Treatment Effects after Treated with PSU-Fixed Functional Appliance in Class II Malocclusion Patients

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A Thesis Submitted in Partial Fulfillment of the Requirements for the Degree of

Master of Science in Oral Health Sciences

Prince of Songkla University

2008

Thesis Title Treatment Effects after Treated with PSU-Fixed Functional Appliance in Class II Malocclusion Patients

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ชื่อวิทยานิพนธ์ การศึกษาผลที่เกิดขึ้นภายหลังการรักษาด้วยเครื่องมือฟังก์ชั่นนอลชนิดติดแน่นของมหาวิทยาลัยสงขลานครินทร์ ในผู้ป่วยที่มีการสบฟันผิดปกติแบบที่ 2

ผู้เขียน นางสาวพิมพลักษณ์ หล่อวิริยากุล

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บทคัดย่อ

เครื่องมือฟังก์ชั่นนอลชนิดติดแน่นที่ประดิษฐ์ขึ้นของมหาวิทยาลัยสงขลานครินทร์ (PSU-FFA)ได้ถูกดัดแปลงมาจากเครื่องมือชนิดเอจไวส์เฮิร์บ เพื่อเพิ่มการเจริญในส่วนกระดูกโครงสร้างใบหน้าด้วยวิธีการกระตุ้นขากรรไกรแบบทีละน้อย ร่วมกับลดการเคลื่อนฟันที่ไม่พึงประสงค์โดยการเตรียมฟันหลักยึดที่ดี ซึ่งในปัจจุบันยังไม่มีการศึกษาถึงประสิทธิภาพของเครื่องมือฟังก์ชั่นนอลระบบใหม่นี้ งานวิจัยนี้มีวัตถุประสงค์เพื่อศึกษาการเปลี่ยนแปลงที่เกิดขึ้นกับส่วนกระดูกโครงสร้างใบหน้าและฟันภายหลังการใช้เครื่องมือ PSU-FFA ในผู้ป่วยที่มีความผิดปกติของการสบฟันประเภทที่2 ผู้เข้าร่วมวิจัยเป็นผู้ป่วยที่มารับการรักษาที่คลินิกทันตกรรมจัดฟัน โรงพยาบาลทันตกรรม คณะทันตแพทยศาสตร์ มหาวิทยาลัยสงขลานครินทร์ เป็นเด็กชาย 9 คน เด็กหญิง 21 คน มีการเจริญเติบโตของกระดูกอยู่ในช่วง MP_3 ซึ่งถูกเลือกมาอย่างสุ่ม ผู้ป่วยถูกแบ่งเป็น 2 กลุ่ม กลุ่มแรกเป็นกลุ่มที่ได้รับการรักษา (Treated group) ผู้ป่วยกลุ่มนี้จะได้รับการรักษาด้วยเครื่องมือ PSU-FFA ระยะเวลาโดยเฉลี่ย 7 เดือน การประเมินผลของเครื่องมือนี้จะนำไปหักลบกับค่าการเจริญเติบโตของผู้ป่วยจริงที่ได้จากกลุ่มควบคุม (Control group) ซึ่งถูกเฝ้าติดตามเป็นเวลา 7 เดือนเช่นกัน ผู้ป่วยในกลุ่มที่ได้รับการรักษาจะถูกติดเครื่องมือจัดฟันและใส่ลวดขนาด 0.018”x0.025” stainless steel ร่วมกับใส่ labial crown torque ที่ฟันหน้าบน ขณะที่ฟันหน้าล่างใส่ lingual crown torque และ cinch back, ที่ฟันเขี้ยวล่างทั้งสองข้างใส่ uprighting spring ใน vertical slots เพื่อทำให้ฟันเอียงไปด้านหลัง จากนั้นกระตุ้นขากรรไกรล่าง ครั้งละ 2 mm. ทุกๆ 2 เดือน ด้วยลวดขนาด 1 mm. stainless steel จนผู้ป่วยสบแบบปลายฟันชนกัน (edge to edge) ระยะเวลารักษาทั้งหมดเฉลี่ย 6.7 เดือน ทำการวิเคราะห์ภาพถ่ายรังสีกะโหลกศีรษะด้านข้างก่อนและหลังการรักษาตามวิธีของ Pancherz เพื่อประเมินค่าเฉลี่ยของตัวแปรต่างๆ ผลการศึกษาพบว่า 1) ผู้ป่วยทุกรายสามารถเคลื่อนขากรรไกรมาด้านหน้าจนเป็น Class I หรือ Class III 2) ขากรรไกรล่างมีการเจริญเติบโตมาด้านหน้าด้วยการกระตุ้นแบบทีละน้อย เฉลี่ย 3.6 mm. ขณะที่ขากรรไกรบนยังคงเดิม 3) ลด overjet ได้เฉลี่ย 5.83 mm. โดยผลส่วนใหญ่ 3.6 mm. (61.75%) เป็นการเจริญของขากรรไกร

ล่าง ขณะที่มีการเคลื่อนของฟันเพียง 2.23 mm. (38.25 %) ผลการศึกษาสรุปได้ว่า การเพิ่มผลต่อกระดูกโครงสร้างใบหน้าด้วยเครื่องมือ PSU-FFA ควรกระตุ้นขากรรไกรแบบทีละน้อย ร่วมกับการเตรียมฟันหลักยึดที่ดีในฟันหน้าบนและล่าง ซึ่งการพัฒนาเครื่องมือฟังก์ชั่นนอลระบบใหม่นี้ ถือเป็นอีกหนึ่งทางเลือกในการนำมาประยุกต์ใช้ทางคลินิกในอนาคต

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Academic Year 2008

ABSTRACT

PSU-fixed functional appliance (PSU-FFA) is modified from edgewise Herbst appliance to enhance the orthopedic effect by mandibular step-by-step advancement (SSA) and to reduce unwanted dental movement by proper anchorage preparation. The efficiency of this new fixed functional appliance has, however, to date not been examined and reported in literature. Our objective was to investigate skeletal and dental changes after treated with PSU-FFA in Class II malocclusion patients. Thirty orthodontic patients, 9 boys and 21 girls during the skeletal maturity stages MP3 would be randomly selected from Orthodontic clinic, Dental hospital, Faculty of Dentistry, Prince of Songkla University. The subjects were divided into two groups. In treated group, the subjects were treated with PSU-FFA for 7 months in average. The treatment effects of this appliance could be estimated by deducting the growth changes obtained from control group which also has been observed for 7 months. In treated group, the upper anterior teeth were torque labially while the lower anterior teeth were torque lingually in cinched 0.018”x0.025” stainless steel wires. The uprighting springs were placed in lower canine bracket vertical slots (for distally tipping). The mandible was advanced 2 mm./2 months (step-by-step advancement) using 1mm. stainless steel protracted wires until the incisors were in edge to edge position. Total average treatment time was about 6.7 months. Lateral head films from before and after fixed functional therapy were analyzed in sagittal plane, according to the method of Pancherz. The means of all measurements were calculated. The results revealed the followings: 1) Bite jumping with the FFA resulted in Class I or Class III occlusal relationships in all treated cases. 2) The forward growth of the mandible with SSA was 3.6 mm. while the maxilla was maintained 3) Overjet correction averaging 5.83 mm. was mainly a results of a 3.6 mm. (61.75%) increase in mandibular base while the dental movement was 2.23 mm. (38.25%) Conclusion: For maximum orthopedic effects

of PSU-FFA, the mandible should be advanced with SSA together with proper anchorage preparation on the upper and lower anterior teeth. Developing a new system of fixed functional appliance to be the one choice for clinical application in the future.

ACKNOWLEDGEMENTS

There are many people who have helped me bring this study to completion. First, I would like to thank my advisors Assoc. Prof. Dr. Chidchanok Leethanakul and Assoc. Prof. Dr. Chairat Charoemratrote for their contribution to this study. They always gave me enthusiastic encouragement and general support, as well as invaluable guidance and advice. I would also like to thank the staffs in the Department of Preventive Dentistry for their assistance.

I wish to express my deepest thanks to my classmate for their help, encouragement and companionship. I would also like to thank all of orthodontic postgraduate students in Prince of Songkla university for their help in data of the subjects.

My special and deepest thanks go to my family. They cherish me and always give me constant encouragement and invaluable support. I also wish to express my sincerely thanks to my subjects for their agreement and participation in this study.

I would like to thank the director of Pakthongchai Hospital, Nakhonratchasima which is my original affiliation for supporting me to bring my study.

Finally, I would like to acknowledgement the Graduate school, Prince of Songkla University and the Thai Association of Orthodontists for the financial support to this study.

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LIST OF ABBREVIATIONS AND SYMBOLS

PSU-FFA = PSU-fixed functional appliance

SSA = Step-by-step advancement

Co = Condyle

ii = incision inferius

is = incision superius

mi = molar inferius

ms = molar superius

pg = pogonion

gn = gnathion

me = menton

ss = subspinale

n = nasion

s = sells

NSL = nasion-sella line

OL = occlusal line

OLp = occlusal line perpendiculare

UI = Upper incisor

PP = Palatal plane

LI = Lower incisor

MP = Mandibular incisor

CHAPTER 1

INTRODUCTION

1.1 Background and Rationale

The decision as to which is the most effective technique to use in the treatment of growing patients with skeletal and dental Class II malocclusion has long been the source of considerable debate within the orthodontic literature. In the previous, functional appliance developed primarily in Europe have been used by many clinicians in an effort to stimulate mandibular growth.[1] Functional orthopedic appliances can be used to correct Class II malocclusions. Its disadvantages of the removable functional appliances are very large in size, unstable fixation, discomfortable, exert pressure on the mucosa (encouraging gingivitis), reduce space for the tongue, cause difficulties in deglutition and speech, very often affect aesthetic appearance and need for patient cooperation. These adverse effects make the adaptation and acceptance of these appliances more difficult.[2, 3]

The lack of success of functional appliances has in some circumstances been attributed to lack of patient compliance in appliance wear. In addition, failure to achieve optimum results has also been attributed at time to the inability to control the amount and direction of mandibular growth. Thus the ideal appliance for the correction of Class II skeletal problems would eliminate the need for patient cooperation, provide the ability to stimulate the overall amount of mandibular growth, and direct this growth in the appropriate direction.

The Herbst appliance was introduced in the early 1900s by Emil Herbst as a fixed bite-jumping device for class II treatment. Since then and up to the seventies, very little was published on his appliance. It was at that time that Hans Pancherz[4, 5] reintroduced into discussion with the publication of several articles on the Herbst. He attempts to address these problems of patient cooperation and control of the direction of mandibular growth stimulation.[4-6] The original device is a banded Herbst design. The Herbst appliance has undergone some changes in its original design but since the seventies has maintained its general shape with only a few modification taking place with regard to methods of application.

The Herbst appliance which is a fixed functional appliance (FFA), has shown to be most effective in the treatment of Class II malocclusions by encouraging mandibular growth and elicit glenoid fossa remodeling.[4-14] Research to date has shown that the Herbst appliance has the ability to inhibit maxillary anteroposterior growth and to produce an increase in mandibular length and lower facial height.[4, 6]

FFA is worn full time, unlike removable functional appliance. Its active treatment time is relatively short and requires little or no patient cooperation. The other advantages are small in size and making hygiene simple. The appliance has orthopedic and orthodontic effects. The Class II correction is accomplished by an increase in sagittal mandibular growth and a "headgear effect" restraining the maxilla, along with a combination of dental changes such as retroclination of the maxillary incisors and proclination of the mandibular incisors. The orthodontic effects are basically a result of anchorage loss. The mandible anchorage loss leads to an unwanted proclination of the incisors most of time. As a rule of Class II malocclusion cannot be treated to a perfect end result with the Herbst appliance exclusively. Most of cases which use fixed functional appliance revealed orthodontic effect more than orthopedic effect.[5, 15-17] Therefore will require a subsequent dental alignment treatment phase with a multibracket appliance with or without extraction of teeth. But by starting treatment with the Herbst appliance the sagittal jaw base relationship is normalized and the Class II malocclusion is transferred to a Class I malocclusion, thus making subsequent treatment with the multibracket orthodontic appliance much easier.

Clinical use of this appliance base on Herbst's original design has remained limited because of problems with band breakage and mandibular incisor proclination. Modifications have included the use of stainless steel crowns on the maxillary first molars and an occlusal coverage bonded splint on the mandible. This bonded design reduced mandibular incisor protrusion, however, it limited tooth eruption and good oral hygiene.

In previous study, Dischinger[9, 18]designed the edgewise Herbst appliance to minimize certain limitations inherent in the Herbst design and to incorporate edgewise brackets and mechanics in the correction of Class II malocclusions. This appliance using a fixed appliance with the stainless steel crown Herbst appliance to maximize the skeletal changes of the treatment because of shortcomings of the banded Herbst and breakage problems. The edgewise Herbst appliance allows orthodontic tooth movements during the orthopedic correction and a smooth transition from Herbst treatment into the edgewise finishing appliance, however, the literature has still contained few reports on the follow-up of patients after fixed appliance treatment.

In 1994, a new design of the Herbst appliance was introduced. It was developed by Larry White,[19] and uses stainless steel crowns on the maxillary first molars and a removable mandibular occlusal coverage acrylic splint. This design allows for temporary removal of the mandibular component to facilitate oral hygiene and adjustments for eruption teeth. Patient compliance is maintained since removal of the mandibular portion leaves the maxillary component of the telescoping mechanism impinging on the buccal vestibular mucosa of the mandible.

In the earlier study,[20, 21] the different anchorage systems were compared. The results revealed that none of the anchorage systems could prevent anterior movement or proclination of the mandibular incisors

In recent years, VanLaecken *et al*[22] reported the use of edgewise Herbst appliance which was described by Dischinger[9, 18] on the short-term and follow-up. They believed that the use of super-torque brackets on the maxillary incisors and negative-torque brackets on the mandibular incisors aids in this recovery of incisors to pretreatment levels. However, the treatment effect showed that the forward movement of mandible was only 1.7 mm. and the mandibular incisors were proclined 3.6 mm. Overall, skeletal change contributed 36.9% of the overjet correction.

According to previous study, the most unwanted dental movement is proclination of lower incisors. To avoid this effect, good anchorage preparation should be carried out. Therefore, it is interesting to develop a new system of fixed functional appliance to enhance the orthopedic effect and improve mandibular anchorage by approaching to reduce orthodontic effect, that so-called **PSU-Fixed Functional Appliance** has been used at the Orthodontic clinic, Faculty of Dentistry, Prince of Songkla University. The efficiency of this new fixed functional appliance has, however, to date not been examined and the clinical references available in published work about treatment effects produced by this fixed functional appliance, no current scientific research and articles has been found and published. The aim of this study is to investigate skeletal and dental changes in patients with Class II malocclusions treated with PSU-fixed functional appliance. Data base from this study will be the one choice for clinical application.

1.2 Review of Literature

Herbst appliance which is a fixed functional appliance holds the lower jaw forward during mandibular functions and change from Class II to Class I jaw relationship, normally known as “The bite jumping appliance” which comprised of a telescopic mechanism attached to the upper first molar and lower first premolar[23-25] working as an artificial joint between the maxilla and mandible.[6, 26, 27] The bilateral telescopic mechanism maintains the protracted position of the mandible even during function. Each device consists of a tube, a plunger, two pivots and two locking screws that prevent the telescoping elements from slipping past the pivots. The original device is a banded Herbst design. The pivots for the tube ususlly is soldered to the maxillary first molar band and the pivot for the pluger is attached to the mandibular first premolar band. The tube and plunger are attached to their respective bands with screws and can freely rotate around their point of attachment. The length of the tube determines the amount of anterior bite jumping. In this investigation the construction bite in all cases was taken with the incisors in an edge-to-edge position. Although conventional orthodontic bands can be used, Pancherz prefers his current approach of casting splints of Chromium-cobalt alloy that incorporate molars and premolars.

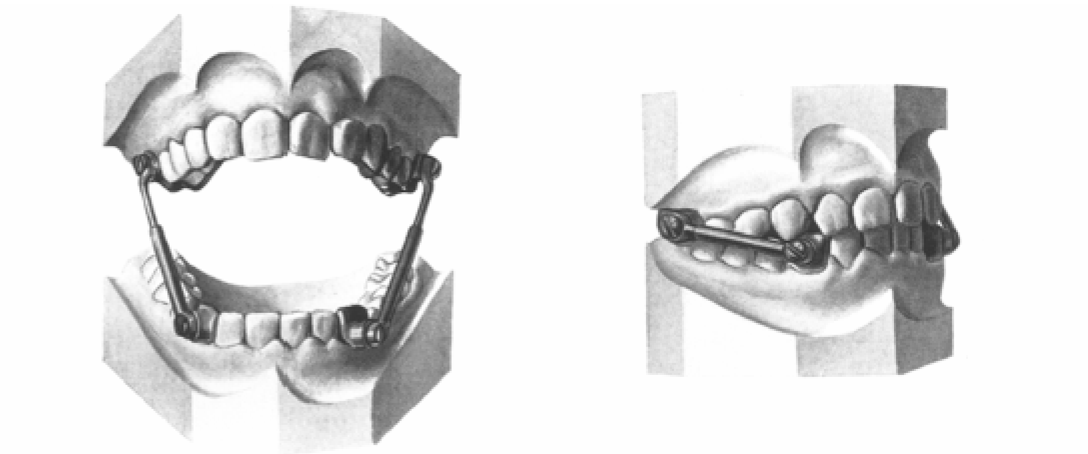


Fig. 1 The original Herbst appliance was introduced by Emil Herbst

Herbst’s advantages

1. The Herbst appliance is non-compliance Class II devices[7, 28] which reduces the need for patient co-operation.

2. It works 24 hours a day[7], which means that there is a continuous stimulus for mandibular growth. Because of this, the threshold for adaptive remodeling processes in the condyle will be attained.[4]

3. The Class II correction is accomplished by an increase in sagittal mandibular growth useful in the treatment of Class II malocclusion with retrognathic mandible.[17, 23-25]

4. Herbst appliance therapy result in redirection of maxillary growth, mesial tooth movements in the mandible and distal tooth movements in the maxilla, all of which certainly were factors of importance for the transformation of the Class II malocclusions into neutral occlusions[5, 6, 17] and to improve facial profile.[29, 30]

5. Produced a **headgear effect**[31] on the maxillary dentition due to intrusive force applied to the maxillary posterior segment and produces an anterior intrusive force on the lower dentition.

6. The mechanism keeps the mandible in a protruded position throughout treatment allows opening and closing movement of the mandible as well as some lateral movement.[25, 32, 33]

7. In arch discrepancy cases the Herbst appliance may be useful for preliminary treatment prior to major multiband orthodontic mechanotherapy.

8. Active treatment time is short (approximately 6 to 8 months)[7]

9. They are small in size permitting better adaptation to functions such as a mastication, swallowing, speech and breathing.

10. According to the appliance impossible for the patient to remove them therefore, is an appliance that allows greater control by the orthodontist.

Herbst's disadvantages

1. Dental movement that takes place during treatment which may not be the most suitable for the type of malocclusion in question. In an attempt to avoid this unwanted dental movement, maxillary and mandibular anchorage is increased by incorporating the front teeth.[6, 24, 25] The dental effects are basically a result of anchorage loss.[21]

2. The mandibular anchorage loss leads to an unwanted proclination of the incisors most of the time.[20]

3. Breakage of the appliance and loose bands were found in some of the patients, especially during the first months of treatment.

4. The thickness of the appliance can impinge on the patient's cheek.

5. High cost and spent time in laboratory.

Effects of Herbst appliance

Normally, in the correction of large sagittal discrepancies, the orthopedic effect of treatment is often of small magnitude when compared with the dentoalveolar changes. Various types of functional jaw orthopedic appliance are used to treat patients with class II malocclusion, an appliance that is primarily tissue borne or tooth borne. Herbst appliance is primarily tooth borne appliance that have a greater dentoalveolar treatment effect than an appliance that was tissue-borne because the Herbst appliance is connected to the teeth, dentoalveolar effects can be expected to occur both anteroposteriorly and vertically.[34]

It is necessary to considerate the important factors such as type of anchorage[20, 21], amount of force[10, 35-38] or age at start of treatment[39-42] to obtain the maximal orthopedic improvement. In order to transfer as much force as possible to the base of the maxilla, splints may be used with an attempt to distribute the force over the total dentoalveolar area for better anchorage purpose.[21] It is important to use the total dentoalveolar area in both the maxillary and mandibular arches as anchorage for transferring forces to affect the interrelationship between maxillary and mandibular basal bones.

As a rule of Class II malocclusion cannot be treated to a perfect end result with the Herbst appliance exclusively. Most of cases which use fixed functional appliance revealed orthodontic effect more than orthopedic effect, therefore will require a subsequent dental alignment treatment phase with a multibracket appliance with or without extraction of teeth. It is interesting to develop the system of fixed functional appliance to enhance the orthopedic effect and to improve mandibular anchorage by approaching to reduce orthodontic effect.

How to maximize the orthopedic effect

1. Anchorage preparation

In an earlier study, Pancherz and Hansen[20] compared five different anchorage systems of the banded type of the Herbst appliance. The results revealed that none of the anchorage systems could prevent anterior movement or proclination of the mandibular incisors. After that Weschler *et al*[21] used a new anchorage system, the so-called cast splint anchorage to improve mandibular anchorage. However this study revealed that the new cast splint anchorage system was not superior to the original banded anchorage system. On the contrary, during treatment, the incisor anchorage loss was largest in the cast splint anchorage group. It can be concluded that none of mandibular anchorage forms used in Herbst treatment could prevent an anchorage loss.

In previous study, Dischinger[9, 18] designed the edgewise Herbst using a fixed appliance with the stainless steel crown Herbst appliance to maximize the skeletal changes of the treatment by incorporating more dental units, lower anchorage may be increased. Unnecessary forward tipping of the lower incisors was avoided by using -10^{o} torque brackets and maxillary arch was tied back to the molar tubes to prevent space from opening between the molars and the second premolars which prevented the distal movement of the maxillary molars. VanLaecken *et al*[22] reported the use of edgewise Herbst appliance which was described by Dischinger.[9, 18]The net effect of the edgewise Herbst treatment in this study was primarily skeletal (85% of the overjet correction and 96% of the molar correction). They believed that the use of super-torque brackets on the maxillary incisors and negative-torque brackets on the mandibular incisors aids in this recovery of incisors to pretreatment levels.

Proper anchorage preparation is critical to achieving successful results. It is necessary to align and level arches until hard wires before insert fixed functional appliance. By fully engaging the brackets in both arches, anchorage is maintained during the activation for preventing unwanted mesial movement of the lower incisors and distal movement of the upper molars. The upper arch wire should be cinched to increase anchorage and minimize dentoalveolar movements. The fixed functional appliance can use in conjunction with fixed appliance lead to get good anchorage preparation.[9, 18, 22]

2. Step-by-step mandibular advancement

It has been indicated in a clinical study[16, 43] that step-by-step advancement of the mandible might enhance mandibular growth more than maximum jumping only. In previous comparison of treatment result over 12 months, it was shown that the improvement in the jaw base relationship produced by the headgear-Herbst appliance with step-by-step advancement of the mandible was twice as large as that of the conventional Herbst appliance with maximum jumping of the mandible.[35] The results of an animal study[38] also indicated that the stepwise advancement produces more skeletal effects than single advancement and a more prominent effect with stepwise advancement was found in the glenoid fossa compared with the condyle. Results of this study showed that forward mandibular positioning led to increased bone formation in the condyle and the glenoid fossa when compared with natural growth. Stretching of the posterior attachment of the fibrous capsule during mandibular advancement causes a series of cellular and molecular events that lead to bone formation in the condyle and the glenoid fossa.[10]

Ruf and Pancherz[44] using magnetic resonance imaging (MRI) have conclusively shown that the use of the Herbst appliance leads to remodeling of the glenoid fossa and the condyle. A recent study[10, 37] showed an increase in bone formation in both condyle and glenoid fossa after mandibular advancement using a fixed functional appliance. Moreover, the amount of bone formation of the condyle and the glenoid fossa was observe to be significantly higher in the posterior region. A better response was believed to occur when advancement took place in a gradual manner, to allow the muscle and condyle to adapt to the new position, an increase in the amount of skeletal effect, a reduction in the amount of dentoalveolar compensation, and better stability.

Falck and Frankel[36] showed that there is an obvious link between the rate of mandibular advancement and the dentofacial changes during treatment with Frankel appliance. In patients, who were advanced the mandible in small steps have significantly improved in jaw discrepancy. The results also indicated that in small-step group the initial position of the condyle relative to the glenoid fossa was maintained during treatment whereas it changed anteriorly in maximum advancement group. Another finding of this study was that maximum advancement group had mainly a tooth-moving effect, whereas in small-step group, basal development of the mandible was simultaneously stimulated sagittaly. Normally, whatever appliance is used for altering mandibular position anteriorly in the treatment of Class II malocclusion, the resultant effect of the stretched retractors on the maxillary structures must be taken into consideration. The results of this study indicate that the restricting effect of these forces on the maxilla can be eliminated, or at least minimized, when the mandible is advanced in small steps because the retractors are only slightly stretched.

3. Appropriate treatment period accelerating to growth

It has previous been shown that mandibular growth during orthodontic treatment was greater in patients treated within a two-year period around the maximum of pubertal growth in standing height compared to those treated before or after that period.[40] Pancherz and Hagg[40] suggested that Herbst therapy be instituted close to peak height velocity to increase in condylar growth response and to reduce time of posttreatment retention. Skeletal development was assessed by judging the skeletal development of the middle phalanx of the third finger of hand-wrist radiograph according to the method described by Fishman. In relation to skeletal maturation, patients treated at the initial closure of the middle phalanx of the third finger (MP3 stage) had the greatest amount of sagittal condylar growth, which occurs close to PEAK and chronological age was a very inaccurate indicator of the sagittal condylar growth capacity.[39](MP3: the middle phalanx of the third finger, epiphysis is as wide as its diaphysis) Early treatment for Class II malocclusion is frequently undertaken with the objective of correcting skeletal disproportion by altering the growth pattern. Tulloch *et al*[41] illustrated that early treatment can reduce the severity of a Class II skeletal pattern, there is 75% chance of improvement in the jaw relationship and functional appliance therapy produce greater increase in mandibular length. For preadolescent children with Class II malocclusion, the optimal timing for treatment remains controversial. Because most of patients with Class II malocclusion have some types of skeletal imbalance, early (preadolescent) treatment often is aimed mainly at modifying the growth of the jaws. This early phase of treatment is usually followed by a second and presumably simpler, later stage of tooth movement during adolescence. Thus patients with Class II malocclusion would benefit from two-stage treatment if skeletal growth could be modified.[42] The option of orthognathic surgery was presented more often in the cases of children who did not undergo early treatment and surgery was less often in the patients previously treated with functional appliances.[42] Herbst treatment is especially indicated in the permanent dentition at or just after the pubertal peak of growth. Mixed dentition treatment is not recommended, as a stable cuspal interdigitation after therapy is difficult to achieve and relapses are prone to accur.[7]

Early treatment children had a significant average reduction in ANB angle, 75% of the treated children showing favorable skeletal response.[42] A few reports of untreated patients that of exist suggest that growth is highly variable,[45-47]Difficult to predict[48], and different from that in normal subjects.[49] It may be salutary for clinicians to keep in mind the variability in growth shown in this and other untreated Class II groups when treatment results are evaluate. It has been suggested that the skeletal changes in early treatment, particularly the increase in mandibular growth seen with functional appliances, may simply represent an acceleration in growth rather than a net gain.[50] One of the goals of mixed-dentition treatment is that later treatment should be simpler, perhaps requiring fewer extractions and less surgery.[51] If early treatment does significantly alter growth and improve jaw relationship, the rates of extraction to camouflage a Class II skeletal pattern or orthognathic surgery to correct jaw relationship should be reduced.

There is great variation in response to early Class II growth modification treatment, approximately 83% of children undergoing early treatment with functional appliance, experience a favorable or highly favorable reduction in skeletal discrepancy. This response to early treatment is significantly different from the growth experienced by similar but untreated children with Class II malocclusion.[52]

4. Prolong the treatment time and retention

Hagg *et al*[10] reported the use of headgear and removable activators after Herbst treatment to maintain positive growth pattern. They claimed that increasing the length of treatment enhances successful outcomes. However, Wieslander[11, 12] stated that, without retention devices, initial skeletal effects were difficult to maintain. In the mixed-dentition patients, maxillary and mandibular lingual arches were used as retainers. Lingual arches are important for stability of the orthopedic correction. Overbite correction was maintained by the lingual wires to prevent relapse of the Class II treatment. The torque on the maxillary incisors was also maintained to prevent Class II relapse. The arch form was maintained and the “E” space was preserved. In the permanent dentition, maxillary and mandibular vacuum-formed retainers were used.[22]

5. Interdigitation

At the end of Herbst treatment, overcorrected sagittal dental arch relationships with an incomplete cuspal interdigitation are a common finding.[4-6] The Herbst appliance can be used successfully in patient who close to pubertal peak of growth.[40] It is most useful in the permanent dentition. Treatment at this stage of dental development makes it possible to obtain a stable cuspal interdigitation after therapy that will counteract an occlusal relapse. Treatment in mixed dentition will make it necessary to retain the result until the permanent teeth have erupted and the occlusal stabilized. Otherwise there is risk of an occlusal relapse.[53] It is advantageous to start the treatment in adolescent patients when the majority of permanent teeth have erupted and 12-year molars can be banded. Fixed functional appliance are not recommended in mixed dentition, especially late mixed dentition to avoid unwanted dental movements and treatment with fixed appliance was more efficient than treatment with removable appliance.[54] On the other hand, Pancherz revealed that the interrelation between maxillary and mandibular posttreatment growth was favorable and did not contribute to the occlusal relapse but the main causes of the Class II relapse in patients treated with the Herbst appliance were a persisting lip-tongue dysfunction habit and unstable cuspal intercuspation after treatment[24] so that the activators were used in patients which, after treatment, still were in the mixed dentition and in which a stable cuspal interdigitation had not yet been established.[3] Posttreatment retention for at least 2 years after Herbst treatment is recommended. The Andresen activator is most suitable device retention[4, 11, 55], this holds the teeth in the desired position and guide tooth eruption. This appliance also trains and accommodates the musculature to the new mandibular position which certainly is a factor of importance for stable treatment result and may counteract recovering growth changes after Herbst treatment as it works as an intermaxillary splint.

The short-term treatment effects produced by the Herbst appliance in the mixed dentition for a period of 12 months by evaluates the dentoalveolar and skeletal cephalometric changes. The results indicated that treatment effects produced in the mixed dentition patients, the mandibular incisors were tipped labially and the maxillary incisors were retruded, a significant increase in mandibular posterior dentoalveolar height occurred and there was a restriction in the vertical development of the maxillary molars. There was in difference in the forward growth of the maxilla between two groups. In comparison with the controls, however, the Herbst treatment produced a modest but statistically increase in the total mandibular length. This increase in total mandibular length, however, was less than observed in adolescent Herbst patients in other studies.[56] Wieslander[11] designed Headgear-Herbst appliance in order to stimulate growth of the mandibular condyles. A short period of the treatment may be indicate to correct skeletal deviations and establish a normal relationship between maxilla and mandible.

Biochemical mediators to enhance mandibular condylar growth

Biomechanical force produced by forward mandibular positioning solicit cellular and molecular changes in the mandibular condyles.[57-61] However, the effect of functional appliances on condylar growth remains a controversial issue.[7] Recently, the researchers identified some cellular and molecular events that are responsible for key process governing condylar growth.[62] In the developing condyles, mesenchymal cells present in the proliferative layer differentiate into chondrocytes. The process of differentiation is regulated by Sox 9 transcription factor.[58, 62] Sox 9 is a high-mobility-group–type transcription factor that controls the differentiation of mesenchymal cells into chondrocytes by directly activating the gene expression for type II collagen.[62] Type II collagen that is synthesized by chondrocytes is the main type of collagen that forms the framework of the cartilage matrix in the growing condyle. After cartilage matrix formation, chondrocytes mature and hypertrophy. Hypertrophic chondrocytes secrete type X collagen, which marks the onset of endochondral ossification. Cells in the upper zone of the hypertrophic cartilage secrete VEGF (vascular endothelial growth factor) which regulates the neovascularization of the hypertrophic cartilage and influences the removal of the cartilage matrix. The invading blood vessels bring osteogenic progenitor mesenchymal cells into the mineralization front and later differentiate into osteoblasts and engage in osteogenesis.

In 2003, Rabie *et al*[61] reported that the expression of Sox 9 and type II collagen are accelerated and enhanced when the mandible is positioned forward. Thus, functional appliance therapy accelerates and enhances condylar growth by accelerating the differentiation of mesenchymal cells into chondrocytes, leading to an earlier formation and increase in amount of cartilage matrix. In addition, they found the number of replicating mesenchymal cells influences the growth potential of the condyle and the glenoid fossa. Forward mandibular positioning causes an increase in the number of replicating cells in the TMJ. This increase is maintained at higher levels or at levels equal to those of natural growth but not at lower levels.[60]

In 2004, Tang *et al*[63] suggested that Indian Hedgehog (Ihh) acts as a mechanical signals resulting from anterior mandibular displacement to stimulate cellular proliferation in condyle cartilage. The interesting finding in the present study is that the accumulation of Ihh expression in the mesenchymal cells during mandibular advancement corresponded to the significant increase of the number of proliferating cells. These findings point out that mechanotransduction and cell proliferation in the condyle are connected by Ihh. Thus the extra-expression of Ihh elicited by functional appliance treatment promotes mesenchymal cell proliferation and subsequently initiates a series of cellular and molecular responses that lead to bone formation in the condyles

The rapid development of recombinant DNA technology has led to the development of growth factor based approach. Using the specific gene encoding the protein, that now able to synthesize large quantities of the therapeutic proteins for treatment purpose. In the recent study[64] provides further evidence that local rAAV mediated VEGF (recombinant adeno-associated virus mediated vascular endothelial growth factor) gene transfer enhances the size of mandibular condyle leading to mandibular condylar growth. VEGF has been shown to play an important role in mandibular condylar growth. It is a potent regulator of neovascularization expressed during endochondral ossification of the condyle. Thus, it provides the basis to regulate mandibular condylar growth for future clinical application. In previous study[65] demonstrated that local administration of insulin-like growth factor (IGF-I) in the mandibular condyle of rats has been shown to induce actual bone formation.

This detailed exposition of the cellular and molecular events participating in bone formation in the condyle is a baseline data against which changes in condylar growth in response to functional appliance therapy could be compared. If the effect of functional appliance therapy on condylar growth is acceleration, then the expression of factors regulating key processes in condylar growth should be accelerated when compared with their expression during natural growth.

In the future, if the orthodontists can evaluate the numbers of individual's mesenchymal cells in the patients, it can be the one way to determine whether the response of the temporomandibular joint (TMJ) to functional appliances is merely an adaptive response or actual growth is to quantify the proliferative cells during functional appliance therapy and to follow and compare their temporal pattern of proliferation to that occurring throughout the somatic growth period. Moreover, the use of expression of factors can influences the growth potential of the condyle and the glenoid fossa and increase patient's response to growth modification therapy.

Effects to lateral pterygoid muscle

Later researches[10, 37, 38] has suggested that it might rather be the tension of the posterior part of the condylar capsule. Therefore, a constant reactivation of the appliance may be indicated to maintain a maximum condylar growth response and treatment intensity. This treatment response is considered to be the result of both skeletal and neuromuscular adaptations. It has been of great interest to investigate changes in the orofacial muscle activity during functional jaw orthopedic treatment. The first experimental study to consider both functional and morphological aspects of adaptation to functional appliance therapy was by McNamara.[66] This study revealed that, an increase in lateral pterygoid activity was associated with the forward repositioning of the mandible. The results of these studies indicated that the growth of the temperomandibular joint in young animal is somewhat adaptive in nature and that the condylar cartilage in such animals is responsive to changes in function. Many investigators have considered the lateral pterygoid muscle to be of critical importance in functional appliance therapy. Similarly, Easton and Carlson[66] provided empirical evidence of and alteration in the function of the lateral pterygoid muscles and the physiologic adaptation of this muscle to mandibular protrusion. This study that examined the relationship between neuromuscular and skeletal adaptations during functional jaw orthopedic therapy with the Herbst appliance, focusing on lateral pterygoid muscle activity. The increased activity of the lateral pterygoid muscles, seen immediately after insertion of the appliance, decreased markedly after 4 to 6 months of treatment. Result of a recent investigation[67] suggested that other muscles (eg. masseter) could affect condylar growth through the mechanical loading on the condyle.

Sagittal changes

Pancherz studies[4, 55] illustrates that in Herbst appliance group the ANB angle was significantly reduced. This was due to a reduction in the SNA angle and an increase in the SNB angle. The lower incisors proclined considerably in the patients treated with Herbst appliance, however, no changes in control group. Pancherz's study[55]indicated that Herbst treatment had only a temporary impact in the existing skeletofacial growth pattern. After the orthopedic interventive period maxillary and mandibular growth seemed to strive to catch up with their earlier patterns. The lower incisors are proclined and the maxillary molar are more posteriorly ,much as with a high-pull headgear.[31, 68] About 90% of post-treatment occlusal change occur during the first 6 months and are mostly of dental origin.

Hansen's study[68] has shown that on a long-term basis the basal jaw relationship is improved, but not normalized by treatment. The sagittal dental arch relationship, on the other hand, was almost normalized. The dental effects can compensate for an unfavourble jaw base relationship. An unfavourable maxillomandibular growth relationship contributes to only a minor degree in early post-treatment changes. The functional appliance group , on average, had the smallest ANB angle at the end of phase2 also had the lowest rate of surgery. The preliminary data from this trial suggest that early treatment may influence both the rate of extraction and the need for orthognathic surgery, but not in the pattern that might have been expected.[11]

Baltromejus *et al*[69] study demonstrated that both Activator and Herbst therapy compared with individuals with normal occlusion induce a skeletal mandibular treatment effect, however, in Herbst group, the TMJ and chin changes were more sagittally orientated. Thus, the Herbst appliance affects mandibular prognathism more favourbly and in a much shorter period of time than the Activator.

Vertical changes

The effects of the Herbst appliance on vertical facial dimension have been focus of attention in several articles.[8, 44, 70] Windmiller[71]and Ruf [72] showed that Herbst treatment is successful in both hypodivergent (small mandibular plane angle) and hyperdivergent (large mandibular plane angle) Class II subjects. On a long-term basis, Ruf and Pancherz[17, 72]demonstrated that the Herbst appliance in hypodivergent and hyperdivergent subjects had no influence on mandibular rotation. Furthermore no statistically significant differences were found between hypodivergent, nomodivergent and hyperdivergent subjects. In Class II malocclusions with deep bites, overbite maybe significantly reduced with Herbst therapy.[4, 68] The change results primarily from eruption of lower molars and intrusion of lower incisors. As noted before, proliferation of lower incisors contributes to the seeming intrusion of these teeth. The Herbst appliance had a pronounced effect on vertical tooth position. The mandibular incisors and maxillary molars were intruded during treatment while the mandibular molars were allowed to erupt freely. As a result of the dental changes the overbite was reduced, lower facial height was increases as well as the angulation of the maxillary and mandibular occlusal planes.[72]

Mandibular length

The patients treated with the Herbst appliance was significantly increased in mandibular length more than control group. The increase in mandibular length could possibly be due to condylar growth stimulation as an adaptive reaction to the forward positioning of the mandible. Thus, the change in the SNB angle may be a result of both an increase in mandibular length and forward displacement of the articular portion of the temporal bone. Besides a possible stimulating effect on mandibular growth, bite jumping seemed to have a restraining effect on maxillary growth.

Long term post-treatment changes

Several effects have been observed 5 to 10 years after treatment in patients treated with the Herbst appliance. A Class I dental arch relationship was maintained by a stable cuspal interdigitation of the upper and lower arched, whereas relapse tends to occur in cases with unstable occlusal conditions. Pancherz believed that long-term stability seems to be dependent on a stable cuspal interdigitation.[7] The most common combination of factors leading to varying degree of stability were a persisting lip-tongue dysfunction habit and unstable cuspal intercuspation after treatment.[53] However, in Pancherz's view, unfavorable posttreatment growth was not a significant factor for occlusal relapse. Pancherz believed that the unstable occlusion, not the timing, was responsible.[17] He noted, however, that the most favorable time to initiate treatment was during the peaks pubertal growth period. Pancherz was totally objective in his intensive and impressive long-term studies.[11]He noted form his own and a number of other studies that basal skeletal sagittal relationship was improved but not totally normalized, whereas the occlual relationship was essentially normalized. The implication was that the Herbst appliance was capable of producing sagittal changes that can compensate for aberrant skeletal relationships and continued functional retention may enhance stability.[4]

TMJ adaptation

In Pancherz's investigation only minor functional disturbances were found during treatment. Chewing problems were experienced only during the first week. Tenderness to palpation of the masticatory muscles and temporomandibular joints was minimal and of a temporary nature. Three adaptive processes in the temporomandibular joint (TMJ) are thought to be responsible for the increase in mandibular prognathism during Herbst treatment :1) increased condylar growth due to condylar remodeling, 2) anterior glenoid fossa displacement due to fossa remodeling, 3) anterior positioning of the condyle within the fossa.[72] Pancherz *et al*[73] revealed after Herbst treatment, the amount and direction of TMJ growth changes were only temporarily affected favorably in the sagittal direction. For glenoid fossa displacement changes, no differences existed between hypodivergent and hyperdivergent subjects. But condylar growth and effective TMJ change, on the other hand, were directed more posteriorly in hyperdivergent than in hypodivergent Herbst subjects during treatment and posttreatment.

Facial profile

The effects on the facial profile have also been studies by Pancherz and associates, In patients that were treated for 7 to 8 month and reexamined 5 to10 years after treatment , a general reduction of both hard and soft tissue profile convexity was note. The upper lip becomes less protrusive, whereas the lower lip remains almost unchanged. However, marked individual variations were noted.

Conclusions

The Herbst appliance is a powerful and effective functional system in the treatment of Class II malocclusion. Normalization of occlusion generally is accomplished in 6 to 8 months. According to this review articles, it is necessary to considerate the important factors such as type of anchorage[20, 21], amount of force[10, 35-38] or age at start of treatment[39-42] to obtain the maximal orthopedic improvement. It is important to use the total dentoalveolar area in both the maxillary and mandibular arches as anchorage for transferring forces to affect the interrelationship between maxillary and mandibular basal bones. Therefore, for better results the orthodontists should attempt to develop the system of fixed functional appliance for enhance the orthopedic effect and reduce orthodontic effect.

1.3 Objectives and specific aims

Objectives

1. To develop a new system of fixed functional appliance for enhancing the orthopedic effects.
2. To determine the treatment effects of PSU-fixed functional appliance.
3. To use as data base for clinical application.

Hypothesis

1. The amounts of orthopedic effects of PSU-fixed functional appliance were greater than orthodontic effects.

Benefits

1. To develop a new system of PSU-fixed functional appliance for enhancing the orthopedic effects (less orthodontic effects).
2. To use this data base as a guideline to decide to use functional appliance in the treatment of Class II malocclusion with retrognathic mandible.
3. To use growth modification to correct skeletal problem or decrease the severity in growing patients.
4. To reduce the cost of treatment: economic reason

CHAPTER 2

MATERIALS AND METHODS

2.1 Sampling selection

Thirty orthodontic patients, 9 boys and 21 girls, age range 9-13 year were randomly selected from Orthodontic clinic, Dental hospital, Faculty of Dentistry, Prince of Songkla University. The inclusion criteria for all subjects were:

- Good general health, no underlying disease.
- Bilateral Class II molar relationship.
- Skeletal Class II was determined when the patients protrude mandible anteriorly their facial appearance were straight profile or look better.
- During MP_3 stage (maximal pubertal growth not yet reached). The patients were assessed by hand & wrist radiographic examination. The epiphysial region of the middle phalanx of the third finger was analyzed, according to the method of Hagg and Taranger[74] (epiphysis equal to diaphysis).
- Complete eruption of the maxillary permanent first molars and mandibular permanent canines which was necessary for the appliance to be attached to the teeth safely.
- All patients were advanced the mandible while they still had growth of the mandible.

Exclusion criteria were:

- Loss of maxillary permanent first molars or mandibular permanent canines or some incisors
- During end stage of growth
- Unable to continue the treatment
- Risk to root resorption

When the patients were satisfied 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. Each patients who agreed to participate in our study signed in consent form.

The new patients who came in Orthodontic clinic, Dental hospital, Faculty of Dentistry, Prince of Songkla University and met the inclusion criteria were randomly included in control group. While, the patients in treated group were selected from the waiting lists.

1. Untreated group (control) : 3 boys and 12 girls were observed for 6-12 months.
2. Treated group (sample) : 6 boys and 9 girls were treated with fixed functional appliance until edge to edge position was achieved or overcorrected in Class I malocclusion.

2.2 Experimental design in sample patients

All patients were treated with upper and lower preadjusted edgewise appliance (Roth's prescription). The brackets were 0.018x0.025 inch slot in anterior teeth (2-2) and 0.022x0.028 inch slot with vertical slot in posterior teeth (3-6). The first stage of treatment was leveling until 0.018"x0.025" stainless steel wires in both arches. After that placed expansion wire which could be made from 1 mm. stainless steel wire overlay with main arch wire and inserted into headgear tubes on the upper molar bands. For patients with narrow arches could use expansion wire in order to expand upper arch. The goals of this phase were to align teeth and harmonize arch form prepared for mandibular advancement. By expanding the maxillary dental arch in order to allowing the mandible to move to a more comfortable anterior position, facilitating Class II correction.

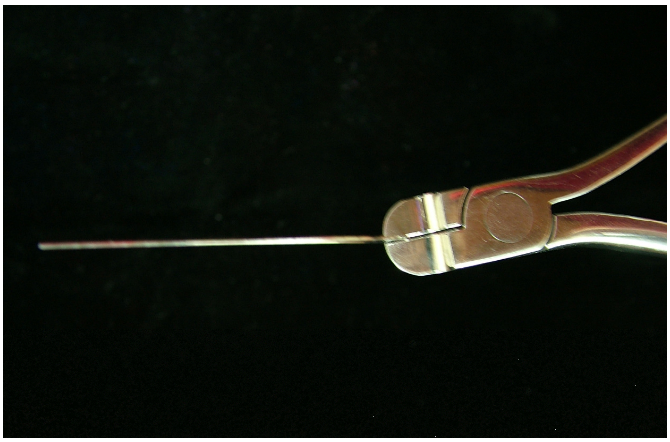


Fig. 2 For anchorage preparation, placed labial crown torque (about 10-15^{o}) in upper incisors while placed lingual crown torque in lower incisors.

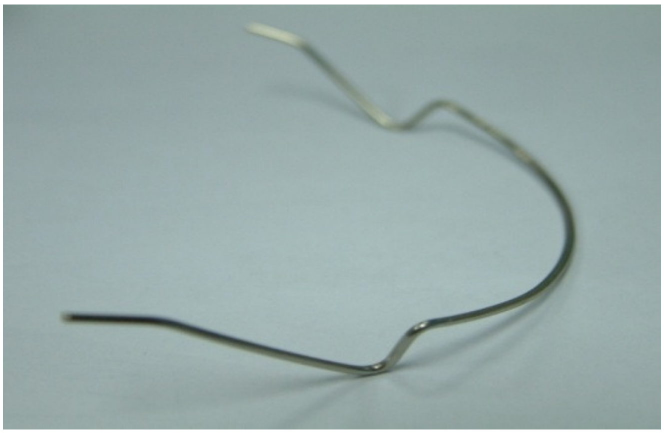


Fig. 3 Expansion wire made from 1 mm. stainless steel wire overlay with main arch wire for expand upper arch.

Fig. 4 Protraction wire with 2 circles ends for mandibular advancement.

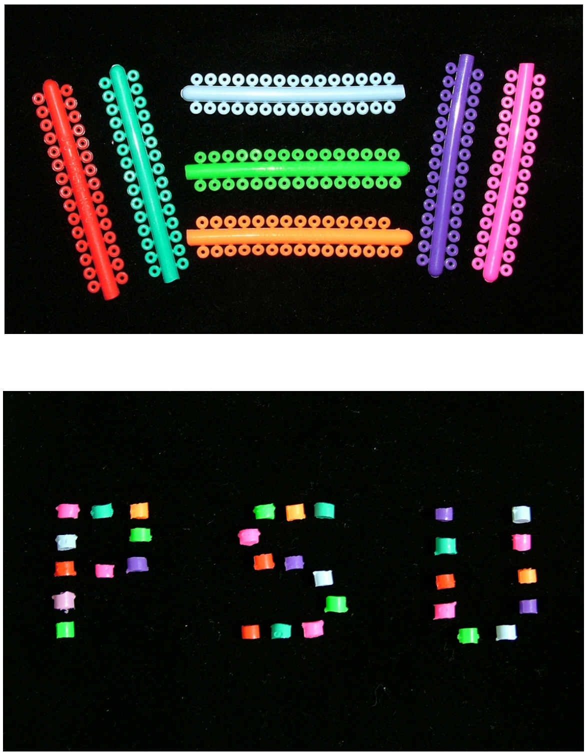


Fig. 5 Elastic stop, used as force absorber between protraction wire and the mandibular canine brackets.

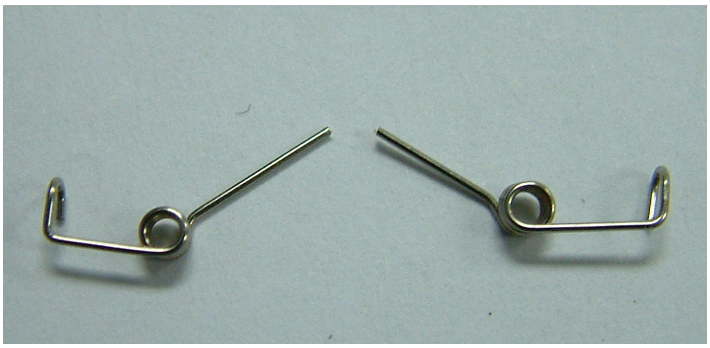


Fig. 6 Uprighting springs for increase anchorage in lower arch (distally tipping for lower canines).

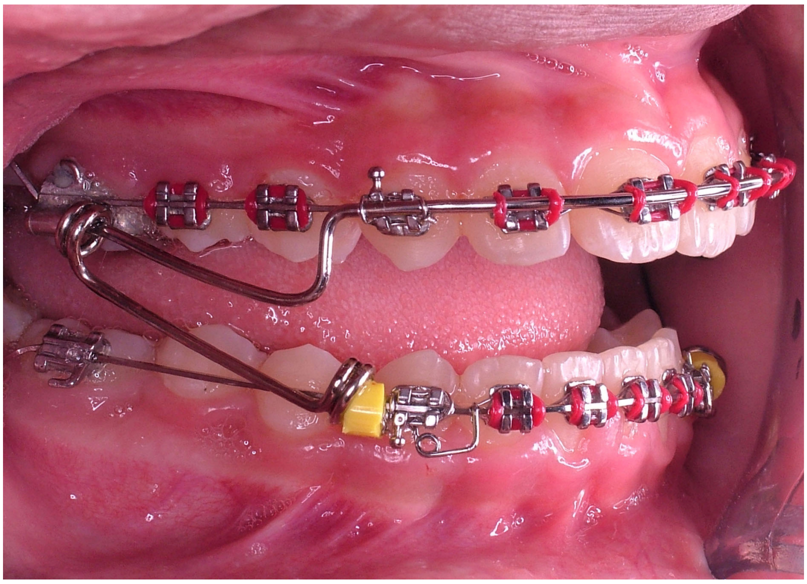


Fig. 7 Showed the components of PSU-fixed functional appliance.

For avoiding unwanted dental movement, good anchorage preparation should be carried out. The maxillary incisors were placed labial crown torque about 10-15° for increasing anchorage while the mandibular incisors were placed lingual crown torque to prevent tipping of these teeth.[22] The upper and lower arch wire should be cinched back to increase anchorage and minimized dentoalveolar movements. The uprighting springs were placed in the mandibular canine bracket vertical slots (distally tipping for lower canines).

These appliances were fixed on the upper and lower arches with protraction wire (1 mm. stainless steel wire) with 2 circles ends to advance the lower jaw. The distal circle was attached to the maxillary molars and the mesial end was placed over the mandibular archwire against the mandibular canine brackets. The length of protraction wire was estimated in centric occlusion. The elastic stop could be used as force absorber between protraction wire and the mandibular canine brackets. For each mandibular advancement by step-by-step advancement technique, the lower arch was advanced initially 2 mm. and thereafter, another elastic stop could be added approximately 2-3 mm. every 2 months. The patients were followed up every 2 months, with activations at each succeeding appointment until edge to edge incisors position was achieved.

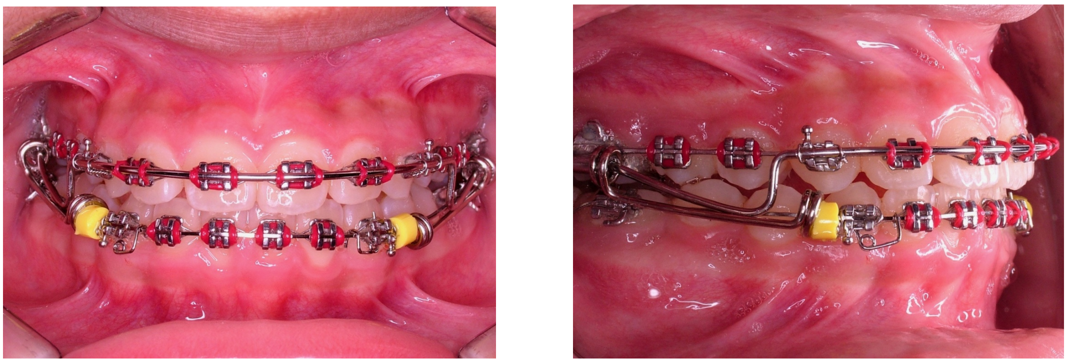


Fig. 8 The first activation for induced forward movement of mandible by step by step advancement.

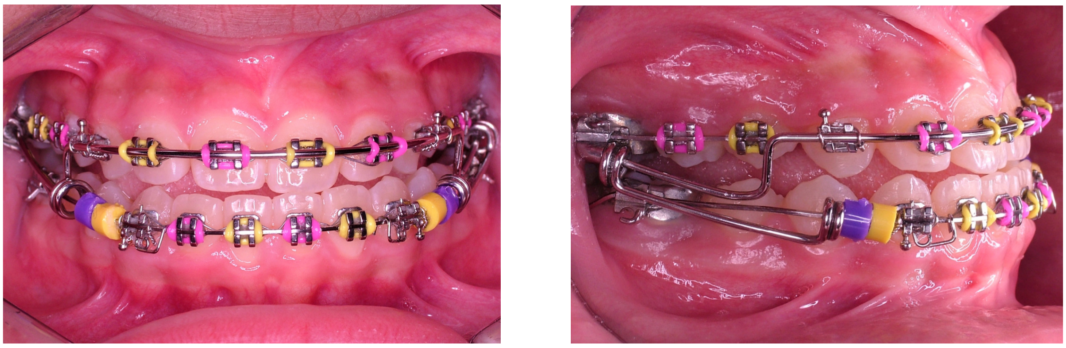


Fig. 9 The second activation, the elastic stop could be added approximately 2-3 mm. until edge to edge incisors position was achieved.

2.3 Data recording

Data recording of control group and sample group (initial record)

- Photo
- Study model
- X-ray (Lateral cephalogram, Hand & Wrist)

Data recording of sample group (Before insert PSU- FFA)

- Lateral cephalogram
- Insert PSU- FFA
- Follow up 2 weeks, 1 month, and every 2 months until overcorrection or edge to edge incisors position

Data recording of control group after observed for 6-9 months and treated group after treatment until become overcorrection or edge to edge incisors position (Final record)

Control group

- Photo
- Study model
- X-ray (Lateral cephalogram, Hand & Wrist)

Sample group

- Remove PSU- fixed functional appliance
- Photo
- Study model
- X-ray (Lateral cephalogram, OPG, Hand & Wrist)

2.4 Cephalometric analysis

The analysis of treatment effects (skeletal and dental changes) was investigated from the tracing of the lateral cephalogram before and after treated with PSU- fixed functional appliance. These data was compared with corresponding data from the control group. The cephalometric systems described by Pancherz[6, 31] were used to analyze the treatment effects. The landmarks were showed in Figure 10. The magnification factor of the lateral cephalograms was found to be similar for the treated and control groups. Therefore no standardization was needed. The measurement for each variable was made with cephalometric protractor. Linear measurements were made to the nearest 0.5 mm and angular measurements were made to the nearest 0.5^{o}which perform on acetate tracing paper.

Three relationships were assessed by using cephalometric analysis in this trial:

- Sagittal position changes of the maxillary and mandibular landmarks
- Vertical position changes of the maxillary and mandibular landmarks
- Angles (^{o})

The measuring points, reference points and reference lines were defined as follows[4,26]:

Measuring points

- Co (condyle) : The most superoposterior point on the curvature of the condylar head
- ii (incision inferius) : The incisal tip of the most prominent mandibular incisor
- is (incision superius): The incisal tip of the most prominent maxillary incisor
- mi (molar inferius) : The mesial contact point of the mandibular prominent first molar
- ms (molar superius) : The mesial contact point of the maxillary prominent first molar
- pg (pogonion) : The most anterior point on the body chin
- gn (gnathion) : The point between menton and pogonion
- ss (subspinale) : The deepest point on the anterior contour of the maxillary alveolar projection

Reference points

- n (nasion) : The most anterior limit of nasofrontalis suture
- s (sell) : The center of sella turcica. The point was used as registration point for all head film.

Reference lines

- NSL (nasion-sella line): The line through n and s. 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.

Measuring procedure

The profile radiographic analysis comprised the following variables :

Sagittal distances

1. is / OLp minus ii / OLp : overjet
2. ms / OLp minus mi / OLp : molar relation
3. ss / OLp : position of the maxillary base

4. pg / OLp : position of the mandibular base

5. co / OLp : position of the condylar head

6. gn / OLp + co / OLp : mandibular length

7. is / OLp : position of the maxillary central incisor

8. ii / OLp : position of the mandibular central incisor

9. ms / OLp : position of the maxillary permanent first molar

10. mi / OLp : position of the mandibular permanent first molar

Vertical distances

11. is / NL : position of the maxillary central incisor

12. ii / ML : position of the mandibular central incisor

13. ms / NL : position of the maxillary permanent first molar

14. mi / ML : position of the mandibular permanent first molar

Angles (^{o})

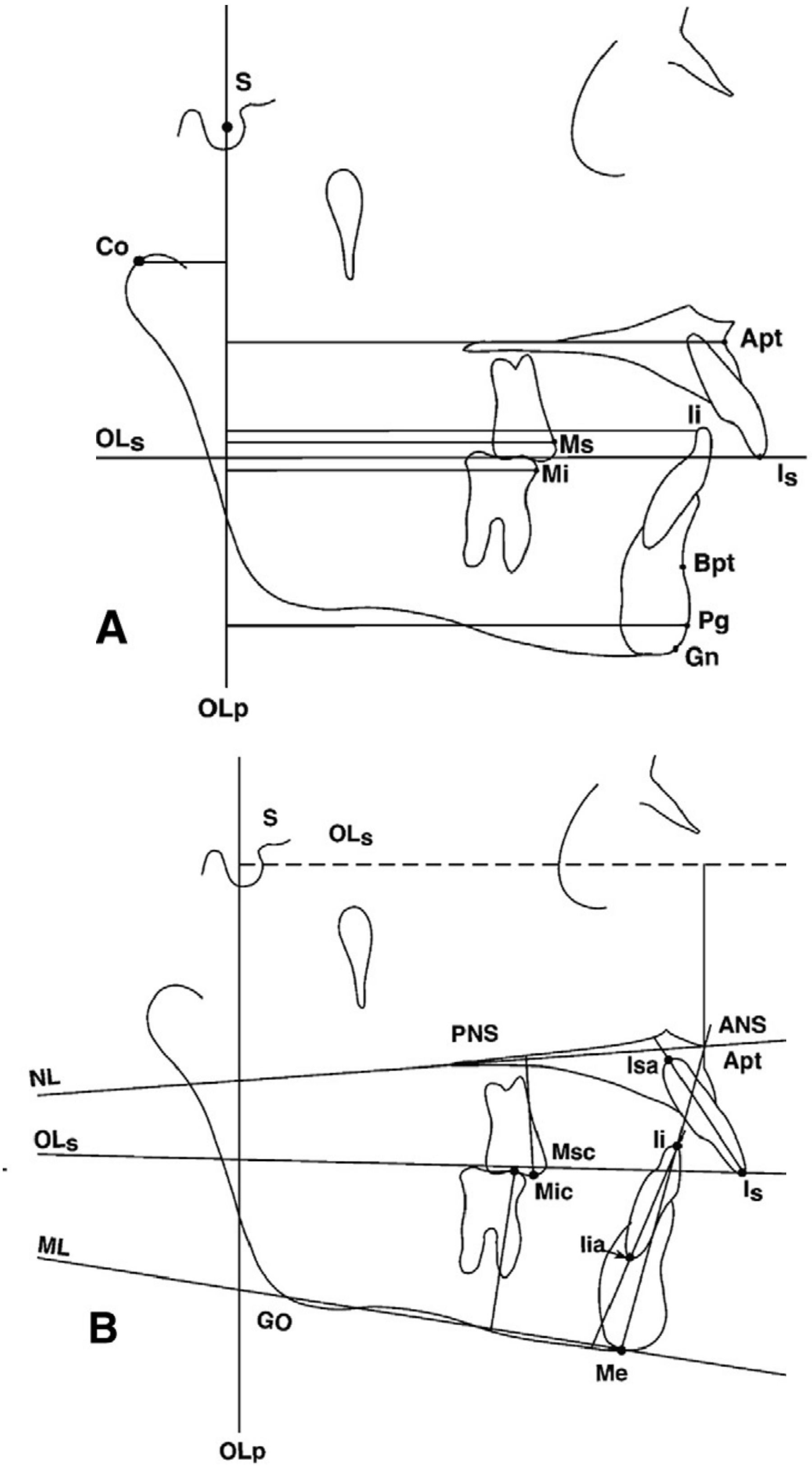
15. SNA : Maxillary position

16. SNB : Mandibular position

17. ANB : Sagittal jaw relation

18. UI to PP : Maxillary incisors inclination

19. LI to MP : Mandibular incisors inclination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OLp

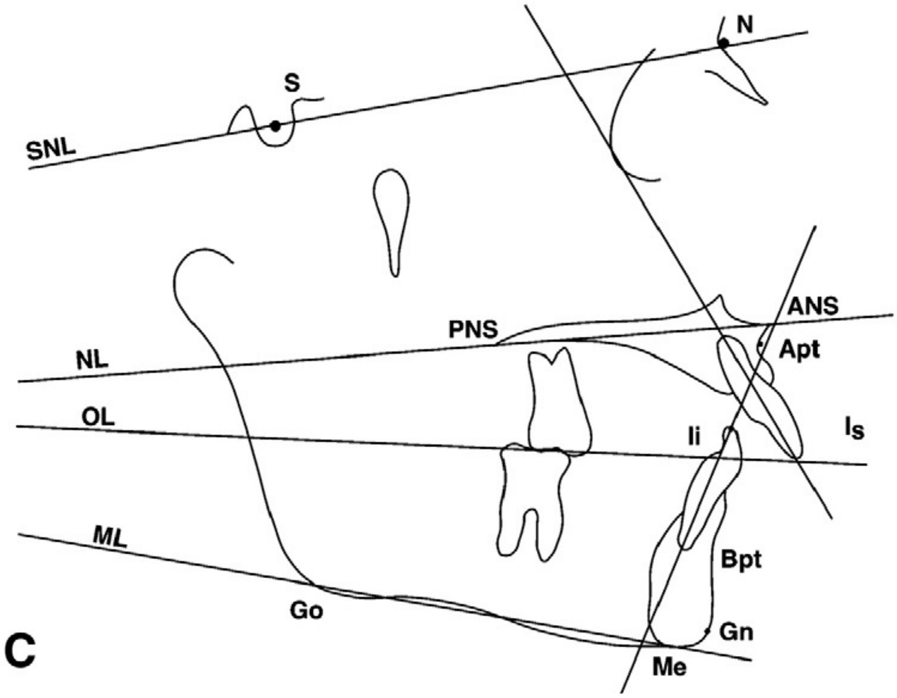

Fig. 10 Cephalometric landmarks for investigated treatment effects: A, Horizontal measurements; B, Vertical measurements; C, Angular measurements.

For all cephalometric landmarks with right and left images, the midpoint bisecting the 2 images was used. The analysis of the sagittal, skeletal and dental changes were recorded along the occlusal line (OL) and to the occlusal line perpendicular (OLp) from the first cephalogram were used as a reference grid. The grid was then transferred from the first tracing to the following tracings by superimposition of tracings on the midsagittal cranial structure.

2.5 Statistical analysis

Mean and standard deviation (SD) of subjects were calculated for all cephalometric variables. Means of cephalometric variable individuals at pre-treatment was T1, post-treatment was T2, pre-observe was C1, post-observe was C2. These data was compared means in difference within sample group (ΔT) and control group (ΔC). Between sample and control groups also were compared means in difference. The statistical comparisons were performed by means of nonparametric test: Mann-Whitney *U* test that were carried out with the aid of a commercial statistical package (SPSS for Windows). The difference of probabilities of less than 5%($P \leq 0.05$) was considered statistically significant.

Error measurement

The errors in locating, superimposing and measuring the changes of the reference points by 1 examiner were measured on the cephalograms. To assess the error of locating the and the digitizing procedure, 10 randomly selected cephalograms were retracted and remeasured after approximately four weeks by the same examiner. The casual error of the method by the Dahlberg formula[75] did not exceed 0.8^{o}or 0.6 mm.

The magnitude of the combined method error (ME) in locating, superimposing and measuring the changes of the different cephalometric landmarks was calculated with the formula

$$ME=\sqrt{(\varepsilon d^2/2n)}$$

where *d* was the difference between 2 registrations of a pair, *n* was the number of double measurements. The error in this study was found to be 0.25 mm (range, 0 to 0.50 mm) for linear measurements, 0.33° (range, 0° to 1.0°) for angular measurements.

2.6 Table of outcome

Cephalometric variables	C1	C2	Control different (ΔC)	T1	T2	Treatment different (ΔT)	$\Delta T - \Delta C$	Sig ($p \leq 0.05$)
Sagittal distances								
1. Overjet								
2. Molar relation								
3. Maxillary base								
4. Mandibular base								
5. Condylar head								
6. Mandibular length								
7. Maxillary incisor								
8. Mandibular incisor								
9. Maxillary molar								
10.Mandibular molar								
Vertical distances								
11. Maxillary incisor								
12. Mandibular incisor								
13. Maxillary molar								
14. Mandibular molar								
Angle(^{o})								
15. SNA								
16. SNB								
17. ANB								
18. UI to PP								
19. LI to MP								

CHAPTER 3

RESULTS

This study was designed to develop a new system of fixed functional appliance to enhance the orthopedic effect and improve mandibular anchorage by approaching to reduce orthodontic effect and investigate skeletal and dental changes in patients treated with PSU-fixed functional appliance. All patients were divided into two groups. The control group consisted of fifteen healthy patients, three boys and twelve girls with mean 11 years 2 months of age at pre-observed period. Each patient had bilateral Class II molar relationship, none of subjects had passed maximal pubertal growth, as assessed by a radiographic examination of hand[74] and no orthodontic treatment was performed during follow up period. In this group, all subjects were investigated growth changes for 7 months in average by analysis of lateral cephalogram from before and after follow up period, according to the method of Pancherz.[6] The subjects mean and standard deviation (SD) were calculated for all cephalometric variables. Between sample and control groups also were compared means in difference. After each variable of results were analyzed by plotting in the histogram curve with normal curve, it found that the data was not the normal distribution curve therefore nonparametric statistical test was used to analyze in this study. The difference of probabilities of less than 5% ($P \leq 0.05$) was considered statistically significant.

The comparison of cephalometric records before (C1) and after (C2) follow-up period was presented in Table I. No statistically significant differences between before and after follow-up period were found in all cephalometric variables. From the representing normal growth changes in Table I, the results could be defined as follows.

Sagittal changes

Sagittal changes in control group was compared in Table I. Overjet reduced 0.1 mm. while molar relationship became more class I 0.4 mm. Both maxillary base (OLp-Apt) and mandibular base (OLp-Pg) moved forward 0.4 and 0.6 mm. respectively. Mandibular length (Co-Gn) increased 1.3 mm. during follow-up period.

Table 1 Comparison of cephalometric records before and after follow-up period (6-12 months)

Variables (mm.)	Control group (n=15)						Sig. (p ≤0.05)
	C1		C2		Control different (ΔC)		
	Mean	S.D.	Mean	S.D.	Mean	S.D.	
Sagittal distances							
1. Overjet	8.20	3.65	8.23	3.72	0.03	0.44	0.983
2. Molar relation	-0.13	1.88	-0.53	1.93	-0.40	0.43	0.401
3. Maxillary base	78.50	5.08	78.90	5.19	0.40	0.34	0.755
4. Mandibular base	82.20	6.93	82.80	7.21	0.60	0.57	0.708
5. Condylar head	8.77	2.78	9.13	2.48	0.37	0.58	0.677
6. Mandibular length	88.10	4.67	89.43	5.14	1.33	0.88	0.204
7. Maxillary incisor	91.17	7.46	91.97	7.68	0.80	0.59	0.506
8. Mandibular incisor	82.97	6.79	83.73	7.11	0.77	0.46	0.575
9. Maxillary molar	55.70	6.14	56.27	6.19	0.57	0.59	0.663
10. Mandibular molar	55.83	6.06	56.77	6.09	0.93	0.75	0.561
Vertical distances							
11. Maxillary incisor	27.37	2.89	27.83	3.09	0.47	0.44	0.472
12. Mandibular incisor	41.33	2.49	42.03	2.47	0.70	0.68	0.333
13. Maxillary molar	20.43	2.01	21.13	1.98	0.70	0.53	0.187
14. Mandibular molar	29.30	2.72	29.83	2.53	0.53	0.35	0.428
Angles(^{o})							
15. SNA	83.87	2.39	84.07	2.38	0.20	0.41	0.752
16. SNB	78.03	2.39	78.30	2.39	0.27	0.37	0.707
17. ANB	5.83	1.99	5.77	2.08	-0.07	0.26	0.900
18. UI to PP	123.37	7.78	123.40	7.32	0.03	0.79	0.917
19. LI to MP	95.60	5.96	96.00	5.86	0.40	0.69	0.818

For the angular measurement, the position of the maxilla (SNA) and mandible (SNB) relative to the cranial base increased 0.2^{o} and 0.3^{o} respectively. ANB angle had a decrease of 0.1^{o}

For the dental changes, the maxillary (Is/OLp) and mandibular (Ii/OLp) incisor showed forward movement of 0.8 and 0.77 mm. respectively. The maxillary and mandibular molars also moved forward 0.6 and 0.9 mm. respectively. The maxillary incisor angle (UI to PP) moved labially 0.03^{o} whereas the mandibular incisor angle (LI to MP) proclined 0.4^{o} during observation.

Vertical changes

For the dental changes, the maxillary incisor (is/PP) moved downward 0.5 mm. and the mandibular incisor (ii/ML) exhibited extrusive movement of 0.7 mm. The maxillary molar (ms/NL) also moved downward 0.7 mm. and the mandibular molar (mi/NL) extruded 0.5 mm. during follow-up period.

In treated group, fifteen other subjects (six boys and nine girls) with mean age of 11 years 11 months and with the same type of malocclusion and dental morphology as the control group were used as a sample group. The average of treatment time was 7 months. The comparison of starting craniofacial morphology of treated and control subjects was showed in Table II and no statistically significant differences between treated and control groups were found in all cephalometric variables.

After treatment, we founded the significant differences of 4 variables which were overjet, molar relation, mandibular incisors position (sagittal distances) and ANB angle as showed in Table III. The treatment result has improved the occlusion which can be defined as follows

Sagittal changes

Sagittal changes in treated group were compared in Table III. The use of PSU-fixed functional appliance induced forward movement of the mandibular base (OLp-Pg) 4.2 mm. The position of the condyle (OLp-Co) was maintained with treatment. Effective mandibular length (Co-Gn) increased 3.6 mm. during treatment.

Table 2 Comparison of starting craniofacial morphology of treated and control subjects

Variables (mm.)	Control group (n=15)		Treated group (n=15)		Sig. ($p \leq 0.05$)
	Mean	S.D.	Mean	S.D.	
Sagittal distances					
1. Overjet	8.20	3.65	8.73	2.05	0.253
2. Molar relation	-0.13	1.88	-0.1	1.80	0.983
3. Maxillary base	78.50	5.08	81.30	4.72	0.184
4. Mandibular base	82.20	6.93	83.17	7.42	0.836
5. Condylar head	8.77	2.78	9.23	3.47	0.868
6. Mandibular length	88.10	4.67	91.30	6.20	0.253
7. Maxillary incisor	91.17	7.46	93.57	6.63	0.493
8. Mandibular incisor	82.97	6.79	84.87	4.98	0.418
9. Maxillary molar	55.70	6.14	57.73	6.99	0.455
10. Mandibular molar	55.83	6.06	57.80	6.96	0.418
Vertical distances					
11. Maxillary incisor	27.37	2.89	27.37	2.98	0.884
12. Mandibular incisor	41.33	2.49	40.87	2.95	0.572
13. Maxillary molar	20.43	2.01	21.03	1.66	0.542
14. Mandibular molar	29.30	2.72	29.47	2.38	0.917
Angles(^{o})					
15. SNA	83.87	2.39	84.23	4.48	0.802
16. SNB	78.03	2.39	78.13	4.01	0.677
17. ANB	5.83	1.99	6.10	1.48	0.601
18. UI to PP	123.37	7.78	123.20	5.41	0.560
19. LI to MP	95.60	5.96	98.13	5.02	0.170

Table 3 Comparison of cephalometric records before and after treated with PSU-fixed functional appliance

Variables (mm.)	Treated group (n=15)						Sig. (p ≤0.05)
	T1		T2		Tx. different (ΔT)		
	Mean	S.D.	Mean	S.D.	Mean	S.D.	
Sagittal distances							
1. Overjet	8.73	2.05	2.93	1.09	-5.80	2.06	0.000**
2. Molar relation	-0.1	1.80	-4.10	1.31	-4.00	1.87	0.000**
3. Maxillary base	81.30	4.72	81.70	4.75	0.40	0.74	0.803
4. Mandibular base	83.17	7.42	87.33	8.58	4.17	2.05	0.135
5. Condylar head	9.23	3.47	9.23	3.43	0.00	0.71	1.000
6. Mandibular length	91.30	6.20	94.93	7.11	3.63	1.99	0.164
7. Maxillary incisor	93.57	6.63	93.60	6.71	0.03	1.08	0.901
8. Mandibular incisor	84.87	4.98	90.67	6.37	5.80	2.46	0.026*
9. Maxillary molar	57.73	6.99	58.57	7.59	0.83	2.23	0.678
10. Mandibular molar	57.80	6.96	62.67	7.42	4.87	2.92	0.097
Vertical distances							
11. Maxillary incisor	27.37	2.98	28.20	3.01	0.83	1.37	0.360
12. Mandibular incisor	40.87	2.95	40.80	3.10	-0.07	0.99	0.867
13. Maxillary molar	21.03	1.66	20.73	2.11	-0.03	1.22	0.769
14. Mandibular molar	29.47	2.38	31.10	2.58	1.63	0.99	0.080
Angles(°)							
15. SNA	84.23	4.48	83.93	4.51	-0.30	0.92	0.818
16. SNB	78.13	4.01	80.07	3.88	1.93	0.68	0.163
17. ANB	6.10	1.48	3.87	1.56	-2.23	0.96	0.001**
18. UI to PP	123.20	5.41	120.93	6.43	-2.27	5.91	0.547
19. LI to MP	98.13	5.02	101.27	7.68	3.13	5.63	0.198

For the angular measurement, the position of the maxilla relative to the cranial base (SNA) had a decrease 0.3° during treatment. The treatment induced forward movement of the mandible 1.9° relative to the cranial base (SNB). ANB angle had a decrease of 2.2°

For the dental changes, the mandibular incisor (Ii/OLp) showed forward movement of 6 mm. after treated with PSU-fixed functional appliance. Overjet improved significantly, showing a decrease of 5.8 mm. after treatment. The maxillary and mandibular molars were moved forward 0.8 and 5 mm. respectively. The molar relationship was altered significantly, with a change of 4 mm. during treatment resulting from forward movement of the mandibular molars. The maxillary incisor angle (UI to PP) moved lingually 0.3° while the mandibular incisor angle (LI to MP) proclined 3.1° during treatment. No statistically significant differences were found in the inclination of lower incisors.

Vertical changes

For the dental changes, the maxillary incisor (is/NL) was extruded 0.8 mm. and the mandibular incisor (ii/ML) exhibited intrusive movement of 0.1 mm. during treatment. The maxillary molar (ms/NL) was intruded 0.03 mm. during treatment while the mandibular molar (mi/NL) was extruded 1.6 mm. during treatment.

The relationship between skeletal and dental changes contributing to Class II correction in the molar and incisor segments was seen in Fig 12. From the representing treatment effects in Table IV, the group differences for the different variables were considered to represent the treatment effects of the PSU-fixed functional appliance. The result can be defined as follows

Sagittal changes

Sagittal changes in patients in treatment and control group were compared in Table IV. Compared with the control group, the treatment effects could maintain the maxillary base (OLp-Apt) while the mandibular base moved forward 3.6 mm. The position of the condyle (OLp-Co) was found to move forward 0.4 mm. Effective mandibular length (Co-Gn) increased 2 mm. during treatment compared with the control group.

For the angular measurement, the position of the maxilla relative to the cranial base (SNA) had a decrease during treatment (0.5°) compared with the control group. The treatment induced forward movement of the mandible (1.7°) relative to the cranial base (SNB). ANB angle had a decrease of 2.2°

For the dental changes, the maxillary incisor (Is/OLp) showed backward movement of 0.8 mm. after treatment compared with the control group. Treatment effects on the position of the mandibular incisor (Ii/OLp) showed forward movement of 5 mm. with treatment. Overjet improved significantly, showing a decrease of 5.8 mm. during treatment resulting from forward movement of the mandibular incisors and backward movement of the maxillary incisors. The maxillary and mandibular molars were moved forward 0.3 and 3.9 mm. respectively compared with the control group during treatment. The molar relationship was altered significantly, with a change of 3.6 mm. during treatment.

The maxillary incisor angle (UI to PP) moved lingually 2.3° but the mandibular incisor angle (LI to MP) proclined 2.7° during treatment. No statistically significant differences were found in the position of lower incisors.

A

B

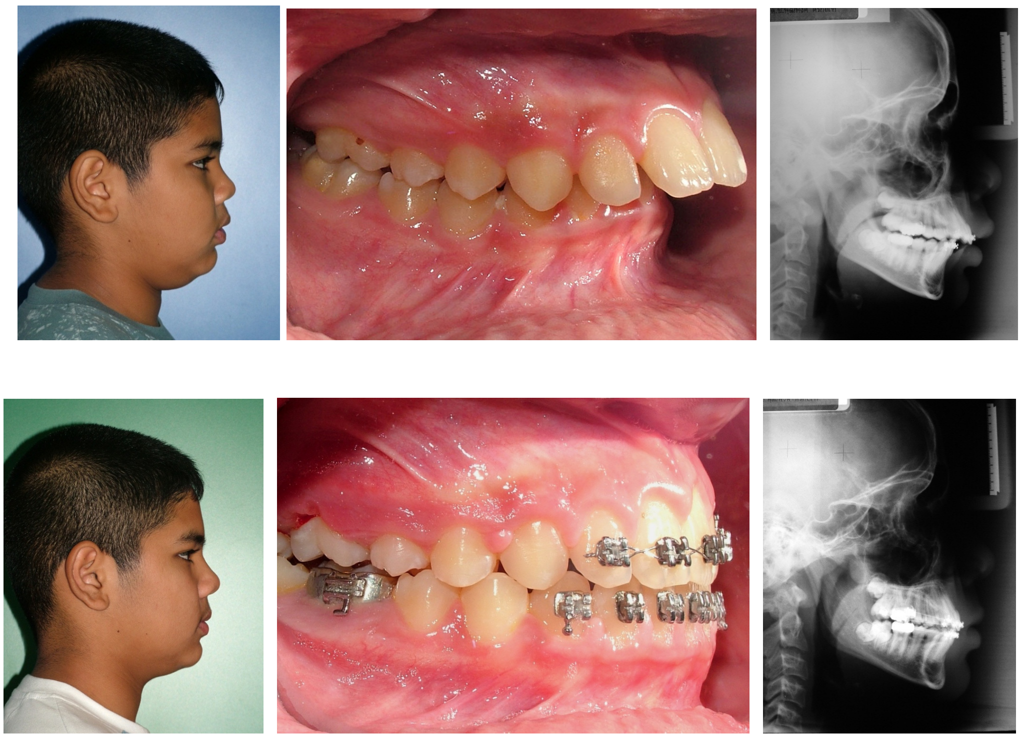

Fig. 11 Extraoral photographs, intraoral photographs (lateral view), lateral cephalogram of boy patient, 13 years of age, treated with PSU-FFA.

A, Before treatment. **B,** After treatment, when the appliance was removed.

A

B

Fig. 12 Extraoral photographs, intraoral photographs (lateral view), lateral cephalogram of girl patient, 10 years of age, treated with PSU-FFA.

A, Before treatment. **B,** After treatment, when the appliance was removed.

Vertical changes

For the dental changes, the maxillary incisor (is/NL) was extruded 0.4 mm. while the mandibular incisor (ii/ML) exhibited intrusive movement of 0.8 mm. compared with the control group during treatment. The maxillary molar (ms/NL) was intruded 0.7 mm. during treatment while the mandibular molar (mi/NL) was extruded 1.1 mm. during treatment.

Table 4 Changes in cephalometric records during the examination period in thirty cases

Variables (mm.)	Treated (ΔT) (n=15)		Control (ΔC) (n=15)		Group difference (Treatment effect)	
	Mean	S.D.	Mean	S.D.	Mean	S.D.
Sagittal distances						
1. Overjet	-5.80	2.06	0.03	0.44	-5.83	0.000**
2. Molar relation	-4.00	1.87	-0.40	0.43	-3.60	0.000**
3. Maxillary base	0.40	0.74	0.40	0.34	0.00	0.659
4. Mandibular base	4.17	2.05	0.60	0.57	3.57	0.000**
5. Condylar head	0.00	0.71	0.37	0.58	-0.37	0.282
6. Mandibular length	3.63	1.99	1.33	0.88	2.30	0.000**
7. Maxillary incisor	0.03	1.08	0.80	0.59	-0.77	0.011*
8. Mandibular incisor	5.80	2.46	0.77	0.46	5.03	0.000**
9. Maxillary molar	0.83	2.23	0.57	0.59	0.26	0.834
10. Mandibular molar	4.87	2.92	0.93	0.75	3.94	0.000**
Vertical distances						
11. Maxillary incisor	0.83	1.37	0.47	0.44	0.36	0.548
12. Mandibular incisor	-0.07	0.99	0.70	0.68	-0.77	0.021*
13. Maxillary molar	-0.03	1.22	0.70	0.53	-0.73	0.013*
14. Mandibular molar	1.63	0.99	0.53	0.35	1.10	0.003*
Angles(°)						
15. SNA	-0.30	0.92	0.20	0.41	-0.50	0.091
16. SNB	1.93	0.68	0.27	0.37	1.66	0.000**
17. ANB	-2.23	0.96	-0.07	0.26	-2.16	0.000**
18. UI to PP	-2.27	5.91	0.03	0.79	-2.30	0.358
19. LI to MP	3.13	5.63	0.40	0.69	2.73	0.090

<u>The relationship between skeletal and dental changes of treated group compared to control group</u>

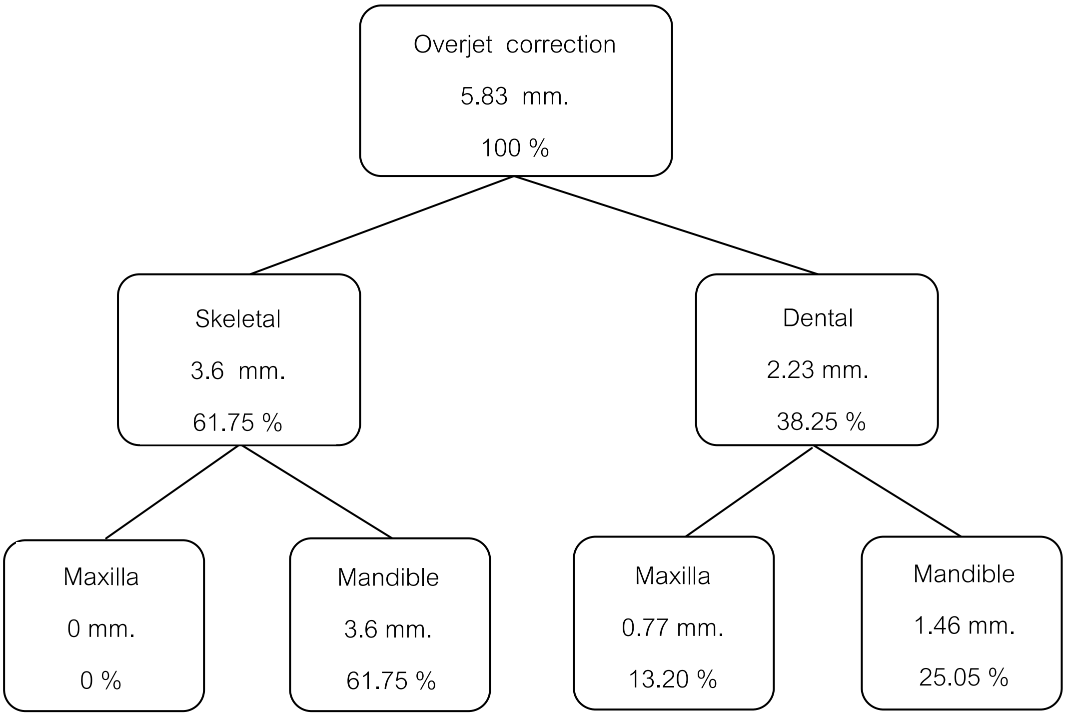

Fig. 13 Show the skeletal and dental contributions to overjet correction. During treatment, overjet correction was 5.83 mm. compared with the control group, 61.75% of this was due to skeletal changes and 38.25% to dental changes.

CHAPTER 4

DISCUSSION

As a new intervention, treatment response to the PSU-fixed functional appliance (PSU-FFA) has not been reported. Our objective was to investigate skeletal and dental changes in patients with Class II malocclusions treated with the PSU-FFA. The present study was conducted in 30 young patients with Class II, division1 malocclusion during the skeletal maturity stages MP3. The subjects were divided into two groups. In treated group, the subjects were treated with the new system of fixed functional appliance, that is so-called PSU-fixed functional appliance (PSU-FFA)[76]. The average of treatment time was 7 months. All subjects were treated with upper and lower preadjusted edgewise appliance combined with PSU-FFA. After an average of PSU-FFA treatment for 7 months, all subjects developed edge to edge position of the incisors or facial appearance was improved to straight profile. In control group, all subjects were not treated. The treatment effects of this appliance could be estimated by deducting the growth changes obtained from control group which also has been observed for 7 months in average. Compared to many previous studies[4, 6, 10, 22, 35, 56, 71], our treatment times were approximately from 6 to 12 months which were comparable to our study. Studies of the Herbst appliance also have consistently shown that mandibular growth was enhanced during the short treatment time for 5 to 7 months only.[4, 5, 11, 12]

From the control group results (Table I), showed small improvements and large individual variations. Some patients improved, some remained unchanged and other get worse. The improvement seen in molar relationship was 0.4 mm. Both maxillary and mandibular base had forward growth whereas mandibular base growth was greater than maxillary base (0.6 and 0.4 mm. respectively). It may be assumed that the condylar growth was regularly taken place at this pubertal growth spurt whereas maxillary growth was already passed.[7, 40] Both of SNA and SNB has demonstrated the same amount of forward growth which resulting in no change of ANB. The inclination of maxillary incisors were not changed whereas mandibular arch showed flaring of mandibular incisors due to a dental compensation for the skeletal discrepancy.

From treatment group results (Table II), the molar relationship and overjet were each improved by 4.0 and 5.80 mm. respectively. There were orthopedic effects in both the maxilla and the mandible producing improvement in skeletal convexity and jaw base relationships. It has showed that the PSU-FFA had the ability to inhibit maxillary anteroposterior growth and to increase growth in mandibular base. There were also increased in mandibular length which was possible resulted from both of anteroposterior growth of condyle (Co) and mandibular base. The forward position of the mandible found after PSU-FFA was mainly a result of an increase in mandibular length supported by several studies[5, 6, 34] which thought to be due to condylar growth stimulation as an adaptive reaction to the forward positioning of the mandible. This would be in agreement with several animal bite jumping experiments in cellular level.[14, 37, 38, 58, 59, 61, 62, 77, 78] This might be a result of remodeling process in the articular fossa as a compensatory reaction following an anterior displacement of the mandible.

The Class II skeletal correction was achieved by forward mandibular growth (SNB=+1.93^{o}) and minimal inhibition of maxillary growth (SNA=-0.3^{o}) which leaded to significant reduction of ANB.

In this study, significant decreased in the amount of overjet were observed. This reduction of overjet was due to maxillary base retrusion, mandibular base protrusion and mandibular incisors forward movement. However, the mandibular plane in treated group was, on average, tend to open about 1^{o} after treatment. The most of samples were counterclockwise rotation (8 subjects), only 4 of all subjects were clockwise rotation. For this reason, it might influence the inclination of mandibular incisors. In some cases, the proclination of mandibular incisors were observed and assumed that was the result from mandibular plane angle changed. As a result of the observed in vertical dimension, the mandibular plane (SN-GoMe) was not affected significantly. Similar findings have been reported by another investigators.[31, 34, 72, 79] In our study, there was a tendency for a counterclockwise rotation of the mandibular plane.

The treatment effect results in this study were estimated by treatment group results deducting with the growth changes in control group (ΔT-ΔC) revealed in Table IV. The improvement seen in sagittal occlusal relationship was higher in skeletal effects (61.75%) than dental effects (38.25%). The position of the maxilla did not change significantly. This indicated that its normal forward growth was significantly restrained as headgear effects.[4, 5, 10, 80] While the mandibular base was improved significantly. The lower jaw moved forward 3.57 mm. during treatment compared with the control group. Since the appliance affects the maxilla minimally, it should not be used when the Class II malocclusion is due to a protracted maxilla.

The combination of restraining maxillary growth and enhancing mandibular growth with PSU-FFA treatment resulted in significant improvements in overjet, molar and jaw-base relationships. Of the 5.83 mm. of overjet change, 61.75% was contributed by skeletal changes and 38.25% by dental changes. Our study has received more efficiency than other studies with the same treatment time (6-8 months) that reported about 50% of the changes from skeletal changes.[5, 10, 80, 81]

Table 5 Skeletal and dental components of Class II molar correction with Herbst appliance compared to PSU-fixed functional appliance

Authors	Tx.time (mo)	Skeletal change	Dental change	Mandibular base change
Lawviriyakul *et al* 2008	7	61.75%	38.25%	3.6 mm.
Pancherz *et al*[6] 1982	6	56.0%	44.0%	2.5 mm.
Hagg *et al*[10] 2002	6	48.28%	51.72%	1.7 mm.
VanLaeken *et al*[22] 2006	8	36.90%	63.10%	1.7 mm.
Pancherz *et al*[4] 1979	6			2.2 mm.
Valant *et al*[79] 1989	10			1.3 mm.
Lai *et al*[82] 1998	12			2.2 mm.
De Almeida *et al*[56] 2005	12			1.6 mm.

The skeletal and dentoalveolar contributions to Class II molar correction during Herbst therapy derived from previous studies were listed in Table V.[4, 6, 10, 56, 79, 82] In these studies, there was a variation in the skeletal and dental changes. The skeletal effects were reported to range from an average of 36.90% in study by VanLaeken *et al*[22] to 56.0% in the study by Pancherz *et al*[6] whereas dental change has been showed between 44.0%[6] to 63.10%.[22] The treatment time were approximately 10 months. The amount of mandibular base forward movement were approximately 2.2 mm. In our study, on average, there is enhanced sagittal growth of the mandible when using the PSU-FFA (3.57 mm.), but this effect varies between individual patients (from 2 to 9 mm. during 7 months of treatment in everage). Therefore, our study was found that the use of PSU-FFA enhance skeletal effect more than other previous studies.

The short and long term effects of Herbst appliance treatment in Class II Division 1 malocclusions have been investigated in many studies.[4-6, 53, 68] The restraining effect on maxillary growth has been reported to be of minor importance in improving maxillomandibular relationships.[4-6, 8, 34] In contrast, previous Herbst studies have documented significant increased in mandibular length compared with untreated controls. These increased in mandibular length ranged from 2.0-2.2 mm. for a six-month period for the banded appliance[5, 6] and from 2.7 to 3.5 mm. for a one-year treatment period for the acrylic splint Herbst appliance.[34] In our study, PSU-fixed functional appliance can increase mandibular length 2.3 mm. within 7 months.

Our study showed no change in maxillary incisors inclination and position during treatment because the labial crown torque used in the main arch wire to counteract the distal force of the appliance while the mandibular incisors position had significantly mesial movement caused by forward growth of mandibular base. In vertical direction, maxillary molars and mandibular incisors were intruded which may be resulted from the effect of appliance by telescopic mechanism and the torquing effects of maxillary and mandibular main arch wire. In contrary, the mandibular molars were extruded that was possible the result from the reaction force of lower main arch wire and normal vertical growth.

Slightly retroclination of the maxillary incisors and proclination of mandibular incisors were noted, the results demonstrated unwanted tooth movement effect and loss of anchorage in anterior teeth. McNamara *et al*[34] reported that the upper incisors move slightly lingually (1.4 mm) relative to the untreated controls, whereas Windmiller[71] observed that the maxillary incisors tipped lingually 4.3^{o}. Consequently the mandibular advancement was limit.

The dental changes seen during PSU-FFA treatment were basically result of anchorage loss in both dental arches. The telescope mechanism[4, 6, 20] produced a posterior-directed force on the upper teeth and an anterior-directed force on the lower teeth, resulting in distal tooth movements in the upper posterior segments and mesial tooth movements in the mandible. The distal movements of the upper molars, in contrast to the normal growth pattern in which these teeth migrate mesially through the alveolar processes, indicate that the Herbst appliance has a pronounced distalizing effect on the maxillary molars.[6, 8, 34, 71, 83] Significant proclination of the mandibular incisors was found in the Herbst group. This proclination of the mandibular incisors probably is a consequence of the resultant mesial force on the lower incisors induced by the telescoping mechanism of the Herbst appliance that produced a downward and forward vector of force. Our observation corroborated the results of Pancherz,[4] who found an increase in IMPA of 5.4^{o} but less proclination in our study (2.73^{o}).

Vertically, maxillary molars and mandibular incisors were intruded similar to previous study.[4, 68, 72] In addition, the eruption of the maxillary posterior teeth were inhibited by the appliance.[8, 79, 82]However, the mandibular molars were allowed to erupt freely. When jumping the bite, occlusal contacts existed only between the incisors while the posterior teeth were out of occlusion. Thus, vertical tooth eruption and growth in the posterior teeth were allowed to take place freely.

Regarding to treatment timing, the study was introduced at permanent dentition stage. After PSU-FFA treatment, all subjects were obtained stable occlusion and interdigitation. However, it is necessary to use of Class II elastics with edgewise appliance to maintain positive growth pattern and prevent relapse. In 1985, Pancherz[40] revealed that we should treat the patient in permanent dentition stage because this stage of dental development makes it possible to obtain a stable cuspal interdigitation after therapy that will counteract an occlusal relapse. Since good retention depends on sharp-cusped bicuspids to stabilize the correction, the absence of bicuspids at the conclusion of functional therapy jeopardizes the retention. The maturation level of the patients was certainly an important factor in the favorable treatment response found. Pancherz and Hagg[40] suggested that Herbst therapy be instituted close to peak height velocity to increase in condylar growth response and to reduce time of posttreatment retention. Franchi *et al*[83] indicated a favorable and clinically significant mandibular increase produced by the acrylic splint Herbst appliance when the patients began treatment at peak of mandibular growth (CVM stage 3 and 4). McNamara *et al*[84] examined a large group of patients treated with the FR-2 appliance of Frankel. Mandibular length increased by 6.4 mm during a two-year period in the younger age group (~8.5 years at the beginning of treatment) and 8.0 mm in the older age group (~11.5 years).

The unwanted movement of the lower incisors were regularly associated with the anterior directed force exerted to the lower anterior teeth by telescopic mechanism was planned to avoid by mandibular anchorage preparation. It should be prevented especially in those with an initial incisor proclination. We were placing labial crown torque in upper anterior teeth and lingual crown torque in lower anterior teeth, however there was proclination of lower incisors that may be the results of the lower canine angulation was improper. When the crown of lower canine tipped forward, the anchorage also reduced. Eventhough, the uprighting springs were placed to reduce this mesial tipping of anterior teeth, some of theses tippings were observed. Therefore, we could predict the success rate of treatment by evaluating the angulation of lower canines.

In our study, the appliance was advanced to an edge to edge incisal relationship with step-by-step advancement. In previous study[16, 35, 36, 38, 43], indicated that step-by-step advancement of the mandible might enhance mandibular growth more than maximum jumping only. In 2002, Hagg *et al*[10] reported an increase in bone formation in both condyle and glenoid fossa after mandibular advancement using a fixed functional appliance. A better response was believed to occur when advancement took place in a gradual manner, to allow the muscle and condyle to adapt to the new position, an increase in the amount of skeletal effect, a reduction in the amount of dentoalveolar compensation, and better stability. Rabie *et al*[38] reported similar results using the headgear-Herbst appliance. The forward growth of the mandible with step-by-step advancement of the mandible was 3.1 mm. in 6 months compared with 3.57 mm. in our study. It has been indicated in a clinical study[16, 43] that step-by-step advancement of the mandible might enhance mandibular growth more than maximal jumping only. In a previous comparison of treatment results over 12 months, it was shown that the improvement in the jaw base relationship produced by the headgear-Herbst appliance with step-by-step advancement of the mandible was twice as large as that of the conventional Herbst appliance with maximum jumping of the mandible.[35]

On the other hand, Pancherz[6] suggested that, for maximal treatment response on mandibular growth especially, the Herbs appliance should be constructed with the mandible displaced anteriorly as much as possible, namely, to an edge to edge position between the incisors.

In our study, we investigated the effects of treatment with PSU-fixed functional appliance with step-by-step mandibular advancement, the results showed that it could reduce unwanted tooth movement and enhance orthopedic effects. The hard and soft tissues (teeth, bone and musculature) would need some time for physiologic adaptation to the new mandibular position. As a result of step-by-step advancement, its allow the muscle and condyle to adapt to the new position, an increase in the amount of skeletal effect, a reduction in the amount of dentoalveolar compensation and better stability.[10, 37]

The advantage of this PSU-FFA was effective to maximize orthopedic effect, the results were not routinely seen with other fixed functional study, this effect significantly contributed to the Class II molar correction by anchorage preparation and step by step advancement. The reduction of mandibular incisors forward tipping effected from anchorage preparation mechanics such as placing lingual crown torque in mandibular incisors[85], using uprighting springs at lower canines, maintaining curve of Spee. To increase molars anchorage, the teeth were cinched back behind the molars. This new system of fixed functional appliance has other advantages such as harmonize shape of dental arch by expansion wire in upper arch, less chance of interference with the appliance because of the smaller size, spend less time in laboratory, lower costs, easily cleaned and making hygiene simple. In this investigation only minor functional disturbances were found during treatment. All subjects accepted the appliance easily, and no any problems in the cooperation. Breakage of the appliance and loose band were found in some of patients, especially during first months of treatment.

During the long treatment time, the mandible has a limited range of motion and patients must learn to chew in a vertical pattern with minimal horizontal movement. There was the complication during PSU-FFA treatment, the stress placed on the archwires through activation caused wire fractures, especially in the lower arch. Avoid having the patient exert too much force on the support systems, causing appliance breakage or unwanted dental movement. For this reason, the use of a mini-stimulator for mandibular advancement is advised. The results of earlier study[10, 35, 36, 38, 43] also indicated that the stepwise advancement produces more skeletal effects than maximum advancement.

After 7 months of active treatment, the net effect on the mandibular incisors seemed to be increased in the inclination, resulting in an approximately 2.73^{o}. Despite the mandible being advanced gradually during the course of treatment in the treated group, assuming that the forces transmitted to the dental arches would become relatively lower compared with maximal jumping of the mandible, in both groups forward movement of the mandibular molars and incisors was very similar. The results of our study seem to show that even by advancing the mandible by only a small amount, sufficient force was transmitted via the appliance to move the teeth forward in the mandible. The dental changes seen during Herbst appliance treatment were basically a result of anchorage loss in the two dental arches.[4, 6] Proclination of the mandibular incisors has been also found in all previous Herbst studies.[6, 15, 16, 34, 86] From treatment results, to maximize skeletal effect on mandibular growth especially, we suggested that PSU-FFA should be constructed with more proper anchorage preparation as following.

1. Placing labial and lingual crown torque about 10-15^{o} in upper and lower arch wire respectively for avoiding unwanted dental movement in order to enhancing orthopedic effects.
2. Maintain initially curve of Spee in order to allowing the mandible to move more anterior position and increasing dental anchorage.
3. Placing uprighting springs to tip lower canines distally for avoiding proclination of lower anterior teeth.
4. Step by step mandibular advancement (2mm./2months) in order to allowing the muscle and condyle to adapt to the new position for increasing orthopedic effects, reducing dentoalveolar compensation and having better stability.
5. Training patient to protrude jaw all the time. All subjects have been adviced to protrude their mandibles forward as much as they can in order to maximize mandibular growth and training muscle in new position. This training also made the dental free from the reaction force.

Further investigation, TMJ radiographs should be analyzed with respect to structural changes in the articular components. X-ray will be taken on all patients before treatment and prior to appliance removal to check that condylar position has not changed. The use of tomographs will be a precise method to determine whether the condyles are in centric relation in the glenoid fossa. In addition, teeth that have been orthodontically moved tend to return to their former positions.[87] However, the long term implications of permanent bite jumping still need to be investigated.

CHAPTER 5

CONCLUSIONS

In our study, we investigated the effects of treatment with PSU-fixed functional appliance (PSU-FFA) with step-by-step mandibular advancement. For maximum orthopedic effects, a combination of factors is critical for the successful outcome of treatment with PSU-FFA. The mandible should be advanced with step-by-step advancement to allow the muscle and condyle to have adaptation for new position of the mandible together with proper anchorage preparation on the upper and lower anterior teeth, sufficient length of treatment and a retention device that maintains a successful outcome.

After PSU-FFA treatment, the results revealed that Class II correction mainly achieved by skeletal change (61.75%) whereas only 38.25% by dental changes. Therefore, we suggest that PSU-FFA can enhance the orthopedic effects and reduce unwanted tooth movement in growing patients by means of proper anchorage preparation and step-by-step advancement . In addition, PSU-FFA could enhance skeletal effect more than other previous studies.

Developing a new system of fixed functional appliance to be the one choice for clinical application in the future for Class II malocclusion with retruded mandible.

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APPENDICES

1. Data of cephalometric variables before observation in control group.

Samples	Cephalometric variables (mm.)				
	Overjet	Molar relation	Maxillary base	Mandibular base	Condylar head
1	4	0	76	82	12.5
2	7	-1	79	82	12
3	5	0	81	90.5	6.5
4	5	-0.5	80	81	8
5	15	3.5	81.5	88	5.5
6	12	-0.5	84	88	6
7	15	0	75	82	8.5
8	5	-2	79.5	87	10
9	8	-2.5	86	86	6.5
10	8	1	87	93	3
11	12	1.5	77.5	80	11
12	6	-2	69	69	11
13	5	-2.5	71	70	11.5
14	9	3.5	75	76	10
15	6	-0.5	76	78.50	9.5

Samples	Cephalometric variables (mm.)				
	Mandibular length	Maxillary incisor (sag.)	Mandibular incisor (sag.)	Maxillary molar (sag.)	Mandibular molar (sag.)
1	91	83.5	79.5	51	51
2	87.5	92	85	52	53
3	95.5	94	89	60	60
4	87	93	88	56	56.5
5	91.5	100	85	60.5	57
6	91	101	89	62.5	63
7	88.5	92	77	54.5	54.5
8	91	93	88	58	60
9	91	100	92	64.5	67
10	91	101	93	66	65
11	88.5	88	76	52	50.5
12	78	80	73.5	49	51
13	79.5	78.5	73	44	46.5
14	84	86	77	53.5	50
15	86.5	85.5	79.5	52	52.5

Samples	Cephalometric variables (mm.)			
	Maxillary incisor (vert.)	Mandibular incisor (vert.)	Maxillary molar (vert.)	Mandibular molar (vert.)
1	27	38	20	29
2	31.5	45	21	29
3	28	40	22	27
4	24	43	15	32
5	27	43	23	30
6	28.5	43	21	31
7	28	40	21	30
8	28	40	21	29
9	29	43	21.5	32.5
10	33	45	20	35
11	28	44	23	30
12	23	38	18	24
13	22	40	20	27
14	28	38	19	27
15	25.5	40	21	27

Samples	Cephalometric variables (^{o})				
	SNA	SNB	ANB	UI to PP	LI to MP
1	82	78	4	110	90
2	83	77	6	119	86
3	83	80	3	124	90
4	82	75	7	129	100.5
5	85	75	10	135	101
6	87	79	8	132	95
7	83	78.5	4.5	130	90
8	85	80	5	119	99
9	87.5	81	6.5	126	105.5
10	84	76	8	106	98
11	83	76	7	126.5	90
12	82	79	3	128	97
13	82	78	4	122	105
14	80.5	75	5.5	122	91
15	89	83	6	122	96

2. Data of cephalometric variables after observation in control group.

Samples	Cephalometric variables (mm.)				
	Overjet	Molar relation	Maxillary base	Mandibular base	Condylar head
1	3.5	-0.5	76	82	12.5
2	7.5	-2.5	79	82.5	12
3	5	0	82	92	6.5
4	5	-0.5	80.5	80.5	8
5	14.5	3	82	89	7
6	11.5	-1	84.5	89	6.5
7	15.5	-1	75.5	83.5	10
8	5	-2.5	80	88	10.5
9	8	-2.5	86.5	86.5	7
10	8	0.5	87.5	94	4
11	13	1	77.5	80	11.5
12	7	-2.5	69.5	69.5	11
13	5.5	-2.5	71	70.5	11
14	8.5	3.5	75	76.5	10
15	6	-0.5	77	78.5	9.5

Samples	Cephalometric variables (mm.)				
	Mandibular length	Maxillary incisor (sag.)	Mandibular incisor (sag.)	Maxillary molar (sag.)	Mandibular molar (sag.)
1	92.5	83.5	80	53	53.5
2	89	94	86.5	52	54.5
3	98	95	90	60.5	60.5
4	88	94	89	57	57.5
5	93.5	100.5	86	61	57.5
6	92.5	101.5	90	62.5	63.5
7	91.5	93.5	78	55	56
8	93.5	94	89	59.5	62
9	91.5	100.5	92.5	64.5	67
10	92	102.5	94.5	67	66.5
11	89.5	89	76	52.5	51.5
12	79	81	74	49.5	52
13	80.5	78.5	73	44	46.5
14	84	86	77.5	53.5	50
15	86.5	86	80	52.5	53

Samples	Cephalometric variables (mm.)			
	Maxillary incisor (vert.)	Mandibular incisor (vert.)	Maxillary molar (vert.)	Mandibular molar (vert.)
1	28	40	21	29.5
2	32.5	46.5	22.5	30
3	28	40	22.5	28
4	24.5	43.5	16	32
5	28	43.5	23.5	30.5
6	29	43.5	21	31.5
7	29	42	22	30
8	28.5	40.5	21.5	29.5
9	29	43	22	33
10	34	45	22	35
11	28	45	23.5	31
12	23.5	38.5	18.5	25
13	22	40	20	27.5
14	28	38	19.5	27.5
15	25.5	41	21.5	27.5

Samples	Cephalometric variables (^{o})				
	SNA	SNB	ANB	UI to PP	LI to MP
1	82	78	4	112	90
2	83	77	6	118.5	88
3	84	81	3	123.5	90.5
4	83	76	7	129	101
5	86	75.5	10.5	134	100.5
6	87	79.5	7.5	131.5	96
7	83	79	4	130	90
8	85	80.5	4.5	118.5	98.5
9	87.5	81	6.5	127	106.5
10	84	76	8	107	99
11	83	76	7	127	90
12	82	79	3	127.5	97
13	82	78	4	122	105
14	80.5	75	5.5	121.5	91
15	89	83	6	122	97

3. Data of cephalometric variables before treatment in treated group.

Samples	Cephalometric variables (mm.)				
	Overjet	Molar relation	Maxillary base	Mandibular base	Condylar head
1	7.5	0	77	76.5	8
2	14	1	88	97	2
3	11.5	-1.5	85.5	91.5	7
4	10	-2	82	91	8.5
5	8.5	-0.5	86	90	5.5
6	7.5	0.5	77.5	74.5	8
7	10.5	5.5	87	87.5	10
8	8.5	1	78	80	11
9	8	-2	86.5	88	10
10	6	-1	79	79	10
11	7.5	-0.5	74	74.5	11
12	9	-0.5	84.5	83	15.5
13	8.5	-1	81.5	84.5	6
14	7	-0.5	78.5	77.5	11
15	7	0	74.5	73	15

Samples	Cephalometric variables (mm.)				
	Mandibular length	Maxillary incisor (sag.)	Mandibular incisor (sag.)	Maxillary molar (sag.)	Mandibular molar (sag.)
1	83.5	90	82.5	53	53
2	98	105	91	68	68
3	97.5	97.5	91.5	69	69
4	99	99	87	64	64
5	94.5	94.5	89.5	61.5	61.5
6	81	81	80.5	53	53
7	97	97	87.5	61	61
8	90	90	82.5	49	49
9	97	97	89	66	66
10	88	88	81	53	53
11	84	84	75	47.5	47.5
12	97.5	97.5	89	55.5	55.5
13	89.5	89.5	86.5	60	60
14	87	87	82.5	56	56
15	86	86	78	50.5	50.5

Samples	Cephalometric variables (mm.)			
	Maxillary incisor (vert.)	Mandibular incisor (vert.)	Maxillary molar (vert.)	Mandibular molar (vert.)
1	28.5	41	21	27
2	27	45	21	32
3	33	47	24	34
4	23.5	39.5	20.5	29
5	32	42	20	31
6	27.5	39.5	23	28
7	28	40	22.5	29
8	28	41	21	29
9	24	41	20	31.5
10	23.5	39.5	19	28
11	26	36.5	19	26
12	31	45	22	33
13	25	37	18	27.5
14	28.5	38	22.5	27
15	25	41	22	30

Samples	Cephalometric variables (°)				
	SNA	SNB	ANB	UI to PP	LI to MP
1	82	74	8	120.5	102
2	86	78	8	130	91
3	85	79	6	121	95
4	81	78	3	136	101.5
5	80	76	4	114.5	91
6	83.5	77	6.5	123	98
7	83	77	6	118	97
8	83	77	6	121	99
9	94	86.5	7.5	119	98
10	88	82.5	5.5	125	92
11	87	82	5	120	96
12	80	74	6	124	101
13	92	84	8	122	96.5
14	80	73	7	124	108
15	79	74	5	130	106

4. Data of cephalometric variables after treatment in treated group.

Samples	Cephalometric variables (mm.)				
	Overjet	Molar relation	Maxillary base	Mandibular base	Condylar head
1	2.5	-3	77.5	80.5	8
2	3	-3	88.5	104	2
3	4.5	-3	85.5	95	7.5
4	3	-4	84	97.5	9
5	3	-3	85	92	6
6	2	-4.5	78	78	8
7	1.5	-3	88	96.5	8
8	2.5	-5.5	79	85	11
9	2.5	-8	86.5	92.5	10
10	2.5	-3.5	79	81	10
11	3.5	-4	74	76.5	11
12	5	-4	84.5	85	16
13	4.5	-4	83	89	6
14	3	-4.5	78.5	80.5	12
15	1	-4.5	74.5	77	14

Samples	Cephalometric variables (mm.)				
	Mandibular length	Maxillary incisor (sag.)	Mandibular incisor (sag.)	Maxillary molar (sag.)	Mandibular molar (sag.)
1	86.5	88.5	86	54.5	57.5
2	105.5	105	102	71.5	74.5
3	100.5	102.5	98	70	73
4	105.5	99.5	96.5	65	69
5	97	99	96	60	63
6	84.5	87.5	85.5	55	59.5
7	104	98.5	97	67.5	70.5
8	94	91	88.5	55.5	61
9	99	95	92.5	61	69
10	90	88	85.5	51.5	55
11	86	82.5	79	45	49
12	98	97	92	55	59
13	94	95.5	91	62	66
14	90.5	89.5	86.5	54.5	59
15	89	85	84	50.5	55

Samples	Cephalometric variables (mm.)			
	Maxillary incisor (vert.)	Mandibular incisor (vert.)	Maxillary molar (vert.)	Mandibular molar (vert.)
1	29	41	21	29
2	29	45	22	34
3	35	47.5	23	36
4	28	39	22	32
5	32.5	41	21	31
6	28	40	22	30
7	30	41	24.5	32
8	27	42	21	31
9	24	41	18	33
10	24	38.5	18	28
11	26	36	18	26
12	30	45	22	34
13	25.5	39	17	30
14	29	37	20.5	29
15	26	39	21	31.5

Samples	Cephalometric variables (^{o})				
	SNA	SNB	ANB	UI to PP	LI to MP
1	81	75.5	5.5	115	95
2	83	79	4	111	100
3	85	81	4	113	104
4	81	80	1	131	101
5	80	77	3	113	100.5
6	84	79	5	125	99
7	82	80	2	116	95.5
8	83	80	3	125	105
9	93	88	5	122	101
10	88	83.5	4.5	124.5	97
11	87	84	3	124	99
12	80	76	4	125	104
13	93	86	7	118	91
14	80	75	5	120	108
15	79	77	2	131.5	119

ใบเชิญชวน

ขอเชิญเข้าร่วมโครงการวิจัยเรื่อง การศึกษาผลต่อกระดูกโครงสร้างใบหน้าในผู้ป่วยที่รักษาด้วยเครื่องมือฟังชั่นนอลชนิดติดแน่น

เรียน ท่านผู้อ่านที่นับถือ

ข้าพเจ้า ทพญ.พิมพลักษณ์ หล่อวิริยากุล ใคร่ขอเล่าถึงโครงการวิจัยที่กำลังทำอยู่ และขอเชิญชวนท่านเข้าร่วมโครงการนี้ เนื่องจากการรักษาผู้ป่วยที่มีความผิดปกติของกระดูกโครงสร้างใบหน้าประเภทที่ 2 ที่มีขากรรไกรล่างถอยไปด้านหลัง สามารถใช้เครื่องมือชนิดฟังชั่นนอลได้ โดยใช้ในผู้ป่วยที่มีปัญหาโครงสร้างใบหน้าและยังมีการเจริญเติบโตของร่างกายอยู่ ซึ่งส่วนใหญ่จะอยู่ในช่วงฟันชุดผสม อายุประมาณ 8-12 ปี

การรักษาในระยะนี้จะช่วยแก้ไขความผิดปกติของโครงสร้างใบหน้า,การทำงานของกล้ามเนื้อ และกระดูกฐานขากรรไกร ก่อนที่จะถึงระยะฟันแท้ ซึ่งผลของการรักษาจะช่วยลดความรุนแรง, ความยุ่งยากในการรักษา และระยะเวลาของการรักษาในอนาคต

ประโยชน์ที่จะได้รับจากการวิจัยนี้ ทำให้สามารถพัฒนาเครื่องมือฟังชั่นนอลชนิดติดแน่นที่ประดิษฐ์ ขึ้นในคณะทันตแพทยศาสตร์ มหาวิทยาลัยสงขลานครินทร์ ให้มีผลกระตุ้นการเจริญของโครงสร้างใบหน้าเพิ่มมากขึ้น, เพื่อเป็นแนวทางในการตัดสินใจเลือกใช้เครื่องมือในการรักษาผู้ป่วยที่มีความผิดปกติของโครงสร้างโครงสร้างกระดูกขากรรไกรและใบหน้าประเภทที่2 ร่วมกับการเจริญของขากรรไกรล่างถอยไปด้านหลัง ส่วนขากรรไกรบนเป็นปกติได้ เนื่องจากเป็นเครื่องมือชนิดติดแน่นจึงไม่ค่อยมีปัญหาเรื่องความร่วมมือของผู้ป่วย, ระยะเวลาที่ใส่เครื่องมือยาวนานตลอด 24 ชม. ทำให้ได้รับผลการรักษาที่ดี, สามารถใช้การเจริญเติบโตที่มีอยู่ แก้ไขความผิดปกติของกระดูกโครงสร้างใบหน้า ในผู้ป่วยที่อยู่ในระยะที่มีการเจริญเติบโต เพื่อลดความรุนแรง, ความยุ่งยากในการรักษา และระยะเวลาของการรักษาในอนาคต สุดท้ายเพื่อลดต้นทุนในการรักษาและลดค่าใช้จ่ายของผู้ป่วยได้ เนื่องจากสามารถประดิษฐ์เครื่องมือขึ้นเอง

ผู้วิจัยต้องการศึกษาผลของเครื่องมือฟังชั่นนอลชนิดติดแน่นที่ประดิษฐ์ขึ้นในคณะทันตแพทยศาสตร์ มหาวิทยาลัยสงขลานครินทร์ ที่มีต่อกระดูกโครงสร้างใบหน้า โดยพัฒนาเครื่องมือ ให้มีผลกระตุ้นการเจริญของโครงสร้างใบหน้าเพิ่มมากขึ้น

ผู้ป่วยและผู้ปกครองของผู้ป่วยทุกคนที่เข้าร่วมโครงการวิจัยจะได้รับการอธิบายขั้นตอนการรักษา และมีความสมัครใจที่จะเข้าร่วมโครงการวิจัย จากนั้นจะแบ่งผู้ป่วยเป็น 2 กลุ่ม คือ กลุ่มตัวอย่างและกลุ่มควบคุม ซึ่งกลุ่มตัวอย่างจะถูกรักษาด้วยเครื่องมือฟังชั่นนอลชนิดติดแน่นที่ประดิษฐ์ขึ้นในคณะทันตแพทยศาสตร์ มหาวิทยาลัยสงขลานครินทร์ เป็นเวลา 6-8 เดือน ส่วน

ผู้ป่วยในกลุ่มควบคุมจะยังไม่ได้รับการรักษา เป็นเวลา 6-8 เดือน ทำการเก็บข้อมูลผู้ป่วยทั้งสองกลุ่มด้วยภาพถ่ายรังสี ดังนี้

กลุ่มควบคุม ถ่ายภาพรังสีทั้งหมด 2 ครั้ง ดังนี้

- ครั้งที่1 ถ่ายภาพรังสีกะโหลกศีรษะด้านข้างและกระดูกข้อมือ
- ครั้งที่2 ถ่ายภาพรังสีกะโหลกศีรษะด้านข้าง หลังจากครั้งที่1 ประมาณ 6-8 เดือน

กลุ่มตัวอย่าง ถ่ายภาพรังสีทั้งหมด 3 ครั้ง ดังนี้

- ครั้งที่1 ถ่ายภาพรังสีกะโหลกศีรษะด้านข้าง และ กระดูกข้อมือ
- ครั้งที่2 ถ่ายภาพรังสีกะโหลกศีรษะด้านข้าง หลังจากปรับระดับฟันด้วย orthodontic appliance เรียบร้อยแล้ว และกำลังจะใช้เครื่องมือฟังชั่นนอลชนิดติดแน่นที่ประดิษฐ์ขึ้นใหม่
- ครั้งที่3 ถ่ายภาพรังสีกะโหลกศีรษะด้านข้าง หลังจากใส่เครื่องมือฟังชั่นนอลชนิดติดแน่นที่ประดิษฐ์ขึ้นใหม่ เป็นเวลา 6-8 เดือน และผู้ป่วยมีการสบฟันเป็น class I แล้ว

ซึ่งโดยปกติผู้ป่วยทุกคนที่ได้รับการรักษาด้วยเครื่องมือฟังชั่นนอล ที่คลินิกทันตกรรมจัดฟันจะต้องได้รับการถ่ายภาพรังสีเป็นระยะๆ เพื่อประเมินถึงการเปลี่ยนแปลงของกระดูกโครงสร้างใบหน้าที่เกิดขึ้น และในขั้นตอนของการเก็บข้อมูลในโครงการวิจัยนี้ผู้เข้าร่วมวิจัยจำเป็นที่จะต้องได้รับการถ่ายภาพรังสีเช่นเดียวกัน ได้แก่ ภาพถ่ายรังสีกะโหลกศีรษะด้านข้างและภาพถ่ายรังสีกระดูกข้อมือ ซึ่งการถ่ายภาพรังสีแต่ละครั้งนั้น มีความเสี่ยงที่จะเกิดอันตรายต่อผู้เข้าร่วมวิจัยน้อยมาก เนื่องจากปริมาณรังสีที่ได้รับน้อยมาก อีกทั้งร่างกายสามารถที่จะซ่อมแซมเนื้อเยื่อที่ถูกทำลายได้ โดยมาตรฐานของแผนกรังสีจะให้สวมเสื้อตะกั่วและ thyroid shield ป้องกันรังสีให้แก่ผู้เข้าร่วมวิจัยทุกราย ดังนั้นรังสีดังกล่าวจึงอยู่ในระดับที่ปลอดภัย และพยายามให้มีความผิดพลาดในการถ่ายภาพรังสีน้อยที่สุด เพื่อลดปริมาณรังสีที่ผู้เข้าร่วมวิจัยจะได้รับโดยไม่จำเป็น การใช้เครื่องมือฟังชั่นนอลชนิดติดแน่นที่ประดิษฐ์ ขึ้นเองนี้ อาจต้องใช้เวลาของการรักษาในคลินิกมากขึ้นกว่าปกติ แต่ผู้เข้าร่วมวิจัยทุกคนจะได้รับสิทธิพิเศษ โดยไม่ต้องเสียค่าใช้จ่ายในการถ่ายภาพรังสีโดยผู้รับผิดชอบโครงการวิจัยนี้คือ

1. ทพญ.พิมพลักษณ์ หล่อวิริยากุล

ตำแหน่ง นักศึกษาหลักสูตรป.บัณฑิตชั้นสูง และหลักสูตรฝึกอบรมทันตแพทย์ประจำบ้าน สาขาทันตกรรมจัดฟัน

ภาควิชาทันตกรรมป้องกัน คณะทันตแพทยศาสตร์ มหาวิทยาลัยสงขลานครินทร์

โทรศัพท์ 074-429876 (ในเวลาราชการ)

2. ผศ.ทพญ.ดร. ชิดชนก ลีธนะกุล

ตำแหน่งวิชาการ ผู้ช่วยศาสตราจารย์ ภาควิชาทันตกรรมป้องกัน

คณะทันตแพทยศาสตร์ มหาวิทยาลัยสงขลานครินทร์

โทรศัพท์ 074-429876 (ในเวลาราชการ)

ถ้าท่านตัดสินใจเข้าร่วมโครงการนี้จะมีขั้นตอนของการวิจัยที่เกี่ยวข้องกับท่านคือ จะได้รับการเก็บข้อมูลก่อนและหลังการใส่เครื่องมือ เป็นเวลาประมาณ 6-8 เดือน

ไม่ว่าท่านจะเข้าร่วมในโครงการวิจัยนี้หรือไม่ ท่านจะยังคงได้รับการรักษาที่ดี เช่นเดียวกับผู้ป่วยคนอื่นๆ และถ้าท่านต้องการที่จะถอนตัวออกจากการศึกษานี้เมื่อใด ท่านก็สามารถกระทำได้อย่างอิสระ

หากท่านมีคำถามใดๆก่อนที่จะตัดสินใจเข้าร่วมโครงการนี้ โปรดซักถามคณะผู้วิจัยได้อย่างเต็มที่

ขอขอบคุณเป็นอย่างสูง

ทพญ.พิมพลักษณ์ หล่อวิริยากุล

ผู้รับผิดชอบโครงการวิจัย

หมายเหตุ :- กรุณาอ่านข้อความให้เข้าใจก่อนเซ็นชื่อยินยอมเข้าร่วมโครงการ

แบบยินยอมเข้าร่วมการศึกษา

วันที่...........เดือน...........พ.ศ...........

ข้าพเจ้า... อายุ...........ปี อาศัยอยู่บ้านเลขที่....................

หมู่ที่....... ถนน...................... อำเภอ......................... จังหวัด................................

เป็นผู้ปกครองของด.ช./ด.ญ..ได้รับทราบถึงรายละเอียดของโครงการวิจัย เพื่อประเมินผลของการใช้เครื่องมือฟังชั่นนอลชนิดติดแน่นที่ประดิษฐ์ขึ้นในคณะทันตแพทยศาสตร์ มหาวิทยาลัยสงขลานครินทร์ ที่มีต่อกระดูกโครงสร้างใบหน้า โดยผู้เข้าร่วมวิจัยจะได้รับการใส่เครื่องมือฟังชั่นนอลชนิดติดแน่น เพื่อกระตุ้นการเจริญเติบโตของขากรรไกรล่าง เป็นเวลา 6-8 เดือน จากนั้นจะได้รับการวิเคราะห์การเปลี่ยนแปลงที่เกิดขึ้น ด้วยภาพถ่ายรังสีกะโหลกศีรษะด้านข้าง ซึ่งโดยปกติผู้ป่วยทุกคนที่ได้รับการรักษาด้วยเครื่องมือฟังชั่นนอล ที่คลินิกทันตกรรมจัดฟันจะต้องได้รับการถ่ายภาพรังสีเป็นระยะๆ เพื่อประเมินถึงการเปลี่ยนแปลงของกระดูกโครงสร้างใบหน้าที่เกิดขึ้น ซึ่งการถ่ายภาพรังสีแต่ละครั้งนั้น มีความเสี่ยงที่จะเกิดอันตรายต่อผู้เข้าร่วมวิจัยน้อยมาก เนื่องจากปริมาณรังสีที่ได้รับน้อยมาก อีกทั้งร่างกายสามารถที่จะซ่อมแซมเนื้อเยื่อที่ถูกทำลายได้ โดยมาตรฐานของแผนกรังสีจะให้สวมเสื้อตะกั่วและ thyroid shield ป้องกันรังสีให้แก่ผู้เข้าร่วมวิจัยทุกราย ดังนั้นรังสีดังกล่าวจึงอยู่ในระดับที่ปลอดภัย และพยายามให้มีความผิดพลาดในการถ่ายภาพรังสีน้อยที่สุด เพื่อลดปริมาณรังสีที่ผู้เข้าร่วมวิจัยจะได้รับโดยไม่จำเป็น ซึ่งผลของการวิจัยนี้จะเป็นประโยชน์ต่อผู้ป่วยในคลินิก

ทันตกรรมจัดฟันต่อไป

หากข้าพเจ้ามีข้อสงสัยประการใด หรือเกิดผลข้างเคียงจากการวิจัย สามารถติดต่อได้กับ ทพญ. พิมพลักษณ์ หล่อวิริยากุล ได้ที่ภาควิชาทันตกรรมป้องกัน คณะทันตแพทยศาสตร์ มหาวิทยาลัยสงขลานครินทร์ หมายเลขโทรศัพท์ 074-429876 (ในเวลาราชการ) หรือหมายเลข 09-7220828 (นอกเวลาราชการ) หรือติดต่อกับ ผศ.ทพญ.ดร. ชิดชนก ลีธนะกุล หมายเลขโทรศัพท์ 074-429876 (ในเวลาราชการ) หรือเมื่อมีปัญหาใดๆเกิดขึ้นเนื่องจากการทำวิจัยในเรื่องนี้ข้าพเจ้าสามารถร้องเรียนไปที่คณบดีคณะทันตแพทยศาสตร์ มหาวิทยาลัยสงขลานครินทร์ อ.หาดใหญ่ จ. สงขลา 90112 โทรศัพท์ 074-287510

หากผู้วิจัยมีข้อมูลเพิ่มเติมทั้งด้านประโยชน์และโทษของการวิจัยนี้ ผู้วิจัยจะแจ้งให้ข้าพเจ้าทราบอย่างรวดเร็วโดยไม่ปิดบัง

ข้าพเจ้ามีสิทธิ์ที่จะของดการเข้าร่วมโครงการวิจัย โดยจะแจ้งให้ทราบล่วงหน้า โดยการงดเข้าร่วมโครงการวิจัยนี้จะไม่มีผลต่อการรักษาที่บุตรของข้าพเจ้าจะได้รับแต่ประการใด

ข้าพเจ้าได้รับทราบจากผู้วิจัยว่า จะไม่เปิดเผยข้อมูลหรือผลการวิจัยของบุตรของข้าพเจ้าเป็นรายบุคคลต่อสาธารณชน

ข้าพเจ้าได้อ่านข้อความข้างต้นแล้ว และมีความเข้าใจดีทุกประการ จึงได้ลงนามในใบยินยอมนี้ด้วยความเต็มใจ โดยนักวิจัยได้ให้สำเนาแบบยินยอมที่ลงนามแล้วกับข้าพเจ้าเพื่อเก็บไว้เป็นหลักฐาน จำนวน 1 ชุด

ลงชื่อ..ผู้ยินยอม

(..)

ลงชื่อ..ผู้รับผิดชอบโครงการวิจัย

(ทพญ. พิมพลักษณ์ หล่อวิริยากุล)

ลงชื่อ..พยาน

(..)

ลงชื่อ..พยาน

(..)

ที่ ศธ 0521.1.03/ 514

คณะทันตแพทยศาสตร์
มหาวิทยาลัยสงขลานครินทร์
ตู้ไปรษณีย์เลขที่ 17
ที่ทำการไปรษณีย์โทรเลขคอหงส์
อ.หาดใหญ่ จ.สงขลา 90112

หนังสือฉบับนี้ให้ไว้เพื่อรับรองว่า

โครงการวิจัยเรื่อง "การศึกษาผลต่อกระดูกโครงสร้างใบหน้าในผู้ป่วยที่รักษาด้วยเครื่องมือฟังชั่นนอลชนิดติดแน่น"

หัวหน้าโครงการ ทันตแพทย์หญิงพิมพลักษณ์ หล่อวิริยากุล

สังกัดหน่วยงาน นักศึกษาหลังปริญญา ภาควิชาทันตกรรมป้องกัน คณะทันตแพทยศาสตร์ มหาวิทยาลัยสงขลานครินทร์

ได้ผ่านการพิจารณาและได้รับความเห็นชอบจากคณะกรรมการจริยธรรมในการวิจัย (Ethics Committee) ซึ่งเป็นคณะกรรมการพิจารณาศึกษาการวิจัยในคนของคณะทันตแพทยศาสตร์ มหาวิทยาลัยสงขลานครินทร์ แล้ว

ให้ไว้ ณ วันที่ 4 ก.ค. 2549

(ผู้ช่วยศาสตราจารย์สุวรรณา จิตภักดีบดินทร์)
รองคณบดีฝ่ายวิจัยและวิเทศสัมพันธ์
ประธานกรรมการ

..............................กรรมการ
(รองศาสตราจารย์วิลาศ สัตยสัณห์สกุล)

..............................กรรมการ
(ผู้ช่วยศาสตราจารย์สรียา ศรีสินทร)

..............................กรรมการ
(นายแพทย์วรพงศ์ เชาวน์ชูเวชช)

..............................กรรมการ
(ดร.สุธี อยู่สถาพร)

..............................กรรมการ
(ผู้ช่วยศาสตราจารย์วรพงษ์ ปัญญายงค์)

..............................กรรมการ
(อ.ทพญ.อังคณา เธียรมนตรี)

..............................กรรมการ
(ผู้ช่วยศาสตราจารย์สุรพงษ์ วงศ์วัชรานนท์)

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