MAXILLARY PROTRACTION WITH SKELETAL VERSUS DENTAL ANCHORAGE IN UNILATERAL CLEFT LIP AND PALATE PATIENTS

A Thesis

by

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Submitted to the Office of Graduate and Professional Studies of
Texas A&M University
in partial fulfillment of the requirements for the degree of

MASTER OF SCIENCE

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May 2020

Major Subject: Oral Biology

ABSTRACT

Introduction: The aim of this study is to investigate the effect of maxillary skeletal protraction with skeletal versus dental protraction in unilateral cleft lip and palate patients. Methods: Patients from three cleft treatment centers were analyzed. A total of 33 unilateral cleft lip and palate (UCLP) patients treated with Bollard miniplates (BM) (mean age 11.72 years) and 33 UCLP patients treated with facemask therapy (FM) (mean age 8.90 years) were included for analysis. Radiographs were obtained from T1 (pretreatment) and T2 (upon the conclusion of active traction). Cephalometric radiographs were constructed from CBCT radiographs, lateral cephalograms were digitally landmarked and traced, and two-dimensional horizontal displacement of maxillary cephalometric landmarks were measured on tracing cranial base superimpositions. Results: Both groups presented with retrognathic maxillae pretreatment, but both differed significantly in T1 SNA angle (with the BM group beginning with more retrognathic maxillae), partially owing to the difference in age between the groups. The BM group experienced a significant, moderate improvement in SNA from T1 to T2, however SNA for the FM group did not significantly improve from T1 to T2. The groups did not differ significantly in SNA change or horizontal displacement of maxillary cephalometric landmarks.

Conclusions: The BM group exhibited significant improvement in SNA, but this difference was not large enough to result in a significant difference from patients treated with FM therapy. Limitations of the current study are discussed.

DEDICATION

This manuscript is dedicated to my sweet Texan baby girl, Devorah (Rory) Wise.

ACKNOWLEDGEMENTS

I would like to thank my committee members for their direction and tireless efforts in helping me with this project.

I would like express my gratitude for the generosity of Drs. Daniella Garib, Ronald Jacobson, and Yong Jong Park for sharing their time and patient records. Without them, this project would not have been possible.

I would like to thank my co-residents in the third year who have all contributed to this project by providing moral support and assisting me in any way they could.

Lastly, I would like to thank my parents for making me believe that I could achieve anything I set my mind to, and my husband Shalom Wise for helping me achieve my goals.

CONTRIBUTORS AND FUNDING SOURCES

Contributors

This work was supervised by a thesis committee consisting of Drs. Peter Buschang and Reginald Taylor of the Department of Orthodontics and Dr. Matthew Kesterke of the Department of Biomedical Sciences.

The data analyzed for Chapter 3 was provided by Drs. Daniela Garib, Dr. Ronald Jacobson, and Dr. Yong Jong Park. The analyses depicted in Chapter 4 were conducted in part by Dr. Peter Buschang.

All other work conducted for the thesis was conducted by the student independently.

Funding Sources

Graduate study was supported by a fellowship from Texas A&M University.

NOMENCLATURE

ANB	A-point Nasion B-point
ANS	Anterior Nasal Spine
BM	Bollard Miniplates
CBCT	Cone Beam Computed Tomography
CLP	Cleft Lip and Palate
FH-NA	Frankfurt Horizontal-Nasion A-point
FM	Facemask
HG	Headgear
PNS	Posterior Nasal Spine
PUFH	Posterior Upper Face Height
SNA	Sella Nasion A-point
SNB	Sella Nasion B-point
T1	First Timepoint (Pretreatment)
T2	Second Timepoint (Posttreatment)
UCLP	Unilateral Cleft Lip and Palate
UFH	Upper Face Height

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CHAPTER I

INTRODUCTION

Most cleft lip and palate patients present with maxillary deficiency due to restricted maxillary growth. Growth modification to advance the maxilla and improve maxillomandibular relations has been attempted in order to ameliorate the need for future surgical correction and to improve patients' appearance during the intervening years until surgery is possible. Conventional growth modification strategies have been constituted of rapid palatal expansion followed by facemask therapy for a period of approximately 12 months. This is usually attempted when the patient is approximately 8 years old for optimal results. Most studies have found an average of 1-5° increase in SNA or 1-2 mm in A-point protraction with the use of facemasks as compared to non-treated control groups.

However, a novel treatment approach was developed by Hugo De Clerck in last ten years with the use of elastics run between maxillary and mandibular miniplates to facilitate maxillary protraction in Class III orthodontic patients. Thus far, investigators have reported moderate success with the use of this technique, with an average of 3-4 mm maxillary protraction achieved,[1,2] and an additional 1-3 mm maxillary protraction above that achieved by conventional treatment modalities (i.e. facemask therapy).[3,4] Several distinct advantages for miniplates have been reported as compared to conventional facemask therapy, including the possibility of treating at a later age, and the ability to apply constant traction forces 24 hours per day due to the enhanced esthetics.[1] However, miniplates have several distinct drawbacks as compared to conventional growth modification strategies as they are more invasive, risks of morbidity due to surgical plate placement, and costs associated with surgical plate placement.

Given their propensity for restricted maxillary growth, the cleft lip and palate patient population is uniquely positioned to benefit from use of miniplates. Additionally, given the significant psychosocial burdens reported by cleft patients due to their facial appearance,[5,6] cleft patients can potentially benefit from the use of miniplates as an intermediate treatment strategy to improve their facial appearance until they have reached the age that would be appropriate for surgical intervention.[7] Few studies have been conducted in recent years investigating the effect of the use of miniplates for maxillary skeletal protraction in cleft patients. A 2017 study by Yatabe et al. compared 20 prospectively treated unilateral cleft lip and palate patients treated with miniplates to 23 retrospectively analyzed non-cleft skeletal Class III patients treated with miniplates.[8] This study concluded that an equivalent amount of maxillary protraction was achieved with the use of miniplates in the cleft group as compared to the non-cleft group. Two additional studies published in 2019 investigated the effects of maxillary protraction with miniplates on cleft patients, with comparison control groups of non-treated cleft lip and palate patients.[7,9] These studies concluded that cleft lip and palate patients treated with miniplates exhibited 1.5 mm greater maxillary protraction[9] or 1.68° greater increase in sella-nasion-A-point (SNA) angle[7] as compared with untreated controls.

To date, no studies have investigated the effect of miniplates on skeletal maxillary protraction in cleft patients as compared to the conventional growth modification strategy (facemask treatment). A direct comparison is necessary in order to determine whether the increased risk and cost posed by the miniplate insertion procedure is warranted in the treatment of this population, which already faces an extremely high treatment burden. Additionally, sample sizes in previous studies have been relatively modest (18-23 subjects per group), and conducting a study with increased sample size from multiple centers can increase the external reliability of the study results.

Thus, the aim of the current study is to investigate the effect of maxillary protraction with miniplates as compared to the conventional growth modification treatment modality of facemask therapy. The current study will use a more a larger, more representative sample drawn from multiple centers.

CHAPTER II

LITERATURE REVIEW

Cleft lip and palate (CLP) is among the most common birth defects.[10,11] Orofacial cleft occur at an estimated rate of 1:700 live births worldwide.[10] It can occur as an isolated cleft palate defect or as cleft lip with or without cleft palate.[10] Cleft lip with or without cleft palate is estimated to occur in 1:940 in the United States.[11]

Typical Treatment Sequence

The typical cleft patient undergoes a prolonged and involved treatment sequence from birth to adolescence to address the issues arising either as a direct result of the cleft deformity, or iatrogenically as a result of prior necessary treatments. A cleft patient typically undergoes lip surgery at 3 months of age and definitive lip surgery at 10 months, followed by hard and/or soft palate closure between 18 and 24 months.[12] Typically, cleft patients undergo orthodontic palatal expansion between 5-7 years of age with facemask as about 8 years old. A superior based pharyngeal flap operation is typically done between 6-8 years old, followed by alveolar bone graft at 6-8 years old. Depending on the extent of maxillary growth restriction, cleft patients may also require definitive maxillary advancement surgery at the age of skeletal maturity

Growth in Unoperated CLP Patients

The unilateral cleft lip and palate patient presents with distinctive dental and skeletal problems, of which the most significant is marked maxillary growth restriction. Observational studies in unoperated cleft lip and palate patients have found that these patients exhibit normal (unrestricted) maxillary growth in the absence of surgical interventions.[13–19] In a study of dry skulls of deceased cleft lip and palate patients, Atherton noted that unoperated CLP patients demonstrated slight retrusion on the cleft side as compared to the non-cleft side.[16] Some studies have noted slight maxillary prognathism in unoperated CLP patients as compared to normal values.[19,20] Shetye posits that this may be due to lack of tissue or perioral muscular continuity leading to a relative increase in outward tongue pressure on the maxilla.[19] Other skeletal findings in studies examining characteristics of non-operated CLP patients include increased mandibular plane angle[18,19,21] and increased lower anterior face height.[20]

Growth in Operated CLP Patients

Conversely, studies examining growth in operated cleft lip and palate patients find restricted maxillary growth to varying degrees depending on the type and nature of surgical intervention. Studies examining the effect of lip repair on maxillary growth restriction found a range of effect on maxillary growth, from no restriction to significant growth restriction. A study in 1954 by Graber examining 19 patients with repaired palate only, 119 patients with repaired lip and palate, and 37 unoperated cleft lip and palate found no significant restriction in maxillary growth restriction in the operated groups compared to the non-operated group.[22] However, three other studies found significant growth restriction in patients with operated lip compared to non-operated patients. In their 1990 study examining 18 CLP patients with repaired lip, 14 CLP patients with repaired lip and palate, and 28 non-operated patients, Mars and Houston found that the patients with operated lip demonstrated intermediate maxillary growth restriction, with maxillary growth more restricted in these patients as compared to the non-operated CLP group but less restricted than the operated lip and palate group.[18] Conversely, a 2006 study by Li et al. found that the CLP patients they examined with repaired lip exhibited maxillary growth restriction equivalent to that observed in the repaired lip and palate group.[23] In fact, Li et al.

contend that lip repair is the most significant factor contributing to maxillary growth restriction in CLP patients.

Animal Studies

Similarly, animal studies examining the effect of lip repair in CLP animal models found significant maxillary growth restriction accompanying lip repair. Bardach et al. found that lip repair in cleft rabbits resulted in increased lip pressure, which contributed to restriction in maxillary growth.[24] Mooney et al. posited that the increase in lip pressure observed in repaired lips is as a result of wound contraction,[25] which in turn results in bone remodelling[26] and resultant aberrant maxillary growth.

Surgical Effects on Maxillary Retrusion

Lip Repair

Reports of studies examining the effect of lip repair on maxillary growth restriction in CLP patients have been mixed. Some studies have generally reported intermediates amount of maxillary growth restriction due to lip repair procedures done in CLP patients: worse than unoperated patients but better than patients with palatal repair.[18] Others have reported no significant growth restriction as a result of lip repair[22], while still others have observed maxillary growth restriction equivalent to that seen in patients with repaired lip and palate.[23]s Maxillary growth restriction observed with lip repair is posited to occur as a result of the increased lip pressure seen due to wound contraction,[25] which has a "bone-bending" and remodelling effect.[26]

Alveolar bone graft

The findings of two studies investigating the effect of secondary alveolar bone grafting on maxillary growth restriction found slightly restriction (~0.5 mm) of maxillary growth associated with alveolar bone grafting.[27,28] However, a single study by Gesch et al. found no significant difference in maxillary retrusion between patients that had received secondary alveolar bone graft versus patients that had not.[29] However, this study had a notably smaller sample size than the other two studies which had found a slight but significant difference in maxillary growth.

Palatal Repair

The most robust effect on maxillary growth restriction has been found in association with palatal repair,[19,30] while lip repair and alveolar bone grafting are secondarily implicated in maxillary growth restriction observed in cleft patients. Early experimental studies in animal models have found that palatal repair results in maxillary growth restriction.[31,32] Studies have also noted associated increases in maxillary height, posterior face height, and mandibular length associated with palatal repair in cleft animal models.

Human observational studies comparing patients with palatal repair versus patients with unrepaired palate have almost universally found that patients with palatal repair demonstrate significant maxillary growth restriction as compared to non-cleft patients[22,28,33,34] and cleft patients with unrepaired palate.[18] A large, multi-center study of 463 repaired cleft lip and/or palate patients from 15 centers concluded that sagittal maxillary growth disturbances can primarily be attributed to iatrogenic (i.e. surgical intervention) factors.[35] The proposed etiology for the observed maxillary growth restriction in repaired cleft lip and palate patients is as follows: while in non-cleft individuals, the maxilla is displaced forward and downward with growth, in patients with repaired palate, the scar tissue at the sutural areas interferes with maxillary downward and forward displacement with growth.[19] This is substantiated by the observation of normal maxillary growth in unoperated cleft patients while operated cleft patients typically exhibit significant maxillary growth restriction. Unfortunately, early palatal closure is necessary to allow for normal speech development and therefore delaying palatal closure is not a viable strategy to prevent maxillary growth restriction.[28]

Other Factors impacting Maxillary Retrusion

Other factors have also been found to impact the extent of maxillary growth restriction observed. These include: age at palatal repair,[22,36] with greater growth restriction observed with repair done at an earlier age, surgical design,[36] treatment protocol, and, most notably, surgeon skill.[35] Ross (1987) reports that surgeon skill was found to be the most influential factor in the amount of maxillary growth restriction observed (greater than both surgical technique and timing of the operation).

Associated Skeletal Findings

Other skeletal findings associated with unilateral cleft lip and palate include increased mandibular plane angle[18] and lower anterior face height,[28] decreased posterior face height,[34] relative posterior positioning due to posterior mandibular rotation,[33] increased gonial angle,[34] but normal growth and mandibular length.[19,37]

Psychosocial Considerations

Cleft patients have been found to experience profound psychosocial impacts as a result of their noticeable facial differences, especially during their formative adolescent years. A qualitative study conducted among cleft lip and palate females found that they reported experiencing teasing, bullying, and staring from others as a result of their altered appearance.[5] The study subjects also reported experiencing anxiety surrounding others' perception of them, and feeling prevented from fully engaging with their community as a result of their insecurity around their appearance. A systematic review found that cleft lip and palate adolescents frequently report issues of bullying and self-consciousness due visible differences in their facial appearance.[6] Finally, a multicenter study of 55 cleft patients found that teasing was reported by 70% of cleft subjects, with 42% reporting daily teasing.[38] These subjects reported experiencing significant negative emotional impacts as a result of the teasing, including sadness and depression, with 30% of patients reporting that they are “marked for life” because of the teasing they experienced. Thus, it is important to consider treatment options that improve cleft patients’ facial appearance, even if it does not definitively correct the facial disharmony rendering surgery unnecessary, in order to mitigate some of the negative psychosocial impacts cleft patients experience as a result of their altered appearance.[7]

Maxillary Protraction Strategies

Several techniques are available to correct skeletal anteroposterior discrepancies in cleft patients. These include: surgical Le Fort I maxillary advancement, maxillary distraction osteogenesis, and growth modification strategies such as facemask or elastics to miniplates. Surgical correction is required in an estimated 25-50% of cleft patients.[39,40] Surgical correction is indicated for correction of moderate maxillary hyperplasia, while distraction osteogenesis is indicated for correction of severe maxillary hypoplasia.[41] It is reported to exhibit less relapse than surgery[42,43] and can accomplish larger corrective movements.

Facemask

Growth modification strategies result in less protraction than surgical treatment, but can be initiated at an earlier age. Facemasks are typically worn in conjunction with an intraoral rapid maxillary expander (RPE) appliance (either banded or bonded) with hooks extending anterolateral to the upper canines. Patients typically wear elastics from the RPE hooks to the facemask appliance, which typically range from 400-800 g of force. Facemask wear is typically prescribed for between 14 and 18 hours per day. Facemask therapy typically continued for approximately 12 months, or until positive overjet is achieved.

Facemask therapy in non-cleft patients has been shown to result in approximately 1-2° increase in SNA[44,45] or between 1.5-5.8 mm[46,47] of maxillary protraction as compared to untreated controls. Orthopedic changes from maxillary protraction with facemask therapy depend on effective distraction of the circumaxillary sutures and changes at the maxillary tuberosity,[48] of which the zygomaticomaxillary suture is said to be the most important target of facemask orthopedic therapy. Baccetti et al found greater evidence of changes at the area of the pterygomaxillary suture in younger patients (treated at 6.75 years) versus patients treated at a later age (10.25 years).[49] Additionally, Melsen & Melsen found that the palatal bone and was more readily disarticulated from the pterygoid process in dry skulls of infantile and juvenile subjects than skulls examined in the late juvenile period.[50]

Changes reported for facemask therapy in cleft patients range between 2-5° increase in SNA,[51–54] or 1-2 mm in A-point protraction,[53,55] with reported treatment durations ranging between 5-12 months. Patients have also consistently demonstrated an accompanying increase in mandibular plane angle and lower face height as a result of mandibular backward rotation with facemask therapy.[1,45,52,54,56]

There are several distinct disadvantages associated with facemask therapy use. Duration of wear is usually restricted to a maximum of 14 hours per day for pragmatic and psychosocial reasons[1] due to the appliance's bulkiness and unaesthetic appearance. It also has the undesirable side-effect of increasing the mandibular plane angle and lower anterior face height. As well, its use is restricted to younger patients (approximately 8-10 year old) due to responsiveness of the sutures.[1,57]

Skeletally-anchored Facemask

A limited number of studies have investigated the effects of skeletally anchored facemask therapy in Class III patients. These studies have found less downward movement of A-point and less opening of the MPA in patients with skeletally-anchored facemask therapy as compared to tooth-borne facemasks.[58,59] Thus, a limited number of investigations support the potential for limiting the undesirable vertical side-effects with skeletally anchored facemask therapy.

Bollard Plates

An alternative method for maxillary protraction via growth modification in Class III patients was developed by Dr. Hugo de Clerck with the use of miniplates. De Clerck first published on the technique in 2009.[1] The technique involves the use of intermaxillary elastics between two sets of miniplates, with the upper miniplates placed in the infrazygomatic crests and the lower miniplates placed between the permanent lateral and canine.[1] Loading with intermaxillary elastics began three weeks after the placement of the miniplates with 100 g elastics, progressing to 200 g elastics after two months. Elastics were worn full time (including meal times) and were replaced once daily. Elastics were worn for a total of 12-16 months. Studies report an average of approximately 4 mm of maxillary protraction with miniplates (one study reported a sample size of 21 patients,[60] while another study has a sample size of 25 patients[2]). When compared to controls treated with facemask, patients treated with miniplates demonstrated between 1 mm[4] and 2-3 mm[3] greater maxillary protraction. Additionally, patients treated with miniplates did not demonstrate the undesirable side effect of increased opening of the mandibular plane angle.

Several studies have been done investigating the efficacy of miniplates for skeletal maxillary protraction in cleft patients. A 2017 study by Yatabe et al. found that response of cleft patients to maxillary protraction with miniplates was equivalent to that observed in non-cleft patients.[8] A 2019 study by Ren et al. comparing 18 unilateral complete cleft lip and palate patients to a control sample of non-treated cleft lip and palate patients found that patients treated with miniplates for 18 months exhibited 1.5 mm greater maxillary protraction than the non-treated cleft group.[9] Lastly, a second 2019 study by Faco et al. found that 23 unilateral cleft lip and palate patients treated with miniplates exhibited 1.68° increase in SNA as compared to 23 matched controls of untreated unilateral cleft lip and palate patients.[7] Thus, miniplates have been demonstrated to produce modest to moderate increases in maxillary skeletal protraction as compared to untreated control cleft patients.

Current Study

To date, no studies have directly compared cleft patients treated with miniplates compared to cleft patients treated with facemask. Thus, the current study seeks to fill this gap in the literature by comparing maxillary protraction obtained groups of unilateral cleft lip and palate patients from multiple sites treated with facemask versus intermaxillary traction with miniplates.

CHAPTER III

MATERIALS AND METHODS

Sample

Samples were drawn from unilateral cleft lip and palate patients treated at three craniofacial centers. Twenty-three patients treated consecutively with Bollard Plates and 8 patients treated with protraction headgear (HG) came from the University of Sao Paulo Orthodontic Clinic in Sao Paulo, Brazil. An addition 10 patients treated with Bollard Plates in a Chicago private practice (Jacobson & Tsou Orthodontics) and 25 patients who were treated with protraction headgear at Children's Medical Center in Dallas, Texas were analyzed. A detailed breakdown of the study's sample composition can be found in Table 1. The study was approved by the Texas A&M University Institutional Review Board (IRB2018-1116-CD-EXP).

Demographics

Mean age at treatment start for patients treated with Bollard miniplates was 11.72 years old and mean age at start of treatment for patients treated with protraction headgear was 8.90 years old. Average duration of patients in the Bollard miniplates group was 23.24 months, and average duration of treatment for the facemask group was 18.03 months. The Bollard miniplates group was 51.5% male and the facemask group was 69.7% male. A detailed breakdown of the demographic characteristics of the study sample can be found in Table 1.

Inclusion/Exclusion Criteria

The inclusion criteria for the Bollard miniplates groups included: non-syndromic patients with unilateral cleft lip and palate treated with Bollard miniplates with pre- and post-treatment conebeam computed tomography (CBCT) or lateral cephalometric images available. Patients were excluded if pre/post-treatment radiographic record quality, view, or scale were inadequate to perform reliable landmarking and tracing or cranial base superimposition.

All patients in the Bollard miniplates group were treated with bilateral upper miniplates installed in the infrazygomatic crest region and lower miniplates installed between the lower lateral and canine. Bollard miniplate therapy was typically initiated 3 months after alveolar bone grafting to allow for adequate healing. Three weeks after miniplate placement, the patients were instructed to wear elastics between the upper and lower miniplates full time. Patients began with 75 g elastics from upper to lower miniplates in the first month, 150 g elastics in the second month, and progressed to 250 g elastics in the third month, continuing to the end of treatment. Patients were instructed to wear elastics full time (including meal times) and change elastics every 12 hours.

To be included in the facemask group, the patient had to have a unilateral cleft lip and palate treated with facemask therapy and adequate pre and post cephalometric radiographic records. Syndromic patients and patients with documented non-compliance were excluded. Patients were also excluded if pre/post-treatment radiographic record quality, view, or scale were inadequate to perform reliable landmarking and tracing or cranial base superimposition.

The facemask group was treated with a rapid palatal expander (RPE) with hooks extending anteriorly for attachment of elastics for anterior traction to the facemask appliance. Facemask therapy was typically initiated 12 months prior to anticipated alveolar bone grafting procedure. Patient were treated with a Multi-Adjustable Facemask (manufactured by Ortho Technology ®) with ½”, 14 oz. (400 g) elastics running from the RPE hooks to the facemask appliance. Patients were instructed to wear elastics to their facemask 12-14 hours per day. Patients were instructed to cross elastics to increase force levels as forces decreased with maxillary protraction. Facemask therapy was typically continued until positive overjet was achieved.

Records and Analysis

Cone beam CT images were obtained pre-treatment (T1) and at the conclusion of active orthopedic traction (T2) for the Bollard Miniplate groups and for the Brazilian Facemask group. Two-dimensional lateral cephalometric images were constructed in Dolphin 3D Imaging software with the image adjusted to the Frankfurt Horizontal reference line (i.e. porion to orbitale). Two-dimensional cephalometric images were then exported to Dolphin software to allow for two-dimensional cephalometric landmarking, tracing, and subsequent cranial base superimpositions. For the Dallas Children's Medical Center Facemask group, two dimensional lateral cephalometric images from pre-treatment and post-treatment records were obtained.

Lateral cephalometric images were landmarked and traced in Dolphin Imaging program and tracing cranial base superimpositions were performed using natural stable structures.[61] The following landmarks were identified: porion, orbitale, sella, nasion, basion, A-point, B-point, pogonion, anatomical gnathion, gonion, menton, ANS, and PNS (Table 2 and Figure 1). The following measurements were calculated: SNA, maxillary length, SN-ANS, maxillary depth, upper face height, and posterior upper face height (Table 3). Two-dimensional millimetric horizontal and linear displacement of A-point and ANS were measured on the cranial base superimposition. Mandibular measurements such as mandibular plane angle, SNB, and ANB angles were not included because a significant number of patients had their mouths open in the CBCT images, and mandibular closed position could not be accurately and reliably ascertained. Additionally, dentoalveolar relationships were not measured because some Bollard miniplates patients were being treated with fixed appliances in conjunction with the primary orthopedic treatment.

Reliability

Cephalometric landmarks were re-identified and retraced on 10% of the sample at two time points at least 7 days apart. The difference were evaluated and reliability was assessed.

Statistical Analysis

Statistical tests were run with Statistical Software Package (SPSS) software. Normality of the samples were verified using skewness and kurtosis statistics, which revealed normal distributions. As such, parametric statistical analyses were used. Pre-treatment differences in ages between groups were analyzed with an independent samples t-test. Subsequently, even distribution of sexes between groups were verified by computing a chi-square statistic for sex distribution between the groups. Lastly, an analysis of covariance was computed with age as a covariate to test for pre-treatment difference for the cephalometric parameters measures (SNA, maxillary length, SN-ANS, FH-NA, UFH, PUFH). Pearson correlation was used to determine the association between initial age, treatment duration, and the cephalometric variables measured.

Post-treatment differences between cephalometric parameters between bollard miniplate and facemask groups were analyzed with an analysis of covariance, with initial age and treatment duration analyzed as covariates. Post-treatment differences for cephalometric parameters within groups were analyzed with paired sample t-tests. Additionally, sex differences in post-treatment results were analyzed with an independent samples t-test.

CHAPTER IV

RESULTS

Pretreatment differences

The Bollard miniplates (BM) and facemask (FM) patients differed significantly in average age (Table 4), with the facemask patients being significantly younger (8.90 years old) at T1 than the Bollard miniplates patients (11.72 years). The groups also differed in the age at T2 and in the duration of treatment, with the Bollard miniplates groups spending approximately 5 more months in treatment than the facemask group. There were no statistically significant differences in sex distribution among the BM and FM groups (p=0.13).

The groups were found to differ significantly in pretreatment SNA, UFH, and PUFH (Table 5). The Facemask group had larger SNA angles than the Bollard plate group (77.2° vs 73.3). Both represent a retrognathic maxillary position compared to cephalometric norms. Additionally, the Bollard plates group began with a greater anterior and posterior upper face height (48.7 mm and 43.0 mm respectively, compared to 43.6 mm and 37.3 mm in the Facemask group). These differences are significantly different beyond that seen due to age differences between the groups (since age was controlled for as a covariate in the analysis).

Within Group Evaluation

The Bollard miniplates group exhibited a mean increase of 1.11° in SNA from T1 to T2, with SN-ANS increasing slightly less (0.9°) and maxillary depth increasing slightly more (1.4°) (Table 6). Similarly, A-point and ANS came forward approximately 1.5 mm when measured on cranial base superimpositions of T1 and T2 lateral cephalometric radiograph tracings (Table 7).

Changes from T1 to T2 were significant for SNA, SN-ANS, FH-NA, and UFH, while changes in maxillary length approach significance (Table 8).

SNA did not increase significantly for the facemask group from pre- to post-treatemnt cephalometric tracings (Table 8). Similarly, maxillary depth (FH-NA) did not change significantly (Table 8). However, maxillary length increased significantly by about 1 mm (Table 8) and A-point and ANS underwent a mean horizontal displacement of 1.25 and 1.67 mm respectively (Table 7).

Between group differences

There were no significant differences between the groups in the pre- to post-treatment changes in any of the cephalometric parameters measured (Table 6) or in the horizontal or vertical displacement measured on cranial base cephalometric tracing superimpositions (Table 7, Figure 3, Figure 4, Figure 7). The Bollard miniplates group exhibited nearly 1° greater mean increase in SNA from pre- to post-treatment but this was not statistically significant.

Sex Differences

Males and females exhibited statistically equivalent changes in the cephalometric parameters measured from pre- to post-treatment. The only significant difference noted between males and females was in average treatment duration, with females undergoing treatment treatment for 5 additional months on average as compared to their male counterparts (p=0.02).

CHAPTER V

DISCUSSION

Children with CLP have retruded maxillae and the effects are age related. In the present study, the pre-treatment maxillary cephalometric measures showed retruded maxillary positions in both groups. The BM group demonstrated a greater degree of overall maxillary retrusion (73.3° SNA) than the facemask group (77.3° SNA). This is largely consistent with previous reports in the literature, with reports of pre-treatment SNA measurements in cleft patients range from 73.68° to 76.4°.[7,9,44–46,56] Moreover, this effect was age related (Figure 5) with the pretreatment SNA angle decreasing with increasing age. SN-ANS relationship to patient age mirrors that of SNA (Figure 6). This reflects maxillary growth restriction commonly observed in operated cleft patients, which has been attributed to the formation of scar tissue in skeletal sutural areas which interferes with normal growth.[19]

Bollard miniplates produce moderate improvements in maxillary profile.in the present study, the BM group exhibited an average of 1.1° improvement in SNA and 1.7 mm forward horizontal displacement from pre- to post-treatment. These changes are consistent with previous reports of CLP children treated with miniplates, who showed 1.7 mm[8] and 1.5 mm[9] forward horizontal displacement and a 1.7° increase SNA.[7] However, this is less than the amount of protraction previously reported for non-cleft patients, which ranges from 2.4[8] to 3.7 mm[2] and 4 mm.[60] This difference may be due to decreased response potential to skeletal traction due to the presence of scar tissue limiting the amount of protraction possible. Yatabe et al noted that there was no significant difference between the cleft and non-cleft group analyzed in her study, which exhibited 1.66 mm and 2.37 mm anterior horizontal displacement, respectively.

Facemasks also produce modest improvements in maxillary profile. The facemask group in the present study exhibited minimal improvement in SNA (0.3°) after 18 months of treatment, but showed modest improvements in horizontal forward displacement of A-point (1.25 mm). It is possible that greater changes were observed in forward horizontal displacement of A-point than in the SNA angle due to continued forward growth of nasion masking maxillary protraction gains, which would limit increases in the SNA angle if the magnitude of maxillary protraction matched the forward growth of nasion. The horizontal displacement of A-point is in line with the 0.8 mm of horizontal protraction of A-point reported by Buschang and coworkers for 21 UCLP patients treated over 1.2 years.[55]

The changes in SNA observed in the present study are slightly (0.3°) less than those reported by Ishikawa et al, who reported a net 0.65° increase in SNA over 2 years of treatment in 26 UCLP children (mean age 6.6 years at the start of treatment).[51] This is possibly attributed to differences in treatment response owing to age differences (with our sample being older), differences in surgical histories between the samples, influence of the chin cup applying an additional reciprocal force to protract the maxilla, or differences in compliance between the samples.[51] A few other studies reported significantly greater improvements in SNA. including Dogan et al (4.78°)[52], Borzabadi-Farahani et al (1.95°)[53], Singla et al (2.4°)[54], and Tindlund (1°)[62]. Dogan et al used significantly greater force (800g), prescribed more hours of wear per day (16), and more closely monitored compliance, recalling patients every 4 weeks.[52] In Borzabadi-Farahani et al.'s study, facemask wear was done in conjunction with fixed appliance therapy, which could have confounded the orthopedic results observed from facemask protraction alone.[53] Singla et al. prescribed more hours of wear per day (16-18), which may have resulted in greater protraction.[54] Tindlund et al's treatment protocol included significantly greater force application (700-800g) and significantly younger patients (6.8 years old).[62] Additionally, compliance and surgical history may play a role in any of the aforementioned differences observed.

Bollard miniplates and facemasks produce similar maxillary changes in UCLP patients. No statistically significant differences were observed in the present study between the skeletal changes observed in the BM versus FM groups. While the BM group exhibited 0.8° greater increase in SNA, between-group differences in the horizontal displacement of A-point (0.48 mm difference favoring the BM group) was minimal. This is the first study to directly compare a sample of UCLP treated with Bollard miniplates versus facemasks. Studies of non-cleft patients treated with either miniplates or facemasks report from 1.1 mm[4] to 2-3 mm[3] (over a 1 year period) more maxillary protraction with Bollard miniplates. However, both studies used different methods to assess treatment changes. Cevidanes and coworkers used a method of superimposition that was different from the one employed in the previous study;[3] Hino and coworkers study analyzed three-dimensional CBCT images directly superimposed and measured maxillary protraction based on the average displacement of the entire maxillary anterior surface (not just at A-point).[4] As such, methodological differences may account for some of the difference in results observed. Additionally, both of the aforementioned studies were conducted using non-cleft patients, who might be expected respond differently to the therapies being analyzed. Furthermore, and perhaps most importantly, the two groups in our study differed significantly in age and initial SNA (with the facemask group being younger and starting with a higher SNA angle). This may have differentially influenced the protraction potential between the two groups, such that greater protraction was possible in the younger facemask group. Baccetti et al showed that patients treated with facemask at a younger age (6.75 years) showed significantly greater maxillary protraction than patients treated at an older age (10.25 years), with the older cohort showing equivalent changes to those seen in an untreated control group.[49] This is posited to occur due to a greater ability to distract the zygomaticomaxillary sutures in patients of early juvenile age, as opposed to patients in early adolescence or late juvenile period in whom this is not readily possible.[50]

There are several limitations associated with the current study. Firstly, the samples began with significantly different initial ages, SNA angles, face heights, and surgical histories. Thus, these factors represent possible confounders to the results observed. While our statistical analysis attempted to control for the effect of age by including it as a covariate in our analysis, the effects of the patients' differing surgical histories could not be controlled for as it was not precisely known for each patient. Secondly, we did not have detailed records concerning patient compliance. This can have a significant effect on the results observed as both treatments are heavily reliant on compliance. This represents an additional confound that may be obscuring the true results. Regrettably, we were not able to assess mandibular parameters due to a significant number of subjects having their mouths in an open position at the time of radiograph acquisition. Thus, true mandibular closed position was not able to be reliably ascertained and as such mandibular measurements were not included. Furthermore, the observed power for the several analyses conducted in this study was low (observed power was 0.41 for SNA changes between groups, 0.17 for A-point displacement between groups, and 0.07 for ANS displacement between groups). Hence, there is a high likelihood of a Type II error. Finally, we did not have access to long term retention data for these patients.

Future studies may improve on the results of the present study by ensuring the mandibular is consistently positioned in the closed position at the time of radiograph acquisition to allow for assessment of mandibular parameters in the study's analysis. Furthermore, longer term retention data, particularly at the time of participants' skeletal maturity, would provide valuable information as to the stability of each treatment and the final outcome achieved with each treatment strategy. Specifically, it would be instructive to determine how many patients from each treatment ultimately required surgical correction for maxillary anteroposterior discrepancies.

Clinical Implications

Based on the results of the present study, we cannot conclude that treatment with Bollard plates consistently produces superior results to those seen with conventional growth modification with facemask therapy. However, these conclusions are limited due to the low power observed. However, treatment with Bollard miniplates may offer distinct advantages over facemask therapy beyond the amount of maxillary protraction that may be expected. These include superior esthetics with resultant improved compliance, and the possibility of achieving orthopedic effects at a later age. These factors should be considered when deciding on a treatment that would be most suitable for a particular patient.

CHAPTER VI

CONCLUSIONS

1. Bollard plates did not produce significantly greater maxillary skeletal protraction than traditional growth modification therapy with facemask.
2. Bollard plates produced moderate and significant improvements in maxillary skeletal protraction.
3. Facemask therapy produced mild (but not significant) improvement in maxillary skeletal protraction in a UCLP sample with a mean age of approximately 8 years old.

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APPENDIX A

FIGURES

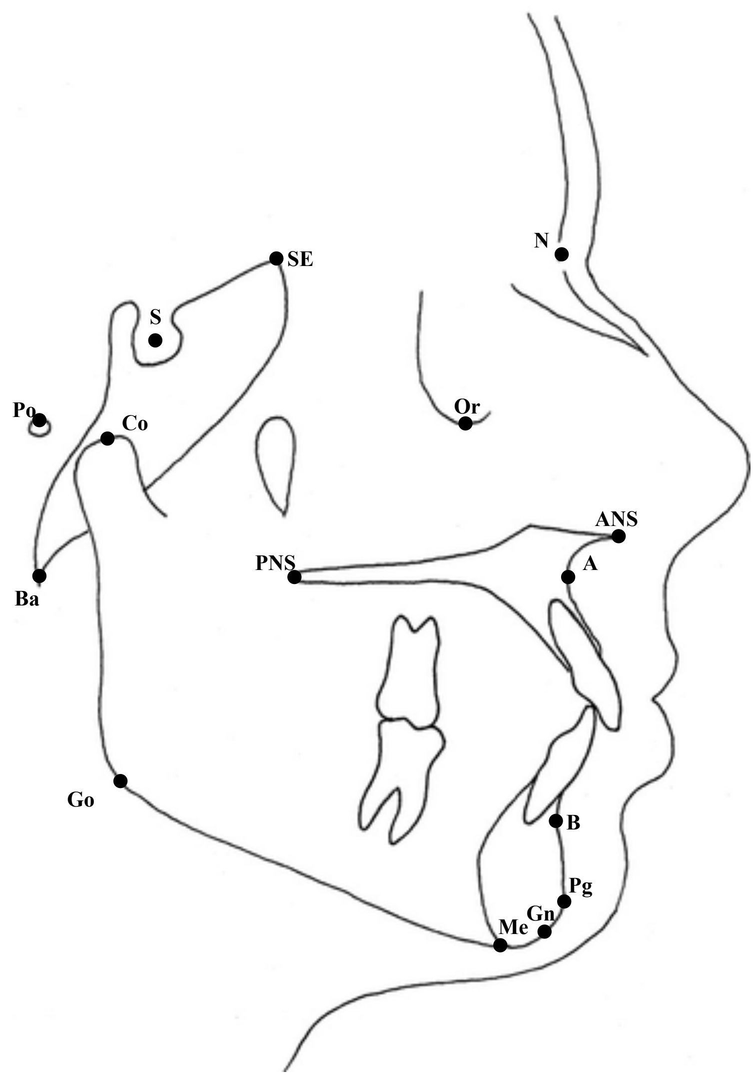


Figure 1: Diagrammatic representation of cephalometric landmarks. (Legend: Po=Porion, Ba=Basion, Co=Condylion, S=Sella, SE=Ethmoid registration point, Go=Gonion, PNS=Posterior Nasal Spine, ANS=Anterior Nasal Spine, Or=Orbitale, N=Nasion, A=A-point, B=B-point, Me=Menton ,Gn=Gnathion, Pg=Pogonion.) Adapted from Tavares et al 2013.[63]

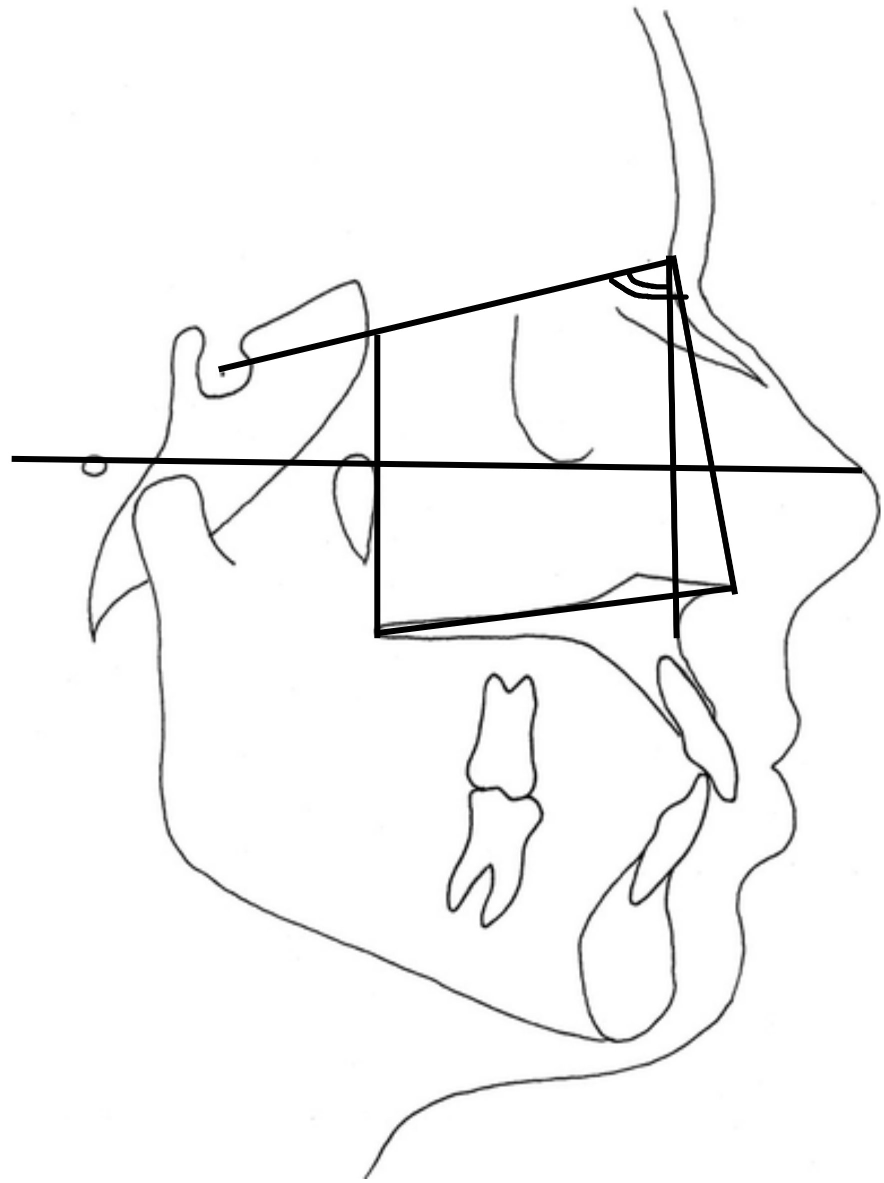
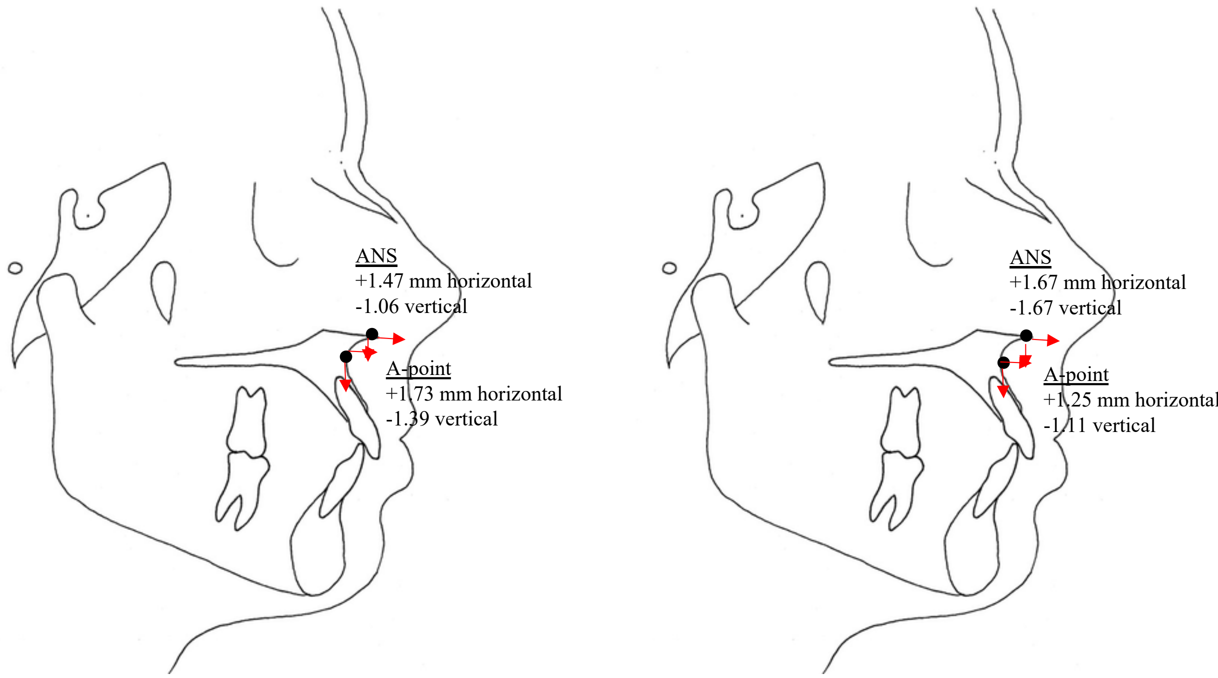


Figure 2: Diagrammatic representation of cephalometric angular and linear measurements: SNA, FH-NA, SN-ANS, Maxillary length (ANS-PNS), UFH (N-ANS), PUFH (SE-PNS). Adapted from Tavares et al. 2013.[63]



Bollard plates patients

Facemask patients

Figure 3: Schematic diagram of mean horizontal and vertical displacements of ANS and A-point in BM and FM groups in tracing superimpositions. Adapted from Tavares et al. 2013.[63]

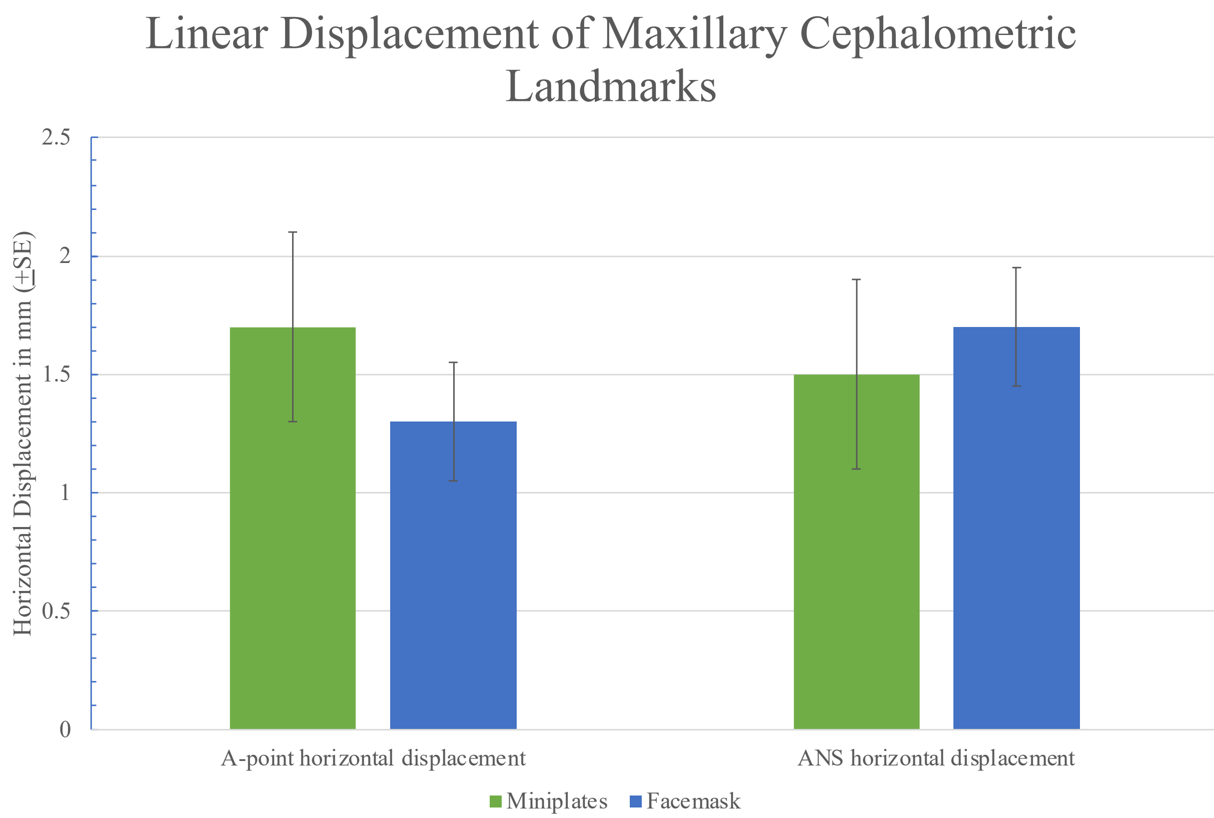


Figure 4: Linear displacement of maxillary cephalometric landmark in BM and FM groups in cephalometric tracing superimpositions

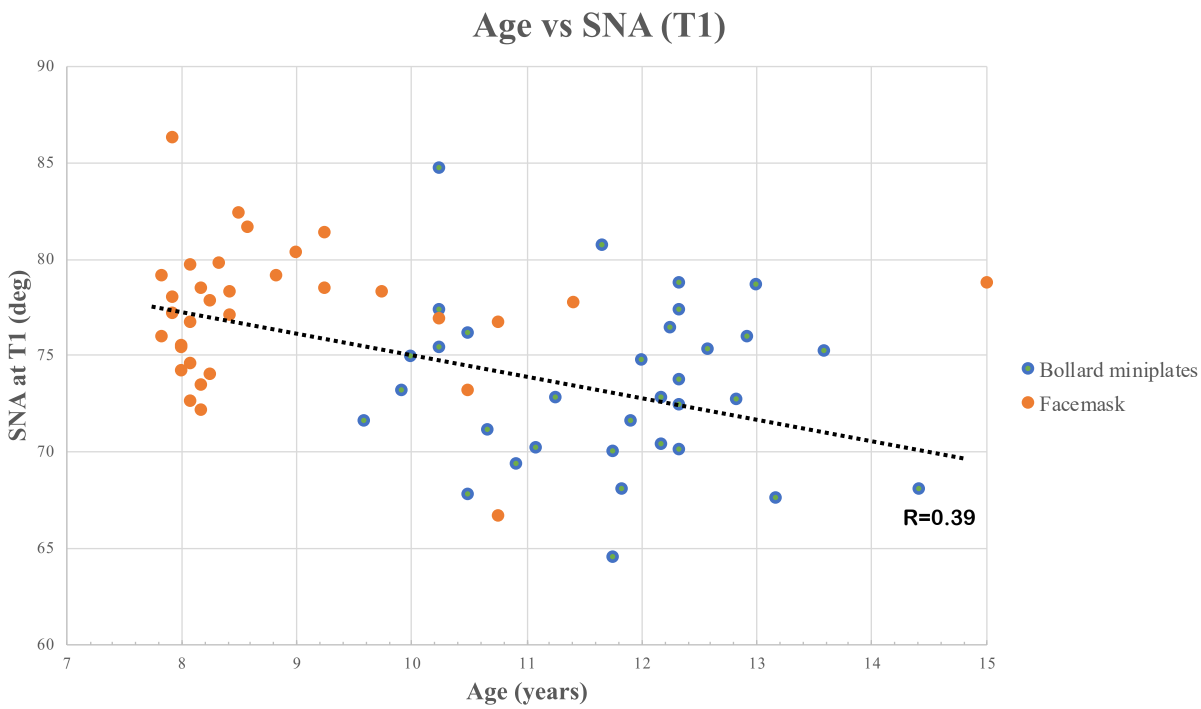


Figure 5: Age versus SNA scatterplot for FM and BM groups with line of best fit depicting trend of decreasing SNA as age increases

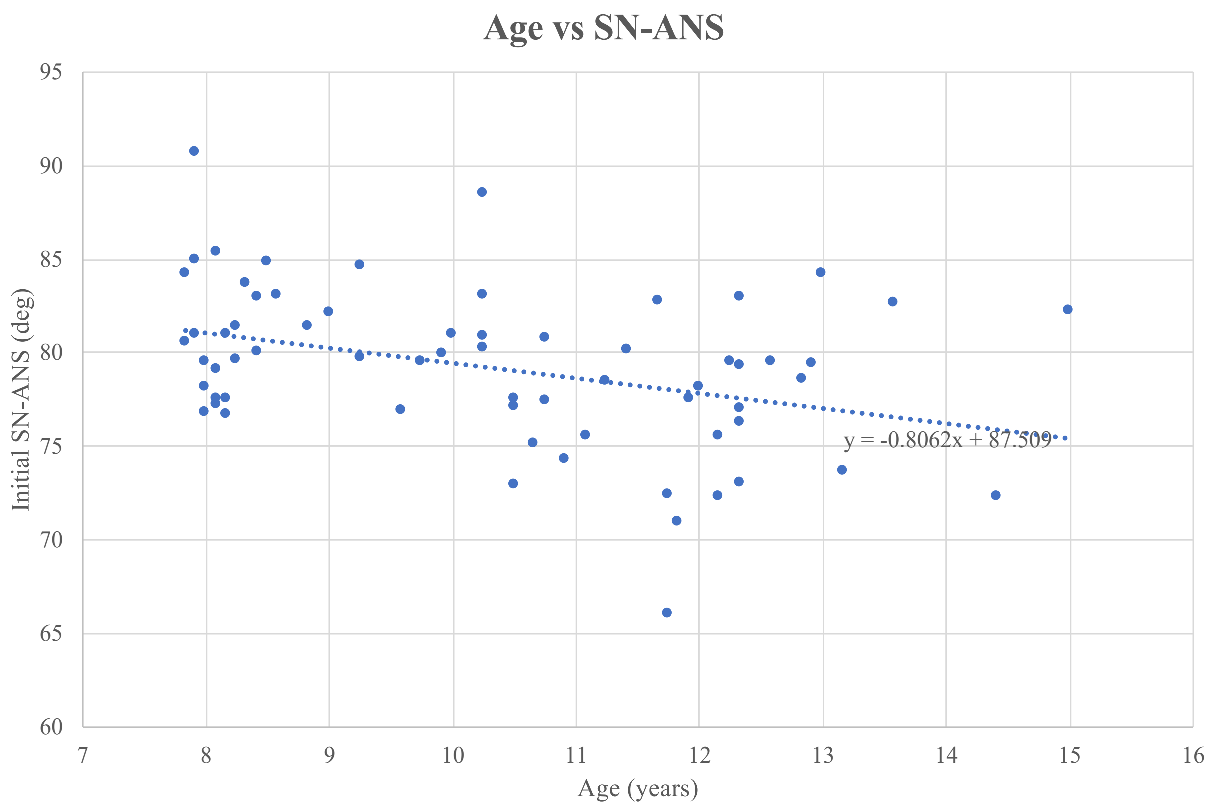


Figure 6: Age versus SN-ANS scatterplot for FM and BM groups with line of best fit depicting trend of decreasing SN-ANS as age increases

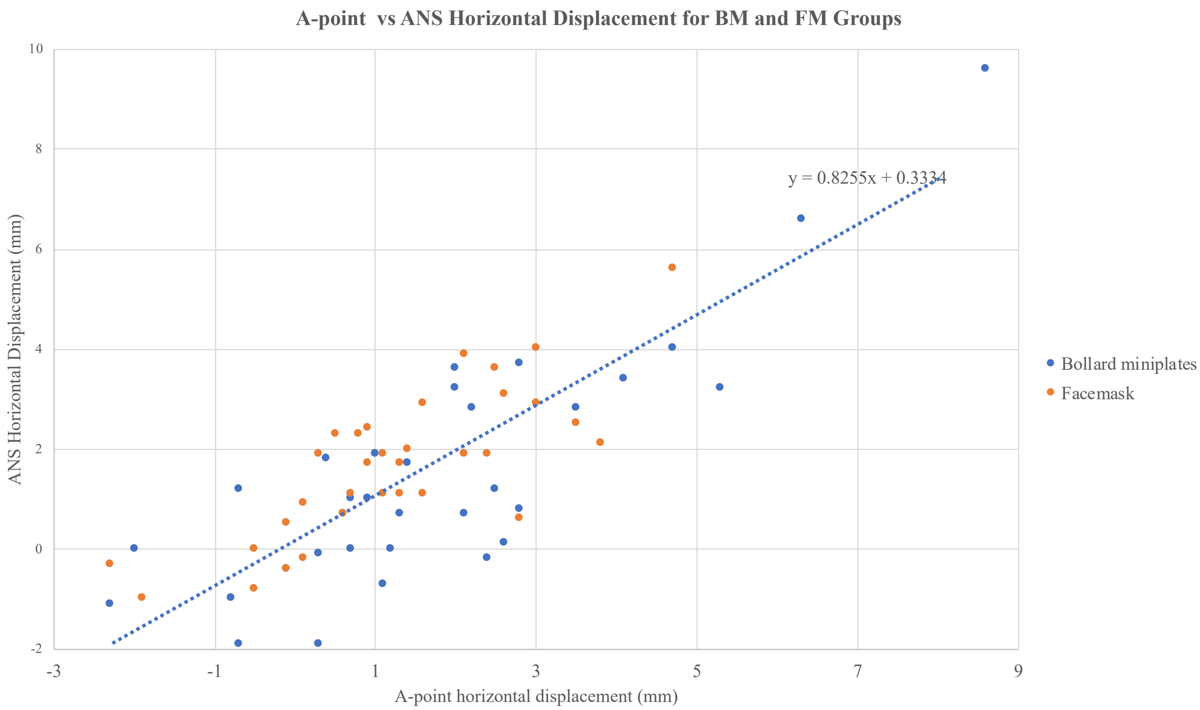


Figure 7: A-point vs ANS Horizontal Displacement for BM and FM groups exhibiting variability within and between the samples

APPENDIX B

TABLES

Table 1: Demographic characteristics of the Bollard miniplates (BM) and Facemask (FM) groups

Sample			Demographic characteristics			
Treatment	**Center**	**n**	**M/F**	**T1 age (years)**	**T2 age (years)**	**T1 to T2 (months)**
Bollard miniplate skeletal protraction	University of Sao Paulo	23	14/9	11.75	13.20	16.74
	Chicago Private Practice	10	3/7	11.65	14.87	38.2
	Total	33	17/16	11.72	13.70	23.24
Facemask therapy	University of Sao Paulo	8	5/3	10.54	12.28	20.5
	Dallas Children's Medical Center	25	18/7	8.38	9.84	17.24
	Total	33	23/10	8.90	10.43	18.03

Table 2: Description of cephalometric landmarks (as described in Dolphin Imaging Software)

Landmark	Abbreviation	Description
Porion	Po	Most superior point of the external auditory meatus
Orbitale	Or	Most inferior point of the external border of the orbital cavity
Sella	S	The geometric center of the pituitary fossa of the sphenoid bone
Nasion	N	Intersection of the internasal suture with the nasofrontal suture in the midsagittal plane
Basion	Ba	Most inferior posterior point of the occipital bone at the anterior margin of the occipital foramen
A point (Subspinale)	A	The most posterior point of the concavity of the maxilla between ANS and prosthion
Anterior Nasal Spine	ANS	Tip of the anterior nasal spine
Posterior Nasal Spine	PNS	Tip of the posterior nasal spine
B point	B	Most posterior point in the concavity along the anterior border of the symphysis
Pogonion	Pg	Most anterior point on the mid-sagitally symphysis
Anatomical gnathion	Gn	Midpoint between the most anterior and inferior point on the bony chin
Gonion	Go	Most convex point where the posterior inferior curve of the ramus meet
Menton	Me	Most inferior point of the symphysis

Table 3: Description of cephalometric measurements

Measurement	Definition
SNA	Internal angle formed between the points sella, nasion, and A-point
Maxillary length	Distance (mm) between ANS and PNS points
Maxillary depth	Internal angle formed by the intersection of Frankfurt Horizontal plane (porion to orbitale) and line drawn between nasion and A-point
Upper face height	Distance (mm) between N and ANS points
Upper posterior face height	Distance (mm) between SE and PNS

Table 4: Mean patient ages and treatment times for Bollard miniplates (BM) and Facemask (FM) groups

Variable	BM	FM	p-value
T1 age (yr)	11.72	8.90	<.01
T2 age (yr)	13.70	10.43	<.01
T1-T2 duration (mos)	23.24	18.03	.03

Table 5: Comparison of pretreatment cephalometric parameters of interest

Variable	BM	FM	p-value	Adjusted BM mean	Adjusted FM mean
SNA	73.3	77.2	.03	73.72	76.83
ANS-PNS	44.2	44.1	.26		
SN-ANS	77.5	80.9	.07	77.89	80.50
FH-NA	83.5	86.5	.06	83.56	86.35
UFH	48.7	43.6	.01	47.65	44.63
PUFH	43.0	37.3	<.01	41.84	38.39

Table 6: Cephalometric measurements at T1, T2 time points and changes from T1 to T2 time points for BM and FM groups

Measurement	Unit	T1 (pretreatment)					T2 (posttreatment)					T1-T2 change				
		BM		FM		Group differences (p-value)	BM		FM		Group differences (p-value)	BM		FM		Group differences (p-value)
		M=	±SD	M=	±SD		M=	±SD	M=	±SD		M=	±SE	M=	±SE	
SNA	deg	73.3	4.3	77.2	3.6	0.03	74.4	4.1	77.5	4.1	0.10	1.11	0.4	0.3	0.3	.59
Maxillary Length (ANS-PNS)	mm	44.2	4.2	44.1	2.6	0.26	44.8	3.3	45.2	3.2	0.11	0.6	0.3	1.1	0.2	.31
SN-ANS	deg	77.5	4.5	80.9	3.1	0.07	78.4	4.5	81.7	3.9	0.06	0.9	0.4	0.7	0.4	.67
Maxillary depth (FH-NA)	deg	83.5	4.0	86.5	4.1	0.06	84.8	4.0	86.7	4.2	0.25	1.4	0.4	0.2	0.4	.18
UFH (Na-ANS)	mm	48.7	3.6	43.6	3.1	0.01	49.8	3.3	45.3	3.3	<0.01	1.1	0.3	1.7	0.3	.99
PUFH (Se-PNS)	mm	43.0	3.9	37.3	3.3	<0.01	44.1	4.3	39.0	3.4	0.02	1.1	0.6	1.7	0.3	.84

Table 7: Mean values for linear displacement of cephalometric landmarks in cranial base superimpositions for BM and FM groups

	BM		FM	
	Mean	**±SE**	**Mean**	**±SE**
A-point X-plane displacement (mm)	1.73	0.40	1.25	0.27
A-point Y-plane displacement (mm)	-1.39	0.37	-1.67	0.39
A-point linear displacement (mm)	3.18	0.37	2.93	0.31
ANS X-plane displacement (mm)	1.47	0.42	1.67	0.26
ANS Y-plane displacement (mm)	-1.06	0.25	-1.11	0.33
ANS linear displacement (mm)	2.63	0.35	2.68	0.28

Table 8: Pre- to post-treatment changes in cephalometric parameters

	BM			FM		
Variable	**T1**	**T2**	**p-value**	**T1**	**T2**	**p-value**
SNA	73.3	74.4	0.005	77.2	77.5	0.338
ANS-PNS	44.2	44.8	0.051	44.1	45.2	<0.001
SN-ANS	77.5	78.4	0.038	80.9	81.7	0.058
FH-NA	83.4	84.8	0.002	86.5	86.7	0.562
UFH	48.7	49.8	0.002	43.6	45.3	<0.001
PUFH	43.0	44.1	0.076	37.3	39.0	<0.001