the first molar in Class II patients with hypodivergent facial profile.

The maxillary molars were moved 6.18 mm distally and 1.32 mm occlusally during 3.82 months with mini-implant anchorage and extruded sectional arch wire. The rate of movement was 1.7 mm per month distally. In previous studies, the cervical headgear moved maxillary molars 3 - 4 mm distally and 1 – 1.5 mm occlusally during 10 -11 months.[18, 31] Additionally, at age from 7.5 to 13.5 years, distal dental relocation by using cervical headgear and edgewise appliances was more significant in the apex of the maxillary molars (0.47 mm/year) and gradually decreased in the center of resistance (0.34 mm/year) and in the molar cusp (0.25 mm/year).[17] Vertically, none of the skeletal (0.67 mm/year) or dental (1.19 mm/year) changes was significant.[17] So it can be implied that mini-implant anchorage and extruded sectional arch wire can move maxillary molars more distally and occlusally than the cervical headgear in shorter period of time.

Compared to other intra-oral molar distalization appliances, our appliance can move molar 6.18 mm distally during 3.82 months. The distal jet moved the crowns of the maxillary first molars distally of an average of 3.2 mm during five months.[3] And the Jones jig moved the maxillary molars 2.8 mm distally with 2.5 months.[31] Additionally, the rate of molar distalization was 1.7 mm per month in our study while the conventional intra-oral appliances distalized the maxillary first molar at the rates of 0.6 to 1.2 mm per month.[3, 8, 18, 24, 27, 32] The amount of distalization in this study is greater than other intraoral techniques due to light continuous force appliance without anchorage movement. The comparison is shown in Table 6.

Table 6 The distance and the rate of molar distalization

Authors	Appliance	Distance (mm)	Time (months)	Rate (mm/months)
Extra-oral appliance				
Taner et al[18]	Cervical headgear	3.15	11.38	0.28
Haydar and Uner[31]	Cervical headgear	3.60	10.7	0.34
Intra-oral appliance				
Bolla et al[3]	Distal jet	3.2	5-7	0.6
Ghosh and Nanda[8]	Pendulum	3.37	6.21	0.55
Taner et al[18]	Pend-X	3.81	7.31	0.52
Bondemark et al[24]	Supercoils	3.2	6	0.53
	Magnets	2.2	6	0.36
Gelgor et al[27]	Screw–supported	3.9	4.6	0.85
Gelgor et al[32]	Intraosseous screw	3.95	4.6	0.86
Haydar and Uner[31]	Jones jig	2.80	2.5	1.12
Our study	Mini-implant	6.18	3.82	1.7

During the molar distalization, the teeth were tipped 18.71 degree. Many reports have found tipping of the first maxillary molar occurring as a result of distalization, which ranges from 4 to 48 degree with the intra-oral appliance and 6.96 degree with the headgear.[3, 8, 18, 33-37] However, the broad range of the standard deviation of angular changes in maxillary first and second molar positions suggest that the amount of distal tipping cannot be predicted for both appliances.[38] The reason of molar tipping is in the fact that the vectors of the distalizing force and the reactive force were located occlusally to the center of resistance (CR) of the molars. In a case when only the maxillary first molar is banded, the center of resistance lies at approximately the trifuracation of the root. When the force vector passes below the center of resistance, then distal crown tipping is introduced. By this way, the moments were generated on teeth, tending to tip the molars distally.

The maxillary molar were moved 1.32 mm occlusally during 3.82 months with the rate of 0.39 mm per month with mini-implant anchorage and extruded sectional arch wire. In normal eruption, the values of the maxillary molars to palatal plane between age 12 to 15 years occurred 2.5 mm in male and 1.1 mm in female.[39] And during mixed to early permanent (9-13 years) and early permanent to adult (13- 20 years) dentition, the means maxillary molar eruption related to the palatal plane were 3.38 mm and 4.42 mm in male and 4.96 mm and 1.63 mm in female, respectively.[40] When measured from Sella, the teeth moved downward 0.4 mm and 4.5 mm in female and 3.5 mm and 3.2 mm in male between 10 to 12 and 12 to 14, respectively.[41] In Class II division 1, the maxillary molar moved downward from Sella 2 mm and 2 mm in female and 3.4 mm and 2.9 mm in male between 10 to 12 and 12 to 14, respectively.[41] This may suggest that the appliance was increase the eruption rate of the maxillary eruption due to light persisting force was applied.

Table 7 Reference line and point of the recent study used to measurement molar movement

Authors	Reference line		Reference point	
	Horizontal	Vertical	Extrusion	Distalization
Taner et al[18]	Maxillary superimposition at ANS		Mesiobucal cusp	Most distal point in a line to palatal plane
Haydar and Uner[31]	CT line	RD1	Mesiobucal cusp	Most distal point
Bolla et al[3] Ghosh and Nanda[8]	PP line	PTV line	Centroid point	
Bondemark et al[24]				
Gelgor *et al*[27, 32]		A line perpendicular of SN pass anterior of sella		Mesiobucal cusp
Gandini *et al*[17]	SN-7°	A line perpendicular of SN-7°	Mesiobucal cusp	
Rana and Becher[35]	Palatal plane		Most distal point	
Joseph and Butchart[33]	Palatal plane		Mesiobucal cusp	
Fudalej et al[39]	Palatal plane		Mesiobucal cusp	
Sinclair and Little[40]	Palatal plane		Central pit	
Rothstein and Yoon[41]	SN-7°		Tip cusp	

The anchorage unit of conventional intra-oral distalization appliance, which consists of the first and second premolars and the incisors, is unable to completely resist the reciprocal force and move mesially during distal movement of the molars.[18, 31] This is contrary to the finding in the headgear appliance in which spontaneous distalization of premolars was observed as a result of the distalization of molar teeth.[18, 31] Similarly, our appliance was able to initiate first and second premolars to freely drift distally with the help of the transeptal fibers. The main reason was the fact that the main anchor was the implant. Likewise, direct palatal mini-implant anchorage allowed distal drift of the premolars with the help of the transeptal fibers while moving the molars distally.[13, 26] Moreover, anterior crowding has been spontaneously corrected because of the stretched transeptal fibers.[26]

The proper correction of Class II malocclusion with hypodivergent facial profile is molar distalization and extrusion to increase the lower facial height. However, when molars are distalized into the wedge, clockwise mandibular rotation may be initiated and the chin was retruded, subseqently. And the backwards movement of the mandible would open the anterior dentition. Consequently, molar distalization is not often recommended as a treatment strategy for hyperdivergent patients (ie, those with open bites or high mandibular plane angles).[42]

Most rapid molar distalization appliances tend to cause the mandible to rotate downward and backward, opening the mandibular plane angle.[4, 8, 18, 24, 34, 38] However, after molar distalization, the mandibular rotation reflects more of the inherent growth pattern of an individual reasserted and rebound is relatively minor.[43] The mandible was return to the initial sagittal and vertical positions, especially because of maintenance of the mesofacial growth pattern throughout treatment.[44] If treatment had been done earlier, so that more growth remained after treatment is expected, and more closing rotation of the mandible will be presented.[43] So that the cases for our study were carefully selected from a growing age group, with younger than 16 year old.

The distalization of maxillary molars is often accompanied by distopalatal rotation, distal tipping, and extrusion of the molars.[1, 2] Moreover, the effects of maxillary molar extrusion is palatal crown tipping. In the study, a transpalatal arch was used to exert a control of molar rotation and palatal tipping.

The overcorrection is necessary because the distalized molars that used as anchorage will be moved forward during the retraction of the premolars, canines, and incisors, so that the overcorrection serves to compensate for the anchorage loss.[27, 45] In addition, distal tipping of the molars produces more crown than root movement, and overcorrection compensates for the subsequent forward movement of the molars into a Class I position because the crowns move mesially more than the roots.[33-35, 37]

There were 2 patients excluded from this study because of the failure of the mini-implant. They showed local inflammation around the mini-implant before or initial force application. Cheng et al[46] stated that two-thirds of the failures were noted before loading or within 1 month after orthodontic loading was initiated. Mini-implants are troublesome for patients because of the severity of the surgery, the discomfort during initial healing, and the difficulty in oral hygiene.[25] The previous study stated that the mini-implant may be lost or become loose as a result of various factors, such as inflammation of the peri-implant tissues and improper placement.[47, 48] Inflammation of the soft tissues around the implant can damage the bone surrounding the neck of the mini-implants. With progressive damage of the cortical bone, the mini-implants can be endangered and produced the mobility and loss of the implants.[49, 50, 51]

Poor attention to oral hygiene lead to inflammation in the tissues around the mini-implants and hastened their loss.[52] At other times, oral hygiene did not affect success, but local inflammation around the mini-implants did.[53] Local inflammation can be exaggerated not only by oral hygiene but also by weak nonkeratinized soft tissue around the neck of the mini-implant.[53]

Peri-implant soft-tissue type, health, and thickness can affect stationary anchorage of the mini-implant.[54] Mini-implants placed in nonkeratinized alveolar tissues have greater failure rates than those in attached tissues.[46] The movable, nonkeratinized alveolar mucosa is easily irritated; soft-tissue inflammation around the mini-implant is directly associated with increased mobility.[49] Additionally, mini-implants placed in regions of thick keratinized tissue are less likely to obtain adequate bony stability.[55]

In patients with thick mucosa, the distance between the point of force application and the center of resistance of the mini-implant will be greater than usual, thus generating a large moment when a force is applied.[56] So that, the mini-implant length was usually determined by the transmucosal depth (the distance between the anchoring bone surface and the emergence point through the mucosa), rather than by the depth of bone available for anchorage.[46] However, the selection of the mini-implant length was according to the thickness of the oral mucosa and recommended to allow 5 to 6 mm of bone support.[52, 57, 58] But the short implant gives sufficient bone fixation, independently of placement.[59] The quality of implantation and bone structure are more important than the length of the orthodontic implant.[59] More bone contact with the implant surface is believed to imply higher implant stability.[59]

In our clinical study, short facial patients mostly have short posterior alveolar height so that the vestibules were shallow with short keratinized tissue. The position for mini-implant placement was limited, so it was placed near the cervical of the teeth to accommodate the distance between the mini-implant and the hook of sectional wire for extrusion. However, buccal soft tissues are thickest, closest to and farthest from the cementoenamel junction (CEJ) and thinnest in the middle.[60] We placed the mini-implant near CEJ where the soft tissue is thick, so that the bone contact with the mini-implant may be less. Luckily, buccal cortical-bone was thickest closest to and farthest from the CEJ and thinnest in the middle.[60] This thick cortical bone can help to hold the mini-implant even it was stay in the bone lonely a couple millimeters. In 14 cases, the all mini-implants were success except 2 mini-implants were loss after loading the force.

CHAPTER 5

CONCLUSIONS

The present study aimed to invent the appliance using the mini-implant anchorage for maxillary molar distalization and extrusion in Class II malocclusion patients with hypodivergent facial pattern in adolescent patients. Class II molar relationships were overcorrected to Class I within 3.82 months. The maxillary first molars were moved by the mini-implant anchorage and the extruded sectional arch wire for an average of 6.18 mm distally and 1.32 mm occlusally with 18.71 of distal crown tipping. The rate of maxillary molar distalization was 1.70 mm per month. Additionally, the maxillary first premolars and the incisors were moved distally without applied force during the maxillary molar distalization.

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APPENDICES

ใบเชิญชวน

ขอเชิญเข้าร่วมโครงการวิจัย

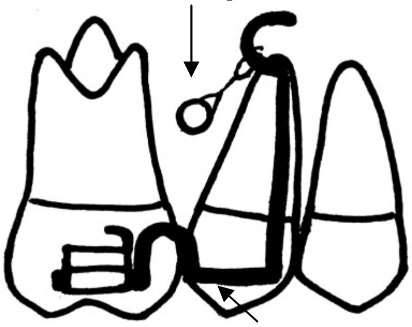
เรื่องประยุกต์ใช้สกรูขนาดเล็ก (mini-implant) ในการเคลื่อนฟันกรามไปทางด้านหลังและลงล่าง

เรียน ท่านผู้ป่วยและผู้ปกครอง

ข้าพเจ้า นางสาว จินตรัตน์ แจ้งศรีสุข กำลังศึกษาอยู่ในหลักสูตรปริญญาโท สาขาทันตกรรมจัดฟัน ภาควิชาทันตกรรมป้องกัน สาขาทันตกรรมจัดฟัน คณะทันตแพทยศาสตร์ ใคร่ขอเล่าถึงโครงการวิจัยที่กำลังทำอยู่ และขอเชิญชวนท่าน/บุตรหลานของท่านเข้าร่วมโครงการวิจัยนี้ โดยผู้วิจัยต้องการศึกษาผลการเคลื่อนฟันทางทันตกรรมจัดฟัน โดยใช้หลักยึดสกรูขนาดเล็กเพื่อเคลื่อนฟันกรามบนไปทางด้านหลังและลงล่างตามขั้นตอนปกติของการรักษาในการสบฟันผิดปกติแบบที่ 2 ร่วมกับมีการสบฟันลึก เนื่องจากการใช้เครื่องมือภายในช่องปากอาจทำให้เกิดการสูญเสียฟันหลักยึด ทำให้เสียเวลาในการเคลื่อนฟันในภายหลัง

<u>ขั้นตอนของการวิจัยที่เกี่ยวข้องกับท่าน</u>

ในการวิจัยจะทำการเคลื่อนฟันกรามบนไปทางด้านหลังและลงล่างด้วยหลักยึดสกรูขนาดเล็กซึ่งมีขนาดเส้นผ่านศูนย์กลาง 1.3 มม. ความยาว 8 มม. ยี่ห้อ Abso Anchor สกรูขนาดเล็กจะถูกปักไว้ระหว่างรากฟันกรามบนซี่ที่ 1 และฟันกรามน้อยบนซี่ที่ 2 และทำการเคลื่อนฟันด้วยลวดสปริง (NiTi coil spring) โดยจะดึงจากลวดเฉพาะส่วน (extruded sectional arch wire: ESAW) ซึ่งดัดมาจากลวดสแตนเลสติวขนาดเส้นผ่านศูนย์กลาง 1 มม. และยึดติดกับฟันกรามซี่ที่ 1 ไปที่สกรูขนาดเล็ก (ดังรูปที่ 1) ก่อนเคลื่อนฟันจะทำการเก็บข้อมูลด้วยการถ่ายภาพรังสีและพิมพ์ฟันทำแบบจำลอง จากนั้นจะให้แรงในการเคลื่อนฟันด้วยแรงชนิดเบาอย่างต่อเนื่อง และทุกๆเดือนจะต้องกลับมาตรวจสภาพและปรับแรงให้คงที่ ภายหลังจากเคลื่อนฟันได้การสบฟันของฟันกรามเป็นชนิดที่ 1 จะทำการเก็บข้อมูลอีกครั้งเหมือนกับก่อนเคลื่อนฟัน หลังจากนั้นผู้ป่วยจะได้รับการรักษาทางทันตกรรมจัดฟันต่อไปด้วยเครื่องมือจัดฟันแบบติดแน่นและหลักยึดสกรูขนาดเล็กจนมีการสบฟันเป็นปกติ และนำหลักยึดสกรูขนาดเล็กออก ค่าใช้จ่ายในการรักษาทางทันตกรรมจัดฟันจะเป็นไปตามปกติ ส่วนที่ยกเว้นคือค่าถ่ายภาพรังสีที่เกี่ยวข้องกับการวิจัย

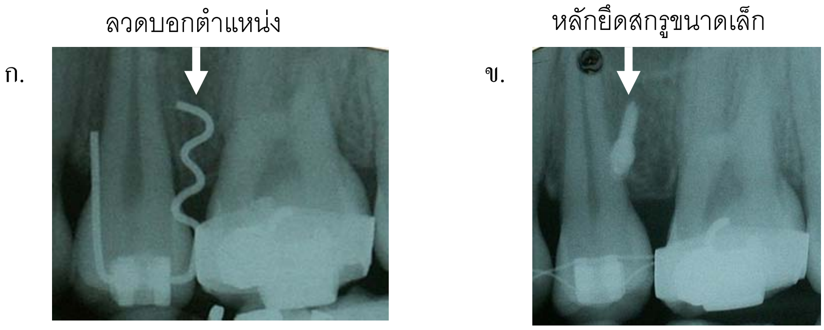


รูปที่ 1 แสดงวิธีการเคลื่อนฟันกรามบนซี่ที่ 1

<u>ความปลอดภัยของผู้เข้าร่วมวิจัยจากความเสี่ยงที่เกิดขึ้น</u>

สกรูขนาดเล็ก มีส่วนประกอบเดียวกับรากฟันเทียม คือ โลหะไทเทเนียม (titanium alloy) ซึ่งใช้กันอย่างแพร่หลาย ในการฝังสกรูขนาดเล็กระหว่างรากฟันนั้น อาจส่งผลให้มีโอกาสเสี่ยงในการฝังโดนรากฟันได้ แต่สามารถป้องกันได้ด้วยการถ่ายภาพรังสีบริเวณปลายรากฟันก่อนที่จะมีการฝังสกรูขนาดเล็ก เพื่อตรวจดูว่าระหว่างรากฟันมีช่องว่างเพียงพอสำหรับการฝังหรือไม่ โดยบริเวณที่จะฝังนั้นรากฟันจะห่างกันประมาณ 5 mm และจะใช้ลวดบอกตำแหน่ง (guided wire) เพื่อบอกตำแหน่งในการฝัง (ดังรูปที่ 2) หากยังมีช่องว่างไม่เพียงพอ จะใช้การจัดฟันทำให้รากฟันเคลื่อนห่างออกจากกันก่อน และถ่ายภาพรังสีตรวจซ้ำอีกครั้งจนกว่าจะมีช่องว่างเพียงพอสำหรับการฝังสกรูขนาดเล็ก ในขบวนการทางศัลยกรรมสำหรับการฝังสกรูขนาดเล็กสามารถทำได้ง่ายด้วยทันตแพทย์จัดฟันหรือทันตแพทย์ทั่วไปภายใต้การใช้ยาชาเฉพาะที่ และฝังให้ตั้งฉากกับผิวเหงือกตามตำแหน่งที่ได้จากภาพถ่ายรังสี ภายหลังการฝังสกรูขนาดเล็กแล้ว การรักษาตัวของแผลที่เกิดขึ้นจะเป็นไปอย่างรวดเร็ว แต่อาจมีโอกาสเสี่ยงที่ในการเกิดการอักเสบหรือการติดเชื้อได้ ในการฝังจึงป้องกันโดยการทายาฆ่าเชื้อบริเวณที่จะฝังก่อน และผู้ป่วยควรดูแลรักษาความสะอาดได้ดี ซึ่งทำได้ด้วยการใช้ผู้ป่วยใช้น้ำยาบ้วนปาก หรือกินยาปฏิชีวนะ หากเกิดปัญหาใดๆขึ้นในการรักษาที่เกี่ยวกับสกรูขนาดเล็กสามารถที่จะรื้อออกได้ทุกเวลาตามที่ทันตแพทย์จัดฟันหรือผู้ป่วยต้องการ และทำการรักษาต่อตามขั้นตอนปกติ โอกาสที่จะฝังหลักยึดสกรูขนาดเล็กโดนรากฟันนั้น เกิดได้น้อยมาก เนื่องจากมีการตรวจสอบระยะห่างระหว่างรากฟันก่อน และมีการระบุตำแหน่งที่ชัดเจนก่อนการฝัง นอกจากนี้ยังมีอาจารย์ผู้เชี่ยวชาญควบคุมดูแลตลอดขบวนการ แต่ถ้าหากมีการทำอันตรายต่อราก

ฟัน เมื่อนำหลักยึดสกรูขนาดเล็กออก เคลือบรากฟัน เอ็นยึดปริทันต์ แบะ กระดูกสามารถซ่อมสร้างกลับคืนมาได้ สำหรับโอกาสในการหลุดของสกรูขนาดเล็กนั้น เนื่องจากการใช้แรงในการเคลื่อนฟันอยู่ในปริมาณที่น้อยไม่ทำให้สูญเสียสภาวะคงที่ของสกรูขนาดเล็กที่ฝังอยู่ในกระดูก จึงไม่มีโอกาสในการหลุดขณะที่ทำการเคลื่อนฟัน



รูปที่ 2 ก. แสดงภาพถ่ายรังสีก่อนฝังหลักยึดสกรูขนาดเล็กโดยใช้ลวดบอกตำแหน่ง
ข. แสดงภาพภายหลังการฝังหลักยึดสกรูขนาดเล็ก

สำหรับการถ่ายภาพรังสีด้านข้างก่อนและหลังการทำวิจัยนั้น ไม่ก่อให้เกิดอันตรายร้ายแรงต่อผู้เข้าร่วมวิจัย เนื่องจากปริมาณรังสีที่ได้รับขณะถ่ายภาพรังสีแต่ละครั้งมีปริมาณน้อยมากเพียงแค่ 2-3 μSv เทียบกับปริมาณรังสีที่ก่อให้เกิดการเสื่อมสภาพของเนื้อเยื่อ 50% ภายหลังจากได้รับรังสี 60 วันที่มีขนาด 3.5-4.0 Sv และยังไม่มีหลักฐานพบว่ารังสีที่ได้รับในระยะสั้นขนาดปริมาณที่น้อยกว่า 50 mSv นั้นก่อให้เกิดอันตรายหรือทำให้เกิดมะเร็ง แสดงให้เห็นว่าการถ่ายภาพรังสีด้านข้างในแต่ละครั้งปริมาณรังสีที่ได้รับนั้นน้อยมากเกินกว่าที่จะก่อให้เกิดอันตรายต่อร่างกายและสามารถป้องกันรังสีได้ด้วยการใส่เสื้อตะกั่วทุกครั้งที่ทำการถ่ายภาพรังสี

<u>ชื่อผู้รับผิดชอบโครงการวิจัย และที่อยู่ที่สามารถติดต่อได้</u>

นางสาว จินตรัตน์ แจ้งศรีสุข (ทันตแพทยศาสตร์บัณฑิต)

ภาควิชาทันตกรรมป้องกัน สาขาทันตกรรมจัดฟัน

คณะทันตแพทยศาสตร์ มหาวิทยาลัยสงขลานครินทร์ 90112

หมายเลขโทรศัพท์ 074-429875, 287669, 287674 (ในเวลาราชการ)

01-7569010 (นอกเวลาราชการ)

ผศ. ดร. ไชยรัตน์ เฉลิมรัตนโรจน์
สาขาทันตกรรมจัดฟัน ภาควิชาทันตกรรมป้องกัน
คณะทันตแพทยศาสตร์ มหาวิทยาลัยสงขลานครินทร์ 90112
หมายเลขโทรศัพท์ 074-429875, 287669, 287674

ผู้ป่วยและผู้ปกครองมีสิทธิ์ตัดสินใจเลือกในการเข้าร่วมหรือไม่เข้าร่วมการวิจัย และไม่ว่าท่านจะเข้าร่วมในโครงการวิจัยหรือไม่ ท่านจะยังคงได้รับการรักษาที่ดีเช่นเดียวกับผู้ป่วยคนอื่นๆ และถ้าหากต้องการที่จะยกเลิกการเข้าร่วมการศึกษานี้เมื่อใดก็สามารถทำได้อย่างอิสระ โดยจะได้รับการจัดฟันจนสำเร็จเสร็จสิ้นการรักษา

หากท่านมีคำถามใด ๆ ก่อนที่จะตัดสินใจเข้าร่วมโครงการนี้ โปรดซักถามคณะผู้วิจัยได้อย่างเต็มที่

ขอขอบคุณเป็นอย่างสูง

(นางสาว จินตรัตน์ แจ้งศรีสุข)
ผู้วิจัย

(ผศ. ทพ. ดร. ไชยรัตน์ เฉลิมรัตนโรจน์)
อาจารย์ที่ปรึกษาการวิจัย

หมายเหตุ :- กรุณาอ่านข้อความให้เข้าใจก่อนเซ็นชื่อยินยอมเข้าร่วมโครงการ

แบบยินยอมเข้าร่วมการศึกษา

วันที่ .... เดือน .... พ.ศ. ....

ข้าพเจ้า... ผู้ปกครองของ...

อายุ................ปี มีความสัมพันธ์เป็น........................... อาศัยอยู่บ้านเลขที่............... หมู่ที่................ ถนน..............................

ตำบล... อำเภอ... จังหวัด...

ได้อ่านและรับการอธิบายจากผู้วิจัยเกี่ยวกับการวิจัยเรื่องการประยุกต์ใช้ micro-implant anchorage แทน cervical pull headgear ในรายละเอียดของการศึกษาวิจัย วัตถุประสงค์ วิธีการวิจัย อันตรายหรือโอกาสเสี่ยงที่อาจเกิดขึ้นจากการวิจัย รวมทั้งประโยชน์ที่จะเกิดขึ้นจากการวิจัยอย่างละเอียดและมีความเข้าใจดีแล้ว

หากข้าพเจ้ามีข้อสงสัยประการใด หรือมีผลข้างเคียงจากการวิจัยหรือการรักษาเกิดขึ้น จะได้รับการแก้ไขและรักษาต่อจนเสร็จสิ้น โดยสามารถติดต่อได้กับ ทพญ. จินตรัตน์ แจ้งศรีสุข หรือ ผศ. ทพ. ดร. ไชยรัตน์ เฉลิมรัตนโรจน์ได้ที่ภาควิชาทันตกรรมป้องกัน คณะทันตแพทยศาสตร์ มหาวิทยาลัยสงขลานครินทร์ หมายเลขโทรศัพท์ 074-429875, 287669, 287674 (ในเวลาราชการ) หรือหมายเลข 01-7569010 (นอกเวลาราชการ) หรือเมื่อมีปัญหาใดๆ อันเนื่องมาจากการทำวิจัยในเรื่องนี้ ข้าพเจ้าสามารถร้องเรียนไปที่คณบดี คณะทันตแพทยศาสตร์ มหาวิทยาลัยสงขลานครินทร์ อ.หาดใหญ่ จ.สงขลา 90112 โทรศัพท์ 074-287510

หากผู้วิจัยมีข้อมูลเพิ่มเติมทั้งด้านประโยชน์และโทษของการวิจัยนี้ ผู้วิจัยจะแจ้งให้ข้าพเจ้าทราบอย่างรวดเร็วโดยไม่ปิดบัง

ข้าพเจ้ามีสิทธิ์ที่จะของดการเข้าร่วมโครงการวิจัย โดยจะแจ้งให้ทราบล่วงหน้า โดยการงดเข้าร่วมโครงการวิจัยนี้จะไม่มีผลต่อการรักษาที่ข้าพเจ้าจะได้รับแต่ประการใด

ข้าพเจ้าได้รับทราบจากผู้วิจัยว่า จะเก็บข้อมูลเฉพาะที่เกี่ยวกับตัวข้าพเจ้าเป็นความลับ จะไม่เปิดเผยข้อมูลหรือผลการวิจัยของข้าพเจ้าเป็นรายบุคคลต่อสาธารณชน จะเปิดเผยได้เฉพาะในรูปที่เป็นสรุปผลการวิจัย หรือการเปิดเผยข้อมูลต่อผู้มีหน้าที่ที่เกี่ยวข้องกับการสนับสนุนและกำกับดูแลการวิจัย

ข้าพเจ้าได้อ่านและรับการอธิบายข้อความข้างต้นแล้ว และมีความเข้าใจดีทุกประการ จึงได้ลงนามในใบยินยอมนี้ด้วยความเต็มใจไว้เป็นหลักฐาน

ลงชื่อ...ผู้ยินยอม

( )

ลงชื่อ...บิดา/ผู้ใช้อำนาจปกครอง

( )

ลงชื่อ...มารดา

( )

ลงชื่อ...หัวหน้าโครงการ

( )

ลงชื่อ...พยาน

( )

ลงชื่อ...พยาน

( )

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