Metallic implants as growth markers in infants with craniofacial anomalies

HANS FRIEDE, BENGT JOHANSON, JOHAN AHLGREN &
BIRGIT THILANDER

Department of Orthodontics, Faculty of Odontology and Department of Plastic Surgery, Sahlgrenska sjukhuset, University of Göteborg, Sweden

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The purpose of the study was to test the retention of metallic implants in bone tissue for evaluation of early facial growth patterns in patients with craniofacial malformations. Implants were inserted in 51 patients (age range: 1–17 months) with different diagnoses, the majority of them with various types of cleft lip and/or palate. Seven positions in the maxilla and four in the mandible were employed. Roentgencephalometric follow-up examinations were carried out at various stages up to the age of about three years. The results indicated that the frequency of implants firmly retained within the bone decreased with time depending on the craniofacial deformity and the implant sites. Stability seemed most critical in positions close to the alveolar processes where more than one-half of the implants inserted were dislocated or lost at the three-year follow-up. For the maxillary implants the patients with bilateral cleft lip and palate displayed the highest failure rate. This investigation did not support continuation of the implant method in infants as used in the present study.

Key-words: Cephalometry, cleft lip, cleft palate, maxillofacial development

Hans Friede, Department of Orthodontics, Faculty of Odontology, University of Göteborg, Fack, S-400 33 Göteborg 33, Sweden

INTRODUCTION

In the study of bone growth different types of reference markers, inserted in the bone tissue, have been advocated for more than two centuries. The technique was confined to experiments in animals until the 1950s, when *Björk* (1955) reported the first facial growth study in man combining metallic implants with roentgencephalometry.

The reference markers must be placed in well-selected sites in the facial skeleton in order to prevent dislodgement or loss during growth. With several years of clinical experience *Björk* (1968) described four regions in the mandible and four in the maxilla as being applicable for implant studies in children. Some of the implant sites were usefull only during certain periods of growth. The age of the individuals at the insertion of the implants varied considerably, but all patients were at least three years old.

Few implant studies on facial growth in infants have been published. *Robertson & Hilton* (1971) analysed the effect of presurgical orthopaedics in unilateral cleft lip

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and palate over a three-month period. Four implant positions in the maxilla and one in the mandible were described by the authors without discussing the retention of the markers within the bone tissue. In a pilot study of three babies with cleft lip and palate *Jacobsson et al* (1976) evaluated postoperative movements of the maxillary segments by use of metallic implants in combination with roentgen stereophotogrammetry. The markers remained stable in one of the segments for more than 18 months. *Pruzansky* (1971), and recently *Friede & Morgan* (1976), employed the implant method to study the growth of the vomero-premaxillary suture in infants with bilateral clefts up to the age of three years.

If the implant method as described by *Björk* (1955) is to be used in growth studies from early infancy careful selection of the implant sites is necessary as the retention of the markers may become more critical at this stage than later during growth. Consequently, the regions described by *Björk* (1968) for juvenile or older children cannot be directly employed in newborn babies. The present investigation was therefore carried out to test potential implant sites in the facial skeleton of infants.

MATERIAL AND METHOD

Metallic implants were inserted in the facial skeleton in a selected number of cleft infants during a 1 1/2-year period. The patients were chosen according to the principle that the cleft should include either the primary and/or secondary palate completely or else have as minimal extension as possible. One infant with a facial cleft and two others with syndromes involving the facial skeleton (Treacher Collin's syndome and hemifacial microsomia) were also included in the test group which comprised altogether 51 patients (Fig. 1). The insertion of the implants was performed under aseptic conditions with the patients under general anaesthesia, as a rule in combination with the first surgical procedure. Two different operators inserted the markers; one in 26 cases and the other in 25.

At the beginning of the test all implants were inserted with Björk's instrument. A modification of this instrument was constructed in a smaller size (Fig. 2). This was used at certain implant sites in the children included later on in the series. The markers were similar to those employed by *Björk* (1968) and had the following dimensions: 1.5 (length) × 0.5 mm (diameter) or 1.2 × 0.37 mm, with the smaller pins fitting the modified instrument.

In most cases 11 implants were inserted, 8 of them constituting pairs with bilateral placement. Pins No. 1–7 were inserted in the maxilla and No. 8–11 in the mandible (Fig. 3). No. 1–3 were placed in the palate close to the median sagittal plane with the most anterior marker (No. 1) slightly in front of the incisive foramen or in cases of complete cleft(s) of the primary palate in front of the vomero-premaxillary suture. Implant No. 2 was inserted immediately posterior to these structures and No. 3 at the posterior border of the hard palate. In patients with unilateral or bilateral cleft lip and palate No. 1 was placed in the premaxilla and No. 2 and 3 in the vomer. Markers No. 4 and 5 were inserted as recommended by *Björk* (1968) in the hard palate behind the deciduous canines. Implant No. 6 and 7 were placed in the zygomatic process of the maxilla, also in agreement with Björk's method. Pins No. 8 and 9 were inserted in the anterior lower part of the mandible on each side of the symphysis, and markers No. 10 and 11 were placed bilaterally below the deciduous molars. The sites used in the mandible were the same as suggested by *Björk* (1968). Implants No. 1, 4 and 5 were inserted in a good half of the cases with our modified instrument while for the rest of the pins Björk's original instrument was used.

The first radiological examination of the reference markers was performed under sedation 4–5 days postoperatively in a cephalometer especially built for infants (*Thilander et al*, 1977). Occasions for later

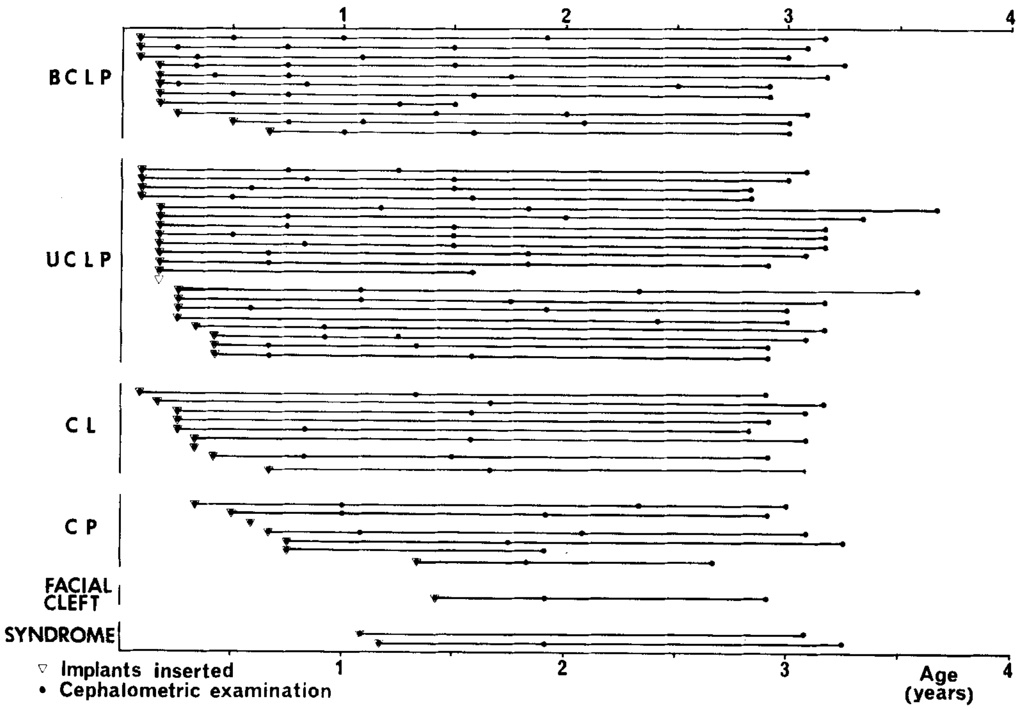

Fig. 1. The pasients grouped according to diagnosis with the period for follow-up and the number of roentgencephalometric examinations indicated for each case. BCLP = bilateral cleft lip and palate; UCLP = unilateral cleft lip and palate; CL = cleft lip; CP = cleft palate.

follow-up cephalometry were determined by the surgical regimen for the individual patient as the radiological examinations were, for practical reasons, carried out during the postoperative period. Patients whose surgical treatment necessitated only one procedure were examined at a separate visit 6–12 months after the insertion of the implants. In most of the patients (88 per cent) a final cephalometric examination was carried out at about three years of age. The rest of the patients (n = 6) had moved from the western region of Sweden or refused final participation in the study.

The retention of the implants within the bone was evaluated by comparing the individual position of each pin immediately after insertion with its position at the follow-up examinations in the lateral and the frontal cephalograms. The same person assessed all implants. If difficulties arose in identifying a patient's mid-sagittal pins in the lateral projection, two lateral films, taken on the same occasion, were superimposed to give as close fit as possible. Mid-sagittal markers could then be distinguished from lateral implants as the latter displayed more or less pronounced double contours.

In all statistical tests of the material the method of *Mantel* (1966) for evaluation of survival data was used. This implied comparisons of the probabilities for implant retention at certain chosen time intervals for the subgroups tested. The results of these comparisons at each interval were then pooled together and the subgroups were thus finally compared in a summarizing test concerning the retention of the pins during the whole period studied.

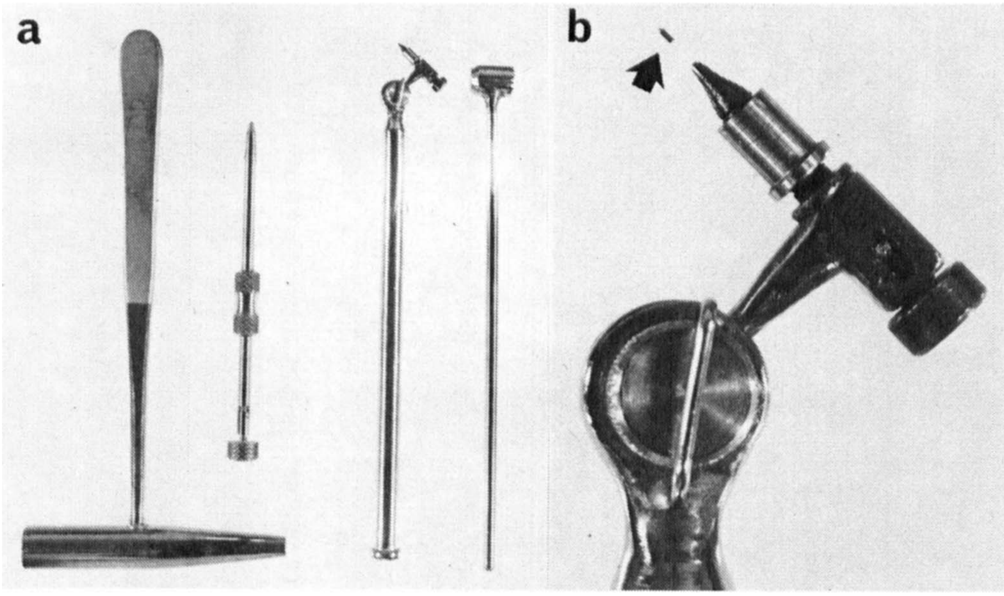

Fig. 2.
(a) *Björk's* (1955) instrument for insertion of the metallic implants (left) and the new construction of a smaller instrument (right).
(b) Close-up view of the smaller instrument with a metallic pin at its point (arrow).

RESULTS

As the implants were inserted by two different operators, tests had to be carried out to see whether this variable influenced the results. The frequency of stability of the reference markers in positions 6–11 i.e. in sites being identical in all diagnoses, did not differ significantly between the patients of the two operators. Neither did the results for these pins differ when the first halves of the two operators' patients were compared to the latter halves. This finding indicates that the experience of the operator did not play a decisive role for long-term implant stability.

The influence of the age of the infant at the placement of the markers on retention was also investigated. Patients with implants inserted during the first two months were compared to infants who had their pins inserted at the age of six months or later. For the latter group of patients, implants 6–11 demonstrated significantly less failures ($p<0.01$) up to the age of three years (Table I). In another test unilateral cleft lip and palate cases with early insertion (1–2 months) were compared to similar patients with insertion at a slightly later age (3–5 months). However, when all implant positions were considered in this comparison no statistical difference in stability was found.

The frequencies of stable pins decreased with time depending on the various implant positions and also on the type of craniofacial

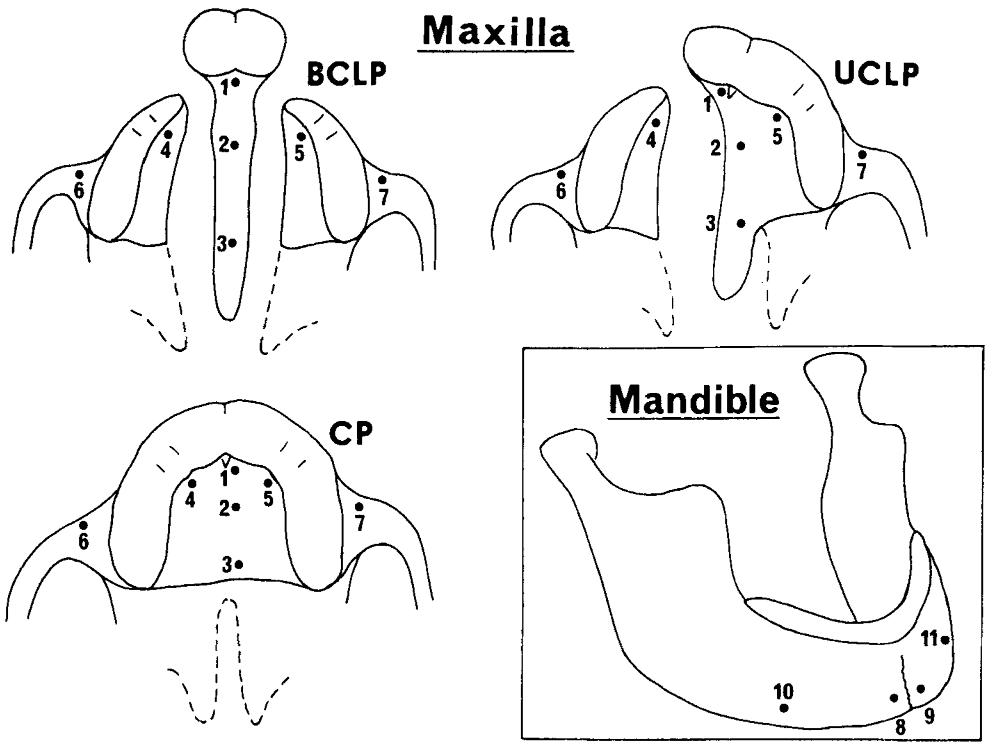

Fig. 3. Schematic illustration of the implant positions; in the maxilla dependent upon the diagnosis of the patient but in the mandible consistent for all cases.

malformation. Markers No. 2, 4, 5, 10 and 11 displayed the least satisfactory results, with more than 50 per cent instability at the final follow-up calculated for all patients (Fig. 4).

The retention of the maxillary implants in positions 1–5 was compared in three subsamples of the material: (A) bilateral cleft lip and palate; (B) unilateral cleft lip and palate; (C) the rest of the patients studied. If these pins were considered as a single group, the bilateral cleft cases (A) demonstrated the poorest result but with statistically significiant difference ($p<0.05$) only compared to the unilateral cases (B) (Table II). With each pin position tested separately no such difference between the bilateral and unilateral cleft patients was found (fig. 5). Both subsamples demonstrated less implant stability in positions 4 and 5 than did the patients of subgroup C. On the other hand, for marker No. 1 the reverse seemed true, but with statistically significant difference only for the patients with unilateral cleft.

DISCUSSION

Metallic implants in combination with roentgencephalometry have proved to be an important research tool, as shown by several facial growth studies in the literature. More detailed information can be gained with this technique than with ordinary

Table I. *Number of stable pins/inserted pins in positions 6–11 with increasing time after insertion. Two subgroups are compared: patients with implants inserted at an early age (≤ 2 months) and individuals with late insertion of the pins (≥ 6 months), the latter demonstrating significantly better implant retention ($p<0.01$)*

Pin age (months)	Sub-group	Previous examination (months)			
		None	≤ 6	7–12	13–24
≤ 6	early	51/69			
	late	25/29			
7–12	early	20/35	25/39		
	late	10/18	9/11		
13–24	early	10/21	17/30	36/62	
	late	13/18	15/18	3/5	
≥ 25	early			5/12	55/104
	late			16/24	13/17

roentgencephalometry, which is of particular importance regarding children with craniofacial anomalies (Fig. 6). The reliability of the implant method for growth studies is, however, decisively dependent upon a firm retention of the markers within the bone tissue. Only in a few papers have failure rates with the method been reported and they range from 3.5 per cent (*Sarnat,* 1968) to 50 per cent (*Julius,* 1974). The corresponding figure for the present study was 47 per cent when all implant positions at the final inspection were considered. Differences in implant stability are related not only to differences in skill and technique among operators but also to variations in the type of markers, bone structures and species studied. In addition, the implant positions as well as the age of the patient and the duration of follow-up are no doubt factors of great importance for the retention of the markers.

The poor stability of our pins was, at least at certain sites, partly due to the very young age of our patients making the insertion procedure crucial. The smaller facial dimensions and also the extensive remodelling during subsequent growth made the placing of the pins in *reliable positions* more critical in infants than in older children. Sites close to the alveolar process (mostly No. 10 and 11; Fig. 3) seemed particularly apt to fail. In these cases interference from erupting teeth was common, confirming similar experience reported by *Björk* (1955, 1966, 1968) and *Robertson & Hilton* (1971). On the other hand, the implants in the zygomatic process of the maxilla (No. 6 and 7) demonstrated the highest success rate at the final follow-up (75 per cent) in contrast to the findings of *Riedel* (1971) who reported this site to be least reliable. However, the results for our infants were in agreement with the experience of *Björk* (1968) for somewhat older children, indicating that the zygomatic implant position may be used from an early age provided that the markers are placed well lateral to the alveolar process.

Another reason for our poor implant retention might be *improper insertion* of the pins in some positions, not least because the mineralization and structure of the bone tissue in infants have not reached maturity. It has been stated that a prerequisite for stability is that the implant is driven into the bone perpendicular to the cortical plate and well under the periosteum (*Björk,* 1955, 1968; *Julius,* 1974). Correct placing of the instrument for such an insertion was particularly difficult to obtain for our implants 1, 4 and 5 and to some extent for No. 8 and 9, due to the confined intraoral space in an intubated, surgically draped infant. However, with the availability of the smaller instrument

Table II. *Number of stable pins/inserted pins in positions 1–5 with increasing time after insertion. Three subgroups are compared: A = patients with bilateral cleft lip and palate; B = individuals with unilateral cleft lip and palate; and C = the rest of the sample. Subgroup A demonstrates significantly poorer implant retention than subsample B if tested statistically with the method of Mantel ($p < 0.05$)*

Pin age (months)	Sub-group	Previous examination (months)			
		None	≤ 6	7–12	13–24
≤ 6	A	30/42			
	B	28/37			
	C	12/16			
7–12	A		18/42		
	B	22/42	7/10		
	C	14/21			
13–24	A	2/8		9/27	
	B	1/3	14/27	19/32	
	C	19/36	11/16	2/5	
≥ 25	A			9/15	9/32
	B	3/5		8/20	29/59
	C			11/16	17/42

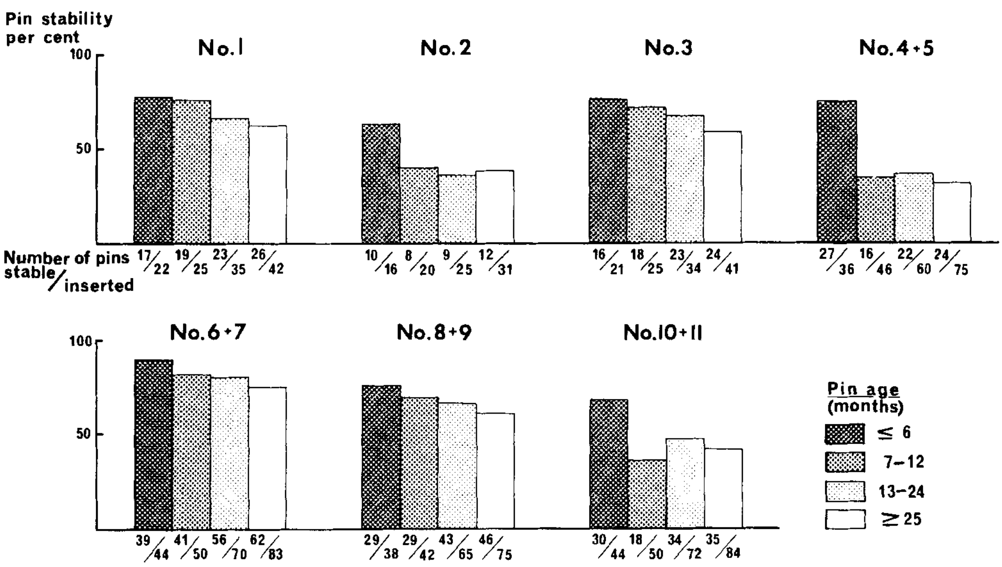

Fig. 4. Diagrams illustrating frequencies and numbers of stable pins in different positions of all patients with increasing time after insertion.

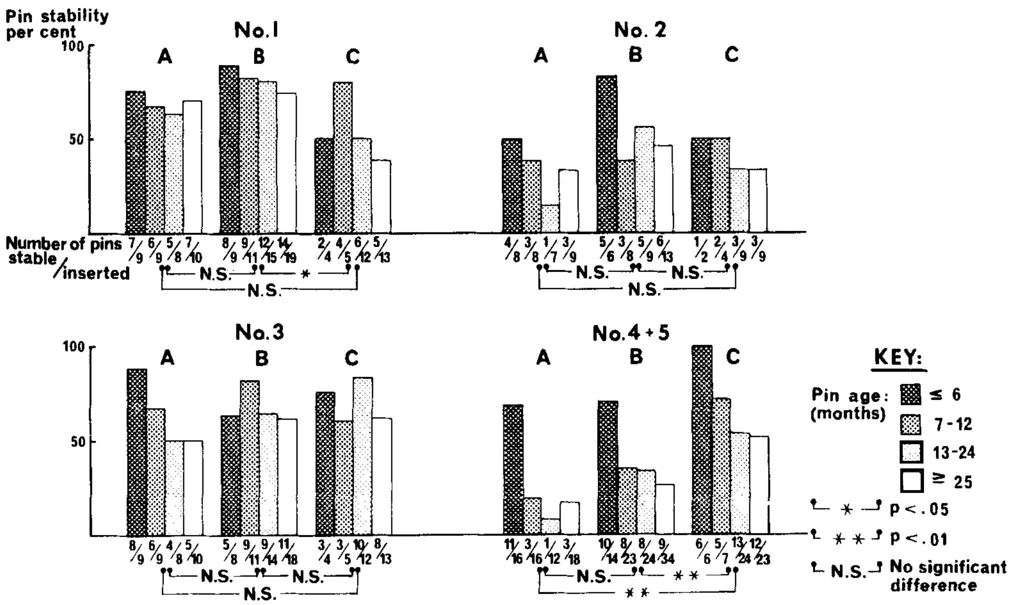

Fig. 5. Diagrams illustrating frequencies and numbers of stable pins in position 1–5 with increasing time after insertion. The patients are grouped according to diagnosis: A = bilateral cleft lip and palate; B = unilateral cleft lip and palate; and C = the rest of the individuals.

for the insertion of the anterior maxillary implants these problems were partly eliminated. Yet, for implant 4 and 5 there was still some uncertainty as to whether even the new instrument was correctly placed in close and firm contact with the bone at the insertion. The same was true regarding implant No. 1 in patients without cleft(s) of the primary palate because of the great thickness of the palatal mucosa near the alveolar process.

Markers without sufficient retention in bone might also be dislodged and/or lost at a *subsequent surgical procedure* if mucoperiosteal flaps are raised from the implant areas. The overall poor stability of maxillary palatal implants in bilateral cleft cases, and especially in positions 4 and 5, might partly be ascribed to more comprehensive surgical treatment in this cleft type than in the other patients studied.

The general results of this investigation do not support continuation of the implant method in infants as used in the present study. More attention should be devoted to the selection of appropriate implant positions. This should be done not only to improve long-term retention but also to eliminate the possibility of the markers interfering with tooth formation at certain sites. Such interferences was registered at our final follow-up among the three-year-olds as a local enamel hypoplasia in the buccal surface in 20 per cent of the mandibular first or second deciduous molars.

Also, the technique for insertion of the markers must be improved in some positions. If the use of the Björk type of instrument is to be continued, a small local surgical exposure of the bone surface is recommended when placing implants in sites with thick covering mucosa. Development of a new type of instrument with better penetration of soft tissue might be another alternative for more optimal implant insertion. Therefore a «syringe-like» instrument similar to the one described by *Aronson, Holst & Selvik* (1974) is presently under construction.

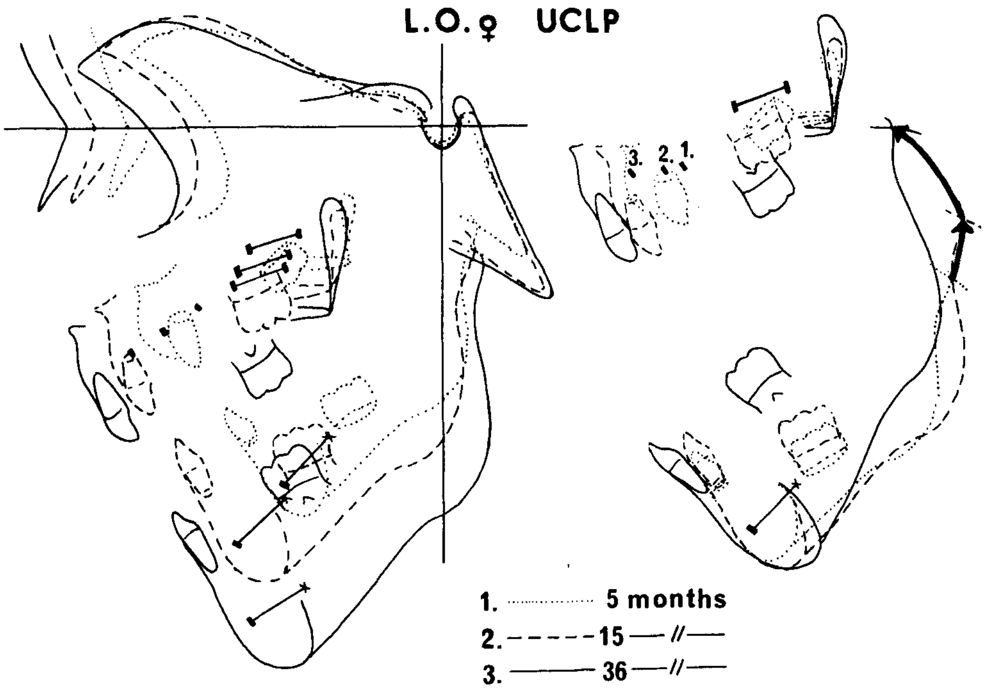

Fig. 6. Example of a patient with unilateral cleft lip and palate (UCLP) studied with a conventional growth analysis and with tracings of the separate jaws superimposed on inserted reference markers. Notice the forward drift of the maxilla relative to the nasal septum and also the anterior rotation of the mandible is clearly demonstrated.

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