Instituto Latino Americano de Pesquisa e Ensino Odontológico

Rocío Altagracia Romero Valdez

Mechanical evaluation of newly designed miniplates for orthodontic skeletal anchorage.

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Dissertation presented to the Latin American Institute of Dental Research and Education, as part of the requirements to obtain the diploma of Masters in Dentistry with Orthodontics concentration.

Advisor: Prof. Dr. Roberto Hideo Shimizu
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Romero, Rocío Altagracia Valdez

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Mechanical evaluation of newly designed miniplates fororthodonticskeletalanchorage

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Summary

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Dedications

This work is dedicated to my lovely parents Rosario and Alberto. You have been with me to always give your unconditional support, emotionally, psychologically and financially. Together we have overcome the worst and the best moments of this journey full filled with values of independence, sacrifice, maturity and most importantly and the main reason of all, to learn and keep on reaching new goals that will make me a better human and professional. Thank you for showing me the way, I have the best role models.

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Thank you, to all may classroom colleagues for receiving me in your country and your houses and helping me built a home away from home.

Abstract

The purpose of this study was to conduct a mechanical evaluation on miniplates newly designed to assure itsclinical applicability in orthodontics. The sample consisted of six 6 of each miniplate design: straight, Y and T (n=18) of 23mm length manufactured in pure titanium grade 2. A three (3) point bend test was performed to validate mechanical yield strength. The test was executed at the NeoOrtho® laboratories (Curitiba, Brazil.). An Instron® fatigue testing system, model 8872, delivered the bending forces. The miniplates were placed flatwise in the testing machine at a support distance of 12.35mm and the test rate was of 5mm/min. The test recorded the values obtained for: yield load, yield displacement, stiffness and bending moments for each miniplate. Statistical analysis included de application of test of normality by Kolomogorov-Smirnov, homogeneity test by ANOVA, multiple comparison tests of Tukey HSD and Games-Howell for homogenous and heterogeneous variances respectively. The Pearsons coefficient determined correlations between the variables. The straight miniplate presented a statistically significant difference of greater stiffness and lees displacement when it was compared to the Y and T miniplates.There is a very strong positive correlation between yield load, yield displacement and bending moment. On the other hand, there is a strong negative correlation between stiffness and yield displacement. All miniplates designs tested demonstrated adequate mechanical properties that withstand orthodontic and orthopedic forces.

Keywords: orthodontics, orthodontic anchorage procedures, mechanical stress, miniplates

1 Introduction

Orthodontic tooth movement results from catabolic bone modeling at the periodontal ligament surface when force is applied to teeth by active devices. [1,2]All these forces are managed by the third law of Newton: for every action there is an equal and opposite reaction; meaning that forces applied to one tooth will react inversely with same intensity in another tooth. To divert unwanted tooth movements orthodontists apply anchorage control; defined as the ability to resist reactive moments and maintain treatment success. Anchorage can be provided by: other teeth, palate, extraoral appliances supported in the head, neck, or implants in bone.[3,4] The desire to have complete control over anchorage is no doubt universal among orthodontists and ever since the beginning of orthodontics has been one of the most discussed and investigated subjects.

The demand for orthodontic treatment methods that require minimal patient compliance, solution for complex treatments, particularly in adults whom have lost more than one posterior tooth and the importance on esthetic considerations by all patients led to the emergence of skeletal anchorage system.[5,6]

The main indications for the use of a bone anchorage system are: the distal movement of the anterior and posterior segments, regardless of whether extraction is required; the mesial movement of the posterior teeth;[7,8] the intrusion of a single tooth or a group of a teeth;[9] the uprighting of a mesially inclined lower molars; the loss of dental anchorage resulting from tooth loss; periodontitis; and orthopedic intermaxillary traction.[6,10,11]

Their chief advantage lies in providing a fixed, stationary anchorage spot inside the oral cavity, which enables orthodontic movements, by preventing the unit of resistance from being displaced.[6,12]Thetitanium miniplates used for anchorage now offers the possibility to apply pure bone-borne orthopedic forces between the maxilla and the mandible for 24 hours per day, avoiding any dento-alveolar compensations.

Currently, miniscrews and miniplates are being widely used because of their small size and superiority over endossous implants due to the fact that they can be immediately loaded. Miniplates have a very high success rate (91.4% - 100%), low morbidity and are usually well accepted by patients.[11,13,14]

Besides these successful case reports, clinical studies regarding miniplates had reported certain failure related to inflammation around the neck and the forces effecting on the stability of the fixation.[15] Inadequate design, non-homogeneous force distribution along the anchorage system, and emergence of force application units that remain on the non-attached gingiva can cause those complications.[16]

In actuality there's no enough studies focused in the mechanical evaluation of miniplates used for orthodontic skeletal anchorage. Failure reports referring to this anchorage system creates on the surgeon-dentist the inquiry to know how much can withstand or resist a miniplate. Fatigue fracture and wear are some of the major problems associated with implant loosening, stress-shielding and ultimate failure,miniplates at some point may be affected also. This study is design to assess the mechanical resistance of miniplates (NeoOrtho®, Curitiba, Brazil) by submitting them to mechanical evaluation: static test. The aim was to obtain and prove a miniplate design capable of successfully withstand orthodontic and orthopedic forces.

2 Literature review

Loukota et al.[17] in 1995 conducted a study to determine the effect of compression and tensile forces on different types of maxillofacial miniplates. A four point bend test flatwise and edgewise was carried out following the recommendations of BS 3531 for 5 miniplates designs commercially available, Champy stainless steel, Champy titanium, Leibinger titanium, DePuy titanium, Stratec/AO titanium. Five specimens of each plate were tested and were positioned symmetrically between the rollers and equal forces were applied through the rollers at constant cross head speed of 1.667 x 10-2 mm s-1. A second set of test were performed on the plates previously bended. For the tensile test the plates were screwed through four holes on to solid metallic blocks which then were mounted in the testing machine. The plates were tested at a constant cross head speed of 1.67x 10-2mm s-1. A second series of test were performed of the plates following a 90o twist at the mid-point of the plate. The analysis of the results involved the record of the peak load during bending and a mathematical formula was applied to calculate bending stiffness. In the flatwise direction all miniplates presented a bending stiffness from 0.022 N N m/deg to 0.028 N m/deg. When bending the plates to simulate clinical practice the bending stiffness decreased. The authors found that the plates have the capacity to perform beyond the requirements of the clinical situation and that the failure occurred in most cases at the screw bone interface.

Cheng et al.[18] in 2004 aimed in a prospective clinical study to assess the risk factors associated with failureof orthodontic skeletal anchorage miniscrews and miniplates. A total of 140 mini-implants in 44 patients mean age 29 $\pm$ 8.9 years old, including 48 miniplates and 92 freestanding miniscrews, were examined in the study. When a miniplatewas to be used, an L-shaped plate was adjusted to fit the contour of the bone surface and fixed by 2 or 3 monocortical miniscrews (5 or 7 mm long). The screw holes were made by a 1.5-mm twist drill at 1,000 rpm with continuous normal saline irrigation. The 2-mm miniscrews were then placed in a self-tapped fashion. The terminal hole at the long arm of the plate was exposed to the oral cavity from the incised wound. Orthodontic treatment was started 2 to 4 weeks after the surgery. The orthodontic load applied to the implants was estimated to be 100 to 200 g. The directions of force applied were mainly lateral; torsional or extrusive load was avoided. Criteria for success validation were: absence of inflammation, absence of clinically detectable mobility and capability of sustaining the function of anchorage throughout the course of treatment. Miniplates, each fixed had a higher success rate than freestanding miniscrews, but the difference was not statistically significant. However, it should be noted that miniplates were used in more hazardous situations; they sustained loads with a longer lever arm or were fixed in thinner bone than were the free standing miniscrews.

Cornelis et al.[19]in 2007 presented a systematicreview of the experimental use of temporaryskeletalanchoragedevices in orthodontics. The aim was to review the experimental literature to determine what was known about functional and morphological tissue actions around orthodontically loaded temporary skeletal anchorage devices (TSAD). The researched was executed in Pubmed electronic database and the reference citations of selected articles were also examined. The inclusion criteria comprehended animal studies about orthodontically loaded skeletal anchorage consisting of metallic bone plates or screw implants of 2.2 mm diameter or less. Studies about any type of palatal, retromolar or prosthetic implant was excluded as well as studies in foreign languages. MeSH terms “Dental implants”, “Bone screws”, “Bone plates” were chosen during the search. Data on healing time, force application, stability, side effects, and osseointegrationwere collected. A total of 34 abstracts were identified, only 8 articles meet the inclusion criteria and were reviewed, two of them about miniplates. This review highlights some positive experimental findings that apply in clinical practice. Conclusions emerged that TSAD certainly offers direct structural functional anchorage; inflammation side effect is infrequent; clinical stability of the device may be sufficient for orthodontic anchorage with low osseointegration. However, questions concerning optimal force systems, surgical techniques and placement, and healing times remain. Future research should be well controlled and based on standardized protocols to test specific hypotheses.

Veziroglu et al.[16]in 2008 carried out a study with application of finite element analysis system to evaluate the biomechanical properties of standard and newly designed plate screw orthodontic anchorage system (1.5 mm, Bollard Zygoma Anchor, Surgi-Tec, Bruges, Belgium). A three dimensional model of the posterior maxilla, including zygomatic butters region, was prepared from a 14 year old patient with a two-dimensional computered tomographic software (I-DEAS Arti- san 4.0 Cad-Cam Software, Structural Dynamics Re- search Corp, Milford, Ohio) then, another software was applied to create the third dimension of the model, MSC-Marc Menthat 2005 soft- ware (MSC Software Corporation, Santa Ana, Calif). Titanium miniplates and screws were inserted into the zygomatic butterness via simulation. All materials were assumed to be homogenous, linear elastics and fixed. A static, horizontal, posterior-anteriorly directed force was applied to the system. The effect of 200g of orthodontic force on the plate, screws, and zygomatic bones was evaluated by finite element analysis. To determine the force distribution, Von Mises stress, principal maximum and minimum stress, and maximum and minimum elastic strain values were evaluated and then compared for each type of miniplate. Results showed that the newly design L-shape miniplates had little decrease of values of stress compared with the standard miniplates. In both designs the highest stress and strain was noted on the threaded bone site next to the site were force was applied. Conclusions of the study embrace that the inferior screws of the miniplates are the most susceptible to stress and strain and to equalize the force distribution new plates designs that change the location of the force application are required.

Leung et al.[20] in 2008 made a study with the purpose to examine the primary stability of connected mini-implants and miniplates. Three different SAS were investigated: (1) two 1.5 mm diametercylindrical mini-implants connected with a 0.021 × 0.025 inch stainless steel (SS) wire, (2) two 1.6 mmdiameter tapered mini-implants connected with a 0.021 × 0.025 inch SS wire, and (3) two 2.0 mm diameter cylindrical mini-implants connected by a titanium locking miniplate. Fifteen standardized bovine bones were prepared, five for each experimental group. Pull-out tests were performed on the 15 bone specimens using three types of skeletal anchorage systems. The systems underwent uniaxial pull-out tests at the midpoint of theconnecting wire or miniplate using a mechanical testing machine Model 1185; Instron, (Norwood, Massachusetts, USA). One-way analysis of variance was usedto determine the difference of the pull-out test results between the groups using the Statistical Package for Social Sciences (Version 13, SPSS Inc., Chicago, Illinois, USA).Both the titanium miniplate and SS wire connection systems showed severe deformation at the screwhead, which broke before the mini-implants failed. The 2.0 mm miniplate system showed the highest pullout force (529 N) compared with the other two wire connection systems. The 2.0 mm system was also stiffer than the 1.6 and 1.5 mm systems. The yield force of the 2.0 mm miniplate (153N) was significantly higher than the 1.5 mm (88 N) and 1.6 mm (76 N) systems. This *in vitro* study demonstrated that the connection of two mini-implants with a miniplate resulted in higher pull-out force, stiffness, and yield force to resist pulling force and deformation. Such a set-up could thus provide a stable system for orthodontic skeletal anchorage.

Trandem et al.[21] in 2011 carried out a study mainly to answer the question if miniplates could withstand orthopedic forces, seeking to determine the range of forces that could be applied to a miniplate without a permanent deformation of the lever arm. Miniplates from Synthes (Kalamazoo, Mich), KLS Martin (Tuttlingen, Germany), and Stryker (West Chester, Pa) brands were used in this study, all FDA approved, in total a sample of thirty-six miniplates, twelve from each brand were tested. The miniplates mounted on a stainless steel block and placed in a lock vise to perform the tests, positioned horizontaly at 2mm from the top and side of the vise.Force was applied continuously from 0 to 100 N at a rate of 1 mm per minute, in vertical direction in aInstron testing machine. (model 5566, Instron, Canton, Mass) Elastic modulus was calculated by bending mechanic techninque while applying tensile loading at the end of the beam. When miniplates reached their proportional limit to elastic-plastic bending it marked the initiation of nonlineal load-displacement response. The arms of the miniplates were extended beyond the force level needed for orthopedic anchorage. The maximum normal stress on the surface of the miniplate arm cross-section was calculated from the load at the proportional limit and represented the yielding stress of the material. The means of yield load, maximum stress at proportional limit, and elastic modulus for each brand were compared.Beam bending analysis was used to determine the yield stress results showed that samples had greater yield strengths, ranged from 1280 to 3000 g, depending on the miniplate type. Modulus results were on 106635 GPa for Stryker, fot the KLS Martin samples were lower at 2364 GPa, and the Synthes samples were 43 6 6 GPa. Based on the testing results authors concluded that all three commercially brands of miniplates could withstand orthopedic forces KLS Martin and Synthes demonstrated higher yield loads that were significantly different from that of Stryker.

Lu et al.[22]in 2011 presented a studywiththepurpose to investigatethemechanicalstrength of miniplates placed in artificial bone. In this study, 10 sets of orthopedic miniscrews and miniplates(Leibinger, Muhlheim-Stetten, Germany) were used to determine their insertion torques and pull-out strengths within synthetic bone (Sawbones, Pacific Research Laboratories, Vashon, WA, USA). Each miniscrews and miniplates orthopedic set was composed of one miniplate and two miniscrews (each 7 mm long). 40 pounds per cubic foot (pcf), g/cm3 of a cellular rigid polyurethane sheet (cortical bone; 2 mm thick) was attached to a 20-pcf block (cancellous bone, 250 mm thick) with an acrylate bond to simulate the jawbone. All miniscrews were manually inserted into the bone to a fixed distance of 7 mm and insertion torque was measured by a digital torque transducer (Lutron, Taipei, Taiwan). The experiments were performed with axially applied force angles of 0° and 180° to the axis of the miniplates for the vertical and horizontal pull-out tests. Pull-out tests were carried out with a material testing machine (Lloyd, Berwyn, PA, USA). The miniplate and the pulling machine were attached by a 0.018 stain less steel arch wire. To test the peak breaking force a five power chains (Ormco, Glendora, CA, USA) were also used. To predict the relationship between the insertion torque and pull-out strength the Pearson's coefficient was applied and to determine statistical differences between the horizontal and vertical forces was applied the Kruskal-Wallis test. Results showed that both groups had similar insertion torques for each miniscrew of 5.6 and 8.6 N cm. Each miniplate andminiscrewset had similar insertion torques of12.4 and15.3 N cm. The pull-out strength in the vertical directionranged 97.3 and 118.7 N cm. The pull-out strengthin the horizontal direction ranged 222.6 and 245.7 N cm. Themean peak level of the breaking force of the power chain was21.9Ncm. The pull-out strengths of the vertical and horizontalforces were greater than the pull-out force of the powerchain. Comparing the pulloutstrengths, that in the horizontal direction was significantlygreater than that in the vertical direction. According to the results demonstrated in the study miniplates can provide retention forces greater than traditional orthopedic and orthodontic forces in the vertical and horizontal directions.

In 2012 Nalbantgil et al.[15] with a finite element analysis study examined and compared the force distribution of the newly designed plate-screw systems with a conventional one. The new miniplate structure had spikes placed on the surface that will face the cortical bone and will avoid non-homogeneously stress distribution when a force is applied. Nextengine (NextEngine Inc. Santa Monica, California 90401 USA) laser scanner was used for three-dimensional scanning and Rhinoceros 4.0 (3670 Woodland Park Ave.,Seattle, WA 98103 USA) three-dimensional software modeling and AlgorFempro (ALGOR, Inc. 150 Beta Drive Pittsburgh, PA 15238-2932 USA) softwares were used for analysis. A model of bone surface with 1.5 mm cortical thickness, along with the two newly designed miniplates and a standard miniplate-screw were simulated. The screws used had a diameter of 2mm and a length of 5 mm. The spikes in the newly proposed miniplate model had a length of 0.7 mm and a base diameter of 0.6 mm and were assumed to be fully penetrated into the bone. In all designs 200 g experimental force was applied to the tip of the miniplates and the consequential effects on the screws and cortical bone was evaluated using three-dimensional finite element method. In all of the miniplates the most increased level of stresses were seen at the neck of the miniplates. The maximum stress values for one-holed spiky miniplate were located around all of the spikes. The highest stress value recorded for the spikes was 43.58 MPa. In all the screws, except the far screw of the two-holed spiky miniplate, the highest stress level was recorded at the neck. The highest stress value was 13.32 MPa at the near screw of the two-holed conventional miniplate. For the two holed spiky miniplate, almost no stress was observed at the far screw. The maximum tension and compression stresses seen at the cortical bone around the near screw at the two-holed conventional miniplate were 1.51 and -1.34 MPa, respectively. The results revealed remarkable difference in the stress distribution at the cortical bone that is in contact with the fixation screws between the conventional and the newly designed miniplates. Also the fixation screws received almost half of the stress values for the new miniplates. These results support that biomechanical properties of the miniplates were remarkably improved.

3 Objectives

3.1 General objective

Mechanical evaluation, bending test of a modified orthodontic miniplate for orthodontic anchorage.(NeoOrtho®, Curitiba, Brazil)

3.2 Specific objectives

- Evaluate whether there is statistically significant differences between the mean values of the variables yield load, yield displacement, stiffness and bending moment for three different shapes of miniplates: straight, Y and T.
- To asses if exists correlations between the variables yield load, yield displacement, stiffness and bending moment.
- Evaluate if the three miniplates designs withstand orthodontic and orthopedic forces.

4 Materials and Methods

4.1 <u>Materials</u>

4.1.1 Miniplates

All miniplates in this study were provided by NeoOrtho® (Curitiba, Parana, Brazil). Three different shapesof miniplateswere submitted to mechanical strength test.They were manufacturedfrom pure titanium grade 2alloy TI6A14V, a biocompatible material that meets the requirements given by the ASTM F67standard.Built with a compact and resistant structure with round and polish borders

Miniplates structure is divided in three parts: body, arm and head. The body has holes for the fixing screws and the head has the bottoms design for closed springs or elastic chain. The arm can be readjusted with a slight deformation to fit better the contourof the bone and provide a good location in the oral cavity.

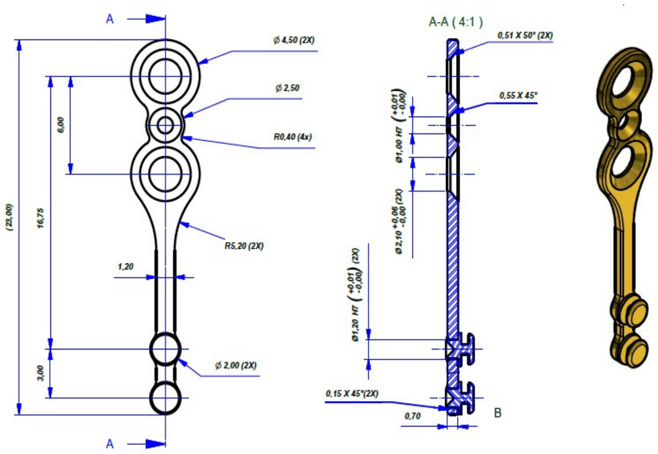

Figure 1-Miniplate I body shape, 23 mm length, circular head (NeoOrtho®, Curitiba, Parana, Brazil)

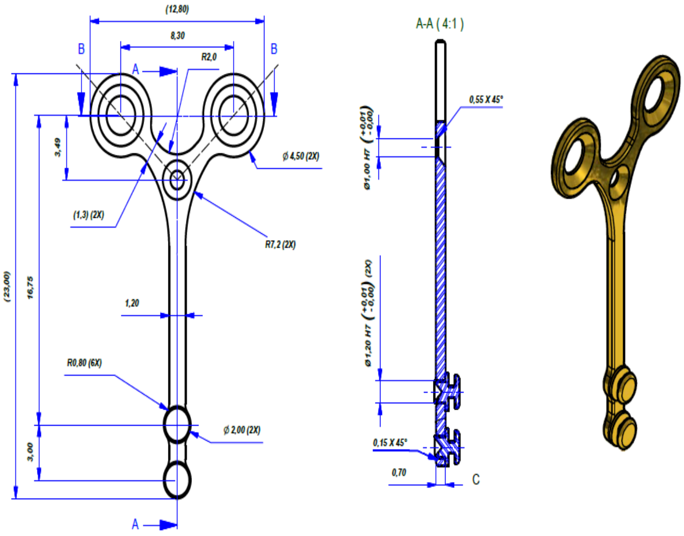

Figure 2- Miniplate Y body shape, 23mm lenght, circular head.
(NeoOrtho®, Curitiba, Parana, Brazil)

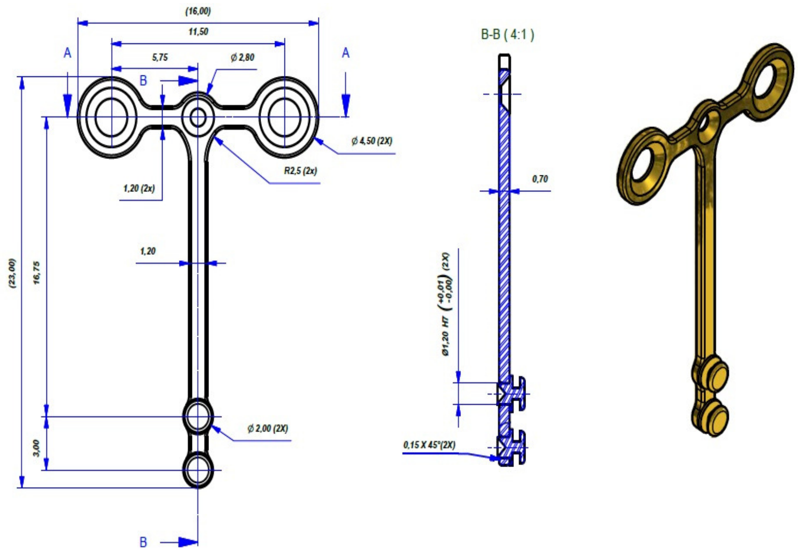

Figure 3- Miniplate T body shape, 23mm length, circular head.
(NeoOrtho®, Curitiba, Parana, Brazil)

4.2 Methods

Mechanical test was performed at NeoOrtho® laboratories (Curitiba, Parana, Brazil) by an Instron® 8872 (Instron®, Norwood, Massachusetts, USA) machine test. In addition, for the better understanding of the outcomes of the mechanical test proper statistical analysis was performed.

4.2.1 Testing machine

Instron® Fatigue and Static testing system, model 8872 (Norwood, Massachusetts, USA) is ideal for testing of biomedical, advanced materials, and manufactured components. It has up to 25kN axial force capacity. (Instron®, Corporation n.d.)

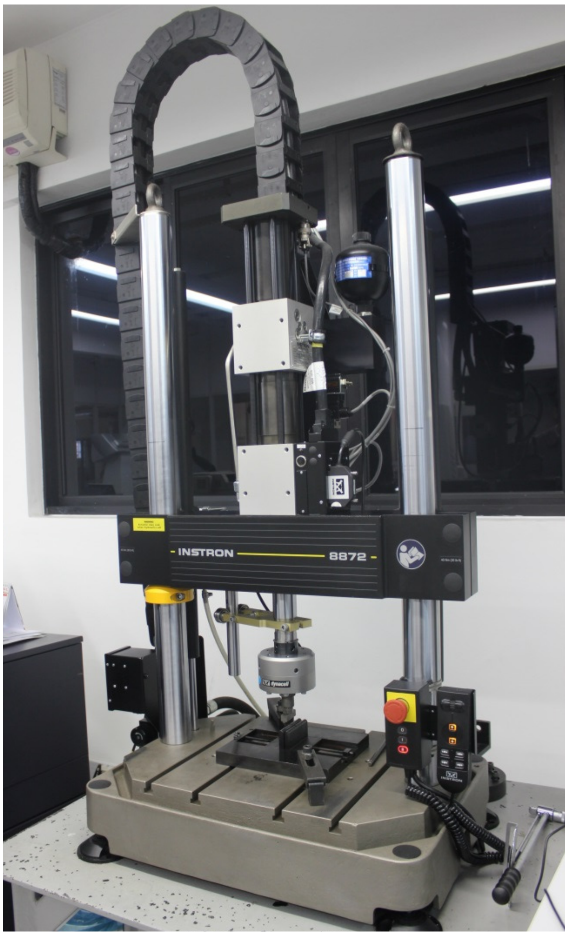

Figure 4- INSTRON 8872 Fatigue Testing System
(Instron®, Norwood, Massachusetts, USA)

4.2.2 Static bending test

A bending test consists of applying a load F in the center of a specific body supported at two points. The initial value of the load applied is zero and continually increases until failure or breakdown of the miniplate. Biomechanical properties obtained from this test include, limit of elasticity in flexion which means the maximum bending stress that the material supports without showing permanent deformation after load removal, also determines the yield strength in flexure and modulus of elasticity.(23)

In this study a3 (three) point bend test was performedto validate mechanical yield strength of the miniplates.A sample of 6 of each design (n=18) was tested.The support distance L was of 12.35mm, as well as a test rate of 5mm/min. The bending strength was obtained from the following equation: where M is the bending strength, F is the yielding load and L is the support distance. Figure 5 shows a schematic representation of the bending test.

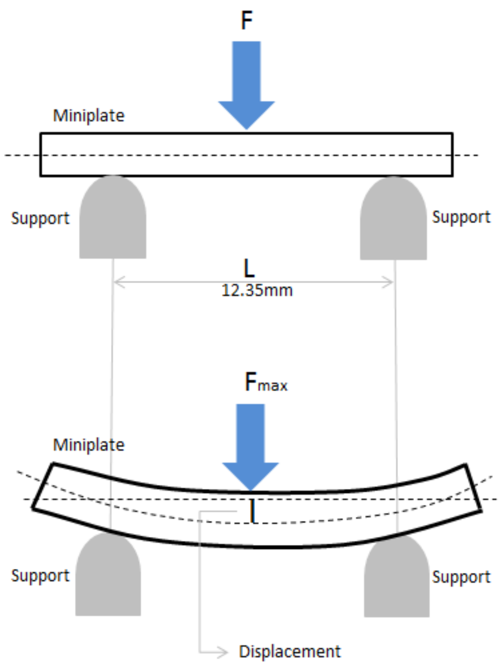

Figure 5- Schematic representation of a 3 points bending test

Miniplates were placed flatwise in the testing machine in a resting position above the points of support and below the point of application of forces. (Figure 6)Variables measured included the yield load (N) and quantity of displacement (mm) at the proportional limit of bending was recorded. Bending moment (Nm) indicated the limit of plastic-elastic deformation of the miniplates.

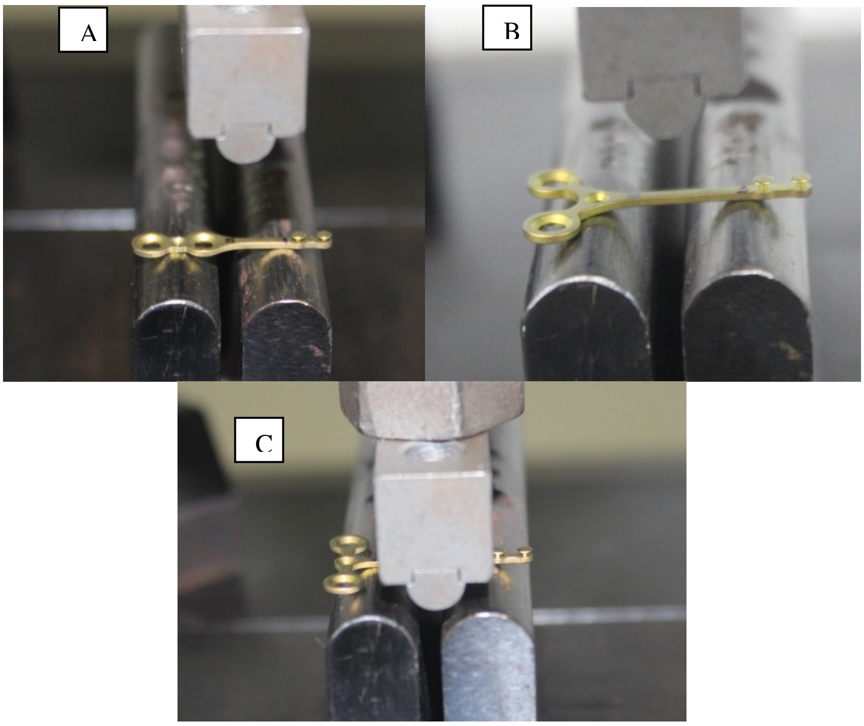

Figure 6- Miniplates placed in the testing machine. A) Straight miniplate. B) Y miniplate. C) Start of test in the T shaped miniplate

4.2.3 Statistical analysis

A one factor variance analysis was applied to determine statistically significant differences between the mean values of the variables, once they presented normal distribution determined by the Kolmogorov-Smirnov test, to 0.05 level of significance.

When the ANOVA indicated the presence of difference between the mean values of the variables analyzed, to identify which groups differed among themselves the multiple comparison test of Tukey HSD for homogeneity of variances was applied, or the multiple comparison test of Games-Howell for heterogeneous variances. The Levenewas used to check the variances homogeneity of four variables between the three miniplates. The significance level was 0.05.

Once the three miniplates presented a normal distribution for the four variables verification of the correlation between them was executed using the correlation coefficient of Pearson. The level of significance adopted was 0.05.

5 Scientific article

5.1 Scientific article 1:

This article was written following the norms of the *Brazilian Oral Research- BOR*

Mechanical evaluation of newly designed miniplates fororthodonticskeletalanchorage

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Abstract

Introduction: The purpose of this study was to conduct a mechanical evaluation on miniplates newly designed to assure its clinical applicability in orthodontics. **Methods:** The sample consisted of eighteen (18) miniplates, six (6) of each different body design: straight, Y and T of 23mm length manufactured in pure titanium grade 2. A three (3) point bend test was performed to validate mechanical yield strength. An Instron® fatigue testing system, model 8872, delivered the bending forces. The miniplates were placed flatwise in the testing machine at a support distance of 12.35mm and the test rate was of 5mm/min. The test recorded the values obtained for: yield load, yield displacement, stiffness and bending moments for each miniplate. Statistical analysis included de application of test of normality by Kolomogorov-Smirnov, homogeneity test by ANOVA, multiple comparison tests of Tukey HSD and Games-Howell for homogenous and heterogeneous variances respectively. The Pearsons coefficient determined correlations between the variables. **Results:** The straight miniplate presented a statistically significant difference of greater stiffness and lees displacement when it was compared to the Y and T miniplates. There was a high positive correlation among yield load, yield displacement and bending moment. Furthermore, a high negative correlation was found between stiffness and yield displacement. **Conclusion:** All miniplates tested showed adequate mechanical properties that withstand orthodontic and orthopedic forces.

Keywords: orthodontics, orthodontic anchorage procedures, mechanical stress, miniplates

INTRODUCTION

Skeletal anchorage system is a revolutionary idea continuously being developed. Orthodontist are still in search of anchorage solutions that leads to the success of complex cases.[1] Orthodontic anchorage can be defined as the control of reactive forces or unwanted tooth movement.[2] In actually it has been well proven how effective can be the reinforcement of orthodontic anchorage with implants. [3–5]

The ideal temporary skeletal anchorage device (TSAD) will provide a fixed, stationary anchorage spot inside the oral cavity, allowing orthodontic movements and preventing the unit of resistance from being displaced.[6] Indications for the use of a bone anchorage system include: the distal movement of the anterior and posterior segments; the mesial movement of the posterior teeth;[7,8] the intrusion of a single tooth or a group of a teeth;[9] the uprighting of a mesially inclined lower molars; the loss of dental anchorage resulting from missing tooth; periodontitis; and orthopedic intermaxillary traction.[10–12]The success rates of miniplates is higher than mini-screws.[13]Miniplates evolved from plates used for surgical rigid fixation. Umemori et al.[14] in 1999 presented the success of correction of open-bite with a modified surgical miniplate L- shaped with a long arm that exposed into the oral cavity. Ten years later, a systematic review founds a success rate of 90% for the orthodontics miniplates.[13]

Considering the large application of miniplates in orthodontics, and the amount of forces that has to be applied during treatment, the study of the mechanical properties of miniplates appears to confirm miniplates resistance to stress when forces are applied.[15,16] Therefore, mechanical tests will be performed to evaluate new miniplates designs.

General objective

Mechanical evaluation, bending test of a modified orthodontic miniplate for skeletal anchorage (NeoOrtho®, Curitiba, Brazil)

Specific objectives

- To evaluate whether there is statistically significant differences between the mean values of the variables yield load, yield displacement, stiffness and bending moment for three different shapes of miniplates: straight, Y and T.
- To asses if exists correlations between the variables yield load, yield displacement, stiffness and bending moment.
- To evaluate if the three miniplates designs withstand orthodontic and orthopedic forces.

MATERIALS AND METHODS

The miniplates used in this study were fabricated in pure titanium grade 2 alloy TI6A14V, 23mm long, 0.7mm width with rounded borders. The head portion was specially designed to set in springs or elastic chains. (Figure1)

A total of eighteen miniplates were tested, six of each design straight, Y and T (NeoOrtho®, Curitiba, Brazil) were submitted to 3 point bending test. The mechanical tests were performed at NeoOrtho® laboratories (Curitiba, Parana, Brazil) using an Instron® 8872 (Instron®, Norwood, Massachusetts, USA) machine test.(Figure 2) The miniplates were positioned at a support distance L of 12.35mm, and the test rate was of 5mm/min. The bending strength was obtained from the following equation: where M is the bending strength, F is the yielde load and L is the support distance. (Figure 3) The yield load and quantity of displacement at the proportional limit of bending were measured and recorded. The bending moment indicated the limit of plastic-elastic deformation of the miniplates.

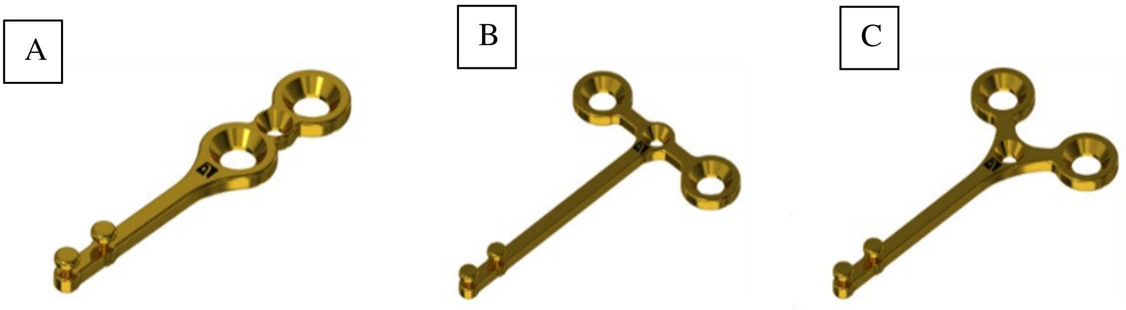


Figure 1. Miniplates design 23mm length.
a)Straight miniplate b)Y miniplate c)T miniplate

Figure 2.INSTRON 8872 Fatigue Testing System
(Instron®, Norwood, Massachusetts, USA

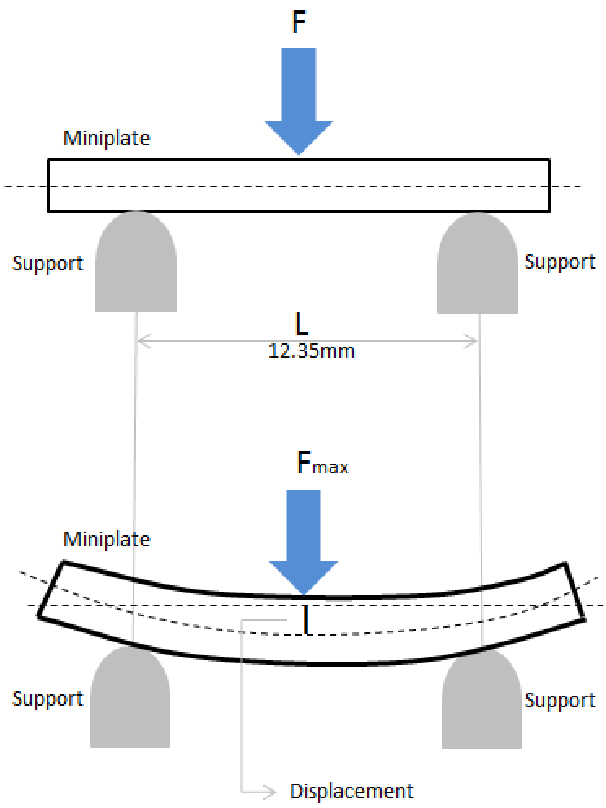


Figure 3. Schematic representation of bending test

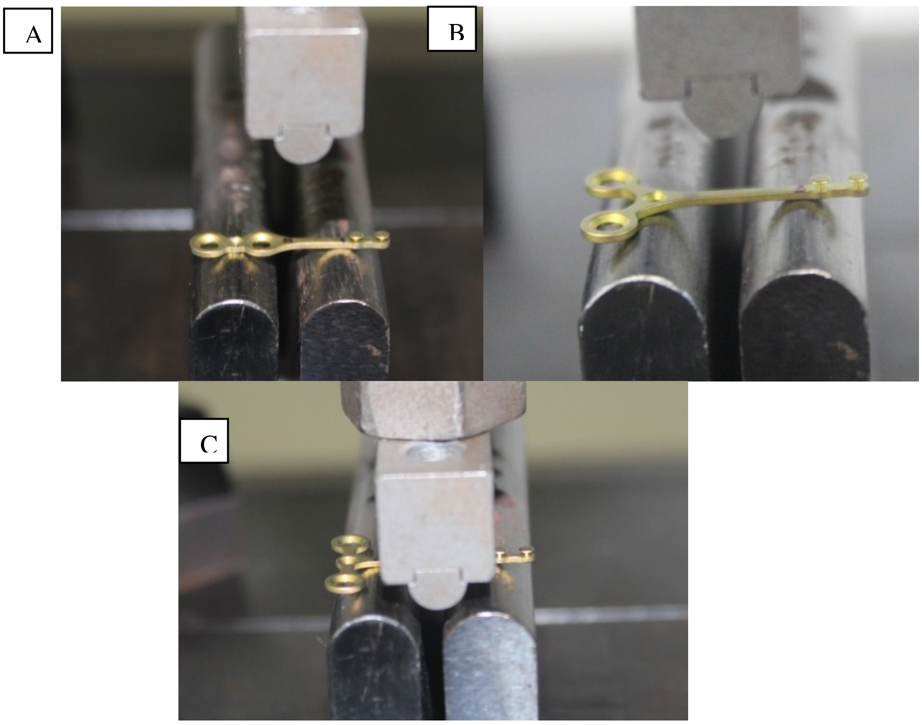


Figure 4. Miniplatespositioned in the testing machine. A) Straight miniplate. B) Y miniplate. C) Start of test in the T shaped miniplate

Statistical analysis was performed with the SSPS software package.

Normal distribution of data was determined by the Kolmogorov-Smirnov test. Significant statistical difference between mean values was found with a variances analysis 1-way ANOVA. When mean differences were found, to identify which types of miniplates differed among themselves the multiple comparison test of Tukey HSD and Games-Howell for homogenous and heterogeneous variances was respectively applied. By means of the Levene variances analysis was determined the homogeneity of the variables. The Pearsons coefficient was applied to detect correlations between the variables.

RESULTS

To perform the statistical analysis, variables such as: size sample, mean values, standard deviation and confidences interval were considered. (Table1)

The Kolmogorov-Smirnov test demonstrated normal distribution for all the variables measured for each miniplate design. The lower limit of real significance for this scale is 0.200. Normality of variables was informed by the value of $p > 0.05$.

A significant difference between the straight miniplates is noted regards yield load and stiffness variables when it is compared to miniplates Y and T. (Graphic 1) (Graphic 2) On the other hand, when considering the yield displacement and bending moment variables, no statistically significant difference was noted between the all shapes of miniplates tested. (Graphic 3) (Graphic 4)

The 1- way ANOVA parametric test demonstrated significant difference between the yield displacement and stiffness ($p>0.01$). For the other two variables the test did not show significant variance ($p>0.05$).

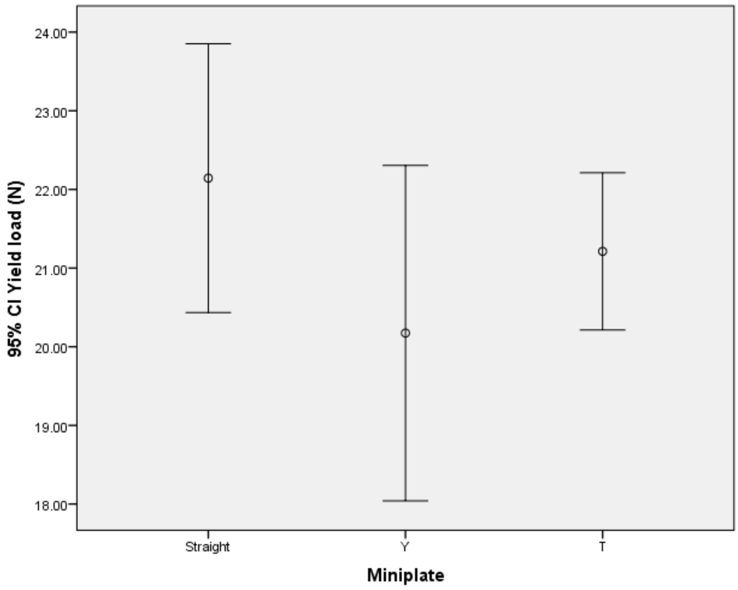
The Levene test of homogeneity of variances determined that the only heterogeneous variable was the yield displacement variable ($p<0.05$). Therefore when applied the Games-Howell test to the yield displacement variable the straight miniplate significantly differs from the Y and T body shapes miniplate ($p<0.05$). In the case of the variable of stiffness, the Tukey HSD for homogeneous variables demonstrated significant difference for the straight miniplates when compared to the Y and T body shaped miniplates ($p<0.05$).

The Pearson test, applied to determine proportionality between variables proved strong (0.9) and positive correlation between the yield loads and bending moment. In addition, a strong (0.9) but negative correlation was showed between stiffness and yield displacement.

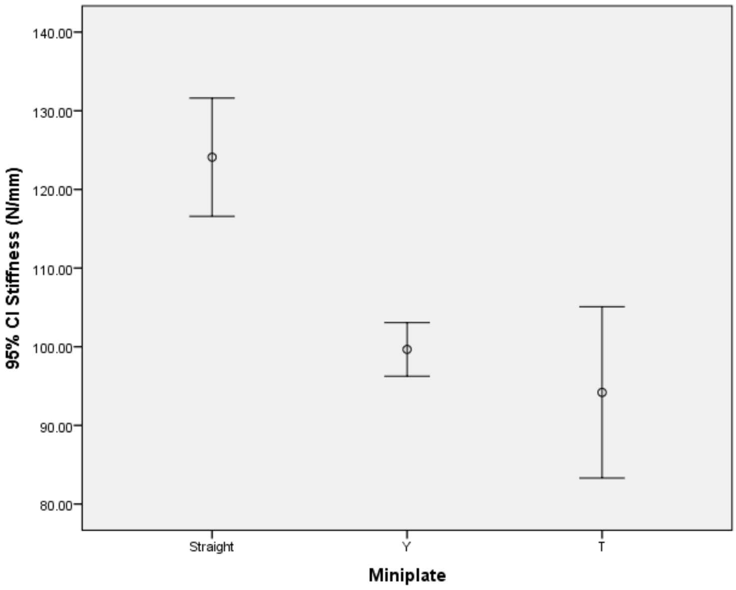
Table1. Descriptive statistics

		N	Mean	Standard deviation	95% confidence interval for mean	
					Lower Bound	**Upper Bound**
Yield load (N)	**Straight**	6	22.1430	1.6280	20.4345	23.8515
	Y	6	20.1734	2.0326	18.0403	22.3065
	T	6	21.2128	0.9521	20.2136	22.2119
Yielddisplacement (mm)	**Straight**	6	0.1921	0.0071	0.1846	0.1996
	Y	6	0.2175	0.0137	0.2032	0.2319
	T	6	0.2375	0.0218	0.2147	0.2604
Stiffness (N/mm)	**Straight**	6	124.0981	7.1561	116.5882	131.6080
	Y	6	99.6611	3.2441	96.2566	103.0656
	T	6	94.1870	10.3794	83.2945	105.0796
Bendingmoment (Nm)	**Straight**	6	0.0686	0.0049	0.0634	0.0737
	Y	6	0.0623	0.0063	0.0557	0.0689
	T	6	0.0655	0.0029	0.0624	0.0686

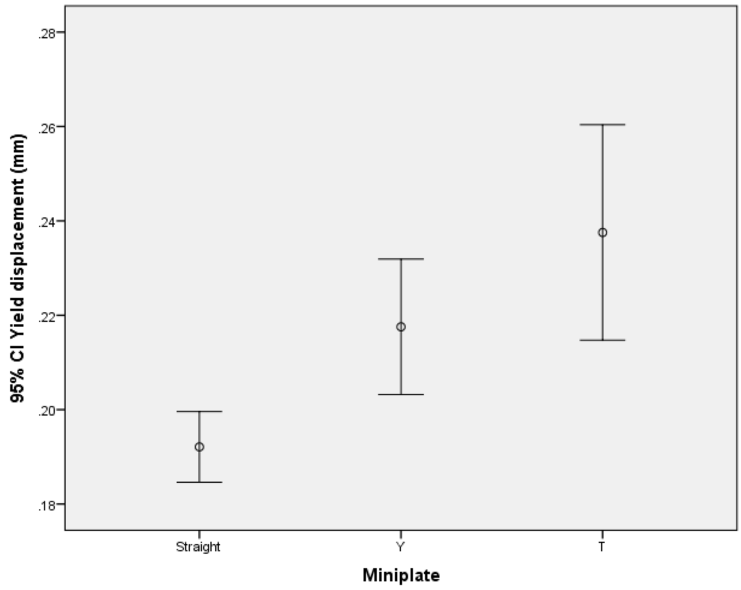
Graphic 1. Yield load results variation



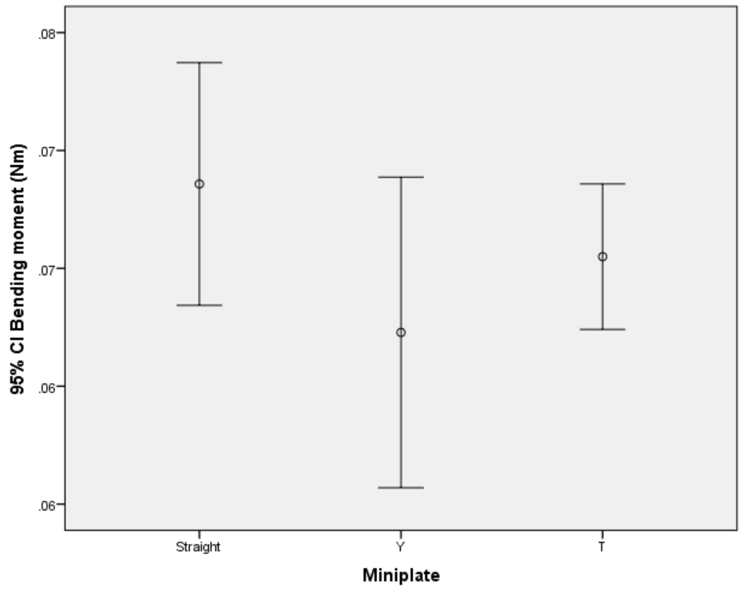
Graphic 2. Stiffness result variation



Graphic 3. Yield displacement result variation



Graphic 4. Bending moment results variation



DISCUSSION

A sophisticated new design for miniplates for orthodontic anchorage has been suggested in the present study. This new design proposes miniplates with compact and resistant structures, thinner arms and rounded and polished borders. This characteristics will provide healing improvements, avoid infection, facilitate hygiene, and beyond that, improve the use for orthodontist with bottoms at the head portion to suitably fit chain elastics.

Mechanical evaluation of the miniplates straight, Y and T NeoOrtho® for orthodontic anchorage demonstrated no differences statistically significant regards the loads supported by each miniplate design. Considering the yield displacement, the straight miniplate presented statistically significant lower values in relation to the miniplates Y and T. Consequently miniplates Y and T not presented differences between themselves. Stiffness presented a value statistically higher for the straight miniplate when compared to the other miniplates design. The miniplates Y and T did not demonstrated any significant difference. Measured values for bending moment did not demonstrated statistically significant differences between all three miniplates design tested.

The present study showed the existence of a high correlation between yield load and yield displacement. As well, a high but inverse proportionality between stiffness and displacement is noted. It can be interpreted that when the yield load increases there will be more displacement, and when the stiffness is increaed there will be less displacement.

Skeletal anchorage originates when orthodontists search for anchorage alternatives other than teeth to resolve difficult cases that require absolutely stable anchorage units.[10] The philosophy of skeletal anchorage supports that reactive forces are absorbed by skeletal structures neutralizing undesirable side effects in teeth.[17] Miniscrews and miniplates have proven to be efficient and suitable anchorage systems.[11,12]Although miniscrews are widely used because they can be easily placed and removed by the orthodontists, also have considerably small size and assessable cost it is known they may present clinical limitations.[17–19] When the orthodontic treatment requires complicated biomechanics and tooth movement conducts to the contact of tooth roots with the miniscrews, practitioners may consider the application of miniplates for anchorage.[20] Another known disadvantage of miniscrews is that its failure rates are higher when compared to miniplates.[21,13]

Miniplates for orthodontic skeletal anchorage were developed from miniplates applied for rigid internal fixation used on orthopedic surgery.[22]The greatest advantage of miniplates relies in their high success rates.[13]The heaviest forces that could be directed to miniplates will be for maxillary orthopedic treatments. Recent studies support the effectiveness of the use of miniplates and intra-oral elastics to correct Class III malocclusion in growing patients.[7,23]A systematic review focused in optimal forces for maxillary protraction with facemask concluded that the force magnitude may range between 180 to 800gr per side.[24] De Clerk et al.[25]applied Class III elastic that reproduced a force from 150 to 250g per side used 24 hours daily. Considering the amount of force stress in miniplates, mechanical studies emerged to confirm the biomechanics reliability of miniplates.[15,16]The present study states that all three miniplates designs are capable to resist greater forces that the ones that could be applied in orthopedic treatment.

The mechanical properties determine the greater or lesser ability of the material has to resist efforts applied.[26] The bending test is most commonly applied to determinate materials properties related to resistance. This capability is necessary not only during the manufacturing process, but also during use. It is very important to understand how materials respond to applied stresses and strains to avoid unexpected deflection, deformation, and failure.[27]

In the case of miniplates for orthodontic skeletal anchorage it is desirable to have a high level of resistance to deformation so miniplates will maintain its shape when stressed. In 2011, Trandem et al.[15]published a mechanical study of miniplatesand indicated three mechanical property values critical for defining the clinical usefulness of miniplates: modulus of elasticity, the load and maximum normal stress at the proportional limit. Considering the author suggestion, it was implied as an important characteristic of bending test that it could provide absolute values for the flexure limit of elasticity which is the maximum flexure tension that the material can support without deformation after load removal, the yield strength in flexure that represents the material border limit of elastic-plastic behavior, and the modulus of elasticity in flexure that is the relation between tension and deformation in elastic behavior.[27]

Over time titanium has been the material of choice for implants and surgical plates due to high biocompatibility properties.[28] The new designs of miniplates tested (NeoOrtho®, Curitiba, Brazil) were fabricated with grade 2 pure titanium alloy TI6A14V. Titanium presents a light weighted structure with high resistance to fracture and pull-out strength, which makes it the ideal material for fabrication of miniplates for skeletal anchorage.[29]When Trandem et al.[15]compared the deformation of miniplatesmade of titanium grade 2 and 4, both miniplates presented considerable high yield load and yielding strengths, demonstrating grade 2 titanium ability to support heavy forces as also demonstrated in this study. Loukota30 tested the bending strength of maxillofacial miniplates constructed of titanium. The authors concluded that the miniplates performed beyond the requirements for clinical situations when related to maximum masticatory forces when other studies have demonstrated a maximum masticatory force of with 4N to 6N in the molars region of young and healthy patients[.31,32]

CONCLUSIONS

- The straight miniplate presented statistically significant differences when it was compare to the Y and T miniplates in relation to stiffness and yield displacement.
- There was a high positive correlation among yield load, yield displacement and bending moment. On the other hand, there was a strong negative correlation between stiffness and yield displacement.
- All miniplates designs tested demonstrated adequate mechanical properties that resists orthodontic and orthopedic forces.

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FIGURE LEGENDS

- **Figure 1.** Miniplates design 23mm length. a)Straight miniplate b)Y miniplate c)T miniplate
- **Figure 2.** INSTRON 8872 Fatigue Testing System (Instron®, Norwood, Massachusetts, USA
- **Figure 3**. Schematic representation of bending test
- **Figure 4.**Miniplates located in the testing machine. A) Straight miniplate. B) Y miniplate. C) Start of test in the T shaped miniplate
- **Graphic 2**. Yield load results variation
- **Graphic 2**. Stiffness result variation
- **Graphic 3.** Yield displacement result variation
- **Graphic 4.** Bending moment results variation

5.2 Scientific article 2

This article was written following the standards of *American Journal of Orthodontics and Dentofacial Orthopedics- AJODO.*

Long-term Stability of Class III Malocclusion Treatment with Reverse-Pull Maxillary Protraction Appliances in Growing Patients: A Systematic Review and Meta-Analysis

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ABSTRACT

Introduction: Maxillary protraction with orthopedic forces is the treatment of choice for young patients with maxillary deficiency. However, considering the late growth of all craniofacial structures, the stability of this therapeutic approach remains uncertain. The aim of this systematic review was to analyze post-treatment long-term dentoskeletal changes to determine if stability is obtained with facemask therapy. **Methods:** Electronic database search included Cochrane, LILACS, PubMed, Scopus, Web of Science, and grey literature (Google Scholar and ProQuest Dissertations & Theses Global). Reference lists of the included articles were screened. The inclusion criteria were: clinical trials and cohort studies published in Latin alphabet, which analyzed the long-term treatment effects through lateral cephalograms. The methodological quality of the selected studies was evaluated with the Meta-Analysis of Statistics Assessment and Review Instrument (MAStARI). **Results:** **I**nitial search identified 604 studies, after critical evaluation and elimination of duplicates, only 17 met the inclusion criteria. Follow-up results of the selected studies demonstrated a 67-70% of stability success. A meta-analysis was conducted based on nine of the selected studies. In some studies, results revealed statistically significant differences in SNB and ANB, verifying mandibular growth and consequently a decrease in maxillomandibular discrepancies in the long-term. Furthermore, a statistically significant increase in the vestibular inclination of the superior incisors and a decrease in the mandibular plane angle were also demonstrated.**Conclusion:** Long-term stability of Class III malocclusion treatment in growing children exists due to skeletal changes achieved during active growth and dentoalveolar compensation made after the completion of craniofacial growth.

Keywords: Class III malocclusion; maxillary protraction; long-term stability; review.

INTRODUCTION

Malocclusions are deviations from ideal occlusion, and they are classified based on dentoalveolar and skeletal discrepancies. More specifically, a Class III malocclusion may present a retrusive/hypoplastic maxilla, a protrusive/hyperplastic mandible, or a combination of both associated with lower vertical disharmony of the facial thirds.[1, 2] The Class III malocclusion prevalence varies among and within populations. The Chinese, Malaysians, Turkish and Mexicans can be pointed out among the populations who have the highest prevalence rates (15.69%, 16.59%, 11.5% and 10.1%).[3-7]

Management for Class III malocclusions in growing patients has been one of the greatest challenges in orthodontics.[8-11] Its relationship with temporomandibular joint (TMJ) disorders and altered functions such as speech, breathing, occlusion, mastication, esthetics, and psychosocial factors suggest that Class III malocclusion may be the most harmful malocclusion type.[12]

It has been suggested that in a relatively short period of time, the spatial relationship of the midfacial bones can be changed by directing heavy forces through facial bones with extraoral appliances.[13,14]Therefore, orthopedic appliances that include a maxillary protraction component could be considered the therapy of choice for young patients presenting a Class III malocclusion.[10, 15-19]A previous systematic review and meta-analysis on the effectiveness of Class III malocclusion treatment with facemasks reviewed 3 articles of randomized clinical trials; a total data of 155 patients was collected. Authors concluded that facemask treatment of Class III malocclusions was effective in the short term, demonstrating statistically significant positive skeletal improvements.[20] In addition, one study[19] reported therapy of Class III malocclusions with a maxillary protraction appliance (facial mask, FM) plus rapid maxillary expansion (RME). RME seems to contribute to a more efficient protraction of the maxilla by disarticulating maxillary sutures while they are still patent.[9, 11]A 2011 publication of a systematic review focused on outcome predictions of orthodontic treatments for Class III malocclusions questions the possibility of accurate outcome predictions due to the high heterogeneity between studies. Out of 14 studies, 5 involved FM and RME in their treatment methods. [21] Several other studies have proven that maxillary growth rates during the post-protraction period are similar in treated and untreated Class III subjects.[9, 13, 22]

Since the stability of facemask therapy is not clear in literature, reports of success and retention remain uncertain until the subjects achieve maximum growth. Many patients receiving early orthopedic treatment may be treated again due to differential skeletal growth of the maxilla and mandible during pubertal growth spurt.[23] This means that despite the elimination of the reverse overjet and the achievement of an acceptable dental arch relationship, relapse may occur.Based on the above, the aim of this systematic review was to respond the following focused question: Is there post-treatment stability in Class III growing patients treated with maxillary protraction appliances?

METHODS

Reported following the Preferred Reporting items for Systematic Reviews and Meta-Analyses PRISMA Checklist.[24]

Protocol and registration

Systematic review protocol was registered at the International Prospective Register of Systematic Reviews-PROSPERO under number CRD 42015030211.

Eligibility criteria

Inclusion criteria

Clinical trials and cohort studies which evaluated long-term stability of orthodontic treatment in patients with Class III malocclusion and maxillary deficiency treated with maxillary protraction appliances were included. The malocclusion was diagnosed through lateral cephalometric analysis. Only studies in Latin (Roman) alphabet were considered.

Exclusion criteria

The following criteria were applied: 1-Studies in which treatment therapy included a chin cap orthopedic appliance; 2- Studies in which treatment therapy involved orthopedic treatment with mini-plates for bone anchorage; 3- Studies not published in Latin (Roman) alphabet; 4- Studies that did not provide long-term treatment results; 5- Studies that searched for predictors of treatment success; 6-Studies that did not apply cephalometric analysis for evaluation of post-treatment stability; and 7- Full paper copy not available.

Information sources and search strategy

Electronic search strategies were developed for each of the following databases: Cochrane (central), LILACS, PubMed, Scopus and Web of Science. Additional partial search of grey literature was performed accessing Google Scholar, by searching the first 60 most relevant hits, and ProQuest Dissertations & Theses Global database. Screening of the reference citations of identified studies was also performed. The final search date was February 15th, 2016.

Appropriate truncation and word combinations were selected and adapted for each database search (Appendix 1). Reference Manager™ software (EndNoteWeb-Thomson Reuters, Philadelphia, PA) organized the references and removed duplicated articles.

Study selection

In phase 1 of the selection process, article titles and abstracts from each electronic database search were independently screened by two reviewers (RRV, IAS). Articles that did not meet the inclusion criteria were excluded. In phase 2, the full texts of the articles screened in phase 1 were rigorously analyzed by the same two reviewers (RRV, IAS). The reference list of the selected studies was assessed to add articles that might have been missed. If there were disagreements between the two reviewers, a third reviewer (RHS) was consulted to make the final consensus decision. (Figure 1)

Data collection process

One author (RRV) gathered the required information from all included studies. The exactitude of the information was checked by a second author (IAS). The data collected consisted of: Study characteristics- author(s), year of publication, country, study design, and objective; Population- total sample, mean age, case and control group characteristics; Intervention- cephalometric analysis of patients with facemask orthodontic treatment; Outcomes- main results and conclusions.

Risk of bias in individual studies

The methodology of selected studies was evaluated using the Meta-Analysis of Statistics Assessment and Review Instrument (MAStARI) from the Joanna Briggs Institute(25). Two reviewers (RRV, IAS) scored each item with “yes”, “no”, “unclear”, or “not applicable”, and assessed the quality of each included study independently. (Table 2, concise assessment) (Appendix 2, detailed assessment)

Synthesis of results

A meta-analysis was planned within the studies presenting enough data in order to answer if there is long-term treatment stability in Class III growing patients treated with maxillary protraction appliances. The meta-analysis was performed with Review Manager Software 5.3.5 (Nordic Cochrane Center, Copenhagen, Denmark) for continuous data following the appropriate Cochrane guidelines. Inverse variance was the statistical method and mean difference was the effect measure. On analysis mode, fixed or random effect was based on heterogeneity values. Heterogeneity was calculated by inconsistency indexes (I^2), a value greater than 50% was considered an indicator of substantial heterogeneity between studies. The choice for random effect was preferred. Significance level was set at 5%.

Risk of bias across studies

Publication bias was not assessed following the recommendation of the Cochrane guidelines.

This systematic review included less than 10 selected studies; a reduced number of studies could lower the power of the test to distinguish real asymmetry through funnel plots.

RESULTS

Study selection

During the initial search (phase 1), 604 different citations were identified across electronic databases. After removing the duplicate articles, 380 articles remained.

An additional 38 references from Google Scholar and 17 from ProQuest Dissertation and Theses Global were considered. After reading 435 abstracts, only 28 full-text articles were evaluated. In phase 2, an additional search of reference lists was executed and 3 articles were added in order to be evaluated. These 31 articles were read in a full-text review and 14 were discarded (Appendix 2). Therefore, 17 articles were finally selected after critical evaluation. Figure 1 shows the identification process for the included studies.

Study characteristics

The 17 selected studies were conducted in Canada[26], China[10, 13, 27, 28], Italy[8, 11, 29], Japan[16], Korea[30], Turkey[18], and United States[9, 15, 31-34]. Facemask treatment stability was evaluated on the basis of angular cephalometric measurements and linear movements of landmarks (horizontal and vertical) at 3 time periods: T1 pre-treatment, T2 end of facemask therapy, T3 post-treatment, 1.5 to 8 years after treatment conclusion. Most of study´s intervention therapy involved RME/FM therapy, some only FM[30], or slow maxillary expansion (SME) with FM[32]. A summary of the study´s descriptive characteristics is shown in Table 1.

Risk of bias in individual studies

Three [9, 10, 29] studies were categorized with low risk of bias (RoB). This was mainly because the sample was truly representative of a population and confounding factors were identified and strategically handled. The other twelve studies[8, 11, 13, 15, 16, 18, 26-28, 30-32, 34]presented a moderate RoB and one[33] a high RoB.

Synthesis of results

After active treatment with a facemask, dentoskeletal changes revealed forward movement of the maxilla measured by an advancement in point A, an increase in the SNA angle [8-11, 13, 15, 16, 18, 26-34], an increase in lower facial height [8, 9, 18, 27, 28], mandibular growth inhibition, a decrease in points B and Pog, a decrease in the SNB angle [8, 10, 11, 15, 26, 28-30], an uprighted tendency of mandibular incisors [15, 27, 29, 32], improvement of Wits appraisal [11, 29, 33], proinclination of maxillary incisors[18, 28], improvement in molar relationships [18, 28, 29, 33, 34], and slight eruption of maxillary molars [9, 28].

Follow-up results demonstrated a slight continuous growth of the maxilla [8, 9, 11, 26, 28, 31, 33], an increase in lower facial height [8, 18, 26-28, 34], a decrease in ANB angle, and SNA stability [10, 11, 13, 16, 29, 30, 33].

A meta-analysis was conducted based on nine of the selected studies which performed evaluations of the post-treatment stage and follow-ups in Class III growing patients treated with maxillary protraction appliances. The cephalometric evaluations used were SNA, SNB, ANB, Wits appraisal, Gonial angle, Mandibular plane angle, Overbite, Overjet, U1-SN, and L1-MP.

The heterogeneity between the studies ranged from 0% for Wits appraisal ($p=0.71$) to 91% for Gonial angle ($p<0.001$), therefore a random model was chosen. The results from this meta-analysis revealed, in some studies, statistically significant differences in SNB and ANB, certifying mandibular growth and, consequently, a decrease in skeletal maxillomandibular discrepancies in the long term. A statistically significant decrease of the mandibular plane angle and an increase of the vestibular inclination of the superior incisors (U1-SN) were also demonstrated. We were also able to identify a decreasing overjet tendency through an increasing of the vestibular inclination of inferior incisors (L1-MP). Finally, when the occlusal plane was considered, there was a slight worsening of the maxillomandibular relationship (Wits). Thus, the long-term monitoring results of these 17 studies demonstrated a 60 to 70% success rate regarding the stability of these Class III malocclusion treatments with maxillary protraction.

DISCUSSION

The present systematic review attempted to analyze the long-term dental and skeletal stability after facemask orthopedic therapy in children with Class III malocclusions caused by maxillary deficiency.

Class III malocclusions result from a combination of anomalies of the facial skeleton and the dentoalveolar structures.[35] Maxillary deficiency is predominant in most cases of this type of malocclusion.[9, 36, 37] Findings in literature confirm a remarkable facial growth during puberty associated with a tendency to maintain the same facial pattern in adulthood. [8, 38-40] For that reason, delaying treatment can cause a progressive worsening of the deformities and intensify problems related to pain, TMJ disorders, speech, breathing, occlusion, masticatory function, esthetics, and even psychological factors. [12, 23, 41]

Many questions arise concerning the most efficient type of therapy to be executed and the adequate time for intervention. Early treatment is done with the purpose of reducing the need for treatment on permanent dentition, when camouflaging or orthognathic surgeries are the only remaining choices.[42]

Orthodontic literature is filled with studies demonstrating favorable skeletal changes achieved by orthopedic forces focused on improving facial asymmetry. Prime studies from Haas[43], Nanda[14], Delaire[35] and Hata[44] provide considerable evidence of the skeletal benefits of palatal expansion and maxillary protraction appliances to correct Class III malocclusions. In 2004, Franchi et al[45], stated that craniofacial changes are induced by early prepubertal orthopedic treatment. The treatment protocol of the studies included in this review involved a maxillary protraction appliance (facemask) combined with either rapid or slow maxillary expansion. All research demonstrated the facemask´s ability to displace the maxilla forward with protraction forces. [8, 10, 11, 15, 26, 29, 30] Authors justified the indication of maxillary expansion to disarticulate the maxillary sutures and allow for much greater maxillary advancement.[9, 13, 15, 34] On the contrary, Lee et al[30] indicated therapy with just a facemask appliance and explained that in cases with a sufficient transverse dimension of the maxilla an expansion is unnecessary.

Pre-treatment mean age of included studies ranged from 5 to 12 years approximately. Reed et al.[33], Masucci et al[29] and Westwood et al[11] even conducted a cervical vertebral maturation analysis during the pre-treatment period to identify the physiologic age, and during the follow-up period to confirm growth cessation.

Short-term cephalometric skeletal changes of all studies coincide in effective advancement of the maxilla, a counterclockwise rotation of the maxilla along with a clockwise or backward mandibular rotation.[13, 16, 18, 30-32] Cephalometric interpretation of these skeletal changes included an anterior movement of point-A, an increase in SNA and ANB angles, along with decreases in Co-Gn and SNB angle; a counterclockwise rotation of palatal plane, an increase in lower anterior facial height, and improvements in Wits appraisal. Some studies also evidence the facemask´s ability to control mandibular growth, which is considered a major factor for successful stability.[10, 29] Treated subjects from the study by Baccetti et al[8] presented favorable changes in the sagittal position of the mandible associated with a more forward and upward direction of condylar growth. Another study[15] agrees and explains that condylar growth could be a response to reciprocal forces from the chin cup component of the FM. In 2005, Ghiz et al[40]developed a formula that could determine the long-term success of orthopedic treatments of Class III malocclusions. This formula included important variables, such as the position of the condyle relative to the cranial base, the ramal length, the mandibular length, and the gonial angle. Masucciet al[29] described the closure of the gonial angle as a favorable growth modification to limit the increase of the mandibular body length, as the gonial angle represents the inclination of the mandibular ramus and the growth direction of the mandible.

In regards to dentoalveolar changes, Chong et al[15] reported a significant posterior movement of mandibular incisors, while Gallagher et al[32] described a flare tendency of the maxillary incisors and the uprighting of mandibular incisors. Furthermore, Ngan et al[9] over-corrected overjet from a -2.0 mean to 3.5mm, anticipating the differential growth of the jaws.

The maintenance of a positive overjet is the usual criteria to assess the success of long-term stability of Class III treatment. However, according to Chen et al[10] it only represents the correction of the dental relationships. A more accurate assessment of long-term stability success is determined by consensus of every variable affected by of the orthopedic therapy, including sagittal and vertical changes of the maxilla and mandible.

In one study[10],cephalometric measures of the stable group indicated that the position of the maxilla and the growth direction of the mandible remain almost unchanged or with a slight decrease in ANB at the follow-up period; on the other hand, a significant decrease in ANB combined with a more horizontal mandibular growth direction were considered unstable, although with a positive overjet. In accordance, other studies also reported not having significant improvement in the sagittal position of the maxilla.[13, 18, 29, 34]Deguchi et al[16] described SNA stability as indicative of Class III growth pattern predominance. Baccetti et al [8] defined relapse as the moment when growth modifications in treated subjects were more unfavorable than in the untreated group. According to that definition, Westwood et al[11] presented a study without significant evidence of cephalometric relapse after 5 years, although a phase with fixed appliances (FA) was included.

Furthermore, other authors [9], [26],[31] reported a slight continuous forward movement of the maxilla 2, 7, and 4 years after facemask removal. Due to the re-establishment of growth after orthopedic treatment, correction of the malocclusion really depends on the amount of beneficial changes obtained during active treatment.

Changes in the anterior-posterior position of the mandible were noted during the observational period with SNB angle and Co-Pg increases.[34] It was also noted that in treated groups the mandible showed significantly less forward growth when compared to untreated control groups.[8, 10, 15, 16, 27, 29]

Some of the studies divided the sample according to the dental developmental stage: primary dentition group and mixed dentition group. Findings demonstrated considerable favorable orthopedic effects for both groups, pointing out a greater anterior maxillary displacement for subjects treated in earlier dental stages.[8, 30, 31] Long-term dental changes were noted in both groups. In the early treatment groups (ETG), dental changes involved more protrusion of the maxillary teeth, while the late treatment groups (LTG) showed increments in the anterior-posterior position of the mandibular teeth. Baker et al[31] adds to the follow-up changes a slight significant maxillary relapse in ETG, but still maintaining a positive ANB angle, a positive overjet, and a class I Wits analysis.

Westwood et al[11] and Chen et al[10] agreed that a fixed appliance immediately after orthopedic treatment significantly benefits the long-term outcomes. Lee et al.[30]add that a FA can influence the skeletal morphology during the retention period.

Studies reported that in orthopedic Class III treatments with FM there is a high rate of long-term success with favorable results (67-70%).[11, 27-29, 46] There still is a potential risk of the need for orthognathic surgery later in life for one-third of the population due to unfavorable growth patterns.[27]

Masucci et al[29] expressed the importance of patient compliance, as 5 of the 22 patients had moderate compliance and unfavorable long-term results. In 1980 Nanda[14] also mentioned the relevance of patient cooperation because one of the most important force variables of an appliance is the duration of its wear, which is directly related to the amount of force delivered to the facial bones. Authors recognize that most of the long-term success could be determined by the amount of skeletal change gained during active treatment.

Limitations

When the literature was critically analyzed, the absence of randomization and blinding in the selected studies was noted.

Inequality among measures in the cephalometric analysis in included studies led to consider nine studies for meta-analysis.

Only three studies assured the cessation of growth during follow-ups by conducting a cervical bone maturation analysis.

CONCLUSION

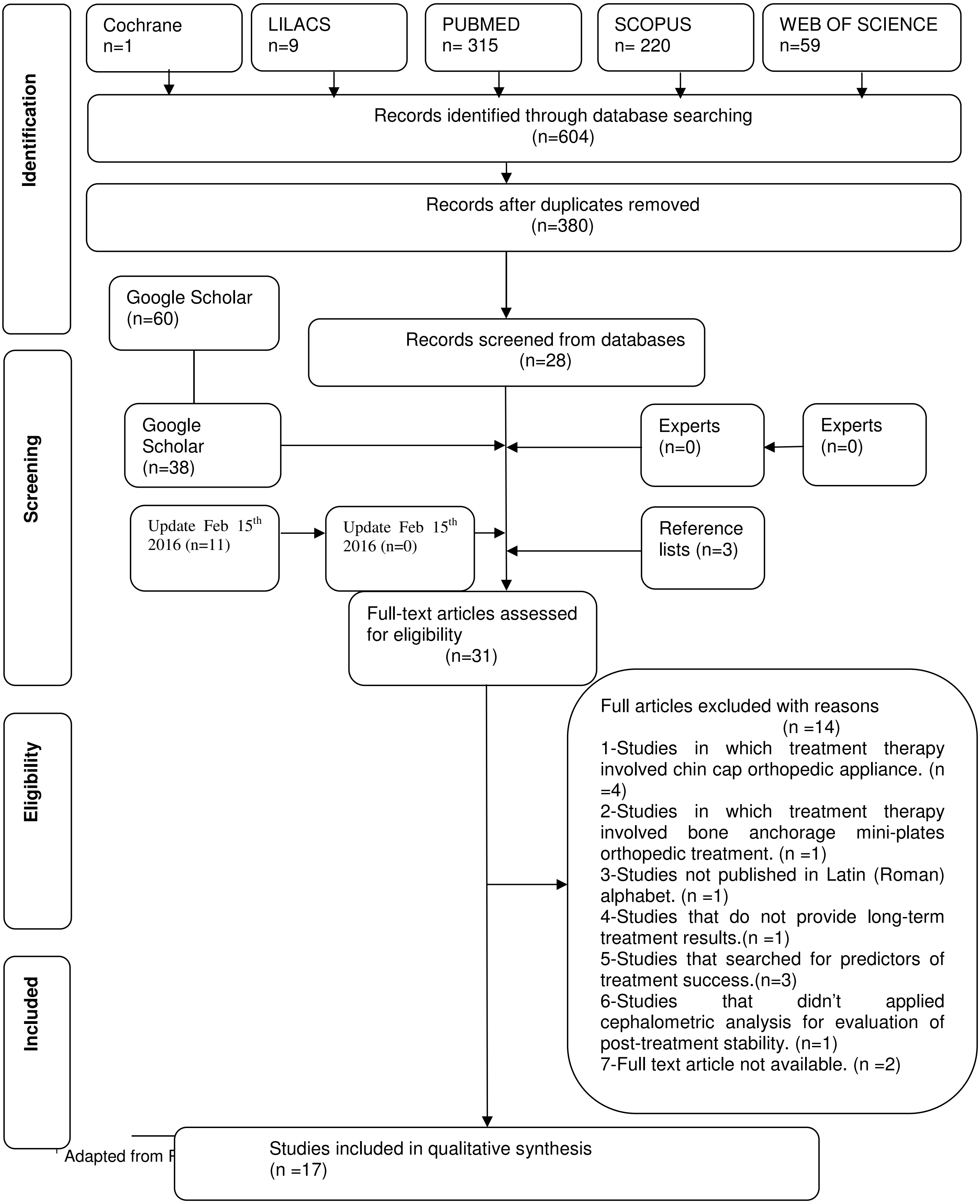
Based on the evidence, long-term stability of Class III malocclusion treatment in growing children exists mainly due to the skeletal changes achieved with treatment and dentoalveolar compensations made after craniofacial growth completion.

Implications for clinical practice

The results of this systematic review and meta-analysis demonstrate that clinicians may consider the treatment of Class III malocclusions with maxillary deficiency in young patients. Waiting for growth cessation will resign the patient to a disfiguring developmental period. The early treatment of Class III anterior crossbite with a slight amount of overcorrection may contribute to a more normal growth pattern.

It is the clinician´s responsibility to inform the patient's parents the therapy´s failure and success rates, considering that the Class III growth pattern may continue expressing itself even after treatment.

Figure. 1 - Flow Diagram of Literature Search and Selection Criteria.[1]



[1] Adapted from F

Appendix 1. Search strategies

Database	**Search** (February 15th, 2016)
LILACS	(tw:(maloclusãoclasse III)) AND (tw:(protrusãomaxilar))
PubMed Scopus Web of Science ProQuest	(child OR children OR adolescence OR adolescent OR adolescents OR teens OR teen OR youth OR youths OR teenager OR teenagers) AND (angle class iii” OR “angle class iii malocclusion” OR malocclusion OR underbite OR underbites) AND("maxillary protraction"[All Fields] OR "maxillary protraction appliance"[All Fields] OR "maxillary advancement"[All Fields] OR chincup[All Fields] OR "orthodontic treatment"[All Fields] OR "facemask" OR “face mask”)AND (Stability OR recurrence)
Cochrane	*"class III" and "maxillary protraction"*
Google Scholar	"class iii malocclusion" AND "maxillary protraction"

Appendix 2. Excluded articles and reasons for exclusion (n=14).

Author, year	**Reason for exclusion**
Baccetti et al 2004	5
Berg et al 1987	7
DeClerck et al 2010	2
Ferro et al 2003	1
Ghiz et al 2005	5
Gu Y et al 2010	7
Lim et al 2004	3
Moon et al 2005	1
Ngan et al 2000	6
Raberin et al 2007	7
Silva Filho et al 1998	4
Uslu et al 2009	1
Wells et al 2006	5
Yoshida et al 1999	1

1-Studies in which treatment therapy included chin cap orthopedic appliance; 2-Studies in which treatment therapy involves bone anchorage mini-plates orthopedic treatment; 3-Studies not published in Latin (Roman) alphabet; 4- Studies that does not provide long-term treatment results; 5-Studies that searched predictors of treatment long-term success; 6-Studies that did not applied cephalometric analysis for evaluation of post-treatment stability; 7-Full paper copy not available.

Appendix 3. Risk of bias assessed by Meta-Analysis of Statistics Assessment and Review Instrument (MAStARI)[1] critical appraisal tools. Risk of bias was categorized as **High** when the study reaches up to 49% score "yes", **Moderate** when the study reached 50% to 69% score "yes", and **Low** when the study reached more than 70% score "yes".

Questions	Answers																
	Baccetti et al. 2000	Baker et al. 2014	Chen et al. 2011	Chon et al. 1996	Deguchi et al. 1999	Gallagher et al. 1998	Hagg et al. 2003	Lee et al. 2010	Masucci et al. 2011	Nevzatogl uet	Ngan et al. 1997	Ngan et al. 1998	Pangrazio et al. 2007	Reed et al. 2011	Shanker et al. 1996	Westwood et al. 2003	William et al. 1997
1. Was the sample representative of patients in the population as a whole?	N	N	Y	N	N	N	N	Y	Y	N	N	Y	N	N	Y	N	N
2. Were the patients at a similar point in the course of their condition/illness?	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
3. Had bias been minimized in relation to selection of cases and of controls?	Y	N	Y	Y	Y	Y	N	N	Y	N	Y	Y	Y	N	Y	Y	N
4. Were confounding factors identified and strategies to deal with them stated?	NA	NA	NA	NA	NA	NA	NA	NA	NA	Y	NA	NA	NA	NA	NA	NA	NA
5. Were the outcomes assessed using objective criteria?	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
6. Was follow-up carried out over a sufficient time period?	N	Y	Y	N	Y	Y	Y	N	Y	Y	Y	Y	Y	N	N	Y	Y
7. Were the outcomes of people who withdrew described and included in the analysis?	N	N	Y	N	N	N	N	N	N	N	N	N	N	N	N	N	N
8. Were outcomes measured in a reliable way?	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
9. Was appropriate statistical analysis used?	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y

% yes/risk																	
	5.5% moderate	5.5% moderate	8.8% low	5.5% moderate	6.6% moderate	6.6 % moderate	5.5 % moderate	5.5 % moderate	7.7 % low	6.6 % moderate	6.6% moderate	7.7 % low	6.6 % moderate	4.4 % high	6.6 % moderate	5.5 % moderate	5.5% moderate

*Y=Yes, N=No, U=Unclear. NA=Not applicable

1 Meta Analysis of Statistics Assessment and Review Instrument (MAStARI). Joanna Briggs Institute Reviewers Manual. Australia: The Joanna Briggs Institute, 2014.

Table 1. Summary of descriptive characteristics of included articles (n=17).

Study characteristics			Population				Intervention		Outcome		
Author, year, country	**Study design**	**Objective**	**N total**	**Sample subjects**	**Mean age**	**Control group**	**Intervention**	**Follow up**	**Main results**		**Main conclusion**
									Post-facemask	Follow-up	
Baccetti et al. 2000 Italy	Cohort	Evaluate treatment and post-treatment changes induced by orthopedic therapy of Class III malocclusions by means of RME/FC in EMD and LMD	50	29 (15 female) EMD=16 LMD=13	ETG=7y LTG=8.8y	ECG2=11 LCG2=10	RME/FM	1y	ETG showed significant increments in maxillary sagittal growth at skeletal dentoalveolar level ($p<0.001$), midfacial length ($p<0.05$) and smaller increments in mandibular length and sagittal position ($p<0.001$) LTG showed increments in inclination of mandibular line ($p<0.01$)), nasal line ($p<0.01$) and lower ant. facial height ($p<0.05$)	ETG showed smaller increments in ant-post position of the maxilla, dentoalveolar maxillary protrusion, midfacial length and lower anterior facial height ($p<0.05$). LGT showed increments in ant-post position of mandibular base ($p<0.05$),and the mandibular dentition ($p<0.05$).	Both early and late orthopedic treatments of Class III malocclusion are able to restrain mandibular growth. There is significant increase in sagittal growth of the maxilla in early treatment, therefore may present more favorable craniofacial changes.
Baker et al. 2014 United States	Cohort	Determine the long-term stability of maxillary	40	ETG:23 LTG:17	ETG: 11.39Y LTG: 14.99Y	x	RME/FM	4.5y	ANB, PP-MP, X axis-A point, X axis- Menton, overjet and Wits	ETG showed differences in SN-MP and overjet ($p<0.05$)	Early treatment group showed more positive significant gains and was,

		protraction and Haas expander in two treated subject groups.							showed for both age groups statistically significant differences ($p<0.05$)	LTG showed difference in SN-OP ($p<0.05$). No significant differences were noted in both age groups in x axis-A point, x axis-Menton and overbite.	therefore, overall more effective. Both groups showed the Class III correction to be stable in retention.
Chen et al. 2012 China	Cohort	Evaluate the effect of RPHG in Class III malocclusion therapy in the late and early mixed dentition and its long-term stability at the time of facial growth completion	39	22 (10 female)	11.38y	17(10 female)	7, RME/FM 15 FM	3y	Forward movement of maxilla 3.93mm ($p<0.05$), increase SNA 2.25^0($p<0.001$), decrease in PP-SN -1.04^0 ($p<0.05$) indicating a maxillary counterclockwise rotation. Inhibition of mandibular growth indicated by a decrease in point B -0.52mm and pogonion -0.36mm ($p<0.001$), clockwise rotation of the mandible decrease in SNB	In SG six patients, the position of the maxilla and the position and growth direction of the mandible remained almost the same, apart for a slight decrease in ANB angle. In UG four patients, the maxilla became retrusive combined with protrusive mandible and horizontal mandibular growth direction resulting in significant decrease of ANB angle	Reliable skeletal effects can be achieved by starting RPHG treatment just before or at the beginning of pubertal growth spurt. SNB angle changes are associated to mandibular post-pubertal growth pattern

									- 1.18^0 (p< 0.001). Increase in ANB +3.42^0 (p<0.001). Significant forward movement of the max. incisors +7.09mm (p<0.01)		
Chong et al. 1996 United States	Cohort	Evaluate treatment effects and post-treatment changes following a short intervention with RPHG for early correction of Class III malocclusion.	29	16 (8 female)	6.5y	13 (5 female)	RPHG Delaire facemask	1y	Significant changes in ANB and overjet (p<0.0024), increase in SNA and decrease in SNB angles (p<0.0024). Significant posterior movement of mandibular incisor (p<0.0038)	There were no different changes in position of the maxilla or mandible. Increased anterior movement of mandibular incisors and reduction in overjet (p<0.05)	Maxillary protraction headgear conducted to significant skeletal and dentoalveolar changes. Overcorrection of de overjet during treatment may be important for maintaining stability
Deguchi et al. 1999 Japan	Cohort	Examine the effects of very early facemask treatment therapy and post-treatment in children with Class III malocclusion	62	40 female	4.2y	22	FM	4.1y	Increase ANB (p<0.01) and FMA (p<0.05) vertical changes in ANS, A-point -4.9mm and -4.1mm respectively. Increase in IMPA (p<0.05)	Significant smaller increase difference in facial angle (P<0.05) and ANB angle from treatment group. FMA increased in treated group (30^0) (p<0.05).	The FM therapy resulted in more advancement of the maxilla and backward rotation of the mandible. Mandible showed significant less forward movement.

Gallagher et al. 1996 United States	Cohort	Evaluate the treatment response and post-treatment follow-up of children with Class III malocclusion	44	22 (13 female)	9.8y	22	SME/FM	1.5y	Significant increase in SNA, ANB, AB/OP and NA-Pg ($p<0.05$). Individual landmark on the maxilla showed an anterior and inf-post displacement of the maxilla. Dental measurements showed an uprighted tendency for mandibular incisors	Significant decrease of ANB, NA-Pg and AB/OP due to increase in SNB. Mandibular plane decrease indicating mandibular forward rotation..	The maxilla showed a relative relapse. Mandible followed a normal downward and forward growth pattern
Hagg et al. 2003 China	Cohort	Investigate the long-term outcome of treatment with reverse headgear in young individuals with reverse overjet and a skeletal Class III malocclusion.	21	21 (17 female)	8.4y	x	RME/FM	8y	Significant increase in overjet, molar relationship improvement, forward movement of the maxilla and maxillary incisors, mandibular retrusion and uprighted mandibular incisors. Increase lower face height ($p<0.08$), increase mandibular plane angle ($p<0.05$)	Less reduction in overjet ($p<0.005$), less change in jaw base ($p<0.01$) and molar relationship ($p<0.05$). The maxilla came more forward. Significant increase in lower face height with eruption of molars and incisors.	Early treatment of maxillary deficiency with reverse headgear resulted in positive overjet in all patients, but at long-term follow-up the positive overjet was maintained only by two out of three patients.

Lee et al. 2010 Korea	Cohort	Determine potential differences in treatment efficiencies of facemask without RME at different early dental stages	49	49 (32 female) PD: 26 (18 female) MD:23 (14 female)	PD:6y MD: 8.4y	x	Delaire facemask	1.5y	Ant-post skeletal discrepancies were greatly improved. Significant difference between PG and MG, decrease in SNB and facial plane angles, while an increase in SNA, ANB, SN-GoGn and mandibular plane angles ($p<0.01$)	ANB angle showed differences from both groups ($p<0.05$), but no significant difference in skeletal changes was noted.	There is a more effective response to orthopedic treatment in the primary dentition but also a higher relapse tendency.
Masucci et al. 2011 Italy	Cohort	Analyze the long term outcomes of RME/FM therapy in Class III subjects.	38	22 (13 female)	9.2y	16	RME/FM	8.5y	Maxillary advancement (Point A-Nperp1.4mm)($p< 0.05$), decrements in the sagittal position of the mandible (Co-Gn, -4.2mm; SNB, -1.6^0; Pog-Nperp, -2.8mm), ($p<0.05$). Improvements in the sagittal max-mand skeletal variables (Wits, 3.9mm; max/mand differential, -5.2mm, ANB, 2.1^0), ($p<0.01$) as well as improvements in overjet and molar	Decrement in sagittal position of the mandible (SNB, -2.0^0), ($p<0.05$). Maintained improvement in max-mand skeletal variables (Wits, 3.0mm; max/mand differential, -3.7mm; ANB, 1.4^0),($p<0.05$). Molar Relationship improvement 3.2mm ($p<0.001$).	In the long-term RME/FC therapy of Class III malocclusion patients still showed significant improved sagittal dentoskeletal relationships.

									relationship, (p<0.01). Reduce proinclination of maxillary incisors (P<0.05)		
Nevzatoglu et al. 2014 Turkey	Cohort	Evaluate short- and long- term treatment results of RME and surgery assistance during maxillary protraction with FM	28	RME/FM: 17 (8 female) S/FM: 11 (8 female)	RME/FM: 11.26y S/FM:12.54y	x	RME/FM Lefort 1/FM	6y	RMEG showed significant maxillary protraction and proinclination of the upper and lower incisors, SNA, Nperp-A, R2-A, R2-ANS (p>0.05)	Significant decreases in SN-MP and SN-UOP, mandibular growth and superior incisor proinclination	In the long-term, these sagittal changes were not stable, whereas RME/FM provided stability.
Ngan et al. 1997 China	Cohort	Summarize the short-term and long-term results on the treatment of Class III malocclusion using the protraction facemask	x	20	8.2y	CG no #	RME/FM	2y and 4y	Positive overjet average change of 6.1mm, forward movement of the max.(1.9mm) and backward rotation of the mandibular (1.3mm). Overcorrection of molar relationship to Class II or I avg. 3.8mm, (p<0.05). Decrease overbite by 1.8mm, significant increase in lower facial height	The maxilla continued to move forward. The mandible outgrew the maxilla in horizontal direction by 2.8mm, however overjet change was only of 0.6mm. Maxillary and mandibular molar continued to erupt and occlusal plane angle continued to flatten with	The treatment was found to be stable after 2 years. Overcorrection of overjet and molar relationship is recommended to anticipate subsequent horizontal mandibular growth. Treatment with facemask is most effective in Class III patients with retrusive maxilla and a hypodivergentgrowt

									(2.8mm), counterclockwise rotation of the palatal plane, inferior movement of PNS (1.0^0). Increase eruption of maxillary molars (1.5mm), open mandibular. angle 1.3^0	respect to SN. Overbite change avg. 0.4mm.	h pattern.
Ngan et al. 1998 United States	Cohort	Evaluate quantitatively: on lateral cephalometric radiographs, the skeletal and dental changes during treatment and 2 years after completion.	x	22 (12 female)	8.4y	CG no #	RME/FM	2y	Avg. overjet correction was 5.5mm ($p<0.001$), molar relationship improvement to Class I of 3.9mm ($p<0.001$). Vertical changes involved increase in lower face height ($p<0.05$) and maxillary and mandibular molar eruption ($p<0.05$). Decrease in overbite ($P<0.05$)	Maxilla moved forward 4.8mm and mandible 5.2mm. Maxillary incisor tipped labially 4.1mm and mandibular incisor tipped lingually 0.9mm. The palatal plane angle showed a clockwise rotation ($p<0.05$).	The results supported early treatment of Class III patients with maxillary protrusion. Overjet was maintained in the majority of the treated patients and the majority of the patient had not reached pubertal growth spurt therefore orthognathic intervention remains to be determined.
Pangrazio-Kulbersh et al. 2007 Canada	Cohort	Compare the effects and long-term stability of protraction facemask treatment with a	x	FMG:17 (9 female)	8.7y	CG no #	RME/FM	7.3y	A-point significantly farther forward $p<0.04$. The SNB decreased $p<0.001$. The maxillary incisors	Forward A-point $p<0.04$. SNB $p<0.01$. IMPA showed flared mandibular incisors $p<0.001$. Increase in ANB	Early treatment with orthopedic forces to advance the maxilla might reduce altogether the need for a surgical

		group control. To compare long-term stability of early FM treatment with later surgical maxillary advancement and determine effectiveness of both treatments approaches.							were uprighted. Greater lower anterior facial height p<0.008.	and Wits appraisal p<0.0001	intervention later.
Reed et al. 2011 United States	Cohort	Determine the immediate and long-term skeletal and dental effects using Dr. Kiebach's modified hyrax expander and facemask therapy in early and late mixed dentition	x	23	6.2y	x	Kiebach appliance/FM	2y	Improvement in overjet and sagittal molar relationship and a decrease in overbite. Statistically significant changes in SNB, ANB, Is/SNL, li/ML (p<0.05). This showed changes in mandibular prominence, incisors angulation.	ANB decrease of 1.17º showing skeletal relapse (p<0.05) Maxilla and mandible continue to move forward by 1.5mm and 3.7mm respectively. Decrease in overjet correction by 0.3mm. Decrease in molar correction by 0.2mm. Wits decrease by 1.4mm. Change in SNL-ML, Is/SNL, li/ML and Is/li (p<0.05) shows that the incisors and mandibular plane changed	Overall, the net overjet corrections observed at T2 were 46% skeletal and 54% dental, comparing it to T3 skeletal contribution was -5% and 105% dental. This shows that over time class III growth pattern remained and the skeletal corrections achieved were masked over time. The same is true for the net molar correction. The net change (T3-T1) shows the maxilla moved forward 4.2 mm and the mandible 4.2mm, labial tipping of

										angulation significantly.	superior incisor of 2.9mm and lingual tipping of inferior incisors of 1.1mm.
Shanker et al. 1996 China	Cohort	Analyze the treatment and post-treatment maxillary changes achieved with maxillary protraction therapy.	50	25 (16 female)	8.4y	25	RME/FM	1y	Significant greater forward ($p<0.001$) and less downward ($p<0.05$) movement of the A point	A point was found to remodel backward and downward	During the 1y post-treatment follow-up no relapse of maxillary changes was noted and the estimated maxillary changes resembled those of the control group.
Westwood et al. 2003 Italy	Cohort	Evaluate post-treatment outcomes of skeletal and dentoalveolarm odification induce by RME/FM in Class III patients.	56	34 (20 female)	8.3y	T1-T3 22 (13 female)	RME/FM	5y	Statistical analysis showed a significant difference ($p<0.01$) between the means of TG and CG. Significant increase in midfacial length Co-PtA, and maxilla sagittal position SNA, PtA-Nperp ($p<0.001$). Decrease in mandibular projection SNB, Pog-Nperp ($p<0.001$). Improvement in	Increases in sagittal position of Point A (1.2mm), SNB angle (-2.6^0,$p<0.001$), sagittal position of Pog (-3.0mm), Wits (6.1mm), closure of ANB angle (2.9^0), max/mand differential (-4.1mm, $p<0.01$), overjet (4.4mm).Decreases in molar relationship (-3.9mm) and point A-Pog ($p<0.001$).	Favorable skeletal change observed over long-term is due almost entirely to orthopedic correction achieved in RME/FC therapy. Establishment of a positive overbite and overjet is essential to long-term stability treatment outcomes.

									intermaxillary relationship Wits, ANB and max/mad difference ($p<0.001$).		
Williams et al. 1997 United States	Cohort	Evaluate not only the short-term treatment effects but also the long-term changes of RME/FM therapy commenced in mixed dentition patients with developing Class III malocclusions.	28	28 (17 female)	8.3y	x	RME/FM	2.5y	PtA moved anteriorly 1.54mm; SNA increased by 0.87^{0}; maxillary incisor moved anteriorly average 1.15mm, ($p<0.05$); class I molar correction and positive overjet ($p<0.05$). Mandibular plane angle increment by 1.0^{0}; ANB increase mean of 1.39^{0}. Increase in lower anterior facial height.	Overjet remained positive, maxillary molar moved anteriorly 2.87mm, SNB angle increase 1.02^{0}. Mandibular length increase 4.92mm, mandibular plane angle decrease 1.48^{0}, mandibular Incisor and molar moved superiorly 1.44mm and 1.83mm, ANB angle decrease 0.91^{0}, lower anterior facial height increase 1.68mm.	The effects of maxillary protraction appear to be stable. The return to a Class III pattern was primarily because of mandibular growth rather than relapse of treatment directed at the maxilla.

Table 2. Risk of bias summarized assessment

Author, year	Risk of bias
Baccetti et al. 2000	Moderate
Baker et al. 2014	Moderate
Chen et al. 2011	Low
Chon et al. 1996	Moderate
Deguchi et al. 1999	Moderate
Gallagher et al. 1998	Moderate
Hagg et al. 2003	Moderate
Lee et al. 2010	Moderate
Masucci et al. 2011	Low
Nevzatoglu et al. 2014	Moderate
Ngan et al. 1997	Moderate
Ngan et al. 1998	Low
Pangrazio-Kulbersh et al. 2007	Moderate
Reed et al. 2011	High
Shanker et al. 1996	Moderate
Westwood et al. 2003	Moderate
William et al. 1997	Moderate

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FIGURE LEGENDS

Figure 1.PRISMA flow diagram of literature search and selection criteria.

Figure 2.Meta-Analysis results.

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7 Anexos

7.1 Normas para elaboração do artigo cientifico 1:

http://www.scielo.br/revistas/bor/iinstruc.htm

7.2 Normas para elaboração do artigo cientifico 2:

https://www.elsevier.com/journals/american-journal-of-orthodontics-and-dentofacial-orthopedics/0889-5406?generatepdf=true