



**Orthodontic Tooth Movement Efficiency Comparisons between
Damon and Custom-Made Passive-Ligating Brackets**

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ชื่อวิทยานิพนธ์	การศึกษาเปรียบเทียบประสิทธิภาพการเคลื่อนฟันทางทันตกรรมจัดฟันระหว่างการใช้เบร็คเกตเดมอนกับเบร็คเกตชนิดแรงเสียดทานต่ำที่ประยุกต์ใช้เอง
ผู้เขียน	นางสาวกนิษฐ์ อู๋รังสิมาวงศ์
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บทคัดย่อ

วัตถุประสงค์ เพื่อเปรียบเทียบประสิทธิภาพการดึงฟันเขี้ยว ระหว่างการใช้เบร็คเกตเดมอนกับเบร็คเกตชนิดแรงเสียดทานต่ำที่ประยุกต์ใช้เอง **วัสดุและวิธีการวิจัย** ผู้เข้าร่วมวิจัยจำนวน 17 คน สุ่มเลือกจากผู้ป่วยที่เข้ามารับการรักษาทันตกรรมจัดฟันที่คลินิกจัดฟันของนักศึกษาหลังปริญญา มหาวิทยาลัยสงขลานครินทร์ ผู้ป่วยต้องได้รับการถอนฟันกรามน้อยบนและ/หรือล่างซึ่งเป็นแผนการรักษาของผู้ป่วย ผู้เข้าร่วมวิจัยจะได้รับการติดเครื่องมือจัดฟันชนิดติดแน่น (straight wire twin bracket) โดยที่ฟันเขี้ยวบนจะถูกสุ่มเลือกติดเบร็คเกตเดมอนที่ข้างหนึ่ง (DB) ส่วนเบร็คเกตของฟันเขี้ยวอีกข้างหนึ่งจะถูกประยุกต์ให้เป็นเบร็คเกตที่มีแรงเสียดทานต่ำ (PB) โดยการทำให้ฟันเขี้ยวบนเบร็คเกต ฝาปิดทำมาจากลวดโลหะไร้สนิมขนาด 0.018" x 0.022" 2 เส้นนำมาเชื่อมติดกันและมีส่วนของลวดโลหะไร้สนิมขนาด 0.010" มาเชื่อมตรงกลางของส่วนที่เป็นฝาปิดเพื่อนำไปมัดเข้าในส่วนของร่องในแนวตั้งของเบร็คเกต ฝาปิดจะมีความยาวมากกว่าความกว้างของเบร็คเกตด้านละ 1 มิลลิเมตรเพื่อใช้เป็นที่ยึดมัดอีกครึ่งหนึ่ง ทำการปรับระดับและการเรียงตัวของฟันจนถึงลวดขนาด 0.016" x 0.022" จากนั้นดึงฟันเขี้ยวไปบนลวดโลหะไร้สนิมขนาด 0.016" x 0.022" ด้วยสปริงนิเกิลไททานเนียมโดยใช้แรงขนาด 150 กรัม ทำการเก็บข้อมูลด้วยการพิมพ์ปากเพื่อเทแบบจำลองฟัน และการถ่ายภาพรังสีกะโหลกศีรษะด้านข้างก่อนและหลังการเคลื่อนฟันเขี้ยวไปแล้ว 3 เดือน ระยะทางที่ฟันเขี้ยวและฟันกรามซี่ที่หนึ่งเคลื่อน และปริมาณการหมุนของฟันเขี้ยวจะถูกวัดจากแบบจำลองฟัน ส่วนปริมาณการล้มเอียงของฟันเขี้ยววัดจากลวด (jigs) ที่ฟันเขี้ยวของภาพภาพรังสีกะโหลกศีรษะด้านข้าง ค่าที่วัดได้ถูกนำมาแสดงเป็นค่าเฉลี่ยและนำไปประเมินและเปรียบเทียบการเคลื่อนฟันเขี้ยวทั้ง 2 ข้าง ผล เบร็คเกตชนิดแรงเสียดทานต่ำที่ประยุกต์ใช้เองมีอัตราการเคลื่อนฟันเขี้ยว (PB = 3.02 มิลลิเมตร / 3 เดือน, DB = 3.03 มิลลิเมตร / 3 เดือน) และการควบคุมการหมุนของฟันเขี้ยว (PB = 2.24 องศา, DB = 2.26 องศา) เทียบเท่าเบร็คเกตเดมอน และเนื่องจากเบร็คเกตชนิดเสียดทานต่ำที่ประยุกต์ใช้เองนั้นมีความกว้างมากกว่าเบร็ค

เกตเดมอนจึงมีการล้มเอียงของฟันเขี้ยวที่น้อยกว่าอย่างมีนัยสำคัญทางสถิติ (PB = 4.62 องศา, DB = 6.85 องศา) **สรุป** แบร็คเกตชนิดแรงเสียดทานต่ำที่ประยุกต์ใช้เองนั้น มีอัตราการเคลื่อนของฟันเขี้ยวและการควบคุมการหมุนของฟันเขี้ยวเทียบเท่าแบร็คเกตเดมอน แต่จะมีการควบคุมการล้มเอียงที่ดีกว่า

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ABSTRACT

Objectives: The objective of this study was to compare the modified straight wire twin brackets to be passive-ligating brackets (PB) with Damon brackets (DB) for the efficiency of canine retraction. **Research methodology:** A sample of 17 patients was randomly selected from the new patient pool at the postgraduate orthodontic clinic, Prince of Songkla University (PSU) with a total of 34 extraction sites for comparisons. All subjects required the removal of first premolars in upper (and/or lower) arches as a part of their orthodontic treatment. Each subject received two different brackets (straight wire twin brackets and Damon brackets) placed on right and left upper canines. The PB composed of straight wire twin brackets and labial cap. The labial cap was made of two soldered 0.018" x 0.022" stainless steel archwires with 0.010" stainless steel ligature wire welded on the middle of the soldered arch wires. This ligature wire of the cap was tied into the vertical slot to secure the cap on the canine bracket. The cap would be wider than bracket width 1 mm per side to allow an additional conventional ligature to tie. The canines were moved distally along 0.016" x 0.022" stainless steel wire by NiTi coil spring with 150 gram of force. Impressions and lateral cephalograms were taken at the beginning and end of experimental period (3 months canine retraction). The canine and molar distance and canine rotation were performed by direct-technique from stone casts. Tooth positional locating devices were attached to the maxillary canines and molars before film exposure at the start and the end of experimental period, which aided in precisely angulations of canines and in locating the first molars before and after canine retraction. These measurements were calculated for the changes of the canine movement. The means of these changes were calculated. **Results:** The results showed that PB had comparable tooth movement rate (PB = 3.02 mm / 3 months, DB = 3.03 mm / 3 months) and rotational control (PB = 2.24°, DB = 2.26°) with DB.

Due to benefit of wide bracket for PB made it less tipping than DB (PB = 4.62°, DB = 6.85°), the difference was statistically significant at P = 0.025. **Conclusion:** The PB had comparable amount of canine movement and rotational control with better tipping control compared to DB.

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CONTENTS

	Page
Contents	viii
List of Tables	ix
List of Figures	x
List of Abbreviations and Symbols	xii
Chapter	
1. Introduction	1
2. Research Methodology	7
3. Results	17
4. Discussion	21
5. Conclusions	30
References	31
Appendices	
Ethical approval	37
Invitation form (Translated)	38
Consent form (Translated)	41
Vitae	43

LIST OF TABLES

Table	Page
1. Bracket characteristics	10
2. Frictional resistance of DB and PB in laboratory study	17
3. Measurement findings on casts and in cephalograms for 3-monthly canine retraction	18
4. Correlation for DB group	20
5. Correlation for PB group	20

LIST OF FIGURES

Figure	Page
1. An Instron testing machine	7
2. Testing friction of DB	8
3. Testing friction of PB	8
4. Damon 3 MX bracket (DB)	9
5. Custom-made passive-ligating bracket (PB)	9
6. The labial cap materials	10
7. Labial caps for PB	10
8. An additional conventional ligature tied the labial cap.	11
9. Clinical management for DB and PB	12
10. Initial model with palatal plug	13
11. Final model with palatal plug	13
12. IM line of initial and final models	13
13. Degree of canine rotation of initial and final models	14
14. Right and left jigs for initial cephalogram	14
15. Right and left jigs for final cephalogram	14
16. Initial and final cephalograms with jigs	15
17. Superimposed initial and final cephalograms	15
18. The pilot study, the width of labial cap equaled the width of bracket.	22
19. The pilot study; unsecured ligation method	23
20. The pilot study; clinical significant rotation for PB	23
21. Clinical picture; greatest tipping degree for DB	25
22. Clinical picture; greatest tipping degree for PB	25
23. Smaller wire can play in larger slot.	26
24. Greatest tipping degree (Θ_T) that 0.016" x 0.022" SS can play in slot.	26
25. Tipping that could be occurred before and after retraction.	27
26. The greatest degree of tipping = $\Theta_T \times 2$.	27
27. Greatest rotational degree (Θ_R) that 0.016" x 0.022" SS can play in slot.	27

LIST OF FIGURES (CONTINUED)

Figure	Page
28. The greatest rotational degree that could be occurred before and after retraction = $\emptyset_R \times 2$.	28
29. Model picture of a case which had the most canine rotation	28

LIST OF ABBREVIATIONS AND SYMBOLS

DB	= Damon bracket
IM line	= Imaginary line, which lined from canine cusp tip to buccal cusp tip of second premolar.
min	= Minute
mm	= Millimeter
PB	= Custom-made passive-ligating bracket
SN line	= Sella turcica to Nasion line
SS	= Stainless steel
°	= Degree
/	= Per
%	= Percentage
”	= Inch
\emptyset_T	= The greatest tipping degree between wire and slot of bracket
\emptyset_R	= The greatest rotational degree between wire and slot of bracket

CHAPTER 1

INTRODUCTION

Background and rationale

The orthodontics fixed appliances consist of different types of attachments (such as brackets, bands, buttons, cleats etc), archwires and ligatures. The developing force from the archwire is transferred to the tooth via an attachment. The most commonly used attachment is the bracket. There are different types of brackets depending on which mechanotherapy one intends to use. The edgewise bracket, the most common bracket type in modern orthodontics, has a horizontal slot, where the archwire is placed and held with a ligature.

Different types of ligatures have been used to hold the archwire in the bracket slot. Steel or elastomeric ligatures, or metal pins have been used. The steel ligature is twisted with a hand instrument. Steel ligatures produce a variable effect on the bracket/archwire junction depending on their tightness.

The advantages with the steel ligatures are that they do not deteriorate in the oral environment and they retain their shape and strength. They also provide less retention of bacterial plaque and are easier to clean than elastomeric ligatures. The disadvantages with steel ligatures are that they are time-consuming and tiresome on the hand of operator. There is a risk for soft tissue laceration. Ligation with steel ligatures can lead to higher frictional force as different operators may use a range of ligating forces.¹ Schumacher *et al*² recommended that a steel ligature should be retwisted for about 90 to 180 degrees next to the bracket, of orthodontic tooth translation is to be achieved. Steel ligatures produce much greater moment for derotation of the teeth in comparison with the elastomeric ligatures, when the width of the brackets is nearly identical.³

Elastomeric ligatures introduced in the 1970s, largely replaced steel ligatures for two reasons: they are quicker and easier to place, and they can be used in chains to close small spaces within the arch or prevent spaces from opening. The physical properties of elastomeric ligatures are imperfect. They stain permanently shortly after being placed in the oral cavity. The elastomeric materials are permanently elongated and undergo plastic deformation. This

deformation is related to the amount of time as well as the amount of stretch given to the material.⁴ The elastomeric ligatures have been shown to increase friction in the sliding mechanic systems^{5,6}, and have been shown to increase the resistance to movement in bracket/archwire systems by 50-175 grams.⁷

The disadvantages with these ligatures are long ligation time, load on the hand of operator, loss of initial shape, tightness, rapid loss of tension, high friction level, discoloration and plaque accumulation. To overcome these disadvantages, self-ligating brackets have been developed.

Self-ligating brackets are ligatureless bracket systems that have a mechanical device built into the bracket to close off the edgewise slot.⁸ The cap holds the archwire in the bracket slot and replaces the steel/elastomeric ligature. With the self-ligating brackets the moveable fourth wall of the bracket is used to convert the slot into a tube.

Brackets of this type have existed for a long time in orthodontics known as the Russell Lock edgewise attachment being described by Stolzenberg in 1935. Many designs have been patented, although only a minority have become commercially available such as Ormco edgeLock, Forstident Mobil-Lock, Orec SPEED, 'A'Company Activa, Adenta Time, Ormco TwinLock, Ormco/'A'Co Damon2, GAC In-Ovation, GAC In-Ovatin R, Adenta Evolution LT, Damon3.

The advantages of self-ligating brackets in biomechanical and technical point of view are as follows;⁹

1. Secure robust ligation
2. Full bracket engagement
3. Quick and easy to use
4. Low friction between bracket and arch wire during tooth movement
5. Less plaque accumulation

The principle clinical advantages arise from the unusual combination of very low friction and excellent control of arch wire engagement. The potential benefits are the rapid tooth movement and facilitation of sliding mechanics. Many previous studies showed that passive-ligating brackets required an average lower treatment time and fewer appointments.

But poor rotational-mesiodistal tipping controlled movement and expensive are limitations that cause self-ligating brackets not so popular.

To reduce these limitations, a custom-made passive-ligating bracket was developed at Prince of Songkla University.

Therefore, it is very interesting for clinical studies to compare efficiency of orthodontic tooth movement between Damon and custom-made passive-ligating brackets (rate and type of tooth movement).

Review of literatures

During orthodontic space closure with sliding mechanics, a frictional force generated at the bracket/archwire interface tends to impede the desired movement. Friction is defined as the resistance to motion which is called into play, when it is attempted to slide one surface over another with which it is in contact.¹⁰ A number of factors have been implicated in influencing frictional forces during orthodontic tooth movement. The sizes and material of the bracket slot and the wire, the bracket width, the dimension of wire, and the method of ligation are all factors affecting the frictional force between the bracket and the archwire. Matsubara *et al*¹¹ found that the rate of decrease in tooth movement with ceramic bracket ranged from 30-60% in comparison with the metal bracket. The wire surface was obviously scratched by the ceramic brackets, whereas slight scratch was observed in the wire with the metal bracket. With wire materials, the nitinol wire gave approximately twice the friction of a stainless steel wire of the same dimension, whereas TMA wire gave frictional resistance some five times greater than that of stainless steel.¹² Thomas *et al*¹³ reported that friction appears to increase as archwire diameter increases and found that self-ligating brackets produce less frictional resistance than elastomerically-tied preadjusted edgewise brackets. The effect of bracket width upon friction was investigated by Tidy¹² who found that frictional force was inversely proportional to bracket width. He measured the frictional resistance to bodily tooth movement along a continuous archwire. A fixed appliance was constructed *in vitro* to simulate tooth movement in a previously aligned arch. It was found that friction was proportional to applied load and inversely proportional to bracket width. Archwire dimension and slot size had little effect. The friction is greatest for narrow brackets. For example to produce a 150 gram force on a tooth with an 0.016 x 0.022 inch stainless steel archwire in an 0.018-inch slot requires the application of a force of 250 grams for a 3.3 mm bracket and 280 grams for a 2.9 mm bracket, thus friction is equaled to 100 and 130 grams, respectively.

In accordance to Proffit and Fields¹⁴, they have shown that wire friction decreases as bracket width increases; although Kapila *et al*¹⁵ have reported increased friction with wide brackets. Frank and Nikolai¹⁶ reported that the frictional resistance was higher for the wide bracket than for the narrow bracket at low angulation of the bracket to the wire.

Between 12% and 60% of the applied force in fixed appliances is lost to friction.¹⁷ Iwasaki *et al*,¹⁸ using an intraoral device, calculated that 31% to 54% of the total frictional force generated by a premolar bracket traveling along a 0.019 x 0.025-inch stainless steel archwire was due to the friction of ligation and the remaining 46% to 69% to elastic binding (bracket-archwire binding). Finite element analysis has shown that 60% to 80% of the applied orthodontic force is lost during retraction by sliding mechanics of a canine along a rectangular archwire.¹⁹

The method of archwire ligation would appear to be an important determinant in generation of friction. Self-ligating bracket was introduced to create a friction-free environment, due to passive ligation. Kapur *et al*²⁰ found dramatically lower friction with both stainless steel and nickel-titanium wires for Damon brackets compared to conventional brackets that ligated to the wire by means elastomeric rings. The wire was allowed to slide through a single bracket slot without any influence from bracket tip or torque. With NiTi wires, the friction per bracket was 41.2 grams with MiniTwin and conventional brackets and 15 grams with Damon brackets; whilst with stainless steel wires, these values were 61.2 and only 3.6 grams, respectively.

Thorstenson and Kusy²¹ compared the resistance to sliding of the conventional brackets, which ligated with stainless steel ligature wire, with the closed self-ligating brackets. The resistance to sliding of the conventional brackets and the opened self-ligating brackets, as a control, was measured at ligation forces ranging from 200 to 600 grams and at angles from -9° to 9°. In the passive configuration, the conventional brackets exhibited similar frictional resistance as the opened self-ligating brackets, whereas the closed self-ligating brackets exhibited no friction. In the active configuration, at all angles the resistances to sliding of the closed self-ligating brackets were lower than those of the conventional brackets because of the absence of a ligation force when the slide restrained the archwire, only about 80 grams.

Thorstenson and Kusy²² studied four designs of self-ligating brackets with 5 types of archwires. The resistance to sliding of each archwire-bracket couple was measured at second-order angles between -9° to 9°. The results showed that the resistance to sliding is

negligible for self-ligating brackets with slides (Damon) coupled to any size of wire as well as for those with clips (SPEED, In-Ovation, Time) when coupled to wires that do not contact the clip. When clearance disappears, the resistance to sliding increased proportionally with the second-order angle. The 0.019" x 0.025" stainless steel wires, which were most stiff, increased at rate between 75 and 85 gram/degree.

Hain *et al*²³ investigated the effect of ligation method on friction and evaluated the efficacy of the new slick elastomeric module, found that SPEED brackets produced the lowest friction compared with the 3 other tested bracket systems when regular modules were used. The use of slick modules significantly reduced friction to below the values recorded in the SPEED groups. Loosely tied stainless steel ligature (unwound by 3 turns) were found to generate the least friction.

Pizzoni *et al*²⁴ found that the self-ligating brackets had a markedly lower friction than conventional brackets at all angulations, and self-ligating brackets, closed by the capping of a conventional design, exhibited a significantly lower friction than self-ligating brackets closed by a spring. The results have reported that in the case of rectangular wires, the Damon bracket was significantly better than SPEED and conventional brackets and should be preferred if sliding mechanics is the technique of choice.

Hain *et al*²⁵ compared the frictional properties of coated modules with those of other common ligation methods. Ligation methods were used with standard stainless steel brackets and 0.019 x 0.025-inch archwire. Two self-ligating (SPEED and Damon 2) brackets were also tested. The result shown that Damon 2 self-ligating brackets produced less friction (no recordable friction of ligation) than the other ligation methods.

Their results corroborate the findings of previous studies such as Voudouris²⁶ and Berger²⁷ offer a passive-ligating brackets could provide substantial advantage in sliding mechanics. All of above showed that they had several factors that have been influencing frictional forces during tooth movement eg. sizes and material of bracket and wire, bracket width, method of ligation. In addition, the normal force on the contact point between the bracket and the wire is modified by the moment placed on the bracket.^{1,28,29} The moment placed on the bracket, which brings about the mesiodistal or labiolingual angulation of the bracket, is determined by the combination of the location of force application relative to the center of resistance and the amount of resistance to movement.^{29,30}

Several studies showed that passive-ligating brackets needed lower treatment time, fewer number of appointments than conventionally ligated edgewise brackets.^{31,32,33} Harradine's study to compare passive-ligating brackets (Damon) to conventional ligation methods found that passive-ligating brackets required an average of four fewer months (from 23.5 to 19.4) and four fewer visits (from 16 to 12) to be treated.³⁴ Eberling *et al*³³ found an average reduction in treatment time of six months (from 31 to 25) and seven visits (from 28 to 21) for Damon SL cases compared with conventional ligation. Bagden³⁵ concluded that single edgewise brackets tied directly to their wings with an elastomeric chain favor the presence of high deflection moments that would lead to rotations, mesiodistal tipping and increased friction showing a slower retraction movement when compare with interactive edgewise twin brackets (i.e. self-ligating brackets). Harradine³² studied the advantages and disadvantages of passive-ligating brackets (Activa) in the light of extensive clinical experience. The principle clinical advantages raised from the unusual combination of very low friction and excellent control of arch wire engagement. The potential benefits were the rapid alignment of very irregular teeth, lower anchorage requirements, and facilitation of sliding mechanics. The important problems of Damon brackets are tipping and rotational control because of the narrower bracket width when compare with conventional brackets. Creekmore³⁶ showed that tipping play depends on the mesial-distal width of the slot and the size of the slot vs the size of archwire. Both bracket width and ligation technique significantly effect the moment produced during axial rotation.³⁷

Objectives

To compare efficiency of canine retraction between Damon and custom-made passive-ligating brackets.

Hypothesis

Efficiency of canine retraction between Damon and custom-made passive-ligating brackets is comparable.

Significances of the study

1. To develop a custom-made passive-ligating brackets with comparable efficacy of canine retraction to Damon brackets.
2. To reduce the cost of passive-ligating brackets.

CHAPTER 2

RESEARCH METHODOLOGY

For this study, it is composed of 2 parts. One is a laboratory study investigating the frictional resistance of Damon brackets (DB) and custom-made passive-ligating brackets. Another is a clinical study comparing efficiency of orthodontic tooth movement between Damon and custom-made passive-ligating brackets.

1. Laboratory investigation; the frictional resistance to sliding compared between Damon and custom-made passive-ligating brackets

Materials and methods

This ex vivo study investigated the frictional resistance between 2 types of brackets prior to clinical study. The measurements of friction between bracket and archwire were done with apparatus shown in Fig. 1, which was presented in Tidy's study.¹²



Fig. 1 An Instron testing machine, which measured the friction between bracket and archwire.

It was consisted of a simulated fixed appliance with the archwire in a vertical position. Four edgewise brackets were bonded to a rigid plastic baseplate at 8 mm intervals with 16 mm space for a movable bracket at the center. The 0.016" x 0.022" SS archwire, with 90-degree bend at the end, was secured with elastomeric. 10 Damon (Fig. 2) and 10 custom-made passive-ligating brackets (Fig. 3) were set up for movable brackets. Drescher *et al*²⁹ estimated that the center of resistance for a maxillary canine was 10 mm from the center of the crown. Thus in our laboratory study, the movable bracket was fitted with 10 mm power arm from which weight of 150-gram could be hung to represent the single equivalent force acting at the center of resistance of the tooth root. The length of the power arm was chosen to represent the distance from the slot to the center of resistance of a typical canine tooth. The movable bracket was suspended from the load cell of the testing machine. All tests were conducted under dry conditions with an Instron testing machine with the crosshead moving upward at a speed of 5 mm/min.

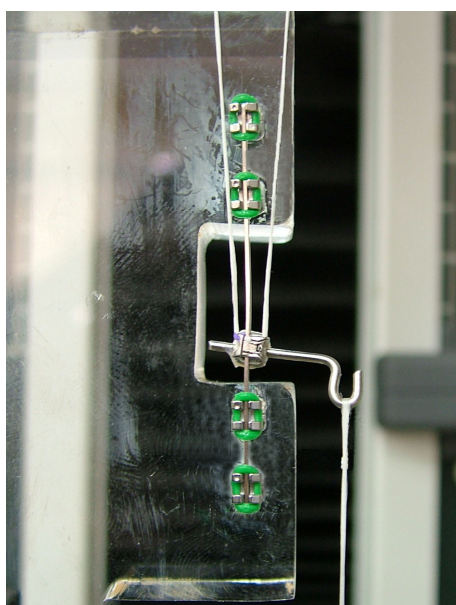


Fig. 2 Testing friction of DB



Fig. 3 Testing friction of PB

The load cell readings represented the clinical force of retraction that would be applied to the tooth, part of which would be lost in friction while the remainder was transmitted to the tooth root. The difference between the load cell reading and the load on the power arm thus represented the friction.¹²

2. A clinical study

Materials and methods

A sample of 17 patients was randomly selected from the new patient pool at the postgraduate orthodontic clinic, Prince of Songkla University. Thus the subjects of this study were 17 individuals with a total of 34 extraction sites for comparison.

The inclusion criteria for the study were as follows;³⁸

- Patients required the removal of first premolars in upper (and/or lower) arches as a part of their orthodontic treatment.
- All teeth mesial to the second molars were fully eruption before commencement of study.
- Canine retraction of at least 4 mm would be required.

The exclusion criteria are as follows;³⁸

- Patients with oral manifestations of diseases (e.g., cysts) or a chronic debilitating disease.
- Loss of periodontal support greater than 10% before treatment.
- Non cooperative patients, e.g., poor oral hygiene and missing an excessive number of appointments.

All patients and their parent(s) were advised of the purpose of this study. The patients and parents or guardians signed a consent form. All patients required the removal of first premolars in upper (and/or lower) arches as a part of their orthodontic treatment. The canine brackets used in this study are both Damon 3 MX 0.022" x 0.027" slot brackets (Fig. 4, DB) and 0.022" x 0.028" slot custom-made passive-ligating brackets (Fig. 5, PB). The both bracket characteristics were shown in Table 1.



Fig. 4 Damon 3 MX (DB)



Fig. 5 Custom-made passive-ligating bracket (PB)

Table 1. Bracket characteristics

Brackets	Slot dimension	Bracket width (measured at slot)	Torque (degree)	Tip (degree)
Damon 3 MX *	0.56 mm x 0.69 mm	2.9 mm	0	+6
	0.022 inch x 0.027 inch	0.114 inch		
Mini Diamond **	0.56 mm x 0.71 mm	3.2 mm	0	+10
	0.022 inch x 0.028 inch	0.126 inch		

*Damon 3 MX, Ormco Corporation, Glendora, Calif.

**Mini Diamond, Ormco Corporation, Glendora, Calif.

**Mini Diamond bracket was applied with labial cap to be a passive-ligation bracket.

The custom-made passive-ligating bracket which be applied from straight wire twin brackets, Roth prescription. Thus, it was composed of straight wire twin bracket and labial cap. The labial cap was made of two soldered 0.018" x 0.022" stainless steel archwires (Fig. 6) with 0.010" stainless steel ligature wire welded on the middle of the soldered archwires (Fig. 7).

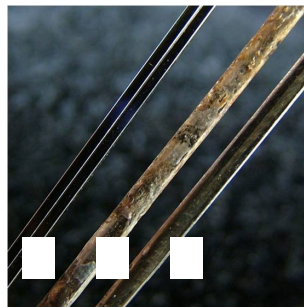


Fig. 6 The labial cap materials; A. 0.018" x 0.022" stainless steel wires,
B. After soldering, C. After polishing

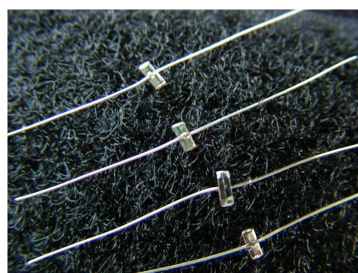


Fig. 7 Labial caps; 0.010" stainless steel ligature wire welded on soldered archwires.

This ligature wire of the cap was tied into the vertical slot to secure the cap on the canine bracket. The cap would be wider than bracket width 1 mm per side to allow an additional conventional ligature to tie (Fig. 8).



Fig. 8 An additional conventional ligature tied the labial cap.

Clinical management

Each subject was placed pre-adjusted edgewise brackets (Roth prescription) on all teeth, except one upper canine was randomly selected to place Damon 3 MX. Teeth would be initially aligned and leveled until they had proper canine position on 0.016" x 0.022" stainless steel archwire. This archwire was placed at least for 4 weeks before canine retraction to ensure that the archwire was passive, by sliding the bracket slot passed the archwire. Impression and lateral cephalogram were taken before canine retraction.

Nickel-titanium coil springs had been shown to produce a constant force over varying lengths, with no decay.³⁹ Thus in this study, canines would be moved along a 0.016" x 0.022" stainless steel archwires using closed coil nickel-titanium spring extending from the hook of first molar tubes to the canine brackets under main archwires (Fig. 9). The force for moving the canine was 150 grams.^{40,41} The preparation of anchorage was maximized by consolidation of second premolar and molar, toe in and tip back wire bending, and uprighting spring at second premolar (Fig. 9).

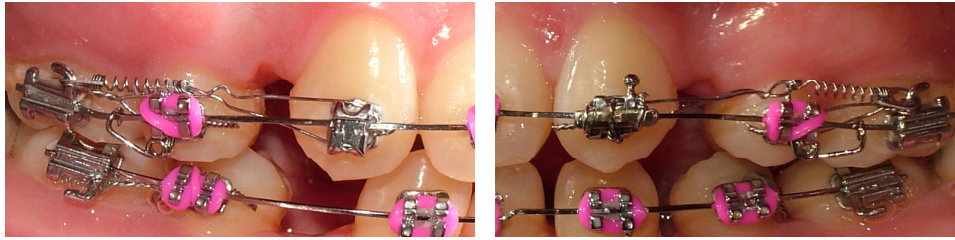


Fig. 9 Closed coil nickel-titanium spring extending from the hook of first molar tubes to canine brackets under main archwires and the preparation of anchorage was maximized (co-ligate second premolar and molar, toe-in and tip-back on the second premolar and molar areas, and uprighting spring on the second premolar).

Patients were recalled for routine reviews at regular intervals of 4 weeks, for 3 visits (12 weeks). In each visit, the amount of canine retraction force was checked with force gauge, to confirm that constant force was produced throughout the experimental period, and the ligated wire of the cap of custom-made passive-ligating bracket was renewed. Impression and lateral cephalogram were taken at the beginning and 3 months after canine retraction.

Determining distance of canine and molar movement

Measurements were performed by direct-technique from stone casts obtained before and at the end of the experimental periods with metal-tipped calipers. Direct cast measurements were used rather than radiographs. This method was considered to be easier and accurate. To measure the movement of each canine and molar, an acrylic palatal plug was made for each maxillary arch. This plug was selected because the anterior palatal vault could be used as a stable reference point.⁴² This plug could thus be transferred from initial cast to the final cast on the same patient. The plug was fabricated from acrylic with reference wires (0.018-inch stainless steel) embedded in the acrylic that extended to the cusp tips of canines and to the central fossa of the first molars. The initial model was used to make the plug (Fig. 10), which was then fitted to the final model (Fig. 11). This superimposition allowed for the direct observation of the amount of canine retraction and molar protraction (anchorage loss).

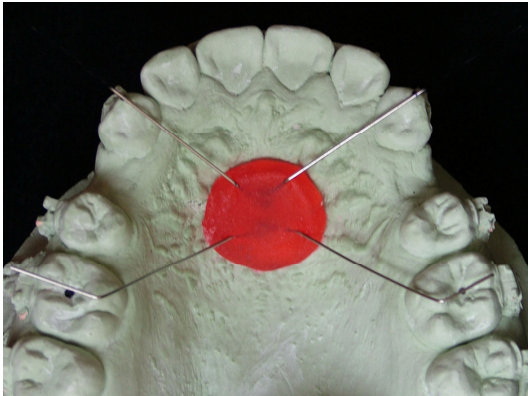


Fig. 10 Initial model with palatal plug

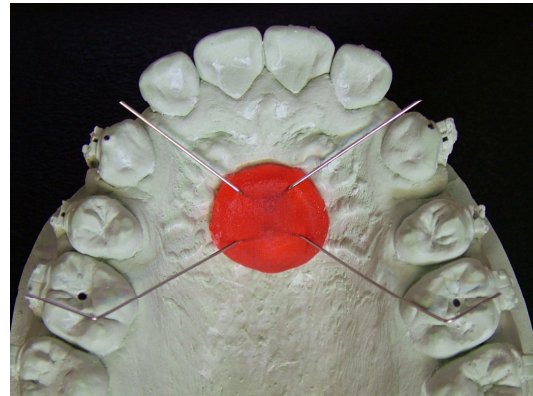


Fig. 11 Final model with palatal plug

Determining canine rotation

Rotational change in canine position was measured from the dental casts. Canine rotation defined as angle formed by a line through the distal and mesial contact points of the canine to the imaginary line (IM line). The IM line represented outline of arch form, which lined from canine cusp tip to buccal cusp tip of second premolar (Fig. 12). Changes of degree of canine rotation between initial and final were used to define the quantity of canine rotation (Fig. 13). Thus canine rotational change was defined as rotational degree at start would be minus with degree at the end of the experimental period.



Fig. 12 IM line of initial and final models

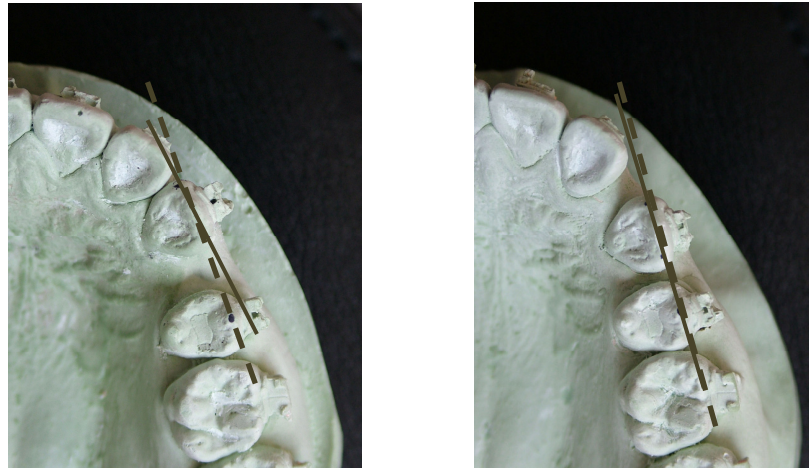


Fig. 13 Degree of canine rotation of initial and final models;

— A line through the distal and mesial contact points

- - IM line

Determining canine angulation

Lateral cephalogram was obtained immediately before canine retraction, as well as at the end of the experimental period. All radiographs were taken with the same cephalostat (Orthophos[®] CD, Siemens, Germany). Tooth positional locating devices were fabricated from sections of 0.018" x 0.025" stainless steel wires that were attached to the maxillary canines and molars before film exposure at the start (Fig. 14) and the end of experimental periods (Fig. 15).⁴³



Fig. 14 Right and left jigs for initial cephalogram



Fig. 15 Same right and left jigs for final cephalogram

These devices aided in precisely angulation of canines and in locating the first molars before and after canine retraction (Fig. 16). The radiographies were traced, superimposed and measured the angular parameters by one investigator (Fig. 17).

Canine angulations were defined as the angle formed by the intersection of the SN line and a line extending from the jig of each tooth. Line and angular that be used in cephalometric analysis were as follows;

SN line : Sella turcica to Nasion line

13/SN : The angle between the marker of 13 and SN

23/SN : The angle between the marker of 23 and SN

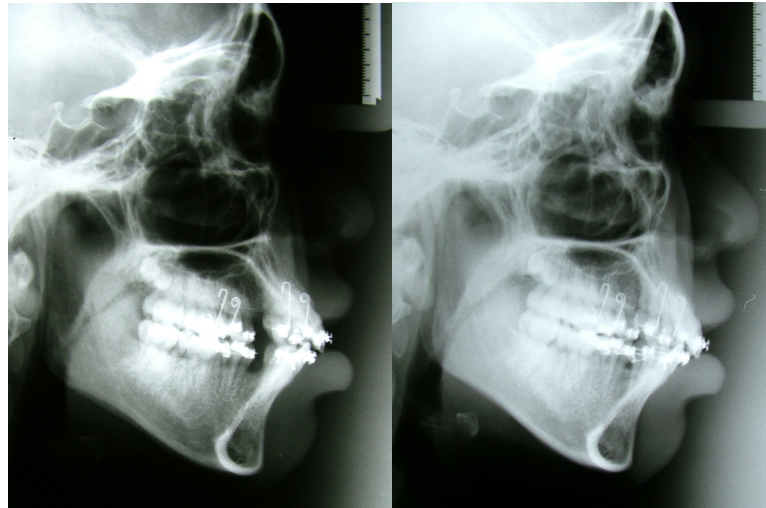


Fig. 16 Initial and final cephalograms with jigs

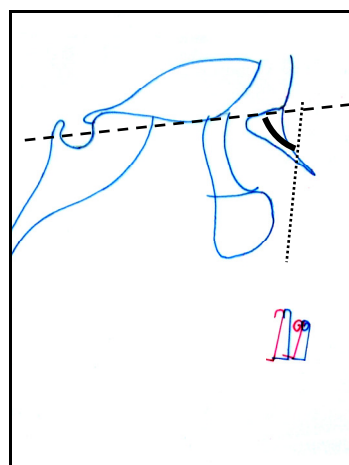


Fig. 17 Superimposed initial and final cephalograms, and measured the angular parameters.

Measurement error

Measurement error in determining distance of tooth movement, canine rotation and tipping

To reduce method error associated with the measurement of the study models, the examiner was blind to the type of brackets used in each quadrant. The study models were measured randomly.

Intra-examiner reliability

Ten study models and ten cephalograms were remeasured 2 months later and the mean of these measurements was compared to the mean of the initial measurements using a paired *t*-test. There was no statistically significant difference between these two results.

Statistical methods

The laboratory data were statistically analyzed using SPSS software (version 13.0, SPSS, Chicago, III). The data shown as means and standard deviations and were tested with independent sample *t*-test. Significance was determined at the 0.05 level.

The clinical data were statistically analyzed by using SPSS software. The results were shown as mean and standard deviations. After the parametric assumptions would be tested to see whether the variables were suitable for non-parametric test, the differences between the 2 dependent measurements would be evaluated with a Wilcoxon signed-ranks test, an alpha significance level of 0.05.

CHAPTER 3

RESULTS

Laboratory investigation; the frictional resistance to sliding compared between Damon and custom-made passive-ligating brackets

The frictional force occurred from the binding between the bracket and archwire during translator bracket movement along an archwire. All measurements are normal distributed when tested with the Kolmogorov-Smirnov statistic with a Lilliefors significance level and Shapiro-Wilks statistic.⁴⁴ As normal distribution could be assumed, the *t*-test could be applied reliably, thus the statistical comparison of the result for two independent groups was done using the independent sample *t*-test with SPSS software.

Table 2 summarized the amount of frictional resistance for DB and PB groups when load of 150 grams were applied on the power arm. The results were shown that the DB had statistically significant ($P = 0.02$) more friction than PB; the DB had frictional resistance of 176.35 ± 55.26 grams while the PB's frictional resistance was 90.41 ± 19.12 grams.

Table 2. Frictional resistance of DB and PB (grams)

N	Mean \pm S.D.		Difference	Sig. (2-tailed)
	DB	PB		
10	176.34 ± 55.26	90.41 ± 19.12	85.93	0.001

A clinical study

A total of 34 extraction sites from 17 patients were compared. There were 2 males and 15 females, ranging in age from 15 to 28 years old (average \pm SD = 21.18 ± 3.52 years old). From the selected patients, eight had Class I malocclusion and nine had Class II, Division 1 malocclusion.

Due to small sample size, non-parametric test was used for statistically testing using SPSS software. The differences between the 2 dependent measurements would be

evaluated with a Wilcoxon signed-ranks test at an alpha significance level of 0.05. Table 3 summarized all measurement findings on casts and in cephalograms for 3-monthly canine retraction. All data were shown as mean \pm standard deviations, maximum and minimum values.

Table 3. Measurement findings on casts and in cephalograms for 3-monthly canine retraction

Measurements	Brackets	Mean	Std. deviation	Maximum	Minimum
Movement (mm)	DB	3.03	0.60	4.00	2.00
	PB	3.02	0.53	4.00	2.20
Rotation (°)	DB	2.26	1.31	5.00	0.50
	PB	2.24	1.56	6.00	0.00
Tipping (°)	DB	-6.85	4.49	-1.00	-17.50
	PB	-4.61*	3.09	-0.50	-11.00
Anchorage loss (mm)	DB	0.84	0.48	2.00	0.00
	PB	0.85	0.51	2.00	0.00

* Significant difference compared to DB 3 tipping (P = 0.020)

Distance of canine movement

The distance of canine retraction for 3 months for both brackets; the maximum distance travelled by the DB and PB was 4.00 mm. The minimum distance travelled was 2.00 mm and 2.20 mm, respectively, whereas the mean of distance was comparable; 3.03 and 3.02 mm, respectively.

Since the study involved left-right comparisons in the same arches, Wilcoxon signed-ranks tests were performed to check for statistical significance. The difference in the amount of movement was not statistically significant (P > 0.05) between DB and PB.

Canine rotation

Table 3 summarized the canine rotation after canine retraction for 3 months for both brackets. During retraction, the canine rotated distopalatally. The maximum rotation occurred in the DB and PB was 5° and 6°, respectively. The minimum degree of rotation was

0.50° and 0°, respectively, whereas the mean of rotation was comparable; 2.26° and 2.24°, respectively. No statistically significant difference ($P > 0.05$) existed when comparing the amounts of rotation between DB and PB.

Canine angulations

Angular changes in canine position were measured from the lateral cephalograms using the radiopaque jigs. During retraction, the canine tipped distally. After retraction for 3 months, found greater canine distal tipping in DB group than PB group. The canine tipped distally of DB was statistically significant ($P = 0.020$) more than that of PB (DB = 6.85° and PB = 4.62°). The maximum distal tipping for the DB and PB was 17.50° and 11.00°, respectively. The minimum degree of distal tipping was 1.00° and 0.50°, respectively.

Anchorage loss

Mean of anterior movement of the maxillary first permanent molar (i.e., loss of anchorage) measured directly from dental casts was comparable (DB = 0.84 mm, PB = 0.85 mm). Difference in the amount of forward movement of the first molars between the two groups was not statistically significant ($P > 0.05$). The maximum movement for the DB and PB was 2.00 mm.

Correlation between measurements

To examine the relationship between distance of canine movement and canine rotation, canine tipping and anchorage loss, in non-parametric technique, a Spearman's rho should be performed.⁴⁴

In DB group, there were no statistically significant correlations between canine movement and canine rotation or anchorage loss. But there was borderline statistically significant correlation ($P = 0.066$) between canine movement and canine tipping, as shown in Table 4. Spearman's rho had a value of -0.46, the correlation is moderate. Thus, more distance of canine movement was associated with more distal tipping (more negative degree of tipping).

Table 4. Correlation for DB group

		Canine		Anchorage loss
		Tipping	Rotation	
Canine movement	Spearman Correlation	-0.46*	0.18	0.16

* P value = 0.066

In PB group, the correlations between canine movement and canine rotation, canine tipping and anchorage loss, respectively, there were no statistically significant of all other correlations, as shown in Table 5.

Table 5. Correlation for PB group

		Canine		Anchorage loss
		Tipping	Rotation	
Canine movement	Spearman Correlation	-0.04	-0.06	0.10

CHAPTER 4

DISCUSSION

A laboratory study

The laboratory study was designed to study the retarding force of two bracket types on sliding bracket movement. The PB, which had wider bracket width than DB, had less frictional resistance than DB. This finding confirms the observation of Tidy.¹² He indicated that the frictional force for narrow bracket was higher than that for the wide bracket. Friction in sliding a bracket along an archwire with the center of resistance at a distance from the archwire can be predicted to a first approximately by simple mechanics. If it is assumed that the classical laws of friction are valid, then

$$P = \frac{2Fh\lambda}{w}$$

where P is the frictional resistance, w is the bracket width, λ is the coefficient of friction between bracket and archwire, and F is the equivalent force that acts at a distance h from the archwire. The coefficient of friction (e.g. archwire-slot materials, ligation techniques) is approximately constant for any given pair of materials. The results obtained in our laboratory study have confirmed the predicted dependence of friction on bracket width.

Kamiyama and Sasaki⁴⁵ reported that the retraction force for the narrow bracket was higher when the bracket was retracted at a point close to the bracket slot. Yamaguchi et al⁴⁶ indicated that the retraction force for narrow bracket was higher than that with the wide bracket for retraction at level of the bracket slot point.

Whereas, the retraction force for the narrow bracket was low when the bracket was retracted at the point which near the center resistance. The angulation of the long axis was less in those combinations of the retarding force and the location of force application. As Frank and Nikolai¹⁶ commented that the retraction force for narrow bracket was higher than that for the wide bracket at high angulations of the bracket to the wire.

According to Thurow's theorizes⁴⁷, it explained that when a tooth tips, pressure is exerted by the ends of the bracket on the archwire, which will cause frictional resistance. From our laboratory study, DB with narrower slot width tips with more angle than wider bracket when

applied retraction forces at the same point (bracket slot) thus the greater pressure exerts by the ends of the bracket on the archwire, and then friction will be increased.

A clinical study

The pilot study for this study was done. The subjects of this pilot study were 5 patients. For PB, we made the width of the labial cap equaled the width of bracket (Fig. 18). And then this ligature wire of the cap was tied into the vertical slot to secure the cap on the canine bracket alone, which was insufficiency tightening ligation (Fig. 19). Thus when the canine was moved distally along 0.016" x 0.022" stainless steel wire, it rotated distopalatally (Fig. 20). The results for this pilot study showed that the PB made in PSU had comparable efficiency for canine retraction to DB, but PB had more clinical significant rotation. To reduce this rotation, the cap was made wider to allow an additional conventional ligature to tie (Fig. 8).

When the cap was made wider than bracket width 1 mm per side to allow an additional conventional ligature to tie, found that this ligatured method of PB was secured and made a conventional bracket to be an efficacy passive-ligating bracket. For these secured ligations, we found little tissue irritation which occurred from margin of the labial cap. After we beveled and rounded all margins and angles, we did not found any side effects or problem again.



Fig. 18 The pilot study, the width of labial cap equaled the width of bracket.



Fig. 19 The pilot study; unsecured ligation method



Fig. 20 The pilot study; clinical significant rotation for PB

This clinical study was designed to compare efficiency of orthodontic tooth movement between two passive-ligating brackets (Damon and custom-made passive-ligating bracket). These brackets were compared efficiency by sliding along 0.016" x 0.022" stainless steel wire with 150 gram of retraction force. Force recommended in this study for optimal canine movement of 150 grams was based on previous studies.⁴⁸⁻⁵⁰ Reitan⁴⁸ stated that initial force application should be light, because this procedures desire biologic effects. These lighter forces will produce less extensive hyalinized tissue that can be readily replaced by cellular elements. He stated that an appropriate force of 150 to 250 grams for maxillary canines should be used for translator movement. Ricketts *et al*⁴⁹ recommended a force of between 115 and 150 gram for canine retraction by a frictionless technique. Storey and Smith,⁵⁰ using a similar technique, concluded that a force of 150 to 200 gram would move lower canines efficiently.

In this study, the mean of canine movement for DB and PB was 3.03 mm and 3.02 mm for 3 monthly canine retractions, respectively. The canine movement of DB was comparable to PB, so there was no statistically significant difference ($P > 0.05$). On the other hand, the laboratory study showed that DB had more frictional resistance when apply load of 150 grams on the power arm than PB and the difference was be statistically significant ($P = 0.002$). Friction between the archwire and the bracket has been shown to be an important factor in orthodontic tooth movement. Thus DB with more friction should have less canine movement than PB. But the canine movement results in this study were not compatible with laboratory frictional resistance study. Explanation for this, it might be that friction was not as a significant factor in the clinical situation as it was in the laboratory. Laboratory study had been done on testing instrument which does not exactly simulate oral conditions. In the mouth, muscular pressures and forces of mastication are thought to displace the teeth fractionally and thereby periodically release the binding between the slot and the archwire.⁵¹ Not only that, the DB had narrow bracket width and more friction, then during tooth was moved along archwire, the binding between bracket and archwire occurred, then archwire was bended and the tooth (DB) was tipped. Thus in this study showed that the DB had equal canine movement, with more tipping.

Rate of canine movement in this study was 1.01 mm per month for both DB and PB. The previous studies focusing on the rate of canine movement found that the tooth with conventional brackets, which been retracted by NiTi spring 150 to 200 grams could moved with rate 0.81 to 1.03 mm per month.^{52,53} Kittichaikarn's study⁵² found the rate of canine retraction was 1.03 mm per month. Her method for distance measuring was difference from our study. The study models at T_0 and T_1 were scanned into a computer with use of scanner. Thus can cause the occlusal plane of models between T_0 and T_1 was not the same. The distance between distal contact point of canine and perpendicular line through the third palatal rugae may be shorter than actual (more rate of canine movement than actual). Whereas Dixon *et al*⁵³ moved canine along 0.019" x 0.025" stainless steel with 200 gram NiTi coil spring and the results showed that the rate of canine retraction was 0.81 mm per month. Vernier caliper was used to measure the maximum distance between the cusp tip of canine to the buccal groove of the first molar. For their measured method, it was a weak point that the distance which their measured might be included the distance of anchorage loss thus made their results had faster rate than the rate of canine retraction actually moved.

The rate of canine retraction of two types of passive-ligating brackets (Damon and custom-made passive-ligating bracket) in our study was very similar (1.01 mm per month), which is comparable to finding by Dixon *et al*⁵³ (0.81 mm per month). However this compared rate may be considered clinically significant when large spaces are to be closed. Theoretically, 8-mm space closure would take 9.88 months with conventional ligation, but 7.92 months with passive ligation.

When focusing on the rate of canine retraction of low-friction brackets, as shown in the study of Deguchi *et al*⁵⁴, found that the rate of canine retraction of Clear Snap was 2 mm per month. In that study, canine retraction rate was measured from the change of amount of remaining space; the mesial wing of the premolar bracket to the distal wing of the canine bracket as reference point. Thus if anchorage loss had occurred, the space remaining would be lost quickly, thus the rate of canine retraction was faster and faster. Not only had that he used small wire 0.016" stainless steel to be an archwire for canine retraction, which can make canine tip easily during retraction. Thus the method of measuring and small archwire was the weak points that made their results had shown very fast canine movement rate when compared with our study.

Common side effects occurring on both brackets were the rotation and tipping of the canine during retraction. In this study DB and PB had mean degree of distal tipping 6.85° and 4.62°, respectively. When tested correlation between canine movement and canine tipping in both groups found that there was not statistically significant correlation ($P > 0.05$) between canine movement and canine distal tipping in both groups. But for DB group, correlation between canine movement and canine distal tipping was moderate (Spearman's rank correlation = -0.46). This meant that in DB group had more canine movement that was associated with more distal tipping. Whereas the PB moved more bodily so the correlation between the movement and tipping can not be found. Fig. 21 and 22 showed patient who had greatest distal tipping of DB and PB, respectively, it was clinically significant between groups.



Fig. 21 Greatest tipping degree for DB

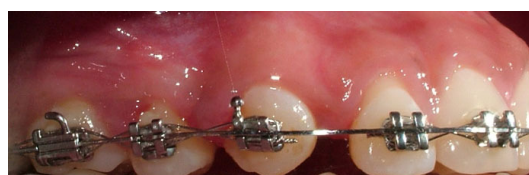


Fig. 22 Greatest tipping degree for PB

In general when smaller wire is inserted in larger slot's bracket, it must have a free play, which is assumed as an angle (\emptyset) between wire and slot's bracket as shown in Fig. 23, then the canine tipping can occur within the space between wire and slot.

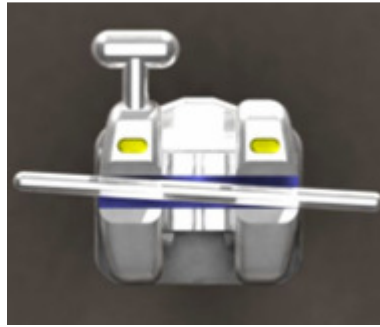


Fig. 23 Smaller wire can play in larger slot.

For this study, we used 0.016" x 0.022" SS wire in 0.022" x 0.027" slot of DB and in 0.022" x 0.028" slot of PB. Thus if this wire played in each slot bracket, it could be produced the greatest tipping degree between wire and slot, equal \emptyset_T degree as shown in Fig. 24.

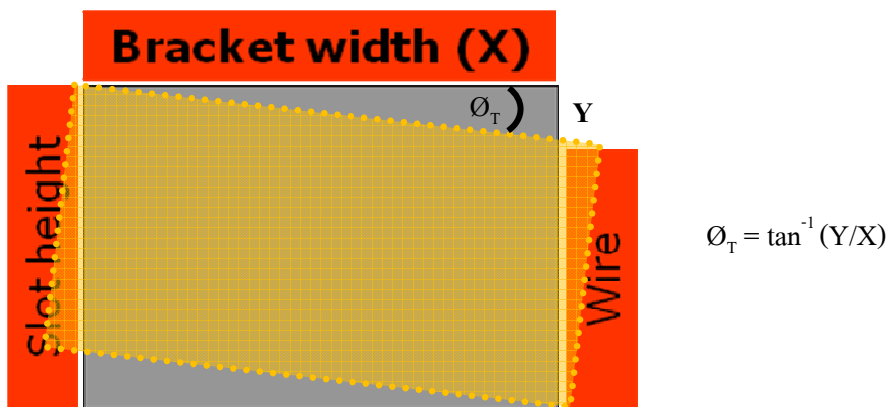


Fig. 24 Greatest tipping degree (\emptyset_T) that 0.016" x 0.022" SS can play in slot of DB or PB.

Thus the greatest tipping degree (\emptyset_T) that wire could play in slot was 2.96° and 2.68° for DB and PB, respectively. All of above meant that during the canine was moved along 0.016" x 0.022" SS wire, the canine may have greatest tipping degree of 2.96° and 2.68° for DB and PB, respectively. So that if the canine had mesial tipping at initial as greatest as \emptyset_T and had distal tipping after retraction as greatest as \emptyset_T (Fig. 25), thus the changed tipping degree would be equal $\emptyset_T \times 2$, as shown in Fig. 26.

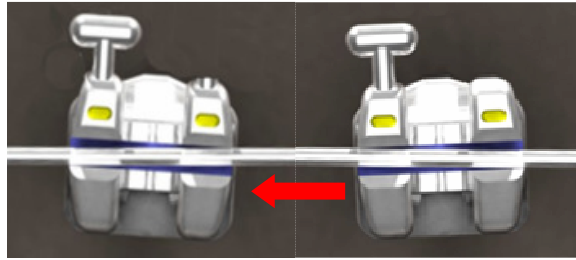


Fig. 25 Tipping that could be occurred before and after retraction.

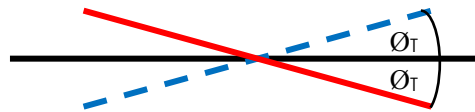


Fig. 26 The greatest degree of tipping = $\emptyset_T \times 2$.

The degree of distal tipping 4.62° for PB from this study was in normal range ($\emptyset_{T, PB} = 2.68^\circ$, $\emptyset_{T, PB} \times 2 = 5.36^\circ$, thus $\emptyset_{T, PB} > 4.62^\circ > \emptyset_{T, PB} \times 2$) which was the freedom that wire could play in slot during canine retraction. In contrast for DB, the tipping degree was 6.85° , which more than 5.92° ($\emptyset_{T, DB} \times 2 = 2.96^\circ \times 2$). These tipping for DB which more than $\emptyset_{T, DB} \times 2$, occurred from wire bending.

As well as tipping degree, when smaller wire played in slot, it could produce greatest rotational degree for $\emptyset_{R, DB}$ and $\emptyset_{R, PB}$; 2.48° and 2.05° , respectively (Fig. 27). And Fig. 28 showed that $\emptyset_R \times 2$ was greatest changed rotational degree during canine movement. The $\emptyset_R \times 2$ for DB and PB was 4.96° and 4.10° , respectively.

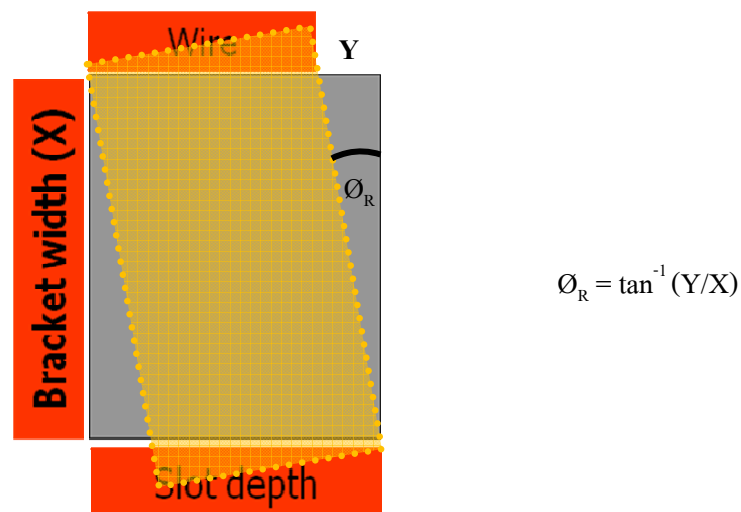


Fig. 27 Greatest rotational degree (\emptyset_R) that 0.016" x 0.022" SS can play in slot of DB or PB.

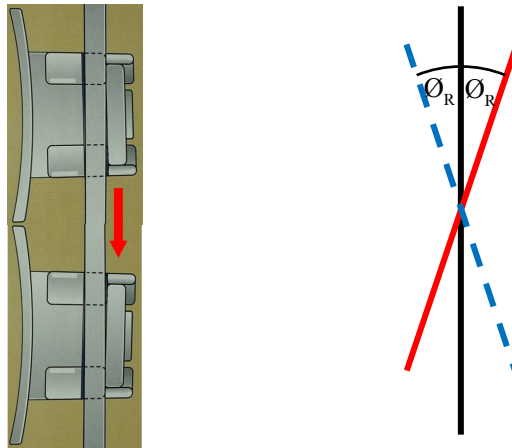


Fig. 28 The greatest rotational degree that could be occurred before and after retraction = $\varnothing_R \times 2$.

The mean of rotational degree for DB and PB in this study was 2.26° and 2.24° , respectively. They were in normal range (less than $\varnothing_R \times 2$ of each bracket type) which was the freedom that wire could play in slot during canine retraction. But for PB group, the maximum rotational degree in the study was 6.00° , which is more than 4.10° ($\varnothing_{R, PB} \times 2 = 2.05^\circ \times 2$). This rotation for PB in this case, which more than $\varnothing_{R, PB} \times 2$, occurred from inadequate tightening ligation. In observed final model, Fig. 29, this figure has shown occlusal view of a case which had the most rotation at the end of our study for DB and PB side, however these rotations were not clinically noticeable easily.

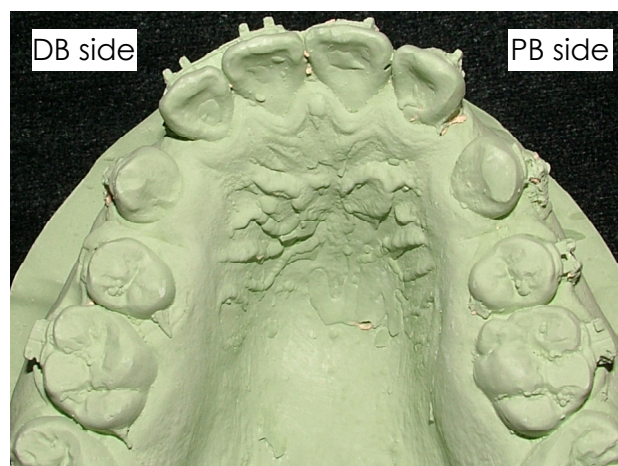


Fig. 29 A case which had the most canine rotation after retraction; DB = 5° and PB = 6°

The means of both tipping and rotational degree for DB group were more than those of PB group, because the narrower brackets produced more space to play between archwire

and slot, which caused more tipping and rotation during canine retraction. In this study, more tipping in DB group was not only caused by more play from narrow bracket, but also they had longer interbracket distance, the longer wire has less stiffness, may caused more tipping from wire bending to add up tipping from free play. Thus for narrow bracket, should be used larger archwire size and adequate stiffness during tooth sliding along archwire, in order to limit wire bending. Friction is an important factor that needs to take into consideration, when we chose to use larger wire size. Andreasen and Quevedo⁵¹ showed that as the frictional resistance increases with progressively larger archwires, proportionately greater forces would be required to overcome friction.

The rotation for PB group, these custom-made passive-ligating brackets had rotational change during canine retraction less than DB group but not statistically significant. Both tightness ligation technique and wider bracket width of these brackets affected the moment produced during axial rotation thus could control rotation of canine comparable with DB can.

A limitation of this study was that only two types of brackets were compared and, therefore, the results apply only to the archwire size, and retraction force used with these two brackets. Further investigations may possibly evaluate the rate of tooth movement, tipping and rotation of PB and DB should be compared to conventional bracket to ensure that passive-ligating brackets especially in PB had more efficiency tooth movement when compared to conventional brackets under a variety of archwire sizes (0.016" x 0.022" and 0.019" x 0.025" stainless steel wire) in vivo.

Even though, the PB had comparable amount of canine movement and rotational control with better tipping and less expensive compared to DB, the PB consumed more time to fabricate and to install that need to develop to reduce these disadvantages in the further investigations.

CHAPTER 5

CONCLUSIONS

PB that created in PSU had comparable amount of canine movement and rotational control with better tipping and less expensive compared to DB. From pilot study was shown that the secure ligatured method of PB was important factor that made a conventional bracket to be an efficacy passive-ligating bracket.

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APPENDICES



ที่ ศธ 0521.1.03/ 995

คณะทันตแพทยศาสตร์
มหาวิทยาลัยสงขลานครินทร์
ตู้ไปรษณีย์เลขที่ 17
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หนังสือฉบับนี้ให้ไว้เพื่อรับรองว่า

โครงการวิจัยเรื่อง "การศึกษาเปรียบเทียบประสิทธิภาพการเคลื่อนฟันทางทันตกรรมจัดฟันระหว่างการใช้ Damon Brackets กับ Passive ligating brackets ที่ประยุกต์ขึ้นเอง"

หัวหน้าโครงการ ทันตแพทย์หญิงอกนิษฐ์ อุรังสิมาวงศ์

สังกัดหน่วยงาน นักศึกษาหลังปริญญา ภาควิชาทันตกรรมป้องกัน คณะทันตแพทยศาสตร์ มหาวิทยาลัยสงขลานครินทร์

ได้ผ่านการพิจารณาและได้รับความเห็นชอบจากคณะกรรมการจริยธรรมในการวิจัย (Ethics Committee) ซึ่งเป็นคณะกรรมการพิจารณาคำขออนุญาตวิจัยในคนของคณะทันตแพทยศาสตร์ มหาวิทยาลัยสงขลานครินทร์ แล้ว

ให้ไว้ ณ วันที่ 19 ธ.ค. 2549

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ใบเชิญชวน

ขอเชิญเข้าร่วมโครงการวิจัย เรื่องการเปรียบเทียบประสิทธิภาพการเคลื่อนฟันทางทันตกรรมจัดฟัน ระหว่างการใช้แบร็คเกตเดมอนกับแบร็คเกตชนิดแรงเสียดทานต่ำที่ประยุกต์ใช้เอง

เรียน ท่านผู้อ่านที่นับถือ

ข้าพเจ้า นางสาวกนิษฐ อุรังสิมาวงศ์ ใคร่ขอเล่าถึงโครงการวิจัยที่กำลังทำอยู่ และขอเชิญชวนท่านเข้าร่วมโครงการนี้ โดยผู้วิจัยต้องการศึกษาผลของการเคลื่อนฟันทางทันตกรรมจัดฟันระหว่างการใช้แบร็คเกตเดมอนกับแบร็คเกตชนิดแรงเสียดทานต่ำที่ประยุกต์ใช้เอง โดยแบร็คเกตทั้งสองชนิดนี้เป็นแบร็คเกตที่แรงเสียดทานต่ำในขณะที่ทำการเคลื่อนฟันเขียว ซึ่งเป็นส่วนหนึ่งของขั้นตอนปกติในการรักษาทางทันตกรรมจัดฟัน คาดว่าจะช่วยเพิ่มอัตราการเคลื่อนฟันทำให้เวลาการรักษาลดลงเมื่อเปรียบเทียบกับแบร็คเกตทั่วไปที่เกิดแรงเสียดทานขณะทำการเคลื่อนฟันเขียว ซึ่งจะเป็นประโยชน์ต่อผู้ป่วยเองและในการรักษาทันตกรรมจัดฟันแก่ผู้ป่วยรายอื่นๆต่อไป

ผู้ป่วยและผู้ปกครองของผู้ป่วยทุกคนที่เข้าร่วมโครงการวิจัย จะได้รับการอธิบายขั้นตอนการรักษา และมีความสมัครใจที่จะเข้าร่วมโครงการวิจัย จากนั้นจะได้รับการรักษาด้วยเครื่องมือจัดฟันชนิดติดแน่นตามขั้นตอนการรักษาตามปกติ โดยเลือกฟันเขียวแบบส้อมด้านหนึ่งใช้แบร็คเกตเดมอน อีกด้านใช้แบร็คเกตที่ประยุกต์ใช้เอง ซึ่งได้รับการดัดแปลงมาจากแบร็คเกตที่นิยมใช้กันอยู่โดยทั่วไป ทำการเก็บข้อมูลผู้ป่วยก่อนการเคลื่อนฟันเขียวด้วยการพิมพ์ปากเพื่อเทแบบจำลองฟัน และการถ่ายภาพรังสีกะโหลกศีรษะด้านข้าง และหลังจากทำการเคลื่อนฟันเขียวเป็นระยะเวลา 3 เดือน ทำการเก็บข้อมูลด้วยการพิมพ์ปากเพื่อเทแบบจำลองฟัน และการถ่ายภาพรังสีกะโหลกศีรษะด้านข้างอีกครั้ง เพื่อนำไปประเมินและเปรียบเทียบการเคลื่อนฟันเขียวทั้ง 2 ข้าง ภายหลังจากนี้ดำเนินการให้การรักษาตามขั้นตอนต่อไป

ความเสี่ยงที่ประชากรที่เข้าร่วมในโครงการวิจัยจะได้รับ

-วัสดุที่นำมาประยุกต์เป็นฝาปิด เพื่อให้เป็นแบร็คเกตที่มีแรงเสียดทานต่ำนั้นมาจากแบร็คเกตที่นิยมใช้กันอยู่โดยทั่วไปกับลวดโลหะไร้สนิม (Stainless steel) ที่ใช้เป็นลวดหลักในการจัดฟัน ดังนั้นวัสดุชนิดนี้จึงไม่ก่อให้เกิดอันตรายแก่ผู้เข้าร่วมวิจัย หากแบร็คเกตที่ใช้ในการวิจัยมีปัญหาหลุดหรือเสียผู้เข้าร่วมวิจัยจะได้รับการเปลี่ยนแบร็คเกตโดยไม่เสียค่าใช้จ่ายเพิ่ม

-ในขั้นตอนของการเก็บข้อมูลนั้น ผู้เข้าร่วมวิจัยจำเป็นต้องได้รับการเก็บข้อมูลด้วยการถ่ายภาพรังสีกะโหลกศีรษะด้านข้าง ซึ่งการถ่ายภาพรังสีแต่ละครั้งนั้น มีความเสี่ยงที่

จะเกิดอันตรายต่อผู้เข้าร่วมวิจัยน้อยมาก เนื่องจากปริมาณรังสีที่ได้รับน้อยมาก โดยปริมาณรังสีที่ได้รับในแต่ละครั้งนั้นน้อยกว่า 10 เท่าของการถ่ายภาพรังสีปอด อีกทั้งผู้ทำการวิจัยทำการขอความร่วมมือไปยังแผนกรังสีให้สวมเสื้อตะกั่วป้องกันรังสีให้แก่ผู้เข้าร่วมวิจัยทุกราย และพยายามให้ความผิดพลาดในการถ่ายภาพรังสีน้อยที่สุด เพื่อลดปริมาณรังสีที่ผู้เข้าร่วมวิจัยจะได้รับโดยไม่จำเป็น

มีการตีพิมพ์ข้อมูลเกี่ยวกับปริมาณและความเสี่ยงของการได้รับรังสีจากการรักษาทางทันตกรรม ซึ่งผลงานเหล่านี้ได้แสดงให้เห็นว่าปริมาณรังสีที่ผู้ป่วยได้รับนั้นน้อยมาก เมื่อเปรียบเทียบกับปริมาณรังสีที่จะก่อให้เกิดอันตรายต่อผู้ป่วย

ถ้าท่านตัดสินใจเข้าร่วมในโครงการนี้จะมีขั้นตอนของการวิจัยที่เกี่ยวข้องกับท่านคือ

ในการเข้าร่วมในโครงการนี้จะมีขั้นตอนของการรักษากับท่านตามปกติ และจะมีขั้นตอนของการวิจัยที่เกี่ยวข้องกับท่าน คือ การพิมพ์ปากและการถ่ายภาพรังสีกะโหลกศีรษะด้านข้างก่อนการเคลื่อนฟันเขี้ยวและหลังการเคลื่อนฟันเขี้ยวไปแล้วเป็นระยะเวลา 3 เดือน โดยผู้เข้าร่วมวิจัยจะได้รับการยกเว้นค่าพิมพ์ปากและค่าถ่ายภาพรังสีกะโหลกศีรษะด้านข้างในขั้นตอนของงานวิจัย

ชื่อผู้รับผิดชอบโครงการวิจัย และ ที่อยู่ที่สามารถติดต่อได้

นางสาวกนิษฐ อุรังสิมาวงศ์

นักศึกษาหลักสูตรฝึกอบรมทันตแพทย์ประจำบ้าน สาขาทันตกรรมจัดฟัน

ภาควิชาทันตกรรมป้องกัน คณะทันตแพทยศาสตร์ มหาวิทยาลัยสงขลานครินทร์

หมายเลขโทรศัพท์ 074-429875, 287669, 287674 (ในเวลาราชการ)

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สาขาทันตกรรมจัดฟัน ภาควิชาทันตกรรมป้องกัน คณะทันตแพทยศาสตร์

มหาวิทยาลัยสงขลานครินทร์ หมายเลขโทรศัพท์ 074-429875, 287669, 287674 (ในเวลาราชการ)

ไม่ว่าท่านจะเข้าร่วมในโครงการวิจัยนี้หรือไม่ ท่านจะยังคงได้รับการรักษาที่ดีเช่นเดียวกับผู้ป่วยคนอื่น ๆ และถ้าท่านต้องการที่จะถอนตัวออกจากการศึกษานี้เมื่อใด ท่านก็สามารถกระทำได้อย่างอิสระ

หากท่านมีคำถามใดๆก่อนที่จะตัดสินใจเข้าร่วมโครงการนี้ โปรดซักถาม
คณะผู้วิจัยได้อย่างเต็มที่

ขอขอบคุณเป็นอย่างสูง

(นางสาว อกนิษฐ์ อู่รังสิมาวงศ์)

ผู้วิจัย

(ผศ. ทพ. ดร. ไชยรัตน์ เฉลิมรัตน์โรจน์)

อาจารย์ที่ปรึกษาการวิจัย

หมายเหตุ : -กรุณาอ่านข้อความให้เข้าใจก่อนเซ็นชื่อยินยอมเข้าร่วมโครงการ
แบบยินยอมเข้าร่วมการศึกษา

โครงการวิจัยเรื่อง การศึกษาเปรียบเทียบประสิทธิภาพการเคลื่อนฟันทางทันตกรรมจัดฟัน
ระหว่างการใช้แบร็คเกตเดมอนกับแบร็คเกตชนิดแรงเสียดทานต่ำที่ประยุกต์ใช้เอง

วันที่.....เดือน.....พ.ศ.....
ข้าพเจ้า.....อายุ.....ปี
อาศัยอยู่บ้านเลขที่.....หมู่ที่.....ถนน.....
ตำบล.....อำเภอ.....จังหวัด.....

ได้รับทราบถึงรายละเอียดของการศึกษาวิจัย เรื่องการศึกษาเปรียบเทียบ
ประสิทธิภาพการเคลื่อนฟันทางทันตกรรมจัดฟันระหว่างการใช้แบร็คเกตเดมอนกับแบร็คเกตชนิด
แรงเสียดทานต่ำที่ประยุกต์ใช้เอง โดยผู้เข้าร่วมวิจัยจะได้รับการติดเครื่องมือจัดฟันชนิดติดแน่น
โดยใช้แบร็คเกตทั้งสองชนิดนี้ที่ฟันเขี้ยวในแต่ละข้าง ทำการเก็บข้อมูลผู้ป่วยก่อนการเคลื่อนฟัน
เขี้ยวด้วยการพิมพ์ปากเพื่อเทแบบจำลองฟันและการถ่ายภาพรังสีกะโหลกศีรษะด้านข้าง ทำการ
เคลื่อนฟันเขี้ยวโดยหลังซึ่งเป็นส่วนหนึ่งของการรักษา เมื่อทำการเคลื่อนฟันเขี้ยวครบเป็น
ระยะเวลา 3 เดือนทำการเก็บข้อมูลด้วยการพิมพ์ปากเพื่อเทแบบจำลองฟันและการถ่ายภาพรังสี
กะโหลกศีรษะด้านข้างเพื่อนำไปประเมินและเปรียบเทียบการเคลื่อนฟันเขี้ยวทั้ง 2 ข้าง โดย
ผู้เข้าร่วมวิจัยจะได้รับการยกเว้นค่าพิมพ์ปากและค่าถ่ายภาพรังสีกะโหลกศีรษะด้านข้างของ
ขั้นตอนงานวิจัย ภายหลังจากนี้ดำเนินการให้การรักษาตามขั้นตอนต่อไป

หากข้าพเจ้ามีข้อสงสัยประการใดสามารถติดต่อได้ที่ ทพญ. อกนิษฐ์ อู๋รังสิมาวงศ์
หรือ รศ. ทพ. ดร. ไชยรัตน์ เกลิมรัตนโรจน์ ภาควิชาทันตกรรมป้องกัน คณะทันตแพทยศาสตร์
มหาวิทยาลัยสงขลานครินทร์ หมายเลขโทรศัพท์ 074-429875, 287669, 287674 (ในเวลาราชการ)
หมายเลข 01-4801944 (นอกเวลาราชการ) หรือเมื่อมีปัญหาใดๆเกิดขึ้นเนื่องจากการทำวิจัยในเรื่อง
นี้ ข้าพเจ้าสามารถร้องเรียนไปที่คณะทันตแพทยศาสตร์ มหาวิทยาลัยสงขลานครินทร์ อ.
หาดใหญ่ จ.สงขลา 90112 โทรศัพท์ 074-287510

หากผู้วิจัยมีข้อมูลเพิ่มเติมทั้งด้านประโยชน์และโทษของการวิจัยนี้ ผู้วิจัยจะแจ้งให้
ข้าพเจ้าทราบอย่างรวดเร็วโดยไม่ปิดบัง

ข้าพเจ้ามีสิทธิ์ที่จะขอการเข้าร่วมโครงการวิจัย โดยจะแจ้งให้ทราบล่วงหน้า
โดยการขอเข้าร่วมโครงการวิจัยนี้จะไม่ผลต่อการรักษาที่ข้าพเจ้าจะได้รับแต่ประการใด

ข้าพเจ้าได้รับทราบจากผู้วิจัยว่า จะไม่เปิดเผยข้อมูลหรือผลการวิจัยของข้าพเจ้า
เป็นรายบุคคลต่อสาธารณชน จะเปิดเผยได้เฉพาะในรูปที่เป็นสรุปผลการวิจัย หรือการเปิดเผย
ข้อมูลต่อผู้มีหน้าที่ที่เกี่ยวข้องกับการสนับสนุนและกำกับดูแลการวิจัย

ข้าพเจ้าได้อ่านและได้รับการอธิบายข้อความข้างต้นแล้ว และมีความเข้าใจดีทุกประการจึงได้ลงนามในใบยินยอมนี้ด้วยความเต็มใจ โดยนักวิจัยได้ให้สำเนาใบยินยอมที่ลงนามแล้วกับข้าพเจ้าเพื่อเก็บไว้เป็นหลักฐาน

ลงชื่อ.....ผู้ยินยอม

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ลงชื่อ.....ผู้รับผิดชอบ โครงการวิจัย

(ทพญ. อภนิษฐ์ อู๋รังสิมาวงศ์)

ลงชื่อ.....บิดา/ผู้ใช้อำนาจปกครอง

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ลงชื่อ.....มารดา

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ลงชื่อ.....พยาน

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ลงชื่อ.....พยาน

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VITAE

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