Dimensional Changes of Facial Soft Tissue Associated with Rapid Palatal Expansion

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DIMENSIONAL CHANGES OF FACIAL SOFT TISSUE ASSOCIATED WITH RAPID PALATAL EXPANSION

by

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ABSTRACT
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Introduction: Orthodontic treatment demands excellent outcomes in both function and esthetics. Despite the popularity of rapid palatal expansion in orthodontic treatment, few studies have examined its consequences on facial soft tissue using direct anthropometric measurements. The primary goal of this study was to determine facial soft tissue changes immediately following rapid palatal expansion.

Materials and Methods: Twenty-eight patients (age range, 8-17 years) attending Marquette Dental School Orthodontic Post-Graduate Clinic were enrolled in the study. Facial soft tissue measurements were taken with digital calipers at two separate time points (T0: initial exam and T1: thirty days following expansion); measurements were recorded with patients sitting in the orthodontic chair in centric occlusion, with Frankfurt Horizontal plane parallel to the floor, and observing a relaxed-lip posture. One examiner took 18 measurements at two different time points (T0 and T1), and was blinded from the initial reading when the second round of measurements were taken. Descriptive statistics were performed and a paired t-test was used to compare measurements taken at the two time points. Regressions models were also conducted to determine the influence of age on the results.

Results: Pearson's correlation coefficient, was found to be $r = 0.998$. This indicates nearly a one-to-one correspondence in the measurements taken at the two time points by the same examiner. Between the two time points, there was a statistically significant difference in intraorbital width, alar nasal width-widest nostrils, mouth width and soft tissue nasion at the tip of nose ($p < 0.001$). Anatomical structures closest to the facial midline appear to be most affected. Statistically significant increase included mouth width, nasal width, orbital width and the length of the soft tissue nose from nasion to the tip of the nose. All points that showed significant differences were directly related to rapid palatal expansion and were independent of age as determined via regression modeling.

Conclusions: This study demonstrated that from a frontal perspective, rapid palatal expansion results in statistically significant facial soft tissue changes. Further assessment is needed to determine if these values are of clinical significance.

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CHAPTER 1
INTRODUCTION

Rapid palatal expansion (RPE) is a common treatment modality for orthodontic patients (Proffit 2012). Indications for RPE treatment include narrow transverse maxillary width, unilateral or bilateral posterior crossbite, and severe maxillary crowding (Proffit 2012, Haas 1961). Several different designs exist for rapid palatal expanders, including both banded and bonded appliances, and those with or without acrylic coverage. Regardless of design, the majority of appliances employ much the same mechanism of action. The primary goal of expansion is to orthopedically create a separation of the midpalatal suture, thereby moving teeth into a broader arch form. The older the patient the more likely the midpalatal suture is fused. Consequently, the use of an expander in these patients more likely results in dental movement, including tipping of teeth in a buccal direction (Krebs 1959, Haas 1961, Wertz 1970, Harberson 1978, Adkins et al. 1990, McNamara 1993, Hesse 1997, McNamara 2000).

Orthodontists utilize rapid palatal expanders on a wide age range of patients, although Proffit (2012) and others recommend their use primarily before the completion of the adolescent growth spurt. Consequently, early treatment of children in the primary or mixed dentition stages often involves palatal expansion, as practitioners aim to capitalize on the patency of sutures in young patients. Yet, the determination of suture patency can be difficult as suture closure can vary significantly amongst patients. A recent study by Angelieri, et al, has focused on the utilization of CBCT to identify the stage of suture maturation (Angelieri et al. 2013). This provides the practitioner with a means of determining the potential success of palatal expansion. However, the benefits of this method must be critically weighed against the potential disadvantage of radiation exposure. Additionally, true separation of the maxillary sutures is not necessarily a prerequisite to successful treatment in all patients, as the resultant increase in transverse width, or “expansion” outcome can still be achieved without orthopedic change.

Anatomically, the midpalatal suture is located on the midline of the maxilla, or the roof of the oral cavity. Subsequently, this roof is shared with the bony floor of the nasal cavity. Indeed, the conclusion can be drawn that changes in the transverse dimension of the oral cavity may have the concurrent effect of altering the nose. Several studies support this conclusion (Derichsweiler 1953, and Haas 1961). Several studies evaluating facial esthetics show that symmetry of the midface, and the nose in particular, constitutes a great role in overall pleasant facial appearance (Naini 2006). The orthodontist places a great deal of emphasis on facial esthetics and thus must be aware of any potential facial changes produced by utilization of a palatal expander. Expected changes in the nasal complex, and the overall net effect on the facial soft tissue drape, must be considered and conveyed by professionals to patients prior to initiation of treatment. The importance of identifying and treatment planning for changes in facial soft tissues have been reinforced within current orthodontic literature (Sarver 2003).

Previous studies examined facial changes produced by palatal expansion via lateral cephalometric radiographs. Such studies have shown that palatal expansion impacts facial soft tissues. Kilic et al (2008), found a significant decrease in the soft tissue facial angle and increases in both the H angle and profile convexity. They hypothesized that these changes were due to a greater forward displacement of soft tissues overlying the maxilla that overcame the negative effect of the flattening of the nose. More recent studies have advanced on these foundations by utilizing novel technologies. Several three-dimensional imaging modalities now exist, the most common of which is the cone beam computed tomography (CBCT). Garett, et al, (2008) used CBCT imaging to study immediate transverse changes occurring from rapid palatal expansion. They showed that palatal expansion resulted in significant widening of the nasal structures as well as narrowing of the maxillary sinus. Habeeb, Boucher, and Chung's (2013) CBCT studies revealed similar results as Kilic's earlier study that rapid palatal expansion results in significant forward movement of the maxilla. Again, however, as discussed earlier, routine CBCT imaging involves exposure to relatively large doses of radiation, and is not commonly used for soft tissue analysis. Therefore a more practical means of determining soft tissue changes would be beneficial for both patients and practitioners.

Beginning in the 1980s, orthodontic treatment goals have gradually placed a greater emphasis on refinement and enhancement of facial soft tissues. As a result of this paradigm shift, parameters and guidelines have been proposed to guide the orthodontist in improving facial esthetics (Arnett 1993). Yet a review of the literature reveals little information regarding changes in the facial soft tissues from palatal expansion. Therefore, a study documenting soft tissue changes produced by rapid palatal expansion would be valuable. Payne (2013) and Mollov et. al (2012) showed that several soft tissue landmarks are both accurate and reliable, and therefore provide the orthodontist with an economic and relatively easy method of analyzing patients in everyday practice. The main goal of this study is to determine the extent of facial soft tissue changes following rapid palatal expansion.

CHAPTER II
LITERATURE REVIEW

The Role of Facial Esthetics in Orthodontics

Orthodontic treatment has the capability to alter facial shape and form, and thus facial esthetics. Consequently, facial esthetics plays a foundational role in orthodontics and should be addressed as early as the initial treatment planning. A review of facial esthetic guidelines is necessary for orthodontists attempting to maximize treatment outcomes. However, a review of literature reveals that several different methodologies have been used for evaluation of facial esthetics. Therefore, a brief history underlining the evolution of facial esthetics and its interrelationship with orthodontic treatment decisions is beneficial.

Charles Tweed argued that a treatment approach focused solely on achieving ideal arch form and occlusal relationships often resulted in poor facial esthetics, with a loss of the balance and harmony of the face (Tweed 1945). Therefore, from examining treatment "successes" and "failures"; he concluded that the most optimal facial esthetics are a result of upright mandibular incisor position as determined by a 90 degree incisor mandibular plane angle. This allowed for a dental and muscular balance that provided pleasing facial results. Incisor position appears prominently in several discussions on facial esthetics throughout orthodontic history. An early study of facial profile esthetics showed that an establishment of balance between the upper and lower incisor position resulted in optimal facial esthetics. The relative convexity of the face in profile guides these final positions, with a more convex face requiring a more upright final incisor position, and vice versa (Riedel 1950).

Increased availability of cephalometric radiology led to its widespread utilization by practitioners as a means of guiding and interpreting treatment outcomes. As a result of its popularity, analyses were developed as a tool to help guide the orthodontist in determining successes or failures. An early cephalometric study demonstrated the importance of a balance between several facial and dental structures and listed several "norms" for achieving ideal facial esthetics. For example, once a balance between the maxilla and mandible (ANB=2) is achieved, the upper and lower incisors can therefore be related to the skeletal landmarks to achieve harmony (Steiner 1953). Some of the earliest landmark studies on cephalometric facial analysis were completed by William B Downs, who concluded that although individuals display a wide array of skeletal and dental types, certain characteristics are common amongst those demonstrating more ideal facial esthetics. Such requirements for ideal facial esthetics include a functionally balanced occlusion, profile balance, and primarily an overall balance of dental and skeletal bases (Downs 1956).

An overriding theme in several of these earlier cephalometric studies was that optimal facial esthetics is a consequence of attaining proper facial balance. For example, Merrifield concluded that lower face balance was of great importance and should not simply be subjectively determined by practitioners. He offered that critical evaluation of a patients' Z angle and soft tissue profile line removes ambiguity and provides proper determination of balance. Furthermore, he stated that a more esthetically pleasing profile is attained by completing treatment with a chin position equal to or more protrusive than the upper lip thickness (Merrifield 1966). As cephalometric studies advanced, an increasing degree of attention was directed towards soft tissue changes. Clearly, soft tissue, and not simply dental and skeletal balance, occupies a central role in facial esthetics.

Review of Palatal Expansion

The utilization of palatal expanders by orthodontists began with the father of orthodontics, Edward Angle, and their utilization has been extensively detailed within orthodontic literature (Angle 1860). Much of the earliest work on expanders and their indications was conducted by Dr. Andrew Haas. In one of his earliest publications, Haas advocated for the use of palatal expanders in five clinical situations, and although not entirely true today, several elements of this article published over 40 years ago are still highly relevant (Haas 1970). Interestingly, as Haas pointed out, the use of palatal expansion as indicated for Class III malocclusions is common, and other prominent authors, such as McNamara, have relayed similar benefits of palatal expansion for Class III correction (McNamara 1987). Indeed, the use of expanders as a treatment modality is still commonly used today primarily to aid with the correction of crossbites, crowding, and transverse maxillary deficiencies (Proffit 2012).

Despite this relatively common use of expansion as a treatment method, multiple modalities and appliance designs exist. These modalities can be categorized by three primary types of expansion: rapid maxillary expansion, slow maxillary expansion, and surgically assisted maxillary expansion (Agarwal and Mathur 2010). Furthermore, four types of expanders exist when categorized by activation protocol. These four groups are screw-type, spring-type, magnetic, and Shape Memory Alloy (SMA) activation.

The screw-type expander category consists of expanders in which manual rotation via a wrench or “key” by either the clinician or patient results in widening of the jack-screw. This design has a well understood and historically common mechanical concept of expansion via turning of a screw-jack. Simply, the amount of screw rotation directly corresponds to the amount of expansion. An advantage of this category includes the flexibility provided to the practitioner to prescribe a certain amount of expansion over a certain period of time. Also, appliances can be adapted to fit a variety of palate sizes and shapes, seemingly limited only by the size and placement of the jackscrew component. However, several drawbacks to the jackscrew appliance do exist. Foremost among these is that upon activation of the screw, a sudden, rapid increase in force is produced which has been shown to possibly result in less physiologic expansion of the palatal suture. Also, this method of expansion places a large responsibility on the patient to comply with expansion protocols, which is a significant disadvantage of this design. Within this category of appliances is the most commonly used Hyrax appliance design, named for its trademarked Hyrax jackscrew (Romanyk et al 2010).

Spring-type expanders are defined as any appliance that funtions via mechanical deformation of a body. This deformation subsequently results in elastic restoration forces that are exerted on the palate and thus results in expansion. This design offers certain advantages, such as less dependency upon the patient to manually activate the expander at a regular interval. Furthermore, theoretically it applies a constant force over a period of time and avoids sudden increases in force as seen in the screw appliances. This predictable amount of force likely results in greater comfort for the patient following initial delivery. The amount of force produced is inversely proportional to the amount of expansion. Therefore, the more expansion produced the less force for further expansion remains and the orthodontist may have to remove and re-activate the appliance if more expansion is needed following treatment. Patient safety is also another concern, as the appliance is delivered “active”. Perhaps the greatest drawback of this design is that although springs provide predictable transverse forces, any deformation of the appliance may result in unwanted force in all other planes of space (Romanyk et al 2010).

Magnetic expanders also exist, and have been referred to as Magnetic Expansion Devices (MED). The goal of magnetic expansion devices is to provide continuous forces of a lesser magnitude than traditional expansion devices. The magnets are applied so that their directionality opposes each other, thus creating a repulsive and expansive force (Romanyk et al 2010). Theoretically, this would result in a more biologically friendly and less traumatic stimulation of maxillary suture growth, similar to spring type appliances. A study by Darendeliler showed the greatest degree of skeletal expansion occurred in banded appliances with four magnets. A set of two magnets were placed apically to the central and lateral incisors and the second set placed between the second bicuspid and first molar. Although the sample size was small, they did show that MEDs provide a relatively effective method of palatal expansion, which did not rely on patient compliance (Darendeliler 1994). Advantages and disadvantages of MEDs are similar to those of the spring type of appliances. However, one significant advantage of MEDs is that they are less prone to deformation and thus have less risk to produce undesirable and unpredictable forces in dimensions other than the transverse. Similar to the spring type, magnetic forces decrease with increasing expansion and therefore also require adjustments like its spring counterparts. This problem can be avoided by placement of magnets of greater strength; however this may result in less patient comfort and less physiologic suture opening (Romanyk et al 2010).

Finally, the fourth category of expanders, shape memory alloy appliances, utilize the properties of nickel titanium wires and are therefore dependent upon the properties of the shape memory alloy incorporated into the device for expansion. Orthodontists have become increasingly familiar with the properties of Ni-Ti wires and therefore it is prudent to assume their incorporation into expansion devices is a natural progression. However, the drawbacks of a conventional spring appliance still exist with these appliances. Of primary concern is that any deformation of the appliance may result in uncontrolled forces transverse to the direction of expansion. More recently, promising hybrid devices have been constructed to include both Ni-Ti wires and expansion jackscrews; however these appliances re-introduce the major disadvantage of patient compliance (Romanyk et al 2010).

As previously mentioned, palatal expanders can also be categorized based on rate of expansion into three broad categories: rapid, slow, and surgically assisted. Rapid palatal expansion (RPE) typically involves two turns per day of a jackscrew expander appliance, commonly a rate of 0.5 mm expansion per day. Indications for rapid palatal expansion include transverse discrepancies of greater than 4mm with dental compensation via buccally tipped maxillary molars, disruption of sutures to aid Class III correction, and moderate maxillary crowding. RPE is contraindicated when there is recession of the alveolar bone on maxillary molars or premolars, presence of anterior open bite, high mandibular plane angle, convex profile and doubtful patient compliance (Agarwal and Mathur 2010). Furthermore, RPE is contraindicated in mature patients beyond the growth spurts, however many practitioners may still choose this treatment modality on older patients. Clinically, patients are instructed to turn the expander once in the morning and once in the evening, or only once a day, commonly for a period of two to three weeks followed by a retention period of at least three months. This rapid rate of activation and relatively large force application is thought to maximize orthopedic skeletal expansion while minimizing dental movements (Agarwal and Mathur 2010). RPEs can be designed as banded or bonded appliances, and can be tooth-borne, tissue-borne, or tooth and tissue borne. Some examples of rapid palatal expanders are the Hyrax expander, Issacson expander, and Haas expander (Agarwal and Mathur 2010).

Slow palatal expansion (SPE) is a process by which light, relatively continuous force levels commonly in the range of 450-900 grams are applied. It is thought that the lighter forces result in less resistance from sutural structures, thus allowing more bone formation and activity in the intermaxillary suture, but possibly less suture opening. Furthermore, post-expansion stability and retention may be greater with SPE. Appliance designs vary greatly for SPE, with some examples being the Quadhelix, the Coffin appliance, magnet expanders, W-arches, and spring jets. The hyrax expander can also be used for SPE, with a maximum of 1 mm expansion per week applied. Finally, surgically assisted palatal expansion occurs when expansion is aided with surgical intervention. Surgical expansion involves either surgically assisted rapid palatal expansion (SARPE) or segmental maxillary surgery such as a Lefort osteotomy. Indeed, this procedure allows for expansion beyond skeletal maturation but is highly invasive and complex (Agarwal and Mathur 2010).

Effects of Palatal Expansion

When palatal expanders are used, widening of the maxillary arch may occur via either orthodontic or orthopedic movements, or a combination of both. Generally, the initial increase in width occurs as teeth compress and stretch the periodontal tissue. This is an orthodontic movement as the teeth are tipped laterally due to sudden force application, and studies have shown that this gain is usually completed within one week (Cotton 1978) (Hicks 1978). Compressive forces continue as long as the expander is active. These forces result in resorption of the buccal alveolar plate at the interface of the tooth root and periodontal attachment, resulting in further orthodontic tooth movement. This movement is bodily movement of the teeth into a wider arch form. Orthopedic expansion of the maxilla occurs via separation of the midpalatal suture. This separation occurs when forces applied exceed the bioelastic tensile strength of the elements within the suture, or the interdigitation of the bony spicules. As long as the transverse force of expansion is greater than this tensile strength, further separation of the suture occurs. Once the expander is locked, the suture reorganizes (Bell 1982).

Palatal expansion, similarly to several treatment modalities in orthodontics, can produce profound changes in a patient's overall facial appearance. Cephalometric studies have historically been used to describe these changes. In one of the earliest studies conducted by Haas, he found that cephalometric analysis revealed an increased internasal width following expansion, concluding that there is "coincidental widening of the nose and lowering of its floor". Of course, these studies focused solely on skeletal changes via radiographic appearance. He also found that there was a widening of the mandibular arch, and postulated that this may be attributed to tongue pressure from inferior displacement by the expansion appliance (Haas 1961). White (1972) examined pretreatment and post treatment records of thirty patients undergoing palatal expansion. He noted clockwise movement of the mandible following expansion treatment. Also of note, however, was that he noticed significant widening of the internasal width on posteroanterior cephalograms. Chung and Font examined pre and post-treatment records on twenty children who were treated with Haas type expanders. The authors also found statistically significant downward and forward displacement of the maxilla, and clockwise rotation of the mandible following expansion treatment. Furthermore, significant facial changes beyond the maxilla and mandible were noted. Anterior facial height and the width of both the maxilla and the nasal cavity increased significantly (Chung and Font 2004).

Similar results were published by Gabriel de Silva Fo, who studied the results of rapid palatal expansion on thirty children, aged 5 to 10 years and 11 months. Haas type expanders were used on all patients, and parents were prescribed 1 turn daily for 1 to 2 weeks. From their results, they concluded that the maxilla always dislocates in a downward and backward manner with respect to the palatal plane, thus significantly altering N-ANS, PNS-PNS’, A-A’, and SN-PP. Furthermore, B point is posteriorly displaced following expansion due to clockwise rotation of the mandible in response to palatal expansion changes. Finally, facial heights were increased significantly, which was attributed to the vertical displacement of the maxilla and maxillary molars (Gabriel de Silva Fo 1991). Similar results were found by Sarver who reported anterior and inferior movement of the maxilla following expansion treatment; however he did note that utilization of a bonded expander device limited this effect (Sarver 1989). This information should be critically evaluated by the orthodontist, as these studies support that expansion treatment changes extend beyond the dental arches.

The advancement of cone beam computed tomographic (CBCT) radiology has allowed orthodontists and researchers to explore changes produced by palatal expansion more precisely. Habeeb evaluated pre and post-treatment CBCT radiographs of twenty eight patients who were treated with bonded Haas expander appliances. The investigator found that both ANS and PNS moved significantly downward from expansion treatment. In addition, they found that while the maxilla was anteriorly displaced, the maxillary central incisors moved posteriorly from their initial position (Habeeb 2013). A similar CBCT study was conducted using thirty patients, mean age of 13.8 +/- 1.7 years, who underwent palatal expansion with a banded Hyrax appliance design. High-resolution CBCT images were taken before and after expansion, which the authors claimed allowed for more accuracy than previous studies. They found that rapid maxillary expansion resulted in a statistically significant increase in nasal width ($p<.0001$). On average, nasal width increased by 1.89 mm, or 37.2% of the mean expansion of the hyrax appliance (Garrett 2008). It may be important to note that this change was due primarily to expansion, independent of aging (Garret 2008). Similar findings occurred in a CBCT study on fourteen children who underwent rapid palatal expansion. All patients were treated with a four-banded Hyrax appliance design and instructed to activate the appliance 1 turn/day for 28 days or until complete correction of pre-existing crossbites. CBCT scans were taken prior to initiation of treatment and again 3 to 4 months following expansion. From their data, the authors agreed with previous studies that RPE indeed may cause significant expansion of the maxilla. Furthermore, they concluded that there is a significant increase in the cross-sectional area of the upper airway following rapid maxillary expansion (Chang et al. 2013). Therefore, recent CBCT studies show agreement with earlier hard tissue studies on expansion effects.

Soft Tissue Effects of Palatal Expansion

Although the studies listed above discuss treatment outcomes that altered facial characteristics of orthodontic patients, it is important to our work to also investigate studies which examine effects of expansion on soft tissues. Mota dos Santos evaluated twenty patients who underwent rapid palatal expansion. Lateral cephalograms were taken prior to expansion treatment, immediately following expansion treatment, and finally after a period of retention. Any conclusions on long-term soft tissue changes based on their data were inconclusive. The authors did note statistically significant changes in the following cephalometric measurements: S–li , H Line–Prn, E Line–Li, E Line–Ls , ANS′–Me′. They concluded these changes were primarily due to the presence of the expander appliance. However, they concluded that following a retention period of six months, minimal soft tissue changes are seen following expansion (Mota dos Santos 2012).

A similar study was conducted which consisted of 18 patients with bilateral posterior crossbite. All patients underwent rapid palatal expansion using bonded Hyrax expanders, the same appliance used in the previous study. Cephalometric radiographs were again taken at three separate time points, prior to treatment, following completion of expansion, and retention (mean 5.95 +/- 0.35 months). All radiographs were taken by a single operator, with caution taken to ensure lips in repose. Holdaway soft tissue measurements were analyzed from the radiographs. The results were slightly different than those of Mota dos Santo's study, as soft tissue facial angle decreased ($P < 0.05$), and H angle and skeletal profile convexity significantly increased ($P < 0.001$) following expansion. Also, the authors noted that while some relapse did occur, both H angle and profile convexity remained significantly altered following retention periods. (Kilic 2008). In summary, the literature database supports the notion that rapid palatal expansion produces soft tissue changes, however the question still remains on the most reliable and efficient method of measuring such changes.

Soft Tissue Measurement

The method of soft tissue evaluation is critical to the overall quality of study results. Therefore, a determination of the most accurate method is necessary prior to data collection. It has been determined that intra-examiner measurements display a higher degree of consistency, accuracy and reliability than inter-examiner measurements (Mollov 2012). Furthermore, certain soft tissue facial landmarks are more accurately identifiable than others. Of all measurements, nasal width (al-al, R=0.992), middle third of the face (N'- Sn, R= 0.989), and upper lip length were the most accurately measured (Mollov 2012).

Much of Farkas' work on soft tissue anthropometry has shown that direct anthropometric measurements on children vary in difficulty of acquiring accurate data. Major factors of influence are age, duration of examination, and cooperation (Farkas 1996). However, much of Farkas' difficulties came on children under the age of five. No individuals below the age of five were included in our project, thus the challenge did not affect our data acquisition. The majority of the measurements in this study were centrally located on the face. Payne (2013) demonstrated that nose and mouth landmarks were amongst the most reliable from frontal photographs. However, photographic examination is time consuming and is only necessary as an adjunct to the initial clinical exam. Yet direct examination and photographic examination are comparable enough that it can be determined that equally reliable anthropometric measurements can be taken on patients at rest position or via photographic examination.

Current State of the Problem

Despite the relatively large volume of literature describing palatal expansion, few studies have reported the effect of rapid maxillary expansion using only facial soft tissue landmarks. This is likely due to the difficulty of controlling large number of variables, including soft tissue thickness, weight fluctuations, and accounting for natural growth of patients. Many of the present studies available rely heavily on radiographic evaluation, rather than photographic or direct patient evaluation. Thus, a void in knowledge is available on a commonly used technique, palatal expansion, and its direct soft tissue clinical effects on a patient. Therefore, a sample of 28 Marquette University School of Dentistry patients were measured before rapid palatal expansion and again following palatal expansion using a digital caliper. In all, eighteen soft tissue measurements were obtained for evaluation. Included amongst these are mouth width, base of the nose, alar of the nose, intraorbital width and other measurements which are of utmost importance to final esthetic treatment outcomes. The outcome of this study will aid orthodontic practitioners, as well as patients, in better understanding what facial soft tissue changes, as well as degree of change, may occur as a result of palatal expansion.

The purpose of this study was to evaluate facial soft tissue changes following rapid palatal expansion using only soft tissue landmarks measured by a digital caliper, at two different time points.

CHAPTER III
MATERIALS AND METHODS

This study was approved by the Institutional Review Board (protocol # HR-2083). Twenty eight subjects (14 males and 14 females), with ages ranging from 7 years, 1 month to 15 years, 5 months, who were enrolled as patients at the Marquette University School of Dentistry Orthodontic Clinic, were included in this study. Subjects were excluded from the study if they (1) had history of any congenital abnormality, (2) had undergone medical/pharmacological treatment that would affect the facial complex, (3) had facial hair that would mask landmarks to be identified, or (4) were unable to follow verbal instructions to allow measurements to be taken. Weight fluctuations were not accounted for in this study.

The RPE appliance designs used in this study consisted of banded Hyrax expanders (24 subjects), banded Haas expanders (3), and a bonded Hyrax expander (1 subject). Study participants turned the expander an average of 25 turns, or 6.25 mm of total expansion. This consisted of a range of 14-38 turns, depending on the amount of expansion needed to obtain a relationship of the maxillary lingual cusp in occlusal contact with the mandibular buccal cusp. Of the 28 subjects, 22 were prescribed 1 turn of expansion every day, 3 prescribed 1 turn every other day, 2 prescribed 1 turn every third day, and 1 failed to report amount of turns per day.

The study did not create any restrictions to normal orthodontic care. Patient treatment plans were determined by the resident and attending faculty members, independently of the study investigators.

Measurement

At orthodontic records or at treatment planning appointments, the principal investigator recorded the initial facial measurements (T0). Patients over 15 years of age consented to participate in the study and patients under 15 assented to participate with written authorization from their legal guardians.

Facial soft tissue measurements were taken in centric occlusion. The subjects were seated in the orthodontic chair with Frankfort Horizontal plane parallel to the floor. Their lips were then manipulated into a relaxed-lip posture, which was attained initially by asking patients to pronounce the word “EMMA” and to hold their teeth together in order to guide the mandible into maximum intercuspation, while keeping their eyes opened. Measurements were recorded for all participants in the form created for this study. (Fig. 1) A relaxed lip position was confirmed by the investigator, and if patients needed assistance to relaxed lip position the investigator gently stroked the lips (Burstone, 1967). Measurements were not recorded until relaxed lip position was attained, and patients were not included in the study if unable to achieve this position. Relaxed-lip posture was used because it is a reasonably reproducible position independent of teeth and supporting alveolar processes.

All eighteen facial soft tissue measurements were taken by the same investigator. A description on how to identify the facial landmarks can be seen on Table 1, Figure 1, and Figure 2. Facial measurements were taken using a 1/8 inch (203.2 mm), sliding digital Mitutoyo caliper (Aurora, IL). The measurement error for all Mitutoyo calipers was identical to the company’s description (0.01 mm). The investigator was trained and calibrated for using the Mitutoyo caliper. Ten subjects were re-measured two-weeks to one month later, prior to treatment initiation (RPE cementation) solely to determine the investigator's intra-examiner reliability.

A second set of measurements (T1) was then performed when RPE treatment was completed and the rapid palatal expander was locked.

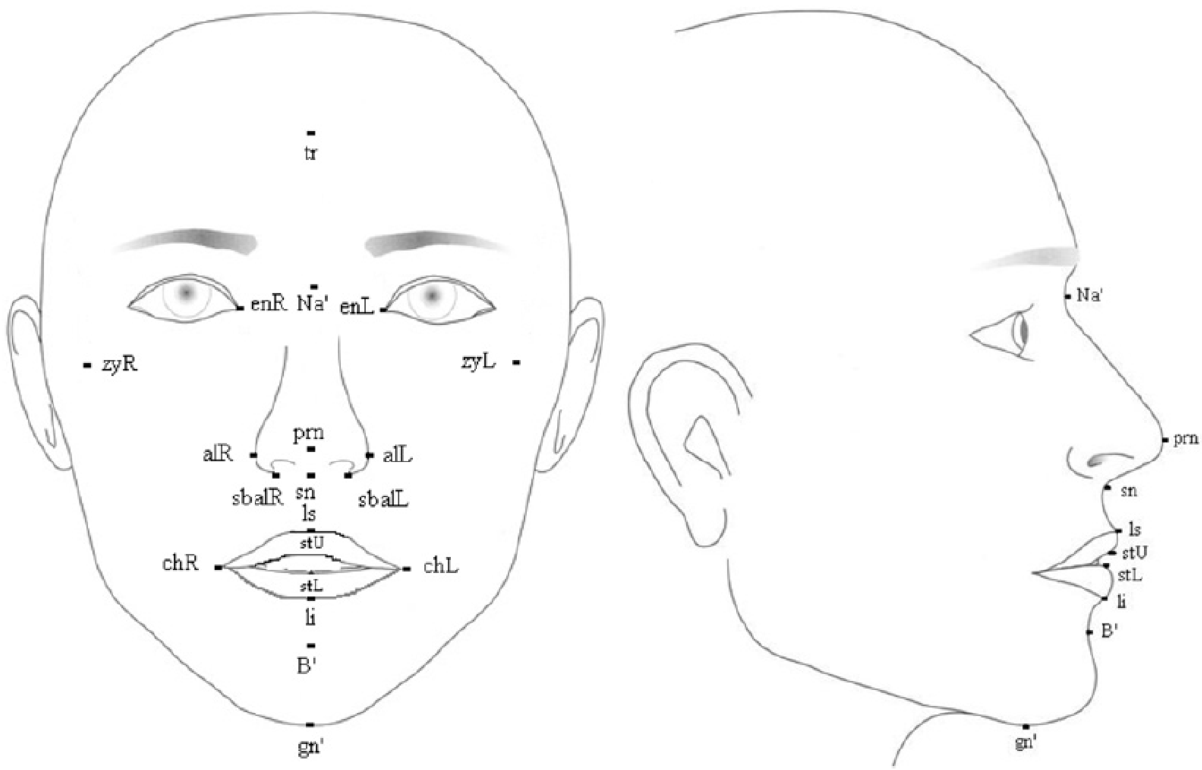

Figure 1. Soft tissue measurements. (These drawings appeared in Arnett GW, Bergman RT. Facial keys to orthodontic diagnosis and treatment planning. Part II. Am J Orthod Dentofac Orthoped 1993; 103(5):395e411 Elsevier, 1993, and in N. Mollov et al., Journal of the World Federation of Orthodontists 1 (2012) e157ee161 Elsevier 2012.)

Figure 2. Examples of facial soft tissue measurements being recorded with caliper.

Table 1. Description of the points utilized for the soft tissue measurements.

trichion (tr)	The point on the hairline in the midline of the forehead. Note: for this project, no participants with visible hair loss or abnormally high hairline were selected for participation
soft tissue nasion (Na')	The soft tissue covering the point located in the midline of both the nasal root and the nasofrontal suture
endocanthion (en)(Left or Right)	The point at the inner commissure of the eye fissure
zygion (zy)(L or R)	The most lateral point of each zygomatic arch; identified by trial measurements.
pronasale(prn)	The most protruded point of the apex nasion
alare (al)(L or R)	The most lateral point on each alar contour
subnasale (sn) (L or R)	The midpoint of the columnella base at the apex of the angle where the lower border of nasal septum and the surface of the upper lip meet
subalare (sbal)(L or R)	The point at the lower limit of each alar base, where the alar base disappears into the skin of the upper lip
labiale superius (ls)	The midpoint of the upper vermillion line
labiale inferius (li)	The midpoint of the lower vermillion line
cheilion (ch)(L or R)	The point located at each labial commissure
stomion (sto) (Upper and Lower)	The imaginary point at the crossing of the vertical facial midline and the horizontal labial fissure between the upper/lower lip and the oral cavity as seen from a frontal view. Note: in this project the study participants were asked to relax their lips, hence the visible border of each lip was used as the horizontal landmark
soft tissue B point (B')	The deepest curvature of the soft tissue between the lower lip and the chin point
gnathion (gn')	The lowest median landmark of the lower border of the mandible
menton (me)	The lowest, or most inferior, point on the mandible from a frontal view

Statistical Analysis

To determine intra-examiner reliability, we calculated Pearson's correlation coefficient, and found it to be $r = 0.998$. This indicates nearly a one-to-one correspondence in the measurements taken at the two time points by the same examiner.

For comparative measurements, we first considered descriptive statistics of the age of the patients and of each of the measurements taken. A paired t-test was used to compare the measurements taken at the two time points. Since conducting multiple t-tests naturally inflates the Type I error, or the probability of finding a significant result simply due to chance, we reduced the significance level from 0.05 to 0.01. (In other words, a result is only significant if the p-value is found to be less than 0.01).

CHAPTER IV
RESULTS

Reliability of Measurements

Pearson's correlation coefficient was calculated and found to be r = 0.998. This indicates nearly a one-to-one correspondence in the measurements taken at the two time points by the examiner. The measurements can be seen in the scatterplot below (Figure 3).

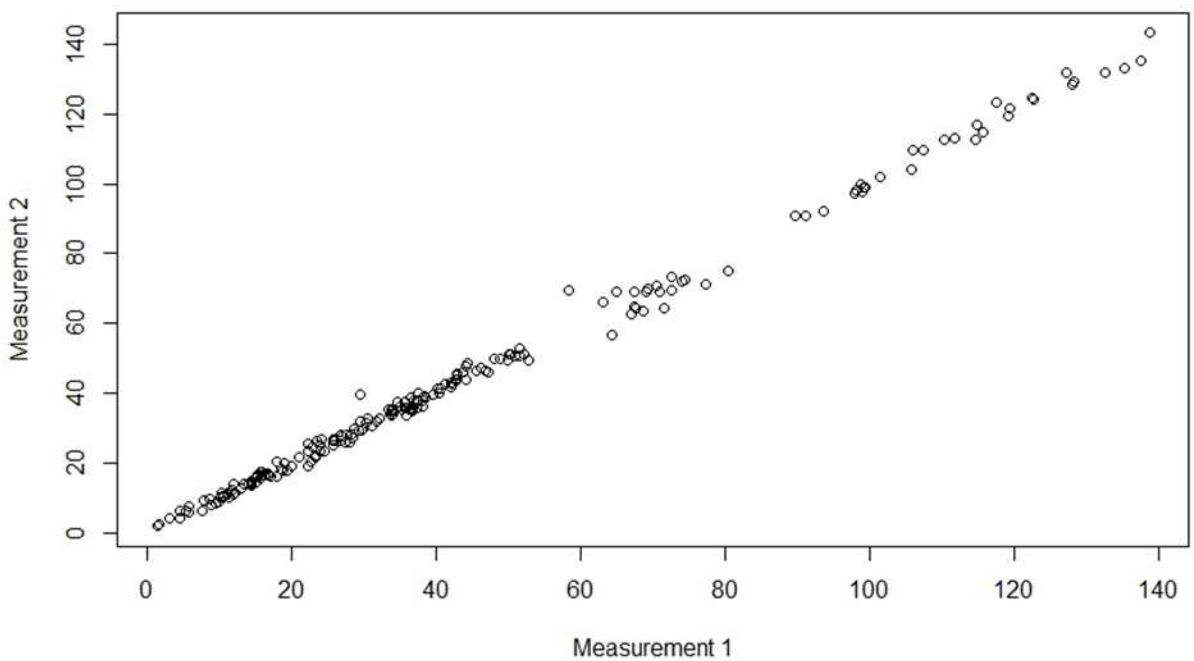

Figure 3. Pearson's correlation coefficient measurements.

Soft Tissue Measurements

We first consider descriptive statistics of the age of the patients and of each of the measurements taken. At the initial time of measurement (T-0), the patient age range was between 7 years, 1 month to 15 years, 5 months. The mean age of the patients was 12 years, 2 months, with a standard deviation of 3.1 years. The average age of the female patients (n=14) was 11 years, 10 months. The average age of the male patients (n=14) was 12 years, 8 months.

The eighteen soft tissue measurements were divided into two subgroups of horizontal and vertical measurements (Table 2 and Table 3). For the horizontal group, the results (Table 3) showed that intraorbital width, nasal width at the widest point of the nostrils ($p<.0001$), and mouth width ($p=0.0035$) were significantly different following rapid palatal expansion. For the vertical group, soft tissue nasion to pronasale, showed a significant difference ($p=0.0008$).

The majority of measurements showed increased values following palatal expansion, but most of them were not statistically significant (Table 3). The following measurements showed a non-statistical decrease: nasal width at base of nose (sbalR – sbalL), stomion lower – soft tissue B point (stL –B'), soft tissue B point – gnathion (B' – gn'), and subnasale – gnathion (sn – gn')). One horizontal, zygomatic width, and one vertical measurement, subnasale-gnathion, showed almost no variation ($p>0.9$).

Of the horizontal group, three of the five measurements demonstrated positive change. Of these three, the alar nasal width at the widest point of the nostrils exhibited the greatest difference after palatal expansion, expanding a mean distance of 1.1mm.

Negative change between T0 and T1 was noted for zygomatic width and alar nasal width at the base of the nose, with alar nasal width at the base of the nose undergoing the greatest change.

Of the vertical group, seven measurements exhibited positive changes, or increases (greatest change: soft tissue nasion to the tip of the nose), five measurements exhibited negative change, or decreases (greatest: soft tissue B point to Menton), and one measurement exhibited no change (subnasale to upper lip vermillion border).

Table 2. Soft tissue measurements.

	Facial Landmark
Horizontal Measurements (mm)	1. Zygomatic Width (zyR – zyL)
	2. Intraorbital Width (enR – enL)
	3. Nasal width at widest nostrils (alR - alL)
	4. Nasal width at Base of Nose (sbalR - sbalL)
	5. Mouth Width (chR - chL)
Vertical Measurements (mm)	6. Subnasale - right commissure (sn e chR)
	7. Subnasale - left commissure (sn e chL)
	8. Hairline - nasion (tr – Na')
	9. Nasion – Pronasale (Na' – prn)
	10. Nasion – SubNasale (Na' – sn)
	11. Pronasale – upper lip (prn - ls)
	12. SubNasale - upper lip (sn- ls)
	13. Mouth height (ls - li)
	14. Interlabial Gap (stU – stL) - if lips are incompetent
	15. Lower lip thickness (stL - li)
	16. Stomion lower – soft tissue B point (stL –B')
	17. Soft tissue B point – gnathion (B' – gn')
	18. Subnasale – gnathion (sn – gn')

Table 3. The paired t-test results (significant values<0.01).

Measurement	*Time*	*N*	*Mean*	*SD*	*t statistic*	*p-value*	*Significance*
Age		28	11.9	3.1			
Zygomatic width (zyR – zyL)	0	28	110.8	8.3	0.08	0.9337	
	1	28	110.7	8.1			
Intraorbital width (enR – enL)	0	28	31.3	2.9	-5.07	<.0001	****
	1	28	32.6	2.7			
Nasal width at widest nostrils (alR - alL)	0	28	33.8	3.8	-7.09	<.0001	****
	1	28	34.9	3.8			
Nasal width at Base of Nose (sbalR - sbalL)	0	28	18.0	3.6	2.04	0.0513	
	1	28	17.4	3.0			
Mouth Width (chR - chL)	0	28	43.8	3.8	-3.21	0.0035	****
	1	28	45.9	4.0			
Subnasale - right commissure (sn e chR)	0	28	35.8	2.6	-2.47	0.0200	
	1	28	36.6	2.7			
Subnasale - left commissure (sn e chL)	0	28	36.2	3.5	-1.11	0.2784	
	1	28	36.6	3.1			
Hairline - nasion (tr – Na’)	0	28	66.0	6.5	-1.38	0.1774	
	1	28	66.9	6.0			
Nasion – Pronasale (Na’ – prn)	0	28	40.4	5.3	-3.79	0.0008	****
	1	28	42.7	4.4			
Nasion – SubNasale (Na’ – sn)	0	28	46.0	4.6	-1.89	0.0691	
	1	28	46.8	4.2			
Pronasale – upper lip (prn - ls)	0	28	25.8	4.8	1.08	0.2891	
	1	28	25.3	3.9			
SubNasale - upper lip (sn- ls)	0	28	12.2	2.9	0.20	0.8459	
	1	28	12.2	2.1			
Mouth height (ls - li)	0	28	23.1	5.5	-1.09	0.2851	
	1	28	23.9	4.3			
Interlabial Gap (stU – stL)	0	28	4.1	3.0	-0.86	0.3991	
	1	28	4.5	2.3			
Lower lip thickness (stL - li)	0	28	10.3	1.6	1.10	0.217	
	1	28	10.1	1.7			
Stomion lower – soft tissue B point (stL –B’)	0	28	16.2	2.6	0.39	0.6989	
	1	28	16.1	2.4			
Soft tissue B point – gnathion (B’ – gn’)	0	28	27.0	3.8	1.62	0.1170	
	1	28	26.0	3.0			
Subnasale – gnathion (sn – gn’)	0	28	67.8	6.6	0.08	0.9407	
	1	28	67.7	6.3			

Regression models were performed for each of the eighteen measurements. These were performed to determine the influence of age on the measurements. One of the eighteen measurements, alar nasal width at the base of the nose, was determined to be significantly influenced by age. For this value, the parameter estimate was -0.290 and the t value -2.07, giving a significant p value ($p<0.05$) of Pr>|t|=0.048. The R-Square value was 0.142 with an adjusted R-Square value of 0.109, indicating the proportion of the variability in the data accounted for by the model. An R-Square value of 1 indicates a perfect fit, with a value of 0 indicating a poor fit. This is shown in table 4 below.

Table 4. Regression model for alar nasal width at the base of the nose.

R-Square	0.1417
Adj R-Sq	0.1086

Parameter Estimates						
Variable	**Label**	**DF**	**Parameter Estimate**	**Standard Error**	**t Value**	**Pr > |t|**
Intercept	Intercept	1	2.93473	1.73972	1.69	0.1036
age	age	1	-0.28958	0.13980	-2.07	0.0484

CHAPTER V
DISCUSSION

Modern dentistry, and especially orthodontics, places an ever-increasing demand to balance treatment goals between function and esthetics. Consequently, in order to appropriately incorporate rapid palatal expansion into a comprehensive orthodontic plan, a greater understanding of the effects of rapid palatal expansion on soft tissues comprising the face is necessary. Therefore, this study was designed to evaluate facial soft tissue changes following rapid palatal expansion.

Studies involving direct measurements of soft tissue require careful attention to both the number of investigators and the timing of measurement. In this particular study, data for both reliability testing and palatal expansion measurements was gathered at a minimum of two weeks apart. This two week time period was chosen in order to minimize the possibility of memory recall of previous measurements that would introduce bias in location of landmarks. This interval is supported several times within the literature (Fernandez-Riveiro 2002, 2003, Anic Milosevic 2008, 2011, Schimmel 2010, Lee 2010, Mollov 2012, Payne 2013).

Furthermore, the question of whether one or several investigators should be recording measurements must be addressed. It is inherently challenging to construct research projects that require measurements directly of facial soft tissues. It has been stated that a major reason for this is that soft tissue contours, as compared to hard tissue elements, have softer contours that are less distinct (Park 1986, Arnett 1999). Thus, it is necessary that the examiner maximizes the reliability of measurement taking, in order to counter the decreased reliability involved with identification of soft tissue landmarks.

One such strategy is to have all measurements recorded by only a single investigator. Consequently, a single examiner, who was calibrated for anthropometric measurements using the Mitutoyo calipers, recorded all measurements in this study. A recent study compared inter- and intra-examiner reliability when attempting to localize soft tissue landmarks on sagittal and frontal photographs. The author concluded that localization of all landmarks had significantly greater intra-examiner reliability compared to inter-examiner reliability (Payne 2013). Consequently, it can be determined that when a single individual is recording all measurements that greater consistency results. It is thought that this is from identification bias and repetition, compared to the rather inconsistent analysis of a landmark by different examiners. This is supported by several other facial soft tissue studies that also utilized only a single examiner for landmark identification (Phillips 1984, Fernandez-Riveiro 2002, Ghoddousi 2007, Anic-Milosevic 2008, Ferring 2008 and Lee 2010).

When evaluating facial soft tissues, a decision must be made to investigate via direct anthropometric measurements or photographs. For our study, direct anthropometric measurements were made for twenty eight patients. In a study by Franke-Gromberg (2010), the authors compared direct anthropometric measurements with measurements made from two-dimensional photography of 27 classic facial anatomic landmarks. The results showed only minor differences between the two modalities, and it was determined that the two methods are similarly valid; however reliability depends on the investigators ability. Aksu et al. (2010) also examined the differences between 2D-photography measurements and direct anthropometric measurements taken with a digital caliper. Caliper measurements were made for 100 subjects, who were placed in centric relation, natural head position, relaxed lip posture and in a sitting position. A total of 16 distances were measured, 8 frontal and 8 sagittal. These results were then compared with measurements taken from frontal and lateral photographs and it was determined that direct measurements are more reliable than photography for frontal assessment. Comparison of three-dimensional photographs with direct anthropometric caliper measurements reveals different conclusions. Aynechi et al (2011) compared the precision of anthropometric measurements when using labeled 3D images, unlabeled 3D images, and direct caliper methods and found that caliper recordings were least precise. Most variation between the three measurements was found for landmarks with less distinct edges, as well as structures around the ears. Much of this variation was attributed to shadows cast on landmarks by the ear. Measurements taken directly with a caliper provide the advantage that the investigator is able to largely eliminate issues related to facial hair, shadowing, and edge delineation.

It is important to note that certain soft tissue landmarks are easier to accurately identify. Payne (2013) revealed that when identifying anthropometric landmarks from a frontal perspective, trichion, soft tissue glabella, right soft tissue gonion, and right tragus were most difficult to accurately locate. Conversely, pronasale, subnasale, philtrum point, stomion inferius, labrale inferius, supramentale, soft tissue pogonion, and right cheilion are more accurately delineated. Therefore, investigators should be aware of the established difficulty to properly identify certain facial landmarks when designing studies. Furthermore, similar difficulties in landmark identification have been noted throughout previous studies (Phillips 1984, Lagravere 2010, Mollov 2012). During rapid palatal expansion treatment, it can be assumed that midline structures will undergo proportionately greater change due to proximity to the midpalatal suture. When evaluating landmarks from frontal images, mouth and nose landmarks are significantly more reliable for use in soft tissue analysis than lateral landmarks such as gonion and trichion (Payne 2013). These results were consistent with those of Farkas (1980), as he found increasing reliability with lip and mouth structures, likely due to the relatively defined edge landmarks. This supports significant values identified in this study in the mouth and lip areas, as well as those along the midline with similarly defined landmarks.

Several of the parameters used in this study were based on anthropometric guidelines published by Farkas (1981). In his studies, Farkas argued that the majority of measurement errors come from three sources. The first, improper measuring technique was eliminated by using a trained and calibrated recorder. The second, problems with the measuring equipment, was minimized by using a 1/8 inch (203.2 mm), sliding digital Mitutoyo caliper (Aurora, IL). The measurement error for all Mitutoyo calipers was identical to the company's description (0.01 mm). Furthermore, all measurements were made in the same manner and within the same clinical setting. The third primary source of error according to Farkas is improper identification of facial landmarks. This was again minimized by using only a single examiner rather than multiple examiners. Also, Pearson's correlation coefficient for this examiner was calculated at a near perfect r value of 0.998, indicating a nearly 1-1 reliability factor. Another possible method for reducing identification error issues is marking the landmarks on the face with some form of identifier. This method has been used in previous studies (Shaner 1998), however it was not utilized in this current study as the evaluator was already trained and clinical time management was required.

The eighteen facial soft tissue points measured in this study were developed from previous anthropometric guidelines established by Farkas (1981) and later adapted by Mollov (2012). The most substantial alteration between the two measurement guidelines is based on lip posture. Farkas had originally defined stomion as the intersection of the facial midline and the horizontal labial fissure of the gently closed lips. In this study, a relaxed lip posture was achieved prior to measurements, resulting in an interlabial gap that excluded use of this definition. Therefore, Mollov adapted this definition to identify stomion upper and stomion lower, respectively, as the intersection of the facial midline with “the lower-most point of the upper lip” and “the upper-most point of the lower lip.” This definition was used for identification of stomion in this study.

From the results, the first change of statistical significance resulting from palatal expansion was the intraorbital width. In this study, we defined intraorbital width as the distance between the two innermost points of the orbit (enR-enL). However, despite statistical significance, the mean increase was only 1.3 mm per patient. Such a minor amount on overall intraorbital width is likely not clinically significant. A literature search failed to reveal data regarding soft tissue orbital effects following RPE. Alterations in orbital dimensions, particularly volumetric changes, have been seen in other studies investigating palatal expansion. Sicurezza (2011) studied thirty patients who underwent rapid palatal expansion using a Hyrax expansion device. The authors looked specifically at volumetric orbital dimensions as well as nasal aperture width, as both were calculated using multidetector computerized tomography (MDCT). All measurements were taken by a single trained and calibrated technician. From their results, they discovered that both orbital volume and nasal aperture width increased significantly following expansion treatment. Specifically, orbital volume increased from a mean of 18.81 ±1.23 mL to 19.53 ± 1.26 mL, and nasal aperture width increased from 36.02 ± 1.24 mm to 37.11 ± 1.01mm following expansion. Such information is particularly important to orthodontists hoping to achieve optimal facial esthetics following expansion. Faure et al. (2002) performed a study in which frontal photographs were manipulated and judged by a panel for overall esthetics using the Visual Analog Scale (VAS). The panel included dental students who were trained to focus on the smile and overall facial proportions. Photographs of thirty six different individuals were shown, three sets of each, with one set having interocular distance increased by 20%. The results demonstrated that increased inter-ocular distance was deemed less esthetically pleasing overall. The authors note that 20% increased width may have affected the results, and that a smaller increase of only 10% may have yielded differing results. As stated earlier, an increase of 1.3 mm is likely not apparent when judging overall facial esthetics. Despite this, the proportions and symmetry of the face may be effected by this increased width and so clinicians should still consider the overall proportions of an individual patient prior to performing palatal expansion.

The second statistically significant value in this study was increased alar nasal width at the widest point of the nostrils. A mean increase of 1.1 mm was seen following RPE treatment. This is likely not clinically significant, as that represents less than a 3% increase of the overall width between these two facial landmarks (33.8 mm prior to expansion). This point was defined in our assessment as the widest portion of the nose in the nostril area (alR-alL). This result coincides with much of the literature present on rapid palatal expansion. A recent meta-analysis on the effects of rapid palatal expansion on facial structures revealed that the overall effect on nasal cavity dimension is “apparent and indicates an enlargement between 17% and 33% of the total screw expansion” (Bazargani et al. 2013). However, this number is more indicative of the overall volumetric changes in the nasal cavity rather than strictly nasal width. Cross and McDonald (2000) looked at the effects of rapid palatal expansion on dental, skeletal, and nasal structures on twenty five patients and compared them to a control group of 25 individuals. Their results were similar to those of our study in that they found a statistically significant mean increase of 1.06 mm ($p<0.001$) in the maximum nasal width. One drawback to these studies is that both deal with evaluation of hard tissue changes following palatal expansion, while our study focused primarily on soft tissues. Conversely, a study performed by Johnson et al. (2010) focused solely on soft tissue changes following palatal expansion, specifically nasal widths. In this study, they examined 79 patients who underwent treatment with a Hyrax appliance. Direct facial measurements were taken using a caliper (similar to this study) before and following treatment. They measured alar base width and greater alar cartilage width. Their results revealed a statistically significant increase in alar base width regardless of gender or pubertal status, and a significant increase in greater alar cartilage width in post-pubertal females and pre-pubertal males. Additionally, the authors concluded that the demonstrated changes, although statistically significant, were not clinically relevant due to all mean differences falling below 1.5mm. These results agreed with those of another soft tissue study which examined the effects of rapid maxillary expansion on nasal morphology (da Silva Filho 2011). They evaluated frontal and profile facial photographs of 60 patients treated with Haas expanders and found no significant changes in nasal width in the middle third or at the base of the nose. Moreover, Johnson (2010) also concluded that pubertal status does not play a role in the overall effect of rapid palatal expansion on nasal soft tissues. This conclusion may be unexpected, as several other studies have found that more significant and successful transverse expansion occurs if completed prior to the pubertal growth spurt (Cameron 2002, Landsberger 1910, Krebs 1964, Baccetti et al. 2001 and Lagravere et al. 2005). However, it does agree with the CBCT study performed by Garrett (2008) who showed that there is significant increase in nasal width but age had no direct effect on the changes. In our study, age was recorded for participants however no data was gathered to determine pubertal growth status. Regression models from the data gathered showed that age only may have played a significant role in one of the eighteen measurements. Future studies may want to examine facial soft tissue change variation amongst pre and post-pubertal groups to determine the effects of intrinsic growth.

The third soft tissue measurement that was shown to have statistically significance was mouth width. In this study, mouth width was defined as the straight line distance between the right and left commissures (chR and chL). Our results showed that mouth width increased a mean amount of 2.1 mm, making it the most affected measurement of the horizontal group. This increase may, but is not likely to be, clinically significant. It does surpass the 1.5 mm guideline as outlined by Johnson (2010), yet the increase represents an overall increase in width of less than 5%. This may not be identifiable in overall facial esthetics. However, as discussed earlier, landmarks involving the lips and mouth are the most reliable and tend to undergo the most significant change. It can be concluded therefore that this result is expected, and largely due to the proximity of the mouth to the maxillary appliance. The drape of the mouth is largely determined by position of the underlying skeletal and dental structures. Chang (2013) compared cone beam computed tomographic (CBCT) scans of fourteen patients treated with rapid palatal expansion. These high resolution, three-dimensional scans were analyzed for effects on the maxillary arch, and confirmed previous studies that width increases are expected following expansion. Specifically, they identified a statistically significant increase at both the maxillary first molar and first premolar, with greater change more anteriorly at the level of the premolar.

This information aids the practitioner, as more dramatic changes occur to the maxillary dentition closer to the oral aperture. Kilic (2008) discusses how a complex relationship exists between hard tissues and soft tissues. Definitive statements on the changes of soft tissue mouth width are difficult to conclude, however, as there is a void in literature on soft tissue mouth width changes following palatal expansion. It can be concluded that soft tissue mouth width will likely increase due to expansion of underlying skeletal and dental structures; however more evidence is certainly needed.

Finally, the fourth measure of statistical significance in this study related to the length of the nose, or soft tissue nasion to tip of the nose. This point was defined as the distance between Na’ and ToN, and showed the greatest change of all eighteen landmarks over the two time points (mean=2.3mm). The 2.3 mm change represents a 6% overall increase, which is likely not clinically significant. This was the only vertical measurement that demonstrated statistical significance. Despite a clinically significant overall change, the length of the nose has been shown to increase over time as a function of age, largely due to the loss of elasticity within the fibers of the nasal drape (Sforza

2010). Combined with RPE treatment, the results of this study show that these age-related effects may be accelerated by expansion.

These findings contradict those of Kilic (2008). In his study, he examined 18 patients who underwent rapid palatal expansion with bonded jackscrew appliances and evaluated them for Holdaway soft tissue changes. The author concluded that there was overall no effect of rapid maxillary expansion on nose prominence. However, different results were yielded by a similar study by Karaman et al (2002). Twenty patients undergoing rapid palatal expansion with a jackscrew appliance were evaluated and it was determined that the nasal tip became more prominent and the length increased following expansion.

Similar downward and forward movement of the nasal tip has been noted following expansion in other studies (Subtelny, 1961, Nanda et al., 1990). This change, similar to mouth width, can likely be attributed to the facial soft tissues following the underlying hard dental and skeletal structures. As the maxilla relocates in a more downward, forward position, and the skeletal complex rotates clockwise, the soft tissue of the nose may also lengthen.

Study Weaknesses and Future Direction

Future studies involving soft tissue changes following RPE treatment are necessary to properly address and determine clinical importance. This study provides only a framework from which to build upon. Several limitations existed in this study which must be addressed. First, no control group was incorporated. A control group with matched age and genders without any orthodontic treatment would have provided information for comparison on changes seen with expected growth, aging, and other time-related alterations. Without a control, only superficial comparisons with previously established norms can be communicated. Secondly, no information was gathered on the immediate effects of placement of the rapid palatal expander appliance on the soft tissue. RPE designs vary in width and bulk, and may cause displacement of soft tissue as well as reposturing of musculature as patients adapt to the appliance. Without this information, it cannot be determined what changes are attributable to orthopedic and dental expansion versus secondary effects of appliance placement. Furthermore, the appliances used were different and the expansion protocol was not standardized. Thirdly, height and weight measurements were not recorded for participants. This information would have provided a method of control for soft tissue changes due to fluctuations of patient weight. Lastly, no retention records were taken. RPE treatment has been shown to have variable relapse following removal of the expansion device. The soft tissue changes noted in this study may have diminished following a retention period, and it would have been beneficial to have measurements taken at a time point six or more months following completion of active expansion treatment. Due to these limitations, few definitive conclusions can be drawn from this study.

CHAPTER VI
CONCLUSIONS

1. In a horizontal dimension, statistically significant increases in intraorbital width, nasal width at the widest nostrils, and mouth width can be expected immediately following rapid palatal expansion.

2. In a vertical dimension, a statistically significant increase in nasal length between nasion and the tip of the nose can be expected immediately following rapid palatal expansion.

3. Despite statistically significant changes produced by RPE, none of the demonstrated changes are likely to be of clinical significance.

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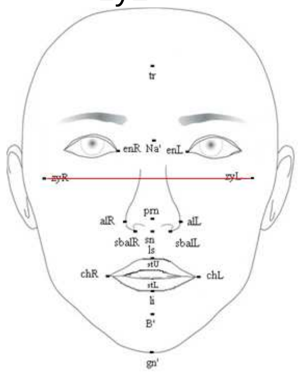
ADDENDUM A

Soft Tissue Landmark Definitions

(Adapted from Previous Study (Mollov 2012))

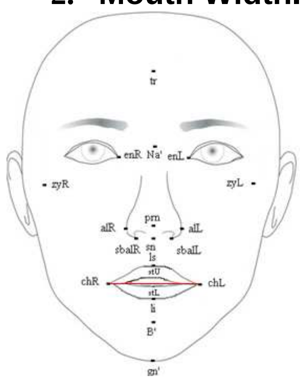
1. **Zygomatic Width.** Defined as the straight-line distance between zyR and zyL.



zyR/zyL are defined as the most prominent points of the cheekbone (zygoma) on either the right or left side. Palpate the area in order to select the point.

Hold the caliper horizontally. Use the longer side to measure the distance.

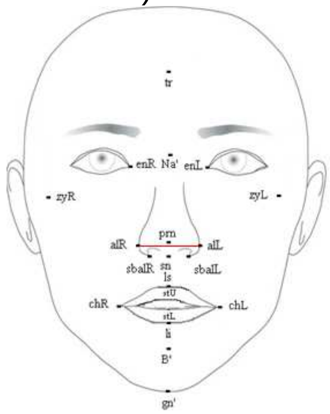
2. **Mouth Width.** Defined as the straight line distance between chR and chL



chR / chL are the commissures of the mouth, or the end points of the mouth in the transverse plane. Locate the points by determining where the upper and lower lip vermillions intersect with the skin of the face.

Hold the caliper horizontally. Use the longer side to measure the distance.

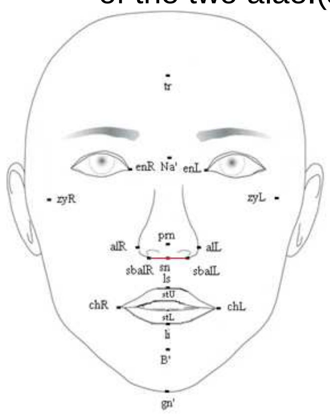
3. **Alar Width.** Defined as widest portion of the nose in the nostril area. (alR-alL)



alR/alL are the points of the alae that yield the widest portion of the nose in the nostril area. Locate the points by determining the most lateral points of the nostrils. Connect the two points to obtain the measurement.

Hold the caliper horizontally. Use the longer side to measure the distance.

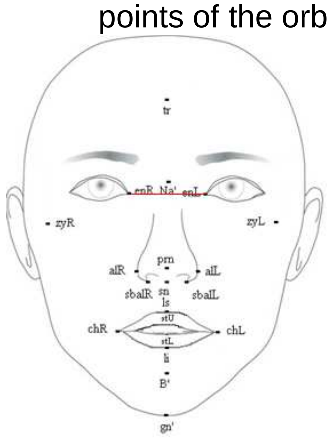
4. **Alar Base Width.** Defined as the straight-line distance between the base of the two alae.(sbalR-sbalL)



sbalR/sbalL are the points where the nostrils connect with the skin of the upper lip. Locate the points by determining the intersection of the nostrils with the upper lip.

Hold the caliper horizontally. Use the longer side to measure the distance.

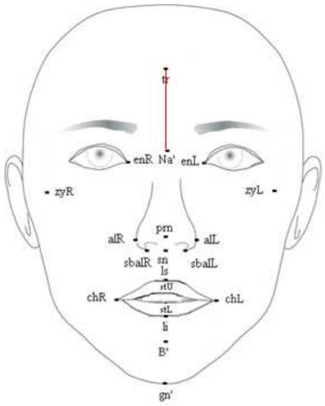
5. **Intra-orbital width.** Defined as the distance between the two innermost points of the orbits (enR-enL)



enR/enL are the innermost points of the right and left orbits. Locate the points by determining the intersection of the orbits with skin of the face.

Hold the caliper horizontally. Use the longer side to measure the distance. The tips of the longer side should be pointing upward and NOT toward the face. Do not touch the points directly. Get as close to the points as possible and project the location of enR/enL.

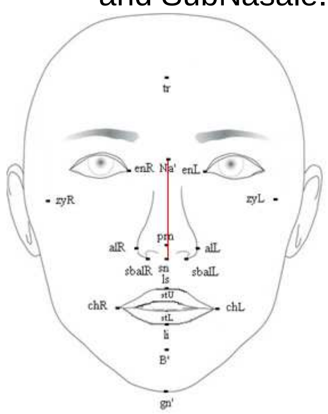
6. **Hairline (tr) – Soft Tissue Nasion (Na').** Defined as the distance between the hairline and Nasion.



tr is located at the intersection of the hair and the skin of the forehead. Na' is the soft tissue point representing the bony intersection between the frontal and nasal bones. Locate Na' by palpating the innermost point between the forehead and nose.

Hold the caliper vertically. Use the short side to measure the distance.

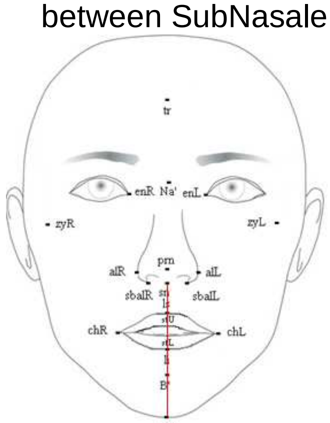
7. **Nasion (Na')– SubNasale (sn).** Defined as the distance between Nasion and SubNasale.



Na' is defined as in **(6)**. sn is defined as the intersection of the columnella with the philtrum.

Hold the caliper vertically. Use the longer side to measure the distance.

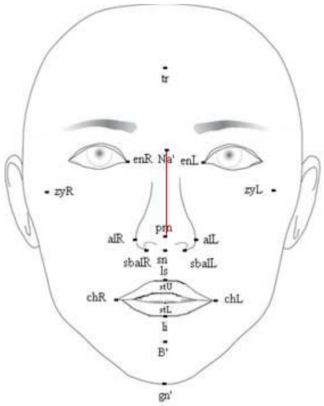
8. **SubNasale (sn) – Soft Tissue Gnathion (gn').** Defined as the distance between SubNasale and menton.



sn is defined as in (7). Me is defined as the most inferior point of the mandible in the midline. In order to determine gn' locate the intersection of the most inferior point of the chin/mandible and midline. Use the philtrum as an indicator for the midline.

Hold the caliper vertically. Use the short side to measure the distance.

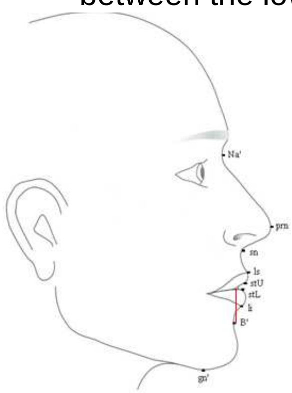
9. Nasion (Na') – Tip of Nose (prn). Defined as the distance between Na' and ToN.



Na' is defined as in **(6)**. prn is the most anterior point of the nose in the alar area. Palpate the nose in order to determine prn.

Hold the caliper vertically. Use the short side to measure the distance.

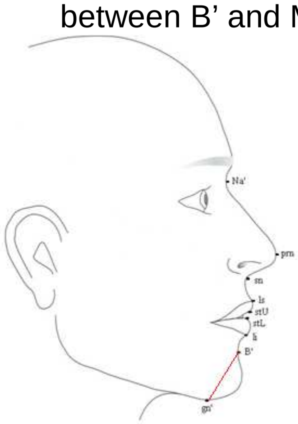
10. Stomion Lower (StL) – Soft tissue B point (B'). Defined as the distance between the uppermost point of the lower lip and the innermost point between the lower lip and the chin.



StL is the uppermost point of the lower lip that you can locate. Locate B' by examining the area below the lower lip and the chin and determining the innermost point. Measure the distance between the two

Hold the caliper vertically. Have the tips of the caliper point toward the participant. Use the short side to measure the distance. NOTE: in order to not touch the participant's chest have the tail of the caliper point upward.

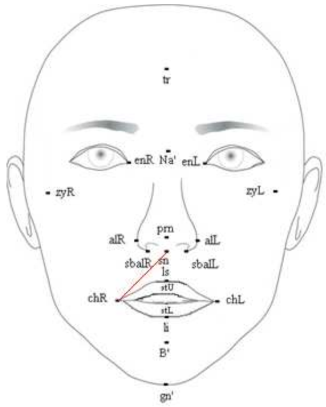
11. Soft Tissue B Point (B') – Menton (Me). Defined as the distance between B' and Me.



B' is defined as in (10). Me is defined as in (8). Measure the distance between the two points.

Hold the caliper vertically. Have the tips of the caliper point toward the participant. Use the short side to measure the distance. NOTE: in order to not touch the participant's chest have the tail of the caliper point upward.

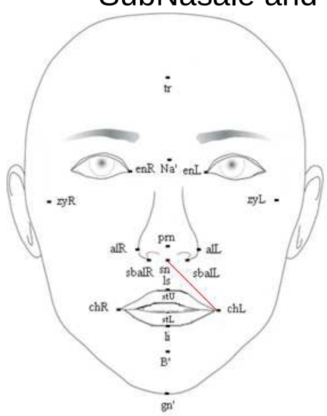
12. **SubNasale – Right Commisure (chR).** Defined as the distance between SubNasale and the right outermost point of the mouth



sn is defined as in (7). chR is defined as the intersection of the upper lip vermillion, lower lip vermillion and right side of the skin of the face. Measure the distance between the two points.

Hold the caliper at an angle/diagonally. Use the short side to measure the distance.

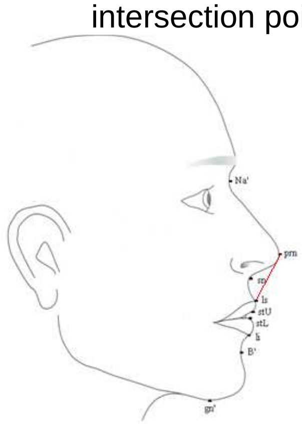
13. **Subnasale – Left Commissure (ch L).** Defined as the distance between SubNasale and the left outermost point of the mouth



sn is defined as in (7). chL is defined as the intersection of the upper lip vermillion, lower lip vermillion and left side of the skin of the face. Measure the distance between the two points.

Hold the caliper at an angle/diagonally. Use the short side to measure the distance.

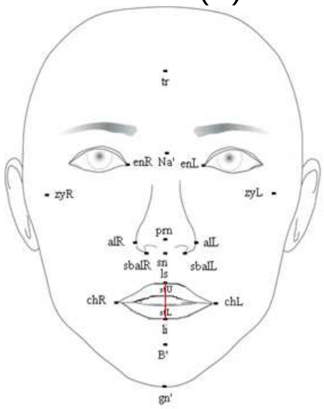
14. **Tip of Nose (prn) – Upper Vermillion Border (ls).** Defined as the distance between the tip of the nose and the line passing through the intersection points of the philtrum with the upper vermillion border



prn is defined as in (9). ls is defined as the imaginary line connecting the intersection of the philtrum columns with the upper vermillion border.

Hold the caliper vertically. Use the short side to measure the distance. Have the tail of the caliper point upward.

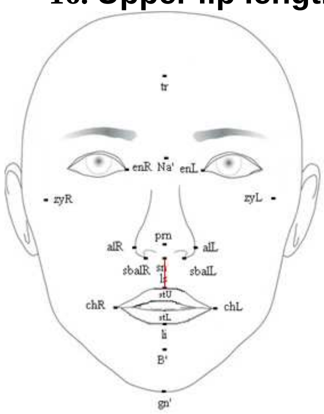
15. **Mouth Height.** Defined as the distance between the upper vermillion border (ls) and the lower vermillion border (li).



ls is defined as in (14). li is the horizontal lowermost line that passes through the intersection of the lower lip with the skin of the face. Measure the distance between the two

Hold the caliper vertically. Use the longer side to measure the distance. Have the tail of the caliper point upward.

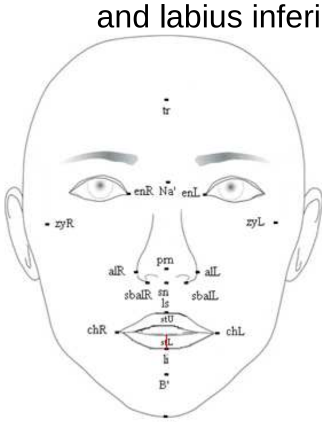
16. **Upper lip length.** Defined as the distance between subnasale and ls.



sn is defined as in (7). ls is defined as in (14). Measure the distance between the two.

Hold the caliper vertically. Use the longer side to measure the distance. Have the tail of the caliper point upward.

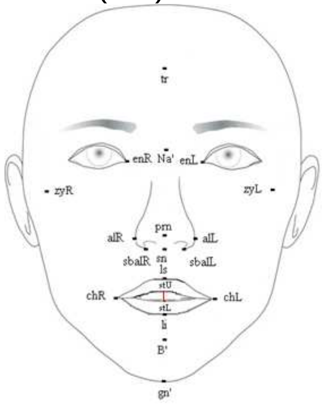
17. **Lower Lip Thickness.** Defined as the distance between stomion lower and labius inferius.



stL is defined as in (10). li is defined as in (15). Measure the distance between the two points.

Hold the caliper vertically. Use the longer side to measure the distance. Have the tail of the caliper point upward.

18. **Interlabial gap.** Defined as any space present between Stomion Upper (stU) and Stomion Lower (stL) when the participant is in repose.



StL is defined as in (10). StU is the lowermost point the you can locate on the upper lip. Measure the distance between the two.

Hold the caliper vertically. Use the longer side to measure the distance. Have the tail of the caliper point upward.

ADDENDUM B

Regression Models

Regression on the difference - zygomatic width

The REG Procedure
Model: MODEL1
Dependent Variable: m3diff

Number of Observations Read	28
Number of Observations Used	28

Analysis of Variance					
Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	1	7.00002	7.00002	0.23	0.6360
Error	26	793.72183	30.52776		
Corrected Total	27	800.72184			

Root MSE	5.52519	R-Square	0.0087
Dependent Mean	-0.08643	Adj R-Sq	-0.0294
Coeff Var	-6392.78580		

Parameter Estimates						
Variable	Label	DF	Parameter Estimate	Standard Error	t Value	Pr > |t|
Intercept	Intercept	1	2.90474	6.33319	0.46	0.6503
age	age	1	-0.24370	0.50892	-0.48	0.6360

Regression on the difference - intraorbital width

The REG Procedure
Model: MODEL1
Dependent Variable: m4diff

Number of Observations Read	28
Number of Observations Used	28

Analysis of Variance					
Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	1	5.91514	5.91514	3.48	0.0735
Error	26	44.20596	1.70023		
Corrected Total	27	50.12110			

Root MSE	1.30393	R-Square	0.1180
Dependent Mean	1.30500	Adj R-Sq	0.0841
Coeff Var	99.91788		

Parameter Estimates						
Variable	Label	DF	Parameter Estimate	Standard Error	t Value	Pr > |t|
Intercept	Intercept	1	4.05463	1.49461	2.71	0.0117
age	age	1	-0.22402	0.12010	-1.87	0.0735

Regression on the difference - alar nasal width at widest nostrils

The REG Procedure
Model: MODEL1
Dependent Variable: m5diff

Number of Observations Read	28
Number of Observations Used	28

Analysis of Variance					
Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	1	1.73523	1.73523	2.80	0.1065
Error	26	16.13486	0.62057		
Corrected Total	27	17.87010			

Root MSE	0.78776	R-Square	0.0971
Dependent Mean	1.09036	Adj R-Sq	0.0624
Coeff Var	72.24822		

Parameter Estimates						
Variable	Label	DF	Parameter Estimate	Standard Error	t Value	Pr > |t|
Intercept	Intercept	1	2.57962	0.90297	2.86	0.0083
age	age	1	-0.12133	0.07256	-1.67	0.1065

Regression on the difference - alar nasal width at base of nose

The REG Procedure
Model: MODEL1
Dependent Variable: m6diff

Number of Observations Read	28
Number of Observations Used	28

Analysis of Variance					
Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	1	9.88425	9.88425	4.29	0.0484
Error	26	59.89405	2.30362		
Corrected Total	27	69.77830			

Root MSE	1.51777	R-Square	0.1417
Dependent Mean	-0.61964	Adj R-Sq	0.1086
Coeff Var	-244.94225		

Parameter Estimates						
Variable	Label	DF	Parameter Estimate	Standard Error	t Value	Pr > |t|
Intercept	Intercept	1	2.93473	1.73972	1.69	0.1036
age	age	1	-0.28958	0.13980	-2.07	0.0484

Regression on the difference - mouth width

The REG Procedure
Model: MODEL1
Dependent Variable: m7diff

Number of Observations Read	28
Number of Observations Used	28

Analysis of Variance					
Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	1	2.51298	2.51298	0.22	0.6433
Error	26	297.57360	11.44514		
Corrected Total	27	300.08659			

Root MSE	3.38307	R-Square	0.0084
Dependent Mean	2.01929	Adj R-Sq	-0.0298
Coeff Var	167.53778		

Parameter Estimates						
Variable	Label	DF	Parameter Estimate	Standard Error	t Value	Pr > |t|
Intercept	Intercept	1	3.81148	3.87780	0.98	0.3347
age	age	1	-0.14601	0.31161	-0.47	0.6433

Regression on the difference - right comissure to subnasale

The REG Procedure
Model: MODEL1
Dependent Variable: m8diff

Number of Observations Read	28
Number of Observations Used	28

Analysis of Variance					
Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	1	0.03397	0.03397	0.01	0.9209
Error	26	87.78880	3.37649		
Corrected Total	27	87.82277			

Root MSE	1.83752	R-Square	0.0004
Dependent Mean	0.84286	Adj R-Sq	-0.0381
Coeff Var	218.01125		

Parameter Estimates						
Variable	Label	DF	Parameter Estimate	Standard Error	t Value	Pr > |t|
Intercept	Intercept	1	1.05124	2.10624	0.50	0.6219
age	age	1	-0.01698	0.16925	-0.10	0.9209

Regression on the difference - left comissure to subnasale

The REG Procedure
Model: MODEL1
Dependent Variable: m9diff

Number of Observations Read	28
Number of Observations Used	28

Analysis of Variance					
Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	1	0.01190	0.01190	0.00	0.9499
Error	26	76.92347	2.95860		
Corrected Total	27	76.93537			

Root MSE	1.72006	R-Square	0.0002
Dependent Mean	0.35286	Adj R-Sq	-0.0383
Coeff Var	487.46546		

Parameter Estimates						
Variable	Label	DF	Parameter Estimate	Standard Error	t Value	Pr > |t|
Intercept	Intercept	1	0.47618	1.97160	0.24	0.8110
age	age	1	-0.01005	0.15843	-0.06	0.9499

Regression on the difference - hairline-soft tissue nasion

The REG Procedure
Model: MODEL1
Dependent Variable: m10diff

Number of Observations Read	28
Number of Observations Used	28

Analysis of Variance					
Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	1	1.67273	1.67273	0.12	0.7295
Error	26	355.90999	13.68885		
Corrected Total	27	357.58272			

Root MSE	3.69984	R-Square	0.0047
Dependent Mean	0.95250	Adj R-Sq	-0.0336
Coeff Var	388.43507		

Parameter Estimates						
Variable	Label	DF	Parameter Estimate	Standard Error	t Value	Pr > |t|
Intercept	Intercept	1	-0.50969	4.24091	-0.12	0.9053
age	age	1	0.11913	0.34079	0.35	0.7295

Regression on the difference - soft tissue nasion-tip of nose

The REG Procedure
Model: MODEL1
Dependent Variable: m11diff

Number of Observations Read	28
Number of Observations Used	28

Analysis of Variance					
Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	1	22.42299	22.42299	2.45	0.1295
Error	26	237.83927	9.14766		
Corrected Total	27	260.26227			

Root MSE	3.02451	R-Square	0.0862
Dependent Mean	2.22607	Adj R-Sq	0.0510
Coeff Var	135.86763		

Parameter Estimates						
Variable	Label	DF	Parameter Estimate	Standard Error	t Value	Pr > |t|
Intercept	Intercept	1	7.57957	3.46681	2.19	0.0380
age	age	1	-0.43616	0.27858	-1.57	0.1295

Regression on the difference - soft tissue nasion-subnasale

The REG Procedure
Model: MODEL1
Dependent Variable: m12diff

Number of Observations Read	28
Number of Observations Used	28

Analysis of Variance					
Source	**DF**	**Sum of Squares**	**Mean Square**	**F Value**	**Pr > F**
Model	1	3.84803	3.84803	0.69	0.4153
Error	26	145.97634	5.61447		
Corrected Total	27	149.82437			

Root MSE	2.36949	**R-Square**	0.0257
Dependent Mean	0.84286	**Adj R-Sq**	-0.0118
Coeff Var	281.12573		

Parameter Estimates						
Variable	**Label**	**DF**	**Parameter Estimate**	**Standard Error**	**t Value**	**Pr > |t|**
Intercept	Intercept	1	3.06059	2.71600	1.13	0.2701
age	age	1	-0.18068	0.21825	-0.83	0.4153

Regression on the difference - tip of nose-upper lip

The REG Procedure
Model: MODEL1
Dependent Variable: m13diff

Number of Observations Read	28
Number of Observations Used	28

Analysis of Variance					
Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	1	3.01007	3.01007	0.52	0.4788
Error	26	151.54620	5.82870		
Corrected Total	27	154.55627			

Root MSE	2.41427	R-Square	0.0195
Dependent Mean	-0.48893	Adj R-Sq	-0.0182
Coeff Var	-493.78788		

Parameter Estimates						
Variable	Label	DF	Parameter Estimate	Standard Error	t Value	Pr > |t|
Intercept	Intercept	1	1.47253	2.76733	0.53	0.5992
age	age	1	-0.15980	0.22237	-0.72	0.4788

Regression on the difference - subnasale to upper lip vermilion border

The REG Procedure
Model: MODEL1
Dependent Variable: m14diff

Number of Observations Read	28
Number of Observations Used	28

Analysis of Variance					
Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	1	9.38749	9.38749	2.75	0.1092
Error	26	88.72709	3.41258		
Corrected Total	27	98.11459			

Root MSE	1.84732	R-Square	0.0957
Dependent Mean	-0.07071	Adj R-Sq	0.0609
Coeff Var	-2612.36765		

Parameter Estimates						
Variable	Label	DF	Parameter Estimate	Standard Error	t Value	Pr > |t|
Intercept	Intercept	1	3.39319	2.11747	1.60	0.1211
age	age	1	-0.28221	0.17015	-1.66	0.1092

Regression on the difference - mouth height

The REG Procedure
Model: MODEL1
Dependent Variable: m15diff

Number of Observations Read	28
Number of Observations Used	28

Analysis of Variance					
Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	1	8.11315	8.11315	0.56	0.4627
Error	26	379.60012	14.60000		
Corrected Total	27	387.71327			

Root MSE	3.82100	R-Square	0.0209
Dependent Mean	0.78107	Adj R-Sq	-0.0167
Coeff Var	489.19921		

Parameter Estimates						
Variable	Label	DF	Parameter Estimate	Standard Error	t Value	Pr > |t|
Intercept	Intercept	1	4.00129	4.37978	0.91	0.3693
age	age	1	-0.26236	0.35195	-0.75	0.4627

Regression on the difference - interlabial gap

The REG Procedure
Model: MODEL1
Dependent Variable: m16diff

Number of Observations Read	28
Number of Observations Used	28

Analysis of Variance					
Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	1	7.47745	7.47745	0.94	0.3422
Error	26	207.71312	7.98897		
Corrected Total	27	215.19057			

Root MSE	2.82648	R-Square	0.0347
Dependent Mean	0.45714	Adj R-Sq	-0.0024
Coeff Var	618.29160		

Parameter Estimates						
Variable	Label	DF	Parameter Estimate	Standard Error	t Value	Pr > |t|
Intercept	Intercept	1	-2.63435	3.23982	-0.81	0.4235
age	age	1	0.25187	0.26034	0.97	0.3422

Regression on the difference - lower lip thickness

The REG Procedure
Model: MODEL1
Dependent Variable: m17diff

Number of Observations Read	28
Number of Observations Used	28

Analysis of Variance					
Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	1	0.09667	0.09667	0.07	0.7891
Error	26	34.39782	1.32299		
Corrected Total	27	34.49450			

Root MSE	1.15021	R-Square	0.0028
Dependent Mean	-0.23464	Adj R-Sq	-0.0356
Coeff Var	-490.19793		

Parameter Estimates						
Variable	Label	DF	Parameter Estimate	Standard Error	t Value	Pr > |t|
Intercept	Intercept	1	-0.58616	1.31842	-0.44	0.6603
age	age	1	0.02864	0.10594	0.27	0.7891

Regression on the difference - lower vermilion border to soft tissue B point

The REG Procedure
Model: MODEL1
Dependent Variable: m18diff

Number of Observations Read	28
Number of Observations Used	28

Analysis of Variance					
Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	1	16.81761	16.81761	3.22	0.0845
Error	26	135.86647	5.22563		
Corrected Total	27	152.68409			

Root MSE	2.28596	R-Square	0.1101
Dependent Mean	-0.17571	Adj R-Sq	0.0759
Coeff Var	-1300.95539		

Parameter Estimates						
Variable	Label	DF	Parameter Estimate	Standard Error	t Value	Pr > |t|
Intercept	Intercept	1	-4.81203	2.62026	-1.84	0.0777
age	age	1	0.37773	0.21056	1.79	0.0845

Regression on the difference - soft tissue B point to Menton

The REG Procedure
Model: MODEL1
Dependent Variable: m19diff

Number of Observations Read	28
Number of Observations Used	28

Analysis of Variance					
Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	1	4.13453	4.13453	0.38	0.5448
Error	26	285.43394	10.97823		
Corrected Total	27	289.56847			

Root MSE	3.31334	R-Square	0.0143
Dependent Mean	-1.00214	Adj R-Sq	-0.0236
Coeff Var	-330.62562		

Parameter Estimates						
Variable	Label	DF	Parameter Estimate	Standard Error	t Value	Pr > |t|
Intercept	Intercept	1	-3.30096	3.79788	-0.87	0.3927
age	age	1	0.18729	0.30519	0.61	0.5448

Regression on the difference - subnasale-gnathion

The REG Procedure
Model: MODEL1
Dependent Variable: m20diff

Number of Observations Read	28
Number of Observations Used	28

Analysis of Variance					
Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	1	8.95547	8.95547	0.90	0.3515
Error	26	258.70622	9.95024		
Corrected Total	27	267.66170			

Root MSE	3.15440	R-Square	0.0335
Dependent Mean	-0.04464	Adj R-Sq	-0.0037
Coeff Var	-7065.85600		

Parameter Estimates						
Variable	Label	DF	Parameter Estimate	Standard Error	t Value	Pr > |t|
Intercept	Intercept	1	3.33862	3.61570	0.92	0.3643
age	age	1	-0.27564	0.29055	-0.95	0.3515

ADDENDUM C

IRB Approval

OFFICE OF RESEARCH COMPLIANCE

MARQUETTE
UNIVERSITY

November 22, 2010

Dr. Jose Bosio
School of Dentistry

Dear Dr. Bosio:

Your protocol number HR-2083, titled, *"Soft Tissue Changes in Response to Orthodontic Treatment"* was expedited on November 18, 2010, by a member of the Marquette University Institutional Review Board.

Your IRB approved adult consent form, parent permission form, and child assent form are enclosed with this letter. Use the stamped copies of these forms when recruiting research participants. Each research participant should receive a copy of the stamped consent form for their records. Each participant, or legal guardian, must also complete the HIPAA authorization form.

Subjects who go through the consent process are considered enrolled participants and are counted toward the total number of subjects, even if they have no further participation in the study. Please keep this in mind when conducting your research. This study is currently approved for 2000 subjects.

If you need to increase the number of subjects, add research personnel, or make any other changes to your protocol you must submit an IRB Protocol Amendment Form, which can be found on the Office of Research Compliance web site: http://www.marquette.edu/researchcompliance/research/irbforms.shtml. All changes must be reviewed and approved by the IRB before being initiated, except when necessary to eliminate apparent immediate hazards to the human subjects. Any public advertising of this project requires prior IRB approval. If there are any adverse events, please notify the Marquette University IRB immediately.

Your approval is valid until November 17, 2011. Prior to this date, you will be contacted regarding continuing IRB review.

A Protocol Completion/Termination Report must be submitted once this research project is complete. The form should be submitted in a timely fashion, and must be received no later than the protocol expiration date.

If you have any questions or concerns, please do not hesitate to contact me. Thank you for your time and cooperation.

Sincerely,

Amanda J. Ahrndt, RN, MS, MSN, CIM
IRB Manager

cc: Dr. Rebecca Bardwell, IRB Chair

Enclosures (3)

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