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Comparative Analysis of Bone vs. Tooth Anchored Maxillary Protraction in Cleft Lip and Palate Patients—A Systematic Review and Meta-Analysis

Vaibhav Gandhi[1] | Amine Fattal[2] | Gina Genova[3] | Sumit Yadav[1] | Nandakumar Janakiraman[4]

[1]Department of Growth and Development, University of Nebraska Medical Center, Lincoln, Nebraska, USA | [2]Private Practice, Elkhart, Indiana, USA | [3]University of Louisville, Louisville, Kentucky, USA | [4]Georgia School of Orthodontics, Atlanta, Georgia, USA

Correspondence: Vaibhav Gandhi (drvaibhavgandhi88@gmail.com)

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ABSTRACT

Management of class III malocclusion in patients with cleft is geared toward improving the maxillary position with maxillary protraction therapy with or without bone anchorage. This study aims at evaluating the effects of bone-anchored maxillary protraction (BAMP) and tooth-anchored maxillary protraction (TAMP) appliances in patients with cleft lip and palate (CLP). A search of PubMed MEDLINE, Embase, Cochrane Central Register of Controlled Trials, Web of Science, ProQuest Dissertations and Theses Global, and ClinicalTrials.gov registry was performed. Prospective studies that evaluated the effect of BAMP and/or TAMP therapy in patients with CLP were screened. A meta-analysis was performed for the cephalometric parameters evaluating sagittal (SNA, SNB, ANB and Wits appraisal), vertical (mandibular plane angle), and dentoalveolar (U1 to PP, IMPA, overjet and overbite) effects following the BAMP or TAMP. Database research, elimination of duplicate studies, data extraction and risk of bias (RoB) assessment were performed by authors independently and in duplication. A random-effect meta-analysis was performed to evaluate the sagittal, vertical and dentoalveolar effects. BAMP increased SNA angle by 1.76 degrees (95% CI: 1.03 to 2.49), ANB angle by 2.08 (95% CI: 0.99 to 3.18), Wits appraisal by 2.17 mm (95% CI: 1.05 to 3.28), and overjet reduction by 2.03 mm (95% CI: 0.98 to 3.08). TAMP increased SNA by 2.56° (95% CI: 1.58 to 3.54), ANB angle by 4.40° (95% CI: 3.61 to 5.18), Wits appraisal by 5.53 mm (95% CI: 4.27 to 6.79). However, TAMP decreased SNB by 2.00° (95% CI: −2.61 to −1.39) and increased mandibular plane angle by 2.75 (95% CI: 1.73, 3.76). Sagittal correction is expected with BAMP and TAMP therapy in children with CLP. However, pronounced vertical or dentoalveolar side effects are expected with TAMP compared to BAMP therapy.

Trial Registration: This systematic review was based on the Cochrane Handbook for Systematic Reviews of Interventions 5.1.0, was registered at the PROSPERO database (CRD42021247529), and reported according to the PRISMA statement.

1 | Introduction

Cleft lip/Palate (CLP) is the second most common congenital defect in the United States, trailing only Down syndrome [1]. Prevalence of CLP is between 1:1600 and 1:2800, and 1:1700 of newborns in the United States [2]. Most patients with a complete CLP exhibit an unfavourable growth pattern of the craniofacial complex. A concave profile, midface deficiency and a Class III skeletal pattern are common clinical presentations of children with CLP. The maxilla may also be deficient in transverse and vertical planes, contributing to posterior skeletal crossbite and reduced midface height [3].

Reverse pull facemask (FM) therapy or tooth anchored maxillary protraction therapy (TAMP) with or without maxillary expansion was the treatment of choice to correct maxillary deficiency

in growing patients. In children with CLP, TAMP showed positive results in the correction of midface deficiency. FM (TAMP) therapy showed favourable results in improving sagittal skeletal relationships in patients with unilateral cleft lip and palate (UCLP) by increasing the SNA and ANB angles [4]. However, lack of compliance and discomfort are a few drawbacks associated with conventional FM (TAMP) therapy. Also, a minimum of 14 h per day is recommended to achieve maximum orthopaedic correction [5, 6]. Due to aesthetic concerns, it is challenging to convince school-going children to comply with the suggested protocol. In addition, FM (TAMP) therapy increases the vertical dimension by counter-clockwise rotation of the maxilla and clockwise rotation of mandible [7, 8]. All these side effects compromise the predictability of the outcome with conventional FM (TAMP) therapy.

Alternatively, skeletal anchorage was proposed to correct the underlying skeletal discrepancy in patients with CLP. Bone-anchored maxillary protraction (BAMP) relies on intraoral intermaxillary elastics as opposed to the conventional FM therapy, where patients need to wear an extraoral appliance for force application; thus, BAMP stands out better in terms of aesthetics and ultimately compliance over FM therapy. BAMP therapy has the added advantage of transferring the force directly to the zygomaticomaxillary complex, leading to maximum orthopaedic correction with minimal or no dentoalveolar effects [9]. Additional advantages of BAMP over FM are the continuous light forces used rather than heavy intermittent forces [10].

2 | Objectives

The objective is to evaluate the skeletal and dentoalveolar effects of bone-anchored and tooth-anchored maxillary protraction appliances in patients with CLP.

3 | Materials and Methods

3.1 | Protocol and Registration

Institutional review board submission and approval were not required for this study. This systematic review protocol was registered with PROSPERO (CRD42021247529). The present systematic review is conducted according to the guidelines of the Cochrane Handbook for Systematic Reviews of Interventions version 5.1.0 [11] and it is reported according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement [12].

3.2 | Eligibility Criteria

The criteria for considering studies for this review (PICOS) were the following: (1) Participants: patients with unilateral or bilateral cleft lip and palate undergoing orthodontic therapy; (2) Intervention: bone-anchored or tooth-anchored maxillary protraction appliance; (3) Comparison: untreated cleft lip and palate or noncleft lip and palate patients; (4) Outcome: skeletal and dental cephalometric parameters; (5) Study design: randomised or non-randomised clinical trials (RCTs), prospective cohort studies.

3.3 | Exclusion Criteria

Exclusion criteria were meta-analysis or systematic reviews; retrospective studies; animal studies; review articles; abstracts; letters from the editor; opinion articles; case reports; case series; and studies with syndromic patients who had CLP.

3.4 | Information Sources and Search Strategy

The health sciences librarian (GG) used sentinel articles to harvest and test search terms; the following search strategy was developed for PubMed/MEDLINE, Embase and Web of Science to retrieve all records using natural language and controlled vocabulary (when available) relating to the concepts of maxillary protraction therapy in CLP patients. We seek in-progress and unpublished studies on the Cochrane Central Register of Controlled Trials (CENTRAL) and ClinicalTrials.gov, as well as dissertations from ProQuest Dissertations and Theses Global. Additionally, we investigated the references of included studies. There were no language or publication date restrictions. The searches were updated before final analysis, and any additional identified studies were retrieved for inclusion. The search strategy was as follows:

('Cleft Lip/surgery'[Mesh] OR 'Cleft Lip/therapy'[Mesh] OR 'Cleft Palate/surgery'[Mesh] OR 'Cleft Palate/therapy'[Mesh] OR 'Malocclusion, Angle Class III/therapy'[Mesh] OR 'cleft lip' OR 'cleft palate') AND ('Orthodontic Anchorage Procedures'[Mesh] OR 'Alveolar Bone Grafting'[Mesh] OR 'Palatal Expansion Technique'[Mesh] OR bone-anchored OR 'bone-anchored maxillary protraction' OR 'maxillary protraction' OR 'maxillary protraction therapy' OR 'maxillofacial protraction' OR 'orthodontic anchorage procedures' OR 'skeletal anchorage procedures' OR 'orthodontic anchorage techniques' OR 'alveolar bone grafting' OR 'palatal expansion technique') AND ('dentoskeletal effects' OR 'maxillary protraction' OR 'maxillofacial protraction' OR 'skeletal effects' OR 'skeletal movement').

This strategy was translated and adapted for other databases. The following databases were searched from the date of inception through July 31, 2024: PubMed MEDLINE (including Pre-MEDLINE and non-MEDLINE; 1945–July 2024), Scopus (Elsevier; 1966–July 2024), Cochrane Central Register of Controlled Trials (Wiley; through July 2024), Web of Science (BIOSIS, MEDLINE, Zoological Record; Clarivate Analytics; 1900–July 2024), and Dissertations & Theses Global (ProQuest; 1637–July 2024). The ClinicalTrials.gov registry was searched on July 31, 2024, as well. No filters were used for language, publication date, or methodology. Additional records were found by references of all full-text records that were selected for study inclusion. EndNote 20 was used to de-duplicate and manage all citations.

3.5 | Study Selection

The titles and the abstracts of all records were reviewed and assessed for inclusion by two authors (VG/AF) independently. They were not blinded to the identity of the authors, their institution, or the research results.

Subsequently, they obtained and assessed, again independently, the full report of records considered by either reviewer to meet the inclusion criteria. Disagreements were resolved by discussion or consultation with another author (NJ). Inclusion criteria were randomised or non-randomised clinical trials and prospective cohort studies only. We included studies investigating the effects of bone-anchored or tooth-anchored maxillary protraction therapy on cleft lip and palate patients.

3.6 | Data Items and Collection Form

A customised data collection form was created and used to gather information from the selected studies. This information included authors, year of publication, type of studies, details of the interventions, characteristics of participants, duration of treatment and outcome measures. The data extraction was performed by authors (VG/AF) independently and in duplication. An attempt to contact the authors was made for any missing information. In case of disagreement, a third reviewer (NJ) was contacted to provide an independent decision on the conflict.

3.7 | Risk of Bias and Quality Assessment of Individual Studies

After imposing exclusion and inclusion criteria, no randomised controlled trial addressing our PICO question was found. To ascertain the validity of eligible non-randomised studies and prospective cohort studies, pairs of reviewers (VG/AF) worked independently and with adequate reliability to assess the risk of bias using the Risk of Bias In Non-randomised Studies of Interventions (ROBINS-I) tool [13]. The consensus was reached by the two reviewers (VG/AF) when there was a difference in opinion on an item. If no consensus was reached, the independent opinion of a third reviewer was decisive (NJ).

3.8 | Summary Measures, Approach to Synthesis and Planned Methods of Analysis

The skeletal and dentoalveolar changes in patients with CLP following BAMP or TAMP therapy were the primary outcome measures. The data were grouped according to the type of intervention into two broad categories: BAMP or TAMP group against untreated cleft lip and palate control group. Most of the studies evaluated cephalometric parameters such as SNA, SNB, ANB, Wits, mandibular plane angle, U1 to PP, IMPA, overjet and overbite, and were selected for meta-analysis. First, pre-treatment and post-treatment changes in cephalometric measurements were considered, assessing the mean difference and standard deviation (SD) within the group. Thereafter, the mean difference between treated patients and untreated controls for each measurement was used for the meta-analysis.

I^2 and Q statistics evaluated the heterogeneity among studies in each subgroup. The between-group comparison was conducted in a mixed-effects meta-regression model assuming a random study effect of intervention type (Bone-anchored maxillary protraction group and untreated control group) and (Tooth-anchored maxillary protraction group and untreated control group). We used RevMan 5.4 to conduct meta-analysis and generate forest plots. A p-value less than 0.05 was deemed to be statistically significant.

Furthermore, the combined effect size of BAMP and TAMP was calculated for each cephalometric parameter using the effect size and standard error (random effect model). Comparison between BAMP and TAMP was conducted for each individual parameter using the combined effect size.

4 | Results

4.1 | Study Selection

The results of the literature search, identification, inclusion and exclusion of the articles are presented in the flow diagram according to the PRISMA statement (Figure S1). Four studies used conventional facemask therapy, two studies were about finite element analysis, three studies had a retrospective design, two were case reports, one study was regarding the secondary bone graft acceptance without maxillary protraction, and one non-randomised prospective study protocol only was removed from the systematic review after full-text review (Figure S1). Seven BAMP studies [10, 14–19] were identified for inclusion in the systematic review, and three studies were included in the meta-analysis (Table S1). Nine TAMP studies [20–28] were identified for inclusion in the systematic review, and four of them [20, 22, 25, 28] were included in the meta-analysis (Table S2).

4.2 | Study Characteristics

To maintain the quality of this systematic review, we targeted prospective studies only. Study characteristics are detailed in (Table S1) for BAMP studies and in (Table S2) for TAMP studies. A summary of the variables and cephalometric parameters of the studies included in the meta-analysis is provided in (Tables S3 and S4). The risk of bias assessment was done using the ROBINS-I index [13] (Table S5). Five [14, 16–19] of the sixteen studies received a moderate score, whereas two studies [10, 15] reported as serious in terms of risk of bias assessment. The most common missing aspect in the studies was the missing information about the unbiased assessment of the outcome measurement. The details about the risk of bias assessment are described in (Table S5).

In the BAMP studies, six [10, 15–19] of the seven studies used infrazygomatic plates in the maxilla and mandibular anterior plates to run intermaxillary elastics. One study [14] evaluated the difference between bone-anchored conventional facemask and bone-anchored intermaxillary elastics, four studies [10, 15–17] compared BAMP with the control group, one study [18] evaluated the effect of maxillary expansion on BAMP, and one study [19] assessed the acceptance of the secondary alveolar bone graft (SABG) with and without BAMP therapy. Three studies [10, 16, 17] had a non-treated CLP group, and one study [15] had a non-cleft group as a control group, whereas three studies

[14, 18, 19] conducted a comparison of two different intervention groups. In addition, three studies [14, 16, 17] assessed the outcome using 2-dimensional cephalometric analysis, three [15, 18, 19] used 3-dimensional superimposition/analysis, and one study [10] conducted 2D cephalometric measurement and 3D superimposition (Table S1).

In the TAMP, an expander type (hyrax or quad helix) was used along with a Delaire type face mask. Four studies used a CLP control group [20, 22, 25, 26]. Three studies used a non-cleft control group [23, 24, 27]. Dogan et al. [21, 28] compared two interventions (Table S2).

4.3 | BAMP Therapy: Treated CLCP Group vs. Untreated CLCP Control Group

Three prospective studies [10, 16, 17] evaluated skeletal and dentoalveolar effects of BAMP therapy in patients with CLP and compared them with untreated controls. Faco et al. [16] mentioned performing maxillary expansion before initiating the maxillary protraction phase. They also mentioned having a secondary alveolar bone grafting procedure 6 months before the maxillary protraction therapy. Ren and Steegman et al. [10, 17] did not provide any information regarding maxillary expansion or secondary alveolar bone grafting. The observation period was 18 months [16, 17]. Steegman et al. [10] provided data for both 18 months and 3.5 years observation periods for the CLCP group, but due to ethical reasons, they provided data of only the 3.5 years period for the untreated CLP group. All three of the studies provided the necessary information regarding the cephalometric measurements to conduct a meta-analysis (Table S3).

4.4 | TAMP Therapy: Treated CLCP Group vs. Untreated CLCP Control Group

Zhang and Tindlund et al. [27, 28] included patients who had secondary alveolar bone grafts done 5–6 months before FM therapy. Singla and Fu et al. [22, 25] did not provide information about bone grafting. Tindlund et al. [27] used a relatively low FM force of 150–250 g on each side. All studies reported similar treatment times of 15–18 months, except Singla et al. reported 11.71 months, and Chen et al. used 7.8 months of treatment time (Table S4).

4.5 | Other Comparisons of BAMP

Jahanbin et al. [14] conducted a comparative study between BAMP + conventional facemask and BAMP+intermaxillary elastics. They did not find any significant difference between both techniques of BAMP. Yatabe et al. [15] compared BAMP with intermaxillary elastics to that of non-cleft class III patients utilising the 3D superimposition method and did not find any significant difference in the maxillary protraction. Elabbassy et al. [18] evaluated the effect of maxillary expansion on the BAMP therapy. They also did not find any significant benefit of maxillary expansion and recommended using it only if there is a posterior crossbite. Finally, Stangherlin et al. [19] evaluated the effect of BAMP on the acceptance of the SABG (rhBMP2) and concluded that BAMP does not affect the performance of the SABG in UCLP patients (Table S3).

4.6 | Other Comparisons of TAMP

Zhang et al. [28] studied the influence of bone graft on the effect of FM therapy and showed that with bone graft there is more SNA increase and less increase in vertical dimension compared to non-grafted cleft patients. Dogan and Seckin et al. [21] showed that more skeletal effects of FM therapy are produced after repeated expansion and constriction of the Alt RAMEC protocol (Table S4).

4.7 | Meta-Analysis

Results of the BAMP random effect models is found in (Figures 1–5). A significant difference was found for SNA, ANB, Wits appraisal and overjet when BAMP and TAMP were compared to untreated controls. BAMP was found to increase the SNA angle by 1.76° (95% CI: 1.03 to 2.49), ANB angle by 2.08° (95% CI: 0.99 to 3.18), Wits appraisal by 2.17 mm (95% CI: 1.05 to 3.28), and overjet reduction by 2.03 mm (95% CI: 0.98 to 3.08). BAMP therapy did not significantly influence SNB, Mandibular plane angle, U1 to PP, IMPA and Overbite. TAMP was found to increase SNA by 2.56° (95% CI: 1.58 to 3.54), ANB angle by 4.40° (95% CI: 3.61 to 5.18), Wits appraisal by 5.53 mm (95% CI: 4.27 to 6.79), U1 to PP by 2.84° (95% CI: −0.41 to 6.10). TAMP significantly reduced SNB by 2.00° (95% CI: −2.61 to −1.39) (Figures 1–5). The mean difference between the experiment and control groups is reported in Tables S3 and S4 for reference.

4.8 | BAMP vs. TAMP (Combined Data)

Comparison of combined BAMP and TAMP data showed a statistically significant difference in SNB (−1.65°, 95% CI: −2.23 to −1.07, $p < 0.0001$), ANB (1.18°, 95% CI: 0.53 to 1.83, $p = 0.0006$), Wits appraisal (2.1 mm, 95% CI: 0.76 to 3.44, $p = 0.0027$), U1 to PP (1.92°, 95% CI: 0.1 to 3.74, $p = 0.039$), SN/GoGn (1.85°, 95% CI: 1.04 to 2.66, $p < 0.0001$), overjet (2.42 mm, 95% CI: 1.73 to 3.11, $p < 0.0001$), and overbite (−1.34 mm, 95% CI: −2.2 to −0.47, $p = 0.0027$). However, SNA and L1 to GoGn are the only two parameters that did not show significant results on BAMP versus TAMP comparison (Table S6; Figure 6).

4.9 | Risk of Bias Within Studies

Table S5 presents the risk of bias within individual studies utilising the ROBINS-I tool [13]. The overall risk of bias within studies was low to moderate, except for two that exhibited a serious risk of bias. Thus, the risk of bias of the individual studies should be considered while extrapolating the results obtained from this meta-analysis.

The heterogeneity analysis results were quite sensitive to the sample size, i.e., the number of studies. A Q value > 25 or $I^2 > 75\%$ implies considerable heterogeneity by the rule of thumb. The

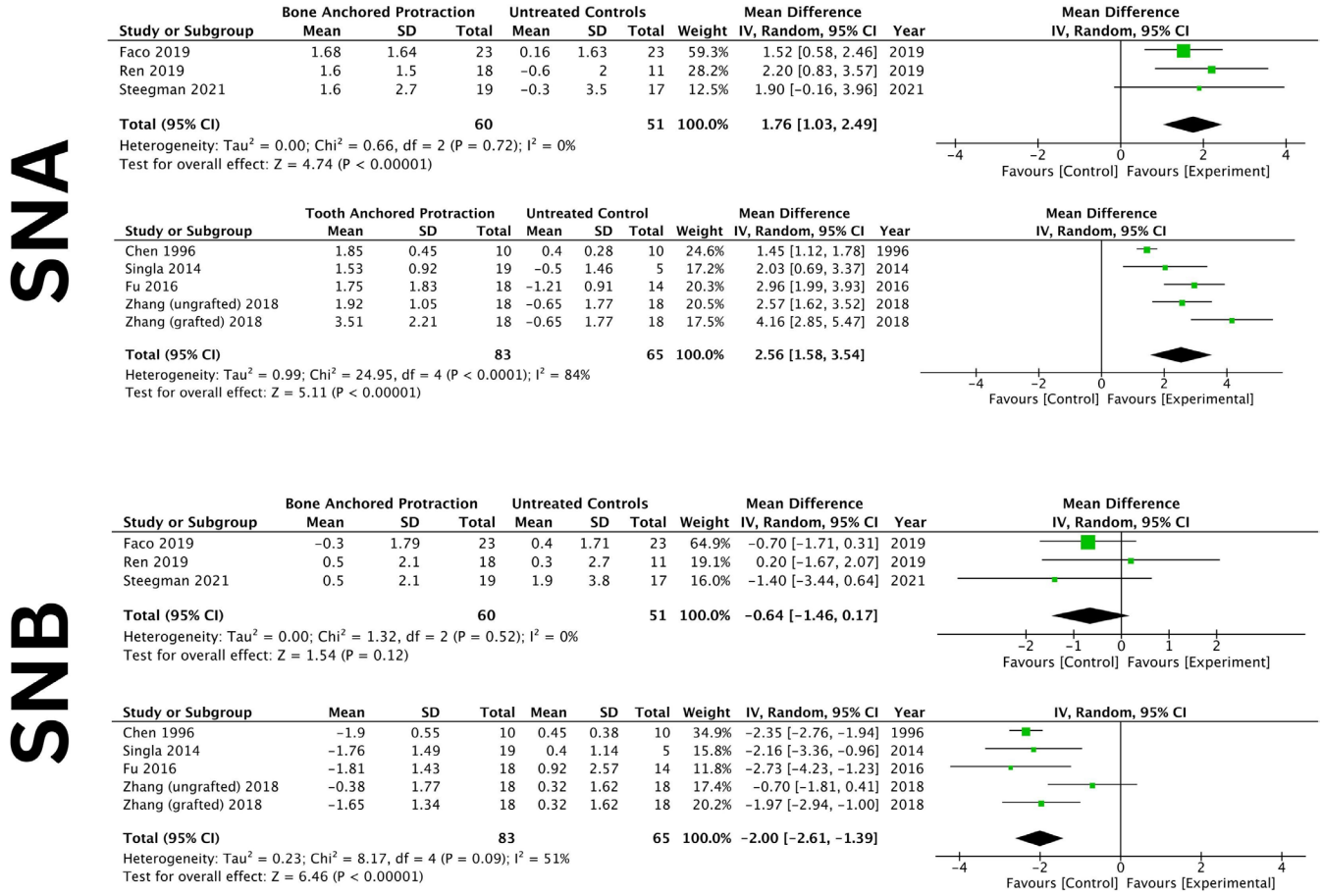

FIGURE 1 | Forest plots compare bone-anchored protraction therapy versus untreated controls and Tooth-anchored protraction versus untreated controls for the sagittal skeletal parameters SNA and SNB in cleft lip and palate patients.

heterogeneity among studies was modelled by a random study effect in the mixed-effects meta-regression model (Figures 1–5).

5 | Discussion

Many studies, including a systematic review, evaluated the effect of conventional FM therapy on patients with CLP or untreated CLP. However, to the best of our knowledge, no systematic review is available that assessed the effect of BAMP therapy in patients with CLP. Thus, the aim of this review was to evaluate the skeletal and dentoalveolar effects of BAMP (either bone-anchored FM or bone-anchored intermaxillary elastics) as well as TAMP (tooth anchored FM) in patients with CLP. To be comprehensive, multiple databases were used. To generate maximum results and minimise bias, no filters were used for language or publication date. The risk of bias assessment of the studies involved in the meta-analysis was done according to the ROBINS-I index for judging the quality of the studies [13]. The meta-analysis comprised studies with the cephalometric evaluation of skeletal and dentoalveolar parameters.

All studies included in the meta-analysis consistently indicated that BAMP appliance in patients with CLP leads to improvement in the sagittal skeletal parameters. SNA showed improvement by 1.96° (95% CI: 1.03 to 2.49), ANB corrected by 2.08° (95% CI: 0.99 to 3.18), and Wits appraisal improved by 2.17 mm (95% CI: 1.05 to 3.28), leading to overjet reduction by 2.03 mm (95% CI: 0.98 to 3.08). However, BAMP did not show a significant change in mandibular plane angle or overbite correction. In addition, dental parameters such as U1 to palatal plane and IMPA did not show significant differences either. Thus, it can be expected that the BAMP therapy in patients with CLP leads to sagittal skeletal correction with minimal dentoalveolar or vertical changes. On the other hand, TAMP showed improvement in SNA 2.56° (95% CI: 1.58 to 3.54), SNB −2.00° (95% CI: −2.61 to −1.39), ANB 4.40° (95% CI: 3.61 to 5.18), Wits appraisal 5.53 mm (95% CI: 4.27 to 6.79), U1 to palatal plane increase of 2.84° (95% CI: −0.41 to 6.10), mandibular plane angle increase of 2.75° (95% CI: 1.73 to 3.76).

Face-mask therapy is often supplemented with maxillary expansion. The theory is that maxillary expansion disrupts the circum-maxillary sutural system and consequently facilitates the orthopaedic effect [29–31]. In this meta-analysis, only one study [16] among the BAMP reported on maxillary expansion phase before starting the facemask therapy. Furthermore, several investigators have reported different results showing no significant differences between the expansion and non-expansion patients in facemask maxillary protraction [32–34]. However, one study among the TAMP [21] showed a better skeletal effect of FM therapy after the Alt RAMEC protocol. Thus, a protocol of utilising active expansion before facemask therapy still warrants future investigation.

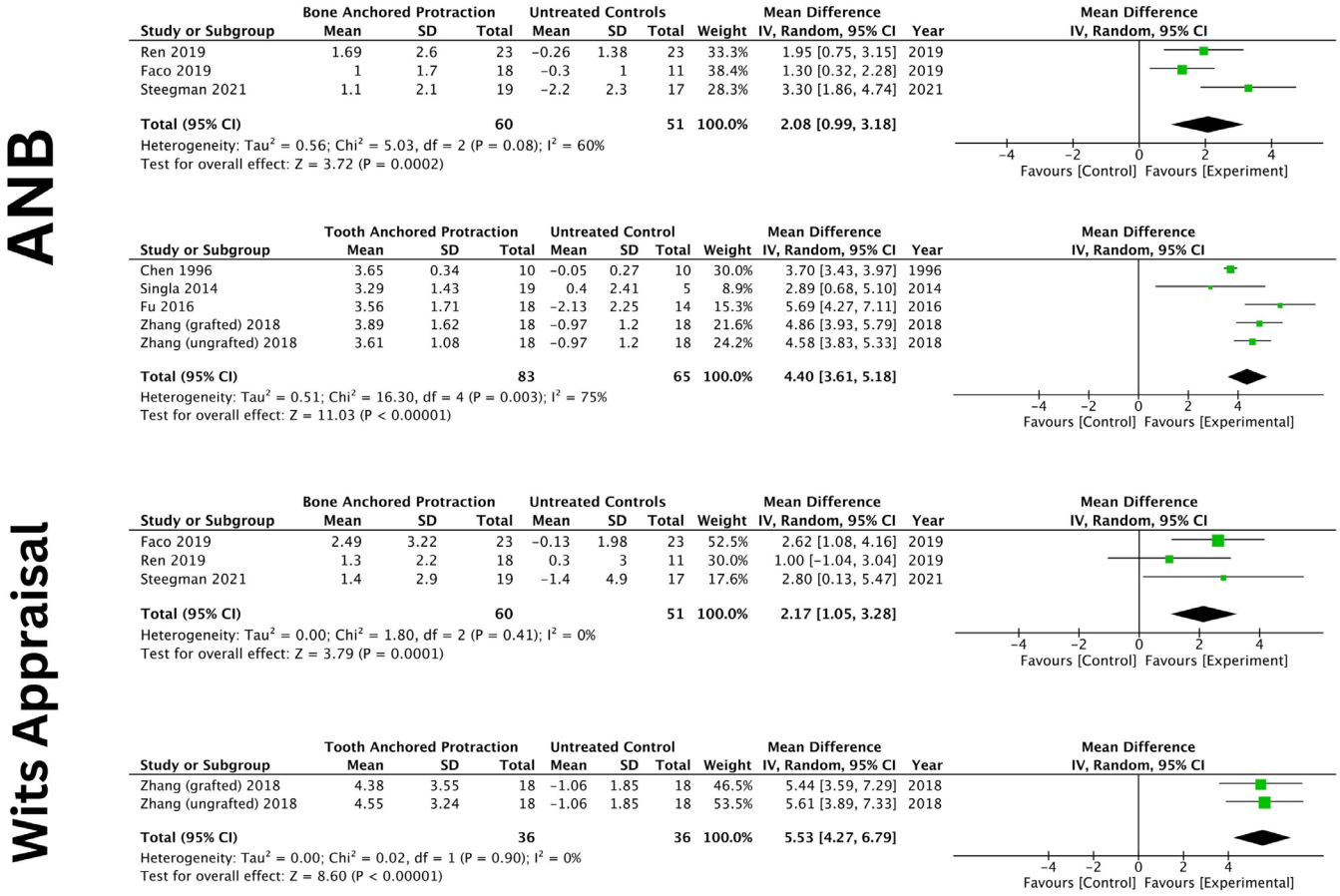

FIGURE 2 | Forest plots compare bone-anchored protraction therapy versus untreated controls and Tooth-anchored protraction versus untreated controls for the sagittal skeletal parameters ANB and Wits appraisal in cleft lip and palate patients.

Another variable in this meta-analysis was the secondary alveolar bone graft. One BAMP study [16], and one TAMP study [28] provided information on the effect of bone graft on maxillary protraction. One study [28] found better results with FM therapy after bone graft. Another study [35] investigated the effect of secondary alveolar bone grafting on maxillary growth and observed no significant difference in maxillary growth for both sagittal and vertical directions. One study [36] reported that the secondary alveolar bone grafting during the mixed dentition does not interfere with the maxillary growth in patients with CLP. Doucet [37] observed a similar outcome and reported that early secondary alveolar bone grafting does not restrict maxillary growth. Therefore, even though the two studies did not provide information about secondary alveolar bone grafts, it would not compromise the quality of this meta-analysis based on the current literature.

More skeletal improvement at the level of SNA and ANB was noted with TAMP, which is counterintuitive even though the treatment time was still longer in the BAMP studies. It is worth noting that the force level in the BAMP was considerably less than the force level used in the TAMP studies (150–250 g and 450–500 g respectively); this might be the reason for the different skeletal effects observed. Moreover, more mandibular backward rotation was noted (SNB decrease of −2.00°) in the TAMP studies. This might be explained by the 20°–30° downward force vector used in the included TAMP studies. This downwards and forward force vector could lead to an extrusive effect on the anchor unit (maxillary molars) and consequently lead to mandible downward and backward rotation. Since there is no dental anchor unit for the BAMP, clockwise rotation of the mandible is not as profound as it is with TAMP. One way to counteract this effect could be to use lower essix with a posterior bite block or to use bonded RME with occlusal bite blocks and hooks for the facemask. Upper incisors proclination observed in the TAMP studies is also another intuitive effect on the dentition using a conventional FM therapy.

6 | Limitations of This Study

To uphold the quality of this review, we restricted inclusion to prospective randomised or non-randomised studies, aiming to strengthen methodological rigour and reduce biases commonly associated with retrospective designs, thereby ensuring a higher level of evidence and internal validity in our synthesis. Therefore, a limited number of studies fulfilled our inclusion criteria. In the future, more prospective studies are required to strengthen our findings. Furthermore, no data was available with the long-term follow-up to evaluate the stability of either BAMP or TAMP. We did not conduct the subgroup analysis based on age, expansion status, secondary bone graft or duration of the facemask therapy because of a limited number of studies. However, those variables can provide valuable information and should be considered in the future.

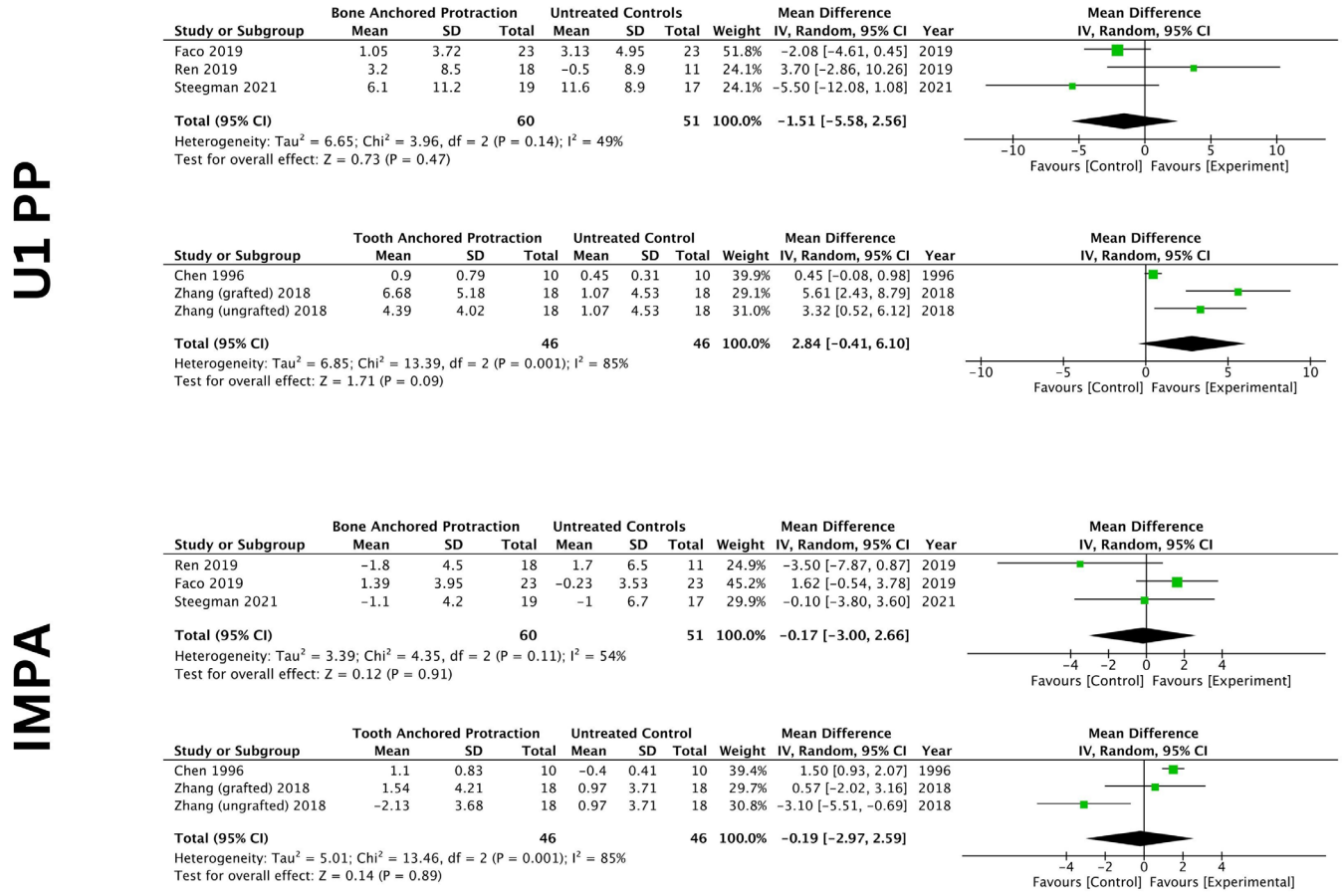

FIGURE 3 | Forest plots compare bone-anchored protraction therapy versus untreated controls and Tooth-anchored protraction versus untreated controls for the dentoalveolar parameters U1 to PP and IMPA in cleft lip and palate patients.

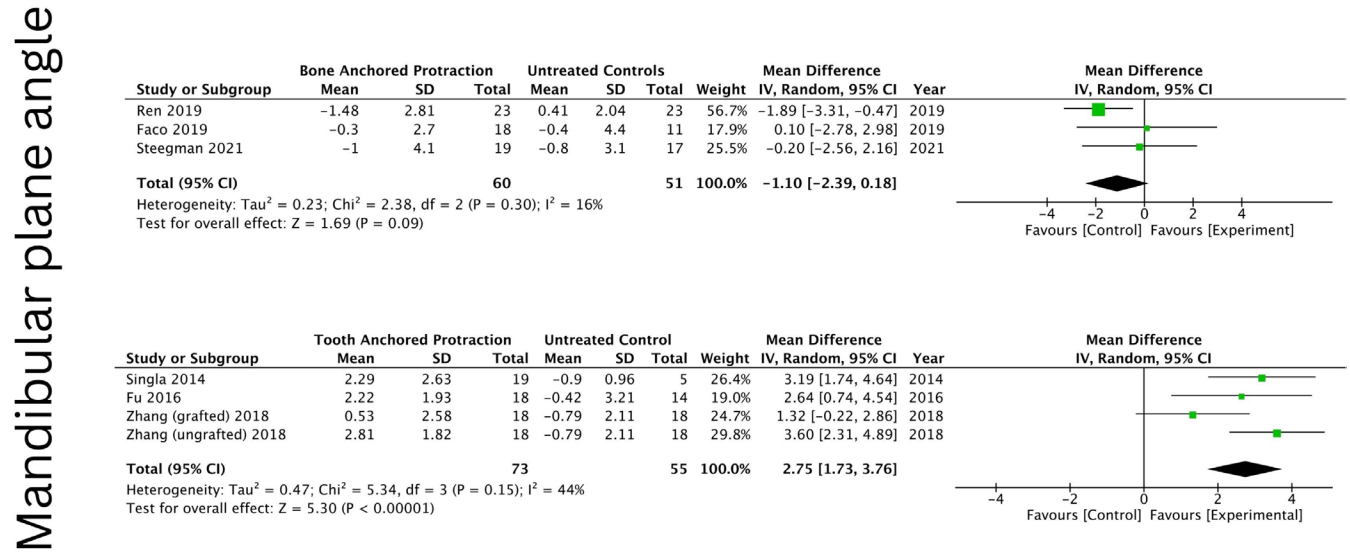

FIGURE 4 | Forest plots compare bone-anchored protraction therapy versus untreated controls and Tooth-anchored protraction versus untreated controls for the vertical skeletal parameter called mandibular plane angle in cleft lip and palate patients.

7 | Conclusion

Despite several limitations, this study concluded that a significant sagittal correction could be expected with both bone-borne and tooth-borne maxillary protraction therapy in children with CLP. A significant difference was observed in terms of the sagittal correction between BAMP and TAMP comparison. In addition, minimal or non-significant vertical effects (mandibular plane angle), as well as negligible dental effects (U1 to PP, IMPA, Overbite), were observed with BAMP therapy in patients with

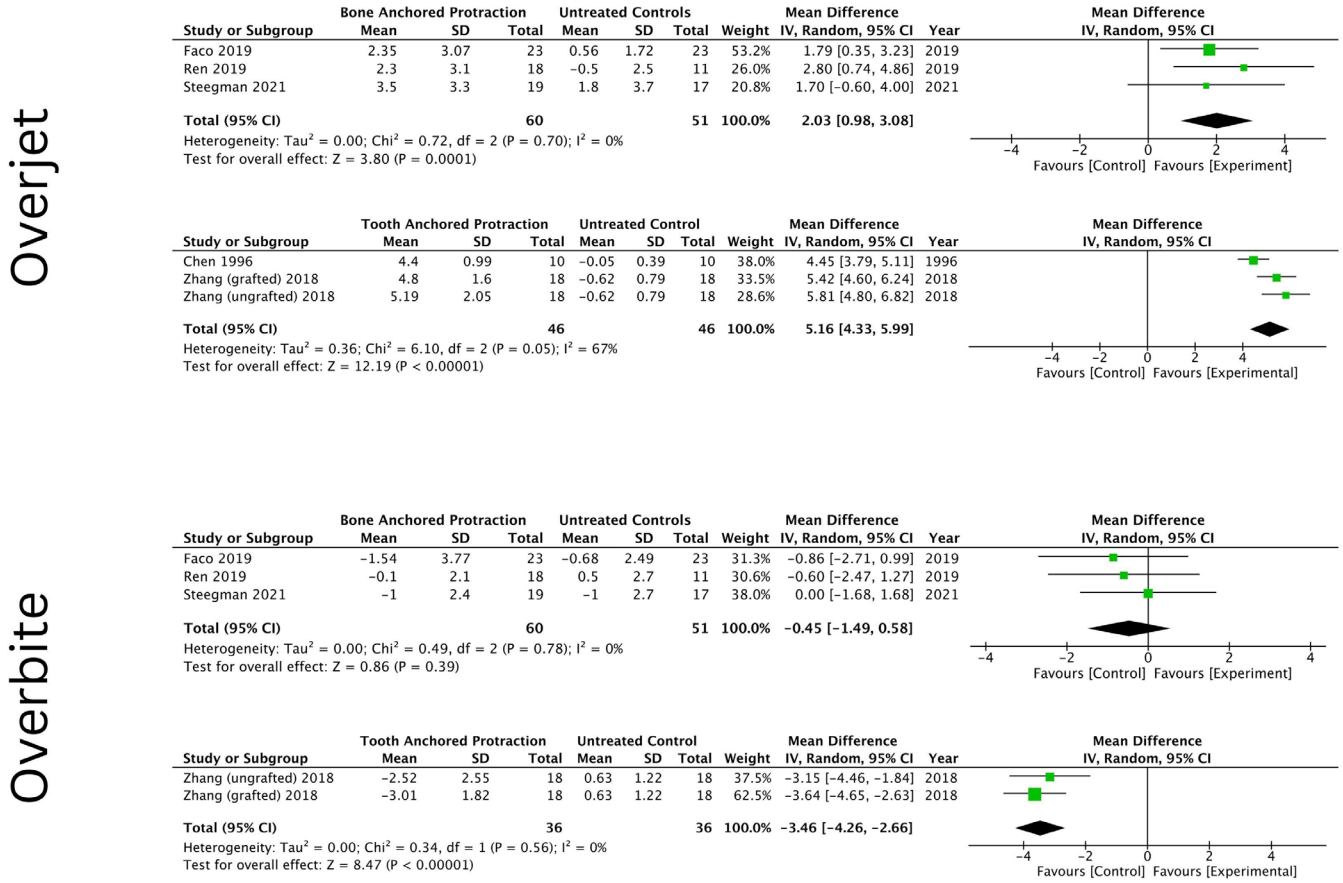

FIGURE 5 | Forest plots compare bone-anchored protraction therapy versus untreated controls and Tooth anchored protraction versus untreated controls for the dentoalveolar parameters overjet and overbite in cleft lip and palate patients.

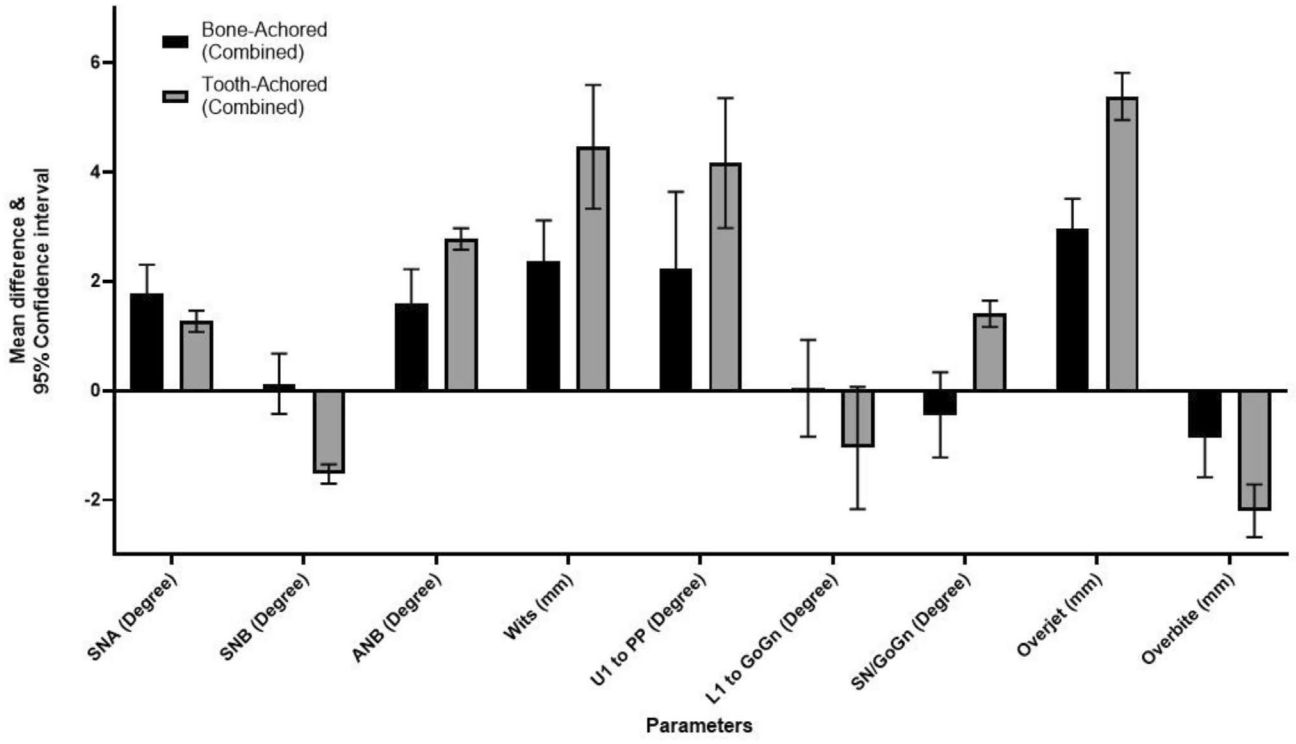

FIGURE 6 | Comparison of the combined data of bone-anchored protraction therapy versus Tooth-anchored protraction for the skeletal and dentoalveolar parameters in cleft lip and palate patients.

CLP; however, those side effects were much more pronounced with the TAMP therapy.

Author Contributions

Vaibhav Gandhi: conceptualization; data curation; formal analysis; investigation; methodology; project administration; resources; software; validation; visualisation; roles/writing – original draft; writing – review and editing. **Amine Fattal:** data curation; project administration; resources; roles/writing – original draft; writing – review and editing. **Gina Genova:** data curation; project administration; resources; software; roles/writing – original draft; writing – review and editing. **Sumit Yadav:** investigation; methodology; resources; software; validation; visualisation; roles/writing – original draft; writing – review and editing. **Nandakumar Janakiraman:** investigation; methodology; resources; software; validation; visualisation; roles/writing – original draft; writing – review and editing.

Ethics Statement

Institutional review board submission and approval were not required for this study.

Consent

Informed consent was not required for this systematic review and meta-analysis, as no human subjects were included in this study. Only data available in previously published study was utilised.

Conflicts of Interest

The authors declare no conflicts of interest.

Data Availability Statement

The data that supports the findings of this study are available in the Supporting Information of this article.

References

1. S. E. Parker, C. T. Mai, M. A. Canfield, et al., "Updated National Birth Prevalence Estimates for Selected Birth Defects in the United States, 2004–2006," *Birth Defects Research. Part A, Clinical and Molecular Teratology* 88, no. 12 (2010): 1008–1016.

2. CDC, https://www.cdc.gov/ncbddd/birthdefects/cleftlip.html.

3. P. Shetye, "Update on Treatment of Patients With Cleft-Timing of Orthodontics and Surgery," *Seminars in Orthodontics* 22, no. 1 (2016): 45–51.

4. G. Palikaraki, M. A. Makrygiannakis, A. A. Zafeiriadis, et al., "The Effect of Facemask in Patients With Unilateral Cleft Lip and Palate: A Systematic Review and Meta-Analysis," *European Journal of Orthodontics* 43, no. 1 (2021): 69–79.

5. P. V. Westwood, J. A. McNamara, Jr., T. Baccetti, L. Franchi, and D. M. Sarver, "Long-Term Effects of Class III Treatment With Rapid Maxillary Expansion and Facemask Therapy Followed by Fixed Appliances," *American Journal of Orthodontics and Dentofacial Orthopedics* 123, no. 3 (2003): 306–320.

6. T. Baccetti, J. S. McGill, L. Franchi, J. A. McNamara, Jr., and I. Tollaro, "Skeletal Effects of Early Treatment of Class III Malocclusion With Maxillary Expansion and Face-Mask Therapy," *American Journal of Orthodontics and Dentofacial Orthopedics* 113, no. 3 (1998): 333–343.

7. C. Sar, A. Arman-Ozcirpici, S. Uckan, and A. C. Yazici, "Comparative Evaluation of Maxillary Protraction With or Without Skeletal Anchorage," *American Journal of Orthodontics and Dentofacial Orthopedics* 139, no. 5 (2011): 636–649.

8. B. Wilmes, M. Nienkemper, B. Ludwig, C. H. Kau, and D. Drescher, "Early Class III Treatment With a Hybrid Hyrax-Mentoplate Combination," *Journal of Clinical Orthodontics* 45, no. 1 (2011): 15–21.

9. T. Nguyen, L. Cevidanes, M. A. Cornelis, G. Heymann, L. K. de Paula, and H. De Clerck, "Three-Dimensional Assessment of Maxillary Changes Associated With Bone Anchored Maxillary Protraction," *American Journal of Orthodontics and Dentofacial Orthopedics* 140, no. 6 (2011): 790–798.

10. R. M. Steegman, A. F. Klein Meulekamp, A. Dieters, J. Jansma, W. J. van der Meer, and Y. Ren, "Skeletal Changes in Growing Cleft Patients With Class III Malocclusion Treated With Bone Anchored Maxillary Protraction—A 3.5-Year Follow-Up," *Journal of Clinical Medicine* 10, no. 4 (2021): 750.

11. J. P. T. Higgins, *Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0* [updated March 2011] (Cochrane Collaboration, 2011, 2016).

12. A. Liberati, D. G. Altman, J. Tetzlaff, et al., "The PRISMA Statement for Reporting Systematic Reviews and Meta-Analyses of Studies That Evaluate Healthcare Interventions: Explanation and Elaboration," *BMJ (Clinical Research Ed.)* 339 (2009): b2700.

13. J. A. Sterne, M. A. Hernan, B. C. Reeves, et al., "ROBINS-I: A Tool for Assessing Risk of Bias in Non-Randomised Studies of Interventions," *BMJ (Clinical Research Ed.)* 355 (2016): i4919.

14. A. Jahanbin, M. Kazemian, N. Eslami, and I. S. Pouya, "Maxillary Protraction With Intermaxillary Elastics to Miniplates Versus Bone-Anchored Face-Mask Therapy in Cleft Lip and Palate Patients," *Journal of Craniofacial Surgery* 27, no. 5 (2016): 1247–1252.

15. M. Yatabe, D. G. Garib, R. A. S. Faco, et al., "Bone-Anchored Maxillary Protraction Therapy in Patients With Unilateral Complete Cleft Lip and Palate: 3-Dimensional Assessment of Maxillary Effects," *American Journal of Orthodontics and Dentofacial Orthopedics* 152, no. 3 (2017): 327–335.

16. R. Faco, M. Yatabe, L. H. S. Cevidanes, H. Timmerman, H. J. De Clerck, and D. Garib, "Bone-Anchored Maxillary Protraction in Unilateral Cleft Lip and Palate: A Cephalometric Appraisal," *European Journal of Orthodontics* 41, no. 5 (2019): 537–543.

17. Y. Ren, R. Steegman, A. Dieters, J. Jansma, and H. Stamatakis, "Bone-Anchored Maxillary Protraction in Patients With Unilateral Complete Cleft Lip and Palate and Class III Malocclusion," *Clinical Oral Investigations* 23, no. 5 (2019): 2429–2441.

18. E. H. Elabbassy, N. E. Sabet, I. T. Hassan, D. H. Elghoul, and M. A. Elkassaby, "Bone-Anchored Maxillary Protraction in Patients With Unilateral Cleft Lip and Palate," *Angle Orthodontist* 90, no. 4 (2020): 539–547.

19. O. Stangherlin Gomes, R. M. Carvalho, R. Faco, et al., "Influence of Bone-Anchored Maxillary Protraction on Secondary Alveolar Bone Graft Status in Unilateral Complete Cleft Lip and Palate," *American Journal of Orthodontics and Dentofacial Orthopedics* 158, no. 5 (2020): 731–737.

20. K. F. Chen and L. L. So, "Sagittal Skeletal and Dental Changes of Reverse Headgear Treatment in Chinese Boys With Complete Unilateral Cleft Lip and Palate," *Angle Orthodontist* 66, no. 5 (1996): 363–372.

21. E. Dogan and O. Seckin, "Maxillary Protraction in Patients With Unilateral Cleft Lip and Palate: Evaluation of Soft and Hard Tissues Using the Alt-RAMEC Protocol," *Journal of Orofacial Orthopedics = Fortschritte Der Kieferorthopädie* 81, no. 3 (2020): 209–219.

22. Z. Fu, Y. Lin, L. Ma, and W. Li, "Effects of Maxillary Protraction Therapy on the Pharyngeal Airway in Patients With Repaired Unilateral Cleft Lip and Palate: A 3-Dimensional Computed Tomographic Study," *American Journal of Orthodontics and Dentofacial Orthopedics* 149, no. 5 (2016): 673–682.

23. H. Jia, W. Li, and J. Lin, "Maxillary Protraction Effects on Anterior Crossbites. Repaired Unilateral Cleft Versus Noncleft Prepubertal Boys," *Angle Orthodontist* 78, no. 4 (2008): 617–624.

24. Y. Lin, Z. Fu, R. Guo, L. Ma, and W. Li, "Maxillary Protraction Therapy in Class III Patients With and Without Cleft Lip and Palate: An Interim Report of a Prospective Comparative Study," *Cleft Palate-Craniofacial Journal* 58, no. 4 (2021): 429–437.

25. S. Singla, A. Utreja, S. P. Singh, W. Lou, and S. Suri, "Increase in Sagittal Depth of the Bony Nasopharynx Following Maxillary Protraction in Patients With Unilateral Cleft Lip and Palate," *Cleft Palate-Craniofacial Journal* 51, no. 5 (2014): 585–592.

26. R. S. Tindlund and P. Rygh, "Maxillary Protraction: Different Effects on Facial Morphology in Unilateral and Bilateral Cleft Lip and Palate Patients," *Cleft Palate-Craniofacial Journal* 30, no. 2 (1993): 208–221.

27. R. S. Tindlund, P. Rygh, and O. E. Boe, "Orthopedic Protraction of the Upper Jaw in Cleft Lip and Palate Patients During the Deciduous and Mixed Dentition Periods in Comparison With Normal Growth and Development," *Cleft Palate-Craniofacial Journal* 30, no. 2 (1993): 182–194.

28. Y. Zhang, H. Jia, Z. Fu, et al., "Dentoskeletal Effects of Facemask Therapy in Skeletal Class III Cleft Patients With or Without Bone Graft," *American Journal of Orthodontics and Dentofacial Orthopedics* 153, no. 4 (2018): 542–549.

29. A. J. Haas, "The Treatment of Maxillary Deficiency by Opening the Midpalatal Suture," *Angle Orthodontist* 35 (1965): 200–217.

30. A. J. Haas, "Palatal Expansion: Just the Beginning of Dentofacial Orthopedics," *American Journal of Orthodontics* 57, no. 3 (1970): 219–255.

31. J. A. McNamara, Jr. and W. L. Brudon, *Orthodontic and Orthopedic Treatment in the Mixed Dentition* (Needham Press, 1993).

32. J. H. Kim, M. A. Viana, T. M. Graber, F. F. Omerza, and E. A. BeGole, "The Effectiveness of Protraction Face Mask Therapy: A Meta-Analysis," *American Journal of Orthodontics and Dentofacial Orthopedics* 115, no. 6 (1999): 675–685.

33. G. Cordasco, G. Matarese, L. Rustico, et al., "Efficacy of Orthopedic Treatment With Protraction Facemask on Skeletal Class III Malocclusion: A Systematic Review and Meta-Analysis," *Orthodontics & Craniofacial Research* 17, no. 3 (2014): 133–143.

34. G. A. Vaughn, B. Mason, H. B. Moon, and P. K. Turley, "The Effects of Maxillary Protraction Therapy With or Without Rapid Palatal Expansion: A Prospective, Randomized Clinical Trial," *American Journal of Orthodontics and Dentofacial Orthopedics* 128, no. 3 (2005): 299–309.

35. T. Levitt, R. E. Long, Jr., and C. A. Trotman, "Maxillary Growth in Patients With Clefts Following Secondary Alveolar Bone Grafting," *Cleft Palate-Craniofacial Journal* 36, no. 5 (1999): 398–406.

36. J. Daskalogiannakis and R. B. Ross, "Effect of Alveolar Bone Grafting in the Mixed Dentition on Maxillary Growth in Complete Unilateral Cleft Lip and Palate Patients," *Cleft Palate-Craniofacial Journal* 34, no. 5 (1997): 455–458.

37. J. C. Doucet, K. A. Russell, J. Daskalogiannakis, et al., "Facial Growth of Patients With Complete Unilateral Cleft Lip and Palate Treated With Alveolar Bone Grafting at 6 Years," *Cleft Palate-Craniofacial Journal* 56, no. 5 (2019): 619–627.

Supporting Information

Additional supporting information can be found online in the Supporting Information section. **Figure S1.** PRISMA Flow diagram of information through the different phases of a systematic review. **Table S1.** Summary of the BAMP study characteristics: participants (sample size, demographic information). **Table S2.** Summary of the TAMP study characteristics: participants (sample size, demographic information), intervention, comparison, observation, results/conclusion and study design. **Table S3.** Summary of the variables and cephalometric parameters of the BAMP studies included in the meta-analysis. **Table S4.** Summary of the variables and cephalometric parameters of the TAMP studies included in the meta-analysis. **Table S5.** Risk of bias assessment of included studies using the ROBINS-I tool. **Table S6.** Combined data for the BAMP and TAMP and comparison of the combined BAMP and TAMP data.