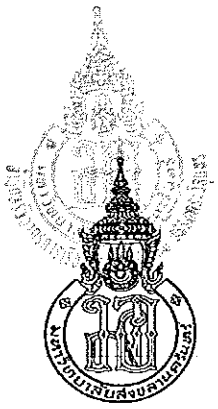

Transverse Maxillary Discrepancy Correction by a Modified Expansion Appliance Fixed with Microimplant in Cleft Lip and Palate Patients

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ชื่อวิทยานิพนธ์ การแก้ไขความผิดปกติของขากรรไกรบนในแนวขวางในผู้ป่วยปากแหว่งเพดานโหว่ด้วยเครื่องมือขยายขากรรไกรดัดแปลงร่วมกับไมโครอิมพลานต์

ผู้เขียน นายกฤษฎิ ปัณณะรัส

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บทคัดย่อ

บทนำ การแก้ไขความผิดปกติในแนวขวางของขากรรไกรบนในผู้ป่วยปากแหว่งเพดานโหว่สามารถทำได้หลายวิธี การใช้เครื่องมือที่มีใช้หลักยึดเป็นฟันจะทำให้เกิดผลข้างเคียงต่อฟันที่เป็นหลักยึด ทำให้ในปัจจุบันมีแนวโน้มในการใช้เครื่องมือที่ใช้กระดูกเป็นหลักยึดเพื่อป้องกันผลแทรกซ้อนดังกล่าว แต่เครื่องมือชนิดนี้ยังคงมีราคาแพงและรูปร่างที่ยังไม่เหมาะสมในการประยุกต์ใช้ในผู้ป่วยปากแหว่งเพดานโหว่ การวิจัยครั้งนี้มีวัตถุประสงค์เพื่อศึกษาผลของการขยายขากรรไกรบนด้วยเครื่องมือขยายขากรรไกรดัดแปลงร่วมกับไมโครอิมพลานต์และประเมินการใช้ไมโครอิมพลานต์เป็นหลักยึดในการแก้ไขความผิดปกติในแนวขวางของผู้ป่วยปากแหว่งเพดานโหว่ **ระเบียบวิธีวิจัย** ผู้เข้าร่วมวิจัยที่ตรงตามข้อตกลงเบื้องต้นเป็นผู้ป่วยปากแหว่งเพดานโหว่ที่มีขากรรไกรบนแคบและฟันหลังสบไขว้จำนวน 6 ราย อายุเฉลี่ย 14.67±2.66 ปี ไม่มีโรคทางระบบซึ่งได้รับการติดเครื่องมือขยายขากรรไกรดัดแปลงร่วมกับไมโครอิมพลานต์บริเวณเพดานปาก ทำการขยายด้วยการไขสกรูขยายฟันสองครั้งในตอนเช้าและเย็นจนหมดเกลียวของสกรูขยายฟันหลังจากนั้นจะทำการถอดเครื่องมือและคงสภาพฟันด้วยเครื่องมือคงสภาพฟัน ผู้ป่วยจะได้รับการเก็บข้อมูลเพื่อนำเสนอการเปลี่ยนแปลงของค่ากึ่งกลางข้อมูล (median) ที่เกิดขึ้นด้วยสถิติเชิงพรรณนา ทำโดยการวัดตำแหน่งอ้างอิงจากแบบจำลองฟัน 9 ตำแหน่ง ตำแหน่งอ้างอิงบนภาพรังสีกะโหลกศีรษะในแนวหลังหน้า 6 ตำแหน่งและแกนของไมโครอิมพลานต์ในตำแหน่งด้านหน้าและหลังที่เปลี่ยนไป และเปรียบเทียบการเปลี่ยนแปลงตำแหน่งอ้างอิงของแบบจำลองฟันและภาพถ่ายรังสีกะโหลกศีรษะในแนวหลังหน้าก่อนและหลังการขยายขากรรไกรบน ด้วยสถิติแบบไม่ใช้พารามิเตอร์ชนิดวิลคอกสันไซน์แรงค์ (Wilcoxon Signed rank test) **ผลการทดลอง** จากแบบจำลองฟันพบว่าความกว้างของขากรรไกรบนบริเวณ ICW, W3, PW4, AAW, BW4, PW6, PAW, BW6 และ W7 เท่ากับ 1.66 มม., 1.63 มม., 3.12 มม., 2.52 มม., 3.29 มม., 3.33 มม., 2.46 มม., 2.73 มม., 1.43 มม. ตามลำดับ จากภาพถ่ายรังสีพบการขยายของขากรรไกรบนของส่วนกระดูกศีรษะบริเวณ IOD, IND, IJD, IMidAD, IAD และ IMD เท่ากับ 0.03 มม., 0.39 มม., 0.47 มม., 1.42 มม., 1.32 มม. และ

1.86 มม. ตามลำดับ แกนของไมโครอิมพลานต์ที่เปลี่ยนแปลงไปหลังการขยายพบว่าด้านขวาเอียงเพิ่มขึ้นเฉลี่ย 15 องศา และด้านซ้ายเอียงเพิ่มขึ้นเฉลี่ย 13 องศา จากการวัดบนแบบจำลองฟันและภาพรังสีกะโหลกศีรษะแนวหลังหน้าก่อนและหลังการรักษา พบว่าความกว้างในขากรรไกรบนเพิ่มขึ้น โดยในทุกตำแหน่งมีค่าเพิ่มขึ้นอย่างมีนัยสำคัญทางสถิติ ($p<0.05$) ยกเว้นตำแหน่ง IOD ในภาพถ่ายรังสีกะโหลกศีรษะในแนวหลังหน้าเท่านั้น สรุป เครื่องมือขยายขากรรไกรดัดแปลงร่วมกับไมโครอิมพลานต์สามารถส่งแรงโดยมีผลต่อกระดูก เพื่อขยายขากรรไกรบนที่แคบในผู้ป่วยปากแหว่งเพดานโหว่ได้ และไมโครอิมพลานต์มีความมั่นคงเพียงพอต่อการทำหน้าที่เป็นหลักยึดด้วยกระดูกสำหรับเครื่องมือขยายขากรรไกรดัดแปลงร่วมกับไมโครอิมพลานต์

Thesis Title Transverse Maxillary Discrepancy Correction by a Modified Expansion Appliance Fixed with Microimplant in Cleft Lip and Palate Patients

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ABSTRACT

Introduction: Transverse maxillary discrepancy in cleft lip and palate patients can be corrected by using several methods. Tooth-borne anchorage appliance has more complications to anchor teeth than bone-borne appliance. Nowadays, the bone-borne anchorages were suggested to solve the problem, but there was still restricted used due to their cost and less applicable in cleft patients. The aims of the study was to determine distance changing after maxillary expansion by using a modified expansion appliance fixed with microimplant in cleft lip and palate patients, and evaluate the using of microimplants as a bony anchorage for transverse maxillary discrepancy correction in cleft patients. **Material and methods:** Six healthy cleft lip and palate patients, who were in agreement with the inclusion criteria, with 14.67±2.66 years in average treated with the modified expansion appliance. Patients were instructed to activate their appliances two turns twice daily at the same time, in the morning and at night, till the bilateral expansion screws were terminated, and retainers were delivered immediately after the appliance removal. Nine landmarks in study model and six landmarks in postero-anterior cephalograms, before and after treatment, were collected for descriptive statistic analysis. Comparisons of different medians of those parameters were tested with Wilcoxon signed rank test. **Results:** From study models ICW, W3, PW4, AAW, BW4, PW6, PAW, BW6, and W7 were 1.66 mm, 1.63, 3.12 mm, 2.52 mm, 3.29 mm, 3.33 mm, 2.46 mm, 2.73 mm, 1.43 mm respectively. And posteroanterior cephalograms before and after treatment data, it was found that IOD, IND, IJD, IMidAD, IAD and IMD were 0.03 mm, 0.39 mm, 0.47 mm, 1.42 mm, 1.32 mm, and 1.86 mm respectively. Those parameters were statistically significance ($p<0.05$), except only IOD that was not. **Conclusion:** The modified expansion appliance fixed with microimplant can exert orthopedic force to expand the constricted maxillary arch found in cleft lip and palate patients,

which affect both dental and skeletal parts. Microimplant is stable enough to use as an anchorage for expanding constricted maxilla in cleft lip and palate patients.

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Krisadi Phannarus

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LIST OF ABBREVIATIONS

ICW	=	Intercanine width
W3	=	The distance between the most prominent points of buccal surface of canines
PW4	=	The most prominent point of palatal surface in the region of premolars
BW4	=	The most prominent point of buccal surface in the region of premolar
PW6	=	The most prominent point of palatal surface of first molars
BW6	=	The most prominent point of buccal surface of first molars
W7	=	The most prominent point of the hindmost molars
AAW	=	Anterior arch width
PAW	=	Posterior arch width
IOD	=	Interorbital width
IND	=	Nasal width
IJD	=	Interjugal distance
IAD	=	Interalveolar distance
IMidAD	=	Inter-midalveolar distance
IMD	=	Intermolar distance
et al.	=	and others
PA cephalogram	=	Posteroanterior cephologram
CLP	=	Cleft lip and palate
SDO	=	Sutural distraction osteogenesis
ODO	=	Osteotomy distraction osteogenesis
RPE	=	Rapid palatal expansion
RME	=	Rapid maxillary expansion
SRME	=	Semirapid maxillary expansion
ABHE	=	Asymmetric maxillary expansion
SARME	=	Surgical assisted rapid maxillary expansion
TPD	=	Transpalatal distractor
RPD	=	Rotterdam palatal distractor

LIST OF ABBREVIATIONS (continued)

MPD	=	Magdeberg palatal distractor
DD	=	Dresden distractor
MWD	=	Maxillary widening device

CHAPTER 1

INTRODUCTION

1. Background and rationale

Maxillary transverse discrepancy, resulting from scar tissue on labial and palatal tissue, is usually found in cleft lip and palate patients. Not only scar tissue formation that inhibits a normal development of maxilla causes both bilaterally and unilaterally posterior crossbite, but also lack of normal intrinsic maxillary tissue development.[1] Transverse discrepancy found in cleft patients is significantly different from non-cleft group.[2] There are many methods resolving a constricted maxilla problem by using teeth as anchors for orthopedic expansion, which generate the undesirable effects, such as tooth tipping, anchorage teeth extrusion, periodontal membrane compression, buccal root resorption, and fenestration of buccal cortex. The side effects of anchors teeth are usually noticed during expansion and retention[3]. Garib and Henrique *et al.*[4] showed that tooth borne (Hyrax) and tooth-tissue borne (Haas-type) expanders tended to produce similar orthopedics effects. In both methods, RME led to buccal movement of the maxillary posterior teeth, by tipping and bodily translation. At present, orthodontic microimplant, or miniimplant is introduced to use as an absolute anchorage in orthodontic treatment for reducing an anchorage-loss problem. Creekmore and Eklund[5] suggested that a small metal screw could withstand a constant force for orthodontic tooth movement. More recently, onplant, miniplate, palatal implant, have been developed for using as skeletal anchorage. But, there is no study about using microimplant as an anchorage for transverse maxillary expansion in cleft patients. It is interesting that if we use the microimplant as the bony anchors for the maxillary expansion, it could be reduce unwanted tooth movement and alveolar bone bending from RME.

2. Reviews of literatures

Etiology of transverse discrepancy in cleft patients

There are many documents[1,6-8] showed the effects of cleft lip and palate itself to dental arch dimension and morphology. Even though, others[2, 9-12] purposed that surgery to the lip and soft palate, together with alveolar bone grafting were considered the most important factors causing the disturbance of maxillary growth and development in patients with cleft lip and palate. These disturbances are due to the traumatic effect of surgery, constriction of the scar tissue, and influenced by type of cleft patterns. The patterns of cleft are the most common consideration. Schultes and Gaggl *et al.*[8] and Honda and Suzuki *et al.*[13] suggested that adult patients with isolated cleft palate showed better model and cephalometric results than patients with cleft lip and palate after orthodontic and surgical treatment. Peltomaki and Vendittelli *et al.*[9] concluded that treatment procedures were definitely easier in both process and satisfactory achievement, which size and severity of cleft site is altogether influenced to treatment results. Moreover, Spauwen and Hardjowasito *et al.*[14], Honda and Suzuki *et al.*[13] and Garrahy and Millett *et al.*[12] suggested that the combination of lip and palate repair in cleft lip and palate patients appeared to influence not only vertical and anteroposterior development in the incisor area, but also the transverse development at the level of the cuspids and first molar was involved. There is no significant differrence in both anteroposterior dimension and posterior maxillary arch width between unilateral and bilateral cleft patients. Schliephake and Donnerstag *et al.*[6] concluded that the negatively asymmetric development was not significant differences between unilateral and bilateral cleft lip and palate patients. On the other hands, within maxillary arch width, deviation from arch symmetry was significant in unilateral clefts both anteriorly and posteriorly compared to non-cleft individuals.

Transverse discrepancy pattern in cleft lip and palate patients: In the early age of life, the intercanine width was significantly larger in the cleft group than in the non-cleft group. A slight increase was seen up to the age of 6 months in the clefts. Thereafter, the intercanine width diminished until the age of 18 months. From then on, intercanine width was significantly smaller in the cleft group than the normal group and remained virtually unaltered up to 4-7 years of age. On the other hand, intercanine width of the normal occlusion children tended to increase continuously until the same period[5] of life. DiBiase and DiBiase *et al.*[2] found no significant

relation between sex and dimension of maxillary arch in primary dentition of cleft lip and palate children which was different from normal children. Growth pattern in cleft patients was merely the same as normal patients, but lack of tissue supported at the cleft site, which induced more severe intermaxillary relationship in all three plane; anteroposterior, transverse and vertical.

Moreover, in the study of dental arches conducted in un-operated cleft lip and palate adult patients by da Silva Filho and Ramos *et al.*[7] showed that the cleft itself, as well as its functional balance, influenced the maxillary dental arch transverse dimension independently of surgical procedures. Nevertheless, in the study of changes in occlusion in treated adult cleft patients by Marcusson[15] concluded that the significant differences between the transverse and sagittal maxillary arch dimensions were also found for all measurements during the follow-up interval for 5 years. This constriction was slight in the molar region and more pronounced in the anterior region. So, the author concluded that when compared untreated cleft lip and palate patients to normal patients, maxillary dental arch dimension and morphology were distorted by the presence of a cleft.

Biomechanic analysis: In order to achieve skeletal expansion effect, the use of stable maxillary expansion appliance is necessary for patients who do not suffer from clefts in the jaw and palate area.[16] This special equipment should be able to produce high forces of up to 120 N[17,18,19] in order to create an opening of the median palatal suture and a lateral bending of the maxillary structures. Unlike the situation with non-cleft individuals, skeletal stability in the transverse direction is reduced in cleft palate patients[20] because of the special anatomical situation in the jaw and palate area, which can even lead occasionally to a collapse of lateral segments in the medial direction.[11,20] With cleft patients, an indication for a transverse maxillary expansion often exists because the maxilla is excessive narrow. In contrast with noncleft patients, the necessary skeletal widening force of the maxilla in cleft patients is not carried out, according to some authors, using a conventional rapid maxillary expansion appliance, but rather using a quadhelix apparatus that is only able to generate orthodontic transverse force up to 5 N. According to Reitan[21], forces in this area are well able to induce a dental effect, but for a skeletal effect, higher orthopedic forces that should be greater than 5 N are requires. Biomechanical studies on the special anatomical situation with cleft lip and palate patients have not been published in the literature up until now, and expanded instruments in skeletal structures study of cleft patients also remain limited.

Expansion instruments in cleft patient: T ransverse maxillary constriction, in adolescents and adults, is frequently seen as an acquired deformity and in congenital deformities that distinguished by a narrow palatal vault, usually produces a posterior crossbite. These characters of deformities can be corrected by means of expansion in both early and late of life. Maxillary expansion devices are traditionally classified into two categories, tooth-borne and bone-borne anchorage devices. Generally, cleft lip and palate patients who suffer from transverse maxillary constriction are usually corrected with expansion appliance before routine orthodontic treatment. In recent years, expansion appliances are introduced in several methods, but to obtain skeletal effects, it is necessary to place force directly across the suture. From the classifications mentioned above, there are many types of appliance in each category.

Distraction osteogenesis

Distraction osteogenesis: Ilizarov[22], who first introduced a new method for lengthening a limb, modified an osteotomy and subsequent separation of osteotomy site by either external or internal distractors, which later called distraction osteogenesis. Distraction osteogenesis is usually involved bone ends are laterally apart, leaving it to nature to fill the gap with bone regeneration over time. Forces generated by distraction devices in the maxilla or other cranial bones are likely transmitted as suture strain, which in turn may induce suture osteogenic response.[23] McCarthy who first dentoskeletal application reported the pioneering work in 1992[24], the principle of distraction osteogenesis has been rapidly and extensively used in the craniofacial skeleton. The application of distraction technique in maxillary and midface hypoplasia has overcome many difficulties associated with traditional orthognathic approaches.[25]

Sutural distraction osteogenesis (SDO)[25] is another kind of technique under the principle of gradual skeletal distraction. The use of SDO arose from orthodontics and has a history of more than 100 years. However, McCarthy firstly proposed the term "sutural distraction osteogenesis" in 2000. SDO has been used by orthodontists to advance the retrograde maxillary dental arch and expand the midpalatal suture for correction of a narrow maxillary arch for decays. There are also some reports dealing with other sutures. This traditional management of maxillary advancement commonly uses a face bow or facemask, an intraoral appliance fixed to the dental arch, and elastics. It has little influence on the retrograde maxillary skeletal because of the lower position of the distraction force. This situation has been changed by the current technique of sutural distraction.

The technique of SDO is the same as the technique of osteotomy distraction osteogenesis (ODO) in that both use forces to gradually distract the bone segments border upon, including new bone formation at the site of their connection. However, there are four additional aspects worth noting; (1) The connection of the bone segments bordering the site of distraction is natural suture in SDO, whereas in ODO, it is newly formed fibrous callus. (2) With the use of SDO, there is no need for osteotomy, fixation of bone segments, and a latent phase waiting for fibrous callus formation. Thus, it is much simpler and easier to manipulate and much less invasive. (3) The suture is, in nature, the growth zone of the craniofacial skeleton, and thus possesses a greater potential of bone regeneration during the developmental age. (4) SDO is suitable only for young patients because of sutural alteration occur with age. In the current technique, there is no limitation from the dental condition. It effectively expands the bone and there is no damage to the teeth.

Tooth-borne anchorage expansion

Fixed appliances that expand the maxilla bilaterally include the banded W-spring, quad helix, tranpalatal arch and modified rapid maxillary expander. These appliances are used to correct crossbite of moderate magnitude. Fixed appliances such as these require little cooperation by the patient. Slow expansion is best with these appliances.[26]

Quadhelix is one of the famous tooth-borne appliances, which applied to solve transverse collapse in maxillary arch. Quad helix appliance, a more flexible version of the W-arch, is an expansion device that consisted of two metal bands cemented onto the upper back molar teeth connecting the bands, which are soldered onto the palatal aspect of the molar band. The wire is constructed with a 38 mil and four helices of wire, hence the name. The helix uses a lot of wire and increases the flexibility of the wire. When activating a quad helix appliance it is important to decide exactly what expansion you wish to achieve. Appropriate forces are produced when the appliance is widened by 3 to 8 mm. The adjustment can be performed either intra- or extraorally but care must be exercised with intraoral adjustment. Overcorrection, attention to soft tissue irritation, and 3 months of retention are also recommended with this appliance.[27]

Rapid palatal expansion (RPE) or Rapid maxillary expansion (RME): RPE had been proposed since the 19th century by Angell[28] RPE occurs when the forces applied to the teeth and the maxillary alveolar process exceeds the limited needed for orthodontic tooth movement.

The appliance compresses the periodontal ligament, bends the alveolar process, tips the anchor teeth then gradually opens the mid palatal suture and separates the maxillary bones. The result is usually an increase in the upper arch transverse dimension, mainly by skeletal alteration associated with dental changes. This depends on the sutural resistance, which increases as individual matures. In generally, the optimal period for performing RPE procedure in patients was between 8-15 years.[28] There are many effects that occur after expanding, such as downward-forward displaced maxilla, vertical growth of maxilla consideration and nasal cavity expansion. Long face and openbite patients are often introduced chin cup or posterior high pull headgear appliance associated with RPE for controlling vertical growth. There has been long-standing controversy over the efficiency of RPE in relieving nasal obstruction and improving respiration. Pogel and Kaban *et al.*[29] observed that the resistance to deformation from circummaxillary sutures and surrounding soft tissue matrix is the main cause of relapse of the rapid palatal expansion. And the duration of the post expansion retention period is controversial, but nine months to five years are usually recommended for the best result.[28]

Semirapid maxillary expansion (SRME): Iseri and Tekkaya *et al.*[30] found that rapid displacement or deformation of facial bones would result in a remarkable amount of relapse in the long term, whereas relatively slower expansion of the maxilla would probably produce less tissue resistance in the nasomaxillary complex. Therefore they suggested RME followed by slow maxillary expansion, immediately after the separation of the midpalatal suture, namely, semirapid maxillary expansion (SRME). The schedule would be two turns each week for the remainder of the RME treatment. This would stimulate the adaptation process in the nasomaxillary complex and would result in reduction of relapse in the post-retention period. Iseri and Ozsoy *et al.*[31] also conclude that rapid expansion followed by slower rates of expansion would allow for physiologic adjustment at the maxillary articulations and surrounding skeletal structures and would prevent the accumulation of large residual loads within the maxillary complex. This would help to minimize relapse in the long term in older adolescents and adults.

Bone-borne anchorage expansion

Traditionally, the distractors for expansion are tooth-borne devices, i.e. hyrax appliances, which have some serious disadvantages such as tooth tipping, cortical fenestration, skeletal relapse, gingival recession, and loss of anchorage. In contrast, with bone-borne distractors most of the maxillary expansion is orthopedic and at a more mechanically desired

level with less dental side effects. In addition the forces are directly on the bone and no tooth tipping and other unwelcome side effects expected. Classic treatments have been purposed to reestablish adequate transverse palatal width including the following three procedures: segmental Le fort I osteotomy and surgically assisted and orthodontic rapid palatal expansion.[32] On the other hands, the absence of the midpalatal suture in cleft lip and palate patients combined with the tremendous soft-tissue tensions caused by scar contracture resulting from multiple surgical interventions cause the risks of relapse and unstable expanded segments of maxilla in the general transverse discrepancy corrections. It is significantly noticed that there are many documents that proved a limitation of tooth-borne appliances. Holberg and Holberg *et al.*[34] concluded in the study of quadhelix ability in transverse correction of cleft lip and palate patients that if a cleft jaw and palate did not present, the maxillary expansion with the quadhelix apparatus could not achieve a relavant skeletal effect at the more remote structures of the midface and the cranial base. They as well suggested that in place of the quadhelix apparatus, other equipments could also be used to generate moderate transverse forces in cleft patients. Enacar and Ozgen[35] reported the use of asymmtric maxillary expansion appliance (ABHE) for reducing risk of over correction in unilateral cleft lip and palate patients who had an asymmetric constricted arch. Surgical assisted rapid maxillary expansion (SARME) was recently introduced to correct constricted upper dental arch. But, there were also many documents confirmed that SARME had a lot of limitation when used for cleft lip and palate patients. The SARME effects decreased mainly from the connecting structures between the maxilla and the pterygoid plate of the sphenoid bone (i.e., pterygomaxillary sutures) and the piriform plate, regardless of the absence of the midpalate.[18]

Because of the successful development of the distraction osteogenesis by Ilizalov[22], this concept has been modified for treating the several types of deformed maxilla patients. Since early in the 21st century various appliances have been developed for bone-borne devices. In the year 1999, Mommaerts[3] presented the transpalatal distractor (TPD), which was the first bone-borne device for SARME. The TPD avoided all of those aforementioned problems that occurred during expansion by tooth-borne devices and presented its stability. Moreover, there was a case report mentioning the use of a bone-borne transpalatal distractor following a maxillary subapical osteotomy to treat an asymmetric transverse discrepancy in an unilateral cleft lip and palate patient.[37] However, Scollozi and Verdeja *et al.*[32] suggested that those method was excellent for reestablishing a continuous maxillary arch and a correct transverse dental relationship. But,

the follow-up period was too short to allow definitive conclusions, and for this reason, it was difficult to suggest this method was available for cleft patients.

A lot of new commercially available bone-borne distractors liked the Transpalatal Distractor (TPD), the Magdenburg palatal distractor (MPD), Dresden distractor (DD) and the Rotterdam palatal distractor (RPD) had proven to be useful in acquired deformation patients. Momaerts[3] first showed, the transpalatal distractor (TPD), in 1999 and concluded that TPD proved to be a reliable and successful method for expansion of the maxilla with minimal segment tilting and without orthodontic and orthopedic relapses or dental and periodontal damage. Scolozzi and Verdeja *et al.*[32] evaluated prospectively the use of transpalatal distractor for surgically assisted rapid palatal distraction osteogenesis in the treatment of severe unilateral maxillary constriction of patients with cleft lip and palate following alveolar bone grafting. The authors concluded that surgically assisted rapid palatal distraction osteogenesis using a transpalatal distractor resulted in a high rate of success in correcting maxillary transverse width discrepancies and dental crossbite and offered a harmonious maxillary arch shape in patients with unilateral cleft lip and palate.

Gerlach and Zahl[37] presented a modified palatal distractor, the Magdeberg palatal distractor®(MPD; KLS Martin, Tuttlingen, Germany) in 2003. The MPD was conduced in adolescents and adult with transverse maxillary deficiency. The modified distractor was applied for bone-borne expansion of the two halves of the maxilla following of the lateral walls osteotomy of the maxillary sinuses and the midpalatal suture. They found the more benefits than the previous appliances that were no relapses and the handling simplicity for the patients. The authors also advocated this appliance for routinely clinical using.

In the year 2006, Koudstaal and van der Wal *et al.*[38] presented an other modified bone-borne palatal distractor, the Rotterdam Palatal Distractor® (RPD; KLS Martin, Tuttlingen, Germany) was developed based on the mechanical properties of a car jack. By activation the nails of the abutments plates penetrated the bone and automatically stabilized the device. Due to the design and the fact that it was a one-piece-device the RPD was easily placed and activated. There was no need for dental anchorage that might cause damage to the dentition or dental tipping. Because there was no dental anchorage, the distractor allowed simultaneous orthodontic treatment with fixed appliances. After the consolidation period the RPD could be easily removed under local anesthesia. However, because of the design of RPD there was a relative

contraindications in cases with class II deepbite; the distractor or the small activation rod on the palate might then interfere with the teeth of the mandible. One absolute contraindication was in case of low palate, which caused this device was not appropriated for Apert's syndrome and cleft patients. The nail of the abutment plates would be loose fixation and the distractor was not stable. A general contraindication for distraction was an immune deficiency and irradiation prior to the surgery.

Hansen and Tausche *et al.*[39] studied the effects of bone-borne, surgically-assisted rapid maxillary expansion with Dresden distractor (DD) and concluded that the DD was an effective therapeutic method that spared the patient the negative side effects associated with tooth-borne RME such as root resorption, bone dehiscence, bite opening and excessive buccal tipping of the teeth. The prerequisite for stable occlusion were brought about by the fact that the expansion was skeletal in nature, with minimal dental tipping.

Seitz and Landes *et al.*[40] developed an up-to-date bone-borne distractor called the maxillary widening device (MWD™) that combined with Glassman's modified LeFort I ostectomy. They found that the MWD™ turned out to be safe easy to handle and reliable bone borne distractor leading to excellent result. It could be used in early adult as well as in syndromal patients.

Stability in expansion procedure

There were restricted documents mentioned about transverse stability after cleft lip and palate orthodontic treatment. Ramstad and Jendal *et al.*[10] concluded that the long term post-treatment transverse stability of the maxillary dental arch in subject with unilateral complete cleft lip and palate showed transpalatal arch width reduction for the first molars indicated that, on average, most of the post-treatment dental change had taken place during the initial five years follow-up. However, complete stability was seemingly not reached even at the final observation (13.5 years). Accordingly, Wertz[41] studied about the relapse tendency in minor transverse discrepancies correction with rapid maxillary expansion and concluded that it tended to increase with skeletal maturation, as less bony displacement and more dentoalveolar movements were observed. Li and Lin *et al.*[42] also concluded that relapse after expansion with a quadhelix followed by preadjusted edgewise treatment always occurs, especially in the upper canine and first premolar region. However, they found that the upper arch width of each region increased significantly.

Lack of midpalatal suture in CLP patient does not promote any benefits to the ability of the modified expansion appliance in this study, because of the maxilla articulates with ten other bones of the face and the cranium. The sphenoid bone lies just posterior to the maxilla, the pterygoid plates of the sphenoid, although bilaterally positioned but lacking midsagittal suture that allows them to be displaced laterally and the pyramidal process of the palatine bone which interlock with the pterygoid plate. This conferring effect of the sphenoid minimizes the ability of the palatine bones to separate at the midsagittal plane. This explains the non-parallel opening of the midpalatal suture in anteroposterior direction.[28,43] Jafari and Shetty *et al.*[44] also concluded that the main resistance to midpalatal suture opening is probably not in the suture itself but in the surrounding structures of sphenoid and zygomatic bones. Moreover, Pan and Qian *et al.*[45] presented the similarities in physical feature exist between cleft and non-cleft skulls. The finite element analysis confirmed the limitations results from the connection between the maxilla and the pterygoid plate of sphenoid bone, regardless of the absence of the midpalate.

Implants as anchors for orthopedic applications

The use of implants in dentistry began when Branemark and Adell *et al.*[46] published the success of the ossteointegrated titanium endosseous implants. Implants in dentistry were mostly used for prosthetic reasons, but in the recently years, they were purposed to the orthodontic anchorage considerations. However, to use implants, good and sufficient surrounding bone was necessary for their placement. In orthopedic treatment, it was common to use appliances to move bones or influence bone growth. The force was transmitted to the bones by a tooth; this implied that skeletal as well as dental effects. In some patients, tooth movement was desirable, but the others, it compromised the outcome. Tooth splinting or controlling force vectors could minimize undesirable movement, but it could not be avoided. Skeletal movement could be accomplished by using teeth as anchorage, but dental side effects often limited the amount of movement. Implants could overcome the limitations by guiding forces directly to the bone.[47] To evaluate the application of implants in sutural expansion, animal studies had been conducted.[48,49] The results showed that the amount of expansion was positively correlated to the force and no detrimental effects of loading on implants to expand sutures.

Stability of orthodontic microimplant

Orthodontic microimplant anchors (*microimplant, microscrew, miniimplant or*

miniscrew) such as titanium screws were used for absolute anchorage during edgewise treatment. Miyawaki and Koyama *et al.*[50] performed the human study about the stability of implant anchors placed in the posterior region and reported that the success rates and factors associated with the stability of titanium screws were examined in relation to clinical characteristics. Furthermore, flap surgery was associated with the patient's discomfort. A high mandibular plane angle and inflammation of peri-implant tissue after implantation were risk factors for mobility of screws. But, they did not detect a significant association between the success rate and the following variables: screw length, kind of placement surgery, immediate loading, location of implantation, age, gender, crowding of teeth, anteroposterior jaw base relationship, controlled periodontitis, and temporomandibular disorder symptoms.

There was a controversy about implants success rate study, but Ohashi and Pecho *et al.*[51] who searched the results and the initial number of abstracts selected according to the selection criteria from the various methodological checklist, presented that the implants showed average higher success rate than did screws on the selected studies. Liou and Pai *et al.*[52] studied about the stationary of miniscrews, they concluded that miniscrews were a stable anchorage but did not remain absolutely stationary throughout orthodontic loading. They might move according to the orthodontic loading in some patients. Deguchi and Takano-Yamamoto *et al.*[53] studied about bone-implant interface of small titanium screws as an orthodontic anchorage and to retrieve an adequate healing period in dog. Overall, successful rigid osseous fixation and the "three-week unloaded" healing group were; increased labeling incidence, higher woven-to-lamellar-bone ratio, and increased osseous contact. All of the loaded implants remained integrated. Mandibular implants had significantly higher bone-implant contact than maxillary implants. The data indicated that small titanium screws were also able to function as rigid osseous anchorage against orthodontic load for 3 months with a minimal (under 3 weeks) healing period.

As microimplant is a temporary anchorage devices and fixed to bone for the purpose of enhancing orthodontic anchorage either by supporting the teeth of the reactive unit or by obviating the need for the reactive unit altogether, and which is subsequently removed after used. It is suggested that a waiting period for bone healing and osteointegration before loading is unnecessary because the primary stability (mechanical retention) of the miniscrew is sufficient to sustain a regular orthodontic loading.[52,54] Kravitz and Kusnoto *et al.*[55] suggested partial osteointegration of microimplant could be achieved after 3 weeks of insertion. While Romanos

and Toh *et al.*[56] showed that immediate loading increased the ossification of the alveolar bone around the implant.

Kyung and Park *et al.*[57] recommend sizes longer than 6 mm in maxilla. The cortical surfaces of the maxilla are thinner and less compact than those of the mandible and accordingly will require longer microimplants. A general rule of thumb should be, to use the longest possible micro-implant, without jeopardizing the health of adjacent tissues. The proper length of microimplant is best selected during the pilot drilling. Furthermore, one has to consider the path of insertion of microimplant, while choosing the right one. Clinically in order to get better mechanical retention, it is good to choose a longer and thicker microimplant, rather than shorter and smaller one. The diameters of Micro-implant from 1.2–2.5 mm are available. The diameter 1.2-1.3 mm can all withstand up to 450 g of orthodontic force when patient has good quality of cortical bone. When using forces greater than 300 g, clinicians should select 1.4 – 1.6 mm in diameter. But, there is no initial tightness with diameter 1.2 – 1.3 mm microimplants, clinicians should select the next larger sizes until there is a close fit between screw and bone.[57]

Kravitz and Kusnoto *et al.*[55] suggested that the key determinant for stationary anchorage is a quality of bone derived from density that was classified into 4 groups based on Hounfield unit (HU). The selected palatal areas, where microimplants were inserted, were anterior and posterior maxilla that categorized into groups of D2 and D3 respectively. D2 group (850-1250 HU) is thick (2 mm), porous cortical bone with coarse trabeculae, and D3 group (350-850 HU) is thin (1 mm), porous cortical bone with fine trabeculae. They claimed that microimplant placed in regions of thick keratinized tissue, such as the palatal slope, are less likely to obtain adequate bony stability.

3. Objectives

1. To determine distance changing after the constricted maxillary arch expansion of cleft lip and palate patients by a modified expansion appliance fixed with microimplant.
2. To evaluate the stability of microimplant, while used as a supplementary component for expanding the constricted maxilla in cleft lip and palate patients.

4. Hypotheses

1. A modified expansion appliance fixed with microimplant can transmit expanding force to maxillary bone.
2. Microimplants are stable enough for using as an anchorage for expanding constricted maxilla in cleft lip and palate patients.

5. Benefits

The modified expansion appliance fixed with microimplant could be an alternative option, which is inexpensive, less aggressive, and individualized, for correcting transverse discrepancy in cleft lip and palate patients.

CHAPTER 2

RESERCH METHODOLOGY

This study was approved by the Standing Committee on Ethnical research in Human of Faculty of Dentistry, Prince of Songkla University.

Patients

The study was performed at Dental hospital, Faculty of Dentistry, Prince of Songkla University. Cleft lip and palate (CLP) patients, who were treated in orthodontic clinic, Dental Hospital during January 2008-December 2009, were recruited into this study. The inclusion criteria for the samples were; 1) ASA category type I patients, 2) all permanent teeth presented, 3) no orofacial clefting as part of a craniofacial syndrome. All patients were treated according to the protocol used by the cleft palate team at the PSU Dental Hospital. Informed consent was obtained from each patient and guardian who would like to participate in the study.

According to the protocol, patients would be taken the common three types of data-records at initial (D1), completed expansion period (D2) and at the date the appliance was removed (D3). The data records were as followed:

1) Standard extraoral and intraoral photographs at D1, D2 and D3.
2) Dental models at D1, D2 and D3.
3) Posteroanterior cephalogram (PA cephalogram) at the date after the modified appliance was place and at D2.

The modified expansion appliance fabrication

The modified expansion appliance consisted of 2 parts, the modified expansion appliance part and microimplants. The modified expansion part was made from self-cured acrylic resin (Orthocryl®; Dentarum Group, Ispringen, Germany), embedded at the center with bilateral expansion screw (Rematitan®; Dentarum, Ispringen, Germany). Four microimplants, a Titanium alloy in composition, self-drilling, and small head type (Absoanchor® SH 1413-10, Daegu, South Korea), were used as bony anchorage. (Fig 1) and placed by using the Torque gauge driver (LHD-B-TG® driver, Dentos Inc. Daegu, Korea) (Fig.2).

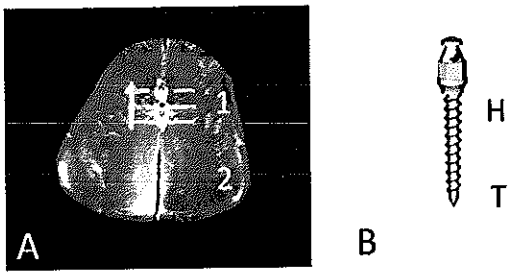


Fig. 1 Components of a modified expansion palate fixed with microimplant.
A. The modified expansion appliance (1) with bilateral expansion screw (2).
B. The SH 1413-10 microimplant; (H=head, T=tail).

Fig.2 Torque gauge driver.

Clinical procedure

After taking an alginate impression, the impression was soaked in Hibiscrub® (Regent Medical Ltd. UK) 15 minutes before 2 sets of dental models were poured with dental stone type IV. A dental model was used as working model and marked the positions for microimplant placement (Fig. 3) while another model was used as reference.

Fig.3 The working model with 4 landmarks for microimplant placement.

The 4 landmarks were copied on the acrylic part of the modified appliance, punctured a hole through each landmark (Fig. 5A) and then transferred to represent the microimplant placement position into oral cavity (Fig. 5B) with Toluidine Blue. The microimplant placement position must be at the thinnest palatal mucosa and at least 10 mm under the contact points between adjacent teeth (Fig.4). Finally, four microimplants were placed (Fib. 5C) into the palatal vault with the Torque gauge driver (LHD-B-TG® driver, Dentos Inc. Daegu, Korea) (Fig. 2). The same operator conducted the step of microimplant placement in this study.

After microimplant placement, the modified expansion appliance was placed above the microimplants Fig. 5D), united each part with self-cured acrylic resin (Orthocryl®; Dentarum Group, Ispringen, Germany), gliding acrylic remnants, and polishing the acrylic part. Patients would be prescribe Paracetamol 500 mg 10 tablets, 2 tablets for pain relief every 4-6 hours, Amoxicillin 250 mg 20 capsules, 1 capsule; 3 times after meals, and Chlorhexidine mouthwash 0.012% mouth rinse before bedtime.

PA cephalogram (Siemens™ Orthophos, Germany) was immediately taken after completely placing the modified expansion appliance. After PA cephalogram was taken, the expansion screw was activated for four turns.

Patients were instructed to start activating the screws themselves 4 turns daily at the same time, 2 turns in the morning and 2 turns at night, until the expansion screw was terminated (Fig. 5E). The complications, obstacles and uncomfortable conditions during treatment were concerned and recorded. If any serious complications were found during treatment time, the expansion procedure was immediately discontinued, and would be referred to deserve the appropriated treatment.

After completed expansion, patients returned to the orthodontic clinic for post-treatment data collection and attended the modified expansion appliance removal. After that, patients were delivered upper removable retainers immediately (Fig. 5F).

The instructions pamphlets were given to patients to treat their own retainers. The final result was collected through extraoral, intraoral photography, and dental model.

Fig.4 The thinnest palatal mucosa was marked at least 10 mm under the contact points between adjacent teeth (A and B).

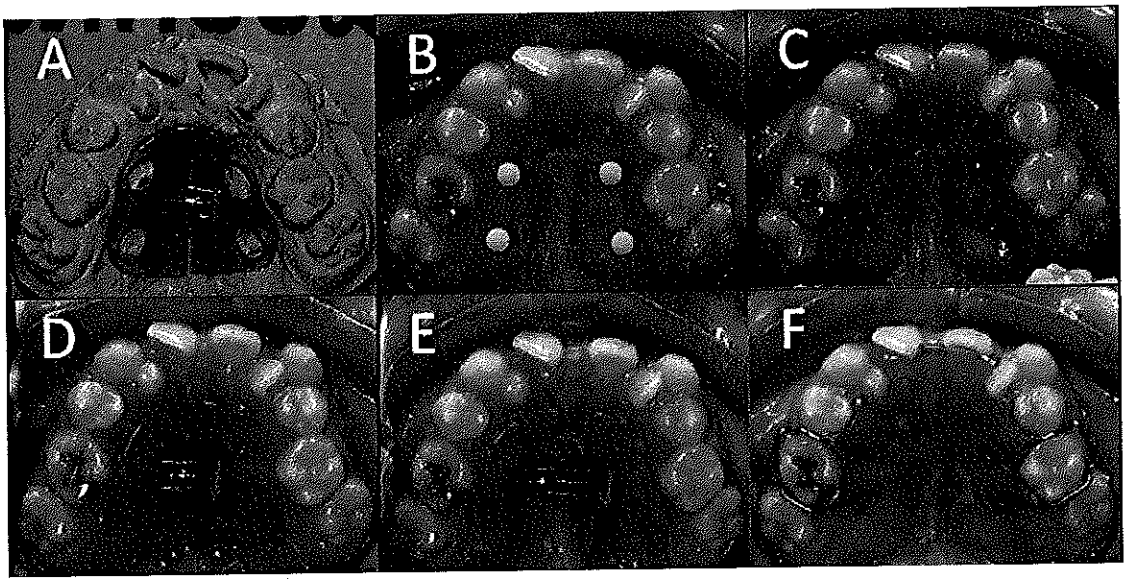


Fig.5 The maxillary expansion procedure: (A) the four holes microimplants placement position on acrylic plate (B) transferring the positions to palate (C) the microimplants placement (D) united the modified expansion appliance and microimplants with self-cure acrylic, (E) complete activation of the appliance, and (F) the removable retainer was given to patient immediately after the modified appliance removal.

Data collection

According to the protocol, patients would be taken the common three types of data-records at initial (T1), and at the date the appliance was removed (T2). The data records were as followed:

1) Standard extraoral and intraoral photographs
2) Dental models
3) PA cephalogram immediately after the modified appliance was placed and at T2.

Linear measurements were accomplished with a digital caliper (Digimatic caliper®, Mitutoyo Corporation, Tokyo, Japan) (Fig.6), and measuring tool in the photograph management computer program.

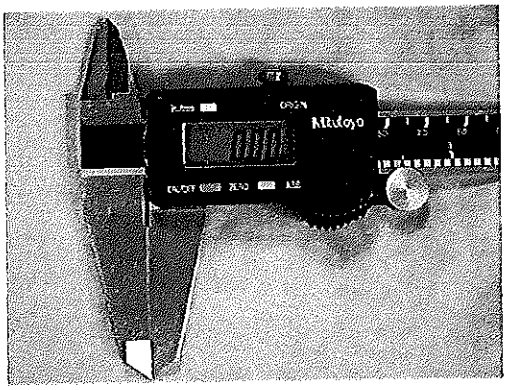


Fig.6 A digital vernier caliper.

Dental model measurements

The 18 points (Fig. 7) would be marked with 0.3 mm 2H-pencil on the surface of all maxillary teeth as reference points for nine transverse linear measurements (Fig.8). Twice measurements, 2 week separately, were directly done by digital caliper with the accuracy to decimal places, and the average dimensions would be recorded (Fig.7).

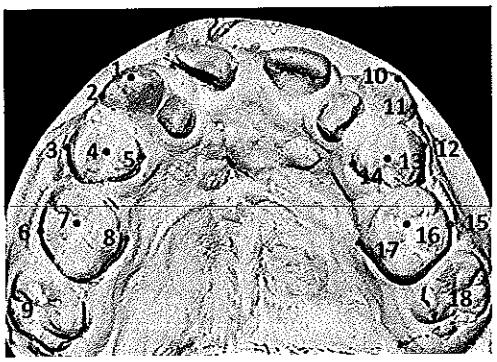


Fig.7 The 18 reference points on maxillary teeth were: cusp tips of canines (1, 10), the most prominent points of buccal surface of canines (2, 11), the most prominent points of buccal surface of premolars (3, 12), central pits of premolars (4, 13), the most prominent point of palatal surface of premolar (5, 14), the most prominent points of buccal surface of first molars (6, 15), central pits of first molars (7, 16), the most prominent points of palatal surface of first molars (8, 17), and the most prominent points of buccal surface of second molars(9, 18).

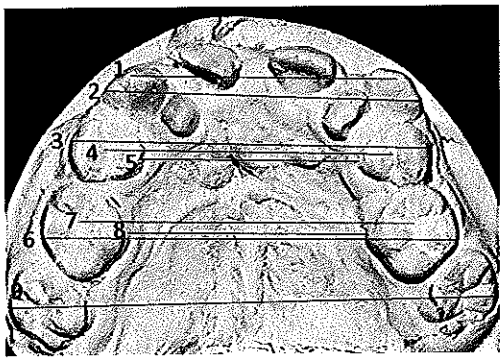


Fig.8 The 9 Linear measurements were:

1.) intercanine width; ICW.

2.) the distance between the most prominent points of buccal surface of canines; W3.

3.) the most prominent point of palatal surface in the region of premolars; PW4.

4.) the most prominent point of buccal surface in the region of premolar; BW4.

5.) the most prominent point of palatal surface of first molars; PW6.

6.) the most prominent point of buccal surface of first molars; BW6.

7.) anterior arch width; AAW.

8.) posterior arch width; PAW.

9.) the most prominent point of buccal surface of second molars; W7.

Posteroanterior cephalograms (PA Cephalogram)

All PA Cephalograms would be taken with vertical guided-head stabilizers, which was individually custom and made by silicone (Silagum® putty type; DMG, Germany), to control vertical head position during PA Cephalogram taking (Fig.9a, 9b).

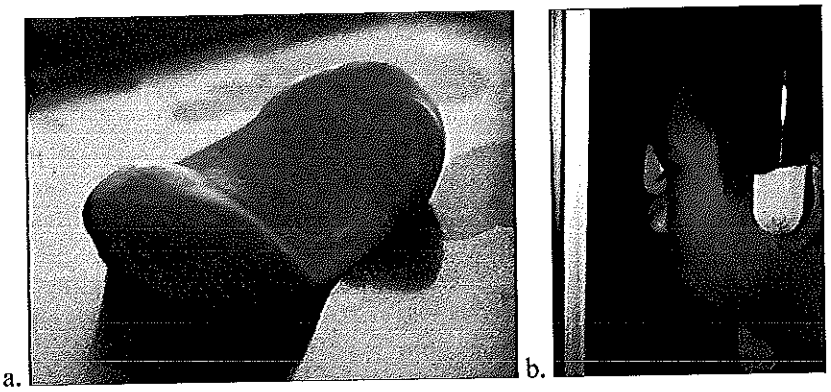


Fig.9 ; **a.** The vertical guided-head stabilizer, **b.** Patient posture when the stabilizer in use.

After that, all PA Cephalograms were traced for left and right reference points (Fig.10) as followed:

1) The intersection between the greater wing of sphenoid bone and the inner cortex of the orbit described as 'interorbital distance' (O-O′)
2) The outermost of inner surface of nasal cavity described as 'internasal distance' (N-N′)
3) Right and left jugal notches described as 'interjugal distance' (J-J′)
4) The half way between jugal notch and the peak of buccal plate of alveolar bone described as 'inter-midalveolar distance' (MidA-MidA′)
5) The peak of buccal plate of alveolar bone described as 'interalveolar distance' (A-A′)
6) The outermost of molars described as 'intermolar distance' (M-M′)

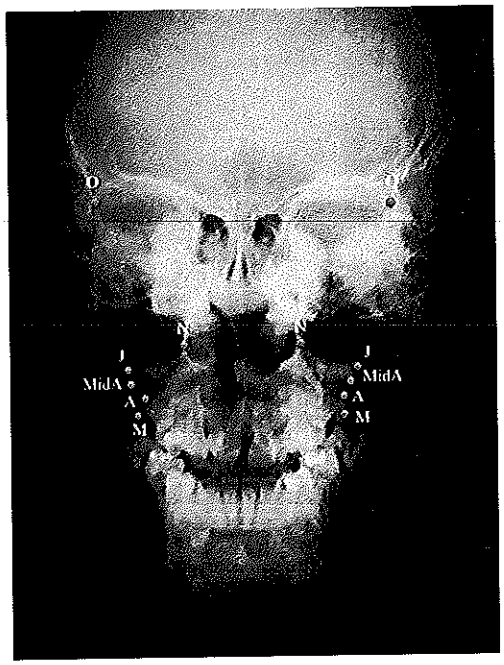


Fig.10 The reference points on PA Cephalogram.

To evaluate the maxillary widening, 6 references lines (Fig. 11) were measured with digital vernier caliper (Digimatic caliper®, Mitutoyo Corporation, Tokyo, Japan) (Fig.6). The 6 reference lines were constructed from right and left references points as followed (Fig.11):

1) interorbital distance (O-O′)

2) internasal distance (N-N′)

3) Interjugal distance (J-J′)

4) interalveolar distance (A-A′)

5) inter-midalveolar distance (MidA-MidA′)

6) intermolar distance (M-M′)

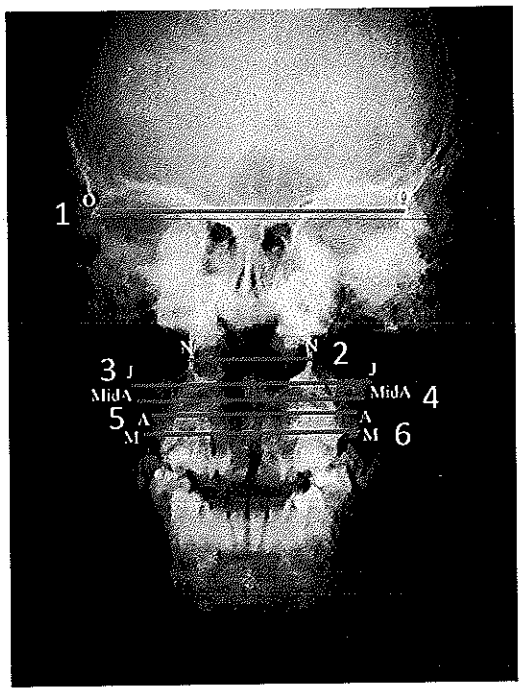


Fig.11 The constructed reference lines.

All linear parameters were measured twice by the same researcher with a time interval of 2 weeks or more, and were averaged.

The microimplants tilting

On PA Cephalogram, the microimplant tilting, at T1 and T2, were analyzed from angle between the microimplants axes and the interorbital line (Fig. 12).

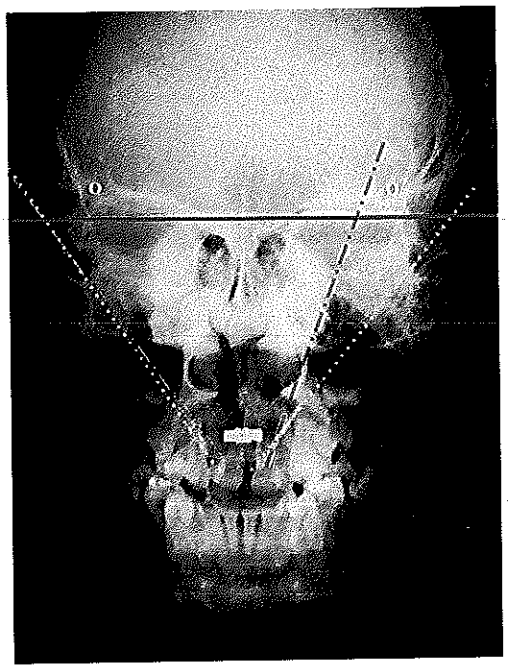
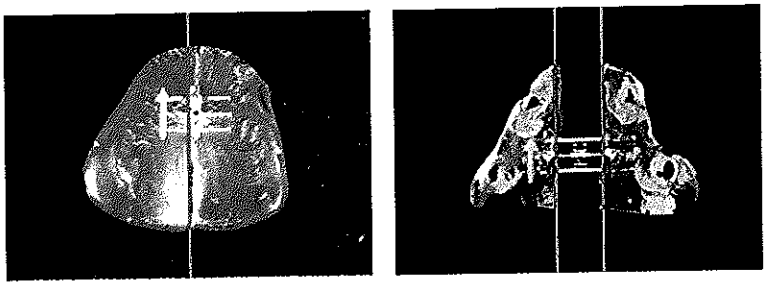


Fig.12 Microimplants tilting measurement; anterior microimplants axes represent as (_ . _ . _ .), posterior microimplants axes represent as (.....).

Appliance widening measurement

To evaluate the amount of screw expansion, the acrylic part widening would be measured after taking off the appliance from patients' mouth (Fig.13) and the amount of screw's turning backward was also recorded at the same time.



Before (A) **After (B)**

Fig.13 The widening of a modified expansion appliance: A) at T1 and B) at T2.

Statistical analysis

These data were statistically analyzed by using SPSS version 13.0 for Windows.

Method error

To minimize the error of landmark identification, radiographic magnification, and digitization of measurements, all of dental models and PA Cephalograms were scanned and digitized at the same time. All parameters were measured twice by the same researcher. The reliability of all measurements would be calculated by the double assessment method using the Dahlburg formula:

$$ME = \sqrt{\sum d^2/2n}$$

Where "n" was the number of measurements and "d" was the difference between the first and second measurements.

Normal distribution test

Kolmogorov-Smirnov test would be done for proving normal distribution of data with the formula;

$$D = \max [F(x) - S(x)]$$

Descriptive statistics

Paley[58] classified the difficulties encountered during surgery, distraction, and consolidation as (A) problems (difficulties that are self-resolving during treatment), (B) obstacles (difficulties that are resolved with specific treatment), and (C) complications (negative effects that are not resolved at the end of treatment). Not only the complications and patient's complaint were recorded, but also the problems and obstacles happened during treatment were reported.

The median and range of all parameters at T1 and T2 would be calculated from dental models, PA cepholagrams and the modified expansion appliance.

Inferential test

Using non-parametric Wilcoxon signed ranks test compared the median differences of all parameters, an alpha significance level of 0.05.

CHAPTER 3

RESULT

1. General patient information

Seven complete cleft lip and palate patients, both unilateral and bilateral, were initially included in this study. There were 4 males and 3 females with average age 14.57±2.44 years. Among unilateral cleft lip and palate patients, all was affected in the left side except one female case was in the right side (table 1).

Table 1 The patients' information.

Patient No.	Sex	Age	Type of cleft (side of cleft)
1	M	14	U (right)
2	F	14	U (left)
3	F	20	U (right)
4	F	13	U (left)
5	M	14	U (left)
6	M	14	B
7	M	13	B

M; male, F; female, U; unilateral complete cleft lip and palate, B; bilateral complete cleft lip and palate

At the end of maxillary expansion, the patient number 5 who is left complete unilateral cleft lip and palate was excluded from the study because the appliance had not been activated properly (only 1.79 mm instead of 6-7 mm of screw widening). Totally six patients, 3 males and 3 females, with averaged age 14.67±2.66 years, were included in this study while the excluded case would be only used for the descriptive analytic discussion.

2. The clinical examination

In this study, no complication but problems and obstacles were found during maxillary expansion. The problems were 1) intra-operative and postoperative intraoral problems were pain during expansion period (n=7), 2) palatal tissue inflammation (n=7), and 3) food impaction under the modified expansion appliances (n=7). All problems disappeared after the appliances were removed.

There were three obstacles happened during maxillary expansion. The first obstacle, at the step of the appliance removal after completed expansion, it was found that a microimplant in one patient was bended, the screwdriver could not attached the microimplant directly and consumed the microimplant removal time longer than the rest but it had no effect to the expansion. The Second obstacle was two anterior microimplants loosed in one case; they caused the modified expansion appliance slippage and the palatal tissue around the microimplants inflammation. The last obstacle was the inconvenience to activate the screw, which could be found in the excluded case.

After the modified expansion appliances were removed, the amount of screw widening was measured. Nevertheless, no other complications, such as serious hemorrhage, nerve damage, infection, and tooth mobility, were seen in all patients (table 2).

Table 2 The problems, obstacles, and the result of screw widening.

Patient No.	Pain	Food impaction	Palatal tissue inflammation	Loosening microimplants	Postoperative microimplant structure	The result of screw widening
1	/	/	/	X	X	/
2	/	/	/	X	/(1)	/
3	/	/	/	X	X	/
4	/	/	/	X	X	/
5[b]	/	/	/	X	X	X
6	/	/	/	X	X	/
7	/	/	/	/(2)	X	/

/ ; positive to treatment. X; negative to treatment. [b] Patient was excluded from the statistic analysis. The number in (-) means the amount of microimplants affected in the treatment.

3. The amount of the modified expansion appliance effects

Dental model measurements

From study models, nine parameters were measured. The average error of all measurements was under 0.03 mm (0.00-0.06 mm). The medians of each parameter, before and after treatment, and the Wilcoxon signed rank test of those medians were shown in table 3.

Table 3 Model measurements before (T1) and after (T2) maxillary expansion.

Measurements	T1		T2		T2-T1	Wilcoxon signed rank test
	Median	Range	Median	Range		
ICW	25.43	(21.51-31.45)	27.09	(22.78-35.25)	1.66	0.028*
W3	32.58	(30.95-39.17)	34.20	(31.04-38.93)	1.63	0.028*
PW4	20.88	(14.49-25.33)	24.00	(15.51-28.96)	3.12	0.043*
AAW	30.88	(21.45-34.28)	33.40	(22.27-35.83)	2.52	0.028*
BW4	39.26	(24.93-44.43)	42.55	(25.99-47.96)	3.29	0.028*
PW6	29.38	(24.23-32.87)	32.70	(26.23-36.84)	3.33	0.028*
PAW	41.61	(30.84-45.38)	44.06	(32.66-48.97)	2.46	0.028*
BW6	51.35	(41.52-56.67)	54.08	(43.29-59.80)	2.73	0.028*
W7	61.20	(53.80-65.91)	62.63	(55.56-68.20)	1.43	0.028*

* Significant differences at $p<0.05$. ICW = intercanine width, W3 = the distance between the most prominent points of buccal surface of canines (mm). PW4 = the most prominent point of palatal surface in the region of premolars (mm). BW4 = the most prominent point of buccal surface in the region of premolar (mm). PW6 = the most prominent point of palatal surface of first molars (mm), BW6 = the most prominent point of buccal surface of first molars (mm). W7 = the most prominent point of the hindmost molars (mm). AAW = anterior arch width (mm). PAW = posterior arch width (mm).

It was found that the difference of median before and after maxillary expansion of eight parameters; ICW, W3, PW4, AAW, BW4, PW6, PAW, BW6, W7 were 1.66 mm, 1.63, 3.12 mm, 2.52 mm, 3.29 mm, 3.33 mm, 2.46 mm, 2.73 mm, 1.43 mm respectively. The median differences between before and after maxillary expansion of all parameters were statistical significance.

In transverse direction, it was more expansion in palatal than buccal aspect. The most palatal expansion was at first permanent molar (3.33 mm) while the most buccal expansion was at first permanent premolar (3.12 mm). On the other hand, the amount of buccal and palatal expansion were nearly the same at first permanent premolar and first permanent molar, but canine was less than others (fig.14). From these data, it could be stated that the modified expansion appliance had more effect in the posterior region than the anterior region.

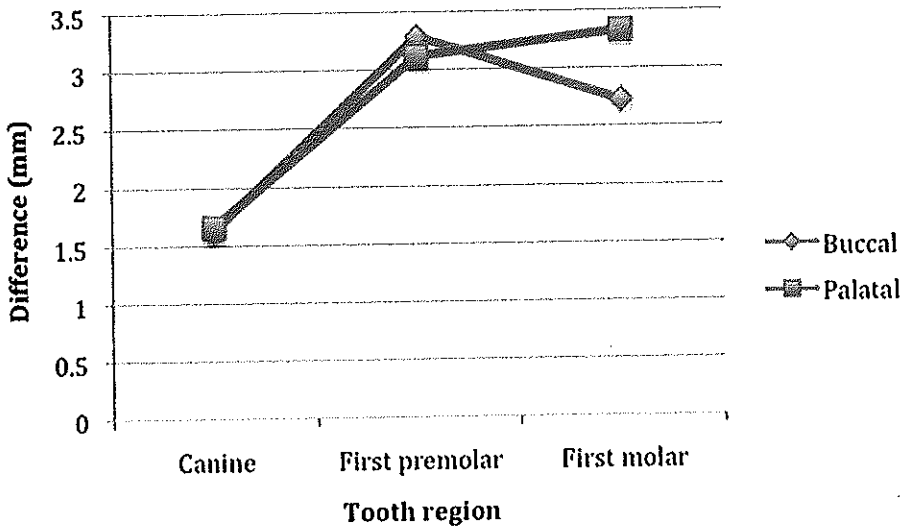


Fig. 14 Buccal and palatal distances changing at canine, first premolar, and first molar region.

Radiographic measurements

Angular measurements

The microimplants' tilting was presented in table 4. Both anterior and posterior microimplants on right side were seemingly more tilted than left side, while the microimplants on the same sides were conformation.

Table 4 The microimplants' tilting; before maxillary expansion (T1), after maxillary expansion (T2), and the mean difference between T1-T2.

Microimplants position		The microimplants' s tilting (degree)					
		T1		T2		T2-T1	
		Mean	SD	Mean	SD	Mean	SD
Right	Anterior	54.67	8.33	69.67	8.48	15.00	5.18
	Posterior	55.75	9.01	71.50	12.44	15.75	9.42
Left	Anterior	63.25	9.93	75.83	14.85	12.58	8.10
	Posterior	61.33	9.11	74.50	15.10	13.17	6.43

Linear measurements

From the PA radiographs, the average error of measurement was under 0.06 mm (0.00-0.12 mm). The mediaans of IOD, IND, IJD, IAD, IMidAD, and IMD, before and after maxillary expansion, and the Wilcoxon signed rank test of those medians were presented in table 5.

Table 5 Posteroanterior cephalographic measurements before (T1) and after (T2) maxillary expansion.

Measurements	T1		T2		T2-T1	Wilcoxon signed rank test
	Median	Range	Median	Range		
IOD	90.86	(89.14-94.39)	90.89	(88.90-94.53)	0.03	0.109
IND	31.61	(28.06-33.53)	32.00	(28.16-33.80)	0.39	0.028*
IJD	66.55	(60.47-71.68)	67.02	(61.44-73.13)	0.47	0.028*
IMidAD	65.93	(59.18-70.98)	67.35	(60.70-71.67)	1.42	0.028*
IAD	62.28	(53.95-65.77)	63.60	(55.55-67.31)	1.32	0.028*
IMD	63.25	(54.79-68.19)	65.11	(56.82-69.78)	1.86	0.028*

* Significant difference at p-value<0.05. Skeletal base; IOD = interorbital width, IND = nasal width, and IJD = interjugal distance. Dentoalveolar base; IAD = interalveolar distance, IMidAD= inter-midalveolar distance, and IMD = intermolar distance.

The least to the most expanded area were IOD (0.03 mm), IND (0.39 mm), IJD (0.47mm), IMidAD (1.42 mm), IAD (1.32 mm), and IMD (1.86 mm) respectively. Pyramidal displacement of maxilla away from the midline was evident from the postero-anterior view. The base of the pyramid was located on the oral side and the apex faced the frontal bone (fig.15). The median differences of all parameters except IOD were statistically significant (table 5).

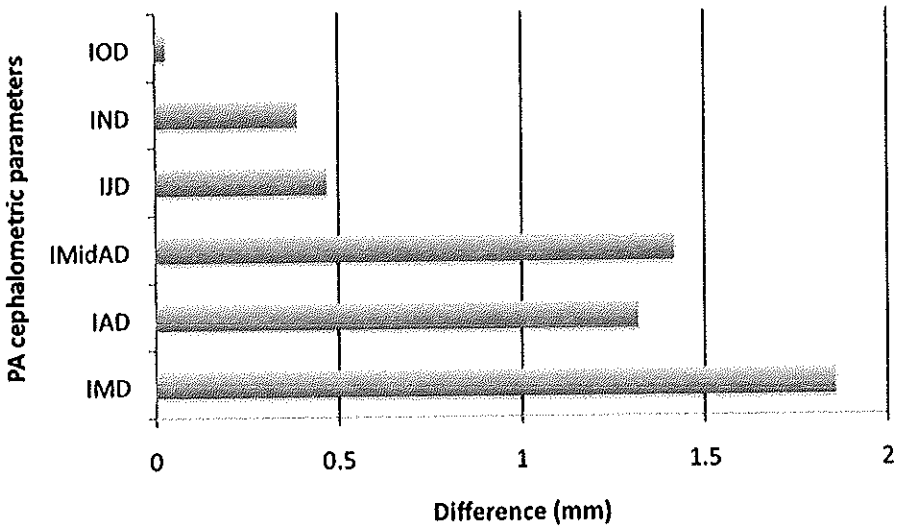


Fig.15 The distance changing after maxillary expansion of IOD, IND, IJD, IMidAD, IAD, and IMD.

CHAPTER 4

DISCUSSION

An indication for a transverse maxillary expansion often exists in CLP patients because of the excessive narrow maxilla. Biomechanic effects of RME in CLP patients are different from those in non-cleft patients, which are due to the special maxillary structure and the variety of palatal morphology of the CLP patient.[43] Recently, a few effectively techniques[32,36,38,39] for maxillary expansion in cleft patients were reported. The seven cases, 5 unilateral and 2 bilateral complete cleft lip and palate in this study, were treated with the modified expansion appliances in an attempt to find out a new treatment technique to correct the constrict maxilla of CLP patients.

The design of appliance

The concept of absolute anchorage or bony anchorage by using microimplant is widely used in orthodontic treatment.[50-53,57] This concept was applied to create the new modified expansion appliance, the modified expansion pate fixed with 4 microimplants, which was performed as a modified skeletal-anchored rapid maxillary expansion in this study. The modified expansion appliance consists of two parts; the modified expansion appliance embedded with bilateral expansion screw part as an expansion unit, and microimplant as a bony anchorage unit. Because this appliance is fabricated from simple materials, which are used in conventional orthodontic treatment such as acrylic plate, expansion screw, or microimplant, so it is less ten to fifteen times expensive than other commercial distractors. Additionally, this appliance is also easily fabricated in orthodontic laboratory.

Although many commercial maxillary distracters[3,32,37-39] are designed and successfully used for maxillary expansion in normal patients but they are limited in the CLP patients. Severities of maxillary constriction in the clefts are varied individual (fig.16). The design of modified expansion appliance used in this study can be applied for every CLP cases.

The acrylic resin used for the modified expansion appliance fabrication can easily adapt to be conformed the individualized anatomy of palate in CLP patient and also gather the palatal tissue in being the bone-tissue borne which cannot be found from other bone-borne anchorage devices (fig.17).

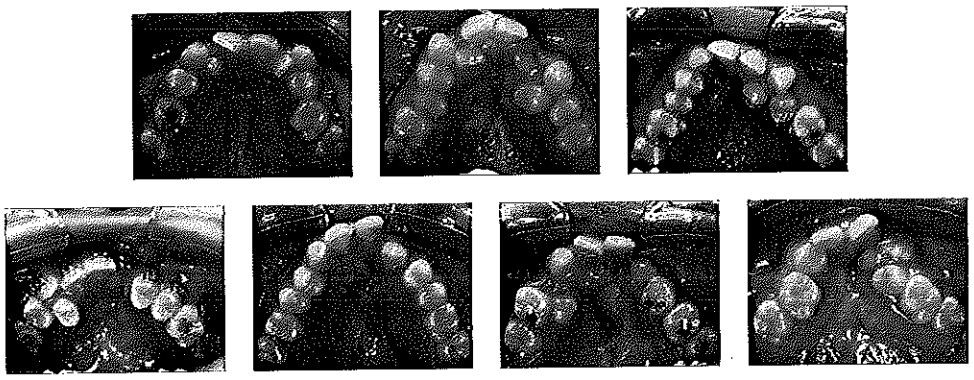


Fig.16 The variety of CLP morphology.

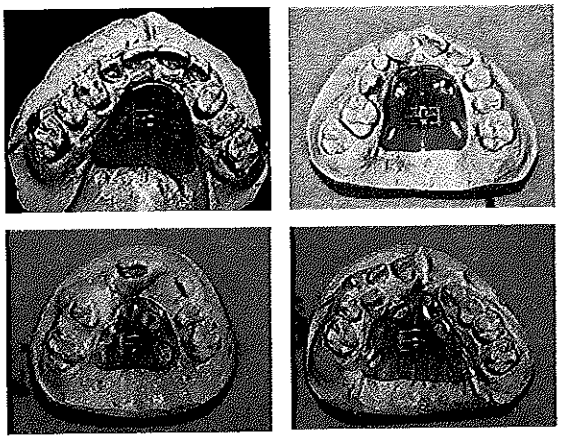


Fig.17 The adaptability of acrylic part of the modified expansion appliance.

Many studies discussed about the relation of an amount of the microimplant resistance to the force loading, and microimplant's diameter and length using as orthodontic anchorage. Holberg and Holberg *et al.*[34] suggested the orthodontic force of below 500 g already sufficed to achieve a skeletal effect in the midface and the cranial base of CLP patients. Although, these force levels are greater than those normally used to move teeth, well controlled in-vitro studies provide valuable insights into anchorage. Furthermore, greater forces are often used by orthodontists to treat patients orthopedically.[51,59] In this study, 4 microimplants were used to

withstand that total force load of bilateral expansion screw.[61] It could be concluded that the optimal orthopedic was used to expand the constricted maxilla in this study.

Then, microimplant's diameter from 1.7 -1.8 mm is designed specially for intermaxillary fixation during orthognathic surgery[57] while the 2.5 mm-diameter microimplant provided greater anchorage force resistance than 1.5 mm-diameter microimplant in the both mandible and maxilla.[59] Concerning with the length of microimplant, Kyung and Park *et al.*[57] recommend the length equal to or longer than 6 mm in maxilla but the longest possible microimplant, without jeopardizing the health of adjacent tissues, is the best. However, not only severe narrowing maxillary arch but also lack of palatal bone support and anatomical limitation of maxillary sinus often found in CLP patients. The safety zones[62] for microimplant placement in palate is located in the midline[63], which never present in CLP patient (fig.18). The bone density is one of the important considerations for primary stability of microimplant. CLP patients always found no midpalatal bone, which is the most recommended area for placing microimplant in the palate.[62] The second choice is the lateral wall of palate that found less dense bone than the mid palate.[55]

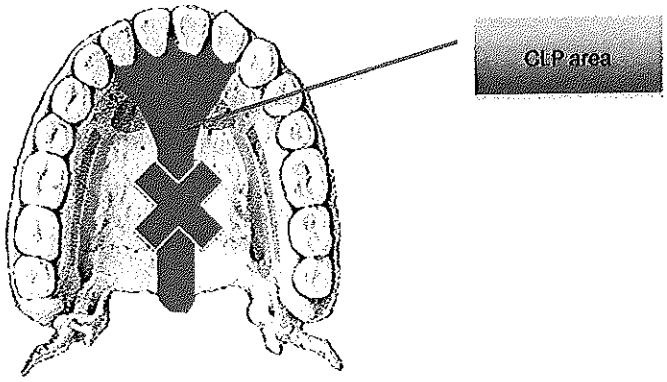


Fig.18 The safety zones of maxilla that do not present in CLP patients. (Courtesy to Lee *et al.*[62])

Moreover, the other studies[64,65] were suggested the screw length according to the thickness of the oral mucosa and allowed 5 to 6 mm insert into the palatal bone. The same conclusion from Tseng and Hsieh *et al.*[60] confirmed the depth of insertion of the microimplant was more importance than its location or length, the recommended length being at least 6 mm. For instance, if the acrylic part was 2 mm thick, the palatal mucosa was 3 mm thick, and

microimplant was inserted into palatal bone 5 mm depth, so that we recommended using a 10-mm long microimplants (fig.19).

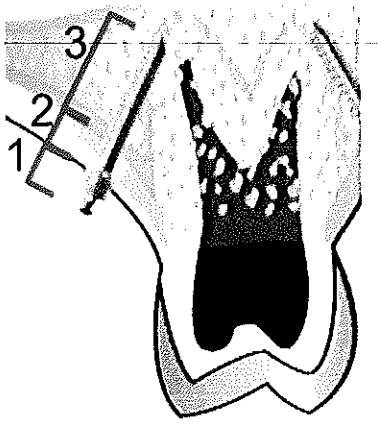


Fig.19 Three components of the surrounding of the inserted microimplant: 1; the thickness of acrylic part, 2; the thickness of palatal mucosa, 3; the essential depth of palatal bone. (Courtesy to Kyung *et al.*[57])

The posterior microimplants were placed at the first molar region, where the maxillary sinus floor is deepest, and on lateral part of palatine process of maxilla, which could endanger to vital structures like greater palatine blood vessel and nerve. The proper microimplant's diameter, 1.4 mm and 10 mm long, was used in this study. Not only about the proper force withstand and microimplant selection, but also its tiny shape which could be easily to place in every narrowed maxillary arch form when compared with others type of distractors.[3,32,37-39]. So, it could be stated that this screw can be effectively used for maxillary expansion in all types of clefts. But, the serious cautions mentioned above must be concerned when planning to place microimplant in this area.

From Liou and Pai *et al.*[52]study, miniscrews were a stable anchorage although some were moved according to the orthodontic loading. In this study, microimplants were used as bony anchorage for maxillary expansion and had got the same result as that study. Totally 28 microimplants used in this study, most of them (25 microimplants), were stable except three microimplants, one bending and two loosening, in two cases. The success rate was 89.29% that was not different from other studies.[63,64]

About the bending microimplant, it may be because of defective in product processing or the increase force torsion stress during screw activation.[55] The two loosening microimplant appeared in the case that the length of head of microimplants were embedded in the modified expansion appliance lesser than the remaining cases. Although the obstacles were found in those two cases, the appliances could be effectively used as maxillary expander as in other cases.

The palatal locations for microimplant insertion were anterior and posterior maxilla that categorized into groups of D2 and D3 in Hounfield unit (HU) respectively. They are more porous and thinner cortical bone than other areas. Moreover, microimplant placed in regions of thick keratinized tissue, such as the palatal slope, were reported of less obtain adequate bony stability.[55] In this study, all microimplants were stable although it was found averagely 13-15 degree microimplant's tilting.

Patient's Compliance

Generally, segmented Le fort I osteotomy, orthodontic rapid palatal expansion with or without surgical assisted have been purposed to reestablish adequate transverse palatal width. The modified expansion appliance placement or removal procedure was very easy and less invasive when compared with those procedures. The modified expansion appliance placement or removal procedure took about 30 minutes without any complications. The operating time was similar to other bone anchorage device procedures.[32,66,67]

Pain was generally found in the previous studies.[64,68,69,72] In this study, the patients were informed in advance about the procedure, the potential discomforts and side effects. They probably did not regard or concerned about the strain as particularly painful, regarding it as temporary and thus not really worth mentioning. Slightly pain was almost found in the first day of expansion process without using any pain relief drug. So, the same protocol for distraction osteogenesis[3,36,54-56], activating the screws 2 turns twice daily at the same time, in the morning and at night, was applied to be used in this study.

Palatal mucosa inflammation found in this study was similar to the report of Haas expander's side effects. Handelman and Wang *et al.*[69] reported the undesirable side effects of Haas expander such as pain, edema, and ulceration. They suggested to a few turn back of the

expander, a rest period of a week, and resumption of expansion at a slower schedule of every other day.

Patient compliance in this study was favorable in the majority of the patients, except patient number 5 who was excluded from the study, because of the improper execution the activation of bilateral expansion screw. The rest of patients could perform the activation of expansion screw completely themselves, and complete activation within a week. The bilateral expansion screw widening distance was reevaluated the actual widening and found the conformation of duration of activation and the actual widening. Hence, it was also objectively confirmed the patients' compliance.

The pattern of maxillary expansion

In vertical direction, most studies[28,43-45] reported that the maxillary expansion was pyramidal in shape, with the base of the pyramid located on the oral side of the bone and the center of rotation near the frontonasal suture, which was nearly unmovable.[11,43-45,70,71] The result in this study was in agreement with those studies, although the cleft has no midpalatal suture. The role of the facial skeleton as a resistance factor in midpalatal expansion was emphasized by the least response of skeletal expansion found in PA cephalogram of patient number 3, who was complete maturation and the averaged microimplants' tilting between 13-15 degrees. It also found that a diminutive slightly expansion at the zygomaticofrontal sutures, IOD, as in the other studies.[34,43,45]

In transverse direction, it was interested to find that the mean differences before (T1) and after (T2) maxillary expansion of posterior arch width was greater than anterior arch width, which indicated that the pattern of transverse dental expansion was affected by scar tissue. This finding was concordant to Pan and Qian *et al.*[45] and Wang and Cheng *et al.*[76] studies that found the most transverse displacement of maxillary arch was the cusp tip of first molar. When compared the mean differences before (T1) to after (T2) maxillary expansion of the most prominent point of buccal surface (BW) and the most prominent point of palatal surface (PW) at the first premolar (BW4-PW4) and the first permanent molar (BW6-PW6), the PW was slightly greater than BW at both premolar and molar areas. From these data, it could be stated that the modified expansion appliance had a tooth tipped-control effect.

Our patients showed very slightly spacing between central incisors. This latter finding was undoubtedly due to the fact that expansion occurred in these patients in the osseous defects, which the soft tissue tension caused by scar of palate and lips contributes to persistence of the space.[45,70]

Efficacy of expansion

The expansion results in PA cephalograms across the molar width (IMD) were 1.86 mm while expansion at the level of the basal bone (IMidAD) and maxillary base (IJD) were 1.42 mm and 0.47 mm respectively. This represents a 76.34% and 25.27% expansion compared to 18% in A-RME in the study of Handelman and Wang *et al.*[69], and 40% in Quadhelix expansion of CLP patients in the study of Li and Lin.[42] At the midpalatal level (IAD), the expansion was 1.32 mm or 70.97% of total maxillary expansion achieved. It was nearly adjacent to Handelman and Wang *et al.*[69] at the same level. Isaacsson and Murphy[70] concluded the lateral movement of basal bone was never greater than approximately 40 percent of the lateral expansion of the dental structure of CLP patients. Krebs[73] reported the efficacy of Haas expander to skeletal effect that not much more than 50% was found in the effect to skeletal part compared to the dental part (table 6).

Table 6 the comparison of the efficacy of expansion at the basal bone base and dental base.

	Normal patients		CLP patients		
	Krebs 1964[73]	Garret *et al.* 2008[75]	Isaacson *et al.* 1964[17]	Li *et al.* 2007[42]	This study 2010
Measure tool	PA ceph	CT	PA ceph	PA ceph	PA ceph
Appliance	Hyrax	Hyrax	Haas	Quadhelix+Edgewise	Modified expansion appliance
Basal bone base / Dental base	<50%	38%	<40%	40%	76.34%

On the other hand, Pinto and Mommaerts *et al.*[74] reported the ability of TPD to expand the constricted maxillary bone. It could expand 2 times more than dental changes. Similarly to Pinto and Mommaerts *et al.*[74], the ratio of basal bone and dental expansion in this

study was more than 50 percent in every case, even in patient number 3 who was complete maturation. Although the result of this study was less distance gaining; the total expansion derived from the appliance was functionally affected in both dental and skeletal aspects.

CHAPTER 5

CONCLUSION AND SUGGESTION

Conclusion

The severity of maxillary constriction is varied individually in CLP patients. Many treatment modalities are suggested to correct this deformity including rapid palatal expansion with or without surgical assisted, slow palatal expansion, distraction osteogenesis and Le Fort I oeteotomy. The modified expansion appliance fixed with microimplant, a modified appliance using simple acrylic plate embedded with bilateral expansion screw as an expansion unit, and microimplant as a bony anchorage unit, can exert orthopedic force to increase the maxillary width found in cleft lip and palate patients especially the bony part and be less effect to dental part. Microimplant is stable enough to use as an anchorage for expanding constricted maxilla in cleft lip and palate patients.

Suggestion

1. The bilateral expansion screw should place in the center of the modified expansion appliance, and be perpendicular to the midpalatal suture for deriving the parallel force expansion.

2. The bilateral expansion screw should place in the halfway between the anterior and the posterior microimplants, because the expanding force could equally distribute to the whole microimplants.

3. The selected microimplants should be enough length and diameter that withstand the expansion force, and be secure for the surrounding vital structures.

4. The acrylic part should be extended as much as possible on the palate, which does not touch any parts of the surrounding teeth.

5. The margin of acrylic part should be round and enough thickness to withstand the expansion force.

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APPENDICES

THE PATIENT DETAILS

Patient number 1 was a 14 year-old boy who had right complete cleft lip and palate. He had both anterior crossbite and posterior crossbite. There were a severe crowding in upper arch and a moderate crowding in lower arch (fig.I).

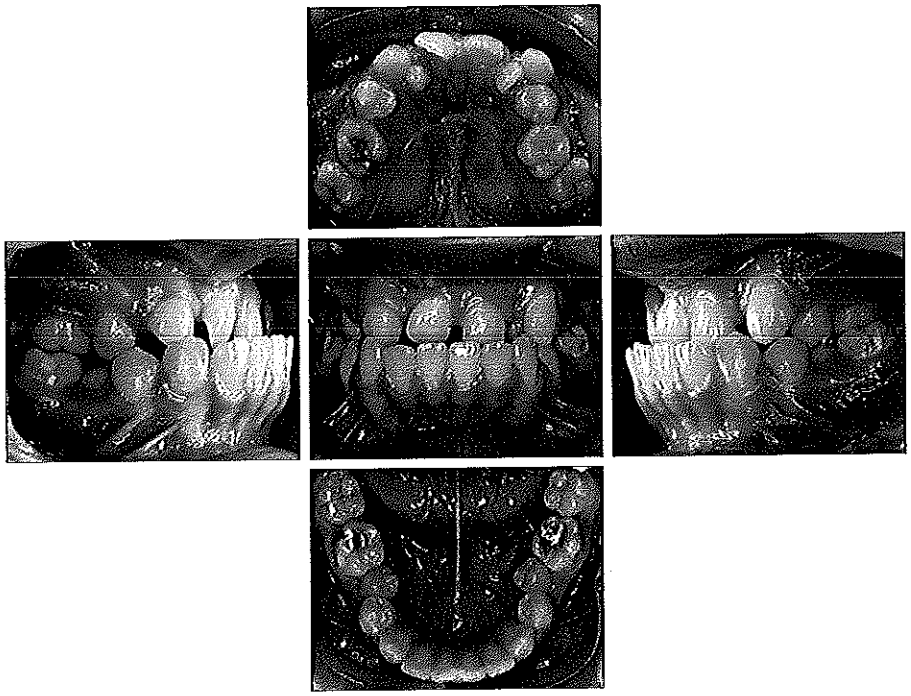

Fig.I Initial intraoral photographs of patient number 1.

Patient number 1 had a consistent palatal bone and no interrupted obstacle resisted to place the expansion appliance. The anterior microimplancts were placed in appropriated area under the contacts of second premolar and first molar, and the posterior microimplants were placed between the first molar and second molar (fig.II-2). After 30 minutes of the microimplants placement under local anesthesia and no complications reported, patient and guardians' instruction for the appliance activation method was done. The appliance could be properly activated until the termination of expansion screw for 7 days. Total treatment time was 16 days, it was implied that the appliance was left intraorally for 8 days after terminated screw. Overall appliance expansion was 6.71 mm.

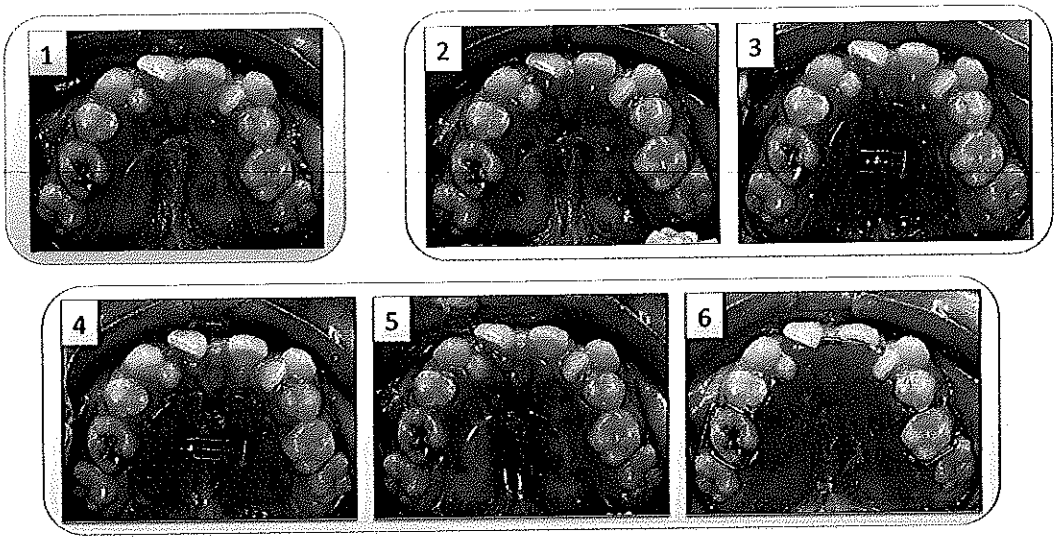

Fig.II Patient number 1 intraorally photographs presented upper arch in each stage of treatment;

1. Initial oral examination, 2. Microimplants placement, 3. Appliance assembly,

4. Completed activation of the modified expansion appliance, 5. Appliance removal,

6. Retainer delivery.

The changes of dental model parameters of patient number 1 were presented in table I and the individual PA cephalometric film changes were presented in table II.

Table I Dental model parameters changes of patient number 1.

Dental model parameters	Patient number 1 (mm)		
	T1	T2	T2-T1
ICW	31.45	35.25	3.80
W3	39.17	42.19	3.02
PW4	25.33	28.96	3.63
AAW	34.07	37.67	3.60
BW4	44.43	47.96	3.53
PW6	27.78	32.41	4.63
PAW	39.59	44.36	4.77
BW6	51.29	54.59	3.30
W7	62.42	64.16	1.74

Table II PA cephalometric film changes of patient number 1.

PA cephalometeric parameters	Patient number 1 (mm)		
	T1	T2	T2-T1
IOD	94.33	94.33	0.00
IND	33.41	34.72	1.31
IJD	70.24	71.64	1.40
IMidAD	68.43	70.59	2.16
IAD	62.41	65.00	2.59
IMD	64.19	66.78	2.59

In this patient, there was found a slightly pain without any interruption to the quality of patient's life. He claimed a better occlusion at the end of treatment. Finally, the upper removable retainer, which consisted of two Adam's clasps on upper first molars, was delivered to wear all the time except meal times (Fig.II-6).

Patient number 2 was a 14 year-old girl who had left complete unilateral cleft lip and palate. In upper arch, less buccal overjet, severe crowding and 25 palatoversion were identified. Her mandibular teeth were bonded with fixed appliance and leveled with 0.016" NiTi wire (fig.III).

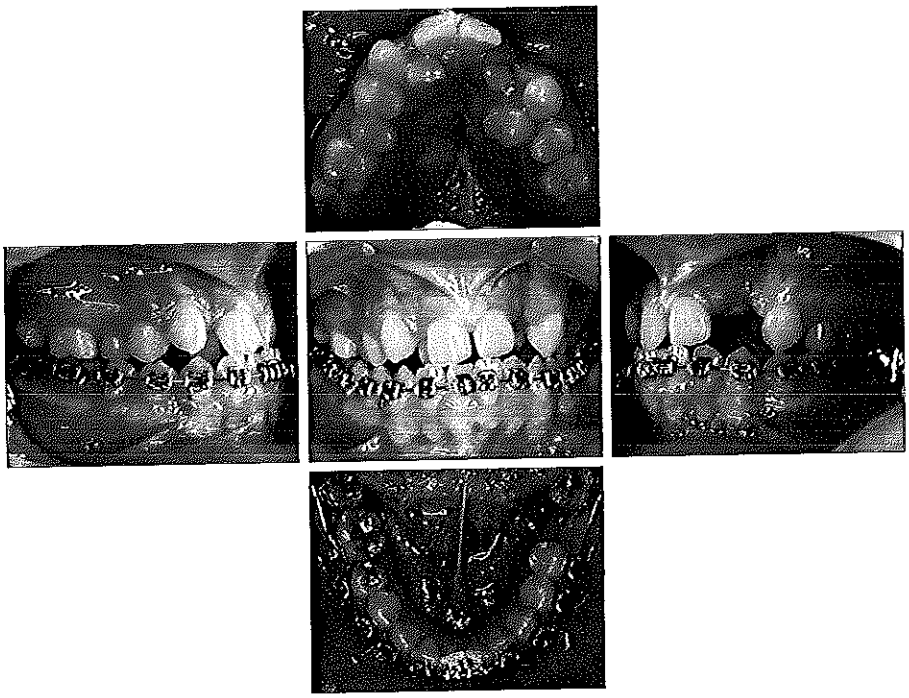

Fig.III Initial intraoral photographs of patient number 2.

The palatal area for appliance placement was deficit, because 25 was palatoversion. There was lacking of appropriate bone for placing the anterior-left microimplant. So, it was necessary to reduce inter-microimplant distance on left side, it caused the right-side miroimplants was asymmetric position (fig.IV-2). However, no complication occurred during microimplants placement operation under local anesthesia. After patient's instruction to the appliance activation method, the appliance was properly activated for 7 days and was left intraorally for 17 days. Total treatment time was 24 days. Overall appliance expansion was 7.14 mm.

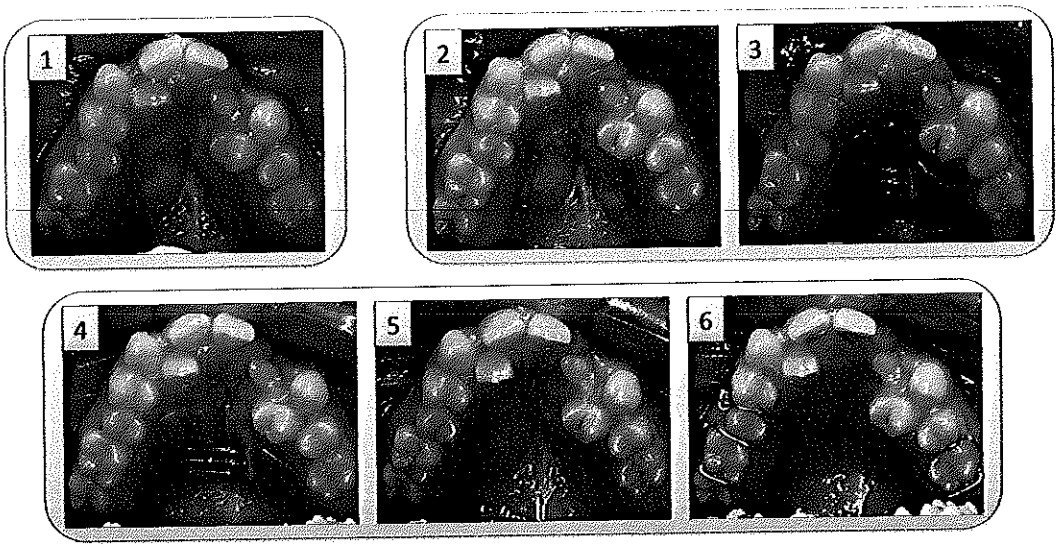

Fig.IV Patient number 2 intraorally photographs presented upper arch in each stage of treatment;

1. Initial oral examination, 2. Microimplants placement, 3. Appliance assembly,

4. Completed activation of the modified expansion appliance, 5. Appliance removal,

6. Retainer delivery.

The changes of dental model parameters of patient number 2 were presented in table III and the individual PA cephalometric film changes were presented in table IV.

Table III Dental model parameters changes of patient number 2.

Dental model parameters	Patient number 2 (mm)		
	T1	T2	T2-T1
ICW	30.23	33.00	2.71
W3	36.88	34.90	2.37
PW4	23.73	28.12	3.39
AAW	23.16	26.31	3.15
BW4	41.42	44.51	3.09
PW6	30.07	32.99	2.92
PAW	41.47	43.76	2.29
BW6	50.50	52.88	2.38
W7	53.80	55.56	1.76

Table IV PA cephalometric film changes of patient number 2

PA cephalometeric parameters	Patient number 2 (mm)		
	T1	T2	T2-T1
IOD	88.81	88.90	0.09
IND	29.96	30.66	0.70
IJD	60.47	61.44	0.97
IMidAD	60.29	61.39	1.10
IAD	53.95	55.55	1.60
IMD	54.79	56.82	2.03

In this patient, there was found a slightly pain without any interruption to the quality of patient's life. Only food impaction was recalled for patient's discomfort. She claimed a better occlusion at the end of treatment.

At the stage of microimplant removal, the anterior-right microimplant was found bending in PA cephalometric radiograph, and also verified really bending at the middle of the microimplant after removal (fig.V). However, the microimplant removal method was not different from the others. There was no complication occurred during the microimplant removal.

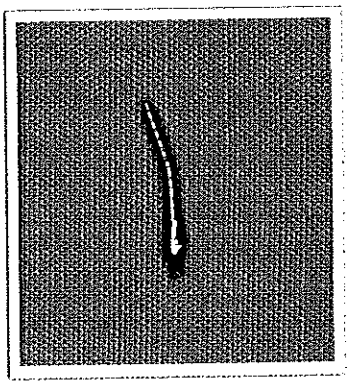

Fig.V The bending of microimplant of patient number 2

Finally, the upper removable retainer, which consisted of two Adam's clasps on upper first molars and a triangular clasp between right second premolar and right first molar, was delivered to wear all the time except meal times (fig.IV-6).

Patient number 3 was a 20 year-old woman with right complete unilateral cleft lip and palate. She had complete buccal crossbite on the right side of maxilla and crossbite of 23, 24 with 33-35. 12 was missing and 24 was ectopic eruption simultaneously palatoversion. She had already bonded lower arch with fixed appliance and leveled with 0.016" NiTi wire. There was a severe crowding in upper arch (fig.VI).

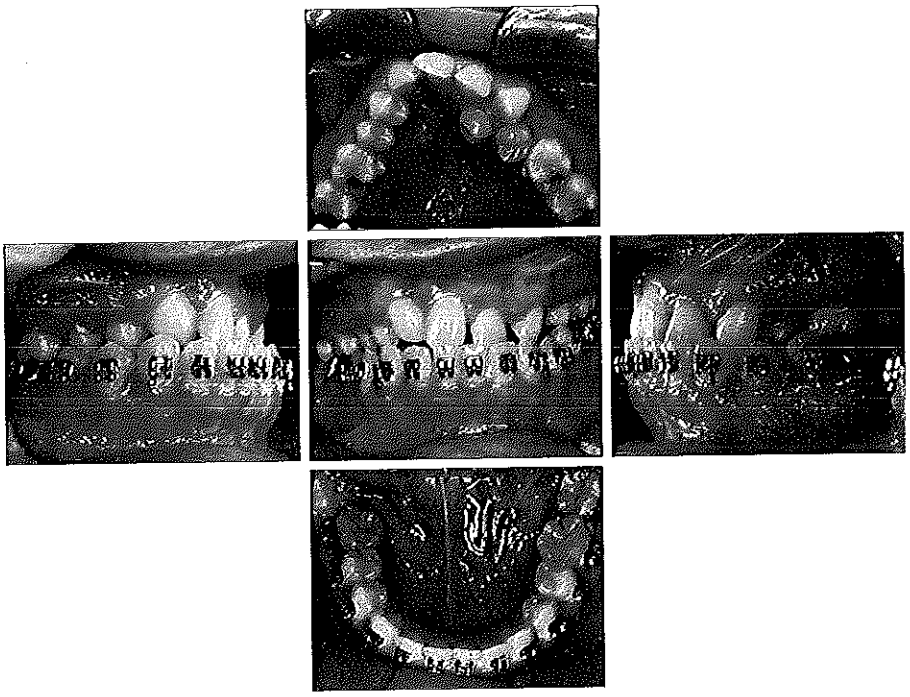

Fig.VI Initial intraoral photographs of patient number 3.

The anterior palatal area was deficit, because 24 ectopic eruption into palatal direction. The anterior and posterior microimplants were determined to stab posteriorly for parallel position. No complication occurred during microimplants placement operation under local anesthesia. After 30 minutes of the microimplants placement, patient's instruction for the appliance activation method was done. At first, patient was refused to activate herself, but there were an extremely considerable encouragement to promote the patient. Finally, she could be succeeding herself activation. The appliance was properly activated until the termination the expansion screw for 9 days. Total treatment time was 15 days, it was implied that the appliance was left intraorally for 6 days after terminated screw. Overall appliance expansion was 6.71 mm.

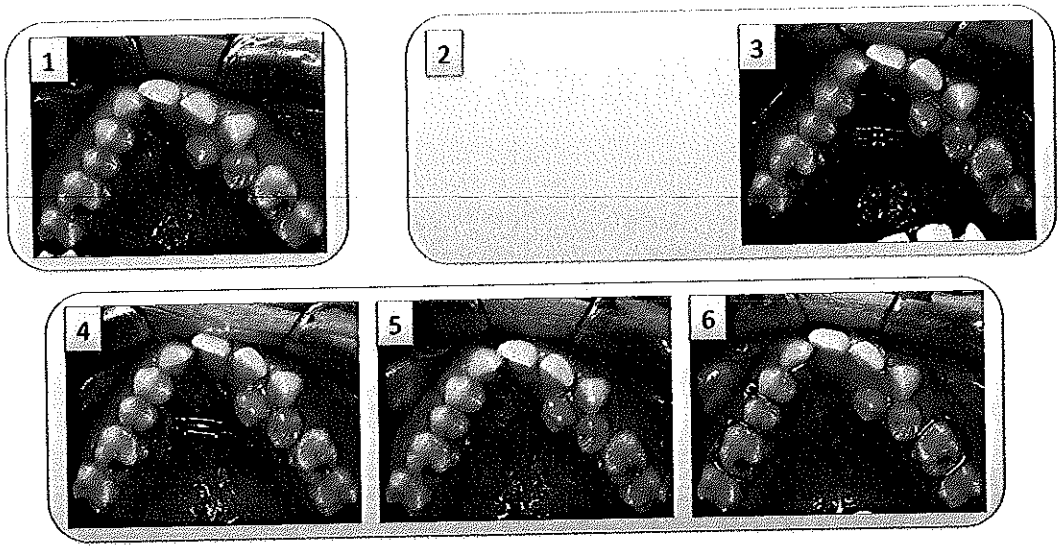

Fig.VII Patient number 3 intraorally photographs presented upper arch in each stage of treatment;

1. Initial oral examination, 2. The picture of microimplants placement was lost,

3. Appliance assembly, 4. Completed activation of the modified expansion appliance,

5. Appliance removal, 6. Retainer delivery.

The changes of dental model parameters of patient number 3 were presented in table V and the individual PA cephalometric film changes were presented in table VI.

Table V Dental model parameters changes of patient number 3.

Dental model parameters	Patient number 3 (mm)		
	T1	T2	T2-T1
ICW	21.35	22.98	1.63
W3	30.31	31.04	0.73
PW4	22.15	24.32	2.17
AAW	28.95	31.55	2.60
BW4	37.10	39.02	1.92
PW6	28.68	29.80	1.12
PAW	41.74	42.84	1.10
BW6	51.43	52.48	1.05
W7	62.44	63.32	0.88

Table VI PA cephalometric film changes of patient number 3

PA cephalometeric parameters	Patient number 3 (mm)		
	T1	T2	T2-T1
IOD	89.14	89.14	0.00
IND	28.06	28.16	0.10
IJD	69.30	69.75	0.45
IMidAD	70.98	71.59	0.61
IAD	62.48	63.32	0.84
IMD	64.14	65.15	1.01

In this patient, there was found a slightly pain without any interruption to the quality of patient's life. Food impaction was recalled for patient's discomfort. The hardness of activation was also declared at the early stage of activation. But, she had a plenty of encourages from her doctor and family; eventually, she could be activating the appliance correctly and properly herself. She claimed that she had a better occlusion at the end of treatment and would like to introduce this method of expansion to other CLP patients. Finally, the expansion appliance was removed and found no complication. The upper removable retainer, which consisted of two Adam's clasps on upper first molars and a triangular clasp between right first and second premolars, was delivered to wear all the time except meal times (fig.VII-6).

Patient number 4 was a 13 year-old girl with left complete unilateral cleft lip and palate. She had a decreased buccal overjet on both sides. 21-23 were missing and 14 was ectopic eruption simultaneously palatoversion. She had already bonded upper and lower arches with fixed appliance and leveled with 0.016" NiTi wire. There was a severe crowding in upper arch (fig.VIII).

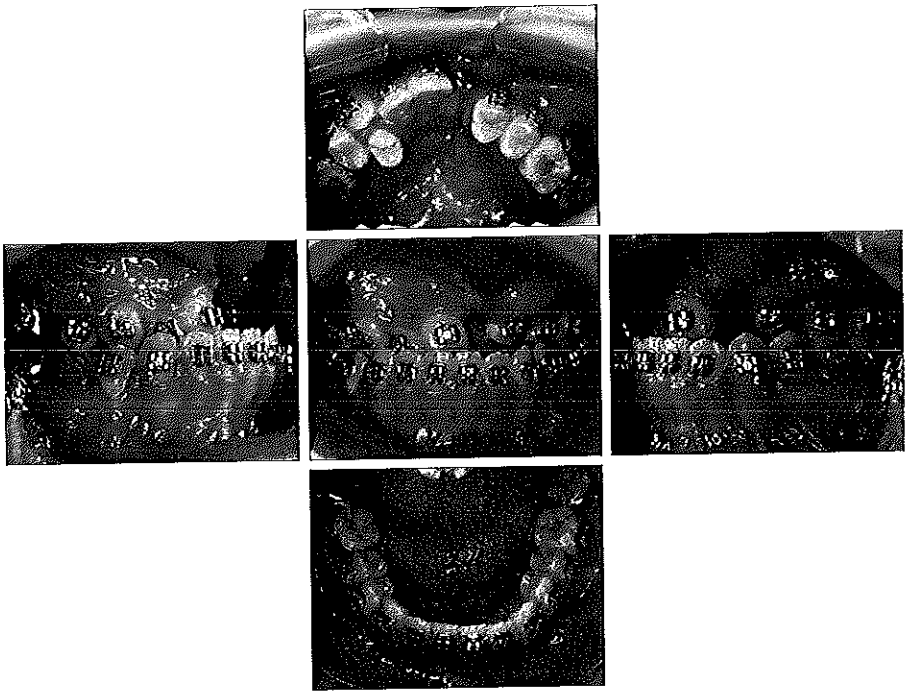

Fig.VIII Initial intraoral photographs of patient number 4.

The anterior palatal area was deficit on the right side of maxilla, because 14 ectopic eruption into palatal direction. But, there was no interference for microimplants placements, because the palatal bone adjacent to the ectopic tooth was appropriated intact. No complication occurred during microimplants placement operation under local anesthesia. After 30 minutes of the microimplants placement, patient's instruction for the appliance activation method was done. The appliance was properly activated until the termination the expansion screw for 7 days. Total treatment time was 35 days, it was implied that the appliance was left intraorally for 29 days after terminated screw. Overall appliance expansion was 7.11 mm.

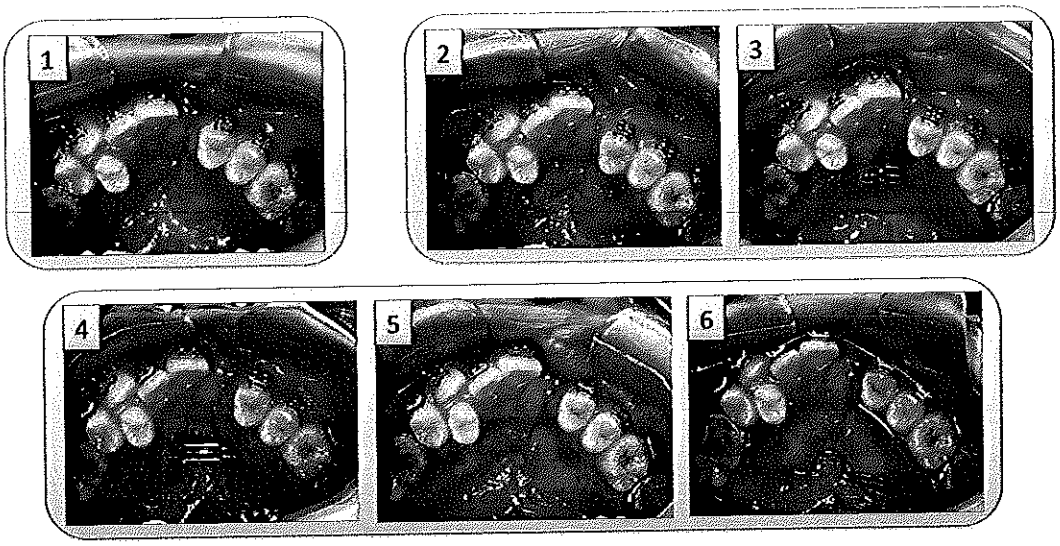

Fig.IX Patient number 4 intraorally photographs presented upper arch in each stage of treatment; 1. Initial oral examination, 2. Microimplants placement, 3. Appliance assembly, 4. Completed activation of the modified expansion appliance, 5. Appliance removal, 6. Retainer delivery.

The changes of dental model parameters of patient number 4 were presented in table VII and the individual PA cephalometric film changes were presented in table VIII.

Table VII Dental model parameters changes of patient number 4.

Dental model parameters	Patient number 4 (mm)		
	T1	T2	T2-T1
ICW	26.97	27.71	0.92
W3	32.62	33.51	0.89
PW4	19.61	21.47	1.86
AAW	34.28	35.24	0.96
BW4	42.81	43.86	1.05
PW6	31.64	33.92	2.29
PAW	44.37	46.61	2.14
BW6	54.00	55.59	1.59
W7	59.98	61.94	1.96

Table VIII PA cephalometric film changes of patient number 4.

PA cephalometeric parameters	Patient number 4 (mm)		
	T1	T2	T2-T1
IOD	92.30	92.30	0.00
IND	33.53	33.80	0.27
IJD	63.79	64.28	0.49
IMidAD	63.42	64.11	0.69
IAD	62.15	63.87	1.72
IMD	62.36	65.06	2.70

In this patient, there was found a slightly pain without any interruption to the quality of patient's life. Only food impaction was recalled for patient's discomfort. She could be activating the appliance correctly and properly herself. She claimed that she had a better occlusion at the end of treatment. Finally, the expansion appliance was removed and found no complication. Because of the fixed appliance in upper arch, the Quadhelix expander was delivered to use as a fixed retainer (fig.IX-6).

Patient number 5 was a 14 year-old boy with left complete unilateral cleft lip and palate. He had a decreased buccal overjet on both sides of posterior segments. 12 and 22 were missing. There were spaces between 21 and 23, and 23 and 24. The lesser segment was collapse into the cleft site. There was a mild crowding in upper arch (fig.X).

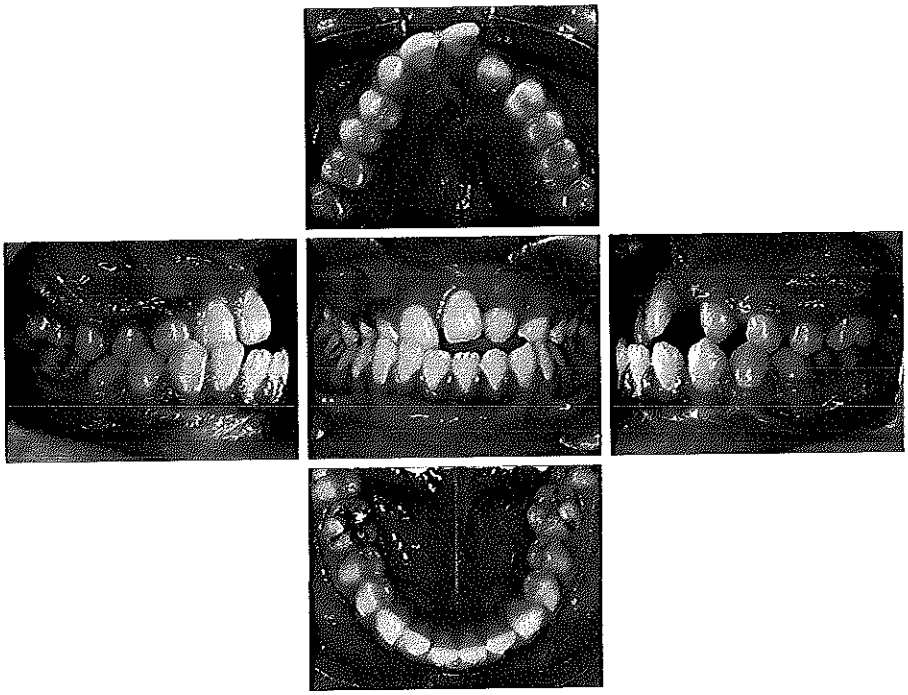

Fig.X Initial intraoral photographs of patient number 5.

The patient's palate seemed broad and wide enough to place the expansion appliance. So, microimplants were stabbed parallel each other. No complication occurred during microimplants placement operation under local anesthesia. After 30 minutes of the microimplants placement, patient and guardians' instruction for the appliance activation method was done. Unfortunately, the appliance was detected that the screw was activated improperly at the expansion appliance removal visit, 4 weeks later. Overall appliance expansion was 1.79 mm (fig.XI-4).

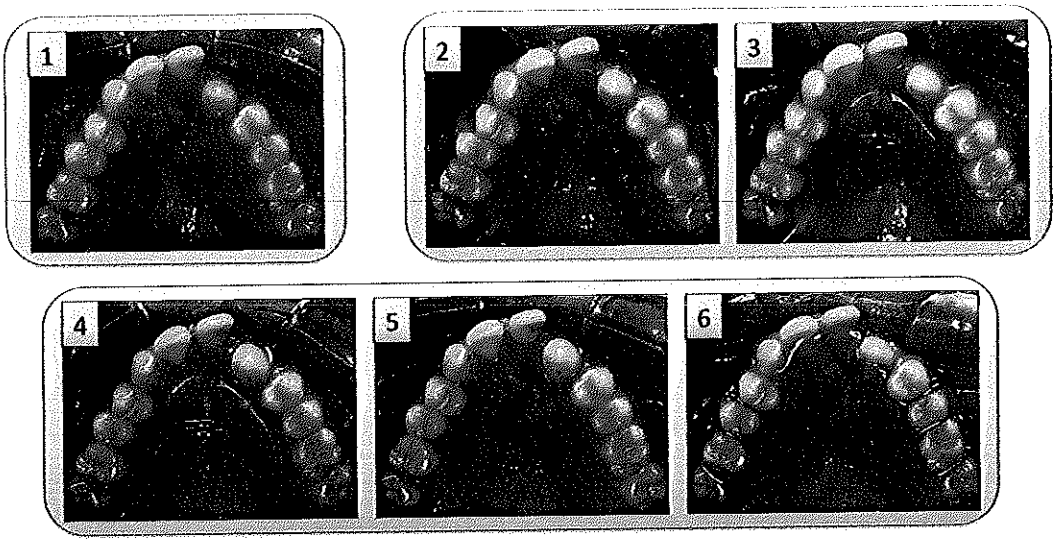

Fig.XI Patient number 5 intraorally photographs presented upper arch in each stage of treatment; 1. Initial oral examination, 2. Microimplants placement, 3. Appliance assembly, 4. Completed activation of the modified expansion appliance, 5. Appliance removal, 6. Retainer delivery.

The changes of dental model parameters of patient number 5 were presented in table IX and the individual PA cephalometric film changes were presented in table X.

Table IX Dental model parameters changes of patient number 5.

Dental model parameters	Patient number 5 (mm)		
	T1	T2	T2-T1
ICW	22.16	22.90	0.35
W3	30.47	30.82	0.35
PW4	22.51	23.15	0.61
AAW	32.16	32.60	0.44
BW4	41.89	42.27	0.38
PW6	35.09	35.42	0.33
PAW	48.96	49.13	0.17
BW6	59.67	59.89	0.22
W7	66.97	67.44	0.47

Table X PA cephalometric film changes of patient number 5.

PA cephalometeric parameters	Patient number 5 (mm)		
	T1	T2	T2-T1
IOD	96.71	96.71	0.00
IND	36.90	37.16	0.27
IJD	69.54	70.03	0.49
IMidAD	67.25	67.75	0.50
IAD	66.01	66.56	0.55
IMD	68.62	69.19	0.57

In this patient, there was found a slightly pain without any interruption to the quality of patient's life. Food impaction was recalled for patient's discomfort a little. The hardness of activation was not declared, but the appliance could not be activated properly. It could be concluded that he and his guardians incorrectly activated the appliance. For this reason, this patient was excluded from the study. However, he claimed a better occlusion at the end of treatment and would like to introduce this method of expansion to other CLP patients.

Finally, the expansion appliance was removed and found no complication. The upper removable retainer, which consisted of two Adam's clasps on upper first molars and two triangular clasps between first and second premolars, was delivered to wear all the time except meal times (fig.XI-6).

Patient number 6 was a 14 year-old boy with complete bilateral cleft lip and palate. He had a decreased buccal overjet on both sides of posterior segments. 64, 65 deciduous teeth were prolonged retention. 22 and 25 were missing teeth and 12, 14 and 24 were unerupted teeth. 15 was ectopic eruption simultaneously with palatal direction. There was severe crowding in upper and lower arches (fig.XII).

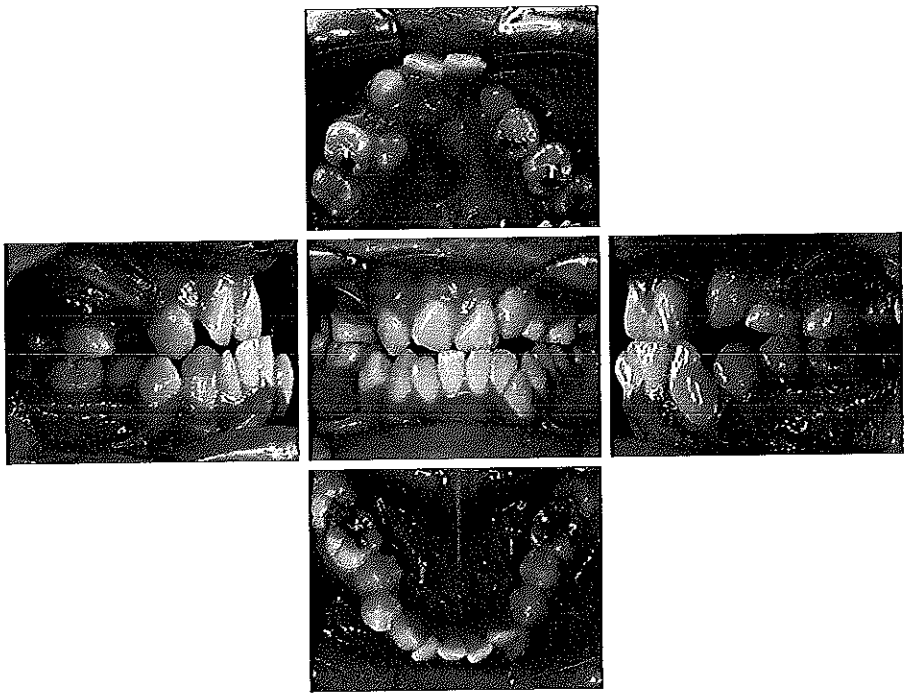

Fig.XII Initial intraoral photographs of patient number 6.

The palatal area for appliance placement was deficit, because a wound of palatal cleft. It seemed lacking of appropriate bone for placing the anterior microimplants. However, no complication was occurred during 30 minutes microimplants placement operation under local anesthesia. After patient's instruction to the appliance activation method, the appliance was properly activated until the termination the expansion screw for 7 days. Total treatment time was 14 days, it was implied that the appliance was left intraorally for 7 days after terminated screw. Overall appliance expansion was 7.07 mm.

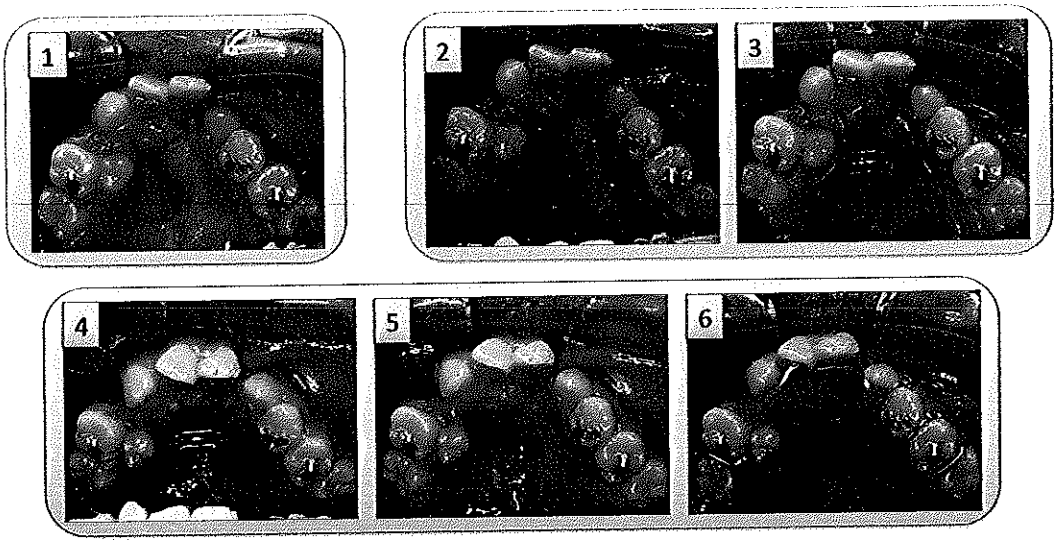

Fig.XIII Patient number 6 intraorally photographs presented upper arch in each stage of treatment; 1. Initial oral examination, 2. Microimplants placement, 3. Appliance assembly, 4. Completed activation of the modified expansion appliance, 5. Appliance removal, 6. Retainer delivery.

The changes of dental model parameters of patient number 6 were presented in table XI and the individual PA cephalometric film changes were presented in table XII.

Table XI Dental model parameters changes of patient number 6.

Dental model parameters	Patient number 6 (mm)		
	T1	T2	T2-T1
ICW	24.06	26.47	2.41
W3	32.53	34.90	2.37
PW4	19.40	23.68	4.28
AAW	32.81	35.83	3.02
BW4	36.66	41.23	4.57
PW6	32.87	36.84	3.97
PAW	45.38	48.97	3.59
BW6	56.67	59.80	3.13
W7	65.91	68.20	2.29

Table XII PA cephalometric film changes of patient number 6.

PA cephalometeric parameters	Patient number 6 (mm)		
	T1	T2	T2-T1
IOD	94.39	94.53	0.14
IND	32.81	33.19	0.38
IJD	71.68	73.13	1.45
IMidAD	70.21	71.67	1.46
IAD	65.77	67.31	1.54
IMD	68.19	69.78	1.59

The patient was complained about slightly pain during expansion, but did not interfere the quality of patient's life. Food impaction was also recalled for a little discomfort. He claimed that he had a better occlusion at the end of treatment and would like to introduce this method of expansion to other CLP patients. Finally, the expansion appliance was removed and found no complication. The upper removable retainer, which consisted of two Adam's clasps on upper first molars and a triangular clasps between left canine and left second deciduous molar, was delivered to wear all the time except meal times (fig.XIII-6).

Patient number 7 was a 13 year-old boy with complete bilateral cleft lip and palate. He had both anterior crossbite and bilateral posterior crossbite. 12, 13, 14, 22, and 24 were missing teeth and 62 was prolonged retention. 23 was ectopic eruption simultaneously with buccal direction. The left lesser segment was collapse into the cleft site. There was a severe crowding in upper arch (fig.XIV).

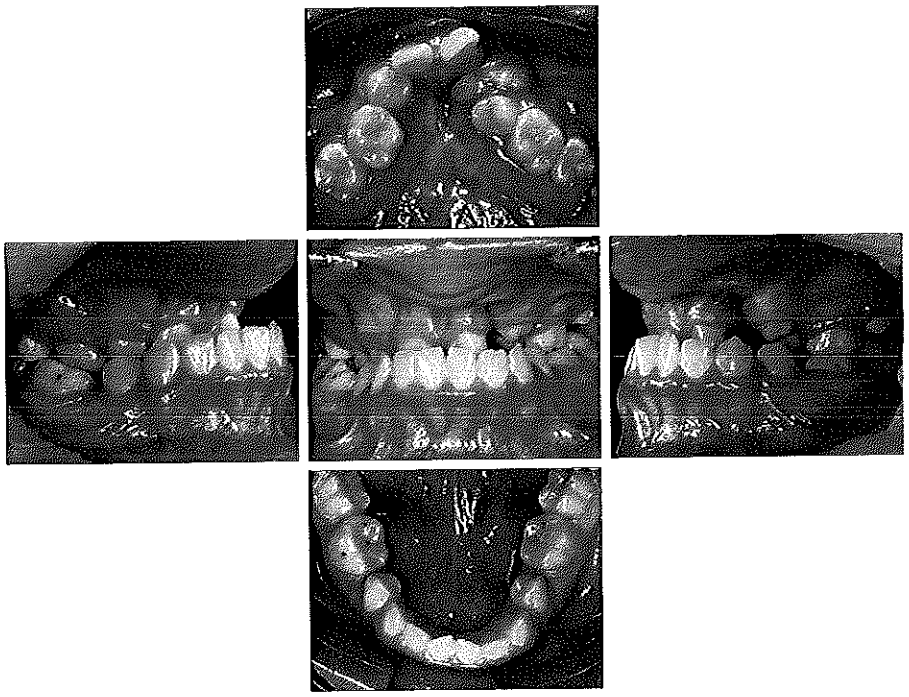

Fig.XIV Initial intraoral photographs of patient number 7.

The palatal area for appliance placement was deficit, because a wound of palatal cleft. It seemed lacking of appropriate bone for placing the anterior microimplants. However, no complication was occurred during 30 minutes microimplants placement operation under local anesthesia. After patient's instruction to the appliance activation method, the appliance was properly activated until the termination the expansion screw for 7 days. Total treatment time was 14 days, it was implied that the appliance was left intraorally for 7 days after terminated screw. Overall appliance expansion was 7.07 mm. We found the anterior microimplants were loose at the expansion appliance removal stage, but still attached with palatal mucosa.

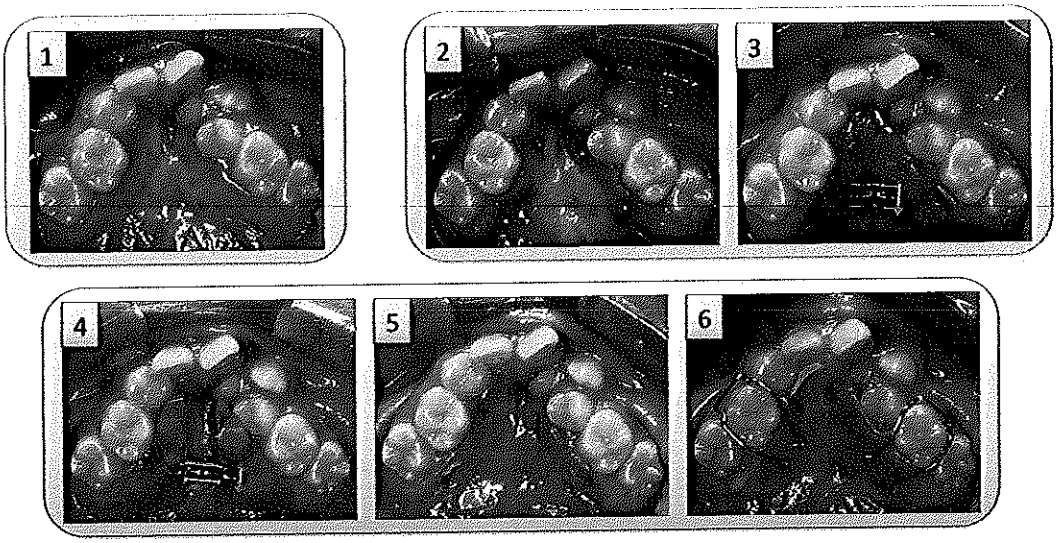

Fig.XV Patient number 7 intraorally photographs presented upper arch in each stage of treatment; 1. Initial oral examination, 2. Microimplants placement, 3. Appliance assembly, 4. Completed activation of the modified expansion appliance, 5. Appliance removal, 6. Retainer delivery.

The changes of dental model parameters of patient number 7 were presented in table XIII and the individual PA cephalometric film changes were presented in table XIV.

Table XIII Dental model parameters changes of patient number 7.

Dental model parameters	Patient number 7 (mm)		
	T1	T2	T2-T1
ICW	21.51	22.78	1.27
W3	30.95	32.27	1.32
PW4	14.49	15.51	1.02
AAW	21.45	22.27	0.82
BW4	24.39	25.99	1.06
PW6	24.23	26.23	2.00
PAW	30.84	32.66	1.82
BW6	41.52	43.29	1.77
W7	55.36	56.96	1.60

Table XIV PA cephalometric film changes of patient number 7.

PA cephalometeric parameters	Patient number 7 (mm)		
	T1	T2	T2-T1
IOD	89.41	89.48	0.07
IND	30.40	30.80	0.40
IJD	61.62	62.48	0.86
IMidAD	59.18	60.70	1.52
IAD	53.98	55.60	1.62
IMD	56.39	58.23	1.84

Patient was complained about slightly pain during expansion, but it was not interfered the quality of patient's life. Food impaction was also recalled for patient's discomfort. He claimed a better occlusion at the end of treatment and would like to introduce this method of expansion to other CLP patients.

At the modified expansion appliance removal visit, the anterior part of the modified expansion appliance was found not to be inherent with the palatal mucosa. There were two loosening microimplants at the anterior part of the palate. The loosening microimplants made the operator removed the expansion appliance difficult; because the loosening microimplants could not be tightly hold. The palatal mucosa was found slightly inflamed (fig.XV-5). However, the palatal expansion was indifferently found at both anterior and posterior part of the palate (table XIII).

Finally, the expansion appliance was removed and found no complication. The upper removable retainer, which consisted of two Adam's clasps on upper first molars, was delivered to wear all the time except meal times (fig.XV-6).

ที่ ศธ 0521.1.03/ **652**

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

หนังสือฉบับนี้ให้ไว้เพื่อรับรองว่า

โครงการวิจัยเรื่อง "การแก้ไขความผิดปกติของชากรรไกรบนในแนวขวางในผู้ป่วยปากแหว่งเพดานโหว่ด้วยเครื่องมือขยายชากรรไกรดัดแปลงร่วมกับไมโครอิมพลานต์"

หัวหน้าโครงการ ทันตแพทย์กฤษฎี ปัณณะรัส

สังกัดหน่วยงาน นักศึกษาหลังปริญญา ภาควิชาทันตกรรมป้องกัน คณะทันตแพทยศาสตร์ มหาวิทยาลัยสงขลานครินทร์

ได้ผ่านการพิจารณาและได้รับความเห็นชอบจากคณะกรรมการจริยธรรมในการวิจัย (Ethics Commitee) ซึ่งเป็นคณะกรรมการพิจารณาศึกษาการวิจัยในคนของคณะทันตแพทยศาสตร์ มหาวิทยาลัยสงขลานครินทร์ แล้ว

ให้ไว้ ณ วันที่ 16 ก.ค. 2551

(รองศาสตราจารย์ ทพ.นพ.ธงชัย นันทนรานนท์)
รักษาการในตำแหน่งรองคณบดีฝ่ายวิจัยและวิเทศสัมพันธ์
ประธานกรรมการ

.....กรรมการ
(ผู้ช่วยศาสตราจารย์ ดร.ทพญ.สุวรรณา จิตภักดีบดินทร์)

.....กรรมการ
(ผู้ช่วยศาสตราจารย์ ทพญ.สรียา ตรีสิทธา)

ไม่ได้เข้าประชุม.....กรรมการ
(ผู้ช่วยศาสตราจารย์ นพ.พรชัย สถิรปัญญา)

ไม่ได้เข้าประชุม.....กรรมการ
(ผู้ช่วยศาสตราจารย์ ทพ.สุทธิพงศ์ เชาวนาดิศัย)

ไม่ได้เข้าประชุม.....กรรมการ
(ผู้ช่วยศาสตราจารย์ ดร.ทพญ.อังคณา เธียรมนตรี)

.....กรรมการ
(ผู้ช่วยศาสตราจารย์ ทพ.นพ สุรพงษ์ วงศ์วัชรานนท์)

ใบเชิญชวนและแบบยินยอมเข้าร่วมการศึกษา

คณะทันตแพทยศาสตร์
มหาวิทยาลัยสงขลานครินทร์

วันที่____เดือน_____พ.ศ. 2552

เรื่อง ขอเชิญเข้าร่วมโครงการวิจัยเรื่อง "การแก้ไขความผิดปกติของขากรรไกรบนในแนวขวางในผู้ป่วยปากแหว่งเพดานโหว่ด้วยเครื่องมือขยายขากรรไกรดัดแปลงร่วมกับไมโครอิมพลานต์"

เรียน ผู้สนใจเข้าร่วมโครงการวิจัยฯทุกท่าน

ข้าพเจ้า ทพ.กฤษฎิ์ ปัณณะรัส นักศึกษาระดับปริญญาโท สาขาทันตกรรมจัดฟัน ภาควิชาทันตกรรมป้องกัน คณะทันตแพทยศาสตร์ มหาวิทยาลัยสงขลานครินทร์ ขอแจ้งรายละเอียดเกี่ยวกับโครงการวิจัยและขอเชิญชวนท่านผู้สนใจเข้าร่วมโครงการฯดังนี้ โครงการวิจัยนี้จัดทำขึ้นเพื่อศึกษาความสามารถและคุณสมบัติของ "เครื่องมือขยายขากรรไกรดัดแปลงร่วมกับไมโครอิมพลานต์" ที่ใช้ในการขยายกระดูกขากรรไกรในผู้ป่วยปากแหว่งเพดานโหว่ที่มีความผิดปกติของขากรรไกรในแนวขวางเป็นเหตุให้เกิดการสบฟันหลังคร่อมของขากรรไกรบนและขากรรไกรล่าง ผู้ป่วยทุกรายที่พบความผิดปกตินี้ จะได้รับการรักษาโดยการใช้เครื่องมือจัดฟันชนิดที่ยึดติดกับฟัน ซึ่งเครื่องมือแบบเดิมที่ใช้ในการรักษา มีผลในผู้ป่วยบางรายทำให้ฟันที่ใช้เป็นฟันหลักเกิดการเคลื่อนที่ออกนอกแนวกระดูกมากเกินความเหมาะสมที่ต้องการในการรักษา อีกทั้งมีความยากในการควบคุมตำแหน่งของเครื่องมือให้อยู่ในระดับที่เหมาะสมตลอดการรักษา เครื่องมือที่ใช้ในการศึกษาครั้งนี้จะไม่ใช้ฟันเป็นตัวยึดเครื่องมือ แต่จะใช้ส่วนของกระดูกเพดานเป็นตัวยึดของเครื่องมือ ซึ่งคาดว่าจะสามารถควบคุมปัญหาดังกล่าวได้เป็นอย่างดี และเป็นเครื่องมือที่ใช้อย่างแพร่หลายในการเป็นหลักยึดสำหรับเคลื่อนที่ฟันในปัจจุบัน

ผู้เข้าร่วมโครงการวิจัยฯจะได้รับการพิมพ์ฟันบนและล่าง เพื่อทำแบบจำลองฟัน ถ่ายภาพภายในช่องปากและถ่ายภาพรังสีโดยได้รับการถ่ายภาพรังสี 3 ครั้ง ในขั้นตอนการตรวจช่องปาก ครั้งแรกจะได้รับการถ่ายภาพรังสีรอบปลายรากฟัน ภาพรังสีพานอรามิค ภาพรังสีของกะโหลกศีรษะในแนวด้านข้างอย่างละ 1 ภาพ สำหรับในขั้นตอนก่อน ระหว่างและหลังการใส่

เครื่องมือขยายขากรรไกรดัดแปลงร่วมกับไมโครอิมพลานต์ จะได้รับการถ่ายภาพรังสีกะโหลกศีรษะในแนวด้านหลังหน้า 1 ครั้ง ในแต่ละขั้นตอนเพื่อประเมินการเปลี่ยนแปลงของขากรรไกรบน

การตัดสินใจเข้าร่วมโครงการวิจัยฯนี้จะมีขั้นตอนของการวิจัย คือ การพิมพ์ปากเพื่อทำแบบพิมพ์ฟันศึกษา การถ่ายภาพรังสีและการถ่ายรูป การยึดไมโครอิมพลานต์จำนวน 4 ตัว บนเพดานปาก เพื่อใช้เป็นหลักยึดของเครื่องมือขยายขากรรไกรดัดแปลงและการไขเครื่องมือขยายขากรรไกรดัดแปลง ตามขั้นตอนที่จะได้แนะนำต่อไปเป็นประจำตามจำนวนและเวลาที่กำหนด ซึ่งจะไม่ก่อให้เกิดความเจ็บปวดและอันตรายต่อเนื้อเยื่อมากไปกว่าการขยายขากรรไกรบนด้วยวิธีอื่นๆแต่อย่างใด ผู้เข้าร่วมโครงการฯต้องมารับการตรวจในช่องปากและรับการยึดไมโครอิมพลานต์และถอดเครื่องมือขยายขากรรไกร ณ โรงพยาบาลทันตกรรม คณะทันตแพทยศาสตร์ โดยไม่เสียค่าใช้จ่ายในการขยายขากรรไกรใดๆทั้งสิ้น สำหรับการยึดไมโครอิมพลานต์นั้นพบว่ามีความปลอดภัยและประสบความสำเร็จในการรักษาสูงแม้ว่าจะมีผลข้างเคียงเกิดขึ้นได้ แต่เป็นผลข้างเคียงที่ป้องกันได้หรือรักษาได้โดยง่าย ในกรณีที่เกิดผลข้างเคียงผู้ป่วยจะถูกถอดเครื่องมือออกจากปากซึ่งจะทำให้ผลข้างเคียงเหล่านั้นหายไปในทันที และจะได้รับการรักษาและแก้ไขผลข้างเคียงนั้นโดยทันตแพทย์ผู้เชี่ยวชาญซึ่งไม่เสียค่าใช้จ่ายใดๆทั้งสิ้น จากการศึกษาผลของการใช้ไมโครอิมพลานต์พบว่าการยึดไมโครอิมพลานต์ในช่องปากนั้นมีความปลอดภัยต่อชีวิตและไม่เป็นอุปสรรคต่อการดำรงชีวิตตามปกติ

ไม่ว่าท่านจะเข้าร่วมในโครงการวิจัยนี้หรือไม่ ท่านจะยังคงได้รับการรักษาที่ดีเช่นเดียวกับผู้ป่วยคนอื่นๆ และถ้าท่านต้องการที่จะถอนตัวออกจากการศึกษานี้เมื่อใดท่านก็สามารถกระทำได้อย่างอิสระ ถ้าท่านมีคำถามใดๆก่อนที่จะตัดสินใจเข้าร่วมโครงการนี้โปรดซักถามคณะผู้วิจัยได้อย่างเต็มที่

ขอแสดงความนับถือ

ทพ.กฤษฎิ์ ปัณณะรัส

ลงนามทราบและยินยอม

_____ผู้ยินยอมเข้าร่วมโครงการวิจัย

_____ผู้ปกครองโดยชอบธรรม/พยาน

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List of Publication and Proceeding

The 4th Conference on Graduate Research, Surindra Rajabhat University, February 20-22, 2010.