SOFT TISSUE PROFILE CHANGES IN PATIENTS WITH CLASS II, DIVISION 1 MALOCCLUSIONS TREATED WITH THE BIONATOR APPLIANCE

by

D. WILLIAM LANGE

Submitted in partial fulfillment of the requirements for the
Degree of Master of Science in Dentistry

Department of Orthodontics
School of Dentistry
CASE WESTERN RESERVE UNIVERSITY

May, 1994

CASE WESTERN RESERVE UNIVERSITY

SCHOOL OF DENTISTRY

GRADUATE STUDIES

We hereby approve the thesis of

D. WILLIAM LANGE

candidate for the degree Master of Science

in Dentistry.

Signed: _____ (Chairman)

Date: 6-22-94

SOFT TISSUE PROFILE CHANGES
IN PATIENTS WITH CLASS II, DIVISION 1 MALOCCLUSIONS
TREATED WITH THE BIONATOR APPLIANCE

Abstract

by

D. WILLIAM LANGE

The bionator is a common modality for the correction of Class II, Division 1 malocclusion in the mixed dentition. The hard tissue changes as a result of treatment with the bionator have been studied extensively, however, the soft tissue profile changes as a result of its use have not been well documented. Thus, the purpose of the study was to determine and compare the soft tissue profile changes in patients with Class II Division 1 malocclusion treated in the mixed dentition with a bionator to that of untreated controls.

The sample consisted of cephalograms of two groups of 30 caucasian individuals who were between 9 and 12 years of age at the start of treatment. The first group was treated with a bionator for an average of 18 months resulting in a Class I molar relationship and successful reduction of overjet. The second group, acting as a control, consisted of cephalograms of individuals obtained from the Bolton-Broadbent Growth Study who did not receive any form of orthodontic treatment. The two groups were closely matched for age, sex, observation time, and dentofacial characteristics. The cephalograms were

analyzed using a soft and a hard tissue cephalometric analysis as well as a cranial base superimposition analysis. Paired t-tests were used to compare the changes between the bionator and control groups.

As compared to the control group, the treated group demonstated the following changes:

1. Increase in the length of the mandible
2. Increase in anterior facial height
3. Decrease in soft tissue profile convexity
4. Increase in mentolabial angle

DEDICATION

This and all I do is dedicated to my girls- Susan, Caitlin, and Lauren;
and to my mother, Barbara Lange, the memories full of laughter will never fade.

ACKNOWLEDGEMENTS

To my classmates, David Cain, Luigi DiBattista, Roger Diels, and Tim Pence, and the members of the classes ahead and behind me, especially Sean O'Callaghan and Kevin Holman, my two years at CWRU have been enjoyable due to you and I'm looking forward to many reunions wherever we may be.

To my committee, Varun Kalra, B. Holly Broadbent, Mike Powers, and Suchitra Nelson, for the thought provoking questions, dedication, and encouragement during my thesis.

To the faculty of the Orthodontic Department, in appreciation for the respect you showed us during our residency; it is fully returned.

To my father, David Lange, not only for the support you gave me in my thesis but the love and devotion you have shown me all my life.

TABLE OF CONTENTS

	Page
ABSTRACT	ii
DEDICATION	iv
ACKNOWLEDGEMENTS	v
LIST OF FIGURES	vii
LIST OF TABLES	ix
INTRODUCTION	1
REVIEW OF THE LITERATURE	3
STATEMENT OF THESIS	30
METHODS AND MATERIALS	32
RESULTS	50
DISCUSSION	69
SUMMARY AND CONCLUSIONS	88
APPENDIX A	90
APPENDIX B	95
LITERATURE CITED	98

LIST OF FIGURES

FIGURE		PAGE
1.	Frontal and Lateral views of Bionator.....	35
2.	Soft Tissue Cephalometric Landmarks.....	36
3.	Skeletal and Dental Cephalometic Landmarks.....	37
4.	Soft Tissue Angular Cephalometric Landmarks.....	42
5.	Soft Tissue Lip Thickness and Length Measurements.....	43
6.	Upper and Lower Lip Procumbency Measurements.....	44
7.	Skeletal and Dental Angular Cephalometric Measurements.....	45
8.	Skeletal and Dental Linear Cephalometric Measurements.....	46
9.	Cranial Base Superimposition Reference Planes.....	47
10.	Cranial Base Superimposition Analysis Landmarks and Measurements (T1-T2).....	48

11. Cranial Base Cephalometric Superimpositional T1-T2 Changes for Bionator Patient JH..... 51

12. Photographs of Pre-Treatment and Post-Treatment Cephalograms for Bionator Patient JS..... 52

13. Mean Changes in G-Sn-Pg Angle for Bionator and Control Groups (T1-T2)..... 53

14. Mean Changes in Lower Lip Length (Stm-B'), Thickness (Ls Th), and Angulation (Mentolabial Angle) during the 18 Months..... 56

15. Mean Increase in Length of the Mandible (Ar-Gn) in Control and Bionator Groups during the 18 Months of the Study..... 61

16. Mean Changes in Skeletal Convexity in the Treated and Control Groups (T1-T2)..... 62

17. Comparison of Dental Changes in the Treated and Control Groups (T1-T2)..... 65

LIST OF TABLES

TABLE		PAGE
1.	Sample Size, Age, and amount of Treatment or Observation Time	33
2.	Comparison of Soft Tissue Changes in the Treatment and Control Groups (T1-T2)	54
3.	Comparison of Soft Tissue Changes in Treatment and Control Groups (T1-T2) as determined by Cranial Base Superimposition	57
4.	Comparison of Hard Tissue Changes in the Treatment and Control Groups (T1-T2)	60
5.	Comparison of Skeletal and Dental Changes in the Treatment and Control Groups (T1-T2) as determined by Cranial Base Superimposition	67
6.	Soft Tissue Measurement and Tracing Error Analysis Results	96
7.	Hard Tissue Measurement and Tracing Error Analysis Results	97

INTRODUCTION

Historically, orthodontics has been primarily concerned with the skeletal and dental tissues since the objective of orthodontic treatment was simply the attainment of normal occlusion(Angle, 1907). However, in the 1950's soft tissue measurements began to be introduced into cephalometrics and recognized as an important factor in treatment planning (Riedel, 1950; Ricketts,1957; Neger, 1959). Since then there have been a number of articles published containing soft tissue cephalometric analyses (Holdaway, 1983; Burstone, 1958). The introduction of soft tissue factors into treatment planning was a result of clinical observations that a single skeletal and dental pattern could have a wide variety of integumental profiles associated with it (Burstone, 1958).

The bionator is a widely used treatment modality for the Class II, Division 1 malocclusion. Functional appliances were developed in Europe and have been prevalent in European orthodontics for the past 50 years. However, the same is not true for the United States. Orthopedic appliances have only become popular and widely used in the U.S. in the past 15 years.

The skeletal and dental effects of bionators have been well documented in both the U.S. and Europe. While the hard tissue treatment effects have been widely studied the conclusions have been mixed. Some studies have reported

skeletal changes (Forsberg and Odendrick, 1981; Mamandras, 1990). Other studies have found only dentoalveolar compensations (Johnston, 1986). There are also articles which attribute the results of treatment to change in muscle function brought about by the functional appliance (Frankel, 1969; Pancherz, 1981). Regardless of how the malocclusion is corrected, the final clinical result is an improvement in facial esthetics.

One component of bionator therapy which has not been quantified is the effect on the integument and consequently esthetics. Therefore, the primary objective of the study was to determine the treatment effects of the bionator appliance on the soft tissue profile and secondarily on the skeletal and dental bony tissues since the integument can be directly influenced by changes in the hard tissue.

The difficulty in determining the treatment effect comes in separating it from normal growth. The cephalograms of 30 subjects treated with a bionator and 30 untreated controls matched for age, sex, observation time, and dentofacial characteristics were utilized to isolate treatment effect. The cephalograms were analyzed using a soft and a hard tissue cephalometric analysis as well as a cranial base superimposition analysis. Then the mean changes of each group were compared by paired t-tests for significant differences. The effect of the bionator could be determined by subtracting the mean changes of the control group from the mean changes of the treated group.

Since the bionator is known to correct the malocclusion, knowledge of the soft tissue effects will aid the clinician in forecasting the treatment results of the appliance before treatment commences.

LITERATURE REVIEW

In the early 1900's, Edward H. Angle referred to the Apollo Belvedere bust as having the ideal profile. However, he felt that the soft tissue was not a treatment planning issue, since the objective of orthodontics was simply the attainment of normal occlusion including the full complement of teeth (Angle, 1907).

This view was challenged by those who felt that the integument should be evaluated in treatment planning in order to attain the most pleasing appearance (Case, 1921; Wuerpel, 1937).

In the 1920's the inclusion of methods for measuring the soft tissue from photographs began to gain support in orthodontic treatment planning (Simon, 1926; Hellman, 1927). In his later years even the resolute Edward Angle changed his views concerning facial esthetics. In a letter to Oppenheim, Angle (1932) expressed the opinion that studying the relationship between the face and jaws through photographs or teleradiographs was a necessary part of a diagnostic examination in planning treatment of the Class II distocclusion.

Tweed (1944) defied Angle and popularized the extraction of teeth in orthodontic treatment citing more pleasing facial esthetics as a result. Since

Tweed established the importance of the integument by basing his treatment on esthetics, many new orthodontic philosophies have been developed in an attempt to address malocclusion as well as soft tissue discrepancies.

Facial Esthetics

Riedel (1950) had 72 Midwestern orthodontists rate the profiles of 24 children between the ages of 8 and 11 years and with normal occlusion. In addition to the 24 child profiles, 4 adult profiles were included. The adult profiles consisted of a Class I malocclusion, a Class II division 1 malocclusion, and 2 identical profiles to test the consistency of the orthodontists. The orthodontists were asked to classify the esthetics of each profile as "good", "fair", or "poor" in an attempt to determine what facial patterns were pleasing to professionals. The clinicians exhibited a uniform opinion on "good" and "poor" profiles. "Good" profiles were found to have ANB angles less than 2.5 degrees, non-protrusive dentitions, and angles of convexity which did not exceed 4 degrees. "Poor" profiles exhibited ANB angles greater than 2 degrees, protrusive dentures, and angle of convexity greater than 4.5 degrees. Thus, the orthodontists chose a straight profile as the most pleasing and a convex profile and skeletal pattern with dental protrusion as the least esthetic.

In a later study Riedel (1957) analyzed the profile characteristics of 30 Seattle Seafair Queen contestants selected by non-orthodontist judges for

beauty, personality, and poise. The purpose of the study was to compare how orthodontic standards for facial esthetics compare to the layman's perception of beauty. Cephalometric analysis used 11 angular and 5 linear hard tissue measurements as well as 4 soft tissue measurements to examine the lips. Almost all of the subjects had a Class I skeletal pattern with an average ANB angle of 3.4 which fell within accepted orthodontic standards. However, the subjects were found to have a greater degree of fullness of the lips than what is accepted as the norm in orthodontics due to protrusion of the dentures. Thus, there was an overall agreement in opinion with a slight difference regarding the most esthetic facial profile between the layman and orthodontist.

Fifty-two professional models, beauty contest winners, and performing stars noted for their appearance were the subject of research by Peck and Peck (1970). All of the individuals were caucasian with a mean age of 21.6 years and 25% of the subjects had had some type of orthodontic treatment. A Margolis cephalostat was used to record lateral cephalograms taken in the relaxed lip position. Then the headfilms of each subject was analyzed using the Margolis, Downs, and Steiner analyses. The angle of convexity, A-B plane to facial plane, and SNA measurements all showed significant increases demonstrating a greater degree of maxillary protrusion than what is accepted by orthodontic norms. Measurements of mandibular position did not vary from the accepted norms. In addition, measurements in all three analyses exhibited mandibular incisor procumbency and maxillary incisors which were not inclined beyond standards but were positioned more forward. Therefore, a comparison of the sample's cephalometric recordings to orthodontic standards revealed that the public admires a fuller profile than cephalometric standards allow.

Cox and Van der Linden (1971) analyzed 241 female and 186 male subjects not preselected on the basis of normal occlusion and facial balance. Thus, the study included caucasian subjects, 18 to 20 years old, with both good and bad facial esthetics. The sample was then broken down into 6 groups of 29 individuals and ten orthodontists and ten layman were asked to rate the subjects of each group from most beautiful profile to least attractive profile sequentially. The judges from both groups were extremely consistant in their determination of "most" and "least" pleasing appearance. Subsequent cephalometric analysis of the sample showed that there was a wide range of most appealing profiles which demonstrated a variety of malocclusions but similar soft tissue characteristics. Examination of the most appealing profiles revealed that they had significantly less overall soft tissue thickness than the least appealing group. The poor esthetic sample demonstrated a more convex skeletal and soft tissue profile and anteriorly positioned incisors.

Foster (1973) used a different approach to facial balance evaluation. Rather than evaluating a large number of different profiles, only a single profile with some alterations was evaluated. The profile which was used as a baseline was from a 18 year old caucasian female. The baseline profile was then altered in the lip region. Three profiles were fabricated by advancing the lip outline in 2mm increments and three more profiles by retruding the lips in 2mm increments. The resulting seven profiles were assessed and assigned an age by several groups. The judging groups included general dentists, art students, orthodontists, a black non-orthodontic, a chinese non-orthodontic, and a white non-orthodontic group. All of the groups related fuller profiles with youth and straight profiles with adults. There was inconsistency within and between the

groups when determining characteistics of an adolescent profile. In the adult profile all of the groups except orthodontists preffered a fuller profile for females. Orthodontists tended to have less difference between the profiles of males and females. The orthodontist group did acknowledge a significant profile difference between the sexes but laypersons judged the difference to be twice that of orthodontists.

Lines, Lines, and Lines (1978) demonstrated a statistically significant sexual preference for esthetically pleasing profiles. A profile with a nose more prominent in relationship to the chin for males and nose less prominent in relationship to the chin for females was found. However, a prominent rather than inconspicuous chin was preferred in both sexes. A more obtuse nasal tip angle and protrusive lips were preferred in females while males displayed acute nasal tip angles, straighter lip profile, and deeper mentolabial folds. It was also noted that orthopedic forces and orthognathic surgery has greatly expanded the ability of the orthodontist to alter the soft-tissue profile.

Bittner and Pancherz (1990) reported the findings of 4 orthodontists and 3 orthodontic residents evaluation of the soft tissue profile of 172 children between the age of 12 and 14 years. A large overjet, increased facial height, and large ANB discrepancies were most often mirrored in the soft tissue. Class III malocclusion, open bite, and the position of the mandible or maxilla were not as easily determined from soft tissue appearance. The authors also noted that early orthopedic therapy was warranted for improved esthetics in Class II, Division 1 malocclusions with prognatic maxilla.

Czarnecki, Nanda, Currier (1993) also found that a straighter profile in males and a slightly convex profile in females was preferred by 545

orthodontists. The least acceptable profile included an extremely recessive chin or extremely convex face. Large noses or chins allowed for more lip protrusion for all subjects. The authors concluded that orthodontic treatment goals should be "attuned to the achievement of balanced and harmonious facial features rather than rigid adherence to standard average dental and skeletal parameters".

Soft Tissue Characteristics

In 1957, Burstone conducted a study with the intention of considering the role and significance of lip posture in orthodontics and treatment planning. He compared two groups. The first was comprised of 32 boys and girls between 13-15 years of age, chosen by non orthodontists for normal facial balance. The second group consisted of 20 boys and girls between 12-14 years of age with full-cusp Class II, Division 1 malocclusions. He concluded that facial disharmonies may be observed in the absence of dentoskeletal discrepancies and that there is an anteroposterior posture of the lips which is independent of the teeth and alveolar process. He also stated that facial esthetics, stability, and the ability to produce an adequate oral seal are the objectives of orthodontic treatment.

Altemus (1959) studied a sample of 37 caucasian and 50 black subjects with Class I occlusion, ages 12-16 years, that had not received any form of orthodontic treatment. Seven soft tissue landmarks were measured on the cephalograms to adjacent hard tissue points parallel to the ANS-PNS horizontal

plane. Both caucasian and black samples illustrated that there was a great deal of soft tissue variability and there was no relationship between the soft tissue and the underlying hard tissue configuration. Altemus concluded that the soft tissue profile should be included in treatment planning.

Burstone published a study in 1959 which investigated direct measurement of the soft tissue and differences between the integument with respect to sex and maturation. The adolescent and adult groups were compared. The first consisted of 37 males and females with a mean age of 14.7 years and the second included 40 males and females with a mean age of 23.8 years. A method for measuring horizontal and vertical extension of the soft tissue was introduced and standards derived from the samples. Burstone found that malocclusions exhibited considerable soft tissue variation, that males had greater horizontal extension in the areas inferior to the nose, and maturational changes between the adolescent and adult groups were noted as the overall profile tended to flatten with age.

In the same year Subtelney reported that developmental changes in the soft tissue thickness can alter the profile. The integumental thickness covering the maxilla increases more than at nasion or pogonion. Therefore, the facial profile tends to become more convex with age as opposed to the underlying skeletal component which straightens with age. The nose grew in a downward and forward direction for all subjects, however, the increases were sustained longer in males and contributed more to vertical face height. Upper lip length and thickness increased more in males than females but the lower lip was comparable in growth for both groups. In all cases the vermillion borders held a stable posture to the position of the incisors. A generalization that the tissue

covering the dentures tended to have a close association to the underlying skeletal component was concluded. Finally, it was noted that due to growth and skeletal displacement of the nose and chin the lips acquired a more receded appearance.

Nanda et al (1990) studied longitudinal data concerning soft tissue growth. Forty caucasians between the ages of 7-18 years were observed. All of the subjects had Class I occlusion, had not received orthodontic treatment, and had a balanced facial appearance. The study analyzed annual soft tissue thickness and profile changes using a plane drawn from the sphenoethmoid synchondrosis to the pterygomaxillary point as the reference line. The average increase in the combined upper and lower lip length in males was 6.9 millimeters compared to 2.65 in females, however, individuals with short upper lips initially tended to have short upper lips at the end of growth as well. Soft tissue thickness at laberale superius in males increased four times that of females. Furthermore, soft tissue pogonion increased an average of 2.4 millimeters in males and 1.5 millimeters in females, however, the majority of displacement was due to skeletal growth. The largest increase in relative size was found in the nose and continued past 18 in males. Females had mostly completed soft tissue growth by age 15. The findings of the study led to the conclusion that the soft tissue changes seen in the nose, lips, and chin suggested sexual dimorphism.

In a 1990 study, Genecov further investigated the sexual dimorphism in soft tissue development. When males and females were compared cephalometrically, both showed similar growth rates and patterns between ages 7-12 years but from 12-17 years there was a marked dichotomy. The

results found that major soft tissue growth changes ceased for females at age 12 while growth continued for males through age 17. Between 12-17 years males demonstrated an average of 4-5mm increase in nose projection, 2mm increase in lip thickness, and 7mm increased hard tissue N-Me vertical length. Angular measurements were an exception to the sexual dimorphism. In all subjects, soft tissue angular measurements remained stable throughout growth. Nasolabial angle rarely varied more than 3 degrees during any point of development.

McNamara, Brust, and Riolo (1992) stated that evaluation of the soft tissue was one of the most important components in orthodontic diagnosis and treatment planning. In an attempt to quantify the soft tissue profile 141 non-growing Caucasians with Class I occlusions and a history of no orthodontic treatment were studied. Three separate investigators evaluated the untraced cephalograms, extraoral photographs, and/or clinical examination to determined which profiles they considered "ideal". If two or more of the investigators chose the same profile as ideal, it was further analyzed. Eleven angular measures, ten linear measures, and lip profile were assessed. The upper lip of females was found to be more protrusive and the nasal tip angle more obtuse than in males. Males demontsrated significantly thicker soft tissue values in all measurements. Both Ricketts and Steiner lip analysis illustrated a more protrusive lower lip in females.

Soft Tissue Analysis

The use of photostatics declined when a method of registering standardized serial lateral cephalograms was introduced by Broadbent in 1937. This monumental step forward for orthodontics provided clinicians with a reproducible, standardized method of visualizing the cranial base, midface, jaws, and dentition. As would be expected, the next advancement was the formation of cephalometric analyses in which the relationships of the components of the head could be measured and quantified. This allowed orthodontists to communicate regarding diagnosis, treatment planning, and treatment results in a manner before unattainable. However, the initial cephalometric analyses tended to focus on the hard tissues and the importance of the soft tissues to treatment planning was diminished.

It was not until the 1950's that soft tissue cephalometric analyses began to be introduced. This reintroduction of soft tissue factors into treatment planning was a result of clinical observations that a single skeletal and dental pattern could have a wide variety of integumental profiles associated with it (Burstone, 1958) and that different forms of treatment on the same skeletal and dental pattern can have different soft tissue results while successfully correcting the malocclusion (Holdaway, 1983).

Burstone (1958) introduced a method for measuring the linear and angular parameters of the soft tissue profile. Seven soft tissue landmarks were identified and served as points of reference for what Burstone termed contour angles and profile components. Contour angles were comprised of three successive soft tissue landmarks. The resulting angular measurement

represented the facial characteristics of that given region of the profile. A profile component was the segment joining two of the soft tissue landmarks which created a linear representation of a given facial contour.

In a later paper Burstone (1959) adopted a system of linear measurements to examine the thickness and length of the soft tissue profile. Two samples were studied, an adolescent group with a mean age of 14.7 years and a young adult group with a mean age of 23.8 years. All of the subjects possessed excellent facial features as determined by a panel of artists. In order to reduce bias possibly introduced by the artists, the sample was then chosen again by a group of housewives. There was no difference between the selections of the artists or the housewives. The soft tissue analysis utilized glabella, subnasale, superior labial sulcus, labrale superius, labrale inferius, stomion, inferior labial sulcus, and menton. The extention of integumental landmarks was measured from skeletal cephalometric points utilizing the nasal floor as a horizontal reference. The length of various components of the integument was determined by the same method substituting a vertical reference plane. The vertical reference was a perpendicular to the nasal floor. It was observed that there was a considerable range of soft tissue deviation with malocclusion as well as sexual dimorphism. Males had thicker soft tissue inferior to the nose than females. Also, the profile tended to flatten as individuals matured. Finally, Burstone developed an extensive set of soft tissue standards for adolescents and young adults.

Ricketts (1964) and Ricketts (1964) focused on the "keystone triad". The triad consisted of the chin, lower alveolus, and enviromental conditions. Ricketts (1968) acted as a summary and included the structures of the lower

face and lip balance. Also, nine factors to consider in analysis of the soft tissues are outlined. The nine factors were further distilled down to Ricketts' "law of lip relationship". The law was defined as follows:

> In the normal white person at maturity, the lips are contained within a line from the nose to the chin, the outlines of the lips are smooth in contour the upper lip is slightly posterior to the lower lip when related to that line, and the mouth can be closed with no strain.

The reference line which is described is the "Esthetic" or "E" plane. The esthetic range for the treatment of children between the ages of 12-14 years was -2.0 +/- 3.0mm measured from the lower lip to the E plane. Measurement of the upper lip was deemed as unnecessary since the curl of the lower lip and its position were determined by the upper incisors. The upper lip was only related to the lower lip.

Legan and Burstone (1980) introduced an orthognathic soft tissue analysis designed to aid the clinician in determining the most desirable facial esthetics in orthognathic surgery cases. The sample consisted of 20 caucasian men and 20 caucasian women between 20 and 30 years of age. All subjects had normal Class I occlusion without orthodontic treatment and balanced facial esthetics. A reference constructed 7 degrees from sella-nasion plane through nasion was used as and given the name "horizontal reference plane". An additional 10 soft tissue landmarks were utilized in conjunction with the horizontal plane to complete the analysis. The analysis addressed two main characteristics of the facial profile: facial form and lip position and form. Six

measurements, their norms, and standard deviations were given for facial form. The soft tissue facial convexity angle is of particular interest and the norm given was 12 degrees with a standard deviation of 4 degrees. Lip position and form was described by seven linear and angular measurements. The norms and standard deviations of these measurements were also recorded. The soft tissue analysis was created to be used in conjunction with hard tissue analyses since hard tissue measurements alone might not lead to a pleasing facial form.

Schiedeman et al (1980) used a 220 point computer cephalometric tracing program to analyze 24 females and 32 males with Class I occlusions, ANB measurements of 0-4 degrees, and normal anterior face heights. The purpose of the study was to incorporate a large number of soft tissue measurements in order to determine esthetic facial profile and proportions. Through hard and soft tissue linear, angular, and ratio values, average male and female faces were generated. Also, the study confirmed Legan and Burstone(1980) facial height G-Sn/Sn-Me' ratio of 1:1 and described a sexual difference for the lower facial height. Males had longer lower facial height.

An eleven measurement soft tissue analysis was developed by Holdaway (1983). Six reference planes were utilized to make the eleven measurements. The analysis introduced 11 soft tissue measurements including Holdaway's H line. The H line was defined as a plane from soft tissue pogonion to the tip of the upper lip. From the H line the degree of lip protrusion was measured parallel to frankfort horizontal. 0.0 to 0.5mm in front of H line were derived as the norm for lower lip position. The remaining measurements address nose and chin prominence, skeletal convexity, soft tissue convexity, sulcus depth,

and soft tissue thickness. Ideal norms were developed and illustrated for all of the measurements and the use of the analysis illustrated through treated cases.

In the second part of the paper Holdaway (1984) recommends that it is practical to approach treatment planning from a soft tissue perspective. He maintains that once the clinician establishes the patients most esthetic soft tissue profile , all other tooth movement necessary in treatment should be for the attinment of that goal.

Park and Burstone (1986) evaluated the facial harmony and amount of variation in successfully treated subjects. Successfull treatment consisted of a Class I molar and cuspid relationship and the lower incisor placed 1.5mm ahead of A-Po line. All 30 subjects initially had a Class II Division 1 occlusion. Post-treatment soft tissue analysis detected a wide variation of the facial profiles. The largest variations fell in the area of the lips. There was 10mm of variation in the position of the lips. Also, total variation in upper lip inclination was 34 degrees and in lower lip it was 52 degrees. 14-16mm of deviation was seen in upper and lower lip to Esthetic plane. These figures represented 95% of the variation in the subjects with 5% of the cases presenting even more disparity. The authors finished by stating that photographs, clinical examination, and soft tissue analysis are essential to the consideration of facial esthetics in treatment planning.

Lip Posture in Cephalometrics

Burstone (1957) tested the reliability of the relaxed lip position in cephalometric radiographs. Ten subjects with a variety of malocclusions were selected and four operators took four cephalograms of each subject. The four readings for each subject were averaged and then the mean deviation was determined. The mean deviation was calculated to be 0.5mm. Norms of 1.8mm +/- 1.2mm and 3.7mm +/- 1.6mm were given for interlabial gap in centric occlusion and centric relation respectively.

Hillesund and Zachrisson (1978) studied the reproducibility of lip position. Two groups of children were considered- the first with normal incisor relationship and the second group with excessive overjet. Cephalograms of both closed lip and relaxed lip position were taken within a three week interval for each subject. The results demonstrated that the reproducibility of Stiener's S line and Ricketts' E line were good while Holdaway's H line was variable. The closed lip position tended to show a reduced lip thickness for all groups. The interlabial gap for the overjet group was greater than the normal group, however, some of the normal incisor group showed large interlabial gap measurements. Reproducibility was not significantly different for either group. The final conclusion of the article was that for both individuals with large overjets and normal incisor position, a relaxed lip position provided the most reliable and reproducible cephalograms.

Yogosawa (1990) also compared a normal occlusion group to a maxillary protrusive group to evaluate relaxed versus closed lip position. The

findings confirmed the conclusion that the relaxed lip position had a greater degree of reliability and reproducibility.

Untreated Class II Malocclusion

Frohlich (1962) examined sequential dental casts of 51 children, from age 6 to 12 years, in order to determine the dental development of Class II malocclusion. None of the subjects had received any form of orthodontic treatment and none of the cases spontaneously corrected. It was observed that the molar distocclusion stayed the same in 70% and got worse in 30% of the subjects. In addition, the canine relationship did not change in 10% and became more Class II in 90% of the sample. The final significant change came in the overjet and overbite. Both measurements continuosly increased with time but to a greater degree with overjet. By 12 years of age overjet had inceased to a range of 6-10mm and overbite was one to two thirds of the incisor crown height.

Soft Tissue Response to Four Bicuspid Extraction

Neger (1959) devised an analysis for either profile photographs or cephalograms. Six soft tissue landmarks and Franfort Horizontal plane served as reference points for the formation of six angular measures. Also, angular relationships between the upper lip, lower lip, and chin were established. The analysis was applied to a sample of Class II Division 1 subjects which had been successfully treated to a Class I occlusion. The results led to the observations that a straight profile is not garranteed by a normal occlusion. Furthermore, a proportionate change in the soft tissue could not always be anticipated following extensive dentition changes. It was noted that in Class II cases with retrognatic mandibles, a correction of the malocclusion often demonstrated very slight change in the chin. This resulted in a continued convex profile and unsatifactory facial esthetics.

Rudee (1964) examined 85 patients from his own practice to study the relationship between hard and soft tissue changes seen with orthodontic treatment. The consecutively chosen subjects ranged in age from 6 years 11 months to 22 years 6 months in age and all were treated with an edgewise appliance with or without a Kloehn cervical headgear. The cephalometric analysis consisted of pre and post treatment headfilms superimposed on the Sella-Nasion plane at Nasion. 7 linear measurements were made to a vertical reference plane constructed from Nasion to the initial Pogonion. The 7 landmarks included: upper incisor, upper lip, lower incisor, lower lip, pogonion, chin, and nose. The findings demonstrated a 2.9:1 ratio between upper incisor

retraction and upper lip retraction. The lower lip was found to retract 1mm for every 0.59mm of lower incisor retraction and 1.0mm for every 1.0mm retraction of upper incisor. Also, the nose grew on average 2.54mm which was almost two times as much as the 1.26mm seen in the chin. Overall, skeletal pogonion moved forward 0.66mm, however, in males the average was 0.98mm and in females 0.44mm was reported. Greater growth at the nose than chin and the retraction of the lips combined for an increase in convexity of the soft tissue profile.

Roos (1972) utilized 30 subjects with Class II, Division 1 malocclusion to demonstrate the skeletal, dental, and soft tissue changes seen with the extraction of four first bicuspids and an edgewise appliance. The subjects were between 8 and 17 years of age, presented with a mean overjet of 9.5mm, and mean overbite of 4.2mm. The pre- and post-treatment cephalograms were analyzed for skeletal and dental change as well as soft tissue thickness. All cases included in the study had a successful correction of the malocclusion. The soft tissue analysis involved superimposing upon the Sella-Nasion plane at Sella, then dropping a vertical line perpendicular to the SN plane from Sella. Linear measurements recording soft tissue thickness were taken from soft tissue landmarks to the constructed vertical parallel to the SN plane. The findings of the investigation supported several conclusions. There was a wide variety of soft tissue responses to orthodontic treatment involving the extraction of four first bicuspids, however, some trends were evident. There was a 2.5:1 mean ratio between the retraction of the upper incisors and the upper lip. In addition, there was a thickening of the upper lip and a thinning of the lower lip concurrent with incisor retraction.

Rains and Nanda (1982) investigated the association between retraction of the maxillary incisors and the soft-tissue contour. The cephalograms, taken in the relaxed lip position, of 30 caucasian female subjects with an average age of 16.6 years were analyzed. 21 of the cases had an original Class II, Division 1 malocclusion and the remaining 9 had Class I malocclusion. Furthermore, all of the subjects underwent premolar extraction followed by incisor retraction during treatment which lasted on average 28.3 months. The cephalometric analysis plotted 14 skeletal, dental, and soft tissue landmarks on a X/Y coordinate system. Constructed Frankfort Horizontal plane served as the X axis and a vertical plane through Sella was produced as the Y axis. A stepwise multiple regression analysis of the treatment effects demonstrated that retraction of either the upper or lower incisors did not correlate well with changes in the lips. Soft tissue Pogonion, however, was found to have a high correlation to its skeletal counterpart. The article concluded that current ratios for lip retraction can not be applied to the treatment prediction of individual cases due to the extreme variability in soft tissue response.

Drobocky and Smith (1989) examined the profiles of 160 patients treated with a fixed appliance and the extraction of four first bicuspid in order to correct a Class II malocclusion. The sample was divided into four groups. The first group consisted of patients treated by Charles H. Tweed. The second group were patients which received the Begg philosophy treatment. The third group were treated with a pretorqued, preangulated appliance and the fourth group had the premolars enucleated. Comparison of the start and finish cephalograms revealed many significant findings. There was a 5.2 degree increase in the Nasolabial angle, the upper lip averaged 3.4mm and the lower

lip 3.6mm retraction measured from the E line. Also, 10-15% of the cases demonstrated an "excessively flat" profile and of the four groups the Tweed group displayed the most lip retraction.

Bionator Appliance

Angle's clinical observations that successful correction of the dentoskeletal malocclusion is not always accompanied by desirable facial esthetics was confirmed by Park and Burstone (1986). The utilization of both hard and soft tissue cephalometric analyses allows orthodontists to evaluate the entire face in treatment planning as well as the resulting changes due to orthodontic treatment.

One form of orthodontic treatment used in cases of mandibular retrognathia is the Bionator. Its predecessor, the Activator appliance, was introduced by Andresen as part of his functional orthopedics philosophy and was designed to address various distocclusions. The bionator is the current derivative of the Activator with some modifications in construction. This appliance is frequently used in the mixed dentition to correct a Class II Division 1 malocclusion. A bionator corrects the malocclusion by positioning the mandible forward while placing a restrictive force on the maxilla. The theory of the correction is that the anterior positioning stimulates growth in the

condylar cartilage thereby increasing the overall length of the mandible while restricting anterior migration of the maxilla. Thus, the bionator addresses both skeletal and dental components of the retrognathic mandible. The net effect of the therapy is a decrease in both the hard and soft tissue profile convexity due to the increased mandibular length and advancement of the dentition.

Condylar Growth

Ricketts (1957) examined facial and denture changes in 50 treated Class II cases. The results showed that similar malocclusions, receiving identical treatment, responded in different facial patterns. It was concluded through cephalometric and laminographic analysis that the facial variety resulted from changes which took place within the temperomandibular complex. Three factors were listed as causing a change in the temperomandibular complex. There was a slight change in the cranial base (NSBa), the condyle moved forward, and what was found to be most important, the amount and direction of growth in the condyle.

In 1961 Baume and Derichsweiler published an article which investigated the response of the condyle to stimulation from a functional appliance. The experiment used 3 female rhesus monkeys between 44 and 50 months of age. Monkey 1 served as an untreated control and monkeys 2 and 3 received anterior positioning appliances. All three monkeys received periodic injections of alizarin red S. Sagittal headfilms were taken at the beginning and end of orthodontic treatment. Monkey 2 was sacrificed after 2.5 months and

monkey 3 after 4.5 months of treatment. Block sections were completed on the temperomandibular joints of each animal. The results of the study provided "concrete evidence" showing that the condylar growth center responds to functional therapy. It was also concluded that the younger the subject, the greater and faster the growth response of the condyles and that the activator bite planes stimulated condylar growth.

Elgoyhen, Moyers, McNamara, and Riolo investigated mandibular response to anterior positioning in the Rhesus monkey in 1972. The study observed 16 juvenile rhesus monkeys, 6 as experimental and 10 as controls. The age af the monkeys corresponded to the human developmental age of 6-8 years. Tantalum pins were placed into the maxilla and mandible of each monkey. Three of the experimental animals received bimaxillary appliances and three received single-arch appliances. After 3 months all of the experimental animals exhibited mandibular prognathism. There was a statistically significant increase in the rate of growth of the head of the condyle. The growth vector of the maxilla changed to a horizontal pattern with a decreased vertical component. There was also a dentoalveolar change. The maxillary dentition showed an inhibition of normal eruption pattern as well as a limited mesial migration of the mandibular dentition.

In 1973 McNamara reported specific neuromuscular and skeletal changes in rhesus monkeys due to altered oral stimuli. After the mandible was positioned anteriorly with a functional appliance, anteroposterior and vertical adaptations were observed in the midface and mandible. The superior head of the lateral pterygoid increased in activity and acted as the principal forward positioner of the mandible during functional movements and during

maintenance of the mandibular postural position. In 10 of the 12 animals exhibiting anteroposterior alteration in the molar relationship, the resulting change was due to a composite of specific complementary adaptations in the craniofacial complex. There was a decrease in the vertical displacement of the maxilla but the horizontal displacement of the maxilla and dentition was variable. McNamara concluded that the nature and extent of the skeletal and dental changes depended on the level of maturation of the animal.

Clinical Trials

In 1951 Bjork published a paper giving an account of the principles involved in the Andresen method of activator treatment or functional jaw orthopedics. In the article the monobloc construction of the appliance is described and varies according to the type of malocclusion. It was noted that in the Class II Division 1 occlusion the activator was most effective in the deciduous dentition(ages 4-7 years), slightly less effective in the mixed dentition(8-12 years), and had little effect in the adult dentition after growth had ceased. Bjork maintains that the molar corrections are attributed to dental alveolar changes but the magnitude of increase in the mandibular length was highly variable individual to individual.

The purpose of Marschner and Harris's (1966) study was to compare the mandibular growth between an untreated sample and an activator treated sample of Class II malocclusions. The control group was comprised of 23 untreated males between the ages of 5-13 years with Class II malocclusions. The treated group consisted of 12 Class II males. The overall mandibular length was recorded from the cephalograms of both samples. The results

showed that the activator group had an average of 3.26mm more mandibular growth than the untreated controls between the ages of 9-12 years. The difference was found to be statistically significant at a 5% level of confidence.

Harvold and Vargervik published a paper in 1971 with the intention of reversing one of their earlier studies which created a Class II Division 1 malocclusion from a Class I occlusion by altering the posture of the mandible. The authors proposed to use an activator appliance to create a morphogenic response which might correct a Class II Division 1 malocclusion. A total of 40 children were included in the study. 20 received treatment with an activator while 20 served as an untreated control. The mean age for the activator group was 9 years 7 months and 8 years 4 months for the control. Treatment time was 1 year or more. The results yielded a correction of the malocclusion and the following conclusions. The length of the mandible did increase in the treated group but not to a statistically significant degree. No forward migration of the mandibular dentition was observed. The restriction of the maxillary growth was found to be statistically significant in the treated group, however, the distal migration of the maxillary dentition was not. The correction of the Class II molar relationship was attributed to normal growth of the mandible, the statistically significant vertical increase of the mandibular alveolar process, and the restriction of the maxilla. The reduction in the overjet was attributed to the restriction of the maxillary growth and lingual tipping of the maxillary anterior teeth. The authors did advise that since the lower facial height increased due to the vertical increase in the mandibular alveolus, an initially large lower facial height would preclude the use of an activator appliance.

Wieslander and Lagerstrom (1979) depicted the dentoalveolar and orthopedic effects of activator treatment. The study was designed to compare a similar untreated group to a group of 30 subjects treated with an activator appliance. The two groups were matched for age, sex, and observation time. Furthermore, all of the individuals had a full Class II molar relationship and a mean ANB difference of 6. The treated group wore the activators for 10-12 hours a day with an average treatment time of 3 years 3 months. Only nonextraction cases with good treatment response were selected. Examination demonstrated the following treatment effects. All 30 cases were corrected to a Class I molar relationship. The majority of correction was found to come from dentoalveolar change with limited orthopedic effect. The authors noted, however, that while the orthopedic effect was limited, some individuals did show excellent orthopedic response. Also, several years after retention there was no sign of relapse.

In 1982 Schulhof and Engel conducted a study comparing the treatment effects of several functional appliances on growing children. Four types of functional appliances, including the Bionator, were analyzed and treatment results compared to growth forecasts and 20 single phase edgewise treatment cases. The bionator sample included 33 patients with a mean age of 12.9 years. Each case had a Class II malocclusion with accompanying deepbite and severe overjet. The Ba-Na increase/corpus length increase and Ba-Na increase/condyle axis increase ratios were both found to be statistically significant. These results support the claim that bionator treatment stimulated mandibular growth. Furthermore, the deep bite was decreased by 3mm and maxillary incisor inclination decreased. Thus, the authors concluded that the

treatment effect was reached by mandibular growth and change in the maxillary dentition.

Tsamtsouris and Vedrenne described the clinical observations in a 1983 case presentation. 3 Class II malocclusion cases treated with bionator therapy were presented. The following treatment effects were reported:

-Correction of Class II malocclusion to a Class I occlusion

-Reduction of deep bite

-Labial tipping of mandibular incisors

-Uprighting of maxillary incisors

-Increased lower facial height

The authors attributed these effects to the bionator since it positions the mandible anteriorly, allows for passive eruption of the mandibular buccal segments, and places a restrictive force on the maxilla and its dentition.

In a study comparing bionator therapy, full fixed edgwise therapy, and non treatment on Class II Division 1 malocclusions, Bolmgren and Moshiri (1986) drew the following conclusions. Bionator treatment retracted and uprighted the maxillary incisors, increased the mandibular plane angle, increased the mandibular length and anterior facial height more than fixed appliances alone. However, mandibular molar eruption was similar for both bionator and fixed appliance treatment.

Jakobsson and Paulin (1990) conducted a cephalometric study evaluating skeletal effects of activator treatment on children with Class II Division 1 malocclusions. The sample consisted of an experimental group of 31 girls and 22 boys, 8-14 years of age, treated with Andresen activators for an average of 2.5 years. A control group of untreated children with matched

characteristics served as a comparison to determine growth and treatment effects. The results showed that the total amount of condylar growth did not differ between the activator and control groups however the direction of growth did. The treated group displayed a more superior-posterior direction of growth thus, contributing to an overall increased length of the mandible. Furthermore, there was a decrease in the ANB angle in all of the treated patients but there was a difference between the boys and girls. The decrease in the ANB angle of the girls was mainly due to the inhibition of forward growth of the maxilla while in boys the change was accounted for by increased mandibular growth.

In 1990, Mamadras attempted to determine what factors led to successful bionator treatment. 20 successfully treated patients were cephalometrically compared to 20 unsuccessfully treated patients. Success was defined as the subject showing at least 3.5mm of pogonion advancement postretention while unsuccessful treatment showed less than 3mm of advancement. The results of the study showed that individuals with small mandibles, as compared to growth standards, and or delayed growth displayed more mandibular development. The authors concluded that patient selection was decisive in bionator treatment success.

STATEMENT OF THESIS

The hypothesis of the study was that there was a favorable soft tissue profile change as a result of treatment with a bionator. The bionator is a common modality for the correction of Class II Division 1 malocclusion in the mixed dentition. However, the soft tissue profile changes as a result of its use have not been well documented. Therefore, the purpose of the study was to determine and compare the soft tissue profile changes in patients with Class II Division 1 malocclusion treated in the mixed dentition with bionator to untreated controls.

The sample consisted of cephalograms of two groups of 30 caucasian individuals who were between 9 and 12 years of age at the start of treatment. The first group was treated with a bionator for 18 months resulting in a Class I molar relationship and successful reduction of overjet. The second group, acting as a control, consisted of individuals obtained from the Bolton-Broadbent Growth Study who did not receive any form of orthodontic treatment. The two groups were closely matched for age, sex, observation time, and dentofacial characteristics. The cephalograms were analyzed using a soft and hard tissue

cephalometric analysis as well as a cranial base superimposition analysis. The mean changes of each group were compared for significant differences with paired t-tests.

METHODS AND MATERIALS

Sample

The study sample consisted of 30 Bionator cases and 30 untreated controls between 9 years and 12 years 5 months of age with Class II Division 1 malocclusion (see Table 1).

In order to be included in the study, each subject had to possess the following characteristics: mixed dentition, ANB measurement of 5+ degrees, FMA measurement of 20-29 degrees, overjet of 6-10mm, positive overbite, complete records including lateral cephalograms taken with lips in repose, and noncontributory medical and dental history.

The 30 patients which were selected had been treated with a Bionator appliance in a private practice for an average treatment time of 18.2 months. In addition to the pre-treatment selection, the treated subjects included in the study had to have been treated successfully. Successful treatment was defined as a Class I molar relationship and less than 4 millimeters of overjet at the end of bionator therapy. Once the treated group had been chosen, it was closely matched for age, sex, treatment time, and dentofacial characteristics as mentioned above, with 30 untreated individuals from the Bolton-Broadbent Growth Study at Case Western Reserve University in Cleveland, Ohio.

Table 1:– Sample size, age, and amount of treatment or observation time

Group	Number	Mean Age Start	S.D.	Mean Tx or Obs. Time	S.D.
Bionator	30	10yr 6mos	1yr 2mos	18.7 mos	4.8mos
Control	30	10yr 6mos	1yr 1mos	18.3 mos	4.9mos
Total	60	10yr 6mos	1yr 2mos	18.5 mos	4.9mos

Appliance Design

The bionator was designed by Balters in the 1950's following the concept of Andresen's activator appliance which was the correction of malocclusion due to muscular function by anterior repositioning of the mandible. At the time of construction, a wax bite was taken in which the mandible was repositioned anteriorly to a point where the dentition was in proper overjet. Thus, the appliance postures and holds the mandible in the proper relationship. The bionator differs from the activator in that it is much less cumbersome (see Figure 1).

The bionator was comprised of connected acrylic upper and lower lingual flanges which extend in the posterior segments of the dentition. The flanges of the bionator are considerably shorter than those of the activator which increases comfort. Also unlike the activator appliance, the bionator does

not have acrylic palatal coverage but rather a palatal wire which leaves the palate clear for easier speech and normal tongue positioning during function.

The maxillary posterior teeth were guided by the acrylic channels allowing for distal eruption in the lingual flanges. In contrast, the mandibular posterior teeth were guided by the acrylic channels allowing for mesial eruption in the lingual flanges. The guiding channels allowed for some molar correction during extrusion. Furthermore, the extusion helped to decrease the deep overbite present in the Class II, Division 1 malocclusion.

The anterior teeth were held by two different means. The maxillary incisors were enclosed by a labial Hawley bow wire which allowed for tipping of the teeth if desired. The mandibular incisors were capped by acrylic to hold the angulation and prevent labial tipping due to the anterior repositioning of the mandible.

When the appliance was in the mouth the patient was asked to keep the lips together to form a lip seal. Upon placement of the appliance the patient was asked to wear it after school for the first day and then after school and at night the following two days. This adjustment period gave the patient time to become familiar with the bionator and was followed up by a telephone call from the orthodontist to address any questions and offer encouragement for compliance. After the 3 day adjustment period the bionator was worn 24 hours a day except during meals.

Full time wear continued throughout the active phase of bionator therapy, but once the treatment objectives were attained the patient began a retention phase. The retention phase lasted until fixed appliances were placed. During the retention phase the bionator was worn at night only.

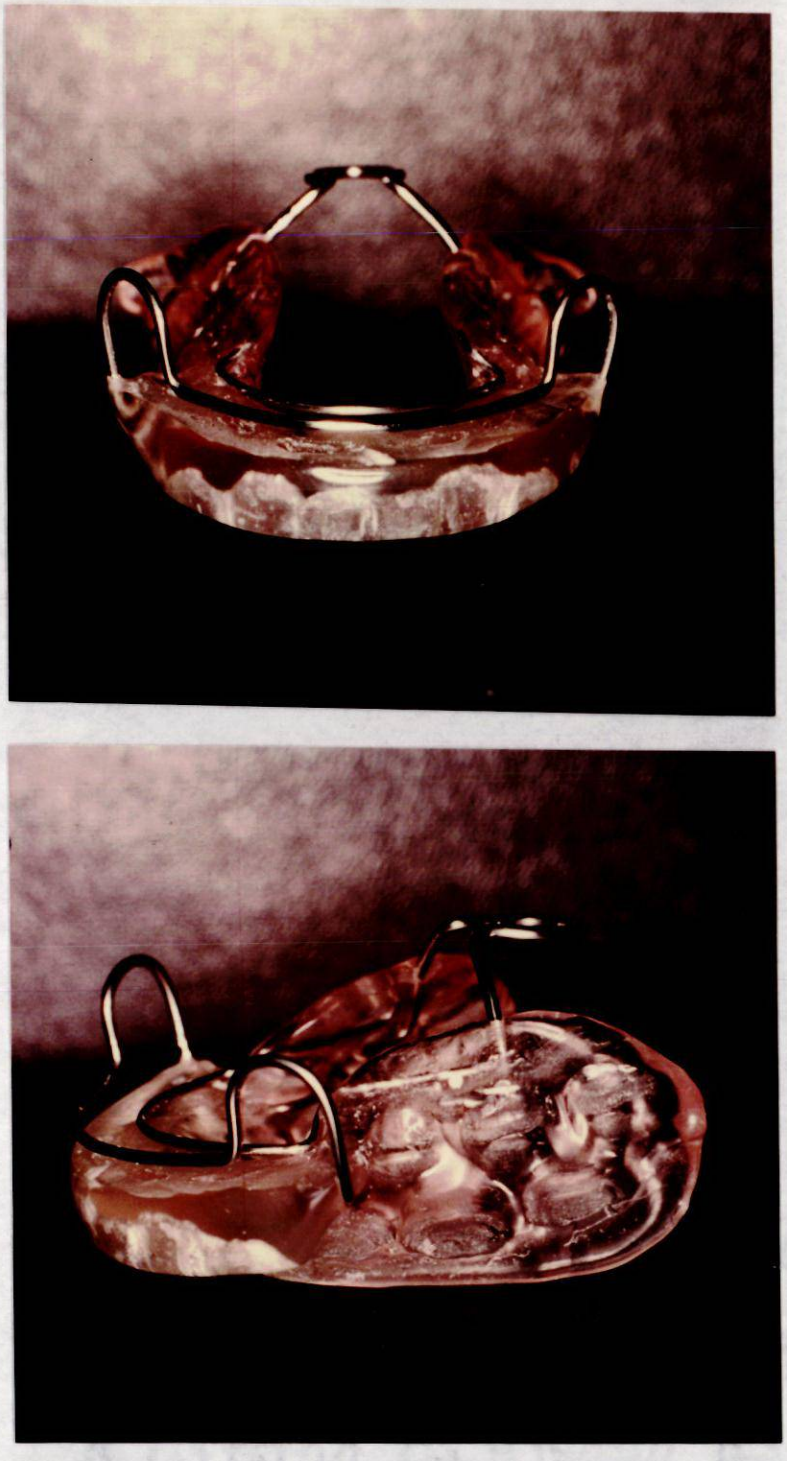


Figure 1. Frontal and lateral views of bionator appliance

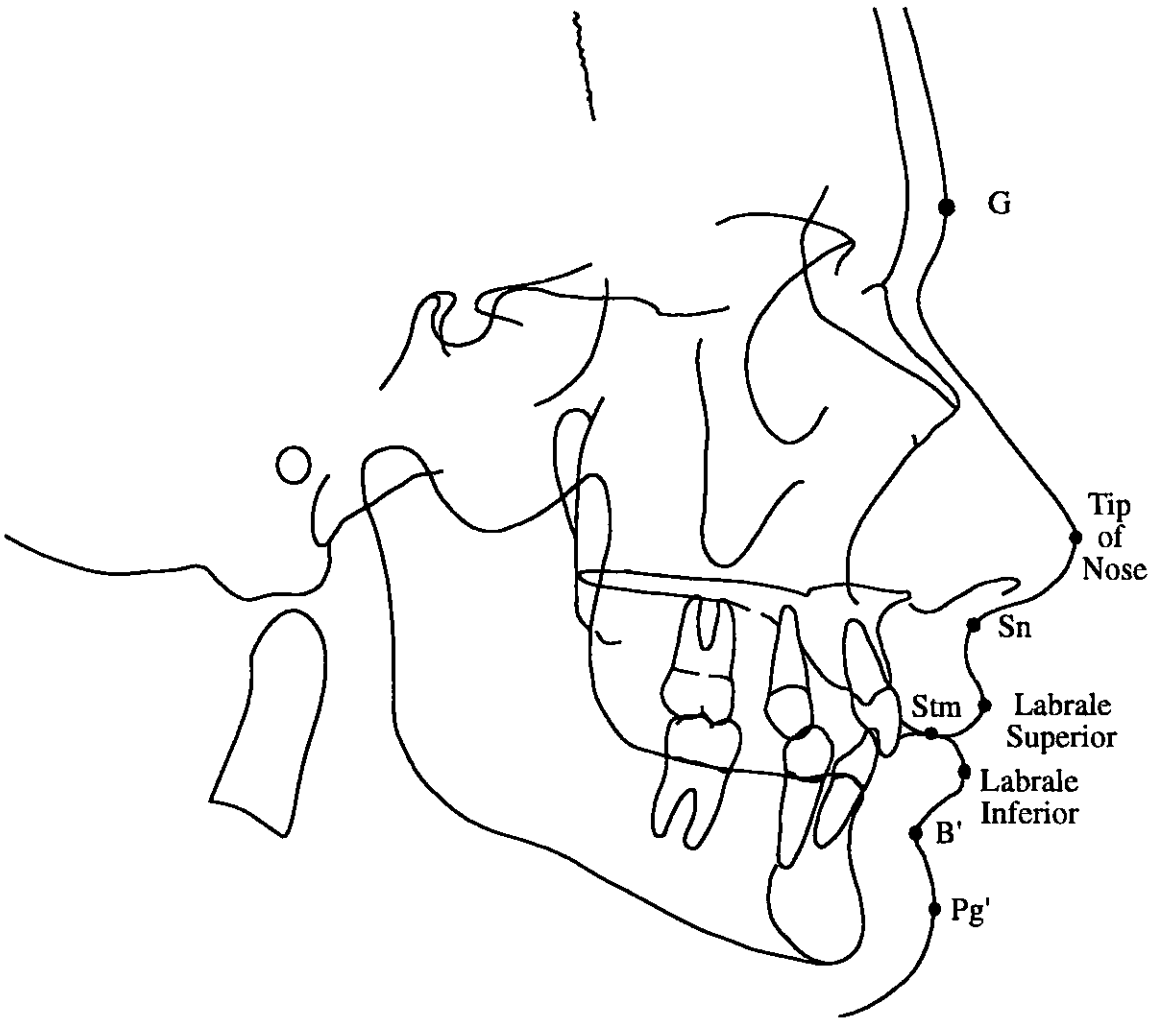


Figure 2. Soft tissue cephalometric landmarks.

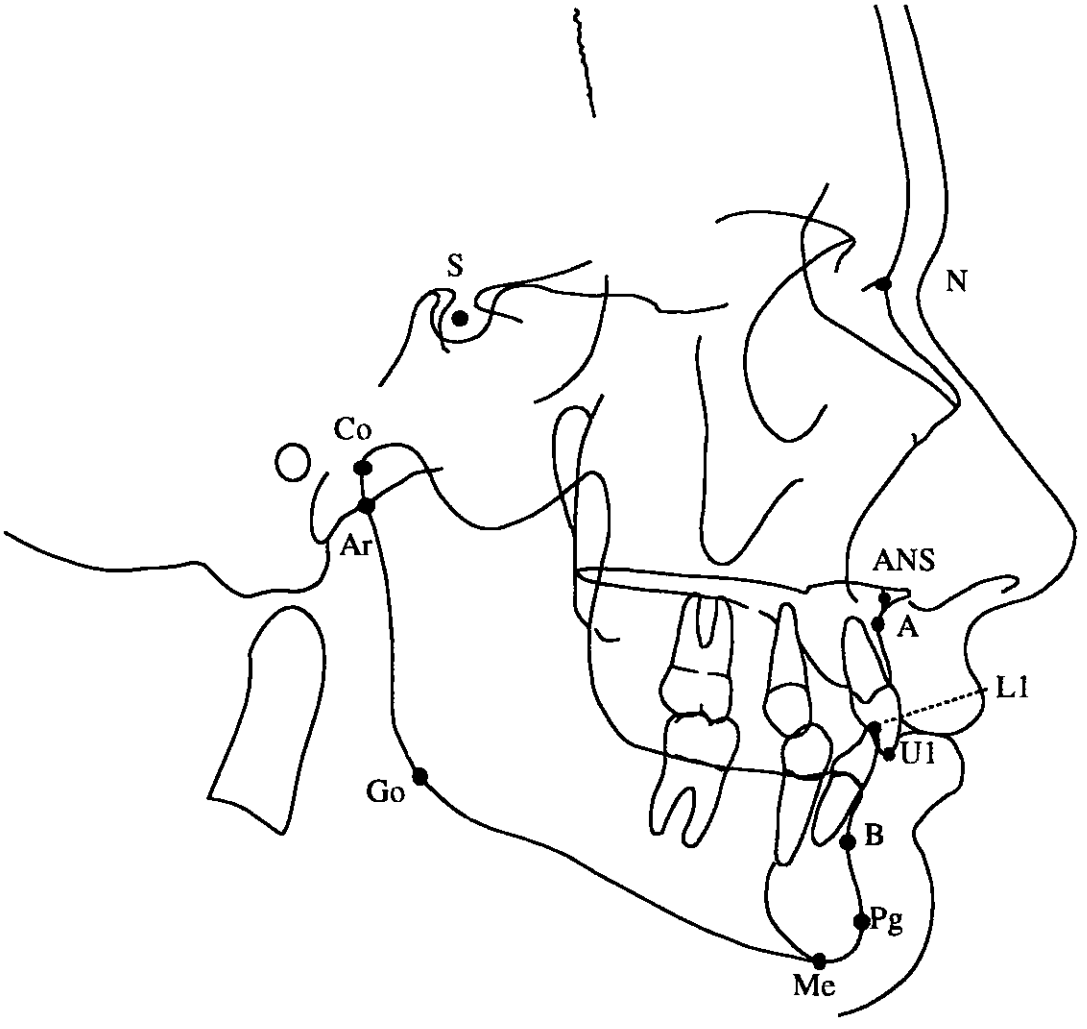


Figure 3. Skeletal and dental cephalometric landmarks

Cephalometric Analysis

Each of the 60 subjects had 2 lateral cephalograms. In the bionator group the cephalograms consisted of a pre-treatment and an end of Phase I radiograph. Since the control group was untreated the radiographs were selected to match the ages of the bionator group. Thus, each pair of subjects contained 2 sets of headfilms which were matched for age and treatment time. Once the subjects had been selected and matched each cephalogram was traced with a 0.5mm mechanical lead pencil on 0.003" matte acetate paper. A total of 23 landmarks were used to determine 40 cephalometric measures. The cephalometric landmarks are depicted in Figures 2 and 3 and are defined as follows:

A (A point):	The deepest midline point on the premaxilla between anterior nasal spine and prosthion (Downs)
A'(soft tissue A point):	The most posterior point on the concavity between Sn and Labrale superior
ANS (anterior nasal spine):	A center point at anterior nasal spine registered at 3mm vertical thickness (Harvold)

Ar (Articulare):	Point of intersection of dorsal contours of mandibular condylar process and temporal bone (Bjork)
B (B point):	The most posterior point in the concavity between infradentale and pogonion (Downs)
B' (soft tissue B point):	The most posterior point on the concavity between Labrale inferior and Pg'
Co (condylion):	The most posterior point on the contour of the condylar head (Harvold)
G (glabella):	Most prominent point in the midsagittal contour of the forehead
Gn (gnathion):	Most anterior and inferior point on the contour of the chin
Go (gonion):	Point on jaw angle that is most inferiorly and posteriorly directed
Labrale Superior:	The most anterior point on the contour of the upper lip
Labrale Inferior:	The most anterior point on the contour of the lower lip
Lower Incisor:	Lower incisal edge
Me (menton):	Lowermost point on the symphysial shadow

N (nasion):	Intersection of internasal suture with nasofrontal suture in the midsagittal plane
Tip of Nose:	The most anterior point on the contour of the nose
Pg (pogonion):	The most anterior point on the contour of the bony chin
Pg' (soft tissue pogonion):	The most anterior point on the contour of the soft tissue chin
S (sella):	Center of Sella Turcica
Sn (subnasale):	The most superior and posterior point on the curvature between the upper lip and inferior border or the nose
Stm: (stomion superior)	The most inferior point on the lower contour of the upper lip
(stomion inferior)	The most superior point on the upper contour of the lower lip
Upper Incisor:	Upper incisal edge

While the bionator affects the hard tissue profile it also directly impacts the soft tissue profile as well. Since a convex profile and severe dental prognathism have been found to be the least appealing profile (Cox & Van der Linden, 1971), the reduction of the mandibular retrognathia should have a positive impact on the overall facial esthetics. Therefore, the 3 angular and 11

linear measures which comprise the soft tissue analysis focus on two main factors: facial convexity and lip posture. Figures 4, 5 and 6 illustrate the measurements utilized in the soft tissue analysis.

The hard tissue analysis was comprised of 14 measurements, 6 angular and 8 linear, which are depicted in Figures 7 and 8. The hard tissue analysis included skeletal and dental measurements to quantify the effects of the bionator on the hard tissues of a growing patient.

The superimposition analysis was utilized to determine the direction of growth and treatment effects of bionator therapy. The pre-treatment and post-treatment radiographs for each subject were superimposed upon the anterior cranial base registering upon the greater wings of the sphenoid (Elmagian, 1959). Once the headfilms were superimposed, a X/Y coordinate system was used to quantify pre-treatment to post-treatment changes (Roos, 1979). Constructed Frankfort Horizontal plane served as the X axis and a vertical reference perpendicular to Frankfort Horizontal and passing through Sella point was the Y axis (see Figure 9). The T1-T2 changes in 12 hard and soft tissue landmarks were recorded to the nearest 0.5mm in both vertical and horizontal planes (see Figure 10).

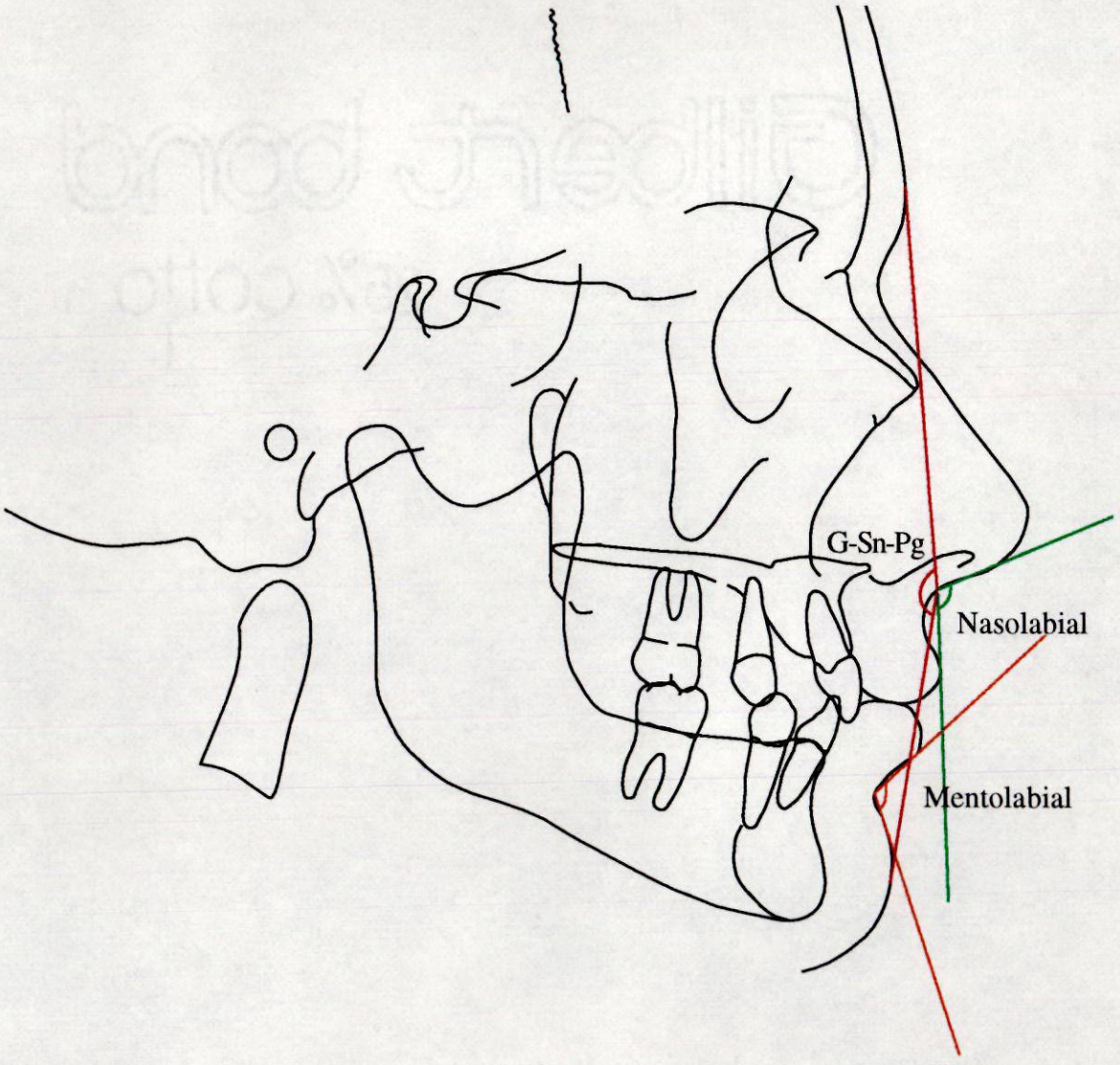


Figure 4. Soft tissue angular cephalometric measurements

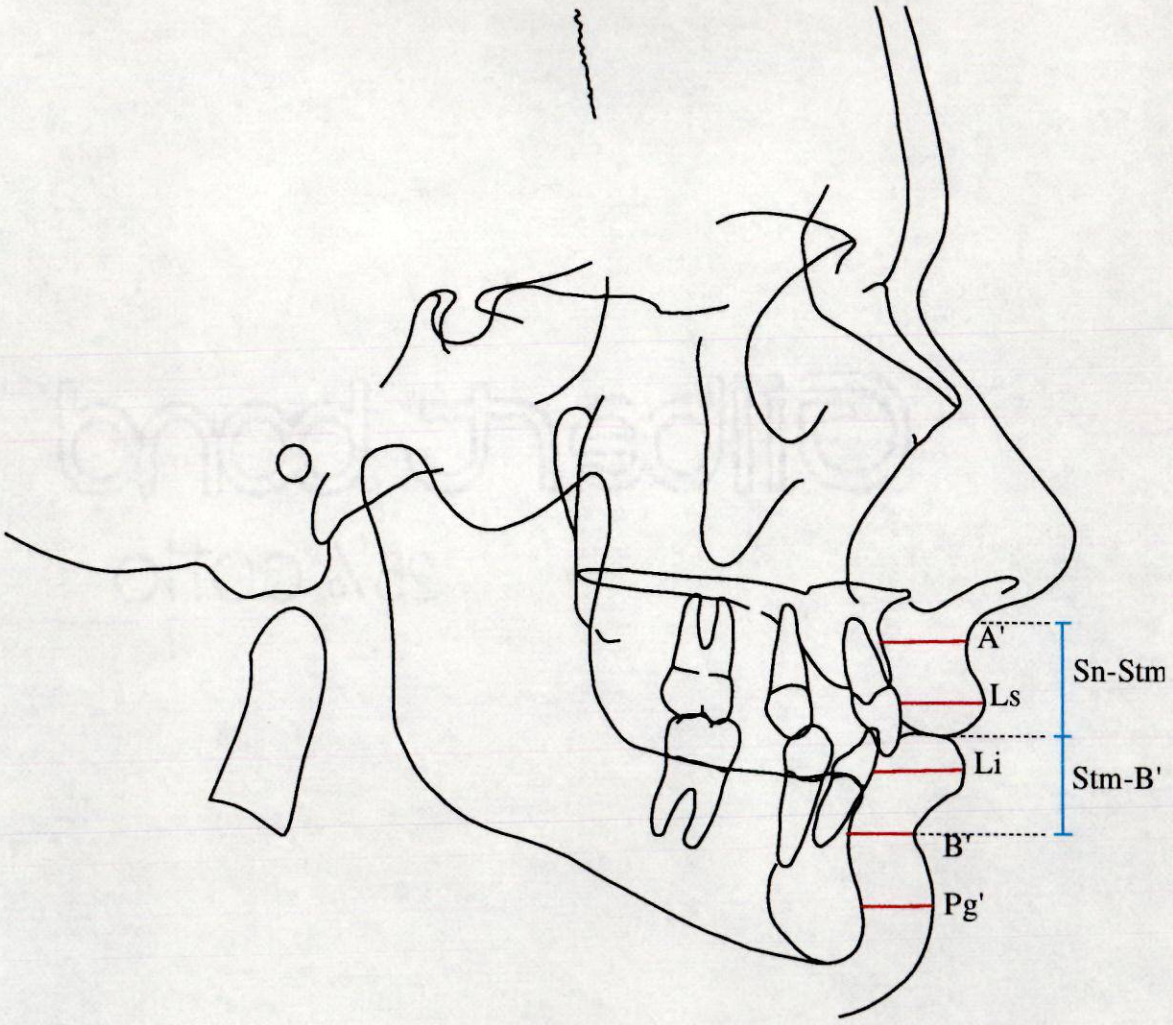


Figure 5. Soft tissue lip thickness and length measurements

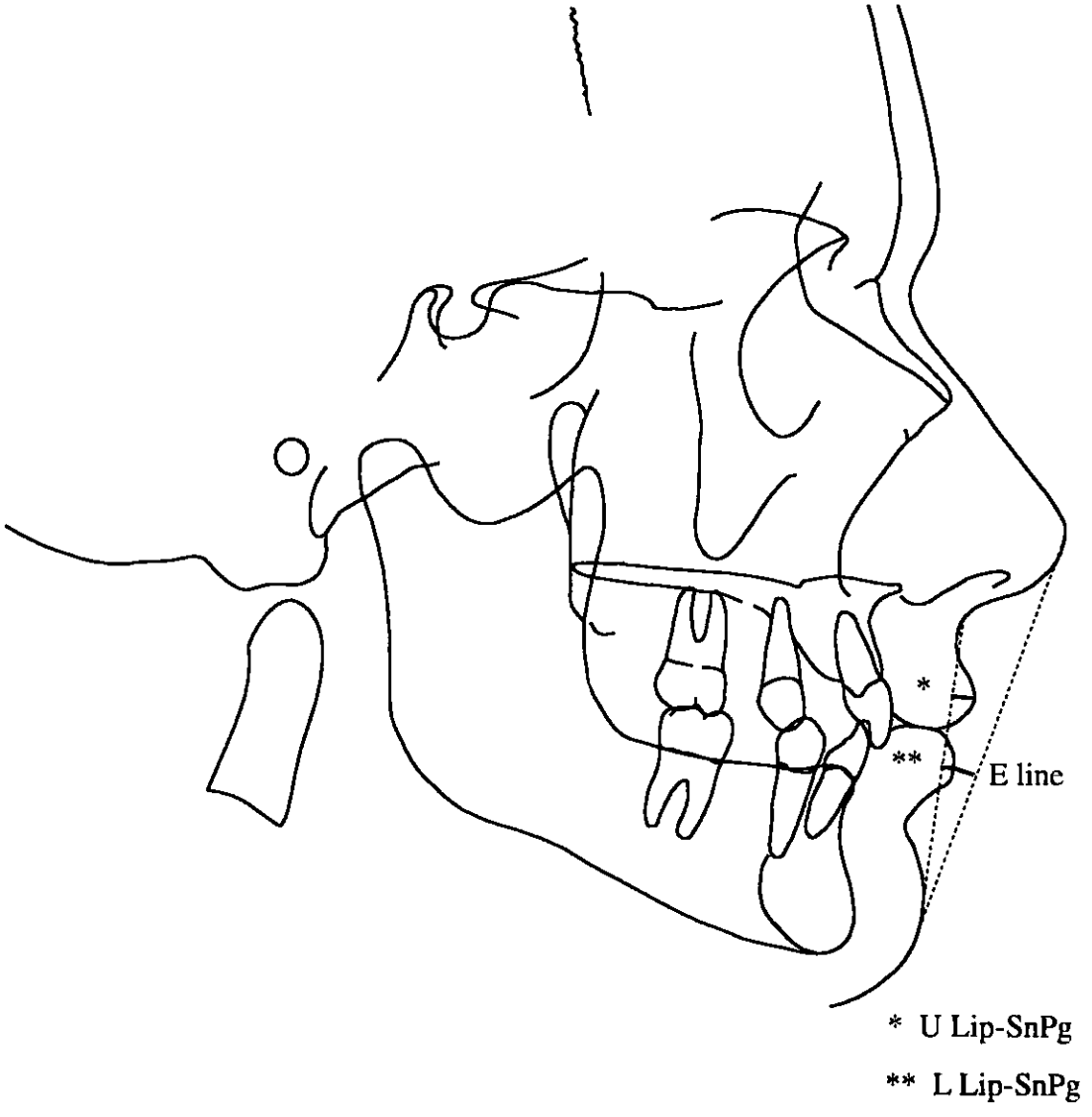


Figure 6. Upper and lower lip procumbency measurements

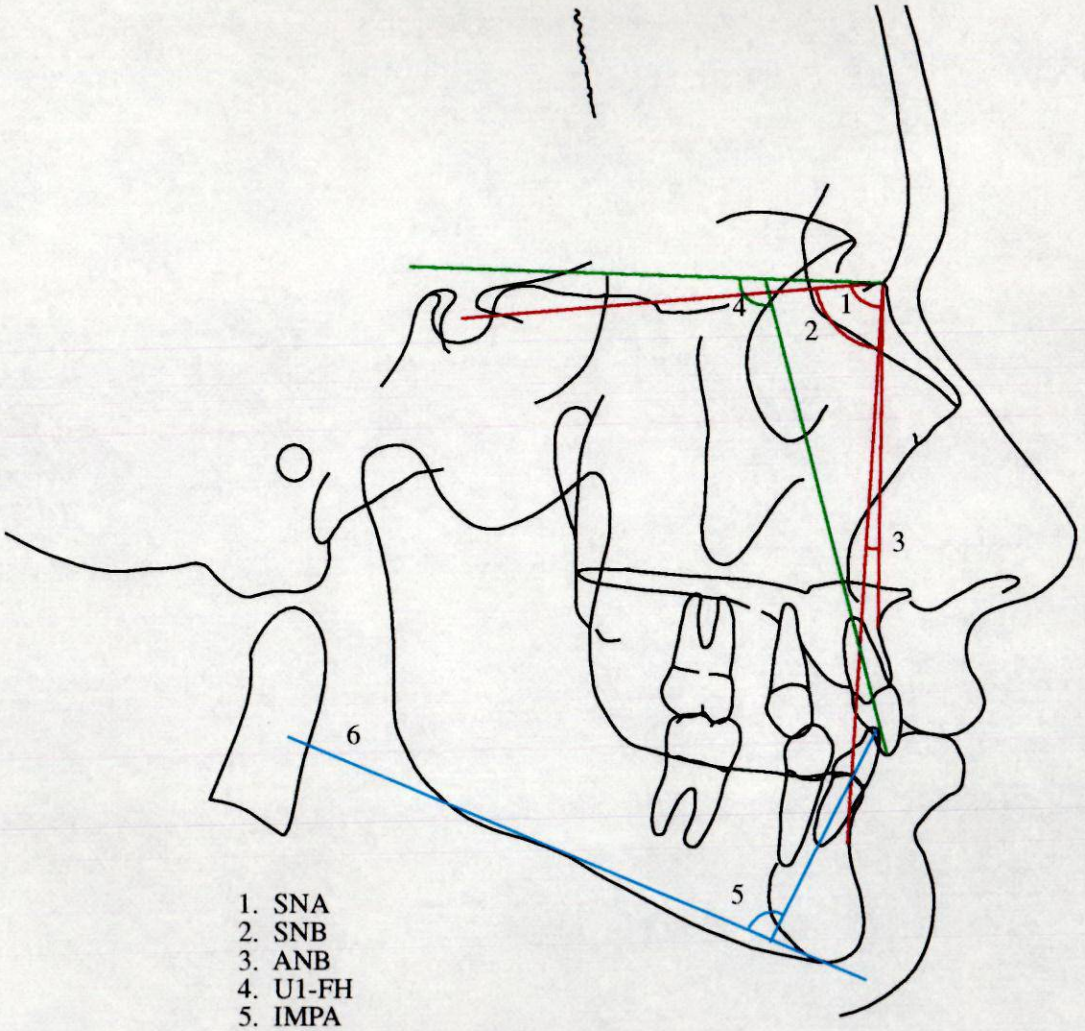


Figure 7. Skeletal and dental angular cephalometric measurements

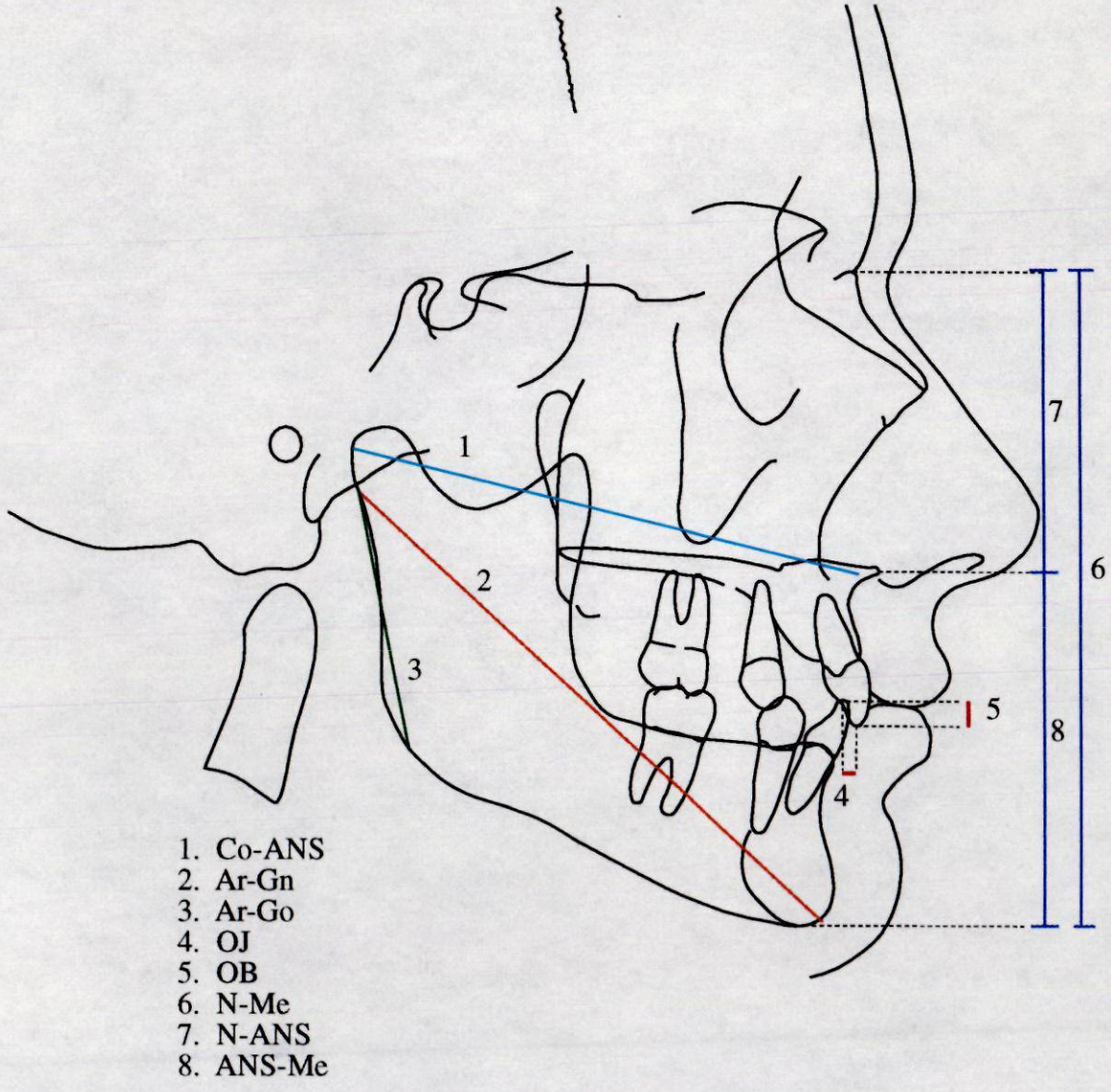


Figure 8. Skeletal and dental linear cephalometric measurements

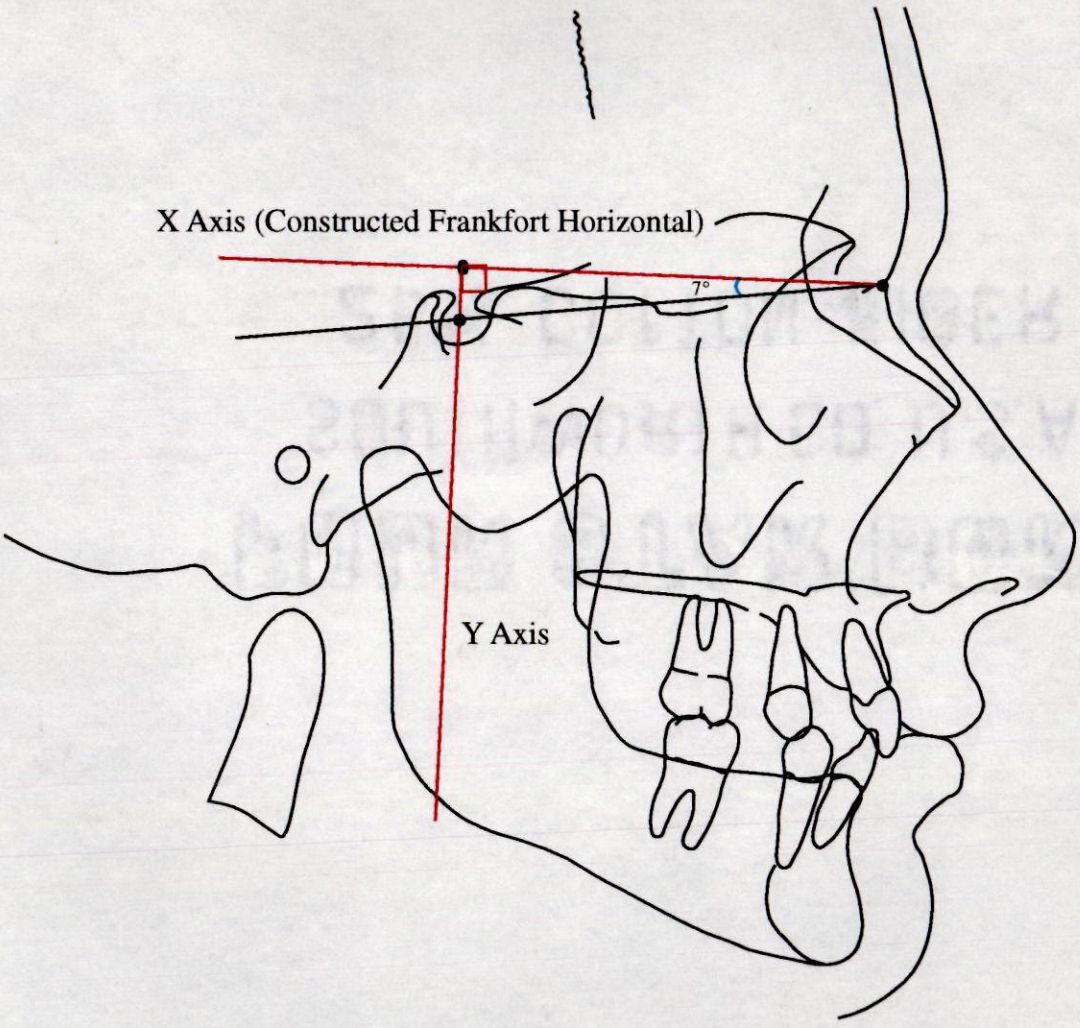


Figure 9. Cranial base superimposition reference planes

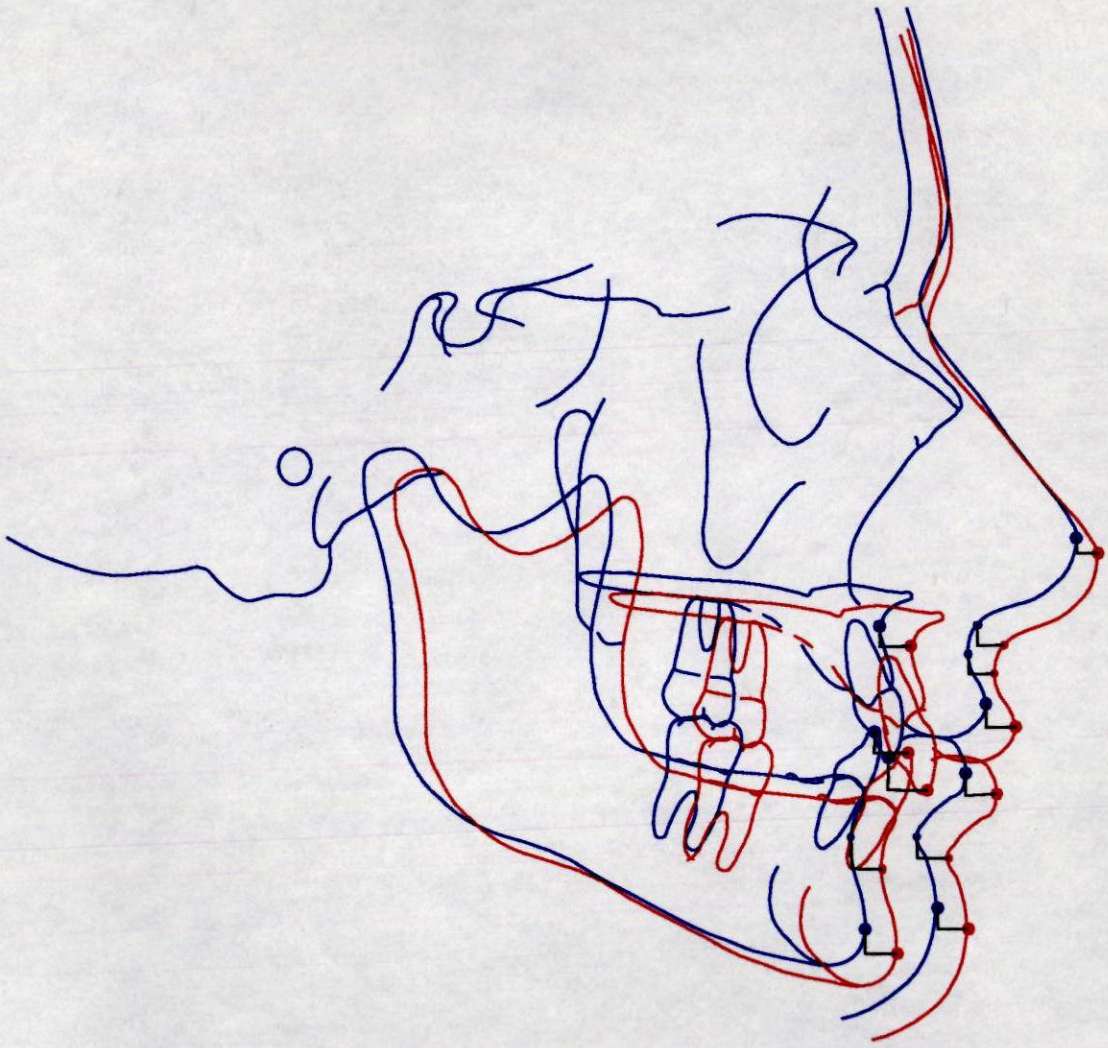


Figure 10. Superimposition analysis landmarks and measurements T1-T2

Statistical Analysis

The objective of the investigation was to determine the treatment effects of bionator therapy. Therefore, a matched sample for age, sex, treatment time, and dentofacial characteristics with paired t-tests were used to isolate treatment effect from normal growth. The statistical analysis was completed using the SPSS statistical software package in the Case Western Reserve Orthodontic Department. The program generated the mean value, standard deviation, standard error, and t value. Then the p values for statistical significance for each cephalometric measure were determined within the bionator group T1-T2, control group T1-T2, and most importantly for the mean change between bionator and control groups. Any p value ≤ 0.05 was a significant difference.

Error Analysis

Ten cephalograms were randomly selected in order to determine the degree of operator tracing and measurement error. The selected headfilms were retraced first then remeasured for all of the cephalometric dimensions. Once the second set of values were completed, statistically significant differences were ascertained using paired t-tests and correlation coefficients.

RESULTS

The matched sample and paired t-test allowed for comparison of the mean changes within both the treated and control group for significant treatment effect. The changes observed during the 18 month observation period in the control group served as a baseline for normal growth in untreated individuals with a Class II, Division 1 malocclusion. Once normal growth had been quantified, the values were subtracted from the changes observed in the bionator group in order to isolate treatment effect from growth. The soft tissue changes within both groups as well as the treatment effects are presented in Tables 2. Also, Figures 11 and 12 demonstrate the overall changes seen within one of the bionator subjects.

Soft Tissue

Facial Form

The most significant treatment effects upon the facial profile was exhibited in the G-Sn-Pg angle. G-Sn-Pg is a measure of soft tissue convexity and decreased 2.22° in the treated group which represented a significant ($p \leq 0.001$) reduction in the convexity of the profile (see Figure 13). Interlabial gap decreased in both groups, however, neither were the changes within the groups nor the mean change between the groups found to be significant.

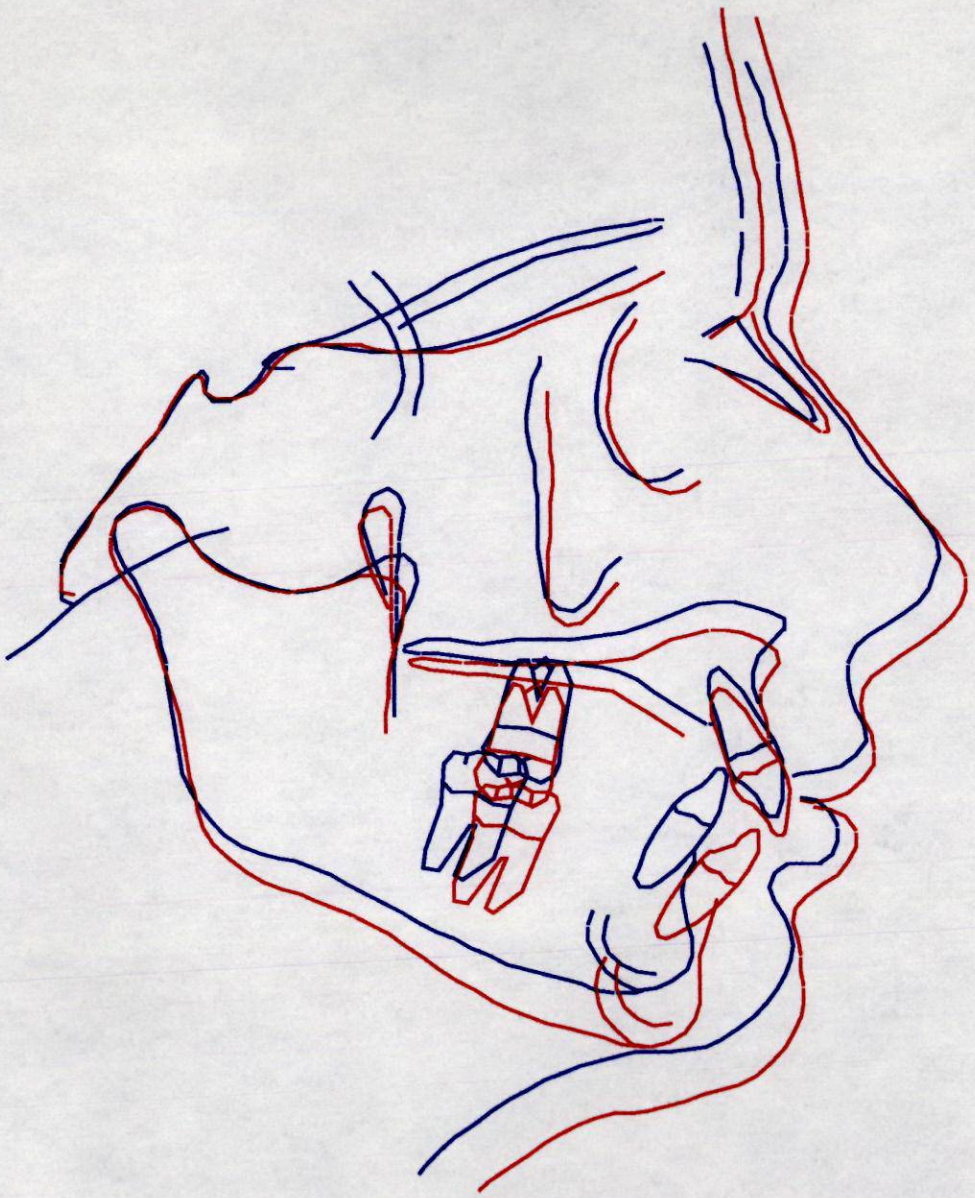


Figure 11. Cranial base superimposition of bionator patient JH
(Blue= pre-treatment/ Red= post-treatment)

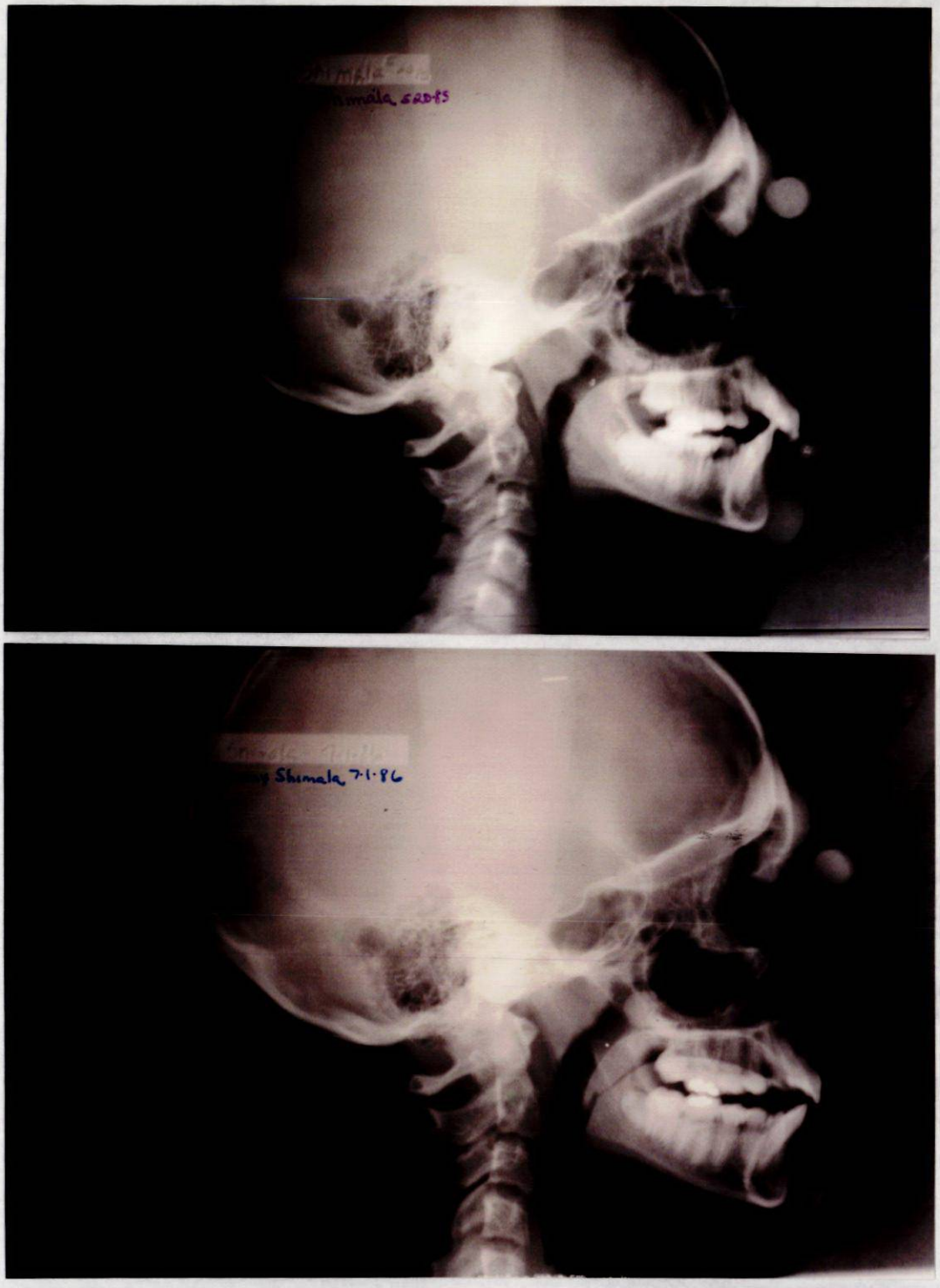


Figure 12. Pre-treatment and post-treatment lateral cephalograms of bionator patient JH (top photograph= T1/ bottom photograph= T2)

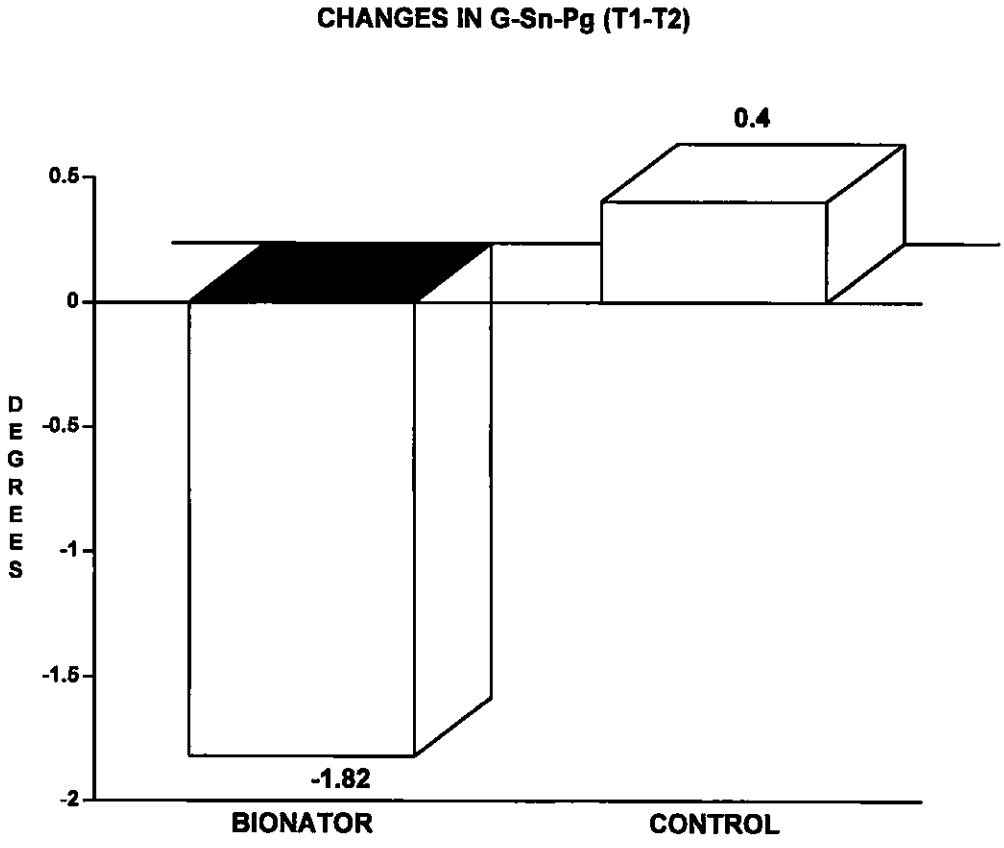


Figure 13. The mean changes in G-Sn-Pg angle for bionator and control groups (T1-T2).

Table 2.–Comparison of soft tissue changes in the treatment and control groups (T1-T2).

Measurements	*Treatment Group (N = 30)*		*Control Group (N = 30)*		*Mean*	
	Mean	*SD*	*Mean*	*SD*	*Difference*	*p value*
Facial						
G-Sn-Pg(°)	-1.82	1.5	0.40	1.9	-2.22	0.000*
Interlabial Gap(mm)	-0.85	2.6	-0.42	1.2	-0.43	0.455
Upper Lip						
Length						
Sn-Stm(mm)	0.58	1.8	0.33	1.0	0.25	0.456
Thickness						
A'(mm)	0.53	1.3	0.31	1.3	0.22	0.561
Labrale Superior(mm)	0.37	1.7	0.48	1.6	-0.12	0.783
Procumbency						
Upper Lip to Sn-Pg(mm)	-1.32	1.3	-0.18	1.3	-1.13	0.002*
Nasolabial Angle(°)	3.10	7.8	-0.12	7.2	3.22	0.144
Lower Lip						
Length						
Stm-B'(mm)	2.63	1.9	0.10	1.7	2.53	0.000*
Thickness						
B'(mm)	0.92	0.9	0.42	1.3	0.50	0.102
Labrale Inferior(mm)	-1.87	2.4	0.78	1.6	-2.65	0.000*
Procumbency						
Lower Lip to Sn-Pg(mm)	-0.22	1.7	-0.28	1.3	-0.07	0.850
Lower Lip to E Line(mm)	-1.07	1.7	-0.60	1.5	-0.47	0.259
Mentolabial Angle(°)	15.20	15.8	-2.20	12.4	17.40	0.000*
Chin						
Thickness						
P'(mm)	0.58	1.1	0.75	1.1	-0.17	0.529

*$p \leq 0.05$

Upper Lip

There was no significant differences between the treated and control subjects for upper lip length, thickness at point A' or labrale superior. All 3 measurements showed less than 0.25mm difference between the bionator and untreated cases. While the difference in nasolabial angle was not found to be

significant, there was an increase of 3° in the bionator group. The one factor which was found to be significant ($p \leq 0.01$) was Upper Lip to Sn-Pg. The protrusion of the upper lip decreased by 1.32mm in the treated cases.

Lower Lip

The lower lip was the region of the integumental profile which demonstrated the majority of the significant changes (see Figure 14). The bionator therapy had an uncurling effect on the lower lip. The uncurling was a result of the significant ($p \leq 0.001$) changes seen in Mentolabial angle, lip length, and tissue thickness. Mentolabial angle increased 15.2° in the bionator cases and decreased 2.2° in the control. Thus, there was an overall opening of the mentolabial angle of 17.4° as a result of treatment. Concurrent with the angular change, the lip length increased 2.53mm and the lip thickness decreased 2.65mm. Both measurements were significant at the 0.001 level. The areas which did not show significant change due to treatment were lower lip procumbency and B' thickness.

Chin

Soft tissue pogonion thickness was not found to be significantly changed as a result of treatment or normal growth. During the 18 month observation period of the study the integumental thickness at Pg' was stable and varied less than 1mm in either group.

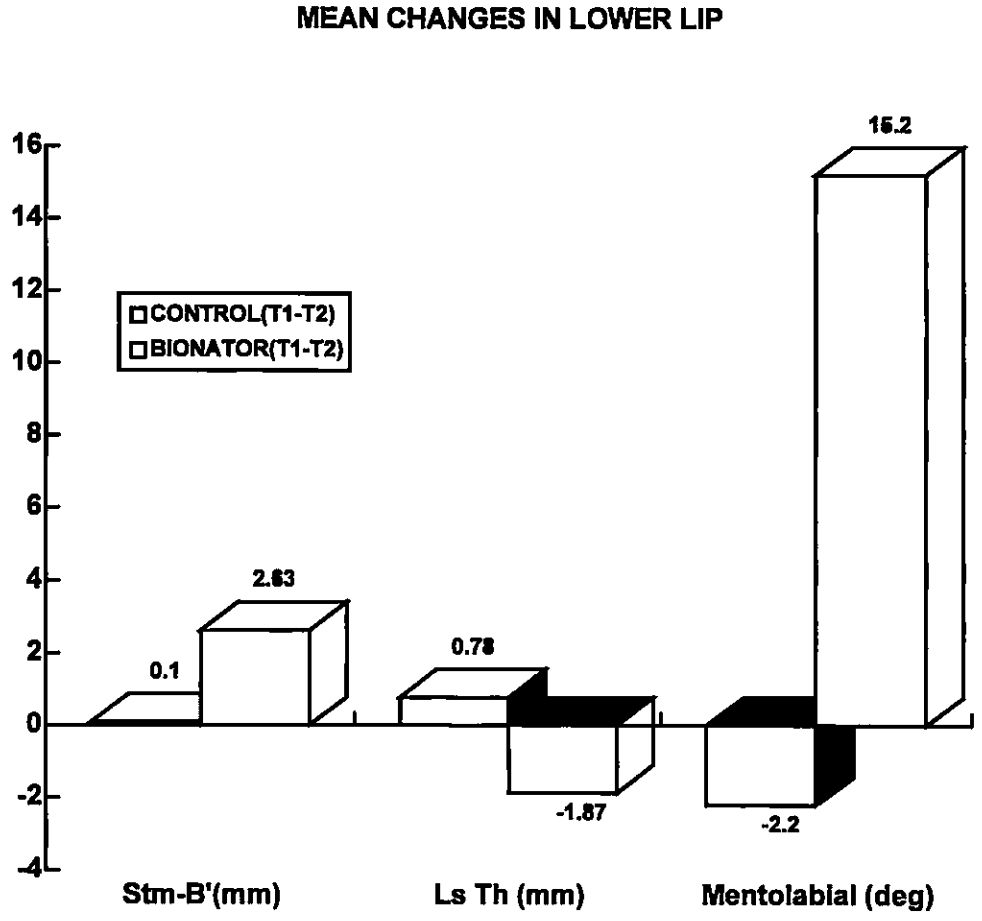


Figure 14. Mean changes in lower lip length (Stm-B'), thickness (Ls Th), and angulation (Mentolabial angle) during the 18 months.

Table 3.–Comparison of soft tissue changes in the treatment and control groups(T1-T2) as determined by cranial base superimposition.

Measurements	*Treatment Group (N = 30)*		*Control Group (N = 30)*		*Mean*	
	Mean	*SD*	*Mean*	*SD*	*Difference*	*p value*
Superimposition						
Horizontal (mm)						
Nose	3.23	1.8	3.38	2.0	-0.15	0.758
Sn	2.10	1.4	2.60	1.4	-0.50	0.158
A'	1.63	1.8	2.73	1.5	-1.10	0.008*
Labrale Superior	1.17	2.0	2.53	1.5	-1.37	0.009*
Labrale Inferior	2.53	2.3	2.82	1.4	-0.28	0.576
B'	3.30	2.0	2.58	1.5	0.72	0.128
P'	3.73	2.0	2.80	1.2	0.93	0.012*
Vertical (mm)						
Nose	2.63	1.8	1.07	1.3	1.57	0.000*
Sn	3.00	1.6	1.83	1.7	1.17	0.009*
A'	4.10	1.8	2.03	1.4	2.07	0.000*
Labrale Superior	3.83	1.9	2.01	1.5	1.82	0.000*
Labrale Inferior	4.33	3.0	1.58	2.0	2.75	0.000*
B'	5.73	2.7	1.67	2.0	4.07	0.000*
P'	5.73	2.9	2.47	2.1	3.27	0.000*

*$p \leq 0.05$

Cranial Base Superimposition

The superimposition technique was utilized to determine the bionator effect of the direction of growth as compared to an untreated control. The changes observed in seven soft tissue landmarks were recorded to the nearest 0.5mm in both the horizontal and vertical planes. The 7 landmarks recorded changes in 4 facial components: nose, upper lip, lower lip, and chin. The results for both treated and control groups are presented in Table 3.

Of the four regions, only the upper lip and chin demonstrated significant change in the horizontal plane. The upper lip was represented by A' and Labrale superior. A' moved anteriorly an average of 1.10mm less in the bionator

group when compared to the control. Similarly, labrale superior moved anteriorly 1.37mm less during treatment as compared to the untreated subjects. Both of these differences were significant ($p \leq 0.01$). There was also a significant change ($p \leq 0.01$) in Pg' witnessed in the patients which underwent bionator therapy. The treated subjects demonstrated an average 3.73mm anterior movement of Pg' and the controls 2.80mm. Thus, the treated group displayed 0.93mm additional anterior movement than the control group.

The nose and lower lip did not demonstrate significant differences between the treated and control groups, however, there was a reduction in anterior migration of both in treated subjects.

The vertical dimension of all the soft tissue regions displayed significant increases ($p \leq 0.001$) during treatment. The tip of the nose dropped downwards 1.57mm more in the bionator subjects than the untreated. A' and labrale superior also moved downwards an additional 2.07mm and 1.82mm in the bionator group when compared to the control. During the 18 months of treatment there was 5.73mm of downward movement in B' point and 2.75mm in Labrale inferior. The same 18 month observation period of the untreated subjects resulted in 1.67mm of downward displacement of B' point and 1.58mm in Labrale inferior. The difference between the groups showed a greater downwards movement of 4.07mm in B' and 2.75mm in Labrale inferior in the treated subjects. Finally, the chin descended 5.73mm in the treated group which was 3.27mm more than the 2.47mm in the control group.

Hard Tissue

While the primary objective of the study was to determine the treatment effect of the bionator on the soft tissue, changes in the underlying hard tissue can have a direct effect on the integumental drape. Therefore, the mean changes as a result of the bionator are included in the study and are presented in Table 4.

Mandible

Mandibular length demonstrated significant increase in both the bionator and untreated subjects during the 18 month period of the study. However, the overall mean difference in Ar-Gn between the two groups was significant ($p \leq 0.001$). In the treated group the length of the mandible increased an average of 3.62mm as compared to 2.83mm in the control group during the 18 month time span (see Figure 15). In addition to the increased length, the SNB angle increased 1.05° more in the bionator cases which was significant at the 0.001 level. One factor which did not differ was FMA angle. The average change in mandibular plane was 0.28° in the treated group and -0.22° in the control group.

Table 4.–Comparison of hard tissue changes in the treatment and control groups (T1-T2).

Measurements	*Treatment Group (N = 30)*		*Control Group (N = 30)*		*Mean Difference*	*p value*
	Mean	*SD*	*Mean*	*SD*		
Mandible						
AP						
SNB(°)	1.58	1.3	0.53	0.7	1.05	0.000*
Length						
Ar-Gn(mm)	6.45	2.0	2.83	1.7	3.62	0.000*
Rotation						
FMA(°)	0.28	1.5	-0.22	1.1	0.50	0.116
Maxilla						
AP						
SNA(°)	-0.50	1.0	0.40	0.7	-0.90	0.001*
Co-ANS(mm)	2.30	2.0	2.77	1.5	-0.47	0.273
Facial Height						
Anterior						
N-Me(mm)	6.33	2.2	2.98	1.9	3.35	0.000*
N-ANS(mm)	3.45	3.4	1.57	1.2	1.88	0.008*
ANS-Me(mm)	2.88	3.8	1.35	1.8	1.53	0.039*
Posterior						
Ar-Go(mm)	3.73	1.2	1.53	1.4	2.20	0.000*
Facial Convexity						
ANB(°)	-2.08	1.0	-0.11	0.6	1.97	0.000*
Dentition						
Overjet(mm)	-4.63	0.8	0.12	0.8	-4.75	0.000*
Overbite(mm)	-2.45	1.8	0.70	1.1	-3.15	0.000*
U1-FH(°)	-4.28	4.4	-0.35	3.6	-3.93	0.000*
IMPA(°)	0.22	3.8	-0.23	3.2	0.45	0.579

*$p \leq 0.05$

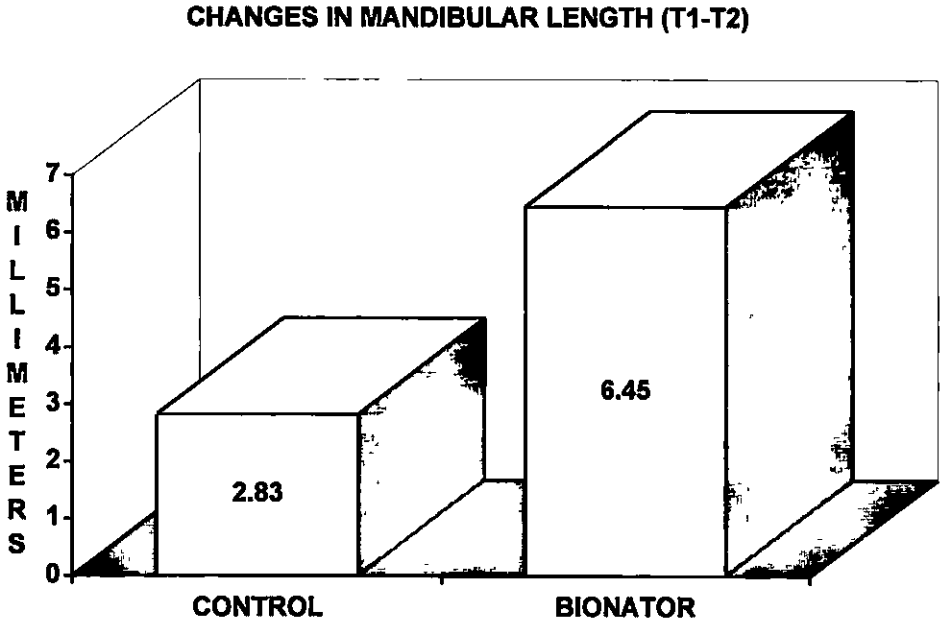


Figure 15. Mean increase in the length of the mandible (Ar-Gn) in control and bionator groups during the 18 months of the study

Maxilla

There was a significant difference found in SNA angle between the treated and untreated group ($p \leq 0.001$). SNA decreased 0.50° in the bionator cases and increased 0.40° in the controls. The mean difference in Co-ANS was not found to be significant, however, the treated cases did demonstrate 0.47mm less anterior movement than what was seen in the Bolton sample.

Facial Convexity

Skeletal convexity was measured by the ANB angle. The mean change in the treated sample was -2.08 degrees and the mean change in the control group was -0.11 degrees. Therefore, there was an overall 1.97 degree reduction of the ANB angle in the bionator group as compared to the control group which was significant at the 0.001 level (see Figure 16).

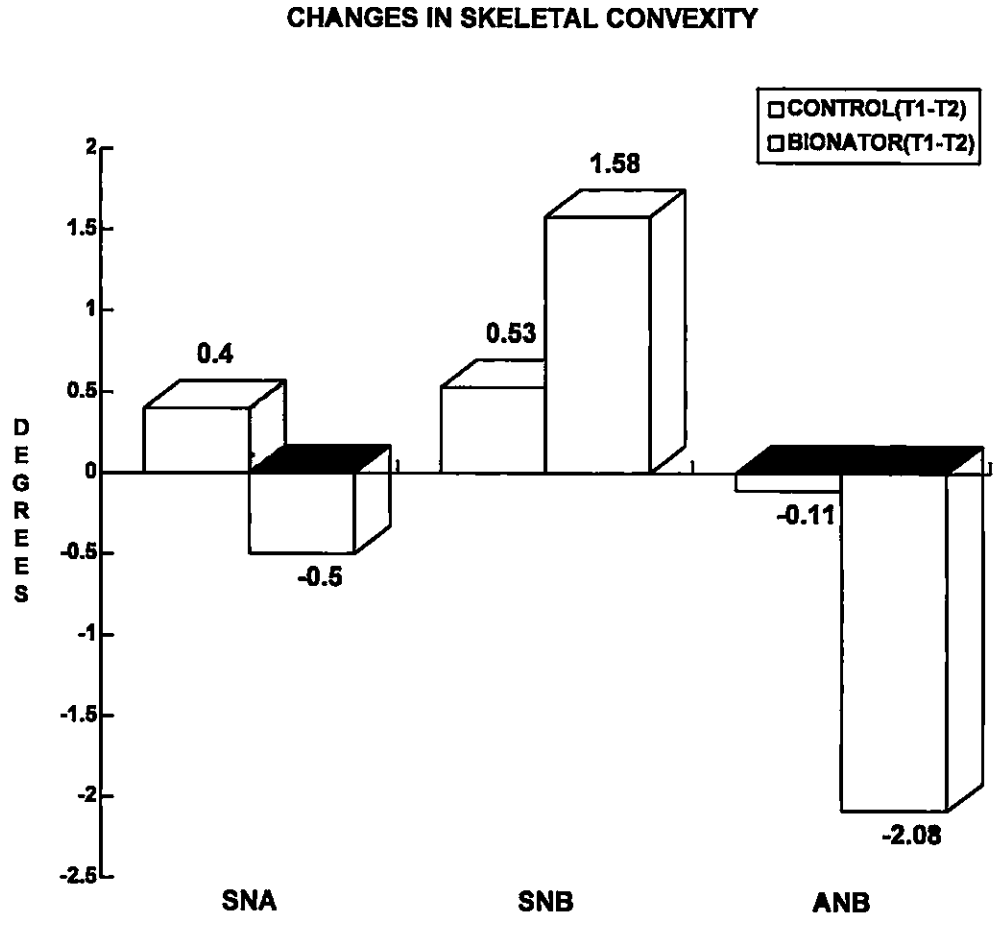


Figure 16. Mean changes in skeletal convexity in the treated and control groups (T1-T2).

Facial Height

Anterior and posterior facial height underwent significant ($p \leq 0.05$) increases between T1 and T2 for both the treated and control groups. The mean differences between treated and control groups for anterior and posterior facial height were also found to be significant. Overall anterior facial height (N-Me) increased 3.35mm more in the bionator patients than the controls ($p \leq 0.001$). Upper facial height, N-ANS, increased an average of 1.88mm more in the treated group which was significant ($p \leq 0.01$). Lower facial height, ANS-Me, also demonstrated a mean increase. The bionator therapy added 1.53mm more lengthening in ANS-Me which was found to be significant ($p \leq 0.05$). Posterior facial height was measured by Ar-Go. The mean difference between bionator and Bolton subjects demonstrated a significant ($p \leq 0.001$) additional increase of 2.20mm in the treated group. Thus, all four measurements of facial height showed a significant increase during the 18 months as a result of normal growth but treatment extended the average increase significantly.

Dentition

The dentition was found to undergo a number of significant changes due to bionator therapy (see Figure 17). Overjet was relatively stable in the control group with an average 0.12mm increase during the observation period. In contrast, bionator therapy demonstrated a 4.63mm decrease in overjet. Therefore, the total bionator effect was a 4.75mm reduction of overjet which was determined to be highly significant ($p \leq 0.001$). Bionator treatment was

also found to have a reducing effect on overbite as compared to normal growth. Overbite deepened 0.70mm during the 18 month period in the control group. The treated group showed a 2.45mm decrease in overbite during the same time for an overall treatment effect of 3.15 reduction. This effect was significant at the 0.001 level.

Bionator treatment did not have the similar effects of the angulation of the incisors. Upper incisor angulation illustrated by U1-FH showed a 3.93° uprighting effect of bionator therapy. The uprighting was significant at the 0.001 level. Unlike the upper incisor effect, lower incisor angulation was shown not to change. IMPA decreased 0.23° in the control and increased 0.22° in the appliance group during the treatment time. The resultant 0.45° mean difference was not determined to be significant.

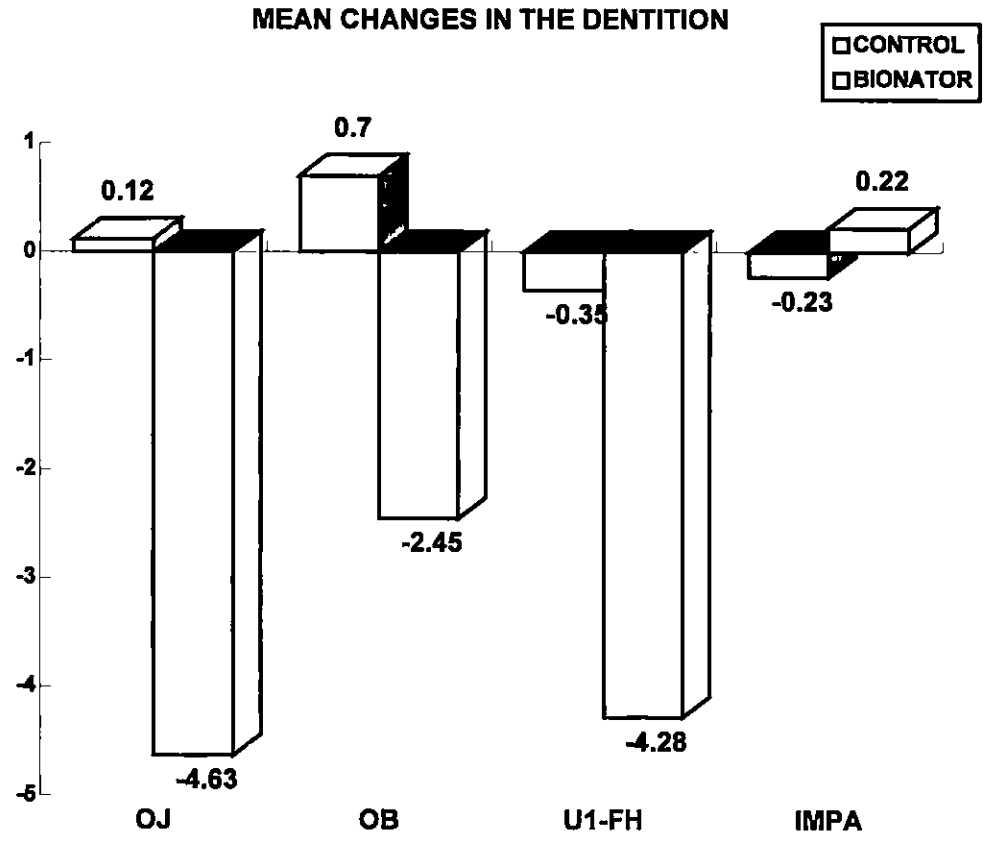


Figure 17. Comparison of dental changes in the treated and control groups (T1-T2)

Cranial Base Superimposition

The 5 landmarks which were tracked in the hard tissue superimposition represented the skeletal and dental components of the midface. A point represented the maxilla, upper incisal edge the maxillary dentition, lower incisal edge the mandibular dentition, B point the mandible, and Pg point the bony chin. The treatment effect of the bionator appliance was followed in the horizontal and vertical planes and demonstrated similar results to the soft tissue effects. The results are presented in Table 5.

The maxillary measures both displayed a posterior tendency in the horizontal plane which were significant ($p \leq 0.001$). A point moved back 1.17mm and upper incisal edge 2.47mm more in the treated group as opposed to the control sample. In contrast, the lower half of the lower face showed an increased anterior movement during treatment. Mandibular dentition (lower incisal edge) moved forward an average of 1.27mm more in the bionator cases. The mandible and chin also moved anteriorly but to a lesser degree than the dentition. B point came forward 0.80mm ($p \leq 0.05$) and Pg point 0.93mm ($p \leq 0.01$).

The vertical component of the treatment effect closely resembled the soft tissue changes. All five measurements demonstrated an additional downward displacement which was significant at the $p \leq 0.001$ level.

Table 5. Comparison of skeletal and dental changes in the treatment and control groups (T1-T2) as determined by cranial base superimposition.

Measurements	*Treatment Group (N = 30)*		*Control Group (N = 30)*		*Mean Difference*	*p value*
	Mean	*SD*	*Mean*	*SD*		
Superimposition Changes						
Horizontal (mm)						
A	0.82	1.3	1.98	1.1	-1.17	0.000*
Upper Incisal Tip	-0.30	1.9	2.17	1.6	-2.47	0.000*
Lower Incisal Tip	3.43	1.7	2.17	1.4	1.27	0.002*
B	2.80	1.8	2.00	1.2	0.80	0.048*
P	3.13	1.7	2.20	1.1	0.93	0.010*
Vertical (mm)						
A	3.53	1.3	1.47	1.3	2.07	0.000*
Upper Incisal Tip	3.23	1.9	1.85	1.3	1.38	0.000*
Lower Incisal Tip	5.60	1.6	1.47	1.4	4.13	0.000*
B	6.13	1.7	2.43	1.8	3.70	0.000*
P	5.97	2.0	2.68	1.6	3.28	0.000*

*$p \leq 0.05$

Error Analysis

Ten cephalograms were randomly selected to determine measurement and tracing error. The 10 radiographs were traced and cephalometric values measured a second time in order to determine significant differences as assessed by paired t-test and correlation coefficient. The results of both analyses are presented in Appendix B. None of the measurements were found

to be signifcantly different, however, Sn-Stm approached significance ($p = 0.089$). In addition, the correlation coefficients were found to be high. All of the measurements were determined to have correlation coefficients above 90% except for Upper Lip Thickness (85.2%) and B' Thickness (87.3%).

DISCUSSION

The bionator is a widely used treatment modality for the Class II, Division 1 malocclusion. Functional appliances were developed in Europe and have been prevalent in European orthodontics for the past 50 years. However, the same is not true for the United States. Orthopedic appliances have only become popular and widely used in the U.S. in the past 15 years.

The skeletal and dental effects of bionators have been well documented in both the U.S. and Europe. While the hard tissue treatment effects have been widely studied the conclusions have been mixed. Some studies have reported skeletal changes (Forsberg and Odendrick, 1981; Mamandras, 1990). Other studies have found only dentoalveolar compenstions (Johnston, 1986). There are also articles which attribute the results of treatment to change in muscle function brought about by the functional appliance (Frankel, 1969; Pancherz, 1981). Regardless of how the malocclusion is corrected, the final clinical result was an improvement in facial esthetics.

One component of bionator therapy which has not been quantified is the effect on the integument and consequently esthetics. Therefore, the primary objective of the study was to determine the treatment effects of the bionator appliance on the soft tissue profile and secondarily on the skeletal and dental

bony tissues since the integument can be directly influenced by changes in the hard tissue.

In order to separate treatment effects from growth, 2 groups of 30 subjects matched for age, sex, treatment time, and dentofacial characteristics was examined. The first group consisted of patients who had undergone successful bionator treatment for Class II, Division 1 malocclusion and the second group was an untreated control from the Bolton-Broadbent Growth Study, Cleveland, Ohio. Finally, cephalometric analysis determined that there were significant changes in the soft tissue profile, skeletal and dental tissues, and direction of growth.

Hard Tissue

Maxilla

The changes seen in SNA was not found to be significant T1-T2 for the control group but the bionator group T1-T2 change was significant at the 0.001 level. SNA angle decreased 0.90° in the treated group.

The cranial base superimposition analysis also displayed restriction of the maxilla in the AP plane for the treated group. The overall anteroposterior change witnessed in the maxilla for the treatment group was a positive 0.82mm. This was 1.17mm less than the anterior change seen in the control group. A point did move forward but the amount was significantly ($p \leq 0.001$) less than normal growth.

While it was noted that bionator treatment had a restrictive force on the maxilla in the AP plane the reverse was true in the vertical plane. A point moved downward 2.07mm more in the bionator group which was significant ($p \leq 0.001$).

Bionator treatment had the effect of inhibiting the anteroposterior change and increasing the vertical descent of the maxilla. These changes were probably the result of the posteriorly directed force placed on the maxilla by the bionator when the mandible was repositioned anteriorly.

Harvold and Vargervik (1971) did find a significant inhibition to anterior maxillary translation. In addition, Forsberg and Odendrick (1981) reported the significant decrease of 0.6°in SNA which closely correlates to the findings of the present study.

Since the changes in the maxilla were clinically significant, the question arose whether or not the changes would remain stable after treatment or prove to be only a temporary treatment effect.

In a study utilizing implants, Melsen (1978) found that there was an inhibition of the maxilla in the AP plane and increase in the vertical descent after 8 months of headgear therapy. Long term follow up 7-8 years later revealed that the maxilla had an increased amount of anterior growth and decreased vertical growth after treatment had ceased. In effect, the position of the maxilla was the same as the untreated controls 8 years after treatment. Thus, the study concluded that the treatment effect was only temporary.

The findings of Wieslander (1993) contradict Meslen's earlier conclusion. Wieslander analyzed a sample which had been treated with a headgear-Herbst appliance follwed by a retention phase. The maxilla moved

posteriorly 1.5mm during treatment which did not relapse at all when the subjects were recalled at 17 years of age.

Similar to Wieslander's results, Pancherz (1991) found the skeletal changes due to Herbst therapy on a Class II malocclusion to be stable 5-10 years later. In this case the functional appliance treatment was followed by 1-2 years of fixed appliance therapy or retainers.

The difference in the findings may be attributed to the retention phase present in Wieslander's and Pancherz's studies but absent in Melsen's. This would suggest that when the maxillary complex demonstrates significant orthopedic changes as a result of treatment, a retention phase may be required to prevent relapse.

Mandible

The bionator group displayed a significant advancement of the mandible. SNB angle increased 1.05° which was significant ($p \leq 0.001$) in the treated group as compared to the control group. Also, the cranial base superimposition analysis demonstrated an additional 0.80mm anterior change in the bionator group at B point which was significant at the 0.05 level. The 0.93mm anterior change at P point was found to be significant ($p \leq 0.01$) as well.

The change in position of the mandible which is described by the superimposition anlysis and significant increase in SNB angle can be explained by the mandibular length. The results of the study indicate that there was additional growth in the mandible in the bionator group (see Figure 12). Ar-Gn,

a measure of mandibular length, increased an average of 2.83mm in the untreated subjects during the 18 month observation time. The subjects which received bionator treatment demonstrated an average of 6.45mm. Thus, there was 3.62mm of additional growth in the mandible over 18 months which was significant at the 0.001 level.

The significant increase observed in the mandibular length of the bionator subjects may be explained by one of 2 mechanisms. The treatment either increased growth beyond the genetic potential or more likely, there was a period of accelerated growth during the treatment time which acheived the genetic potential of the individual.

The results observed in the current study were supported by Mamandras (1990). In a sample chosen for successful bionator treatment there was an average of 6.2mm of mandibular growth over a 1 year 7 month period. Furthermore, Marschner and Harris (1966) reported 6.52mm on total mandibular growth during two years of successful activator wear. These findings coincided closely to the 6.45mm of total growth witnessed over 18 months in the treated group of the present study.

Wieslander (1984) found a similar response in mandibular increase with a different functional appliance. After 5 months of treatment with a headgear Herbst appliance there was 4.4mm of additional growth. Furthermore, McNamara et al (1990) found an annual 2.2mm more growth in the mandible in patients treated with a Frankel appliance as compared to untreated controls. The annual increase in the present study was 2.0mm.

These studies which have utilized activators, Frankel, and Herbst appliances, regardless of treatment time, had all demonstrated similar amounts

of mandibular increase. This would tend to support the accelerated growth mechanism in which a finite amount of growth was reached within the individual's genetic potential.

There have also been studies in which no mandibular response to activator treatment was reported. Harvold and Vargervik (1971) concluded that there was no additional growth in the mandible as a result of bionator therapy. However, the sample had a wide range of ages from 7-13 years. A first phase of treatment may be risky at the upper end of this age range. Females especially may have passed the optimal time for growth modification and the results might have been confounded by non-growing subjects.

Jakobsson (1967) also showed that there was no increase in mandibular growth. While this was the conclusion of the study it should be noted the study examined Andresen activators which were only worn a maximum of 11 hours a day according to Andresen's method. Changes in skeletal components may require that the appliance be worn full time as was the case in the current study.

Another component which might have contributed to the increase in the mandibular length is the direction of the growth at the condyle. While this was not analyzed in the present study, other studies have made significant observations. In later studies Vargervik and Harvold (1985) and Jakobsson and Paulin (1990) again studied activator treatment on Class II malocclusion and again found no increase in condylar growth. However, in these studies they also analyzed the direction of condylar growth. The results concluded that activator therapy did not lengthen the condyle but it did change the direction of its growth. The condyle growth changed 15° in a more superior-posterior

direction than the untreated controls and did contribute to effective mandibular length.

One note of caution when considering the results of all of these studies. Similar to the the present study, the subjects which were included had been selected for successful treatment. The patients displayed the optimum cooperation and growth potentials. Therefore, careful patient selection when considering an early phase of treatment and further study to quantify predictors of positive skeletal response to activator therapy would be warranted.

Facial Convexity

There was a significant ($p \leq 0.001$) change in the ANB angle which measures skeletal convexity. The untreated control demonstrated a mean decrease of 0.11° during the observation period, however, the treated subjects showed a mean decrease of 2.08° during the same time. The difference, therefore, was a 1.97° decrease in the ANB angle in the bionator group which was significant ($p \leq 0.001$).

The change in ANB was due to the significant changes noted previously in both SNA and SNB angles (see Figure 10). The changes seen in SNA and SNB were not found to be significant T1-T2 for the control group but the treatment effect of the bionator was significant at the 0.001 level for each measurement. The change in ANB was accounted for by almost equal change in the mandible and maxilla.

There is not a concensus of opinion concerning the skeletal effects of bionator treatment in previous research. The changes in skeletal convexity

presented by the study were both supported and refuted by previous research.

Forsberg and Odendrick (1981) reported significant decreases of 1.1° in ANB angle. Jakobsson and Paulin (1990) compared 53 boys and girls to a similar control group of 60 individuals. The findings of the study indicated that there was a significant annual reduction in the ANB angle of 0.76°.

Harvold and Vargervik (1971) did find a significant inhibition to anterior maxillary translation but concluded that activator therapy attained a Class I molar relationship mainly due to dentoalveolar changes. Algren and Laurin (1976) concluded that the correction of a Class II malocclusion was primarily due to dentoalveolar changes. They did note a significant decrease in the ANB angle but did not include SNA or SNB values in the findings or offer an explanation of the change.

The difference between the results seemed to be the sample criteria rather than method as noted by Vargervik and Harvold (1985). The studies which cited skeletal change due to bionator therapy tended to have samples drawn from individuals undergoing successful treatment and thereby optimum results (Mamandras, 1990; Marschner and Harris, 1966). In contrast, the studies which demonstrated a dentoalveolar correction of the malocclusion tended to use consecutively selected samples (Harvold and Vargervik, 1971; Jakobsson, 1967). Therefore, the subjects which were included tended to have much wider ranges of ages, treatment times, and dentofacial characteristics. Many of these studies also noted that while dentoalveolar change was responsible for correction, some individuals did show significant skeletal response to bionator treatment (Bjork, 1951).

Mamandras and Allen (1990) compared successful bionator treatment to unsuccessful treatment. The changes seen in the 2 groups were similar except for mandibular growth. The successfully treated subjects tended to have smaller than average mandibles at the outset of treatment. The findings of this study indicate that either result is possible but careful patient selection is required when using a bionator appliance.

Facial Height

The treatment effect of the bionator was a significant increase in both anterior and posterior facial height. The control group showed an increase in anterior facial height of 2.98mm and 1.53mm in posterior facial height due to normal growth during the 18 months. While these increases themselves were found to be significant ($p \leq 0.001$), the additional increase in vertical height for the treated group was significantly more than growth alone. Anterior facial height (N-Me) increased 6.33mm overall for the bionator group. Therefore, the treatment effect of the appliance was an additional 3.35mm of change which was determined to be highly significant ($p \leq 0.001$). Additional change beyond growth in posterior facial height, measured by Ar-Go, was significant at the 0.001 level as well. During the treatment Ar-Go increased 3.73mm overall and 2.20mm of that was in excess to growth.

Both the anterior and posterior facial height was found to increase significantly. This accompanied by remodelling of the gonial angle probably accounted for the stability observed in FMA and therefore the lack of

autorotation of the mandible. This finding was supported by Ahlgren and Laurin (1976).

The anterior facial height was broken down into upper anterior facial height (N-ANS) and lower anterior facial height (ANS-Me). The total vertical increase was almost evenly divided between the 2 components. N-ANS increased an average of 1.88mm due to bionator treatment and ANS-Me increased 1.53mm.

It was noted earlier that the maxilla moved downward significantly more in the treatment group than the control group. The increase in upper anterior facial height was due to the directional change in maxillary movement seen in the bionator group. This phenomenon was also supported by previous studies.

Jakobsson (1967) examined 30 subjects treated with activators and 30 with headgear. Both of the treatment groups demonstrated an increase in upper anterior facial height due to the vertical descent of the anterior nasal spine. Another result witnessed in the activator group was a significant ($p \leq 0.001$) increase in lower facial height. Melsen (1978) also demonstrated an increased upper anterior facial height due to downward movement of anterior nasal spine when orthopedic forces were applied to the maxilla with a headgear.

The significant ($p \leq 0.001$) increase found in the lower anterior facial height was also seen in Jakobsson (1967). The reason the increase occurred lies in the appliance design. The bionator used in the present study was designed to open the bite by allowing for eruption of the mandibular posterior teeth.

Dentition

Some of the largest changes due to treatment were found in the dentition. Overjet tended to remain unaltered in the control subjects but the treated cases demonstrated an average 4.63mm decrease. The total treatment effect was 4.75mm reduction of overjet. This change was significant ($p \leq 0.001$). Forsberg and Odenrick (1981) reported a similar 4.1mm reduction of overjet during 1.9 years of activator treatment in 47 successfully treated children.

Overbite also showed a significant treatment effect. The untreated group demonstrated an increase in overbite of 0.7mm during the 18 months. The bionator subjects had an average 2.45mm opening of overbite. Therefore, the treatment effect of the bionator was an average of 3.15mm decrease in overbite. As with the changes in overjet the reduction witnessed in overbite closely correlated to other findings. Schulhof and Engel (1982) showed just under 3mm of reduction in overbite during 1 year and 9 months of bionator treatment in 33 children.

The reduction of overbite was explained by the fabrication of the bionator. Subjects with Class II, Division 1 malocclusion often display a deep bite as was the case in the present study. In these cases the bionator which was used was designed to open the bite. The guide channels described previously allowed for the eruption of the posterior teeth. The eruption of the buccal segments had the effect of opening the bite and thereby reduced the overbite.

The reductions in both overjet and overbite were similar to the skeletal changes, however, the dental effects were larger in magnitude. The hard tissue superimposition analysis indicated that the upper incisal tip moved back 2.47mm due to the bionator. This was more than double the skeletal treatment

effect of 1.17mm. Furthermore, lower incisal tip moved anteriorly 1.27mm and B point only 0.80mm due to treatment. This was an indication that the bionator effected the alveolus and dentition more than the bony components which was supported by Bjork (1951).

This was due to the posteriorly directed force placed on the maxillary dentition by the bionator. The maxillary dental changes which were shown to be greater than the skeletal change was explained by the fact that the bionator is a tooth-born appliance. The restrictive force was applied directly on the maxillary dentition and indirectly on the maxilla through the teeth.

The results also indicated that the lower incisors in the treated subjects did not significantly differ from the change in the controls which is supported by Schulhof and Engel's (1982) study which also used incisal capping in the appliance design to prevent labial tipping. The upper incisors were found to undergo significant angular changes during treatment. There was a 4° uprighting of the upper incisors which contributed to the reduction of overjet.

The effect of the changes in overbite and overjet was to reduce the amount of lip entrapment. As the maxillary dentition was retracted there was a lessening of lower lip curl. Also, as the mandibular dentition moved anteriorly due to treatment, the result was a diminished lower lip thickness.

Soft Tissue

Facial Convexity

Figure 10 illustrates the change seen in facial convexity. The angle G-Sn-Pg was a measure of facial convexity. The control group, which represented normal growth in a Class II malocclusion, had a mean increase in the angle. The soft tissue profile became more convex by 0.40° during the observation period of 18 months which was not found to be statistically significant. However, the increase in convexity witnessed in the untreated subjects does show that with time there is no spontaneous correction of convex profiles but rather a tendency for stability or possibly becoming worse.

In contrast to the control group, there was a significant change in the profile for the treated cases. The 30 subjects which underwent bionator therapy displayed a mean decrease of 1.82° the G-Sn-Pg angle. The bionator T1-T2 change was significant at the 0.001 level. The treatment effect of the appliance was determined by subtracting the change in the control group from the change in the treated group. In the case of facial convexity the bionator treatment during the 18 months improved the profile 2.22° which was also significant at the 0.001 level.

The improvement in the facial profile was determined to be a product of both horizontal and vertical factors in the superimposition analysis. There was an inhibitive force witnessed in the AP plane in the upper lip region. The mean treatment effect on A' point was a 1.10mm retraction which was significant ($p = 0.008$). In addition, there was an overall 0.50mm retraction of the Sn point which was not statistically significant but would have an opening effect on the

G-Sn-Pg angle. In contrast to the upper lip, the soft tissue chin exhibited a significant ($p \leq 0.01$) advancement of 0.93mm. The restriction of Sn point and advancement of Pg' both contributed to the decreased facial convexity angle.

Korkhaus (1960) supported these findings. He examined the change brought about by activator treatment in 123 Class II, Division 1 cases. His results led to the conclusion that activator therapy decreases the convexity of the soft tissue profile by advancing the mandible.

Later, Forsberg and Odenrick (1981) studied the effects of an activator on the profiles of 78 treated and untreated subjects. The results demonstrated that there was a significant ($p \leq 0.01$) increase in the advancement of Pg' which had the effect of decreasing the convexity of the treated patients.

Upper Lip

The upper lip procumbency, measured from labrale superior to the Sn-Pg' plane, remained relatively unaltered in the control group and was found to decrease significantly ($p \leq 0.002$) in the treated group. The total difference was 1.32mm of lip retraction in the bionator group. The cranial base superimposition analysis also demonstrated 1.37mm less anterior change ($p \leq 0.009$) in labrale superior of the treated subjects as compared to the untreated controls.

The changes in the upper lip and maxillary dentition were observed to be closely related. As stated previously upper incisor was found to upright by 3.93° in the treated group. Furthermore, upper incisal tip moved anteriorly 2.47mm less in the treated subjects than the controls over 18 months.

The significant amount of upper lip retraction was due to the retraction and lingual tipping of the maxillary dentition. Rudee (1964) analyzed 85 patients which had 4 bicuspid extraction for the concomitant soft tissue changes. The results concluded that there was a 2.93:1 ratio between the upper incisor and upper lip retraction. In the present study the ratio was approximately 1.8:1.

The smaller ratio of upper lip retraction in the bionator group might be explained by Rains and Nanda (1982). In a sample of 30 subjects which underwent bicuspid extraction treatment, regression analysis demonstrated that upper lip retraction was related to upper and lower incisor retraction. In contrast to extraction therapy, there was no lower incisor retraction present in the bionator group which might effect the upper lip retraction ratio. Another possibility was that the amount of incisor retracton was much less in the bionator treatment than what was seen in extraction therapy and therefore the ratios differed.

Lower Lip

Another major treatment effect of the bionator on the integument was witnessed in the lower lip. The length, thickness and posture all demonstrated significant changes beyond normal growth. Two of the selection criteria all of the subjects in the study were initally chosen for was an overjet $\geq$ 6mm and an ANB angle of $\geq 5°$. A result was a curled lower lip which was entrapped by the upper incisor. Therefore, the change in the lower lip can be accounted for by changes in both the soft and hard tissue.

The mean change in lower lip length (Stm-B') for the control T1-T2 was 0.10mm. In the treated group the lip length had an overall increase of 2.53mm as compared to the control. The increase in lower lip length coincided with the increase in lower anterior facial height and overbite discussed earlier.

The soft tissue cranial base superimposition analysis also depicted the overall vertical increases illustrated by the increase in lower lip length. Bionator therapy was found to have a significant ($p \leq 0.001$) effect on the vertical changes seen during the 18 months of treatment (see Figure 14). In the control group B' dropped down an average of 1.67mm and labrale inferior moved downwards an equal 1.58mm. The vertical change in the treated group was determined to be significantly ($p \leq 0.001$) more than the change in the control group. The analysis showed that B' point dropped inferiorly 5.73mm and labrale inferior only dropped 4.33mm during bionator therapy.

The disparity between the vertical recordings of B' and labrale inferior was explained by the uncurling of the lip. As the entire lip was translated in a downward direction, the upper part of the lip was also uncurling upwards which caused the difference between B' and labrale inferior overall superimposition vertical changes.

The uncurling of the lower lip was most directly measured by metolabial angle. In the control group mentolabial angle dereased 2.2° which denoted an unfavorable esthetic change. In contrast, the bionator group presented a 15.2° increase in mentolabial angle. Therefore, there was a total of 17.4° increase in mentolabial angle which caused an uncurling of the lower lip and an improvement in esthetics.

Similar to mentolabial angle, the control group had an increase in lower lip thickness during the observation period which indicated an increase in lower lip curl and therefore poorer esthetics. The treated group, however, demonstrated an improvement in esthetics with a decrease in lower lip thickness of 1.87mm and an overall treatment effect of 2.65mm. This change was significant ($p \leq 0.001$).

While lower lip thickness decreased during treatment neither lower lip to Sn-Pg nor lower lip to E line showed significant change in the bionator subjects. Thus, lower lip protrusion was not effected by bionator treatment but the thickness decreased. Upon close examination, the change in thickness was due to the method of measurement. All soft tissue thickness measurements were taken from the soft tissue landmark to the hard tissue parallel to Frankfort Horizontal. The difference in the lower lip was the excessive amount of lip entrapment. Initially, the portion of the inner surface of the lip did not contact the labial surface of the mandibular incisors but held a more superior position due to the excessive curling. The resulting gap between the lower lip and teeth was incorporated into the measurement. By the end of treatment, the reduction of overjet due to skeletal and dental advancement in the mandible allowed the mandibular dentition to meet the lower lip as it uncurled. The relative thickness of the lower lip decreased but the tissue itself as well as the protrusion was not effected.

Forsberg and Odenrick (1981) did find a significant ($p \leq 0.05$) amount of lower lip retraction. The lower lip was retracted 0.80mm from E line. When compared to the 0.47mm of retraction which was not found to be significant in the present study the difference is only 0.33mm.

The improvement in lower lip curl which was demonstrated in the treated group was a product of the skeletal and dental changes. The increase in both skeletal facial height and overbite contributed to the inrease in lower lip length. At the same time the increase in mandibular length and resulting decrease in skeletal convexity as well as decrease in overjet improved the mentolabial angle and lip thickness. While the control group did not demonstrate any significant improvement but rather an unfavorable change in the lower lip esthetics, the hard tissue vertical and anteroposterior changes in the bionator group caused an improvement in lower lip curl. The effect of the changes was a significant improvement in lower lip esthetics.

Another mechanism which might have contributed to the lower lip changes and post-treatment posture was muscle tonicity. During bionator therapy the patient was asked to keep a lip seal over the appliance. The effect fo the additional lip strain was as Frankel (1969) stated "requires the muscles to adopt a new permanent target of operation and causes a re-education of the muscles".

Pancherz (1985) presented evidence which supported this theory. A group of 22 subjects with a Class II, Division 1 malocclusion which were treated with a Herbst appliance was compared to a control of 20 subjects with a Class I occlusion. The initial EMG activity of the masseter was impaired in the Class II subjects. During treatment which resulted in a successful correction of the maloccluion, the EMG activity in the treated subjects changed to a pattern similar to that found in the individuals with normal occlusion.

Thus, the improvements in lower lip might have been due to a combination of hard tissue and muscle tonicity changes.

Clinical Significance

The results of the study indicate that bionator therapy improved both skeletal and dental relationships in a Class II, Division 1 malocclusion. Skeletal convexity was improved, facial height increased, there was no mandibular autorotation, the molar relationship was corrected to a Class I, and both overjet and overbite demonstrated significant decreases. These changes indicated that the bionator would be appropriate for Class II, Division 1 maloccluisons with the exception of cases with greatly increased facial height.

The soft tissue results indicated that during 18 months of bionator treatment, there was greater than 2° decrease in convexity, uncurling and lengthening of the lower lip, and that the upper lip did not change much. These findings also demonstrated that the bionator was an appropriate treatment modality for the convex profile which usually accompanies a Class II malocclusion.

A profile with a protrusive upper lip would not be likely to benefit as greatly from bionator therapy since the effects of treatment did not change the upper lip much. Also, one of the major effects of treatment on the profile was the lower lip change. Therefore, if an improvement of lower lip curl was not a treatment objective of bionator treatment the expectations of soft tissue change would be diminished.

SUMMARY AND CONCLUSIONS

The bionator is a common modality for the correction of Class II, Division 1 malocclusion in the mixed dentition. The hard tissue changes as a result of treatment with the bionator have been studied extensively, however, the soft tissue profile changes as a result of its use have not been well documented. Thus, the purpose of the study was to determine and compare the soft tissue profile changes in patients with Class II Division 1 malocclusion treated in the mixed dentition with a bionator to untreated controls.

The sample consisted of cephalograms of two groups of 30 caucasian individuals who were between 9 and 12 years of age at the start of treatment. The first group was treated with a bionator for an average of 18 months resulting in a Class I molar relationship and successful reduction of overjet. The second group, acting as a control, consisted of cephalograms of individuals obtained from the Bolton-Broadbent Growth Study who did not receive any form of orthodontic treatment. The two groups were closely matched for age, sex, observation time, and dentofacial characteristics. The cephalograms were analyzed using a soft and a hard tissue cephalometric analysis as well as a

cranial base superimposition analysis. Paired t-tests were used to compare the changes between the bionator and control groups.

As compared to the control group, the treated group demonstated the following changes:

1. Increase in the length of the mandible
2. Increase in anterior facial height
3. Decrease in soft tissue profile convexity
4. Increase in mentolabial angle

APPENDIX A

DEFINITIONS OF CEPHALOMETRIC MEASUREMENTS

Soft Tissue Measurements

1.	A' Thickness	The distance (mm) measured from A' parallel to Frankfort Horizontal to the underlying hard tissue structures
2.	B' Thickness	The distance (mm) measured from B' parallel to Frankfort Horizontal to the underlying hard tissue structures
3.	E Line	The distance (mm) between the most prominent point on the lower lip perpendicular to the plane formed by the Tip of the nose and Pg' plane
4.	Interlabial Gap	The distance (mm) measured perpendicular to Frankfort Horizontal from Upper Lip Stm and Lower Lip Stm
5.	G-Sn-Pg	The angle formed by G-Sn plane and Sn-Pg plane
6.	Lower Lip to B plane	The distance (mm) measured from Labrale Inferior perpendicular to Stm-B' plane
7.	Lower Lip Thickness	The distance (mm) measured from Labrale Inferior parallel to Frankfort Horizontal to the underlying hard tissue structures

8.	Mentolabial Angle	The angle formed by planes from B' tangent to curvature of the chin and from B' tangent to the inferior point of the lower lip
9.	Nasolabial Angle	The angle formed by the planes from Sn tangent to the inferior border of the nose and from Sn to the superior point of the uper lip
10.	Pg' Thickness	The distance (mm) measured from Pg' parallel to Frankfort Horizontal to the underlying hard tissue structures
11.	Sn-Stm	The distance (mm) measured perpendicular to Frankfort Horizontal from Sn to Stm
12.	Stm-B'	The distance (mm) measured perpendicular to Frankfort Horizontal from Stm to B'
13.	Upper Lip to B plane	The distance (mm) measured from Labrale Superior perpendicular to Stm-B' plane
14.	Upper Lip Thickness	The distance (mm) measured from Labrale Superior parallel to Frankfort Horizontal to the underlying hard tissue structures

Hard Tissue Measurements

15.	ANB	The angle formed by the anatomical points A, Nasion, and B
16.	ANS-Me	The distance (mm) measured from Anterior Nasal Spine to Menton
17.	Ar-Gn	The distance (mm) measured from Articulare to Gnathion
18.	Ar-Go	The distance (mm) measured from Articulare to Gonion
19.	Co-ANS	The distance (mm) measured from Condylion to the point of 3mm thickness of ANS
20.	FMA	The angle formed between contstructed Frankfort Horizontal plane and Mandibular plane
21.	IMPA	The angle formed between the long axis of the lower incisor and Mandibular plane
22.	N-ANS	The distance (mm) measured from Nasion to Anterior Nasal Spine
23.	N-Me	The distance (mm) measured from Nasion to Menton
24.	OB	The vertical distance (mm) measured perpendicular to Frankfort Horizontal from Upper Incisor tip to Lower Incisor tip
25.	OJ	The horizontal distance (mm) measured parallel to Frankfort Horizontal from Upper Incisor tip to

		Lower Incisor tip
26.	SNA	The angle formed by the anatomic points Sella, Nasion, and A
27.	SNB	The angle formed by the anatomic points Sella, Nasion, and B
28.	U1-FH	The angle formed between the long axis of the Upper Incisor and Frankfort Horizontal

APPENDIX B

Table 6.–Soft Tissue Measurement and Tracing Error Analysis Results.

CEPHALOMETRIC MEASUREMENTS	MSMT 1		MSMT 2		RELIABILITY COEFFICIENT	P VALUE
	Mean	SD	Mean	SD		
A Thickness	12.85	1.2	12.65	1.2	0.922	0.223
B Thickness	10.25	1.3	9.95	1.2	0.873	0.168
E Line	0.70	0.7	0.80	0.8	0.989	0.443
Interlabial Gap	1.40	3.0	1.35	3.0	0.993	0.678
G-Sn-Pg	12.60	4.7	12.50	4.6	0.998	0.343
Lower Lip to B plane	4.10	2.8	4.35	3.0	0.987	0.177
Lower Lip Thickness	14.25	1.4	14.30	1.5	0.976	0.678
Mentolabial angle	112.8	15.0	112.2	16.1	0.997	0.274
Nasolabial angle	105.8	14.1	105.5	13.9	0.995	0.193
Pg' Thickness	11.40	1.7	11.60	1.6	0.978	0.104
Sn-Stm	20.50	2.3	20.15	2.2	0.967	0.089
Stm-B'	15.70	2.5	15.65	2.5	0.976	0.780
Upper Lip to B plane	5.85	2.4	5.90	2.4	0.998	0.343
Upper Lip Thickness	12.70	1.8	12.65	1.6	0.852	0.872

Table 7.–Hard Tissue Measurement and Tracing Error Analysis Results.

CEPHALOMETRIC MEASUREMENTS	MSMT 1		MSMT 2		RELIABILITY COEFFICIENT	P VALUE
	Mean	SD	Mean	SD		
ANB	4.65	2.3	4.50	2.1	0.989	0.279
ANS-Me	59.80	4.4	59.85	4.5	0.986	0.840
Ar-Gn	102.8	6.1	102.95	5.7	0.997	0.496
Ar-Go	43.30	3.2	43.20	2.8	0.943	0.780
Co-ANS	89.20	4.4	89.25	4.1	0.991	0.811
FMA	26.50	2.2	26.35	2.5	0.940	0.604
IMPA	96.25	3.9	96.05	3.5	0.996	0.309
N-ANS	46.30	3.4	46.45	3.5	0.995	0.193
N-Me	106.10	3.4	106.25	3.7	0.988	0.434
OB	3.80	1.6	3.90	1.7	0.992	0.168
OJ	4.90	2.9	4.95	2.9	0.999	0.343
SNA	83.30	1.8	83.40	2.0	0.981	0.443
SNB	78.65	2.6	78.80	2.5	0.976	0.434
U1-FH	117.45	6.5	117.55	6.0	0.996	0.693

LITERATURE CITED

Ahlgren, J. and C. Laurin. 1976. Late Results of Activator Treatment: a cephalometric study. Br. J. Orthod. 3:181-187.

Altemus, LA. 1959. Comparative Integumental Relationships. Angle Orthod. 29:189-200.

Angle, EH. Malocclusion of the Teeth, ed. 7, S.S. White Dental Mfg. Co., Philadelphia, 1907, p.64.

Angle, EH. and A Oppenheim. 1932. A Message Bearing on the Treatment of Class II, Division 1 Malocclusion. Angle Orthod. 2:121-126.

Baume, LJ and HD Derichswieler. 1961. Is the condylar growth center responsive to orthodontic therapy? J. Oral Surg. 14:347-362.

Bittner, C and H Pancherz. 1990. Facial morphology and malocclusions. Am. J. Orthod. 97:308-315.

Bjork, A. 1951. The principle of the Andresen method of orthodontic treatment, a discussion based on cephalometric x-ray analysis of treated cases. Am. J. Orthod. 37: 437-458.

Bolmgren, GA and F Moshiri. 1986. Bionator Treatment in Class II, Division1. Angle Orthod. 56:255-262.

Broadbent, BH. 1937. Bolton Standards and Technique in Orthodontic Practice. Angle Orthod., 7: 209-223.

Burstone, C J. 1958. The Integumental Profile. Am. J. Orthod. 44: 1-25.

Burstone, C.J. 1959. Integumental Contour and Extention Patterns. Angle Orthod. 29:93-104.

Burstone, C J. 1967. Lip Posture and its significance in Treatment Planning. Am. J. Orthod. 53: 262-284.

Case, CS. Dental Orthopedia. C.S. Case Co., Chicago, 1921, 183.

Cox, NH and PGM Van der Linden. 1973. Facial Harmony. Am. J. Orthod. 60:175-183.

Czarnecki, ST, RS Nanda, and GF Currier. 1993. Perceptions of a balanced facial profile. Am. J. Orthod. 104:180-187.

Drobocky, OB and RJ Smith. 1989. Changes in facial profile during orthodontic treatment with extraction of four first premolars. Am. J. Orthod. 95: 220-230.

Elgoyhen, JC, EM Moyers, JA McNamara and ML Riolo. 1972. Craniofacial adaptation to protrusive function in young rhesus monkeys. Am. J. Orthod. 62:(5) 469-480.

Elmagian, KE. 1959. A Serial Study of Facial Growth as related to Cranial Base Morphology. Masters Thesis, U. of Washington, Seattle, Washington.

Forsberg, CM and L Odenrick. 1981. Skeletal and soft tissue response to activator treatment. Eur. J. Ortho. 3: 247-253.

Foster, EJ. 1973. Profile Preferences Among Diversified Groups. Angle Orthod. 43:34-40.

Frankel, R. 1969. The treatment of Class II, Division 1 malocclusion with functional correctors. Am. J. Orthod. 55:265-275.

Frohlich, FJ. 1962. Changes in Untreated Class II Type Malocclusions. Am. J. Orthod. 32:167-179.

Genecov, JS, PM Sinclair, and PC Dechow. 1990. Development of the nose and soft tissue profile. Angle Orthod. 60: 191-198.

Harvold, EP and K Vargervik. 1971. Morphogenic response to activator treatment. Am. J. Orthod. 60: 478-490.

Hellman, M. 1927. The Face and Occlusion of the Teeth in Man. Int. J. Orthodontia, 13:921-945.

Hillesund, DF and BU Zachrisson. 1978. Reliability of Soft-Tissue Profile in Cephalometrics. Am. J. Orthod. 74: 537-550.

Holdaway, RA. 1983. A soft-tissue cephalometric analysis and its use in orthodontic treatment planning. Part I. Am. J. Orthod., 84: 1-28.

Holdaway, RA. 1984. A soft-tissue cephalometric analysis and its use in orthodontic treatment planning. Part II. Am. J. Orthod. 85:279-293.

Johnston, L. E. :"A comparative analysis of Class II Treatments". Clinical Reaearch as the Basis of Clinical Practice, Vol 18 Craniofacial Growth Series. Univ of Michigan, Ann Arbor, 1986. 103-148.

Jakobsson, SO. 1967. Cephalometric evaluation of treatment effect on Class II, Division 1 malocclusions. Am. J. Orthod. 53:446-457.

Jakobsson, SO and G Paulin. 1990. The influence of activator treatment on skeletal growth in Angle Class II:1 cases. A roentgenocephalmetric study. Euro. J. Orthod. 12:174-184.

Legan, HL and C.J Burstone. 1980. Soft tissue cephalometric analysis for orthognatic surgery. J. Oral Surgery, 38:744-751.

Lines, PA, RR Lines, and CA Lines. 1978. Profilemetrics and facial esthetics. Am. J. Orthod. 73:648-657.

Mamandras, AH and LP Allen. 1990. Mandibular response to orthodontic treatment with the Bionator appliance. Am. J. Orthod. 97: 113-120.

Marschner, JF and JE Harris. 1966. Mandibular Growth and Class II Treatment. Angle Orthod. 36:89-93.

McNamara, JA. 1973. Neuromuscular and skeletal adaptaions to altered function in the orofacial region. Am J. Orthod. 64:(6) 578-606.

McNamara, JA, RP Howe, and TG Dischinger. 1990. A comparison of the Herbst and Frankel appliances in the treatment of Class II malocclusion. Am. J. Orthod. 98:133-144.

McNamara, JA, EW Brust, and ML Riolo. "Soft Tissue Evaluation of Individuals with an Ideal Occlusion and a well-balanced Face," in Esthetics and the Treatment of Facial Form, ed. McNamara, JA. Ann Arbor. University of Michigan. 115-146.

Melsen, B. 1978. Effects of cervical anchorage during and after treatment: An implant study. Am. J. Orthod. 73: 526-540.

Nanda, R, H Meng, S Kapila, and J Goorhuis. 1990. Growth changes in the soft tissue facial profile. Angle Orthod. 60: 177-190.

Neger, M. 1959. A Quantitiative Method for the Evaluation of the Soft-Tissue Facial Profile. Am. J. Orthod. 45: 738-751.

Pancherz, H. 1981. The effect of continuous bite jumping on the dentofacial complex: a follow-up study after Herbst appliance treatment of Class II malocclusions. Eur. J. Orthod. 3:49-60.

Pancherz, H. 1985. The Herbst appliance- Its biologic effects and clinical use. Am. J. Orthod. 87:1-20.

Pancherz, H. 1991. The nature of Class II relapse after Herbst appliance treatment: A cephalomentric long-term investigation. Am. J. Orthod. 100:220-233.

Park, YC and CJ Burstone. 1986. Soft-tissue profile–Fallacies of hard-tissue standards in treatment planning. Am. J. Orthod. 90:52-62.

Peck, H and S Peck. 1970. A Concept of Facial Esthetics. Angle Orthod. 40:284-317.

Proffit, WR. Contemporary Orthodontics. C.V. Mosby Co., St. Louis, 1986, 119.

Rains, MD and R Nanda. 1982. Soft-tissue changes associated with maxillary incisor retraction. Am. J. Orthod., 81: 481-488.

Ricketts, RM. 1957. Planning Treatment on the Basis of the Facial Pattern and an Estimate of its Growth. Angle Orthod. 27: 14-37.

Ricketts, RM. 1964. The Keystone Triad. I. Anatomy, Phylogenetics, and Clinical References, Am. J. Orthod. 50: 244-264.

Ricketts, RM. 1964. The Keystone Triad. II. Growth, Treatment, and Clinical Significance. Am. J. Orthod. 50: 728-750.

Ricketts, RM. 1968. Esthetics, enviroment, and the law of lip relation. Am. J. Orthod. 54:(4) 272-289.

Riedel, RM. 1950. Esthetics and its relation to orthodontic therapy. Angle Orthod. 20: 168-178.

Riedel, RM. 1957. An Analysis of Dentofacial Relationships. Am. J. Orthod. 43:103-119.

Roos, N. 1972. Soft-tissue profile changes in Class II treatment. Am. J. Orthod. 72:165-175.

Rudee, DA. 1964. Proportional profile changes concurrent with orthodontic therapy. Am. J. Orthod. 50: 421-434.

Satravaha, S and KD Schlegel. 1987. The significance of the integumentary profile. Am. J. Orthod. 92: 422-426.

Schiedeman, GB et al. 1980. Cephalometric Analysis of Dentofacial Normals. Am. J. Orthod. 78:404-420.

Schulhof, RJ and GB Engel. 1982. Results of Class II Functional Appliance Treatment. J. Clin. Orthod. 16:587-599.

Simon, PW. Fundamental Principles of Systematic Diagnosis of Dental Anomalies, Stratford Co., Boston, 1926. 375.

Subtelny, JD. 1959. A Longitudinal Study of Soft Tissue Facial Structures and their Profile Characteristics, defined in Relation to underlying Skeletal Structures. Am. J. Orthod. 45: 481-507.

Tsamtsouris, A and D Vedrenne. 1983. The use of the Bionator Appliance in the treatment of Class II, Division 1 malocclusion in the Late Mixed Dentition. J. of Pedodontics. 8: 78- 100.

Tweed, CH. 1944. Indications for the extraction of teeth in orthodontic procedure. Am. J. Orhod. 30: 401-460.

Vargervik, K and EP Harvold. 1985. Response to activator treatment in Class II malocclusions. Am. J. Orthod. 88: 242-251.

Wieslander, L. 1984. Intensive treatment of severe Class II malocclusions with a headgear-Herbst appliance in the early mixed dentition. Am. J. Orthod. 86:1-13.

Wieslander, L. 1993. Long-term effect of treatment with the headgear-Herbst appliance in the early mixed dentition. Stability or relapse? Am. J. Orthod. 104:319-329.

Wuerpel, EH. 1937. On Facial Balance and Harmony. Angle Orthod. 7:81-89.

Yogosawa, F. 1990. Predicting soft tissue changes concurrent with orthodontic treatment. Angle Orthodontist. 60(3): 199-206.

27 229CS
06/95 TH 4987
00-104-07