A New Device for Fixing the Premaxilla with Osteotomy in a Child with Complete Bilateral Cleft Lip and Palate in the Mixed Dentition Period -A Preliminary case Report-

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In the treatment of a protruded premaxilla associated with complete bilateral cleft lip and palate, some patients require surgical setback of the premaxilla with osteotomy as functional and aesthetic treatment. No satisfactory surgical approaches have been established for the setback because it is usually difficult to fix the premaxilla after osteotomy in the mixed dentition period. This paper reports the new method for fixing the premaxilla with osteotomy in a child with a severely protruded premaxilla in the mixed dentition period. To fix the segment, we fabricated a device consisting of a palatal bite plate and an anterior tray before surgery. The space between the tray and the premaxilla was filled with soft resin during surgery so that the reposition of the premaxilla could be adjusted. This approach produced a favorable result. Our device has several advantages. It allows the adjustment of repositioning of the premaxilla during surgery. It can change the range of the adjustment according to the intended position of the premaxilla. It allows secure fixation of the segment. It is removable for tooth brushing and observation of bone union. Our device can be applied to many children similar to our patient reported in this paper.

Key words: Premaxilla, Device, Cleft Lip, Cleft Palate, Osteotomy

INTRODUCTION

A protruded premaxilla associated with complete bilateral cleft lip and palate (BCLP) can cause various problems during the treatment. In infancy, cheiloplasty is difficult to perform and does not solve cosmetic problems satisfactorily. At the preschool to school age, a protruded premaxilla may cause incomplete lip closure and dysarthria, complicate orthodontic treatment, and result in a large residual oronasal fistula.

In the treatment of a protruded premaxilla, orthodontic treatment and functional jaw orthopedics are often effective. However, some patients require surgical setback of the premaxilla with osteotomy as occlusal and esthetic treatment. The best timing of the setback varies with children, but the surgery is performed typically in the mixed dentition period in which the need of patient's cosmetic improvement increases in a social life. No satisfactory surgical approaches have been established for the setback because it is usually difficult to fix the premaxilla after osteotomy in the mixed dentition period.

This paper reports the use of a new device for fixing the premaxilla with osteotomy in a child with a severely protruded premaxilla in the mixed dentition period. To fix the segment, we fabricated a device consisting of a palatal bite plate and an anterior tray before surgery. The space between the tray and the premaxilla was filled with soft resin during surgery so that the reposition of the premaxilla could be adjusted. This approach produced a favorable result. Our device has several advantages. It allows the adjustment of repositioning of the premaxilla during surgery. It can change the range of the adjustment according to the intended position of the premaxilla. It allows secure fixation of the segment. It is removable for tooth brushing and observation of bone union. Our device can be applied to many children similar to our patient reported in this paper.

SUBJECTS AND METHODS

The investigation conforms with the principles outlined in declaration of Helsinki. We used our new device in premaxillary setback with osteotomy performed on a 6-year-old boy with complete BCLP. He was born with a gestational age of 40 weeks and 5 days. The birth weight was 3200 g. He was referred to our hospital at 7 days of age for the treatment of complete BCLP (**Figure 1**). The initial examination showed a well-grown but protruded premaxilla.

The patient underwent cheiloplasty at 3 months of age with a weight of 5.8 kg (**Figure 1**). After the operation the premaxilla was retracted by the labial pressure but descended with its clockwise rotation that caused a palatal inclination of incisor teeth, resulting in a deep bite.

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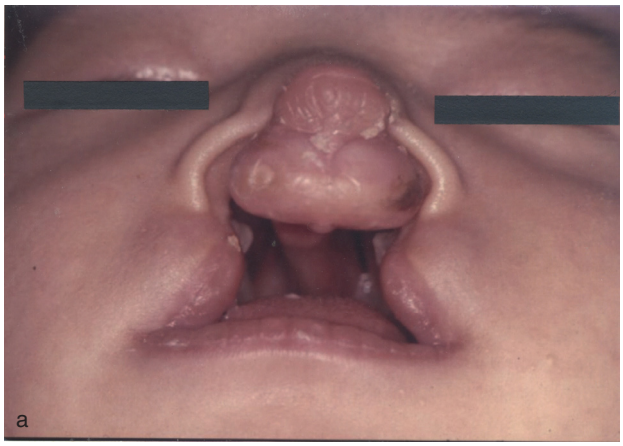


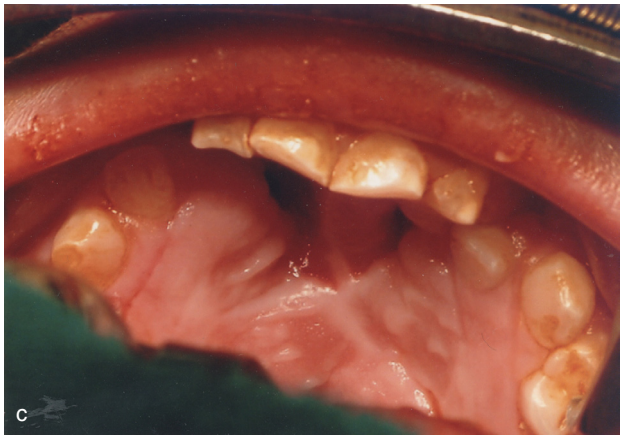


Fig. 1. a): The photograph of patient on 7 days of age. The initial examination showed a well-grown but protruded premaxilla.
b): The patient underwent cheiloplasty at 3 months of age, and pushback palatoplasty at 1.5 years of age. The wound was covered with an artificial dermis graft.
c): a residual oronasal fistula in the site of alveolar cleft**.**

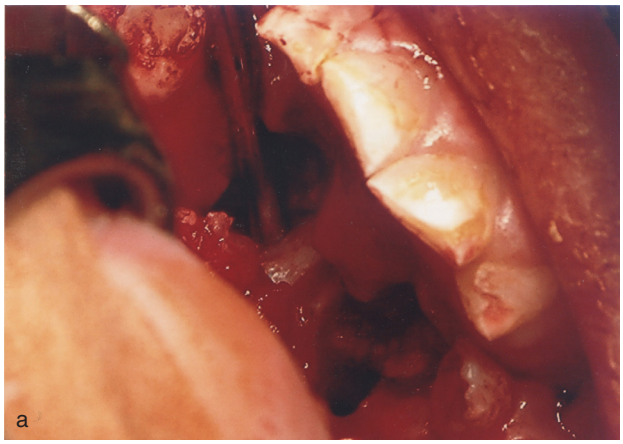
Fig. 2. a): The maxilla collapsed rapidly and reduced the inter-canine distance. premaxilla was shifted forward and downward. Surgical setback of the premaxilla with osteotomy was planed on the patient at 6 years of age, before he entered an elementary school.
b): Lip protrusion, a markedly obtuse columella-labial angle, and severe nostril deformity due to an anteroinferior shift of the nasal base.

The patient underwent pushback palatoplasty at 1.5 years of age. The wound was covered with an artificial dermis graft. His nasopharyngeal closure and articulation improved subsequently. The maxillary growth was sufficient for maintain normal molar occlusion. The maxilla collapsed rapidly because of poor alveolar alignment. This collapse reduced the inter-canine distance and shifted the premaxilla further forward and downward. This caused aesthetic problem of lip protrusion, a markedly obtuse columella-labial angle, and severe nostril deformity due to an anteroinferior shift of the nasal base **(Figure 2)**.

The functional problem also existed due to the poor occlusion. An instability and malposition of premaxilla caused difficulty of tearing a food off by his anterior teeth. But the masticatory efficacy was still preserved because of posterior teeth occlusion. Liquid and paste food discharge from nose and an inaudible nasal emission were observed from oro-nasal-fistula at the residual alveolar cleft.

He had no distorted articulation but hypernasality due to a residual oronasal fistula in the site of alveolar cleft **(Figure 1)**.

Since the patient's parents wished his facial appearance improved before he entered an elementary school, we performed surgical setback of the premaxilla with osteotomy on the patient at 6 years of age **(Figure 3)**. To maintain blood supply from both the nasal and



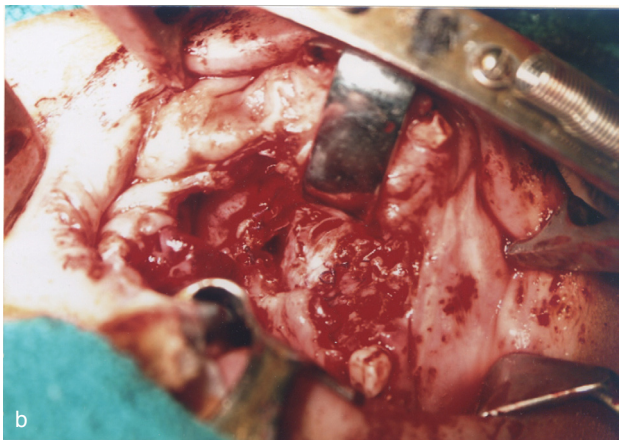


Fig. 3. a): To maintain blood supply from both the nasal and vestibular sides of the premaxilla, all mucous membranes on the vestibular side were preserved intact. A palatal incision was placed to expose alveolar clefts and the anterior portion of the vomer for osteotomy.
b): Resected vomer fragments were grafted into both sides of the cleft to induce bone bridge formation between alveolar ridges. No iliac bone grafts were performed
c): The elevated part of the bone was not removed so that no tooth germs of central incisors and canines were injured.

vestibular sides of the premaxilla, all mucous membranes on the vestibular side were preserved intact. A palatal incision was placed to expose alveolar clefts and the anterior portion of the vomer for osteotomy. The vomer was resected with a bone chisel. In the completely mobilized premaxilla, sufficient blood supply was maintained through both the mucoperiosteum on the vestibular part of the premaxilla and the mucoperiosteum continuing from the nasal septum and floor **(Figure 3)**. Although the premaxilla was placed in the intended position, the amount of its setback was not sufficient as planned. An elevated bone at the cleft edge facing the alveolar cleft interfered with the premaxilla. The elevated part of the bone was not removed so that no tooth germs of central incisors and canines were injured. The nasal floor was closed with absorbable sutures. Resected vomer fragments were grafted into both sides of the cleft to induce bone bridge formation between alveolar ridges. No iliac bone grafts were performed **(Figure 3)**.

In order to fix the premaxilla, we fabricated a new device consisting of an anterior tray and a palatal bite plate. The bite plate covered the palate and all maxillary teeth including molars on a dental cast. Model osteotomy was performed on the cast model to determine the position of the premaxilla **(Figure 4)**. Based on this cast, the bite plate was fabricated to cover alveolar ridges and teeth. To allow for deviation of the premaxilla from its intended position during surgery, we made the anterior portion of the plate that covered the premaxilla larger than the segment. No vertical space was allowed because the vertical positioning of the premaxilla is important to achieve favorable occlusion. Horizontal and sagittal space was allowed for potential rotations **(Figure 4)**. The device was fabricated by pressing and molding a heat-reversible polyester sheet of 1.5 mm in thickness (Duran Inc., Lyme, Conn., USA). Large undercuts were blocked out, and small undercuts were left under the survey line for retention.

After the premaxillary set back and bone graft, the wound was closed with sutures. Following a try-in of the device in the mouth, the space between the premaxilla and the tray was filled with soft resin (Tissue conditioner ™ Syofoo Inc.,Kyoto Japan) to fix the premaxilla securely. The tray was applied into the mouth before the resin polymerized. To fix the premaxilla in the best position, the segment was hold with instruments in the mouth until resin polymerized **(Figure 4)**.

RESULTS

The patient made favorable progress after surgery, without complications such as poor blood circulation in the premaxilla, wound dehiscence, wound infection, and exposed bone grafts. The device did not affect oral hygiene against expectation.

At 6-month post operative period, The surgery markedly improved the premaxillary protrusion, facial appearance in both frontal and lateral views, and occlusion **(Figure 5)**. When postoperative occlusion was compared with preoperative occlusion, the overbite changed from 9 to 1 mm, and the overjet changed from 7 to 2 mm.

The premaxilla was fixed completely after surgery. Computed tomography showed sufficient bone bridge

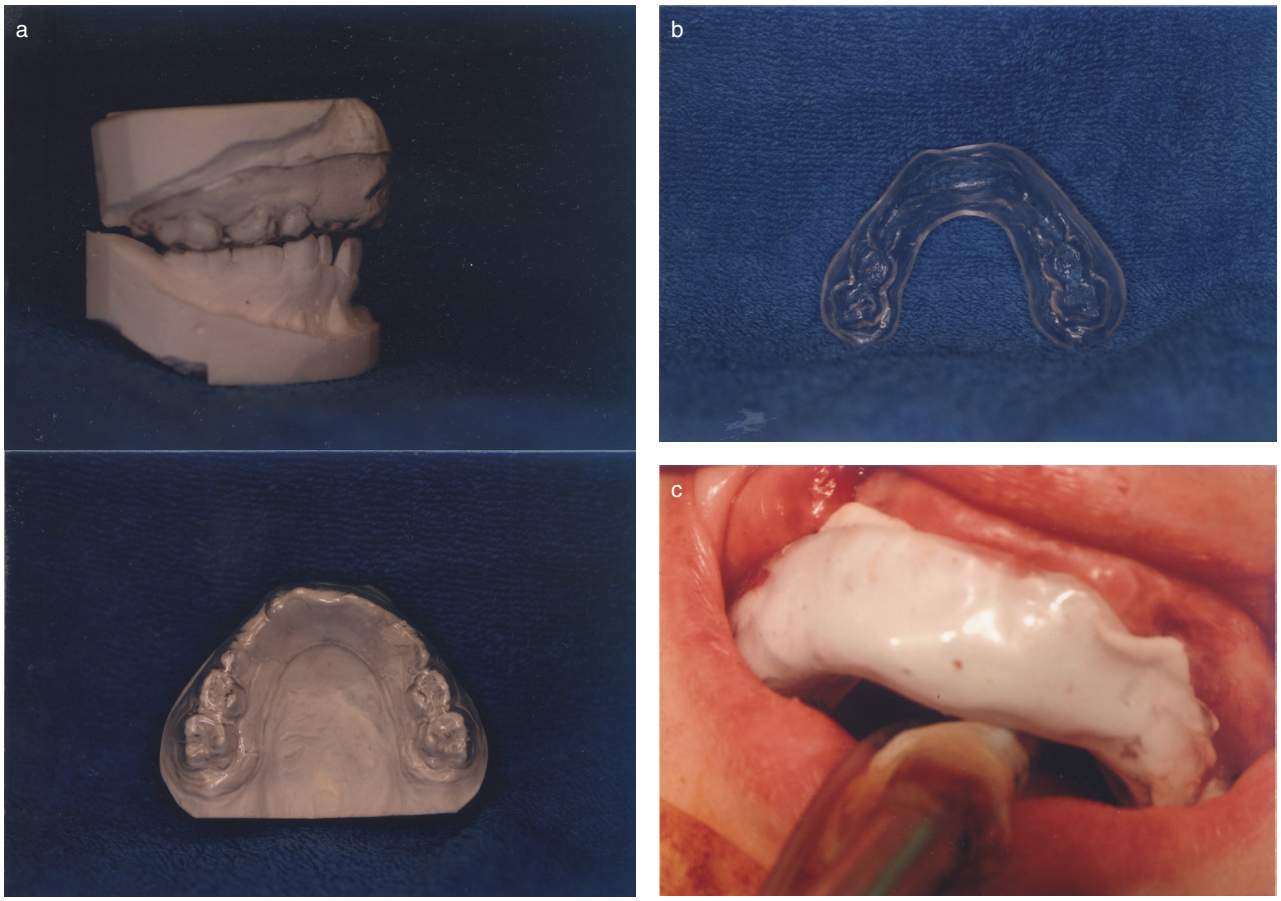


Fig. 4. a): Model osteotomy was performed on the cast model to determine the position of the premaxilla. Based on this cast, the bite plate was fabricated to cover alveolar ridges and teeth.
b): No vertical space was allowed because the vertical positioning of the premaxilla is important to achieve favorable occlusion. Horizontal and sagittal space was allowed for potential rotations.
c): The space between the premaxilla and the tray was filled with soft resin (Tissue conditioner ™ Syofoo Inc.,Kyoto Japan) to fix the premaxilla securely. The tray was applied into the mouth before the resin polymerized. To fix the premaxilla in the best position, the segment was hold with instruments in the mouth until resin polymerized.

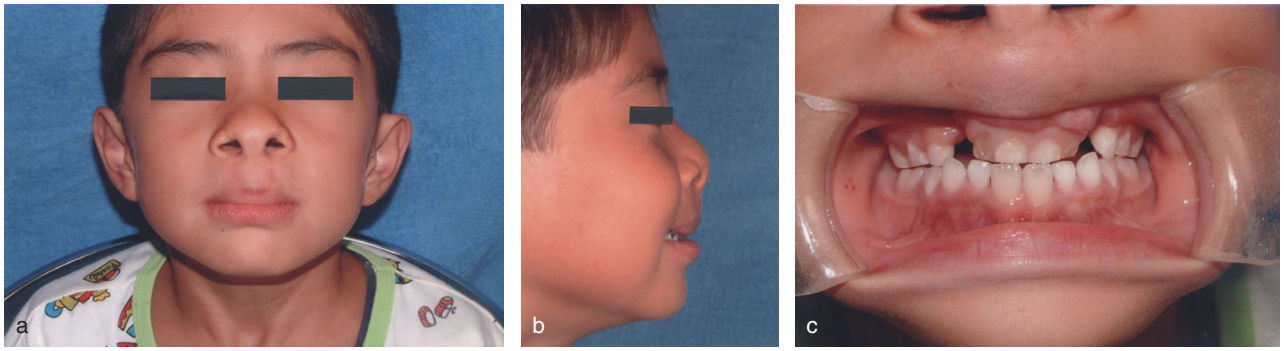


Fig. 5. a): b): c): Facial appearance in both frontal and lateral views, and occlusion. When postoperative occlusion was compared with preoperative occlusion the overbite changed from 9 to 1 mm, and the overjet changed from 7 to 2 mm

formation on the nasal floor side, although no continuity was found in alveolar ridges. Preoperative and postoperative computed tomographys, and the dental casts are presented **(Figure 6)**.

The functional evaluation at 6-month post operative period reveled that the functional problem was also improved. A rigid and properly positioned premaxilla improved stability of anterior teeth. And ideal oberbite and overjet brought good function of tearing a food off. Liquid and paste food discharge from nose were resolved by closing oro-nasal-fistula at the residual alveolar cleft. An inaudible nasal emission was also resolved. Speech pathologist comented that patient had no distorted articulation and hypernasality due to a residual oronasal fistula after operation.

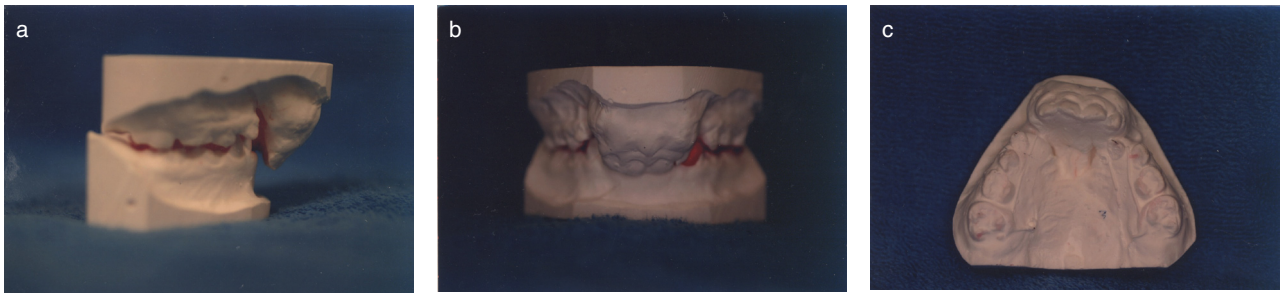


Fig. 6. a): b): c): Preoperative dental casts are presented.

Fig. 7. a): b): c): Postoperative dental casts are presented.

DISCUSSION

In children with complete BCLP, a protruded premaxilla can cause various problems during the treatment[1) 2)]. In infancy, cheiloplasty often causes unaesthetic result due to a wide distance between both edges of the cleft. This is likely to widen the philtrum, resulting in poor aesthetic improvement of the lips. Other problems in infancy include upper lip protrusion, philtral deformity associated with a wide middle portion of the upper lip, a markedly obtuse columella-labial angle, and nostril deformity.

At the preschool to school age, there are four major problems caused by a protruded premaxilla: (1) maxillary protrusion can cause incomplete lip closure and dysarthria; (2) an unstable premaxilla complicates orthodontic treatment; (3) an oronasal fistula often remains because of wide alveolar clefts; and (4) such clefts are likely to complicate bone grafting, require a large amount of bone grafts, and lead to a poor treatment outcome.

To avoid or solve these problems, presurgical orthopedic treatment has been performed. In some patients, the treatment is not indicated or is not satisfactorily effective if performed. We have treated such patients successfully with the Latham's elastic chain premaxillary repositioning appliance.[1)] However, not many patients with complete BCLP have been treated with the appliance. The above-mentioned problems remain a significant clinical challenge.

In the majority of complete BCLP children with no or ineffective presurgical orthopedic treatment in infancy, a premaxilla severely protrudes forward and downward due to its considerable vertical shift. Orthodontic treatment alone cannot correct the premaxilla. Orthognathic surgery is usually needed for the correction. It can improve malocclusion and incomplete lip closure, stabilize the premaxilla with simultaneous bone grafting, and close an oronasal fistula. Osteotomy and repositioning of the premaxilla, however, may cause necrosis of the segment and damage to tooth germs of central incisors due to poor blood supply, complications such as tooth loss and bone graft infection, and scars in alveolar clefts before bone grafting. These benefits and risks should be assessed thoroughly before surgery in each candidate for the treatment.

Some researchers have reported iliac bone grafting of alveolar clefts with osteotomy in complete BCLP children aged 8 to 10 years, who are older than our patient. The grafting at the school age can reduce the frequency of surgeries, but most parents of BCLP children strongly wish children's facial appearance improved before the children enter an elementary school, as with our case.

The iliac bone grafting with osteotomy at the preschool age is also beneficial to complete BCLP children, as described in many recent reports. However, the grafting in preschool children has not been accepted widely. Advantages of early bone grafting have not been established. Some preschool children are too small to harvest adequate iliac bone grafts.

When the grafting is performed simultaneously with osteotomy not only to form a bone bridge for premaxillary fixation but also to align the permanent teeth, it is often difficult to maintain adequate blood supply to the premaxilla during surgery.

Mishimmaki *et al.* reported the grafting with osteotomy in six children with complete BCLP[3)]. None of the children experienced bone graft rejection or complications including necrosis and infection of the premaxilla. To prevent poor blood circulation in the premaxilla, the researchers propose that the grafting with osteotomy should be limited to complete BCLP children whose alveolar clefts are not too wide, who do not have many scars associated with the initial surgery,

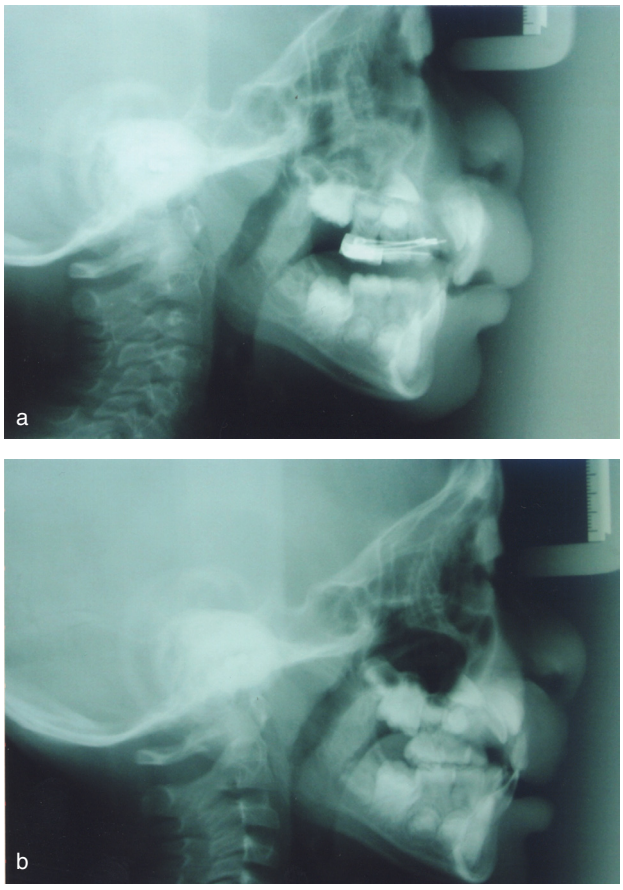


Fig. 8. a): Preoperative Cephalogram
b): Postoperative Cephalogram

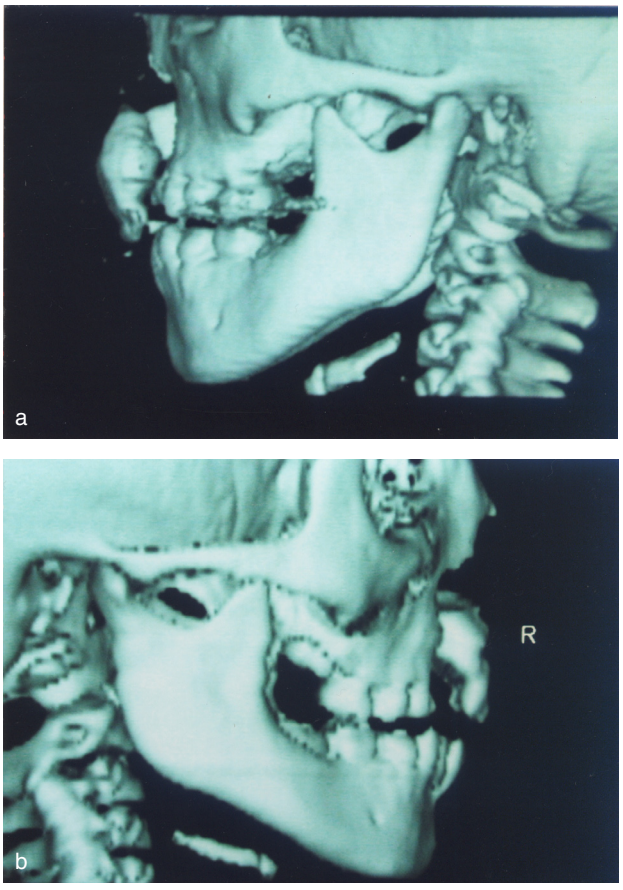


Fig. 9. a): Preoperative 3D computed tomography
b): Postoperative 3D computed tomography

and whose periosteum is available for graft beds. In addition, they emphasize that multiple blood pathways to the premaxilla should be established during surgery.

Iino M *et al*. reported premaxillary osteotomy with two-stage iliac bone grafting of alveolar clefts[4]. The initial grafting was performed on one cleft. Six months later, the second grafting was performed on the other cleft. This two-stage procedure could prevent poor blood circulation in the premaxilla during surgery.

Three methods have been reported for fixing the premaxilla after osteotomy: internal fixation with a plate; fixation to adjacent the dental arch with orthodontic brackets and wire applied to the teeth; and fixation with a bite splint that is fabricated as an anchorage before surgery[4) 5)].

Internal fixation of the premaxilla with a plate is often effective in adult patients with complete BCLP. Highly fixative and strong plates, such as miniplates of 2.0 mm in diameter, can be used. The adult patients have no risk of tooth germ damage. In complete BCLP children, particularly preschool children like our patient, a large plate cannot be used because of limited space availability. A small plate cannot fix the premaxilla as securely as a large plate. Regardless of its size, a plate should be removed later because it may affect maxillary growth, resulting in the increased frequency of surgeries. In the mixed dentition period, a plate may cause damage to tooth germs in the alveolar bones in both the premaxilla and the maxilla. Therefore, plate internal fixation should be avoided in the mixed dentition period.

The fixation of the premaxilla with an orthodontic wire is seldom indicated in complete BCLP children in the mixed dentition period. In most cases, anchor teeth cannot be obtained because of loss of deciduous teeth and incomplete root formation of permanent teeth.

The fixation of the premaxilla with a bite splint is a common technique as reported in some literature.[4)] Before surgery, the best position of the premaxilla is decided, and a bite splint is fabricated according to this position. In some cases, the premaxilla cannot be guided to the intended position during surgery. The segment usually deviates from its intended position in the direction, distance, or angle of repositioning. The causes of the deviation include the limited region for flap elevation due to poor blood circulation in the premaxilla, hard soft-tissue scars around the premaxilla, and insufficient removal of the alveolar bone because of presence of tooth germs.

In our case, the vomer could be osteotomized and removed sufficiently. However, an elevated bone at the cleft edge facing the alveolar cleft interfered with the premaxilla. The degree of setback of the premaxilla was not as much as planned. The elevated part of the bone was not removed so that no tooth germs of impacted central incisors and canines were affected.

The arch expansion of the lateral segments seemed to be accomplished based on the inter-canine width but was unsatisfactory for avoidance of the bone interference with the premaxilla. This cannot be anticipated completely with preoperative axial or three-dimen-

sional computed tomography. The perfect simulation of three-dimensional alignment of premaxilla after osteotomy is difficult. In addition, decreased soft tissue elasticity due to scars may impede the repositioning. For these reasons, a device for fixing the premaxilla after osteotomy should have some flexibility in positioning.

We fabricated a device consisting of a palatal bite plate and an anterior tray before surgery. The space between the tray and the premaxilla was filled with soft resin during surgery. This approach produced a favorable result. Our device has several advantages over currently available devices for fixing the premaxilla. It can accommodate deviation of the premaxilla from its intended position during surgery. It covers alveolar ridges as well as teeth to allow secure fixation of the premaxilla, whereas conventional bite plates typically involve only the incisal part of incisors in the fixation. Soft resin used for our device is not as elastic as to permit premaxillary mobility.

A device for fixing the premaxilla should be designed to place the segment in the intended position as much as possible. The original purpose of use of a bite splint that is fabricated before surgery is to place the premaxilla in the intended position as much as possible during surgery. To achieve this purpose, our device allows no vertical but some horizontal space.

The disadvantage of our device is an increased risk of caries because the device covers teeth as well as alveolar ridges. A removable device for fixing the premaxilla can be designed. Tooth brushing should be begun with the device removed when the premaxilla is fixed substantially (approximately 7 days after surgery).

CONCLUSIONS

A new device for fixing the premaxilla with osteotomy produced a favorable result in a child with complete BCLP in the mixed dentition period. Our device allows the adjustment of repositioning of the premaxilla during surgery. It can change the range of the adjustment according to the intended position of the premaxilla. Intraoperative polymerization of soft resin between the device and the premaxilla allows secure fixation of the segment. Our device can be applied to many children with complete BCLP.

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