

An Analysis of Presurgical Orthopedics in the Treatment of Unilateral Cleft Lip and Palate

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Review of Literature

Renewed interest in clefts of the lip and palate during the past twenty years has resulted in many advancements in therapy. One of the new methods of treatment that has received considerable attention is neo-natal presurgical orthopedics.

C. Kerr McNeil (1, 2, 3), the originator of presurgical orthopedics, outlined his approach to infant clefts in the early 1950's. McNeil claimed that normal growth factors—periods of accelerated growth and high osteogenic potential could be stimulated to bring about reduction of cleft palate defects prior to surgery. In McNeil's technique, a maxillary impression of the infant was taken and a plaster model poured. The model was sectioned and the maxillary segments repositioned to a more normal arch configuration. A removable acrylic appliance was then fabricated to fit the corrected model. The appliance was inserted several days after birth and replaced at monthly intervals with a new appliance modified even further towards normality. In this manner McNeil claimed to exert gentle pressure on the alveolar segments and hard palate in order to achieve favorable arch configuration prior to lip surgery. Following lip surgery new appliances were again inserted at regular intervals in an effort to maintain arch alignment until age 15–18 months, at which time palatal surgery was performed.

McNeil's goal was to control the dental arch in early infancy and prevent the high degree of arch collapse commonly associated with cleft palate patients following surgical procedures.

McNeil's approach was eventually adopted in Europe and the United

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States by several cleft palate centers. Clinical research into orthopedic treatment of infants at these centers resulted in some modifications of the original technique.

Several clinicians (4, 5, 6) varied from the rigid acrylic appliance designed by McNeil and combined a hard and soft acrylic material, with the latter extending into the cleft area as well as part of the nasal cavity.

Rosenstein (7, 8, 9), Horton (10), Brauer (11), and Graf-Pinthus (5) recommended autogenous bone-grafting in conjunction with presurgical orthopedics in order to maintain arch stability.

More recently, Wood (12, 13), pointed out that presurgical orthopedic correction of the deformed maxillary arch by the McNeil method did not approach the problem from a three-dimensional aspect. Wood attempted to improve the vertical height of the middle one-third of the face by sectioning the plaster model of the infant's maxilla at the approximate position of the pre-maxillo-maxillary suture and then correcting for the upward tilt of the pre-maxilla before constructing his appliance.

Despite these modifications to McNeil's original technique, the goals of presurgical orthopedic treatment remained basically unchanged: to achieve optimal alignment of the maxillary segments prior to surgery, thus decreasing the incidence of a constricted collapsed maxillary arch and a subsequent crossbite malocclusion. Additional benefits which were claimed (14-24) to result from the use of presurgical orthopedics are as follows:

1. The appliance facilitated feeding since it mechanically blocked off the cleft and provided the infant with an artificial palate against which he could suck normally.
2. Since lip surgery was delayed until optimal maxillary alignment was achieved (usually about age three to six months with unilateral complete clefts), the esthetic result of lip surgery was enhanced because growth had provided tissues which were of increased size, more vascular and easier to manipulate.
3. The constant, gentle pressure of the appliance against the palatal tissue served as a stimulus to growth of underlying bone. This resulted in a narrowing of the palatal cleft and thus greatly benefitted surgical repair.
4. Use of the appliance and the home care that it required allowed the mother to become an integral part of the cleft palate team and had a positive psychological effect on her.

Despite its theoretical promise, McNeil's approach was not widely accepted. Pruzansky became one of the most outspoken critics of presurgical orthopedics. His 1964 report (25) refuted each advantage claimed by the "McNeil school". Citing previous longitudinal growth studies of cleft lip and palate children (26, 27) Pruzansky asserted that the presurgical orthopedists not only had failed to provide the proper controls for their clinical research but lacked the scientific evidence to support it. In subsequent articles (28, 29), he reported the prevalence of arch collapse and malocclusion in unilateral complete clefts of the lip and palate where purely surgical intervention had occurred. In so doing he provided the necessary control

groups for presurgical orthopedics and challenged its advocates to compare their long-term results with his.

Others cast doubt on the technique on the basis that it interfered with the development of normal speech. Subtelny (30, 31) suggested that pre-surgical orthopedic manipulation of the maxillary segments could serve initially to widen the cleft in the posterior region. Surgical repair of the palate would therefore be more difficult. Swoiskin (32) also proposed that any procedure that inhibited the collapse of the palatal segments normally seen after lip surgery would have a detrimental effect on repair of the velopharyngeal mechanisms.

To date only a few clinicians (9, 16, 33, 34) have reported the relative incidence of arch collapse and malocclusion following presurgical orthopedic intervention. This study was undertaken to evaluate a group of unilateral cleft lip and palate children who were treated with presurgical orthopedics at the Tufts-New England Medical Center Hospitals. The investigation encompassed three parts:

1. Arch form evaluation of infant models.
2. Quantitative analysis of infant models.
3. Evaluation of occlusion in the deciduous and mixed dentitions.

Materials and Method

The subjects in this investigation consisted of forty-eight cases of unilateral complete clefts of the lip, alveolar ridge, hard and soft palate. Each case had been treated with presurgical orthopedics at the Tufts-New England Medical Center Hospitals (T-NEMCH) and represented part of a continuing longitudinal study into the efficacy of this method of treatment for cleft lip and palate children. The technique employed was outlined previously in a preliminary report (14) and was adopted from the early work of McNeil (1-3) with modifications after Burston (35, 36).

The distribution of the sample population according to sex and affected side appears in Table 1. Surgical repair of the lip (mean age 175 days) consisted of a LeMesurier quadrilateral flap at the vermilion border. A modern Langenbeck procedure was employed for palatal surgery (mean age 403 days). None of the patients were treated with bone grafting procedures. All surgical procedures for the lip and palate were carried out by the same surgical team.

TABLE 1. Distribution of complete unilateral cleft lip and palate sample according to sex and affected side.

	<i>right</i>	<i>left</i>	<i>total</i>
males.....	12	16	28
females.....	5	15	20
total.....	17	31	48

PART I. ARCH FORM EVALUATION OF INFANT MODELS. In each of the forty-eight cases, the plaster model obtained just prior to palatal surgery was evaluated clinically and classified according to the following anatomical criteria:

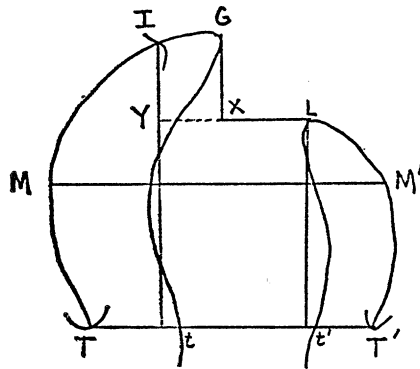
1. Approximation of the alveolar segments with contact (i.e. abutment)
2. Approximation of the alveolar segments without contact
3. Overlap of the alveolar segments (collapsed arch form)

PART II. QUANTITATIVE ANALYSIS OF INFANT MODELS. The quantitative method for xerographic analysis of infant cleft models described by Stockli (37) was utilized for this phase of the investigation. A total of 262 serial plaster models were analyzed. The anatomical landmarks on the models were determined and marked according to methods of Stockli (37) and Sillman (38). The marked models were then placed on the duplicating surface of a xerox copying machine to convert them into a two dimensional system. The xerox machine had been loaded with KE #461510 millimeter graph paper. Use of the graph paper was found to be of value not only in the eventual measurement process but also as an additional guide to proper orientation of the models on the glass of the copying machine.

Figure 1 illustrates the reference points on the photostatic copies of the models which Stockli defined to serve as the basis of the measurement system.

The only variant from the reference points recommended by Stockli is point Y. Stockli's point Y was located at the intersection of a transverse line from L (parallel to the base line T-T') with the outline of the medial border of the greater segment. Since the labial frenum is generally considered the anatomical midpoint of a normal maxillary arch, an attempt was made in this study to observe the linear changes in distance between the lesser segment and the anatomical midpoint of the maxilla during the course of presurgical orthopedic treatment. Therefore, the change in location of point Y from the medial border of the greater segment to the perpendicular from I to the base line T-T' was necessary.

FIGURE 1: Diagram of maxillary arch unilateral complete cleft lip and palate with reference points and lines of measurement system.



From the reference points, the following measurements were carried out:

Transverse measurements of the maxillary arch:

T-T' Intertuberosity width or posterior width of the maxillary arch

M-M' Middle width of the maxillary arch.

t-t' Width of cleft at the tuberosities or posterior cleft width.

Antero-posterior measurements of the maxillary arch:

I-TT' Sagittal length of the maxillary arch as determined by the length of the perpendicular from the base line (T-T') to the interincisal point (I).

L-TT' Sagittal length of the lesser segment as determined by the length of the perpendicular from the base line (T-T') to point L.

Transverse and antero-posterior measurements in the region of the alveolar cleft:

LX Transverse relation of the lesser segment to the greater segment.

LY Transverse relation of lesser segment to the anatomical midpoint of the anterior maxilla.

GX Antero-posterior relation of the lesser to the greater segment.

PART III. EVALUATION OF OCCLUSION IN THE DECIDUOUS AND MIXED DENTITIONS. This phase of the investigation consisted of an evaluation of the maxillary and mandibular models of twenty-eight children from the original sample that had completed the eruption of their deciduous dentition. The occlusion was evaluated in terms of the type of crossbite malocclusion, if any, that was present. The maxillary lateral incisor on the affected side was not considered in determining the presence of crossbite since this tooth is almost always displaced palatally as a result of the cleft.

Findings

PART I. ARCH FORM EVALUATION OF INFANT MODELS. The prevalence of arch collapse in the study population treated with presurgical orthopedics at the Tufts-New England Medical Center Hospitals is shown in Table 2. These figures are compared with Pruzansky's 1967 report of ninety cases in which purely surgical intervention occurred. The group treated with presurgical orthopedics displays a much smaller percentage of arch collapse. Chi square statistical analysis reveals that these data are significant at the one percent level. (Chi square = 9.278, df = 2)

TABLE 2. Prevalence of arch collapse in complete unilateral cleft lip and palate.

	<i>Pruzansky Eur. Orth. Soc. 1967</i>		<i>T-NEMCH 1973</i>	
	<i>N</i>	<i>percent</i>	<i>N</i>	<i>percent</i>
approximation with contact.....	32	35.6	23	47.9
approximation without contact.....	19	21.1	17	35.4
overlap (collapse).....	39	43.3	8	16.7
	90	100%	48	100%

PART II. QUANTITATIVE ANALYSIS OF INFANT MODELS. Each of the 262 models was measured following the xerographic reproduction process previously described. The error inherent in this process was found to be insignificant by Stockli (37) and Krischer (39).

The measurements for each model were recorded and then transferred to an IBM 370 Computer for ease of computation. The eight measurements for each of the models were grouped within their respective category and plotted against increments of time (in days). A least square fit curve was employed to determine the trends for each category. In summary, the following trends could be identified.

Transverse Measurements of the Maxillary Arch:

T-T' The intertuberosity width or posterior width of the maxilla displayed a slight tendency toward increase in size. (Chart 1)

M-M' Changes in the middle width of the maxillary arch did not correlate with age. (Chart 2 and Table 2)

t-t' The width of the cleft at the tuberosities showed a rapid trend toward decreasing size which was sustained throughout treatment. (Chart 3-Note: computer designation for t-t' is T-T'')

Antero-posterior Measurements of the Maxillary Arch:

I-TT' The sagittal length of the maxilla exhibited a steep trend toward increasing size. (Chart 4)

L-TT' The sagittal length of the lesser segment also showed a definite trend toward increasing size, although noticeably less than that of I-TT' (Chart 5)

Transverse and Antero-posterior Measurement in the Region of the Alveolar Cleft:

LY The transverse relation of the lesser segment to the anatomical midpoint of the anterior maxilla displayed a narrowing tendency. (Chart 6)

LX The transverse relation of the lesser to the greater segment also showed a definite tendency toward narrowing. (Chart 7)

GX The antero-posterior relation of the lesser segment revealed a wide scatter of points. However, a slight tendency toward decreasing values can be demonstrated. (Chart 8)

A linear regression analysis (Table 3) was employed to determine the significance of each trend. The product moment correlation (R) for each dependent variable was calculated. When this value is squared (R^2 = coefficient of determination) and multiplied by one hundred, the resulting percentage represents the proportion of the variation in one dependent variable that is accounted for by another.

The sharp narrowing trend observed in the posterior cleft width measurement (t-t') throughout the course of orthopedic treatment prompted further investigation. Aduss and Pruzansky (40) reported the width of the cleft at the level of the tuberosities in a series of 106 cases of unilateral complete cleft lip and palate. None of these patients had been treated with presurgical orthopedics. Early lip surgery (average age seven to nine weeks) had been performed on this sample population and the data were, therefore listed according to chronologic age in six month increments.

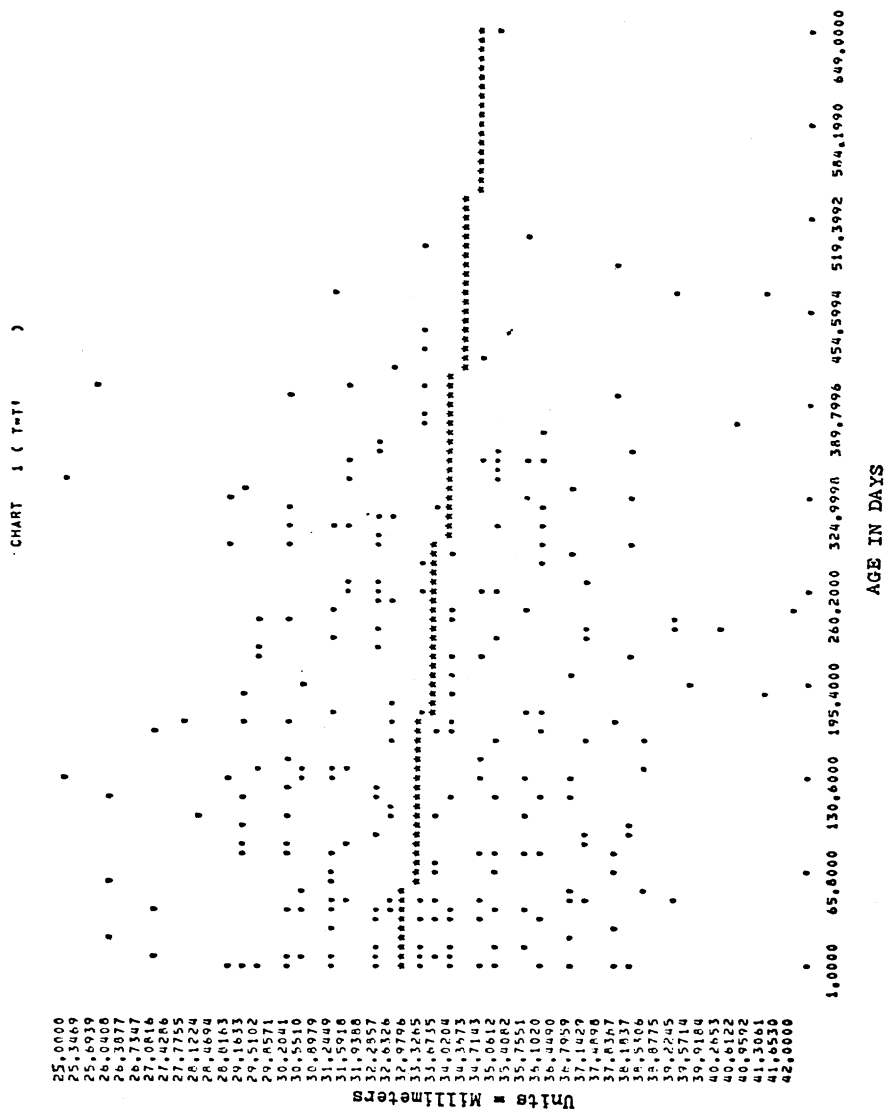
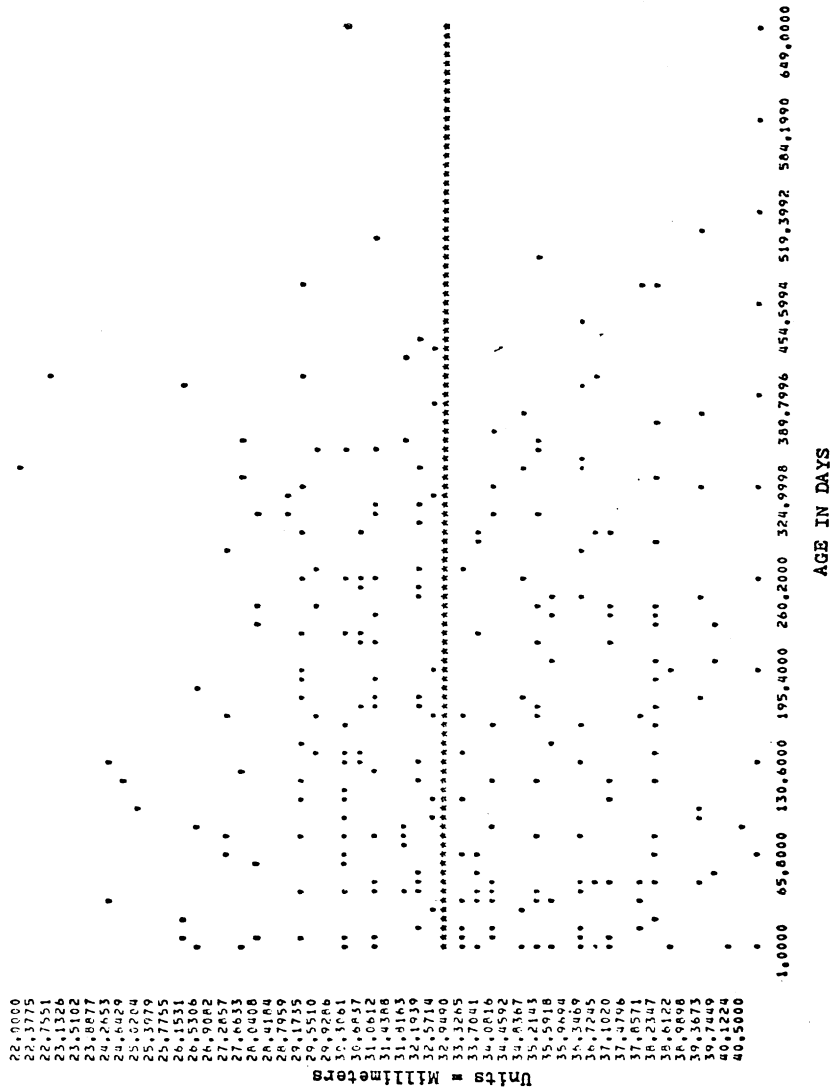


CHART 2 (M-M1)



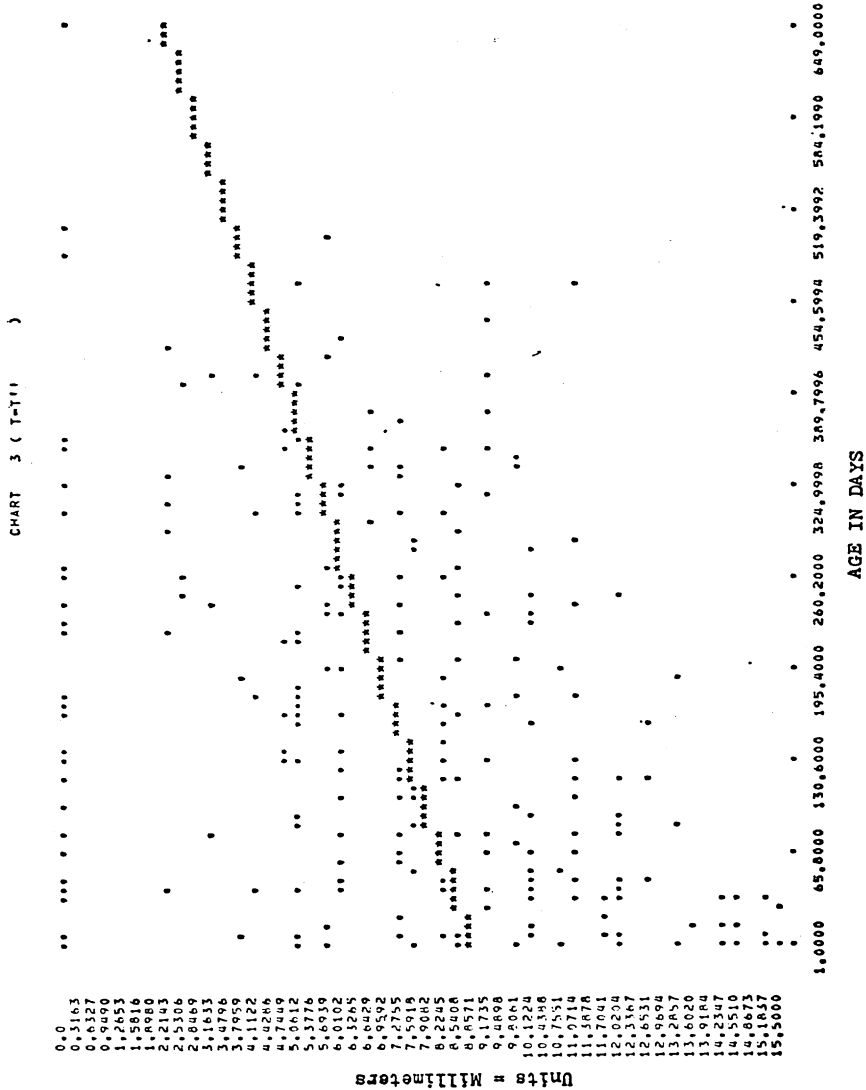
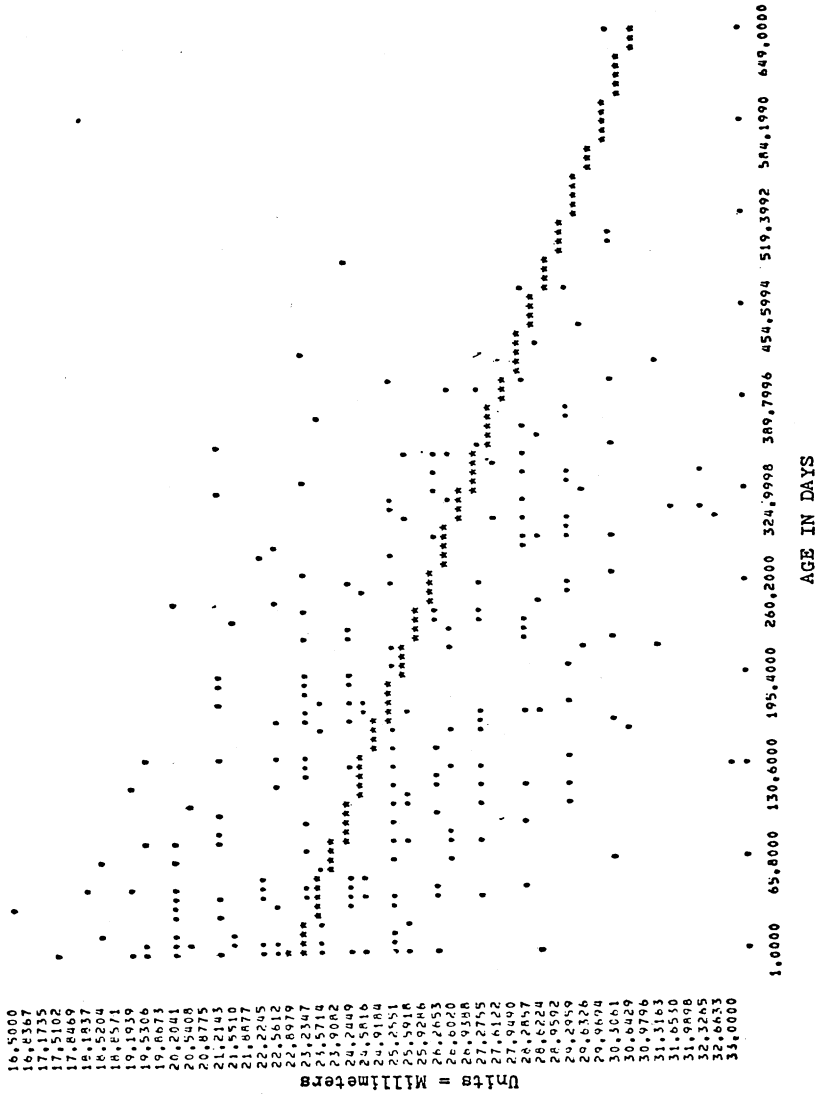
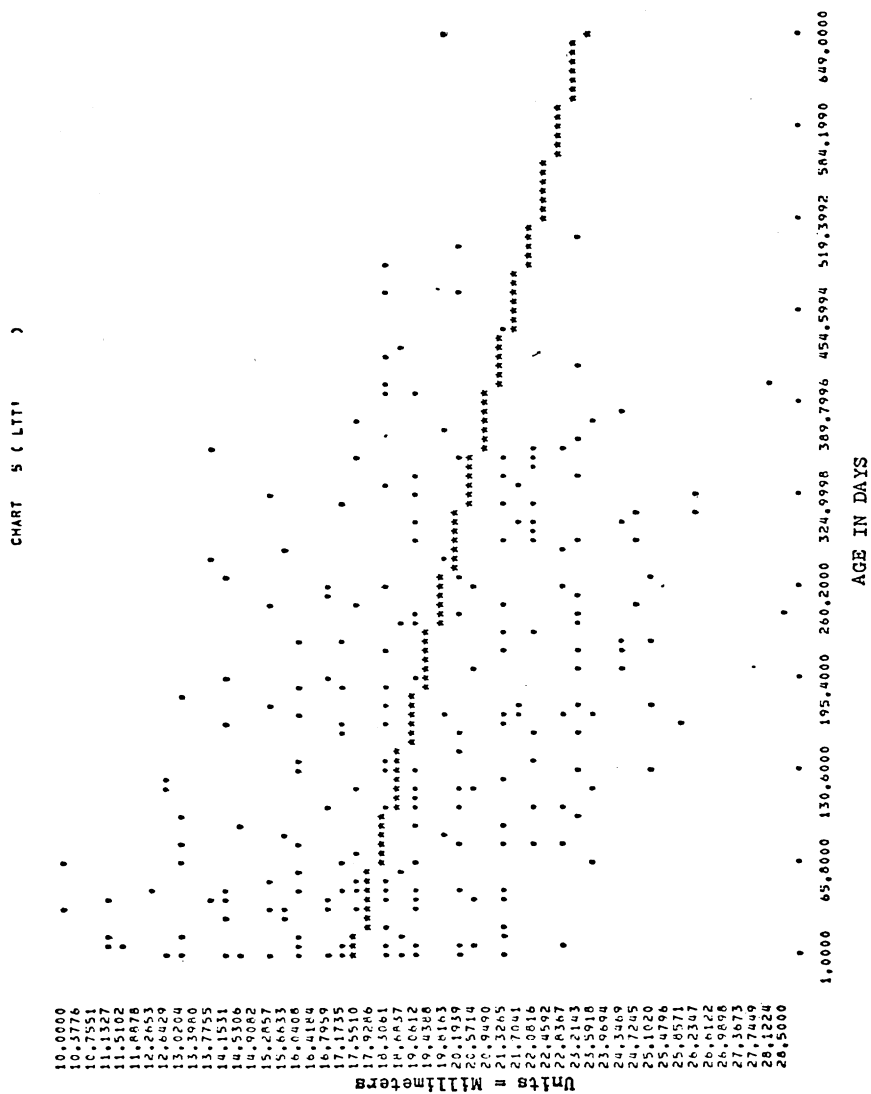
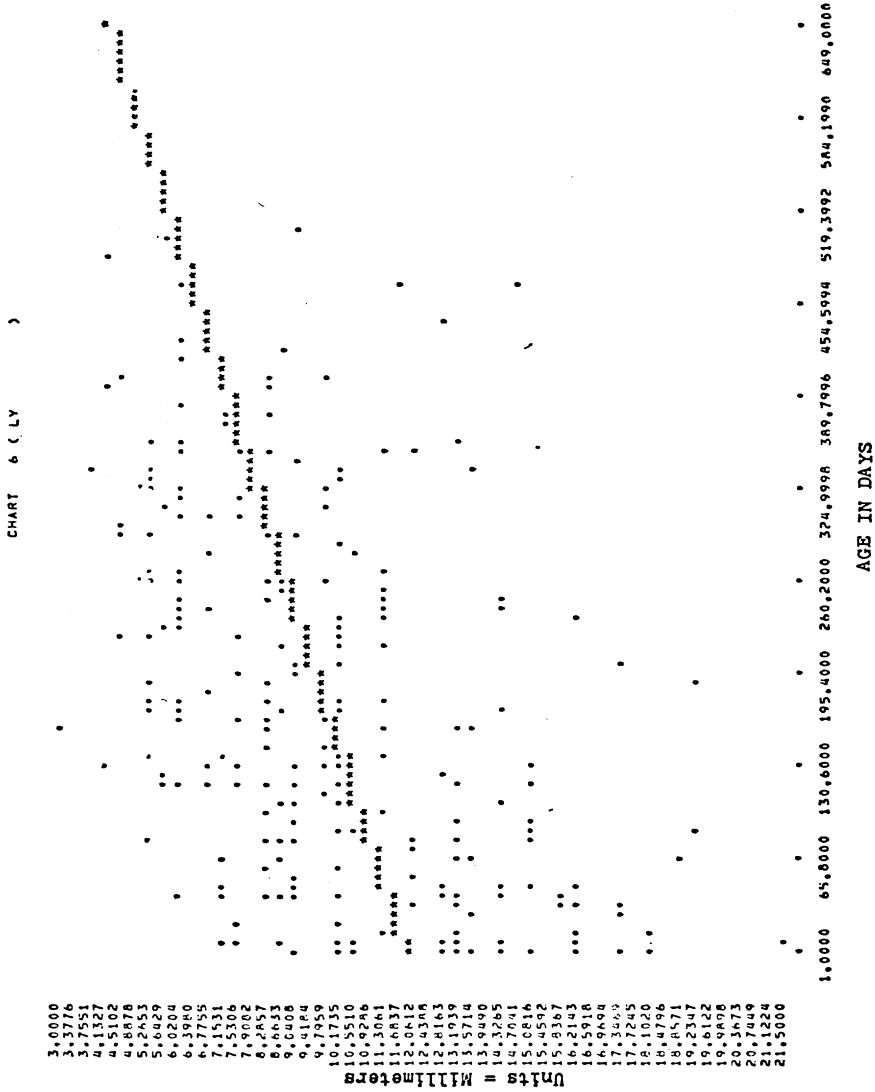


CHART 4 (ITTI)







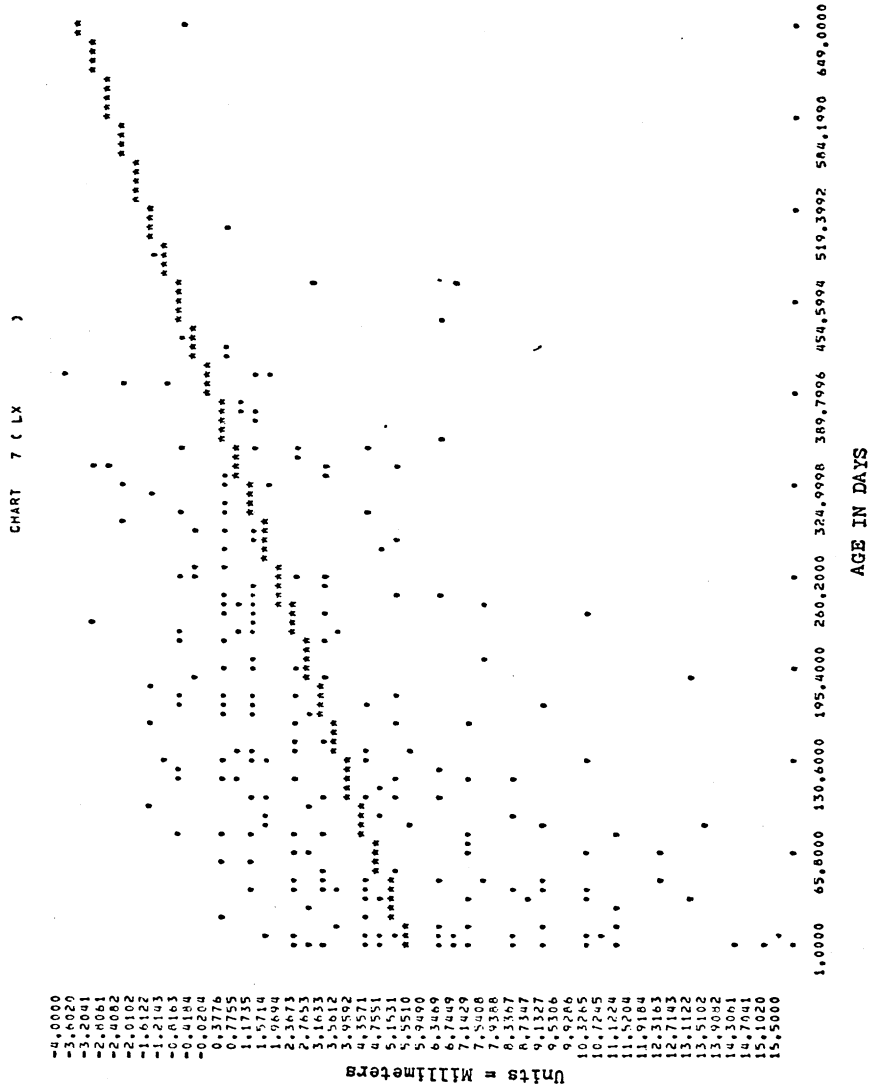


CHART 8 (GX)

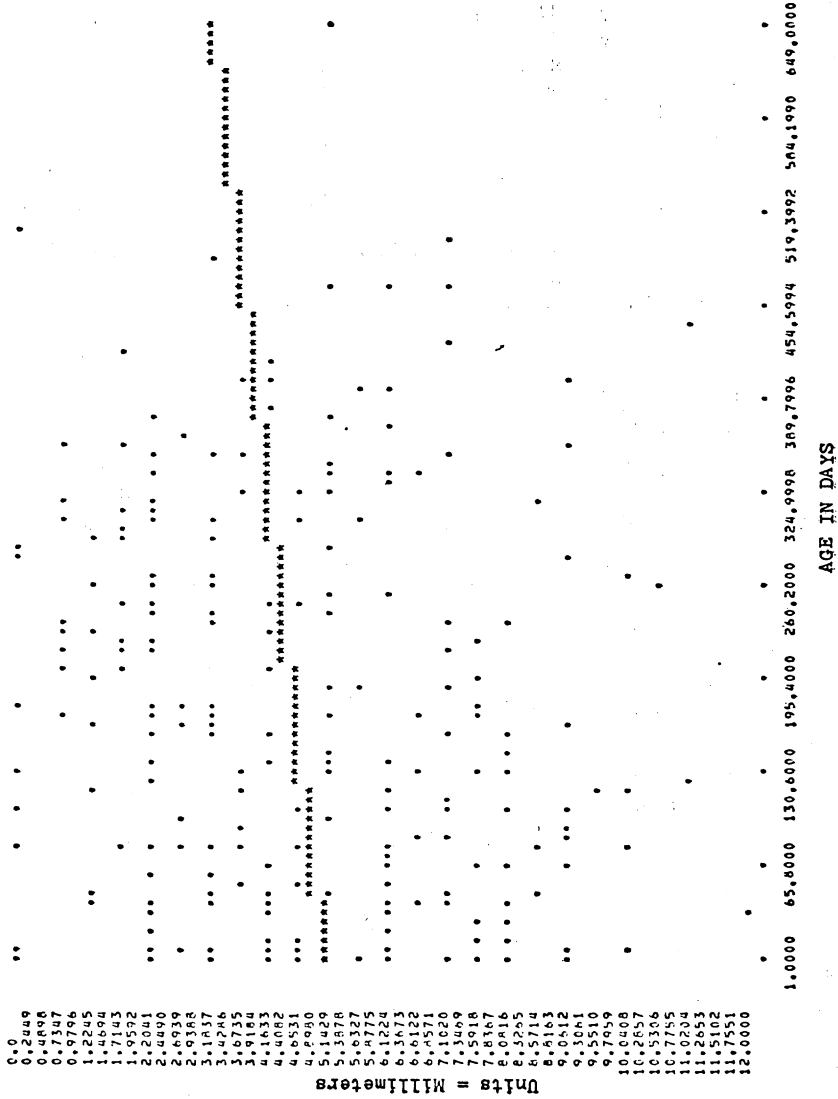


TABLE 3

<i>dependent variable</i>	<i>regression equation*</i>	<i>product moment correlation</i>		<i>slope significant at 5% level?</i>
T-T'	$y = -32.771 +$	.003x	0.122	yes
M-M'	$y = 33.035 -$	.001x	0.032	no**
T-T''	$y = 8.741 -$	.01x	0.345	yes
ITT'	$y = 22.806 +$	.013x	0.529	yes
LTT	$y = 17.250 +$	.010x	0.389	yes
LY	$y = 12.172 -$	.014x	0.495	yes
LX	$y = 5.854 -$	.016x	0.548	yes
GX	$y = 5.117 -$	.004x	0.173	yes

* y = dependent variable (units = millimeters).

x = age (units = days).

** Note that Chart 2 has a horizontal regression line.

A comparison of the Aduss-Pruzansky data with that of the T-NEMCH is presented in Table 4.

The non-orthopedically treated group exhibits an overall reduction in posterior cleft width of 22.3% in the eighteen months following lip repair; the group treated with presurgical orthopedics and subsequent lip surgery (average age six months) exhibited a 45.4% reduction in the same eighteen month period. Moreover when the data in Table 4 are analyzed, the presurgical orthopedic sample exhibits a 28.5% reduction in posterior cleft width during the period before lip surgery. A student's t-test of the data in Table 4 reveals no difference in the first model means of the Aduss-Pruzansky and T-NEMCH groups ($t = 1.659$, $df = 134$, $p > .05$). However, the difference in means of the eighteen month models was significant at the two percent level ($t = 2.425$, $df = 63$).

PART III. EVALUATION OF OCCLUSION IN THE DECIDUOUS AND MIXED DENTITIONS. The findings of this phase of the study are shown in Table 5 where the patients treated with presurgical orthopedics are compared with previous reports (41-44) of the prevalence of crossbite malocclusion in surgically repaired cleft lip and palate patients.

In evaluating cleft lip and palate children, most clinicians would agree that, in terms of crossbite malocclusion, a favorable situation exists when there is no crossbite or a single tooth is in crossbite. Therefore, for comparative purposes, the "no crossbite" and "canine only" columns are grouped together.

Statistical analysis of the favorable-unfavorable distributions in Table 5 reveals significance at the .001 level for the comparison of the T-NEMCH figures with those of Pruzansky and Graf-Pinthus (conventional) (Chi-square = 12.53 and 13.29 respectively, and $df = 1$). However, the comparisons of the T-NEMCH data with that of Bergland and Mazaheri were not statistically significant (Chi square = 2.19 and 1.71 respectively, $df = 1$, $p > .05$). Bergland's results are noteworthy in that lip surgery is delayed

TABLE 4. Comparison of "mean" posterior cleft widths in control sample and group treated with presurgical orthopedics.

Aduss-Pruzansky:

<i>measurement</i>	<i>mean</i>	<i>std. dev.</i>
prior to lip repair.....	9.9834 (mm)	2.6108
subsequent models by age		
(0-6 months)*.....	8.3111	2.6702
(7-12 months)*.....	8.0000	2.7774
(13-18 months)*.....	7.7529	2.6361

Overall percentage reduction = 22.3%.

* All Cases Following Lip Repair 7-9 weeks.

Tufts-New England Medical Center Hospitals:

first model (13 days).....	10.919 (mm)	3.311
subsequent models by age		
(0-6 months).....	7.250	2.751
(7-12 months)*.....	6.559	2.364
(13-18 months)*.....	5.964	2.756

Overall percentage reduction = 45.4%.

* Following Lip Repair at Average Age Six Months.

first model (13 days) (mm).....	10.919	3.311
last model prior to lip repair (139 days).....	7.767	2.443

Percentage reduction attributable to presurgical orthopedics = 28.5%.

TABLE 5

	<i>Graf-Pinthus 1970</i>	<i>Pruzansky 1973</i>	<i>Mazaheri et al 1971</i>	<i>Bergland 1967</i>	<i>O'Donnell 1974</i>	<i>Graf-Pinthus 1970</i>
no crossbite	2	17	12	11	10	9
canine only	1	12	7	8	13	2
buccal	9	23	8	3	4	2
anterior	1	0	1	0	0	3
anterior & buccal	2	16	2	6	0	1
anterior & canine	0	3	0	3	1	0
total cases	15	71	30	31	28	17
% of no crossbite or canine only	19	41	63	61	82	65
	conventional treatment				pre-surgical orthopedics	

until the infant is approximately six months of age. Since delayed lip repair is also characteristic of presurgical orthopedics, further studies are indicated to distinguish between the effects of the orthopedic appliance and that of the delay in surgery.

The occlusal relationships reported by Mazaheri et al. does not differ significantly from that of the T-NEMCH group. However, since no data is available to determine if the two sample populations are comparable prior to therapy, the validity of this comparison cannot be established.

Discussion

Many variables determine the functional and cosmetic rehabilitation of a cleft lip and palate patient. Of prime importance are the growth of the child and the expertise of the surgeon performing the lip and palatal repair. The timing of the surgical procedures may also play a critical role in the final outcome. In the evaluation of a group of cleft palate children, the effect of these variables should not be minimized. For comparative purposes, however, the present investigation considered the effects of growth and surgery as constants, as these factors, in some form, were common to all the studies being considered. Interest is focused on presurgical orthopedics, the variable that distinguishes the T-NEMCH treatment plan from the treatment plans of the other studies. Part I and Part III, therefore, demonstrate that, in terms of arch collapse and crossbite malocclusion, significantly better results are observed in unilateral complete cleft lip and palate patients that have been treated with presurgical orthopedics. It may be argued that the high percentage (83.3%) of "non-collapsed" infant models in the T-NEMCH group is not a valid indication of arch collapse, since the models evaluated were obtained just prior to and not after palatal surgery. However, a high percentage (82.1%) of patients in the presurgical orthopedic sample display a "favorable" occlusal relationship as well. Collapse of the arch following palatal surgery does not appear to occur to any great extent in this group of patients. Therefore, evaluation of the infant models just prior to the time of palatal surgery (age thirteen months) seems justified.

The xerographic analysis of the infant cleft palate models in Part II provides quantitative information regarding the effects of the orthopedic appliance itself. Previous reports (30-32) had suggested that presurgical orthopedics could serve to widen the cleft initially and impede medial movement of the maxillary segments. Hawthorne (45) stated that following presurgical orthopedics the surgeon "no longer has a little gap of maybe four to five millimeters to close. Now the gap is as big as a centimeter and a half". The data obtained from the xerographic analysis indicate that quite the contrary is true. The program of presurgical orthopedics as applied to the T-NEMCH sample results in a decrease in posterior cleft width, while the intertuberosity width of the arch was maintained. This confirms the earlier work of Huddart (46) and tends to substantiate Mc-

Neil's early belief (1, 2) that the appliance stimulates tissue growth, thereby reducing cleft width.

The transverse measurements across the anterior cleft (LX and LY) showed marked trends toward smaller values indicating approximation of the two displaced segments. No difference in the relative rates of decrease could be detected.

Further studies are indicated to supplement our knowledge of the effects of presurgical orthopedics in the treatment of cleft lip and palate infants. The total amount of palatal tissue before and after presurgical orthopedic intervention should be determined. A three-dimensional analysis appears to be necessary for an investigation of this nature. These data should then be compared with study populations having received purely surgical treatment. If the "tissue deficiency" theory of cleft palate morphology is true, then it is important to identify any technique which provides a stimulus to tissue proliferation. Additionally, it is now generally accepted that different subgroups of clefts may exist within the same morphological classification. The response of each subgroup to different treatment procedures may vary. It is hoped, therefore, that the quantitative information provided by this study and others like it will help to identify such variations.

Summary

A study was undertaken to evaluate forty-eight unilateral cleft lip and palate children who were treated with presurgical orthopedics at the Tufts-New England Medical Center Hospitals. Based upon this study the following conclusions were reached:

1. Unilateral cleft lip and palate patients who have been treated with presurgical orthopedics demonstrate lower incidences of arch collapse and crossbite malocclusion than those treated by surgery alone.
2. A program of presurgical orthopedics results in a reduction of posterior cleft width throughout the course of treatment.
3. The greatest amount of reduction (28.5%) occurs during the period prior to lip repair and the total amount of reduction (45.4%) exceeds that of previous reports of patients who received purely surgical treatment.
4. Further studies are indicated to supplement our knowledge of the effects of presurgical orthopedics in the treatment of cleft lip and palate infants.

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