

EFFECTIVENESS OF THE PALATAL ORTHOPEDIC APPLIANCE
IN TREATMENT OF THE UNILATERAL CLEFT
LIP AND PALATE PATIENT

by

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Submitted to the Faculty of the Graduate School in partial fulfillment
of the requirements for the degree of Master of Science in Dentistry,
Indiana University School of Dentistry, 1988.

Thesis accepted by the faculty of the Department of Pediatric Dentistry, Indiana University School of Dentistry, in partial fulfillment of the requirements for the degree of Master of Science in Dentistry.

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ACKNOWLEDGMENTS

I would like to express sincere thanks to Dr. David Avery, Dr. Carolyn Bryson, Dr. Bruce Johnson, and Dr. James E. Jones for their participation on my Graduate Committee. Their encouragement and support throughout my project are greatly appreciated. Special gratitude goes to Dr. Jones for all his valuable assistance and guidance in the analysis and interpretation of my data. My thanks to Professor Paul Barton for the editing of my manuscript and to Mary Beth Piland for the typing of my final manuscript. Lastly, I wish to thank my wife, Diane, for her love and understanding during this period of work on my thesis project.

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INTRODUCTION

The purpose of this study was to examine the effectiveness of the maxillary obturator appliance in infants born with complete unilateral clefts of the lip and palate. Three aspects of therapy were evaluated. The first centered on parental evaluation of the appliance in reference to ease of manipulation, decrease in feeding time, and the psychology of immediate parental participation in their child's therapy. Secondly, weight gain of infants over a one-year period was examined to find percentile weight loss or gain. These data were compared to non-cleft standards. Finally, sequential study casts of unilateral complete clefts of the lip and palate were evaluated, using the Relationship Measurement Method of Analysis for cleft lip and palate patients, to determine post-treatment arch symmetry.

REVIEW OF THE LITERATURE

Cleft lip and palate is a severe congenital anomaly that occurs in approximately one of every 750 to 1000 live births in the United States.¹⁻³ The incidence varies among races. The anomaly occurs in about one of every 800 white births, one of every 2000 black births; and one of every 500 Japanese and Navaho Indian births. Cleft lip and palate together account for about 50 percent of all patients, while isolated cleft lip and cleft palate occur in about 25 percent each. The degree of involvement may influence the success of cosmetic and functional repair.

For most parents, the prenatal period is filled with anticipation. As the woman psychologically prepares for the child's birth, she envisions a perfect child. The fulfillment of having a perfect child aids the mother in responding positively to her infant and helps in establishing the mother-infant bond. When a child is born with a birth defect, the effect on the parents may be significant.⁴ Parents react with strong feelings of disappointment and resentment consistent with an acute state of grief. The mother especially feels inadequate, because of her inability to produce a normal child and may respond to the child with avoidance, withdrawal, isolation, and denial.^{4,5} Rubin's⁶ study demonstrated that the normal progression of maternal touch is delayed in mothers of handicapped newborns.

To help the parents work through emotions associated with the birth of a handicapped child, it is necessary for the hospital staff

to be supportive. Unfortunately many hospitals do not have a special orofacial anomalies team and offer little or no special training for their personnel in this area.⁷ Information provided to parents in many institutions may not be current and may further increase parental apprehension. A recent survey by Strauss and Broder⁸ showed that there are more than 200 cleft lip and palate teams in university medical centers, state public health facilities and private hospitals. These teams usually include a plastic and reconstructive surgeon, oral and maxillofacial surgeon, pediatric dentist, orthodontist, maxillofacial prosthodontist, patient care coordinator, pediatrician, medical geneticist, psychologist, nursing specialist, speech pathologist, audiologist and a social worker. The goal of the team is to coordinate services and establish a treatment protocol for each child.⁹ By early referral of cleft newborns to an established team, the parents will be provided with current information on cleft management. This will decrease anxiety associated with the unknown.

The remainder of this review will be presented under the following headings: feeding, obturator therapy, maxillary orthopedics, cheiloplasty, primary autogenous alveolar bone graft, palatoplasty, and the importance of maxillary arch form.

I. Feeding:

During the first few weeks of life, parents of a cleft lip and palate child must face the immediate demands of the defect. The extent of the child's defect and the child's response to the mother

are factors in the mother's ability to adapt. The emotional support system for the mother provided by the father and other important people is also a key to adjustment.⁵ Within a relatively short time most parents of cleft lip and palate children are able to adjust from the initial shock and ensuing grief.¹⁰

One of the immediate problems that arise with a newborn cleft child is the feeding process. As with many congenital malformations, the cleft lip and palate child tends to have birth weight below average. Many mothers have to contend with this complication and the extra importance of the feeding process in weight gain.¹¹⁻¹⁴ In unilateral or bilateral complete clefts of the lip and palate, there is direct communication between the oral and nasal cavities and the child is unable to create the proper suction to receive adequate nourishment. Proper suckling requires that the nose be sealed off from the oral cavity to create a negative pressure in the mouth.¹⁵ Failure in this function often results in discharge of formula or milk through the nose. Normally, an infant obtains milk by positioning the nipple between the gum pad and tongue. He then moves the tongue backward, while pressing the nipple against the hard palate. Because of an incomplete hard palate to press the nipple against, many newborn cleft infants experience decreased nutritional input.⁴ Other problems that the cleft infant may experience are: 1) excessive air intake during feeding, 2) choking, 3) nasal discharge, and 4) excessive time required for adequate nutrition.¹⁵⁻¹⁷ Often the feeding process can last from 30-60 minutes and may be frustrating for parents.

Few studies are available that evaluate weight gain in cleft lip and palate children, as compared to control groups. Ranalli and Mazaheri¹⁸ reported a longitudinal study of height and weight gain in cleft children grouped by cleft type. A comparison between the unilateral cleft group and the non-cleft control group showed that the cleft group tended to weigh more than the controls at birth. Soon after delivery, the cleft group began to lag behind the controls, theoretically because of early feeding problems, as well as more frequent upper respiratory tract infections and repeated hospitalizations. None of the cleft children had palatal obturation during the study period. By the age of three years, the cleft group tended to catch up in weight with their non-cleft peers.

Weight gain records for the first six months of life for a limited number of cleft palate patients were cited by Avedian and Ruberg.¹⁹ The median birth weight was in the thirtieth percentile on a standardized growth curve, but fell to the twentieth percentile soon after birth. These children did not recover to their previous place on the growth curve until six months of age. Although the sample size was small, the authors felt this trend was often observed. Initial feeding problems appear to contribute to early weight gain impairment.

Paradise and Williams²⁰ observed that when first seen in the University of Pittsburgh Cleft Palate Center, most cleft infants under one year of age were undergrown. These infants had histories of difficult feeding and an average weight gain of less than 500 grams per month during their first few months of life. Infants with isolated cleft lip tended to feed and gain weight normally. This seems to

rule out hospitalizations as a cause of poor weight gain since both groups had surgical lip closure prior to six months of age. Adequate weight gain is especially important as initial lip closure and subsequent surgical procedures, all under general anesthesia, require a well nourished child.

An additional problem faced by many cleft infants is that the defect limits their participation in the feeding process. Constant interruption of the feeding rhythm, because of gas build-up or nasal discharge, frustrates both mother and infant.⁵ Fatigue may cause the infant to cease feeding before adequate nutrition has been achieved. Tisza and Gumpertz⁵ observed that this tension may account for a cleft infant's tendency to have less body contact with the mother during feeding. Although current theories tend to negate the importance of feeding in the development of attachment, this situation could inhibit establishment of optimal feeding conditions.

II. Obturator Therapy:

Many devices and techniques have been designed to circumvent the problem of inadequate nutrition and facilitate feeding in cleft infants. Specially designed nipples, syringes, and bottles, as well as different feeding positions, have been advocated. One such modification is the crosscut enlargement of the standard nipple to allow adequate milk ejection.¹² When these methods fail to produce an adequate weight gain, more aggressive measures such as in-dwelling gastric tubes or intravenous nutrition have been advocated.¹¹

To facilitate feeding in infants born with cleft lip and palate, a maxillary obturator has been developed. This acrylic appliance is positioned over the cleft palate defect to close the oronasal communication and create a false palate against which the child can suckle.^{11,16,17,21-23} Jones, Henderson and Avery¹⁶ utilizing obturation in cleft infants, reported a decrease in choking, nasal discharge, and the time required to complete feeding. They also found that parental apprehension decreased during feeding. This may be attributed to the ease of feeding coupled with the feeling that parents were more involved in their infant's care. The parents became active therapists in the rehabilitation of their infant. Additionally, as parents had more contact with the pediatric dentist or orthodontist, they developed a more realistic insight into their child's problem and received continued support.²⁴

III. Maxillary Orthopedics:

Maxillary orthopedics is a term denoting the molding of maxillary segments in complete clefts of the lip and palate. This is accomplished by inserting an acrylic plate to control the relationship of these segments to each other and to the mandibular arch, utilizing pressure created by surgical closure of the lip.²⁵ The original appliance for maxillary orthopedics is attributed to McNeil.²¹ The appliance was designed to stimulate the natural growth centers in the maxilla to accelerate the approximation of the hard palate cleft, as well as producing a more normal arch form. McNeil felt that sur-

gical lip repair was made easier when a normal arch form was present. Additionally, the resulting approximation of the cleft segments augmented palatal repair.

One theory of craniofacial growth and development, although controversial in nature, is the Functional Matrix Theory.²⁶ It states that skeletal growth is a response to functional matrix growth, which comprises the soft tissues and spaces that approximate the facial bones. Some functional matrices of the craniofacial complex are respiration, digestion, olfaction, and speech. Abnormal functional matrices may result in abnormal skeletal development. This theory centers on muscular function and its ability to change bony growth and architecture. Abnormal muscle function produces an imbalance in facial structures that results in bony distortion. Recently deposited bone tends to be the most susceptible to this distortion, and the neonatal period is one of the most prolific for craniofacial skeletal growth. These skeletal muscles are controlled by combinations of neuromuscular reflexes such as swallowing, coughing, and sucking. A cleft palate may change such reflexes by the altered oronasal architecture. The resulting abnormal patterns of reflexes change the functional matrix and thus facial growth. The pre-surgical orthopedic appliance produces a more normal anatomic relationship for such functions, which may stimulate more natural facial skeletal growth. An appliance over the palate prevents the tongue from entering the nasal cavity, which should produce a more normal functional matrix, as well as decrease nasal irritation.²⁴ Unfortunately the theory is very difficult to test objectively. Most of its support is from subjective conjecture and observation.

Another theory of craniofacial growth involves the importance of the nasal septum.²⁶ In early post-natal growth, up to six years of age, the cartilagenous nasal septum is proposed to have tissue separating forces that affect midface growth. Supporting evidence for this theory focuses on the fact that resection of the septum retards anteroposterior growth and midface deficiency is seen with septal agenesis. In an argument against the use of the pre-surgical orthodontic appliance, Pruzinsky²⁷ stated that too much emphasis is placed on the nasal septum, while ignoring the role of musculature in craniofacial growth. He felt that muscles dictate arch form, and that by restoring proper muscle function, the arch will be molded spontaneously into a favorable alignment. The use of an orthopedic appliance was therefore unnecessary. More recent authors tend to recognize the importance of the musculature, as well as the septum, in facial growth.^{24,28} It would seem that the orthopedic appliance, aided by pressure created by surgical lip closure, would be beneficial in attaining optimal alignment of the maxillary arch. Once arch symmetry is obtained, perioral musculature should function to maintain optimal arch relationship.

Four goals of early treatment of the cleft lip and palate patient utilizing pre-surgical orthopedics may be stated as follows:²⁹

1. Alignment of the maxillary segments establishes a symmetrical arch form allowing a more normal facial growth pattern.
2. Establishing arch symmetry improves the position of the individual teeth within the dental alveolus. This may reduce the need for extended orthodontic treatment later in life.

3. The patient has a more esthetic dentition during the developing years.

4. The alignment of the maxillary segments facilitates surgical closure of the lip and palate.

McNeil²¹ originally advocated repositioning alveolar cleft segments through the use of a series of appliances. Each successive appliance applied pressure to the segments to mold them into a more favorable alignment.³⁰ After lip closure, a new appliance was inserted to maintain arch symmetry until palatal surgery. This tended to delay the initial cheiloplasty for several months, which allowed tissue growth of the lip for easier manipulation during the procedure. Many authors now utilize pressure created by the lip surgery to mold segments into a more normal position utilizing a passive appliance designed specifically for this purpose.^{22,24,29-31}

Prior to lip surgery, usually one or two days after the child's birth, a passive maxillary appliance is placed to maintain lateral maxillary dimension. The appliance is constructed to cover the entire maxillary arch extending to a point distal to the premaxillary area of the greater segment. This frees the anterior part of the greater segment to rotate distally and medially to approximate the anterior part of the lesser segment, while preventing arch collapse.^{22,29,32}

Pressure following lip surgery will initiate the molding action.

If an appliance is not utilized to hold the segments in their proper position following lip closure, the maxillary arch may collapse.³³

The resulting defect will necessitate correction later in life.

Collapse of the maxillary arch could result in a protrusive premaxil-

lary segment with poor esthetics in the lip repair, lack of nasal base support, and a deviant facial profile.²⁴ Ideally the teeth should be able to erupt into their proper position in the arch without the need to correct an arch malalignment.³¹ Following lip closure, the obturator maintains the segments until bony union can be completed via primary alveolar cleft bone grafting.^{28,34}

Collapsed maxillary segments occur in some complete unilateral clefts of the palate at birth. This could be the result of external pressure applied to the lateral maxillary segments in utero, by an abnormal fetal position or decreased amniotic fluid.²⁴ As the child grows, the primary teeth erupt in crossbite, which tends to produce an underdeveloped maxilla. Waiting until the child can tolerate an expansion appliance for the primary or permanent dentition may result in deficiency in anteroposterior or lateral arch development.²⁹ If crossbite correction is delayed until the full permanent dentition is present, a lack of space for the maxillary teeth could develop, as well as abnormal mandibular development. By placing a maxillary obturator with an expansion screw, the collapsed segments can be repositioned to a more normal relationship.^{3,29,31,35} Once expansion is achieved, lip closure can be completed, with molding of the anterior part of the greater segment.

Not all authors believe that obturator therapy has long-term benefit in the cleft palate patient. Huddert³⁶ reported favorable short-term results with the obturator prior to lip closure, but by five years of age, optimal arch form was not achieved. It should

be noted that his subjects were not stabilized with a primary alveolar cleft bone graft; thus maxillary arch collapse was seen after the obturator was removed. Norden et al.³⁷ and Peat³⁸ reported similar results.

Other authors consider that long-term results of maxillary orthopedics substantiate the use of obturator therapy. Robertson³⁹ reported a significantly better occlusion of the treated versus non-treated cleft patients, but conceded that part of the success may be due to improved palatal surgery techniques. Rosenstein⁴⁰ reported less dental crossbite after maxillary orthopedics, when accompanied by primary alveolar cleft bone grafting. Troutman²⁹ found patients treated with a passive appliance had a 31.1% decrease in lateral crossbite occurrence and a 30.2% decrease in buccal crossbite, when compared to patients without appliance therapy. Similar results were reported by O'Donnell et al.³⁰ and Graf-Pinthus and Bettex.⁴¹ They said that treatment seemed to minimize the severity of later orthodontic deformities. In most long-term studies, some patients had a dental crossbite in the canine or anterior segment, but usually to a lesser extent than without primary alveolar cleft bone grafting.⁴² It is important to remember that a genetic potential exists in some patients to develop a malocclusion, even when the effects of a cleft lip and palate are negated. The literature indicates that approximately 40-50% of complete unilateral cleft lip and palate patients develop posterior crossbites in the deciduous dentition following surgical closure of the lip.⁴³ Crossbite development is thought to

be related to increased pressure produced from surgical closure of the lip, pushing the maxillary deciduous centrals into lingual version.⁴⁴ A decrease in the incidence of posterior crossbite, achieved with obturator therapy, produces a more functional maxillary arch form.²¹

Advocates of the appliance feel that there are instances where maxillary obturator therapy may not be indicated in the newborn cleft infant. These include:³¹

1. A case in which the larger segment is not initially rotated upward and anteriorly.

2. A lesser segment that may be of sufficient size and lateral placement to predict a favorable alignment without collapse after lip closure.

3. Isolated cleft palates, where the alveolus is either notched or uninvolved, so alignment is initially correct.

As in all types of therapy, advocates of pre-surgical orthopedics emphasize that it should be used selectively.

IV. Cheiloplasty:

Cheiloplasty refers to surgical repair of a defect of the lip. Various procedures are advocated in cleft centers across the nation. The most common unilateral cleft lip repair is the Rotation-Advance-ment Technique of Millard. According to a 1981 survey by Osborn and Kelleher,⁴⁵ this technique is taught in 91% of responding programs. The Triangular Flap varies between institutions, but is commonly used

in 20% of the programs. The cheiloplasty is often performed by the third month of age. This allows the child to gain weight and stabilize after birth, so the procedures will be less risky than if performed earlier.

At the time of the cheiloplasty, the original obturator, which was placed a few days after birth,⁹ is often loose and needs replacement. While the child is under general anesthesia for the lip repair, an impression is obtained and a new obturator is constructed. This prosthesis is fabricated and inserted 10 to 14 days after cheiloplasty. The original obturator remains in place during this period to prevent arch collapse. In a study of lip repair on rabbits with surgically created clefts of the lip, alveolus, and palate, the greatest amount of pressure created by the lip repair was measured at two to four weeks post-operatively. This pressure remained significantly higher for the 20 weeks of the study.⁴⁶ In a two-year study of cleft lip and palate children, Bardach and associates⁴⁷ demonstrated similarly higher lip pressures which continued through the study. Optimal arch symmetry may be obtained as early as four weeks after lip closure, but this may take two to four months.^{32,48} Chierici⁴⁹ hypothesized that eventually a balance between lip pressure and segmental position would be achieved, and the resulting lip pressures would be similar to those of non-cleft children. Since the Bardach study demonstrated continued higher lip pressures through age two, the authors concluded that either the shape of the alveolus was not optimal or the recording device had an error built in. Chierici⁴⁹ felt that

any such imbalance in lip or alveolus could function to influence the developing maxilla or tooth position.

Many researchers believe that the inhibition of facial growth seen in persons with cleft lip and palate is due mainly to surgical closure of the palate.^{50,51} Mazaheri et al.⁵² noted a significant pattern of anteroposterior and lateral dimensional retardation after surgical closure of the palate, which persisted until five years of age. They attributed this primarily to contracture of the palatal scar rather than to any lip effect, although the decrease in intercanine width could have been due to the cheiloplasty pressure. Some authors have detected this growth inhibition starting in the post-cheiloplasty period. Bardach et al.⁴⁶ demonstrated that, in rabbits, shortening of the maxillary complex occurred following lip repair, when compared to controls. They postulated a relationship between the amount of lip pressure and the inhibition of anteroposterior growth following the cheiloplasty. It is interesting that eruption of the deciduous dentition in the anterior segments coincides with increased lip pressure resulting from lip repair. This could result in the anterior crossbites seen in many of the crossbites noted, whether the obturator was utilized or not.

Once the maxillary segments have been positioned in optimal alignment, the segments are ready for primary alveolar cleft bone grafting. This will maintain the optimal arch form and allow a more normal alveolus in the cleft region.

V. Primary Autogenous Alveolar Bone Graft:

Alveolar bone grafting was first advocated in the early 1950s as a way of bridging the gap between the alveolar cleft segments with bone to establish and preserve optimal maxillary arch form.⁵³ The primary autogenous alveolar bone graft was developed to further assist with preservation of arch form and function. The primary purpose of the bone graft is to stabilize the mobile segments, to create a bone matrix for the eruption of teeth, and to increase more alar base support for the nose.

Once the lateral segments of the alveolus have moved into an end-to-end approximation from the lip pressure, around six months of age, they can be stabilized with a primary autogenous alveolar bone graft.⁴⁸ The bone graft procedure utilizes a two-centimeter section of rib that is harvested and split in half. An incision is made in the upper buccal sulcus in the region of the cleft and small flaps are reflected from the margins. Dissection is continued down to bone on either side of the cleft to create a pocket in which the harvested bone will be placed. After insertion, the chips from the second half of the rib are packed behind the main bone graft to increase the total volume of bone. This surgery does not approximate the prevomerine suture (an area important in stimulating anteroposterior maxillary growth) and involves a limited dissection.⁹ The obturator is worn until a few weeks prior to palatal surgery, at approximately 18 months of age, to stabilize the maxillary segments during healing. Boyne⁵⁴ tested autogenous particulate cancellous bone and

marrow grafts in bilateral surgically-produced alveolar clefts in young rhesus monkeys. He found complete osseous regeneration in the cleft area with the tooth buds on either side showing no disturbance. Rosenstein and Jacobson³¹ considers it imperative that the appliance be worn for at least six months after the graft procedure to allow for stabilization of the segments during the demineralization of the graft and subsequent reossification by the host bone.

Rosenstein and associates⁴⁸ have followed patients who underwent obturator therapy and primary bone grafting procedures as described above. The group ranged in age from 12 to 15 years, and all had unilateral complete clefts of the lip and palate. The authors found no difference in real growth or speech when compared to the group of unilateral complete clefts of the lip and palate patients who did not receive bone grafting. Arch form and integrity were excellent. Teeth had erupted in, around, and through areas that had previously been cleft. The principal differences between this procedure and earlier techniques center upon the separation of the lip repair and bone graft, which allows for better alignment of the segments before the graft is placed. Monroe et al.³² noted that the bone graft and palatoplasty need to be separated long enough to allow the graft to strengthen and resist collapse. When the procedures were carried out simultaneously, the resultant contracture often positioned the lesser cleft segment into a collapsed relationship. Lynch and associates^{55,56} studied groups of patients grafted either before eighteen months or after six years of age and found no change in the A-B dif-

ference as a standard of maxillary growth. This is the ANB angle measured from A point on the anterior maxilla to Nasion point and down to B point on the anterior mandible. It relates the positions of the maxilla and mandible relative to the craniofacial complex. They also reported better ridge form and function. Horton et al.³³ found that bone grafts aid in the development of teeth adjacent to the graft, help fill out the alveolar ridge contour, and improve the cosmetic appearance of the lip and nose. Nylen and others⁵⁷ reported the incidence of major lateral crossbite was lower with the primary bone graft procedure than cases who did not have the procedure. A similar technique of a maxillary prosthesis combined with an autogenous bone graft was used by Wood and Robinson.^{58,59} They concluded after five years that this procedure has definite merit. As Jacobson and Rosenstein³¹ stated, the integrity of the maxillary arch should be established so that teeth may later erupt into or be orthodontically repositioned into the cleft area. This method has proven effective in producing these results and reducing the time and effort needed to correct a malalignment that could have been prevented in the first place.

Not all authors are advocates of primary autogenous alveolar cleft bone grafting. Stenstrom and Thilander⁶⁰ reported a disturbance in maxillary growth after bone grafting in animal experiments. Pickrell, Quinn, and Massengill⁶¹ found that 88% of their primary osteoplasties (cheiloplasty and bone graft completed at the same time in infancy) did not prevent collapse of the lateral segments. It should be noted that the lip and graft procedures were completed

simultaneously, which is not advocated by the proponents of primary alveolar cleft bone grafting. Robertson and Jolleys⁶² reported that one-half of all cases of early secondary osteoplasty (bone grafting after the complete eruption of the primary teeth in the cleft area) produced incisal retrusion with dorsal position of the anterior nasal spine. Following further analysis, they concluded, as did Davies,⁶³ that bone grafting impairs maxillary growth. Koberg⁶⁴ felt that not enough late results (at least 10 years after the bone grafting procedure) have been published to establish the benefits of this technique. Johanson and Friede,⁶⁵ in evaluating the results of Rosenstein and associates, felt that the authors were able to prove that the grafting procedures did not jeopardize the proper anteroposterior relationship between the maxilla and mandible. They noted, however, that no measurements were presented to evaluate the overall function, esthetics, and stability of the permanent dentition. Knowing the amount of periodontal bone support of the teeth adjacent to the cleft, the number of cleft areas without probable need for prosthetic replacements or stabilization, or the number of useful lateral incisors on the cleft side would be beneficial in determining long-term success, but this information was not adequately established.

VI. Palatoplasty:

The timing of the palatoplasty has been a subject of contention for many years. Some advocate an early repair around three to seven months of age. Others consider it best to wait until 18 to 24 months

or even four to six years of age.⁴⁵ The most common palatoplasty technique used in the United States is the V-Y Pushback procedure, which accounts for 68% of surgical operations used in training programs. The Von Langenbeck procedure is used in 46% of the programs, while the Vomer Flap is used in 35%. The repair of the soft palate varies from three months to six years of age, with 83% closed by 18 months of age. Two out of three programs close the hard and soft palate together, again with a range of three months to six years of age. Proponents of early surgical closure center on the belief that speech development early in life is integrally linked to the status of the velopharyngeal apparatus. Randall and associates⁶⁶ emphasized that respiratory movements and vocalization-type action occur in utero. Programming for these functions is well developed at birth. A child with a cleft palate may already be incorrectly programmed at birth to compensate with various substitution steps which become more established with time. Randall argued that repair of the cleft apparatus at an early age, such as three to six months of age, would help overcome the development of abnormal patterns developed early in life. He and his associates studied two groups of cleft palate closures performed at different ages in reference to speech development. They found that a majority of early palatoplasty patients (three to six months old at time of surgery) had unusually good speech that was free, easy and relaxed. Patients with later closures (12 to 18 months of age) tended to have more articulation errors, nasal resonance, and a changed voice quality. Even when the speech had no errors, it was somewhat strained, forced, and more difficult for the patient.

The progression of language in infants starts with crying after birth. By the end of the first month of life, the infant is producing many different vocalizations and babbles by the middle of the first year. Patterned speech emerges at the close of the first year, as the child begins to put different series of vowel and consonants together into meaningful words.^{67,68} Misarticulation of consonants seen in adults and children with repaired palatal clefts can be traced to the chronology of the palatal surgery.⁶⁹ Problems that were documented before surgical repair were noted to persist postoperatively. Perhaps repair at an earlier age would reduce these articulation errors. Schultz⁷⁰ has postulated that the persistence of compensatory articulation, after velopharyngeal adequacy has been restored, occurs because abnormal speech production had been well established prior to reconstruction. Dorf⁶⁹ studied two groups of cleft palate patients who had palate repair either before or after 12 months of age. The late closure group had a high percentage of residual compensatory articulations, while a small percentage of early closures had such problems. In determining the timing of the palatoplasty, the key seems to be the patient's articulation age rather than chronologic age. This accounts for deviations from the trend that Dorf reported. Witzel and associates⁷¹ conducted a review of the rationale and supporting evidence for late closure of the palatal defect. Many studies of late closure were subjective in their evaluation of articulation and velopharyngeal function. Few objective measurements were used. They found that six studies with speech pathologists as authors, five noted that groups of patients with delayed hard palate

closure suffered severe speech problems both before and after surgery. In an interesting side note, Markowitz¹⁵ found that the infants with obturators did not have the characteristic sounds of the usual cleft infant. Instead, they had speech that was clearer and consisted of more diverse sounds. Perhaps the obturator helped these infants in the initial stages of speech development.

Koberg⁶⁴ and Rohrich et al.⁷² found no difference between the degree of hearing problems or otitis media when considering early and late closures. They felt that overall speech intelligibility, articulation, and nasal escape were significantly poorer in the delayed closure group. Other problems associated with delayed palatal closure center upon abnormal continuity between the oral and nasal cavities, which contributed to feeding problems.⁷³ Another problem seemed to be a failure of the eustachian tube to dilate normally, which prevented equilibration of middle ear pressure with that of the atmosphere. Food debris and bacteria also contribute to a culture media around the eustachian tube orifices.

Although many authors favor earlier palatal surgery, others believe in the traditional theory that early procedures do not significantly improve speech patterns and could actually result in poor facial growth. Hotz and associates⁷⁴ found that speech development was better in a delayed palate closure group than in a group undergoing early surgical closure. They felt that late closure patients had less need for pharyngeal flaps later in life. Jorgenson et al.⁷³ studied a group of 32 patients with unilateral cleft lip and palate who had had palate surgery either before or after four years of age.

They concluded that the late closure group had better maxillary growth and more normal palatal dimensions than those closed earlier. The trend seems to suggest that atraumatic surgery (not involving bone) accomplished later in life produces a more normal facial profile and palatal dimensions. Whether the involvement of bone or the timing of the surgery is more important in the final outcome remains unclear. Olin and associates⁷⁵ found early postsurgical contracture in palatal mucoperiosteal excision wounds was similar to that previously reported for skin wounds. Data suggested that a convergence of 15 to 40 percent of the original distance takes place during early healing, while unwounded areas of the palate diverged eight to 12 percent in the same time frame. The authors also noted major interruptions in increases in the arch width coinciding with the period of soft tissue contracture, suggesting that this could be the first link in a causal chain leading eventually to secondary skeletal deformities.

VII. The Importance of Maxillary Arch Form

Researchers feel that one of the primary determinants of success in cleft lip and palate rehabilitation is an esthetic and functional maxillary alveolar arch. In recent years, a number of different analyses have appeared in the literature. Butow⁷⁶ classified these into three major groups: 1.) an index system; 2.) a direct measurement system for models; and 3.) a direct measurement system for occlusal radiographs.

The index system is like an IQ-system and has been used by such authors as Van Kirk and Pennell⁷⁷ and Draker.⁷⁸ Koberg⁶⁴ introduced

an index system in which vertical, transverse, and anteroposterior occlusal discrepancies are assessed. The index ranged from: 0 = no occlusal discrepancy to 3 = a variation of more than 5mm with significant displacement of the cleft segment cranially. The resulting formula is $I = \text{sum of } G/6$, where I is the index ranking, sum of G is the sum total of all occlusal variations, and 6 is a constant. The index is used for evaluation of the cleft segment and is only a subjective evaluation. Unfortunately, the index requires a complete dentition for occlusal evaluation and cannot be used for the measurement of infant study models where teeth are still unerupted.

Many forms of direct measurement have been described. One such example is that utilized by Mazaheri.⁵² In this method, a photocopier was used to produce an accurate one-to-one copy of the study models. Landmarks were marked on the copies which consisted of: 1.) the crest of the alveolar ridge, 2.) margins of the cleft, 3.) tuberosity points, 4.) canine points, and 5.) the anterior edge of the greater and lesser segments. Measurements of width and length dimensions (anteroposterior) were made in various regions. Averages of different dimensions were determined for patients with cleft lip and palate, cleft palate only, and normal arches. Comparisons were made within and between each group as age changed. A few measurements provided the spatial relationship of the greater and lesser segments at the alveolar cleft.⁵² This method allows for analysis of dimensional changes of various points in the developing arch as the child grows (in the edentulous arch as well as in an arch with teeth present).

The Relationship Measurement Method has been proposed by Butow⁷⁶ to aid in an objective assessment of cleft segments. The technique is described in Appendix D. Butow fixed the occlusal plane at three points to make a specifically oriented photograph from which a drawing was made. The center of the alveolar ridge is traced from one post-gingival point to the other, placing the two post-gingival points on the X-axis. Since this is a geometric linear analysis, X- and Y-axes are created, and a series of lines is constructed. The measurements are made in such a way that the arch width, length, etc., are related between the cleft and non-cleft sides of the same arch. This is based on the assumption that the non-cleft side position is symmetrical and functional. By using this method, each model serves as its own standard for measurements, and a direct assessment may be obtained without reference to other models and standards. Arch symmetry may thus be compared between different ages and patients, with and without teeth present. An adult and child may be compared, since the analysis is independent of growth. Inherited orthognathic problems can be ignored, since the analysis does not include the mandibular arch. Discrepancies in tooth position may be negated, since the analysis considers the center of the alveolus, not individual tooth positions. One disadvantage of this method is that it can only be used for unilateral complete clefts of the lip and palate, as it assesses the differences between the cleft and non-cleft sides of the maxillary arch.⁷⁶ Overall, the method is a simple way to measure arch symmetry.

METHODS AND MATERIALS

The present study was designed to consider three issues involving obturator therapy in unilateral complete cleft lip and palate. First, a questionnaire was used to subjectively assess observations, feelings, and concerns of the parents of cleft infants. The questions focused on parental acceptance of the therapy, ease of appliance usage, and overall benefit to the child. Second, the weight gain records of cleft infants were analyzed to document weight gain over the first year of life. The data were compared to normalized weight gain averages for infants of the same age groupings to assess adequate gain in the cleft sample. Third, assessments were made of maxillary alveolar arch symmetry, using the Relationship Measurement Method of Analysis. This compared the cleft and non-cleft sides of each infant's maxillary arch for crossbite tendency in the posterior, canine, and anterior regions.

The 45 children who participated in the study were born with a unilateral complete cleft of the lip and palate. They ranged from one to six years of age at the time of the study. None of the children had any other congenital anomalies that would interfere with the routine treatment protocol prescribed by the Cleft Lip and Palate Team at James Whitcomb Riley Hospital for Children, Indianapolis, Indiana. Because of incomplete growth records on some infants, weight gain (N = 32) and arch symmetry analysis (N = 26) sections did not utilize all of the patients that were contacted for the parental questionnaire.

Most infants had an acrylic obturator placed within a few weeks of birth to prevent maxillary lateral segmental collapse and to aid in the feeding process (See Appendix A for details of construction of the acrylic obturation appliance). Parents were instructed in the correct usage of the obturator, as well as how to use a cross-cut nipple to facilitate adequate nutrition for their children. The nursing staff coordinated all feeding instructions to parents. In most cases, several subsequent obturators were made to coincide with the growth of oral structures. The appliance was retained for approximately one year, allowing for the cheiloplasty and primary alveolar bone graft to be completed and adequately stabilized. Lip repair surgery was performed at about three months of age and the primary autogenous alveolar cleft bone graft surgery was completed between six and nine months of age. Palatoplasty was performed between one and two years of age.

I. Parental Questionnaire:

Since controversy over the benefits of obturator therapy still exists, this section focused on the subjective opinions of parents of cleft children in reference to the overall benefits of the appliance. A questionnaire was mailed to 45 parents of cleft lip and palate infants (Appendix B). Parents were asked to rank each statement from "strongly agree" to "strongly disagree" (a five-point Likert scale), as each statement pertained to their own experiences. Some questions focused on the principal attributes of the palatal

appliance. Other questions established the psychological impact of the obturator with regard to parental bonding and feelings of adequacy in the child's treatment. These questionnaires did not list any parent or child names to insure more accurate responses. Each questionnaire included a self-addressed stamped envelope to encourage return mailing. Twenty-eight completed questionnaires were received, yielding a final response rate of 62 percent.

II. Factors Related to Infant Weight Gain:

In order to document potential feeding benefits for these infants, weight gain records over the first year of life were maintained. All infants were fed using the cross-cut nipple technique.⁹ The medical records for 32 children with unilateral complete clefts of the lip and palate who had obturators were examined to determine weights from birth to one year of age. These weights were plotted on standard weight curves for infants to determine the infant's original status in terms of birth weight, in comparison to a large group of essentially healthy children across the nation. The data for the growth charts are from the Fels Research Institute, Wright State University School of Medicine, Yellow Springs, Ohio (See Appendix C for Growth Charts). Once the original weight group percentile was established, subsequent measurements were recorded at three and nine months of age to follow the infant's growth. Statistical analysis of the data was done using the Statistical Package for the Social Sciences to investigate if a significant benefit exists in the usage of obturator therapy in reference to

adequate weight gain in these children. A child who remained in his original weight percentile or gained in his percentile was considered to have adequate or better nutrition. A child who declined from his original weight category was considered to have inadequate nutritional input to maintain steady growth.

III. Factors Relating to Arch Form Symmetry:

This section of the study determined symmetry of the alveolar arches from serial models of unilateral complete cleft lip and palate patients treated with obturator therapy. Sequential study models of 26 cleft infants were assessed, using the Relationship Measurement Method of Analysis for complete unilateral cleft lip and palate cases, as proposed by Butow⁷⁶ in 1984 (See Appendix D for a detailed explanation of this method). Each model was measured to determine the amount of deviation from perfect arch symmetry in terms of lateral and segmental crossbite tendencies.

RESULTS

I. Parental Questionnaire Results:

The parents of 28 unilateral complete cleft lip and palate infants responded to mailed questionnaires. The average age at which the obturator was first inserted was 5.4 weeks (range 1 to 19 weeks). All 28 infants accepted the appliance and wore it consistently for an average of 10 months. The infants underwent lip surgery to repair the cleft lip at various ages, with an average age of 3.5 months. Some cleft infants received primary alveolar bone grafts at the mean age of 9.2 months, and the palatoplasty was performed at an average age of 19.5 months.

Parents reported that their physicians had mixed concerns about weight gain before the obturator appliance was used (Figure 1). Some physicians related immediate concerns about the child's weight gain, while others felt it was very adequate. After the obturator was placed, 93% of the parents reported that their physicians considered the child's weight gain adequate.

Before the obturator was used, 20 parents agreed or strongly agreed that their cleft infants had difficulties with feeding (Figure 2). For all cleft infants, there were reports of drainage from the nose upon feeding, with 89% having some to a great amount of drainage (Figure 3). Twenty parents said that feeding often took at least 30 to 45 minutes to complete (Figure 4). Following obturator therapy,

the infants had much less difficulty with feeding. The feeding time was also reduced to between 15 and 30 minutes for 75% of the patients reported. The obturator reduced the drainage during feeding to a point where 54% had little or no drainage, and only 2 patients still had a great amount.

Parents reported some degree of discomfort with feeding their cleft infant in 46% of the cases before obturator delivery (nine agreed and four strongly agreed). After obturator therapy began, 82% stated they were comfortable about feeding (Figure 5). Results relating closeness to their infant before and after obturator delivery were also reported. Of special interest was the fact that two parents did not feel close before appliance usage, but later reported increased closeness (Figure 6). After one month of usage, only one parent still had apprehensions about the removal and cleaning of the appliance (Table I, Number 1). Twenty-four infants wore the obturator 24 hours per day (Table I, Number 2). All but one of the parents rated the obturator as useful in their child's therapy and would recommend the obturator to other parents of cleft children (Table I, Number 3). This parent also expressed continued apprehension associated with the feeding process and obturator usage. Ninety-six percent reported that they would recommend obturator therapy to other parents of infants who have cleft lip and palates (Table I, Number 4). In 86% of the cases, parents felt that the obturator was an effective way to participate in the rehabilitation of their cleft infant (Table I, Number 5).

II. Weight Gain Analysis:

The medical records of 32 cleft lip and palate patients were obtained to assess weight gain over the first year of life. The infants consisted of 21 with primary alveolar bone grafting and optimal obturator use, 3 with the graft and sub-optimal obturator use, and 8 with no primary alveolar bone grafting but obturator use. Cheiloplasty surgery was completed at approximately 3.7 months of age on the average for all the infants, and primary alveolar bone grafting was performed at 8.7 months of age for those that had the procedure. Because of the small number of patients in the sample, all of the data will be considered in one grouping.

At birth, these cleft lip and palate infants had an average weight of 7.22 pounds (range 5.44 to 9.88 pounds). When plotted on the standardized growth scale, the weights had a mean ranking between the 25th and 50th percentile. This was slightly below the standardized weights for infants born without medical problems (Figures 7 and 8, Table II). These rankings ranged from the 5-10% category to the > 95% category.

By the age of three months (mean age of 3.4 months), mean weight had increased to 12.79 pounds, with a range of 9.8 to 18.1 pounds. This resulted in an average of 25-50% on the standardized scale, although values tended to be on the high side of this category. One infant was in the < 5% category, while none were in the 5-10% area. Nine cleft children (19% of the total cleft sample population) were in the over 50% range. Of these patients, 18 either maintained

their original weight percentile category or increased to a higher weight category. Two infants increased their weight categories by two. Twenty-two infants (69% of the total cleft sample group) either maintained their original weight category or just dropped into the next lower percentile category.

At the age of nine months (mean 9.6 months old), mean weight had increased to 19.46 pounds (range 14.88 to 24.88 pounds). This resulted in a percentile ranking of 25-50% on the standard growth curve. Although below the standard curve mean, this represents a slight decrease when related to the birth and three-month-old weights. As in the three-month-old group, rankings for the nine-month-olds ranged from <5% to 75-90% categories. Seventeen patients either did not change or increased weight percentile groupings from the third to the ninth month. Between birth and nine months, 13 patients either maintained their weight percentile overall or increased it. Eighteen infants (56% of the total cleft sample group) either maintained their original weight percentile category or just decreased to the next lower weight percentile category.

III. Arch Symmetry Analysis:

The models of 26 patients were analyzed at one, four and ten months of age using the Relationship Measurement Method of Arch Analysis to determine the amount of arch symmetry or collapse present (Appendix D). There were 16 infants with primary alveolar bone grafting and optimal obturator use, three with grafting and sub-optimal obturator use and seven with no primary alveolar bone grafting

but obturator use. Cheiloplasty was performed at a mean of 4.0 months of age, and the primary autogenous alveolar bone graft at a mean of 9.6 months of age. The palatoplasty, on those who were old enough for the procedure, was completed at a mean of 19.8 months of age. Again, because of the limited number of patients in the sample population being studied, the data were considered as one group. The infants began obturator therapy at a mean age of 4.3 weeks.

The initial models were obtained at a mean of 1.2 months of age (range 1-2 months), and represented the pre-treatment dental arches of the cleft lip and palate infants. The amount of lateral crossbite in the posterior segment of the infant's dental arch (first-second primary molar area) was assessed by the CF/BF ratio (Table III). In ideal arch symmetry, the CF/BF ratio should be 1.00, showing that each posterior segment is equidistant from the midline. The average ratio of the initial arches for all the cleft infants was 0.851 (range 0.539-1.113), which indicates a 15% arch collapse when the lesser segment is compared to the greater arch segment. Only seven infants had a 10% or less arch collapse at one month of age. The amount of sagittal crossbite was assessed for the anterior region on the one-month-old infants by the AF/BF-0.956 ratio (Table IV). A normal infant's arch was found to have a ratio of 0.956. The one-month-olds had a mean ratio of 0.664, ranging from 0.233 to 1.023. This indicates a significant anterior crossbite tendency (34%) before treatment for many of the cleft infants. Three cases were within 10% of the ideal ratio, showing

that many of the infants had a collapsed anterior segment (greater segment). In the canine region, the arch segment/45° measurement (EF/DF ratio) revealed the amount of arch collapse, when relating the greater to the lesser segment (Table V). A ratio of 1.00 is ideal, and shows no arch collapse of the lesser segment. The cleft infants had an average EF/DF ratio of 0.755, indicating a 25% collapse of the lesser segment in the canine region. Only three infants had a 10% or less canine arch reduction.

The arches of the cleft lip and palate infants were evaluated at the age of four months (mean age of 4.1 months). This was after approximately three months of obturator therapy. The CF/BF ratio for these infants was 0.899 (ranging from 0.683 to 1.119), indicating a lateral posterior crossbite of about 10% from ideal. This is an improvement of 5% from the pre-treatment measurement. Fourteen patients fell into the category of being within 10% of a symmetrical posterior arch. In the anterior segment, the AF/BF-0.956 ratio was an average of 0.782 (range 0.459 to 1.198), an improvement of 12% over the initial arch presentation. The canine area showed an EF/DF ratio of 0.800 (range 0.624 to 1.000), a 20% collapse from ideal symmetry on the lesser segment. This is a 5% improvement over the original cleft arch presentation.

At the age of approximately 10 months (mean of 9.8 months), the cleft infants were again evaluated (Table VI). These patients had their lip repair surgery at an average age of four months, with the obturator therapy continued at least through this observation period. The CF/BF ratio for the infants was 0.877, with a range

of 0.620 to 1.025, indicating a 12% lateral posterior crossbite when compared to the ideal alveolar arch. Eleven patients were within 10% of a perfectly symmetrical posterior arch. The AF/BF-0.956 ratio was 0.757 (range of 0.493 to 0.937), which shows an anterior crossbite of 24%. The canine area showed an EF/DF ratio of 0.792, with a range of 0.553 to 1.035. This is approximately a 20% collapse from ideal arch symmetry, and no change from the four-month arch measurements.

FIGURES AND TABLES

FIGURE 1. Parental Questionnaire: "According to our physician, my infant is (was) gaining the desired amount of weight."

PARENTAL QUESTIONNAIRE: "ACCORDING TO OUR PHYSICIAN,
MY INFANT IS (WAS) GAINING THE DESIRED AMOUNT OF WEIGHT."

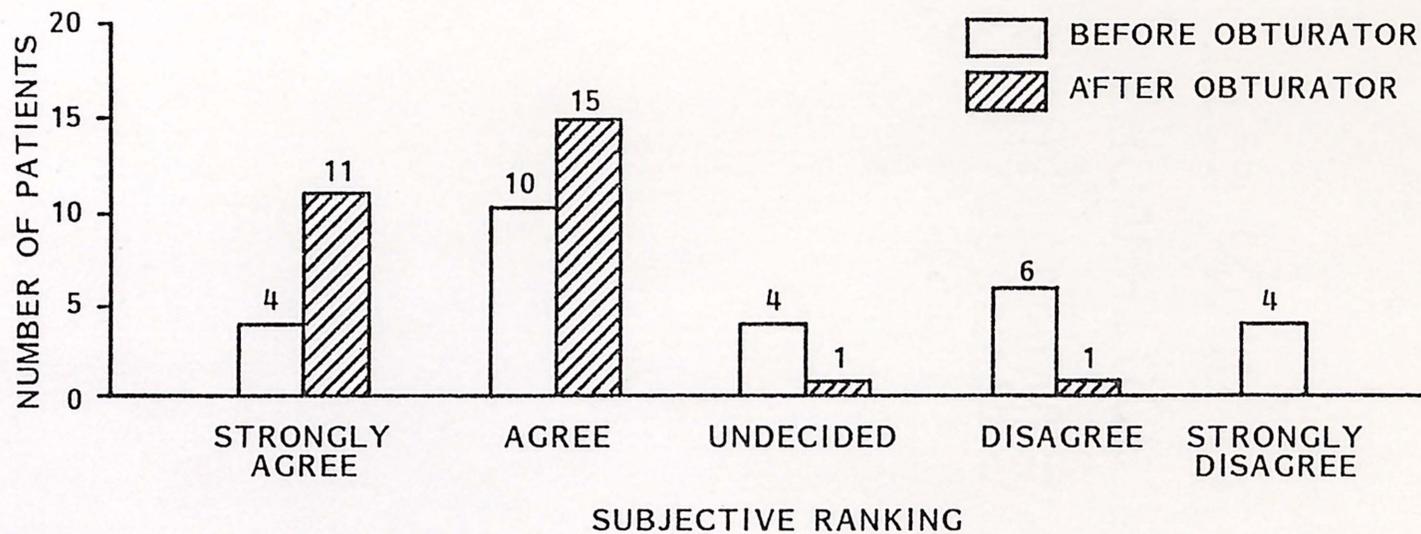


FIGURE 2. Parental Questionnaire: "My infant had difficulty in feeding."

PARENTAL QUESTIONNAIRE: "MY INFANT HAD DIFFICULTY IN FEEDING."

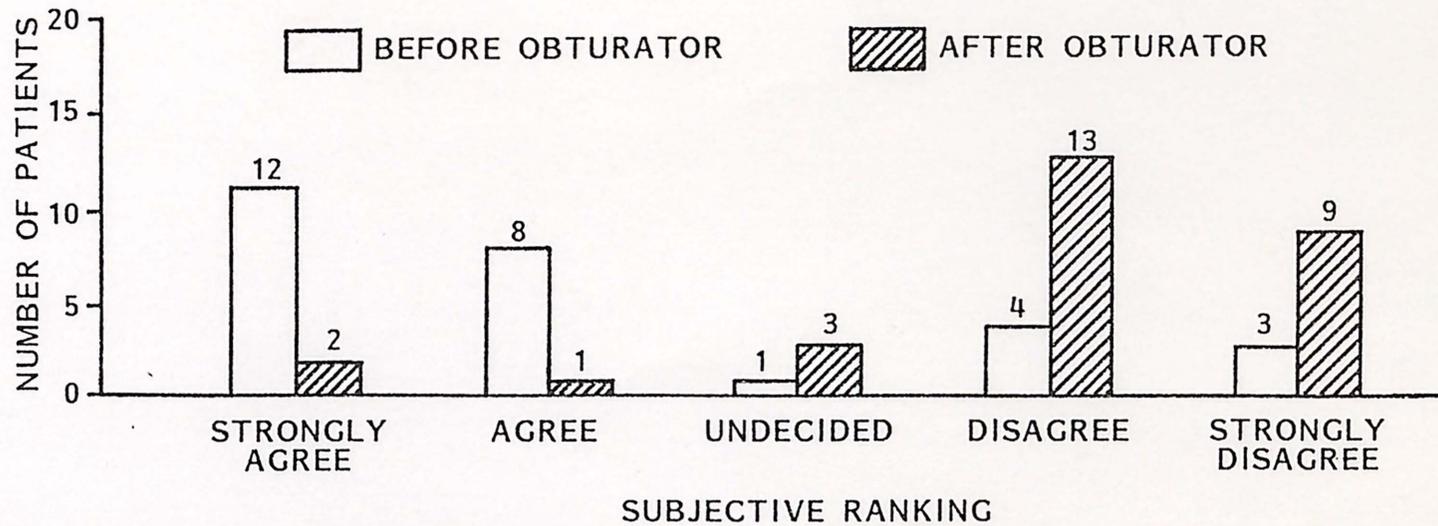


FIGURE 3. Parental Questionnaire: "Did your infant have drainage of food and liquids through the nose during feeding?"

PARENTAL QUESTIONNAIRE: "DID YOUR INFANT HAVE DRAINAGE OF FOOD AND LIQUIDS THROUGH THE NOSE DURING FEEDING?"

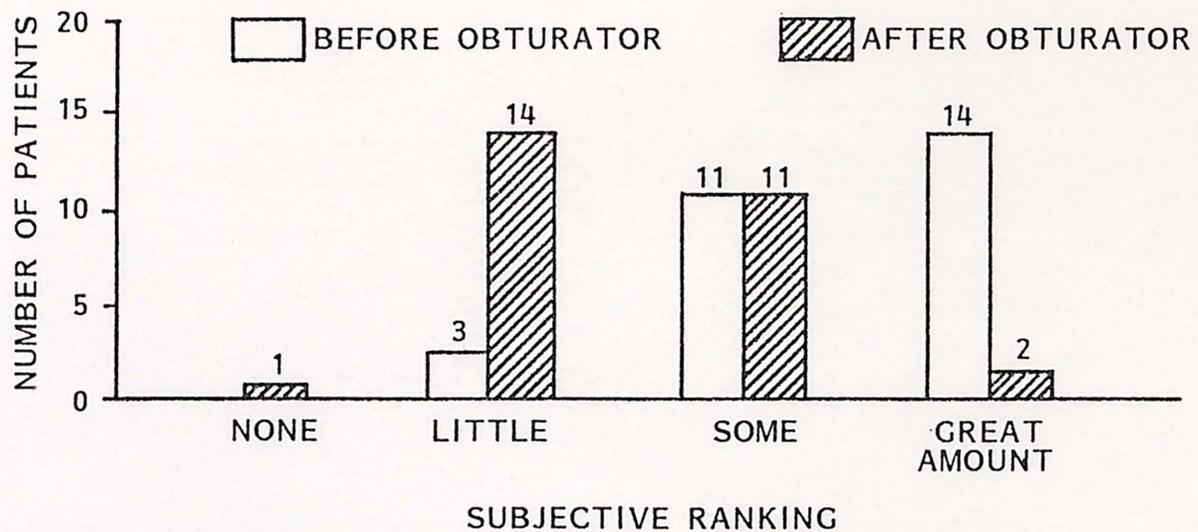


FIGURE 4. Parental Questionnaire: "The average feeding time for my infant was _____."

PARENTAL QUESTIONNAIRE: THE AVERAGE FEEDING TIME
FOR MY INFANT WAS ____."

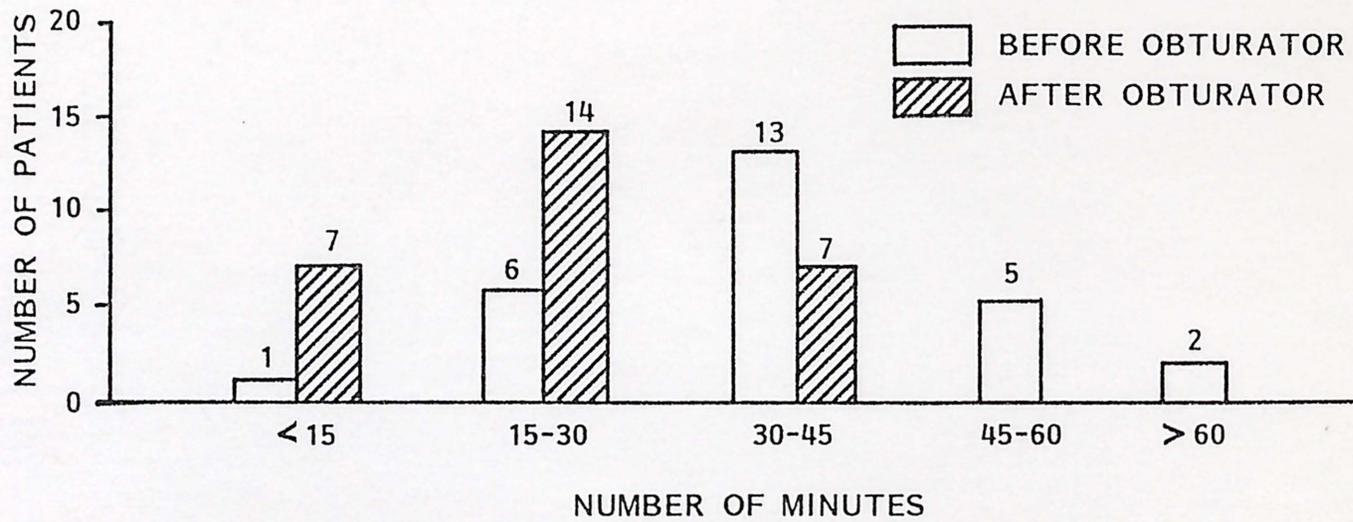


FIGURE 5. Parental Questionnaire: "I felt uncomfortable in feeding my infant."

PARENTAL QUESTIONNAIRE: "I FELT UNCOMFORTABLE IN FEEDING MY INFANT."

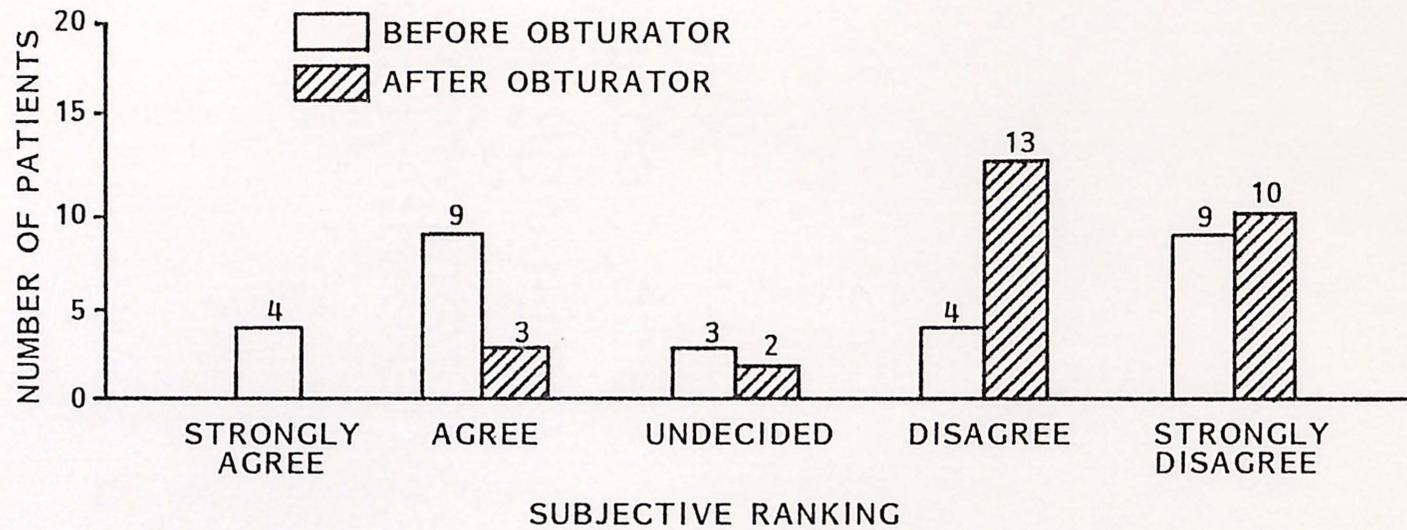


FIGURE 6. Parental Questionnaire: "I felt very close to my baby during feeding time."

PARENTAL QUESTIONNAIRE: "I FELT VERY CLOSE TO MY
BABY DURING FEEDING TIME."

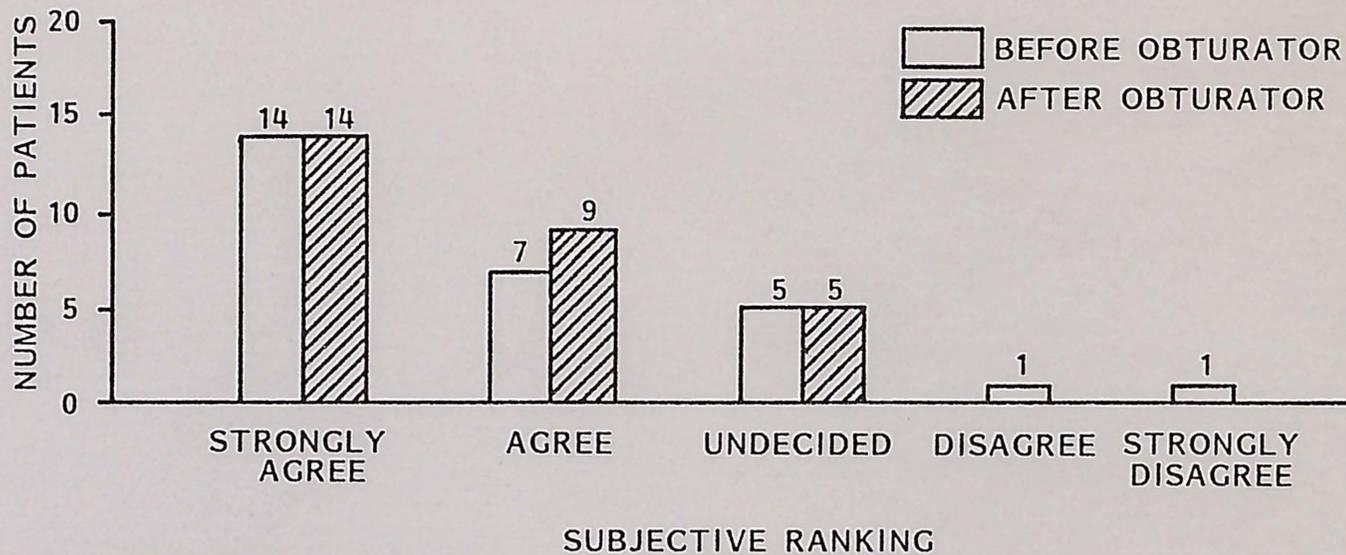


FIGURE 7. Weight Gain: Average weight of cleft infants at birth, three, and nine months of age compared to normal infants.

WEIGHT GAIN: AVERAGE WEIGHT OF CLEFT INFANTS AT BIRTH, THREE, AND NINE MONTHS OF AGE COMPARED TO NORMAL INFANTS.

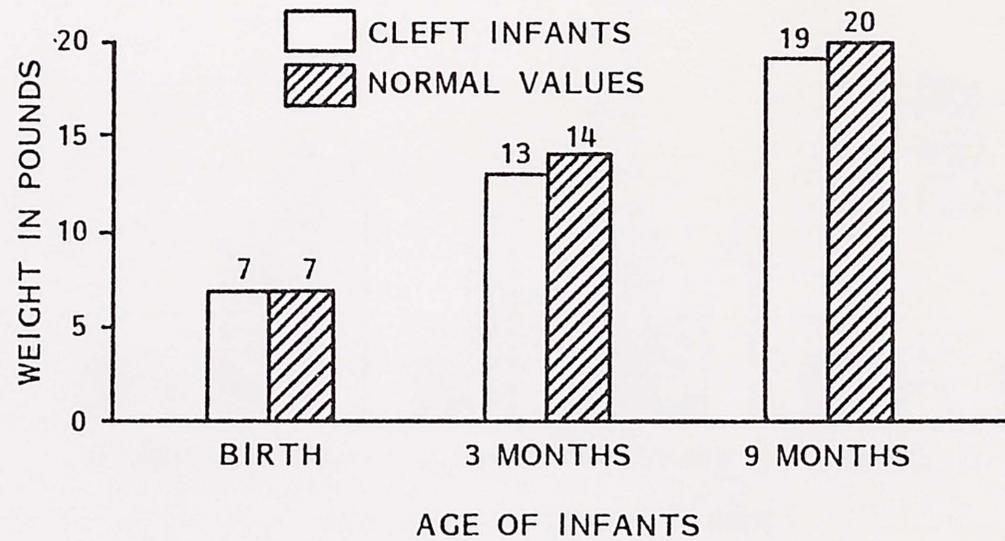


FIGURE 8. Weight Gain: Weight percentile rankings of cleft infants at birth, three and nine months of age compared to normal infants.

WEIGHT GAIN: WEIGHT PERCENTILE RANKINGS OF CLEFT INFANTS AT BIRTH, THREE, AND NINE MONTHS OF AGE COMPARED TO NORMAL INFANTS.

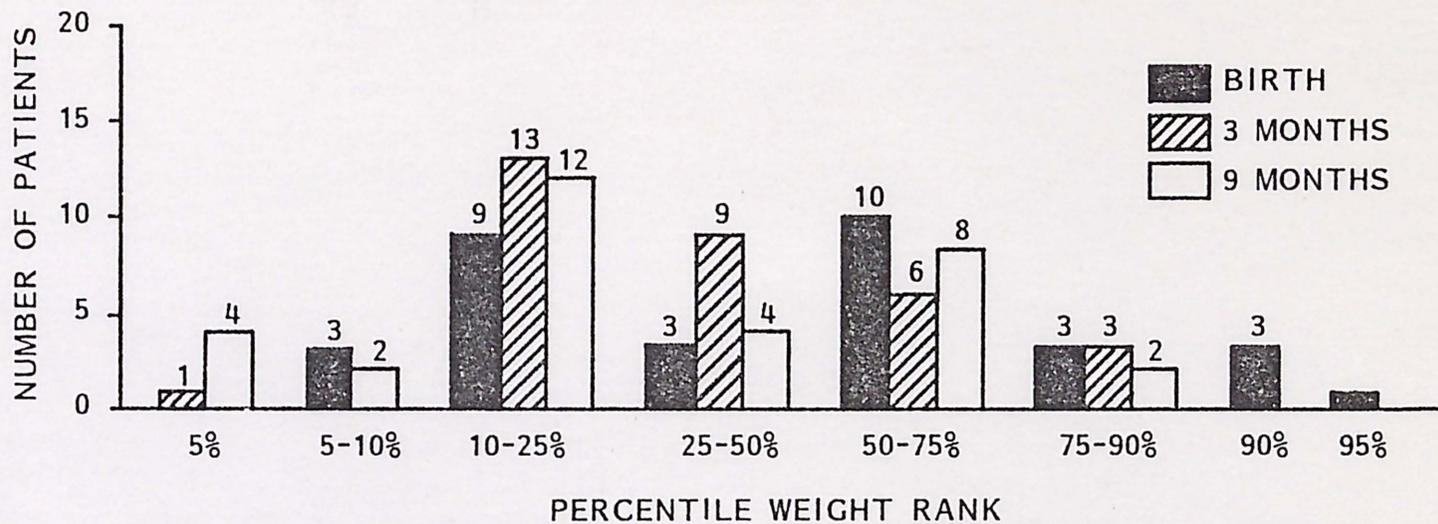


TABLE I

Parental Questionnaire

Results from parental evaluation of the obturator.

1. "I initially felt uncomfortable with the insertion and removal of the obturator, but by the end of one month, I felt confident of its usage."

Strongly Agree	17/28
Agree	8/28
Uncertain	2/28
Disagree	0/28
Strongly Disagree	1/28

2. How long does (did) your infant wear the obturator each day?

All Day and Night	24/28
All Waking Hours	4/28
Only During Feeding	0/24

3. What was your overall rating of the obturator used by your infant?

Great Usefulness	23/28
Somewhat Useful	4/28
Undecided	0/28
Slight Usefulness	0/28
No Usefulness	1/28

4. Would you recommend the use of an obturator to other parents with infants who have cleft lip and palate?

Yes 27/28

No 1/28

5. "I felt that the obturator was an effective way I could participate in my child's rehabilitation and treatment."

Strongly Agree 16/28

Agree 8/28

Undecided 3/28

Disagree 0/28

Strongly Disagree 1/28

TABLE II

Weight Gain: Mean Weight Percentile Ranking for Cleft
Infants at Birth, Three and Nine Months of Age

<u>Age (in months)</u>	<u>Mean Percentile Rank</u>	<u>Note</u>
Birth	25-50%	(Lower Part of Category)
Three	10-25%	(Higher Part of Category)
Nine	10-25%	(Higher Part of Category)

TABLE III

Arch Symmetry: Mean CF/BF Ratio at Ages One, Four and 10
Months to Assess Lateral Posterior Crossbite Tendency

<u>Age (in months)</u>	<u>Mean CF/BF Ratio</u>	<u>Percentage of Normal</u>
One	0.851	85%
Four	0.899	90%
Ten	0.877	88%

TABLE IV

Arch Symmetry: Mean AF/BF - 0.956 Ratio at Ages One, Four
and 10 Months to Assess Anterior Crossbite Tendency

<u>Age (in months)</u>	<u>Mean AF/BF - 0.956 Ratio</u>	<u>Percentage of Normal</u>
One	0.664	66%
Four	0.782	78%
Ten	0.757	76%

TABLE V

Arch Symmetry: Mean EF/DF Ratio at Ages One, Four, and 10
Months to Assess Canine Area Crossbite Tendency

<u>Age (in months)</u>	<u>Mean EF/DF Ratio</u>	<u>Percentage of Normal</u>
One	0.755	76%
Four	0.800	80%
Ten	0.792	79%

TABLE VI

Arch Symmetry: Mean 10-month-old Ratios of the Three
Assessment Parameters (Overall Treatment Outcome)

<u>Ratio Category</u>	<u>Ratio Value</u>	<u>Percentage of Normal</u>
CF/BF	0.877	88%
AF/BF - 0.956	0.757	76%
EF/DF	0.792	79%

DISCUSSION

The psychological impact on the parents of a cleft lip and palate child can be significant. They often react with a sense of grief and may blame each other in an effort to cope with the situation.^{5,15,79} Hospital personnel and health care providers can serve an important function by counseling the parents on the possible causes of the cleft defect and the steps involved in rehabilitation of the infant.

One of the immediate areas of intervention is the feeding process. Because of an incomplete hard palate, the cleft infant is unable to compress the nipple, often resulting in decreased nutritional intake.^{4,14} Retaining the mother and child in the hospital for several days enables the staff to educate parents in successful feeding techniques. Unfortunately an extended stay can produce a large financial burden. If the mother is discharged too soon, however, she may not be equipped to adequately feed her infant.

The mother-infant bond that naturally develops is enhanced by the feeding experience. An infant with a cleft lip and palate often has impaired intake and the feeding process may take 30 to 45 minutes.^{4,16,17} This can lead to frustration and may create a negative relationship between mother and infant.⁵ The current study seems to confirm previous findings.^{4-12,15-17,79} The responding parents reported difficulty feeding their infants before using the obturator, and the feeding time often took 30-45 minutes. This indicates that much of the mother's day was spent in feeding the child. However,

the parents did report feelings of closeness to their infants. In a similar study by Jones,¹⁶ parents reported that feeding time and difficulty were primary causes of concern with their cleft infants. Other authors had similar results, as the usually gratifying feeding process became a source of anxiety.^{11,15-17}

Previous studies have indicated that, as with many infants who have severe congenital anomalies, the birth weight of a cleft palate infant is usually below average.^{11,19,20} Difficulties in the feeding process can further potentiate this situation, causing these infants to fall further behind in weight gain during the first few months of life. It may take six months or more to recover to their original weight percentile ranking.^{12,18} This study, like that of Jones,¹⁶ found that the infants' physicians had a mixed degree of concern about their weight gain progress before obturator therapy was initiated. The variety of responses may be because most appliances were placed within a few weeks of the birth, with a mean age of 5.4 weeks. This would not allow the cleft child to lose enough weight to be of consequence to the physician, in contrast to the child who has inadequate nutritional intake for several months. The wide range of insertion times for the obturator in this study is attributed to the fact that many infants did not receive obturation until a time closer to the lip repair surgery. During this time, proponents were stressing the orthopedic benefit of the appliance and did not place as much emphasis on the feeding benefit. Currently, the obturator is utilized for improved feeding as well as maxillary orthopedics, so it is used much earlier in life. Another reason for the delay of obturator therapy

was that many infants were not referred to the cleft lip and palate team by their primary physicians until several months of age, when the time for the cheiloplasty was approaching. As a result of improved communications and physician education, the infants are currently referred to the team at about one or two weeks of age.

Following obturator therapy, the parents reported that their physicians had more unified responses on their infant's weight gain. Most felt that the infant was achieving adequate nutritional intake. This seems to confirm the belief that use of the obturator helps to attain desired weight gain in the unilateral cleft lip and palate child.

Once the parents and infants became accustomed to the appliance, a reduction of 15 to 30 minutes in feeding time was reported. The parents also reported a decrease in the amount of nasal drainage upon feeding, which further reduced the anxiety of the experience. Overall, parents reported that the infants had less trouble and seemed more relaxed. Of particular interest in the parents' response was the decrease in apprehension during the feeding process. Similar results were obtained by Jones.¹⁶ All but one parent reported being comfortable with the appliance after the first month. This parent still felt that she was traumatizing her child each time she used the appliance, and because of personal apprehension that persisted, she never did gain confidence in the feeding process.

A great majority (96 per cent) of the parents felt that obturator therapy was valuable to their child's rehabilitation, and 86 per cent agreed that they would recommend it to other parents of cleft lip

and palate infants. As with many treatments in the health care, unless the parents are convinced of the benefits and are willing to follow through with the necessary therapy, a specific treatment regimen may be less than optimal.

Infants with cleft lip and palate, as well as other severe congenital malformations, tend to have lower birth weights than the average infant.^{11,19,20} The report by Ranalli and Mazaheri¹⁸ was the only exception to this trend, with their cleft lip and palate population weighing more than the control group. The control values were not defined, so a comparison between studies was not possible. The infants in the present study had an average birth weight of 7.22 pounds (25-50th percentile). The mean birth weight listed for the standardized weight scale was about 7.30 pounds, indicating that cleft infants in this study were just slightly below average for birth weight. The closeness of the two groups could be due in part to a more normal gestation time, better maternal nutrition and health, or a variety of other factors. These results are consistent with the views held by other authors,^{11,19,20} but since the sample size is small, the values may be artificially low or high.

By three months of age, the infants had a mean weight of 12.79 pounds, which placed them just below the 50th weight percentile on the standardized scale. While most cleft infants were close to this percentile, one was significantly lower. An interesting finding was that 56% of these children actually retained their weight percentile ranking or increased to the next higher category and 69% either maintained their percentile weight category or just dropped into the next

lower category. Two infants even advanced two ranking groups. By the third month of life, several researchers had reported that their cleft groups had already fallen in weight categories.^{19,20} Maintenance of weight percentile shows an adequate nutritional intake by the infant. These results seem to point to improved nutritional intake of cleft infants using obturator therapy, in contrast to studies of cleft children where no such therapy was used.

At the age of nine months, the mean weight of the cleft infants had increased to 19.46 pounds, which still placed them in the 25th-50th weight percentile category. This represented a slight decrease from the near 50th percentile ranking seen at birth and three months of age, but it does not necessarily indicate a significant downward shift in the cleft infants' growth patterns. This could be attributed to a variety of causes, including recovery from the initial lip closure at three months of age or from the primary autogenous alveolar cleft bone grafting surgery that took place at 8.7 months of age for 75% of the sample group. Since the mean age for this group was 9.6 months, many of these cleft infants would have been just a few weeks out of the hospital. One must also remember that this is major surgery that takes several hours to complete. These infants may have still been gaining back to their pre-surgical weight, as well as trying to regain their normal activity pattern which was disrupted by surgery. Unfortunately, weight gain records past the alveolar cleft graft surgery were sporadic, preventing a comprehensive review of 12-month figures.

Maxillary orthopedics via obturator therapy has been advocated by researchers in the field of cleft lip and palate rehabilitation.^{16,21,24,25,29-32} The therapy has four primary goals: 1.) alignment of the maxillary segments to establish a symmetrical arch form to allow more normal facial growth; 2.) improvement of individual tooth position within the alveolus to reduce the need for later extensive orthodontic treatment; 3.) creation of a more esthetic dentition during the developing years; and 4.) alignment of the alveolar segments to facilitate surgical closure of the lip and palate.²⁹ Usually the appliance is placed within a few weeks after birth to prevent collapse of the segments. By molding the cleft segments with the pressure created by the cheiloplasty around the palatal appliance, the malpositioned alveolar segments can be directed towards a more normal symmetrical arch form. If the appliance is not utilized or not retained until the arches are stabilized, collapse of the lateral segments may result.³³ Long-term results of maxillary orthopedics substantiate the use of obturator therapy.^{29,30,39-41} Some authors feel that extended results of this therapy indicate that posterior segmental collapse was still present.³⁶⁻³⁸ Unfortunately, the methods of evaluation for arch symmetry in most of these studies, both by advocates and dissidents, were largely subjective in nature.

A goal of the present study was to provide an objective evaluation of unilateral complete cleft lip and palate patients treated with obturator therapy at James Whitcomb Riley Hospital for Children within the past six years. The Relationship Measurement Method of Analysis proposed by Butow⁷⁶ was an effective way to evaluate these

arches for symmetry. Although this method has not received widespread usage in current research, it could prove to be valuable for objective comparison of arch symmetries between different patients and age groups in the future.

At the time of the initial evaluation of infants by the Cleft Lip and Palate Team, at a mean age of 4.3 weeks, approximately 15% presented with a lateral posterior crossbite with varying degrees of severity. Unless a severe crossbite was detected at this age, a passive obturator was placed to maintain the segmental arch relationship. By four months of age, the lateral posterior crossbite had been reduced to about 10% from ideal. This was a 5% improvement from the initial alveolar presentation, and it could have been attributed to growth in the maxillary arch combined with the prevention of further arch collapse with the obturator in place. The primary function of the obturator is a molding appliance. Total correction is not expected, especially at this early stage. Since the cheiloplasty was performed at approximately 4.0 months of age, pressure from the lip repair had not exerted its greatest effect, so any arch collapse that could be seen at this time may either be due to other perioral muscles, a lack of maxillary growth, or hereditary factors.

Arch form at 10 months of age resulted in a 12% lateral posterior crossbite. This was a 2% relapse from the four-month-old arches. The mean measurement from midline to the posterior segment on the greater segmental side was approximately 17.1mm (BF measurement) at 10 months of age. A 12% collapse of this measurement would result in an average of 15.1mm on the lesser segmental side. This 2mm de-

crease is not significant as the normal maxillary molar is 10.0mm wide, and the typical maxillary molar is located 1-2mm to the buccal of its mandibular counterpart.⁸⁰ This would mean that a 2mm collapse may place the maxillary and mandibular molars in an end-to-end relationship.

The lip repair surgery was performed six months before this, so the full extent of pressure resulting from the procedure would be manifested in any arch collapse that would occur by this time.⁴⁶ The autogenous primary alveolar bone graft was performed at this time to stabilize the maxillary segments, which further helps to prevent future collapse of the segments that could occur with the palatoplasty. Unfortunately, not enough of these infants had sequential study models to evaluate the arches six to 12 months after grafting, so the posterior crossbite tendency at this time could not be assessed. Since reports in the literature indicate that 40-50% of complete unilateral cleft lip and palate patients develop posterior crossbites in the primary dentition following lip repair surgery, the average 12% collapse from ideal would seem to indicate a lesser extent and number of definite crosssites.⁴³ Unfortunately, it was not possible to compare the amounts of arch collapse considered to be in crossbite for the various studies by Graf-Pinthus, O'Donnell, Rossenstein, and others, since they used a subjective type of arch analysis.^{29,30,36-43}

With regard to the evaluation of sagittal crossbite in the anterior maxilla, the infants initially had a 34% collapse of the anterior segment, which indicated a significant anterior crossbite.

By four months of age, the crossbite had decreased to 22% from ideal, which is a major shift toward a more normal anterior position. Since the obturator was not designed to specifically treat this condition, the improvement seen may have been due to the lack of lip pressure or maxillary growth. One reason that it still remained in the crossbite position, although reduced, could be a tissue deficiency that would have resulted in an anterior deficiency when the greater segment was molded to approximate the lesser one.^{29,32} By 10 months of age, the anterior collapse was 24% from ideal arch symmetry, which represented a slight regression (2%) from the four-month-old arches. This may have been due to the lip pressure created by the cheiloplasty at four months of age, although the presence of the obturator did not allow a significant amount of collapse to occur.

In the canine region, the infants originally presented with a 25% collapse from ideal arch symmetry. By four months of age, the situation had improved to a 20% collapse from ideal, probably attributable to the same reasons as in the anterior arch. This remained fairly constant through the 10-month arch measurements.

This study could later be expanded to further explore some of the topics addressed here. One area of further investigation would be weight gain maintenance over the first two or three years of life. Another investigation could focus on maintenance or improvement of arch symmetry in these infants over the first six years of their lives. This would demonstrate continued benefit of maxillary orthopedics in cleft lip and palate therapy.

SUMMARY AND CONCLUSIONS

Obturator therapy has been proposed for many years as an aid in maxillary orthopedics for the complete unilateral cleft lip and palate infant. The present study evaluated the success of obturator therapy for these infants by considering three issues. First, a parental questionnaire was used to subjectively assess observations, feelings, and concerns of the parents of cleft infants. Second, the weight gain records of cleft infants were analyzed to document weight gain over the first year of life. Third, assessments were made of maxillary alveolar arch symmetry, using the Relationship Measurement Method of Analysis. Based on the results of the study, the following conclusions were drawn:

1. Parental acceptance was very positive. Most parents (96%) rated obturator therapy as very beneficial for their infant's treatment and would recommend its use to other parents with cleft infants.
2. Usage of obturator therapy resulted in maintenance of adequate weight gain and nutritional supplementation. At three and nine months of age, a number (69% and 56% respectively) had maintained their original weight percentile rankings or had just dropped into the next lower category. This represents improvement over previous problems with inadequate weight gain prior to obturator therapy.

3. Arch symmetry demonstrated a gradual reduction in lateral posterior, canine, and anterior crossbite tendency over the first 10 months of life when obturator therapy was utilized. The resultant arch symmetry values were much closer to normal, and more improvement was expected as the maxilla developed.

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APPENDIXES

APPENDIX A
OBTURATOR CONSTRUCTION FOR MAXILLARY ORTHOPEDICS

Adapted from: Jones, J.E. and R. Kerkhof, Obturator Construction for Maxillary Orthopedics in Cleft Lip and Palate Infants. *Quintessence of Dental Technology*, 8(9):583-586, 1984.²²

Impression Technique and Construction of Obturator:

1. A stock or custom tray is used to make an irreversible hydrocolloid impression of the maxillary arch.
 - a. A custom tray may be constructed from various-sized maxillary models from previous patients (this will save time when taking future impressions, since there will be a custom tray which will adequately accommodate every arch size presenting for impression).
 - b. The infant is held in an upright position by the dental assistant to prevent aspiration of excess material. A hemostat is kept nearby to remove any remaining impression material from the cleft site. Oxygen and suction should always be available in case of emergency.
 - c. Ideally the impression should exhibit good anatomic detail with coverage of the entire maxillary arch.
2. The impression is poured in dental stone.

3. Obturator construction
 - a. Block out undercuts with modeling dough or wax (modeling dough is easier to remove from the finished obturator).
 - b. Apply separating agent to entire stone model.
 - c. Mix soft, autopolymerizing acrylic resin and pour into the cleft to the level of the palate. (This adds retention by gently contouring into undercuts.)
 - d. Place model in warm, moist environment to cure for 20 minutes.
 - e. Salt and pepper autopolymerizing acrylic resin to the palate (extend into the mucobuccal fold).
 - f. Place model in a warm, moist environment to cure for 20 minutes.
 - g. Remove appliance from the model.
 - h. Trim and finish appliance (be sure acrylic is relieved in the anterior portion to allow for the posterior and medial rotation of the greater segment towards the lesser one).
4. If expansion is needed to place the lateral segments in a more favorable position, then an expansion screw may be added to the appliance fabrication process.
5. Delivery and clinical management
 - a. Place obturator into infant's cleft and insure that excessive pressure is not being exerted on the infant's maxilla (selectively grind the areas that cause tissue blanching).

- b. Educate parents in placement and care of obturator (child is to wear the obturator 24 hours per day, with removal only after meals for cleaning).
- c. Provide periodic observation of obturator and construction of a new obturator as needed.

APPENDIX B
PARENTAL QUESTIONNAIRE

Adapted from: Jones, J., et al. Use of a feeding obturator for infants with severe cleft lip and palate. *Special Care in Dentistry*, 2(3):116-120, 1982.¹⁶

1. According to our physician, my infant is (was) gaining the desired amount of weight before the obturator was utilized.

Strongly agree (5); Agree (4); Undecided (3);
Disagree (2); Strongly Disagree (1)

2. According to our physician, my infant is (was) gaining the desired amount of weight after the obturator was used.

5 4 3 2 1

3. My infant had difficulty in feeding before the obturator was used.

5 4 3 2 1

4. My infant had difficulty in feeding after the obturator was utilized.

5 4 3 2 1

5. The average feeding time for my infant before the obturator was utilized was:

5. less than fifteen minutes
4. fifteen to thirty minutes
3. thirty to forty-five minutes
2. forty-five minutes to one hour
1. greater than one hour

6. The average feeding time for my infant after the obturator was used was:

5. less than fifteen minutes
4. fifteen to thirty minutes
3. thirty to forty-five minutes
2. forty-five minutes to one hour
1. greater than one hour

7. I felt uncomfortable in feeding my infant before the obturator was utilized.

5 4 3 2 1

8. I felt uncomfortable in feeding my infant after the obturator was used.

5 4 3 2 1

9. I felt very close to my baby during feeding time before the obturator was used.

5 4 3 2 1

10. I felt very close to my baby during feeding time after the obturator was utilized.

5 4 3 2 1

11. Did your infant have drainage of food and liquids through the nose during feeding before using the obturator?

great amount _____ some _____ little _____ none _____

12. Did your infant have drainage of food and liquids through the nose during feeding after using the obturator?

great amount _____ some _____ little _____ none _____

13. I initially felt uncomfortable with the insertion and removal of the obturator, but by the end of one month, I felt confident of its usage.

5 4 3 2 1

14. How long does (did) your infant wear the obturator each day?

3. all day and night
2. during all waking hours
1. only during feeding

15. What did you most like about using the obturator?

16. What did you most dislike about using the obturator?

17. Would you recommend the use of an obturator to other parents with infants who have cleft lip and palate?

yes _____ no _____

18. What was your overall rating of the obturator used by your infant?

- 5. great usefulness
- 4. somewhat useful
- 3. undecided
- 2. slight usefulness
- 1. no usefulness

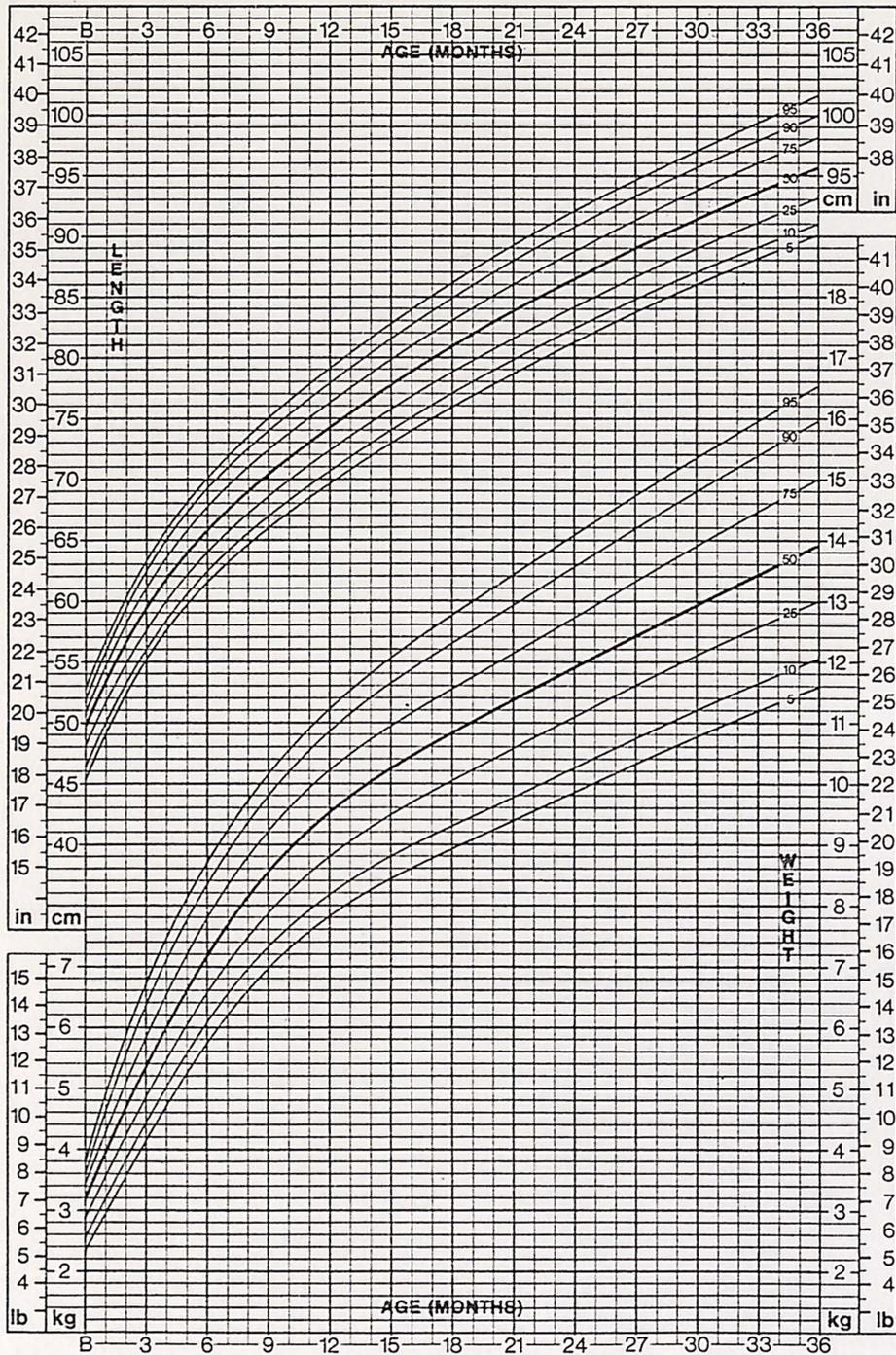
19. I felt that the obturator was an effective way I could participate in my child's rehabilitation and treatment.

5 4 3 2 1

**GIRLS: BIRTH TO 36 MONTHS
PHYSICAL GROWTH
NCHS PERCENTILES***

NAME _____

RECORD # _____



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*Adapted from: Hamill PVV, Drizd TA, Johnson CL, Reed RB, Roche AF, Moore WM. Physical growth: National Center for Health Statistics percentiles. *AM J CLIN NUTR* 32:607-629, 1979. Data from the Fels Research Institute, Wright State University School of Medicine, Yellow Springs, Ohio.
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APPENDIX D
RELATIONSHIP MEASUREMENT METHOD OF ARCH ANALYSIS

Adapted from: Butow, K., A relationship measurement method for the analysis of complete unilateral cleft lip and palate cases. Cleft Palate Journal, 21(4):317-322, 1984.⁷⁶

1. Acetate paper tracing of the maxillary model
 - a. Diagnostic table constructed of a clear Plexiglass top and four bolt leg.
 - i. Rubber bands will be stretched diagonally across the bolts to hold the study model under the table with the alveolar ridge flush with the Plexiglass for accurate tracing (From: Lubit, E., Cleft palate orthopedics: why, when, how. American Journal of Orthodontics, 69(5):562-571, 1976).
 - b. Place acetate paper across top of diagnostic table above the model and trace the center (height of contour) of the alveolar ridge for each cast from one post-gingival point to the other.
 - c. Mark the post-gingival (tuberosity) points as P on the side of the greater segment and P' on the lesser segment side.
 - i. If the cleft is on the left side, use the tracing as drawn;

- ii. If the cleft is on the right side, flip the tracing over so the cleft appears to be on the left side of the paper.

2. Graphic Representation and Line Construction

- a. Point P is the point where the X and Y axis cross each other (located at right angles to each other).
- b. The X axis passes through P and P'.
- c. Point A is the most anterior point on the alveolar ridge of the greater segment.
- d. Draw a perpendicular line passing through the point X/2 (one-half the distance from P to P') and parallel to the Y axis (should pass through point A).
- e. Draw the line Y/2 where Y/2 is the same distance along the Y axis from point P as X/2 is from point P along the X axis.
- f. The intersection of lines X/2 and Y/2 is the fixed constant F.
- g. Draw 2 lines originating from point F that are 45 degrees above the line Y/2 (one to the right segment which is D-F and one to the left segment which is E-F).
- h. The distance between point A and point F on the X/2 line is defined as Line A-F (L_{A-F}).
- i. The distance on the line Y/2 from point F to the center of the alveolar arch on the normal or greater segment side (point B) is defined as Line B-F (L_{B-F}).

- j. The distance on the Y/2 line from point F to the center of the alveolar ridge on the cleft or lesser segment side (point C) is defined as Line C-F (L_{C-F}).
- k. The distance between point F and the center of the right alveolar ridge (point D) along the 45 degree line passing through point F is defined as Line D-F (L_{D-F}).
- l. The distance between point F and the center of the left alveolar ridge (point E) is defined as Line E-F (L_{E-F}).

3. Calculations

- a. Lateral Crossbite: L_{C-F} / L_{B-F}
 - i. In an ideal parabola, the distance L_{C-F} is equal to L_{B-F} ($L_{C-F} = L_{B-F}$), indicating arch width symmetry.
 - ii. If $L_{C-F} / L_{B-F} < 1$, then a lateral posterior crossbite is found.
 - iii. If $L_{C-F} / L_{B-F} > 1$, then a buccal lateral posterior crossbite is found.
- b. Sagittal Crossbite: L_{A-F} / L_{B-F}
 - i. In an ideal parabola, $L_{B-F} + L_{C-F} = 2L_{B-F}$, again indicating arch width symmetry. In a normal Class I type of Occlusion, the L_{A-F} / L_{B-F} relationship will produce a value of 0.956.
 - ii. If L_{A-F} / L_{B-F} decreases from the "normal" value, an anterior crossbite exists.

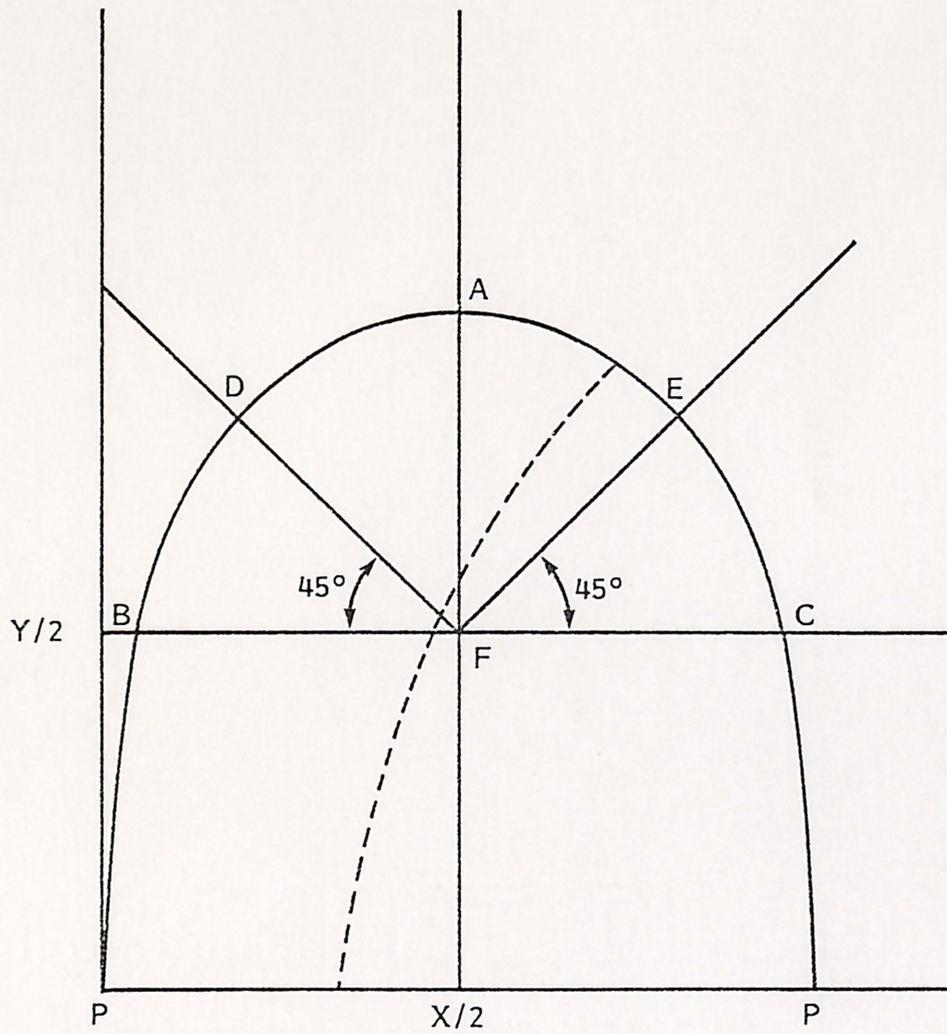
c. Arch Segment / 45

- i. Ideally the lines L_{D-F} and L_{E-F} should be equal, indicating arch symmetry in the canine region.
- ii. If $L_{E-F} < L_{D-F}$, then the canine region on the lesser segment is in a crossbite situation.

4. Results:

This analysis will provide an objective analysis of posterior and anterior crossbite tendencies in complete unilateral cleft lip and palate cases of all ages, whether the dentition is present or not.

ARCH ANALYSIS LANDMARKS



CURRICULUM VITAE

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August 25, 1958	Born to Dave and Marilyn Robbins in Kokomo, Indiana
1972-1977	Northwestern High School, Kokomo, Indiana
May, 1981	B.S. General Biology, Purdue University, West Lafayette, Indiana
July 23, 1983	Married to Diane K. Ludington
May, 1985	D.D.S., Indiana University School of Dentistry, Indianapolis, Indiana
June 1987	Certificate in Pediatric Dentistry, Indiana University School of Dentistry/ James Whitcomb Riley Hospital for Children, Indianapolis, Indiana
July 1987 to present	Private Practice of Pediatric Dentistry, Elkhart, Indiana
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Professional Organizations

American Academy of Pediatric Dentistry
American Dental Association
American Society of Dentistry for Children
Elkhart Dental Society
North Central Dental Association of Indiana
Indiana Dental Association
Indiana University Pediatric Dentistry Alumni Association
Indiana Society of Pediatric Dentistry

ABSTRACT

EFFECTIVENESS OF THE PALATAL ORTHOPEDIC APPLIANCE
IN TREATMENT OF THE UNILATERAL CLEFT
LIP AND PALATE PATIENT

by

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Obturator therapy has been proposed for many years as an aid in maxillary orthopedics for the complete unilateral cleft lip and palate infant. The obturator appliance had the added benefit of providing a false palate against which the infant can suckle. This has aided in the feeding of these infants to assure adequate nutrition with the least effort for parent and child. The current study assessed three aspects of obturator therapy at James Whitcomb Riley Hospital for Children, Indianapolis, Indiana.

Parental evaluations of the obturator proved to be very positive. Almost all parents (96%) rated it as beneficial and would recommend its use to other parents with cleft lip and palate infants. Weight gain analysis over the first nine months of life demonstrated that these infants were only slightly below the average for birth weight. At three and nine months of age, a number (69% and 56% respectively) had maintained their original weight percentile rankings or had just

dropped into the next lower category. Thus, many of the infants were able to achieve adequate nutrition, a problem noted by many authors when obturator therapy was not used. It should be emphasized that each infant underwent either one or two major surgical procedures during this time period.

Arch symmetry assessments at one, four and ten months showed a gradual reduction in lateral posterior crossbite, canine crossbite, and anterior crossbite tendency. Although the arches still showed some collapse at the end of ten months of age, the pattern was much better than at initial presentation, with values much closer to normal. Improvements in arch symmetry was expected as the maxilla grew. From the results of this study, obturator therapy appears to be beneficial in maxillary orthopedics by helping to maintain adequate weight gain and gain parental acceptance.