

**The Treatment Effects of Maxillary Molar Distalization and Extrusion System
in Class II Growing Patients**

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Thesis Title The Treatment Effects of Maxillary Molar Distalization and Extrusion System
in Class II Growing Patients

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บทคัดย่อ

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กรรมบนไปด้านหลังและด้านบดเคี้ยวนี้สามารถเคลื่อนฟันกรรมบนไปด้านหลังและด้านบดเคี้ยวได้
อย่างมีประสิทธิภาพ โดยระบบการเคลื่อนฟันนี้ไม่มีการสูญเสียหลักยึด ไม่ต้องอาศัยความร่วมมือ
ของผู้ป่วยและไม่ต้องผลิตเครื่องมือในห้องปฏิบัติการ

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Abstract

Class II malocclusion with deepbite can be corrected by maxillary molar distalization and extrusion. Several treatment modalities existed for distal movement of maxillary molars. Despite the fact that, the commonly used appliance such as cervical pull headgear can provide acceptable treatment results, it requires a considerable patient's compliance. Numerous complications have been reported from the other appliances available, in particular, an anchorage loss. Laboratory processing occasionally is also needed. So the maxillary molar distalization and extrusion system was developed. **Objectives:** The aim of the present study was to develop the system and evaluate its treatment effects contributing to class II corrections with deepbite by means of maxillary molar distalization and extrusion. The newly developed system intended to reduce complication such as anchorage loss. Moreover, patient's compliance and laboratory procedure were not required. **Materials and methods:** Twenty six patients with class II malocclusion were divided into 2 groups. Thirteen (6 males and 7 females) were treated with fixed orthodontic appliances ,which anchorage preparation was introduced by placing the upper incisor brackets upside down and applying uprighting springs on both upper first and second premolars. 0.017"x 0.025" TMA with distal L loops were then used to distalize and extrude maxillary molars. The remaining subjects were classified into control group who underwent growth monitoring for 6-12 months. Lateral cephalometric films were used to evaluate the difference of mean values before and after treatment. T-test was also used for statistical analysis of the differences between treatment and control group at significance level of 0.05. **Results:** In the treatment group, maxillary molars were distalized 3.46 ± 0.88 mm., extruded 1.60 ± 0.44 mm. and tipped distally 3.10 ± 1.85 degree. The mean treatment time was 3.35 ± 0.47 months for distalization and 3.08 ± 0.76 months for extrusion. Molars were distalized and extruded with the rate of 1.06 ± 0.31 mm. and 0.54 ± 0.13 mm. per months, respectively. The distances of upper molar movement in all three dimensions were statistically significant ($P<0.01$). There was no statistic

significant in the difference between the position and angulation of upper first premolars and incisors before and after treatment, except the upper first premolars which were significantly intruded ($P<0.05$) with no clinical significance. Moreover, the upper molar position and angulation in the treatment group were also different significantly compared with the control group ($P<0.01$). **Conclusion:** The maxillary molar distalization and extrusion system can effectively distalize and extrude upper molar with no anchorage loss. This system does not require any patient's compliances and laboratory processing.

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CONTENTS

	Page
CONTENTS	x
LIST OF TABLES	xi
LIST OF DIAGRAMS/ FIGURES	xii
LIST OF ABBREVIATIONS AND SYMBOLS	xiii
CHAPTER	
1. INTRODUCTION	
- Background and rationale	1
- Review of Literatures	1
- Objectives	10
2. RESEARCH METHODOLOGY	
- Samples	11
- Materials and methods	12
- Cephalometric analysis	16
- Statistical analysis	21
3. RESULTS	
- Treatment group	23
- Control group	26
- The comparison of treatment and control groups	27
4. DISCUSSIONS	28
5. CONCLUSIONS	33
REFERENCES	34
APPENDICES	38
VITAE	45

LISTS OF TABLES

Table		Page
1	Pretreatment cephalometric records of the treatment and control groups	23
2	The initial age of the treatment and control groups	23
3	The position and angulation of upper molar before and after upper molar distalization and extrusion	24
4	The position and angulation of right and left upper molar before and after upper molar distalization and extrusion	25
5	The position and angulation of upper molar between left and right sides	25
6	The position and angulation of upper first premolar before and after upper molar distalization and extrusion	25
7	The position and angulation of upper incisor before and after upper molar distalization and extrusion	26
8	The position and angulation of upper molar at before and after observation periods	26
9	Treatment effects of maxillary molar distalization and extrusion system between treatment and control group	27

LISTS OF DIAGRAMS/ FIGURES

Figure		Page
1	The high-pull headgear and cervical-pull headgear	3
2	Pendulum	4
3	Acrylic cervical occipital	4
4	Superelatic NiTi coil	5
5	Jones jig	6
6	Superelastic NiTi wire	6
7	NiTi double loop system	7
8	The overall components of maxillary molar distalization and extrusion system	13
9	The configuration of distal L loops in first, second and third visit of treatment	14
10	Universal testing machine and testing method	14
11	The tooth positional locating devices	16
12	Cephalometric landmarks for investigated treatment effects	
	A. horizontal measurements	19
	B. vertical measurements	20
	C. angular measurements	20
13	Intraoral photographs before and after maxillary molar distalization and extrusion	22
14	Extraoral photographs before and after maxillary molar distalization and extrusion	32

LISTS OF ABBREVIATIONS AND SYMBOLS

mm.	=	millimeter
et al	=	and others
g	=	gram
gmm	=	grammoment
Fig.	=	figure
”	=	inch (es)
/	=	per
°	=	degree
TMA	=	Titanium Molybdenum Alloy
NiTi	=	Nickel Titanium
SD	=	standard deviation
T1	=	before upper molar distalization and extrusion
T2	=	after upper molar distalization and extrusion
C1	=	before growth monitoring
C2	=	after growth monitoring
<u>6</u>	=	upper first molar
<u>4</u>	=	upper first premolar
<u>1</u>	=	upper incisor
OL	=	a line through incisal tip of maxillary incisor and the distobuccal cusp of the maxillary permanent first molar
OLp	=	a line perpendicular to OL through Sella
OLs	=	a line parallel to OL through Sella
SNL	=	a line through Sella and Nasion
RT	=	right side
LT	=	left side

CHAPTER 1

INTRODUCTION

Background and rationale

Class II malocclusion in growing patients with deep overbite combined decreased lower facial height can be properly corrected both anteroposteriorly and vertically. Maxillary molar distalization and extrusion is one of the successful treatment methods used for class II correction with the use of bite opening mechanic.

Several treatment modalities existed for distal movement of maxillary molars. Among all appliances, cervical pull headgear is one of the most common used appliances.¹ However, there are many problems existed i.e. co-operation needed, patient discomfort and difficult in producing bodily movement.²

In recent years, many non-compliance appliances have been invented such as Pendulum, Jones jig and open coil springs. However, these intraoral appliances do not move only the maxillary molars, but also the upper premolars and anterior teeth, which are the anchorage.³

To enhance anchorage control, these appliances have to cooperate with some components such as the Nance button and transpalatal arch. Consequently, Orthodontists and technicians have to deal with many steps of laboratory procedures in constructing these appliances or the patients are informed to use the class II elastics.

Therefore, the system of maxillary molar distalization and extrusion has been developed without the need for laboratory preparation, patient compliance and no anchorage loss.

Review of Literatures

Class II malocclusion

Edward H. Angle developed the classification of occlusal relationship in 1890s. Angle stated that the upper first molars were the key to occlusion and that the upper and lower

molar should be related so that the mesiobuccal cusp of upper molar occludes in the buccal groove of the lower molar.⁴

From the glossary of orthodontic terms⁵, class II malocclusion (Distocclusion, Postnormal occlusion) is defined as a malocclusion which the buccal groove of the mandibular first permanent molar occludes posterior or distal to the mesiobuccal cusp of the maxillary first permanent molar.

Class II correction in growing patients

Many strategies and appliances have been invented to correct class II malocclusion. In 2007, Proffit et al⁴ stated 4 major approaches to class II problems in adolescents as follows:

- Growth modification with headgear or functional appliance
- Three variations of tooth movement
- Retraction of maxillary incisors into a premolar extraction space
- A combination of retraction of the upper teeth and forward movement of lower teeth
- Distal movement of maxillary molars, and eventually the entire upper dental arch

First of all, growth modification is a successful treatment in growing patients. Refer to the cephalocaudal gradient of growth, the more growth occurs in the lower limbs than the upper limbs in the post natal life.⁴ This phenomenon reflects to a differential jaw growth and can apply in correction class II malocclusion.

The example of an appliance is headgear which can modify growth of maxilla and maintain or distalize maxillary teeth whereas allowing differential growth of mandible. Moreover a growth modification by removable or fixed functional appliances, holding the mandible in forward position to correct class II malocclusion is another approach to stimulate growth of mandible.

Fixed appliances with class II elastics is a procedure to move lower teeth forward and retract upper teeth at the same time, resulting in effect of class II correction.

Premolar extraction is often used to retract upper incisors to premolar extraction space and protract the lower molars to create dental class I relationship.

Finally, distal movement of upper molars can correct class II molar malocclusion and provide space into which the other maxillary teeth could be retracted. This method can be accomplished with many appliances.

The distalization appliances

Headgear

Headgear that is an extraoral traction appliance composes of 3 types base on the line of action of the force: High pull, combi pull, and cervical pull. The high-pull headgear produces mostly intrusion of the upper molars with hardly any movement posteriorly. The combi-pull headgear has principally a sagittal effect whereas, the cervical pull delivers extrusion and posterior displacement of the molar.² It was widely accepted that headgear has been used to correct class II malocclusion not only from orthodontic effect but also create orthopedic effect.



Fig. 1 The high-pull headgear and cervical-pull headgear⁴

Although headgear has several advantages such as extraoral anchorage, easy application, the treatment success depends on patient co-operation. This method require wearing the headgear 12-14 hours per day but only half of patients follow the dentists' prescribed time.⁶

Pendulum

Pendulum was first proposed by Hilger in 1992.⁷ This appliance consists of a Nance button and four occlusal rests that will be bonded on the occlusal surface of the premolar teeth or deciduous molars. The pendulum's active component that moves the molar posteriorly is TMA 0.032" spring, inserting to the lingual sheath of the molar band. The springs were activated

only one time of approximately 60 degree to produce a force of 230 gm per side.

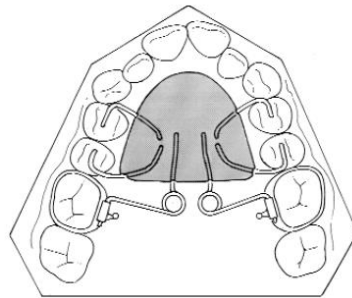


Fig. 2 Pendulum⁸

Many studies claimed that pendulum has many advantages including molar distalization with minimal dependence on patients' compliance, ease of fabrication and one time activation. However, pendulum creates distal tipping of maxillary first molar and anterior tipping of the premolars and undesirable anterior displacement of the anterior teeth.³

Acrylic cervical occipital (ACCO)

ACCO developed by Dr. H Margolis. The appliance consists of an acrylic palatal section to disclude the posterior teeth, modified Adam's clasp on the premolar teeth, labial bow across the anterior teeth and finger springs against the mesial aspect of the first molar. The finger springs can be made of round or rectangular wire and when activated of finger springs create no more than 100-125 g of force. The appliance is intended to be worn 24 hours a day, except during meals that co-operation with extraoral traction force from cervical pull headgear at night.⁹

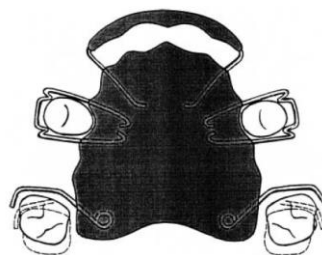


Fig. 3 Acrylic cervical occipital²

The purpose of appliance fabrication was intended to apply a constantly acting force that enhances the rate of molar movement and provide asymmetrically molar distalization. However, Patients' compliance and distal tipping are indicated when using this appliance.^{9,10}

Superelastic NiTi coil

Gianelly et al 1991¹¹ proposed superelastic NiTi coil springs that exert approximate 100 g of force to move maxillary molar distally. The springs are placed between the first premolars and first molars on 0.016x0.022 wires with stop that abut the distal wings of the premolar bracket. The coil springs are activated 8 to 10 mm. by compressing and maintaining against the molar by crimpable hooks or Gulin locks. In addition a Nance type appliance is cement onto the first premolar and bite plate is added to incisal portion to disclude the posterior teeth slightly. To enhance the anchorage further, an 0.018" uprighting spring is placed in the vertical slot of premolar bracket slot and class II elastics will be used in case of second molars are erupted.

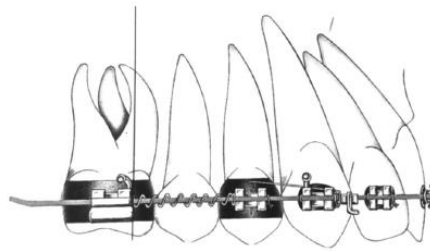


Fig. 4 Superelastic NiTi coil¹²

Papadopoulos et al,¹³ indicated that this appliance is simple intraoral appliance in the means of distalizing first and second maxillary molar simultaneously with minimal patient's cooperation. However, it presented some disadvantages in terms of anchorage loss in anterior segment and distal tipping of the molars.

Jones Jig

Jones Jig is an appliance composing of an active arm and an anchorage unit. To activate an appliance, the sliding hook is tied back with ligature at the molar bracket and an open NiTi coil spring was compressed 1-5 mm. within 0.030" stainless steel wire. This system delivers approximate 70-75 g of force per side to the molars.² At the anchorage unit, a modified Nance a palatal button co-operated with 0.036" stainless steel wire is critical to the used of the Jones Jig that a conventional Nance button can be attached to either the first premolar or deciduous second molars.¹⁴

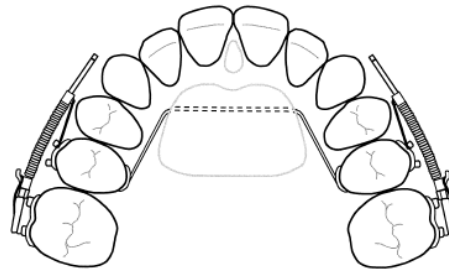


Fig. 5 Jones jig¹⁵

In 1992 Jones and white¹⁴ reported the using a sectional jig in correction of class II molar relationship to class I in 120 to 180 days. This intraoral appliance can provide rapid molar movement, also. The demand of patient cooperation is minimal and the force application is continuous. However, a slight forward movement of the premolars and the anterior teeth, as well as the increased mandibular plane angle were observed.¹⁶

Superelastic NiTi wire

Locatelli et al in 1992¹⁷ used the superelastic NiTi wire with shape memory (Neosentalloy) to move molar distally. The superelastic NiTi wire ia an 0.018"x0.025" inch wire that also applies 100 g of force.¹² A wire will be placed and deflected gingivally in an area between first premolar and first molar. To set an anchorage unit, an archwire was crimped with the hooks between lateral incisors and canines, and patient was instructed to use 100-150 g class II elastics against the first premolar.

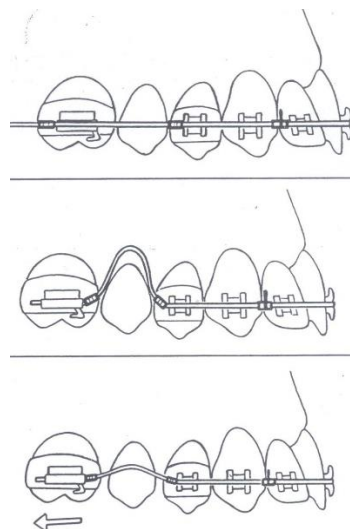


Fig. 6 Superelastic NiTi wire¹⁷

In 1998, Giancotti and Cozza¹⁸ proposed Nickel Titanium double loop system consists of two Neosentalloy superelastic NiTi wires for simultaneous distalization of maxillary first and second molars. An 80 g Neosentalloy lower archwire is placed on the maxillary arch and compressed. Maxillary molars and premolars are banded, uprighting spring are inserted into the vertical slot of first premolar and class II elastics (6 oz., 5/16") are placed between the mandibular first molar and the maxillary canine bracket hooks. However, there was no study of treatment effect of this system.

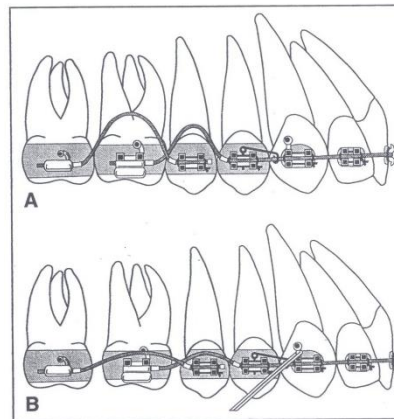


Fig. 7 NiTi double loop system¹⁸

To control the anchorage situation in this appliance, the mechanic of uprighting springs are used as follows:

The uprighting spring

In the Begg technique¹⁹, a preformed uprighting spring which made of a 0.020" Australian wire is inserted into the vertical bracket slot and activated by hooking onto the archwire for upright the canine root after tipping the crown into the spaces. Activation of uprighting spring is an extending the arm of spring, forming a 60-70 angle to the base of archwire. After activated, an uprighting spring express a force of 200-250 g.

With the differential moment concept, Gianelly et al.²⁰ modified the uprighting springs to use in edgewise brackets with vertical slots. The spring will rotate slot of bracket within the limit of the wire/bracket relationship and tooth inclination will be changed. The uprighting spring is used for anchorage support while mesialize the posterior teeth by tipping the root of canine into the space, resulting in increased anchorage of anterior teeth.

The effect of distalization appliances

From many literatures, the treatment effects of the distalization appliances can summary as follows:

Maxillary molar movement

The rate of maxillary molar distalization was reported in several studies. Fuziy et al in 2006²¹ evaluated the amount of molar distalization received by Pendulum appliance. The study demonstrated that the rate of maxillary molar movement was 1.23 mm./month. Gianelly et al¹¹ used Japanese NiTi open coil springs in continuous archwire and reported a mean molar movement of 1 to 1.5 mm/month. The study of Gulati et al in 1998¹⁶ presented the rate of maxillary molar distalization with sectional jig assembly 0.86 mm/month.

Various amount of upper molar distalization was seen in many studies. In 1978, Melson¹ studied the effect of cervical pull headgear, showing the maxillary molar moved 3.75 mm. distally. Greater movement was found in the study of Fuziy et al in 2006.²¹ In the treatment group of Pendulum appliance was shown the amount of upper molar distalization 4.6 mm. However, 14 patients treated with Jones jigs, the mean maxillary molar distalization was reported only 1.4 mm. by Papadopolous et al, 2004¹³

As known that while using the distalization appliance, there is a vertical movement of maxillary first molar teeth in the same time. So many studies reported the amount of vertical movement of maxillary molar in the distalization appliance. The study of Melson in 1987¹, 1.42 mm. of extrusion was found when using the cervical pull headgear. Gulati et al¹⁶ reported 1.60 mm. extrusion when using sectional jigs assembly in 10 subjects. On the other hand, there was an intrusion of maxillary molar in many studies of Pendulum appliances. For examples, the study of Ghosh and Nanda in 1996³ revealed the intrusion of maxillary first molar 0.1 mm.

The distal tipping of maxillary molar was also simultaneously found. Brondemark and Karlson in 2005²² reported the distal crown tipping 3° of maxillary first molar when treated with cervical pull headgear by implant method. Ghosh and Nanda³ found tipping of maxillary first molar 8.36° relative to SN plane. In the study of Ferro et al¹⁰, 70 per cent of 110

cases treated with ACCO had 3.93° distal tipping relative to palatal plane. Likewise, 3.50° distal tipping relative to the SN plane was found in the study of Gulati et al in 1998.¹⁶

Anchorage loss

While distalization of maxillary first molar, there is also a reciprocal force that exert to the group of anterior teeth segment, causing mesial movement of anchorage unit. In this situation, anchorage loss was seen with mesialization and mesial tipping of premolar teeth and incisors.

The amount of mesialization of first premolar and upper incisors were reported during upper first molar distalization. In the study of Ghosh and Nanda³, there was the reciprocal mesial movement of the first premolar 2.55 mm. and 0.65 mm. at maxillary incisors when using pendulum appliance in 41 subjects. In addition, Gulati et al¹⁶ reported the effect of sectional jigs assembly that the maxillary first premolar move forward only 1.10 mm. However, Brickman et al²³ presented the effect of Jones jig compared with cervical headgear. The results presented no significant difference of final position in either linear or angular measurements of the maxillary first molars and corresponding premolar-incisor anchor units. From this study, there were mesial movement of maxillary first premolar and incisors 2 and 0.14 mm., respectively.

Mesial tipping of upper first premolar and upper incisors are the results of the reciprocal force, derived from anchorage loss. In the group of Pendulum appliances, Ghosh and Nanda³ reported only 1.29° upper first premolar mesial tipping with labial tipped of upper incisor 2.40° . Whereas, the greater of labial tipping of upper incisors (4.9°) was found in the study of Joseph and Butchart.²⁴ The similar result was found in the Jones jigs appliances, Brickman et al²³ presented 4.76° of mesially tipped of maxillary second premolar and the mesial tipping of second premolar 2.6° was found in the study of Gulati et al.¹⁶

Patient selection for molar distalization

With non-extraction treatment, patients should be carefully selected to be treated by molar distalization. This type of tooth movement can either be translation or control tipping followed by uprighting. Therefore when using this appliances, anchorage situation include molar extrusion and mesial movement of anterior teeth segment must be controlled.

However, molar extrusion is one of the most common method to correct deepbite and it is an efficacious method for bite opening. Even though an anterior deepbite may be associated with other of malocclusion, it was found that deepbite frequently occurs with class II malocclusion.

Patients to be treated by distalization technique should be²⁵ a dental class II relationship or a minor skeletal class II or class I relationship with hypodivergent or normodivergent pattern, class II relationship with mesial migration of maxillary molar due to premature loss of primary molars, a patient with minimal or no mandibular arch length discrepancy and meso- or brachi-facial types and potential remaining growth.

Objectives

1. To develop a system for maxillary molar distalization and extrusion without loss of anchorage, patient's cooperation needed and laboratory processing.
2. To present the treatment effects of this system.

Hypothesis

1. The system can move maxillary molars distally and occlusally.
2. There is no anchorage loss in premolar and upper incisors.

Significance of the study

The molar distalization and extrusion system is another option for correcting of a class II malocclusion with deepbite in growing patients that is non-compliance method and no need for laboratory procedure.

The limitation of the study

This system provides only the orthodontic effect for upper molar distalization and extrusion and it cannot be applied to the adult patients because there is no compensatory mandibular growth to rotate the mandible from the extrusion of maxillary molar.

CHAPTER 2

RESEARCH METHODOLOGY

Samples

The patients, boys and girls, age range from 10-14 years were randomly selected from Orthodontic clinic, Dental hospital, Faculty of Dentistry, Prince of Songkla University.

The inclusion criteria for this study are as follows:

- Good general health, no underlying disease.
- Class II molar relationship (did not exceed end to end molar relationship)
- Skeletal class I or class II relationship with hypodivergent or normodivergent pattern, defined by angulation of mandibular plane to SN did not exceed 35 degree.
- During MP₃ stage (maximal pubertal growth status has not yet reached).
The patients were assessed by hand & wrist radiographic examination. According to the method of Grave and Brown²⁶, the epiphysial region of the middle phalanx of the third finger shows epiphysis equal to diaphysis.
- All of teeth in maxillary arch are presented and fully erupted.

The exclusion criteria for the study are as follows:

- End stage of growth
- Patient who has a pathologic lesion in the maxilla.
- In case of maxillary first molar has some unwanted position such as severe rotation that affect treatment plan and treatment time.

Sample size calculation

The sample size was calculated from the formula of Kittika²⁷ in 1999:

$$\text{Sample size (n)} = \frac{(Z_{(1-\alpha)} + Z_{(1-\beta)})^2 \sigma^2 \text{ diff}}{(\bar{x}_2 - \bar{x}_1)^2}$$

The values of parameters are taken from the study of Gulati et al¹⁶ as follow:

$\bar{x}_2 - \bar{x}_1$ (difference of mean between before and after treatment) is 2.75

σ diff (standard deviation of total change) is 3.24

The level of significance of the change is established at 95%.

The power of the test in this study is established at 80%.

From this formula, the required sample size was 11 patients per group.

From the sample size calculation, however, there were 26 patients of orthodontic clinic, dental hospital, faculty of dentistry, prince of Songkla university and met the inclusion criteria, they were invited to join this project. All patients and their parents were informed about the purpose of this study and steps of treatment and signed in the consent form. This study was proved and accepted by the ethics committee of the faculty of dentistry, prince of Songkla University.

To evaluate the treatment effects on class II malocclusion growing patients, a comparison between before and after upper molar distalization and extrusion in treatment group and untreated patients (control group) and treatment group were done. The control group derived from the patients in growth monitoring project that waiting for treatment at orthodontic clinic, dental hospital, faculty of dentistry, prince of Songkla University

1. Control group: 6 male and 7 female were observed for 6-12 months.
2. Treatment group: 6 male and 7 female were treated with the maxillary molar distalization and extrusion system until class II malocclusion was overcorrected into Class III relationship of 1 mm.

Material and methods

System design

The maxillary molar distalization and extrusion system comprises of:

- Roth's prescription preadjusted edgewise bracket system. The bracket slot of canines, premolars and molars are 0.022"x 0.028" inches. The bracket of premolar teeth must have a vertical slot for uprighting spring application. The

brackets slots of upper incisors are 0.018" x 0.025" inches and there were bonded upside down. The upper canines were bonded with the lower canine brackets.

- 0.017" x 0.025" TMA archwire with

- Distal L loops in front of mesial wing of the upper first molar brackets

- Stop bending behind the distal wing of the upper canine brackets

- 0.016" Stainless steel uprighting springs (clockwise rotation) in the vertical slots of brackets of the first and second premolar teeth

- The second premolar from the left side to the right side were coligated with the 0.010" stainless steel wire to create anterior anchorage unit.



Fig. 8 The overall components of maxillary molar distalization and extrusion system

Treatment protocol

Roth's prescription preadjusted edgewise bracket system with 0.022" x 0.028" inch slot were bonded from the canine to the molars with vertical slot in the first and second premolar brackets for uprighting springs application. In the area of upper incisors teeth will be upside down bonded with 0.018" x 0.025" inch slot in the incisors brackets. The upper canines were bonded with lower canine brackets.

The patients' teeth were aligned and leveled. The archwire was changed until the size of arch wire was 0.016" x 0.022" NiTi wire. Before maxillary molar distalization and extrusion, the teeth from the second premolar on the right side to the left side were coligated to be one unit by 0.010" stainless steel wire, then 0.017" x 0.025" TMA wire with stop and distal L loop was used for the main archwire. The upright springs were placed in the vertical slot of the first and second premolar on the both sides.

The patients were recalled for routine checks every 4 weeks. In each visit, the distal L loop were reactivated 1 mm. for distalized and extruded upper first molars and the uprighting springs were readjusted to maintain the initial configuration. The archwire was readjusted and reactivated until the patients' occlusion were overcorrected in dental class III relationship 1 mm.



Fig. 9 The configuration of distal L loops in first, second and third visit of treatment

Pilot study was done to test the distalization and extrusion force that produce from distal L loops by universal testing machine. Sectional archwire with various sizes of distal L loops were tested for the appropriate size that can produce the optimum force. Each sectional archwire was placed and tied with elastomeric ring in an acrylic plate that fixed with premolars and molar brackets. Then the acrylic plate was fixed in the platform. Force was measured and will be applied in the clinic.

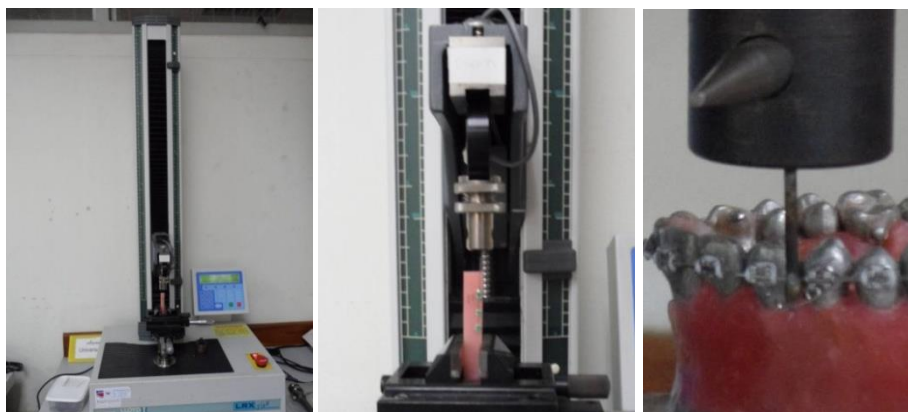


Fig. 10 Universal testing machine and testing method

The pilot study shown distal L loop exerted the horizontal force about 60 g and vertical force about 30 g. Hence the force level that applied in the clinic to move maxillary molar distalization and extrusion was 70 g.

From literature reviews, there are many force levels used in each distalization appliances. The Jones jig is a fixed distalization appliance that expressed lowest force level from a compression of open NiTi coil spring 1-5 mm. in 0.030" stainless steel wire. This appliance delivers approximate 70-75 g of force per side to the molars.² Thus, the new maxillary molar distalization and extrusion system used the same force level as Jones Jig appliance.

On the anchorage unit, to obtain the same force level derived from a reaction force. The pilot study was done to calculate the force level from uprighting springs. Before activation, the springs were made by the investigator. The length of arm is 5 mm. with forming 25 degree angle to the base of archwire. When activated, the spring exerted the force of 70g. From the study of Halazonettis²⁸, the center of resistance of the upper premolar tooth located 10 mm. from the bracket slots. So the moment of force from the uprighting spring is 700 gmm.

Data measurement

Data was gathered from the control and treatment group for evaluation the treatment effect. In the control group, the growth monitoring records were taken in the periods of 6-12 months (C1 at the initial and C2 for after growth monitoring). In the treatment group, the records were kept 3 times, first at the initial (T0), second at before distalization and extrusion of maxillary molars (T1) and final record when obtaining dental class III relationship of 1 mm. (T2).

Data recording requirement are as follow:

- Photograph taking (Intraoral and extraoral photograph)
- Study model
- Radiographic examination
 - Lateral cephalogram
 - Panoramic radiograph
 - Hand & Wrist radiograph (at the initial record)

For precise measurement of tooth angulation and separating right and left side, tooth positional locating devices (wire jigs) were fabricated from section of 0.021" x 0.025" stainless steel wire. The horizontal part was inserted on the slot of the bracket of the upper first premolars and upper first molars before sending patients to take T1 and T2 radiograph. The vertical part of the wire jigs was bended perpendicularly to the teeth angulation. On the right side, the wire jigs were bent into a circular shape but the rectangular shape was represented for the left side.²⁹

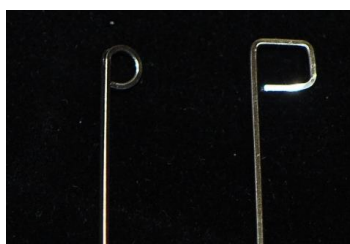


Fig. 11 The tooth positional locating devices

All radiographs were taken with the same cephalostat (Orthophos[®] CD, Siemens, Germany). Lateral cephalometric films were taken from natural head position which the patients looked straight ahead into a mirror. The patients were observed to ensure the position of pupil is in the middle of the eye, and the head did not be tilted or tipped.

Cephalometric analysis

The analysis of treatment effects was investigated from the tracing of the lateral cephalogram before and after completely treated with maxillary molar distalization and extrusion system. These data was compared with the data in the control group. The cephalometric system described by Pancherz³⁰ was used and modified to analyze the treatment effects. The landmarks show in Figure10. The magnification factor of the lateral cephalograms was similar for the treatment and control groups. The tracings were done on acetate paper and then, reference points and lines were marked with 0.3 mm in diameter of mechanical pencil by one observer to avoid interoperate errors. The measurement for each variable was made with cephalometric protractor. Linear measurements were made to the nearest 0.5 mm and 0.5° of angulation on acetate tracing paper.

The treatment effects of the system were assessed by using cephalometric analysis are:

- Horizontal changes of the maxillary landmarks (a positive value indicates a mesial movement and a negative value indicates distal movement.)
- Vertical changes of the maxillary landmarks (a positive value indicates an extrusion and a negative value indicates an intrusion.)
- Angular changes of the maxillary landmarks (a positive value indicates a mesial tipping and a negative value indicates a distal tipping.)

When all measurements were calculated, horizontal and vertical movement within a month will be converted to the rate of upper molar distalization and extrusion.

Measuring points

- Is (incision superius): The incisal tip of the most maxillary incisor
- Ps (molar superius): The mesial contact point of the maxillary first premolar
- Ms (premolar superius): The mesial contact point of the maxillary first molar
- Ss (Subspinale): The deepest point on the anterior contour of the maxillary alveolar projection determined by a tangent perpendicular to occlusal line.

Reference points

- N (nasion): The most anterior limit of nasofrontalis suture
- S (sella): The center of sella turcica. The point was used as registration point for all head films.

Reference lines

- SNL (sella-nasion line): The line through S and N. The line was used for orientation of all head films.

- OL (occlusal line): A line through incisal tip of maxillary incisor (Is) and the distobuccal cusp of the maxillary permanent first molar. The line from the initial head film was used as reference line for measurements on all head films.
- OLp (occlusal line perpendicular): A line perpendicular to OL through S. The line from the initial head film was used as reference line for measurements on all head films.
- OLs: A line parallel to OL through S. The line from the initial head film will be used as reference line for measurements on all head films.

Measuring procedure

The cephalometric analysis comprises the following variables:

Sagittal distances

1. $\underline{1}/OLp$: The distance from OLp line to the incisal tip of maxillary incisors
2. $\underline{4}/OLp$: The distance from OLp line to the mesial contact point of maxillary first premolar
3. $\underline{6}/OLp$: The distance from OLp line to the mesial contact point of maxillary first molar

Vertical distances

4. $\underline{1}/OLs$: The distance from incisal tip of the maxillary incisors perpendicular to the OLs line
5. $\underline{4}/OLs$: The distance from the lowest of the maxillary first premolar perpendicular to the OLs line
6. $\underline{6}/OLs$: The distance from the lowest of the maxillary first molar perpendicular to the OLs line

Angulation (°)

7. $\underline{1}$ /NSL: The angle of the intersection of the long axis of the maxillary incisors
8. $\underline{4}$ /NSL: The angle of the intersection of the long axis of the maxillary first premolar
9. $\underline{6}$ /NSL: The angle of the intersection of the long axis of the maxillary first molar

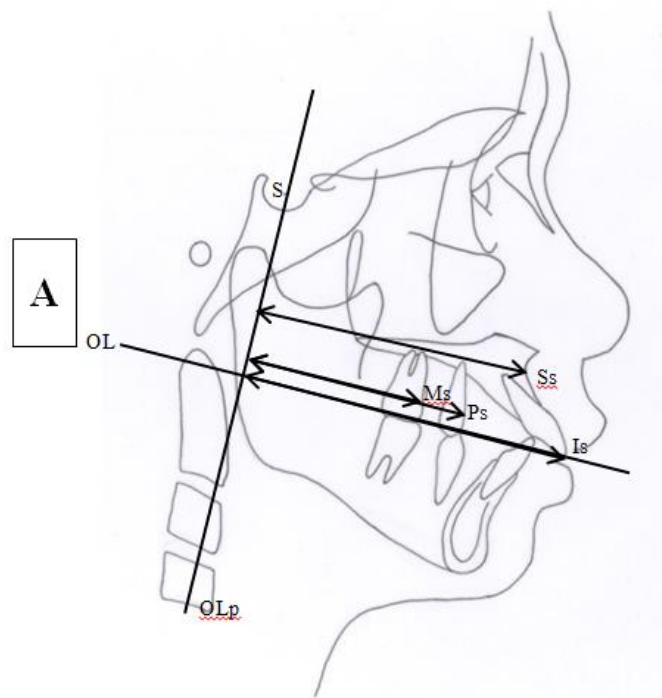


Fig. 12 Cephalometric landmarks for investigated treatment effects: A. Horizontal measurements, B. Vertical measurements and C. Angular measurements

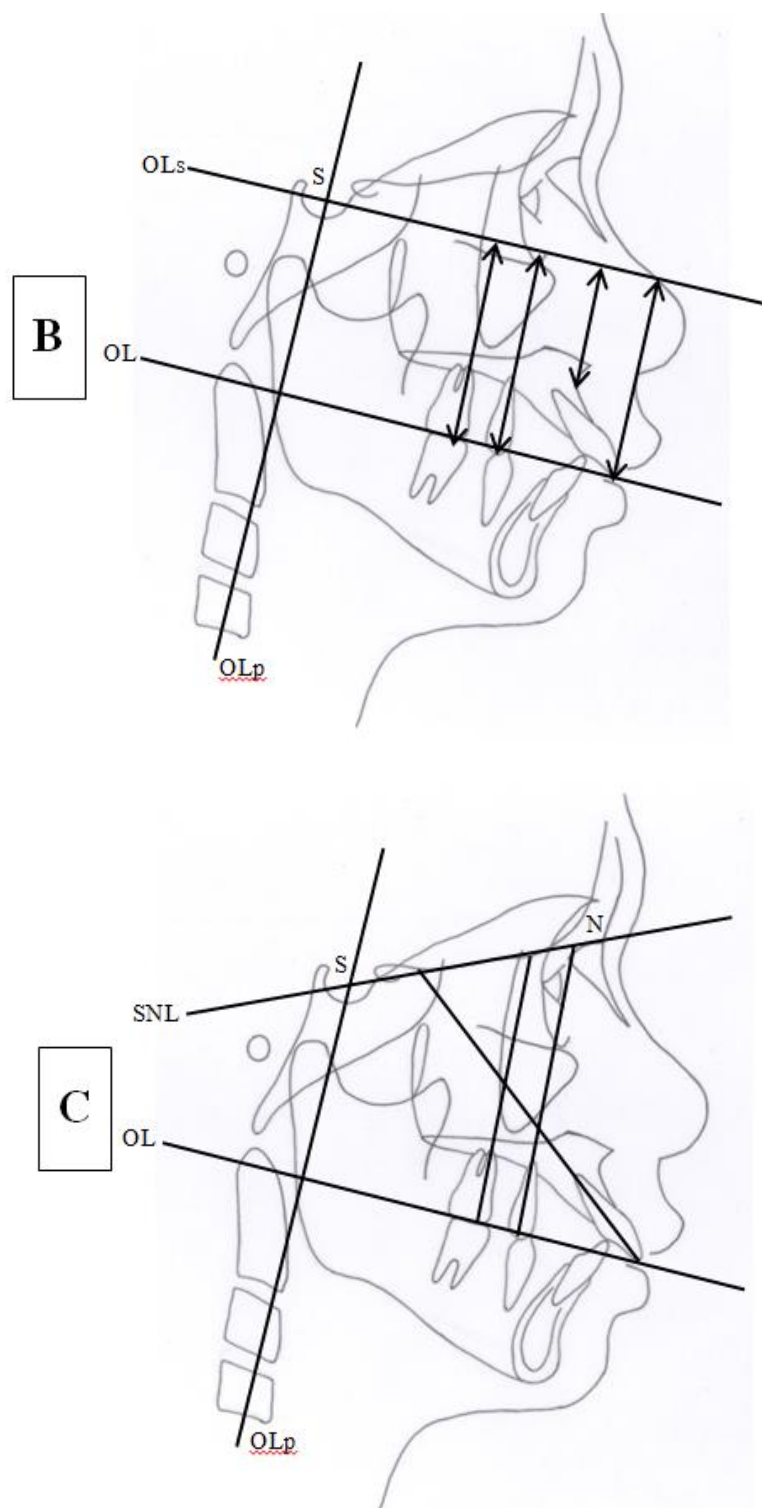


Fig. 12(Cont.) Cephalometric landmarks for investigated treatment effects: A. Horizontal measurements, B. Vertical measurements and C. Angular measurements

Because there was a combination of skeletal and dental changes in an observation period, changes of measuring points in relationship to reference plane were registered by

calculating the difference (d) in the landmark position. So the variables only for the dental changes were calculated as follows:³⁰

10. 6/OLp(d)- SS/OLp(d): Horizontal change in position of the maxillary first molar
11. 6/OLs(d)- SS/OLs(d): Vertical change in position of maxillary first molar

Statistical analysis

All data was analyzed with R statistical program. Mean and standard deviation (SD) were calculated for all cephalometric variables. Means of cephalometric variables in the treatment group at pre-treatment were T1 and the post-treatment variables were T2 whereas in the control group the pre-observe variables were C1 and the post-observe variables were C2. The means in difference were compared within group (T1 and T2, before and after maxillary molar distalization and extrusion) and between treatment group (T2-T1) and control group (C2-C1) by *t* test at alpha significance level of 0.05.

Error measurement

The errors in locating, superimposing and measuring the changes of the reference points by an examiner were measured on the cephalograms. To assess the error of locating, ten cephalograms were retraced and remeasured after approximately two weeks in separate occasions by the same examiner. The error of the method by the Dahlberg formula³¹ did not exceed 0.5° or 0.5 mm.³²

Method error (ME) in locating, superimposing and measuring the changes of the different cephalometric landmarks will be calculated with the formula.

$$ME = \sqrt{\frac{\epsilon d^2}{2n}}$$

When d is the difference between 2 registrations of a pair, *n* is the number of double measurements. The error in this study was found to be 0.25 mm. for linear measurements, 0.33° for angular measurements.

CHAPTER 3

RESULTS

In this study, a maxillary molar distalization and extrusion system was developed for class II malocclusion correction. All patients were divided into 2 groups (the treatment and control group). The cephalometric records of both groups are presented in Table 1. Before the examination periods, no statistically significant differences between the treatment and control groups were found for any of the cephalometric variables investigated. However, from the statistical test of all variables, there was a normal distribution. The mean and standard deviation (SD) of the variables were presented. The treatment and control groups also were compared means in difference at alpha significance level of 0.05.



Fig. 13 The intraoral photographs before (right) and after (left) maxillary molar distalization and extrusion

The thirteen untreated patients (six male and seven female) in the control group derived from the growth monitoring project. The mean initial age was 11.38 ± 0.96 years, range from 10 to 14 years. The average observation time in this control group was 8.77 ± 3.09 months, range from 6 to 12 months. However, all patients in this group were finally treated with their proper treatment plan after ending their observation periods. The samples in the treatment group comprised of thirteen patients (six male and seven female) same as the control group. The mean pretreatment age was 12.08 ± 1.38 years, range from 10 to 13 years. Table 2 presents no statistically significant difference for the mean initial age in the both groups.

Table 1 Pretreatment cephalometric records of the treatment and control groups

Parameter	Treatment		Control		t	Sig.
	Mean	SD	Mean	SD		
SNA	82.69	2.72	84.08	3.03	1.17	NS
SNB	78.92	3.13	79.5	2.00	0.56	NS
ANB	3.85	1.94	4.58	2.00	0.95	NS
SN-MP	30.69	3.25	30.85	2.73	0.13	NS
Occl-SN	16.08	3.48	15.92	3.86	-0.11	NS
NSGn	66.38	2.84	66.00	2.12	-0.40	NS
UI to PP	127.00	6.23	125.31	5.36	-0.74	NS
LI to MP	97.77	7.07	102.38	6.38	1.75	NS

NS No significant difference

Table 2 The initial age of the treatment and control groups

Group	Mean	SD	Range	t	Sig.
Treatment	12.08	1.38	10-13	-1.48	NS
Control	11.38	0.96	10-14		

NS No significant difference

Treatment group

The upper molars were distalized and extruded to an overcorrected class III molar relationship of 1 mm. Treatment time for upper molar distalization and extrusion were 3.35 ± 0.47 months and 3.08 ± 0.76 months, respectively. The mean distance of upper molar distalization was 3.46 ± 0.88 mm, range from 2 to 5 mm, and they extruded 1.60 ± 0.44 mm. There was a distal molar tipping at a 3.10 ± 1.85 degree. The rate of upper molar distalization and extrusion were 1.06 ± 0.31 and 0.54 ± 0.13 mm, per month, respectively.

Table 3 presented descriptive statistics of cephalometric measurements at before and after upper molar distalization and extrusion. There was a statistically significant difference ($P < 0.01$), of the horizontal, vertical position and angulation of the upper molar between before and after upper molar distalization and extrusion. The upper molar were effectively distalized, extruded and tipped distally. Table 4 presents the position of the left and right upper molars that were both statistic significant differences ($P < 0.01$) between before and after distalization and extrusion. When comparing on the left and right side, no statistic significant differences in the upper molar position shown in Table 5.

The upper first premolar moved distally 0.15 ± 0.52 mm. and intruded 0.19 ± 0.25 mm. with distal tipping 0.83 ± 1.67 degree. Table 6 indicates no statistic significant difference between before and after treatment for the upper first premolar distal movement and distal tipping. However, the statistically significant difference ($P < 0.05$) was found in vertical position of upper first premolar though there was no clinically significant difference.

At the upper incisors, there was no horizontal movement but intruded 0.15 ± 0.38 mm. with distal tipping 0.46 ± 1.56 degree. Table 7 presents all variables revealed no statistically significant differences between before and after upper molar distalization and extrusion.

Table 3 The position and angulation of upper molar before and after upper molar distalization and extrusion

Measurement	Before(T1)		After(T2)		T2-T1		t	Sig.
	Mean	SD	Mean	SD	Mean	SD		
$\underline{6}$ -OLp(mm.)	57.36	4.19	53.90	4.01	-3.46	0.88	-14.23	**
$\underline{6}$ -OLs(mm.)	59.81	4.89	61.04	5.20	1.60	0.44	4.36	**
$\underline{6}$ -SNL(deg.)	80.58	2.32	77.48	2.58	-3.10	1.85	-6.03	**

**P < 0.01

Table 4 The position and angulation of right and left upper molar before and after upper molar distalization and extrusion

Measurement	Before(T1)		After(T2)		T2-T1		t	Sig.
	Mean	SD	Mean	SD	Mean	SD		
Right side								
<u>6</u> -OLp(mm.)	57.38	4.51	53.96	4.18	-3.42	1.00	-12.38	**
<u>6</u> -OLs(mm.)	59.84	4.98	61.19	5.21	1.58	0.40	5.14	**
<u>6</u> -SNL(deg.)	80.77	2.28	77.69	2.56	-2.92	1.98	-6.16	**
Left side								
<u>6</u> -OLp(mm.)	57.35	4.24	53.85	4.20	-3.50	0.87	-14.57	**
<u>6</u> -OLs(mm.)	59.77	4.82	61.08	5.06	1.62	0.51	4.25	**
<u>6</u> -SNL(deg.)	80.38	2.51	77.27	2.83	-3.12	1.96	-5.73	**

**P < 0.01

Table 5 The position and angulation of upper molar between left and right sides

		<u>6</u> -OLp(mm.)		Sig.	<u>6</u> -OLs(mm.)		Sig.	<u>6</u> -SNL(deg.)		Sig.
		RT	LT		RT	LT		RT	LT	
T2-	Mean	-3.42	-3.50	NS	1.58	1.62	NS	-2.92	-3.12	NS
T1	SD	1.00	0.87		0.40	0.51		1.98	1.96	

NS No significant difference

Table 6 The position and angulation of upper first premolar before and after upper molar distalization and extrusion

Measurement	Before(T1)		After(T2)		T2-T1		t	Sig.
	Mean	SD	Mean	SD	Mean	SD		
<u>4</u> -OLp(mm.)	69.88	3.45	69.73	3.62	-0.15	0.52	-1.08	NS
<u>4</u> -OLs(mm.)	59.79	3.44	59.60	3.49	-0.19	0.25	-2.74	*
<u>4</u> -SNL(deg.)	89.46	4.54	88.63	4.50	-0.83	1.67	-1.79	NS

NS No significant difference, *P < 0.05

Table 7 The position and angulation of upper incisor before and after upper molar distalization and extrusion

Measurement	Before(T1)		After(T2)		T2-T1		t	Sig.
	Mean	SD	Mean	SD	Mean	SD		
\perp -OLp(mm.)	86.42	6.54	86.42	6.73	0	0.58	0	NS
\perp -OLs(mm.)	59.50	3.80	59.35	3.73	-0.15	0.38	-1.48	NS
\perp -SNL(deg.)	119.15	6.18	118.69	6.17	-0.46	1.56	-1.07	NS

NS No significant difference

Control group

At the mean observation time 8.77 ± 3.09 months of the control group, There were a mesial movement of upper first molar 1.18 ± 1.03 mm., extrusion 1.58 ± 0.61 mm. with molar mesial tipping 0.46 ± 2.11 degree. The rate of upper molar mesialization and extrusion were 0.22 ± 0.14 and 0.19 ± 0.08 mm. per month, respectively. Table 8 demonstrates that a comparison between pre and post-observation time presented statistically significant differences ($P < 0.01$) in the horizontal and vertical movement of upper molar but no statistically significant difference in the molar angulation.

Table 8 The position and angulation of upper molar at before and after observation periods

Measurement	Before(C1)		After(C2)		C2-C1		t	Sig.
	Mean	SD	Mean	SD	Mean	SD		
$\underline{6}$ -OLp(mm.)	52.96	4.06	54.77	4.47	1.81	1.03	6.32	**
$\underline{6}$ -OLs(mm.)	57.15	3.08	58.73	3.13	1.58	0.61	9.37	**
$\underline{6}$ -SNL(deg.)	74.46	5.30	74.85	4.26	0.46	2.11	0.73	NS

NS No significant difference, ** $P < 0.01$

The comparison between treatment and control groups

According to Pancherz's analysis³⁰, the dental measuring points were represented for a combination of skeletal and dental changes. So the real dental changes within the maxilla were calculated. Furthermore, to present the treatment effect of an upper molar distalization and extrusion system, the comparison between the treatment and control group was analyzed in the same examination periods.

When adjusting the upper molars movement with the control group in the same period of time, the upper molar was distalized 3.66 mm., extruded 1.09 mm. with distal tipping 3.56 degree. Table 9 presents the treatment effect of a maxillary molar distalization and extrusion system and descriptive statistics of cephalometric measurements between treatment and control group. There were statistical significant differences ($P < 0.01$). in all variables between treatment and control group.

Table 9 Treatment effects of maxillary molar distalization and extrusion system between treatment and control group

Upper molar movement	Treatment		Control		Treatment effect (Group difference)		
	Mean	SD	Mean	SD	Mean	t	Sig.
Horizontal	-3.46	0.08	0.31	0.20	-3.66	15.12	**
Vertical	1.60	0.44	0.51	0.10	1.09	-9.34	**
Angulation	-3.10	1.85	0.46	2.11	-3.56	4.57	**

**P < 0.01

CHAPTER 4

DISCUSSIONS

In the patient with class II malocclusion and deepbite, molar distalization is one of the treatment strategies that correct class II malocclusion back to a dental class I relationship. In cases of hypo-or normodivergent patients, molar extrusion can also improve deepbite. Several methods have been developed including cervical pull headgear, a Pendulum, a Jones jig and open coil springs. However, the treatment success depends on the patient's complying and follows the prescribe time using headgear or class II elastics. Several appliances have to deal with many steps in banding and processing in the laboratory room. Moreover, many problems have been reported such as social concern, safety use, discomfort, and anchorage loss². Therefore, the aim of this study was to develop the non-compliance maxillary molar distalization and extrusion system with no need for patient co-operation and no need for banding, laboratory processing and present the treatment effect of this system.

From the study of Locatelli et al¹⁷ presented that superelastic NiTi wire expressed 100 g per side for distalize upper molars. With this new system, the distalized and extruded force was reduced to 70 g per side and the 0.017" x 0.025" TMA archwire with distal L loop was chosen. When the distal L loop was activated, the upper molars were distalized simultaneously with extruded. Consequently, the class II malocclusion and deepbite were corrected at the same times. Moreover, the effect of step bending at distal L loop creates distal tipping of upper premolars that is an advantage in class II malocclusion correction.

As the upper molars were distalized and extruded, there was a reaction force against the anterior teeth segment. There would be an anterior teeth proclination and mesialization of upper premolars which was an anchorage loss. To control an anchorage, upper incisors were upside down bonded with 0.018" x 0.025" inch slot brackets, upper canines were bonded with lower canine brackets and the teeth from the second premolar on the right side to the left side were coligated to be one unit by 0.010" stainless steel wire. With non-compliance system, 0.016" stainless steel uprighting springs (clockwise rotation) were placed in the vertical slots at both sides of the first and second premolar brackets.

From pilot study, distalized and extruded force that derived from universal testing machine was 70 g. It comprised of 60 g. horizontal force and vertical force of 30 g. However, during distal L loop activation, there was a moment creation simultaneously with distalized and extruded force. That was a limitation of this pilot study that cannot calculate the amount of this moment.

In this study, Pancherz's cephalometric analysis³⁰ was used and modified to analyze the treatment effects of this system for both before and after treatment measurement. Each linear measurement was performed to the same references lines making it suitable for evaluate the relationship of composite movement between skeletal and dental changes and for eliminate the orthopedic tooth displacement due to the growth and remodeling changes of the maxilla. Hence, the real dental changes within the maxilla were presented.

Furthermore, in cephalometric study involving treatment in the growing patients, it was reasonable to distinguish a treatment effect from growth that would occur during the treatment.³³ So the comparison between the treatment and the control group was designed in this study and the treatment effect of this system was proposed. However, all patients in the control group were finally treated with their proper treatment plan after ending their observation periods.

From the results, the new maxillary molar distalization and extrusion system is capable to distalize and extrude the upper molars 3.46 mm. and 1.60 mm., respectively. There was a distal molar tipping 3.10 degree. The distalization treatment time was 3.35 months whereas the extrusion treatment time was 3.08 months. The rate of molar distalization and extrusion were 1.06 and 0.54 mm. per month, respectively. These findings were comparable with cervical pull headgear. Taner et al in 2003³⁴ reported that the upper molars were distalized 3.15 mm., extrude 1.42 mm. with distal tipping 6.96 degree. Their total treatment time was 11.38 months that was more than this study. Bondemark and Karlsson²² found the molar distalization 1.7 mm. within 6.4 months. The study of Gandini et al³⁵ reported that the rate of molar distalization was 0.34 mm. per month. To compare this new system with cervical pull headgear, the new maxillary molar distalization and extrusion system can move the upper molar distally and occlusally more than the cervical pull headgear in shorter period of time and no need for patient co-operation.

When comparing with other intraoral appliances, a Pendulum can move molar distally 2.8 mm., occlusally 0.95 mm. with distal tipping 7.85 degree during 2.5 months.³⁶ A Jones jig move the maxillary molars 2.8 mm. distally with 6.8 degree distal tipping within 17.5 weeks.³⁷ The mean molar distalization distance from open coil springs was 1.4 mm. with distal tipping 6.8 degree in a mean treatment period of 16.5 weeks.¹³ The rate of molar distalization from Pendulum varies from 0.6-0.8 mm. per month.^{3, 21, 38} while the rate of a Jones jig and open coil springs were 0.86 and 0.37 mm. per month, respectively.^{13, 16} However, comparing the distance and rate of molar distalization, this new system can move upper molar distally more distance than other appliances with better rate of tooth movement.

During molar distalization and extrusion in this system, 3.10 degree distal tipping was observed. This finding was in accordance with many studies. Haydar and Uner³⁶ reported that cervical pull headgear distalized and extruded upper molars with 3.80 degree distal molar tipping. A study of Pendulum by Bussick and McNamara⁸ found 10.6 degree tipping while an open coil spring moves molar distally tipping with 6.80 degree.¹³ From the point of biomechanic tooth movement, exactly, when the distalized force acts on the upper molars, the force will be placed beneath the center of resistance of this teeth. So the distalized force and clockwise rotation moment will be created resulting in the molars were distalized simultaneously with distal tipping. However, this system created the distal tipping of upper molars same as the cervical pull headgear but lessor degree of molar tipping when comparing with other appliances.

Maxillary first premolar was distalized 0.15 mm., intruded 0.19 mm. with distal tipping 0.83 degree. However, during upper molar distalization and extrusion in this study, the upper first premolars did not tend to tip mesially as found in many intraoral appliances^{13, 34} such as a Jones jig presented a mesial movement of upper first premolar 2 mm. with mesial tipping 4.76 degree²³ and molar distalization with Pendulum moved upper first premolar forward 2.55 mm. with tipped mesially 1.29 degree.³

This study showed that upper first premolars were distalized and distal tipped for small extent which no statistic significant differences between before and after treatment were found. These findings could be a result of force and clockwise rotation moment derived from uprighting springs on both upper first and second premolars. On the other hand, there was a

statistically significant difference in vertical position of upper first premolars. The upper first premolars were intruded while the distal L loop extruded upper first molars. However, the upper first premolar intrusion was no clinically significant difference.

A mesial reaction force from upper molar distalization can cause mesial movement and proclination of upper incisors in many studies^{39, 40} such as upper incisors were moved mesially 0.90 mm. and 3.6 degree proclination in a Pendulum appliance.⁸ However, this study presented no horizontal movement of upper incisors but intruded 0.15 mm. and distal tipping 0.46 degree. It was known that upside down bonded upper incisors and lower canine brackets created a negative torque control in upper incisors and canines. Therefore, it was possible that a negative torque brackets created clockwise moment to against a mesial reaction force and moment that were created during upper molar distalization and extrusion.

In the control group, there was a mesial movement of upper molar 1.18 mm. and extrusion 1.58 mm. with mesial tipping 0.46 degree within 8.77 months. The rate of upper molar mesialization and extrusion were 0.22 and 0.19 mm. per month, respectively. These findings were similar to the normal tooth eruption from many studies.^{41, 42} Comparison with the treatment group, forward movement and mesial tipping of upper molars was not found. Therefore, it was implied that when treatment in this growing patient, this system can overcome the effect of normal growth during treatment periods. However, from the normal growth of maxilla, there are forward and downward movement with a parallel- vertical growth of dentoalveolar complex. Therefore, normal tooth eruption can also come along with molar extrusion from this new system.

Therefore, the skeletal changes were eliminated both horizontal and vertical variables from the initial composite results and the group difference between treatment and control was done to calculate the real treatment effect of this new maxillary molar distalization and extrusion system. Consequently, treatment effect this system were presented that the upper molar were distalized 3.66 mm., extruded 1.09 mm. with distal tipping 3.56 degree.

When determining the success of this maxillary molar distalization and extrusion system, although this system can only create the orthodontic effect to the patient, the upper molars were distalized more distance than other appliances and this system created better rate of molar distalization with non- compliance and no need for laboratory processing. In vertical plane,

this system can extrude upper molars but not increase lower anterior facial height of the patient. So muscle exercise is recommended while using this maxillary molar distalization and extrusion system. Other advantage of this system was creating less molar distal tipping when comparing with other appliance. However, this study did not evaluate the transverse changes of the upper molar before and after treatment but there was no any transverse problem occurred in all patients.



Fig. 14 Extraoral photographs before (right) and after (left) maxillary molar distalization and extrusion

For further investigation, because the sample in this study was less than the others,^{2, 23} increasing of sample size is suggested although the results from this study had normal distribution and small SD. Moreover, long term study is needed to evaluate the stability of the upper molars after completed orthodontic treatment in these patients.

In class II malocclusion patient with hypodivergent pattern, molar distalization and extrusion is the proper treatment that can improve deepbite and increase lower facial height. However, when molars are distalized and extruded, It will be an observation of clockwise rotation of mandible, increased mandibular plane angle and retruded chin.¹⁶ So, the molar distalization and extrusion is not indicated in a patient with hyperdivergent pattern.⁴³ However, the mandible would be return to the initial sagittal and vertical position, reflecting the inherit growth individual pattern of each patient.⁴⁴ So the remaining growth after molar distalization is necessary and forward rotation of the mandible will be observed.³³

CHAPTER 5

CONCLUSIONS

A maxillary molar distalization and extrusion system can effectively correct class II malocclusion with deepbite. The upper molars were significantly distalized and extruded with no anchorage loss. This system was successfully developed with non-compliance method and no need for laboratory processing.

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APPENDICES

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Documentary Proof of Ethical Clearance

Research Ethics Committee (REC)

Faculty of Dentistry, Prince of Songkla University

The Project Entitled : The treatment effects of maxillary molar distalization and extrusion system in class II growing patients

REC Project No. : EC5505-20-P

Principal Investigator : Miss Natthawee Phaoseree

Approved by Research Ethics Committee (REC), Faculty of Dentistry, Prince of Songkla University.

This is to certify that REC is in full Compliance with International Guidelines for Human Research Protection such as the Declaration of Helsinki, the Belmont Report, CIOMS Guidelines and the International Conference on Harmonization in Good Clinical Practice (ICH-GCP).

Date of Approval : 21 November 2012

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ใบเชิญชวน

ขอเชิญเข้าร่วมโครงการวิจัยเรื่อง ผลของระบบการเคลื่อนฟันกรามบนไปด้านหลัง และด้านบดเคี้ยวในผู้ป่วยที่มีการสบฟันผิดปกติประเภทที่ 2 ที่มีการเจริญเติบโต

เรียน ท่านผู้อ่านที่นับถือ

ข้าพเจ้า ทพญ.ณัฐวีร์ เผ่าเสรี นักศึกษาระดับปริญญาโท สาขาทันตกรรมจัดฟัน ภาควิชาทันตกรรมป้องกัน คณะทันตแพทยศาสตร์ มหาวิทยาลัยสงขลานครินทร์ ใ้รขอเล่าถึงโครงการวิจัยที่กำลังทำอยู่และขอเชิญชวนท่านเข้าร่วมโครงการนี้ ดังนี้

โครงการวิจัยนี้จัดทำขึ้นเพื่อพัฒนาวิธีการที่ใช้ในการแก้ไขการสบฟันผิดปกติประเภทที่ 2 ในผู้ป่วยที่มีการเจริญเติบโตด้วยระบบการเคลื่อนฟันกรามบนไปด้านหลังและด้านบดเคี้ยว ซึ่งระบบดังกล่าวจะสามารถแก้ไขจนได้การสบฟันปกติ นอกจากนั้นยังเป็นระบบการเคลื่อนฟันที่ไม่ต้องอาศัยความร่วมมือของผู้ป่วยและไม่ต้องผลิตเครื่องมือในห้องปฏิบัติการ

ผู้ป่วยที่เข้าร่วมโครงการวิจัยจะถูกเลือกเข้ากลุ่มแบบสุ่ม ให้เป็นผู้ป่วยในกลุ่มควบคุมหรือกลุ่มทดลองอย่างใดอย่างหนึ่ง โดยกลุ่มควบคุม ผู้ป่วยจะได้รับการติดตามการเจริญเติบโต (growth monitoring) เป็นระยะเวลา 6-12 เดือน โดยจะทำการบันทึกข้อมูล ได้แก่ การถ่ายภาพรังสีกะโหลกศีรษะด้านข้าง 2 ครั้ง ระยะเวลาห่างกันเป็นเวลา 6-12 เดือน เพื่อติดตามการเจริญเติบโตของกระดูกโครงสร้างและขากรรไกร ซึ่งปฏิบัติตามขั้นตอนทั่วไปของโครงการติดตามการเจริญเติบโตในผู้ป่วย (Growth monitoring project) คลินิกทันตกรรมจัดฟัน มหาวิทยาลัยสงขลานครินทร์ หลังจากนั้นผู้ป่วยจะได้รับการรักษาโดยแยกการรักษาจากคิวปกติ

กลุ่มทดลองผู้ป่วยจะได้รับการจัดฟันโดยเครื่องมือจัดฟันชนิดติดแน่นร่วมกับระบบการเคลื่อนฟันกรามบนไปด้านหลังและด้านบดเคี้ยว ผู้ป่วยที่เข้าร่วมวิจัยจะได้รับการรักษาทางทันตกรรมจัดฟัน โดยได้รับการแยกการรักษาจากคิวรักษาปกติเช่นกัน และได้รับการตรวจและบันทึกข้อมูลซึ่งประกอบด้วย การซักประวัติ เช่น ข้อมูลทั่วไป ประวัติทางทันตกรรม ประวัติทางการแพทย์ ได้รับการตรวจนอกช่องปากและภายในช่องปาก การถ่ายภาพภายนอกและภายในช่องปาก การถ่ายภาพรังสี กะโหลกศีรษะด้านข้าง (lateral cephalometric radiograph) ภาพถ่ายรังสีกระดูกข้อมือ (Hand-wrist radiograph) ภาพถ่ายรังสีพานoramิก (panoramic radiograph) และการพิมพ์ปากเพื่อทำแบบจำลองฟัน โดยมีขั้นตอนในการรักษา คือ

- บันทึกข้อมูลเบื้องต้นก่อนการรักษา
- ติดเครื่องมือจัดฟันติดแน่น

- ปรับระดับฟัน
- บันทึกข้อมูลก่อนการเคลื่อนฟันกรามบน ไปด้านหลังและด้านบดเคี้ยว
- เคลื่อนฟันกรามบน ไปด้านหลังและด้านบดเคี้ยว
- บันทึกข้อมูลหลังการเคลื่อนฟันกรามบน ไปด้านหลังและด้านบดเคี้ยว
- ให้การรักษาความผิดปกติของการสบฟันในตำแหน่งอื่นตามแผนการรักษาจนรักษาเสร็จ

โครงการวิจัยนี้เป็นเพียงส่วนหนึ่งของการรักษา ในช่วงการรักษาจัดฟันที่เป็นงานวิจัย ผู้เข้าร่วมวิจัยต้องมารับการรักษาจัดฟัน 10 ครั้ง เดือนละ 1 ครั้ง ตลอดระยะเวลาในงานวิจัยรวม 10 เดือน โดยมาปรับระดับฟัน 4 ครั้ง เคลื่อนฟันกรามบน ไปด้านหลังและด้านบดเคี้ยว 6 ครั้ง รวมเป็น 10 ครั้ง หลังจากนั้นจะให้การรักษาตามแผนการรักษา ต่อเนื่องจนเสร็จซึ่งระยะเวลาในการรักษาขึ้นกับแผนการรักษาในผู้ร่วมวิจัยแต่ละราย

ในกรณีที่ระบบการเคลื่อนฟันกรามที่ออกแบบในงานวิจัยไม่สามารถเคลื่อนฟันกรามบน ไปด้านหลังและด้านบดเคี้ยวได้ในระยะเวลา 3 เดือน ทางผู้วิจัยจะเปลี่ยนวิธีการรักษา โดยการใช้แรงที่อยู่ในช่วงแรงปกติที่ใช้ในการเคลื่อนฟัน หรือใช้เครื่องมือชนิดอื่นที่มีความเหมาะสม ขึ้นอยู่กับความร่วมมือและการตัดสินใจของผู้ป่วยและผู้ปกครอง

ผู้เข้าร่วมวิจัยต้องเสียค่าใช้จ่ายในการจัดฟันตามปกติโดยมีค่าใช้จ่ายในการเก็บข้อมูล, พิมพ์ปาก, ถ่ายรูป, การจัดฟันแบบติดแน่น และ ภาพถ่ายรังสีในการรักษา ซึ่งเป็นค่ารักษาในอัตราปกติของคลินิกทันตกรรมจัดฟันและแผนกรังสี โรงพยาบาลทันตกรรม คณะทันตแพทยศาสตร์ มหาวิทยาลัยสงขลานครินทร์ ในกรณีที่ต้องเปลี่ยนการรักษาเพราะงานวิจัยไม่สำเร็จ จะไม่มีการเสียค่าใช้จ่ายในการรักษาเพิ่ม ส่วนค่าใช้จ่าย สำหรับภาพถ่ายรังสีกะโหลกศีรษะด้านข้าง และค่าพิมพ์ปากเพื่อทำแบบจำลองฟันก่อนการเคลื่อนฟันกรามบน ไปด้านหลังและด้านบดเคี้ยว ทางคณะผู้วิจัยจะรับผิดชอบค่าใช้จ่ายในส่วนนี้ให้

ในแง่ของการควบคุมความเสี่ยงที่อาจจะเกิดขึ้น เนื่องจากปริมาณแรงที่ใช้ในการเคลื่อนฟันเป็นแรง ขนาดเบาแต่มากรวมๆ ทำให้เกิดการเคลื่อนฟัน จึงมีความปลอดภัยในการเคลื่อนฟันไม่แตกต่างจากการเคลื่อนฟันด้วยวิธีการรักษาปกติ อย่างไรก็ตามผู้เข้าร่วมวิจัยจะได้รับการตรวจประเมินอาการและอาการแสดงที่บ่งชี้ว่ามีความผิดปกติอันเกิดจากการเคลื่อนฟันในทุกๆครั้งที่มาพบทันตแพทย์ผู้ให้การรักษา หากตรวจพบที่มีความผิดปกติจะหยุดการรักษาในทันที

ถ้าท่านและบุตรหลานของท่านตัดสินใจเข้าร่วม โครงการวิจัยนี้จะมีขั้นตอนของการวิจัยที่จำเป็นต้องขอ ความร่วมมือของท่านและบุตรหลานตามที่กล่าวมาข้างต้นซึ่งจะไม่ก่อให้เกิดความเจ็บปวดและอันตรายต่อเนื้อเยื่อมากไปกว่าการใช้เครื่องมือจัดฟันติดแน่นชนิดอื่นแต่อย่างใด โดยผู้เข้าร่วม โครงการฯ ต้องมารับการรักษา ณ คณะทันตแพทยศาสตร์ มหาวิทยาลัยสงขลานครินทร์ และติดตามผลตามระยะเวลาที่กำหนดอย่างเคร่งครัด

หากท่านมีข้อสงสัยหรือเกิดผลข้างเคียงจากการวิจัย สามารถติดต่อกับ ทพญ.ณัฐวีร์ เผ่าเสรี ได้ที่ ภาควิชาทันตกรรมป้องกัน คณะทันตแพทยศาสตร์ มหาวิทยาลัยสงขลานครินทร์ หมายเลขโทรศัพท์ 081-592-6677 หรือ เมื่อมีปัญหาใดๆ เกิดขึ้นเนื่องจากการทำวิจัยในเรื่องนี้ ท่านสามารถร้องเรียนได้ที่คณบดี คณะทันตแพทยศาสตร์ มหาวิทยาลัยสงขลานครินทร์ อ.หาดใหญ่ จ.สงขลา 90112 หมายเลขโทรศัพท์ 074-287500

ไม่ว่าท่านจะเข้าร่วมในโครงการวิจัยนี้หรือไม่ ท่านจะยังคงได้รับการรักษาที่ดีเช่นเดียวกับผู้ป่วยอื่นๆ และถ้าท่านต้องการที่จะถอนตัวออกจากการศึกษานี้เมื่อใดท่านก็สามารถทำได้โดยอิสระ

หากท่านมีคำถามใดๆ ก่อนที่จะตัดสินใจเข้าร่วมโครงการนี้ โปรดซักถามจากคณะผู้วิจัยได้อย่างเต็มที่

ขอขอบคุณเป็นอย่างสูง

ทพญ.ณัฐวีร์ เผ่าเสรี

หัวหน้าโครงการ

หมายเหตุ : กรุณาอ่านข้อความให้เข้าใจก่อนเซ็นชื่อยินยอมเข้าร่วมโครงการ

แบบยินยอมเข้าร่วมการศึกษา

โครงการวิจัยเรื่อง ผลของระบบการเคลื่อนฟันกรามบนไปด้านหลังและด้านบดเคี้ยวในผู้ป่วยที่มี
การสบฟันผิดปกติประเภทที่ 2 ที่มีการเจริญเติบโต

วันที่.....เดือน.....พ.ศ.....

ข้าพเจ้า.....ผู้ปกครองของ ค.ช./ค.ญ./นาย/น.ส.....

อายุ.....ปี อาศัยอยู่บ้านเลขที่.....ถนน.....ตำบล.....อำเภอ.....

จังหวัด..... ได้อ่าน/ได้รับการอธิบายจากผู้วิจัยถึงวัตถุประสงค์ของการวิจัย วิธีการวิจัย

อันตรายหรือ อาการที่อาจเกิดขึ้นจากการวิจัยหรือจากยาที่ใช้ รวมทั้งประโยชน์ที่จะเกิดขึ้นจากการ
วิจัยอย่างละเอียดและมีความเข้าใจดีแล้ว

หากข้าพเจ้าได้รับผลข้างเคียงจากการวิจัย ข้าพเจ้าจะได้รับการปฏิบัติ/การชดเชย
ดังนี้ ข้าพเจ้าจะได้รับการยกเลิกวิธีการรักษาที่ใช้ในงานวิจัยและได้รับการรักษาทางทันตกรรมจัด
ฟันด้วยวิธีการรักษาปกติจนถึงสุดการรักษาต่อไป โดยผู้รับผิดชอบโครงการวิจัยนี้ คือ ทพญ.ณัฐวีร์
เผ่าเสรี ภาควิชาทันตกรรมป้องกัน คณะทันตแพทยศาสตร์ มหาวิทยาลัยสงขลานครินทร์ หมายเลข
โทรศัพท์ 081-592-6677 หรือเมื่อมีปัญหา ใดๆเกิดขึ้นเนื่องจากการทำวิจัยในเรื่องนี้ ข้าพเจ้าสามารถ
ร้องเรียนไปที่คณะทันตแพทยศาสตร์ มหาวิทยาลัยสงขลานครินทร์ อ.หาดใหญ่ จ.สงขลา
90112 โทรศัพท์ 074-28-7500

หากผู้วิจัยมีข้อมูลเพิ่มเติมทั้งด้านประโยชน์และโทษที่เกี่ยวข้องกับการวิจัยนี้ ผู้วิจัย
จะแจ้งให้ข้าพเจ้า ทราบอย่างรวดเร็ว โดยไม่ปิดบัง

ข้าพเจ้ามีสิทธิที่จะขอการเข้าร่วม โครงการวิจัยโดยไม่ต้องแจ้งให้ทราบล่วงหน้า
โดยการงดการเข้าร่วมการวิจัยนี้ จะไม่มีผลกระทบต่อ การได้รับบริการหรือการรักษาที่ข้าพเจ้าจะ
ได้รับแต่ประการใด

ผู้วิจัยรับรองว่าจะเก็บข้อมูลเฉพาะที่เกี่ยวกับตัวข้าพเจ้าเป็นความลับ จะไม่เปิดเผย
ข้อมูลหรือผลการ วิจัยของข้าพเจ้าเป็นรายบุคคลต่อสาธารณชน จะเปิดเผยได้เฉพาะในรูปที่เป็น
สรุปผลการวิจัยหรือการเปิดเผย ข้อมูลต่อผู้มีหน้าที่ที่เกี่ยวข้องกับการสนับสนุนและกำกับดูแลการ
วิจัย

ข้าพเจ้าได้อ่าน/ได้รับการอธิบายข้อความข้างต้นแล้ว และมีความเข้าใจดีทุก
ประการ จึงได้ลงนามใน ใบยินยอมนี้ด้วยความเต็มใจโดยนักวิจัยได้ให้สำเนาแบบยินยอมที่ลงนาม
แล้วกับข้าพเจ้าเพื่อเก็บไว้เป็นหลักฐาน จำนวน 1 ชุด

ลงชื่อ.....ผู้ยินยอม

ลงชื่อ.....บิดา/มารดา/ผู้ใช้อำนาจ
ปกครอง

ลงชื่อ.....หัวหน้าโครงการ

ลงชื่อ.....พยาน

ลงชื่อ.....พยาน

หมายเหตุ: ผู้เข้าร่วมโครงการที่ยังไม่บรรลุนิติภาวะและสามารถเขียนหนังสือได้ให้เซ็นชื่อยินยอม
เข้าร่วม โครงการด้วย

VITAE

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Educational Attainment

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List of Publication and Proceeding

Phaoseree N, Charoemratrote C. The new maxillary molar distalization and extrusion system in correction of class II malocclusion with non-compliance method. Proceedings of The 15th Graduate Research Conference; 2014 March 28; Khon Kaen, Thailand. Khon Kaen University; 2014