LITERATURE REVIEW

ORTHOPEDIC MAXILLARY PROTRACTION IN GROWING PATIENTS WITH BILATERAL CLEFT LIP AND PALATE: AN INTEGRATIVE REVIEW OF THE LITERATURE

PROTRAÇÃO MAXILAR ORTOPÉDICA EM PACIENTES EM CRESCIMENTO COM FISSURA BILATERAL: REVISÃO INTEGRATIVA DA LITERATURA

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ABSTRACT

The therapeutic management of patients with cleft lip and palate is challenging, and complete bilateral clefts are the most difficult to treat. These patients have a growth deficit related to early reconstructive procedures. This study aimed to review the literature on maxillary protraction protocols and their effects in growing patients with bilateral cleft lip and palate. The PubMed, ScienceDirect, Cochrane Library, and Virtual Health Library, and Scopus databases were searched using keywords "maxillary protraction", "bilateral cleft", and "orthodontic" combined with the Boolean operator "AND". In total, three protocols for protraction in patients with bilateral cleft lip and palate are reported: face mask protraction with dental anchorage, face mask protraction with skeletal anchorage, and intermaxillary traction with skeletal anchorage. The results suggest that dental and skeletal anchorage protraction therapies effectively treat patients with maxillary hypoplasia, although the specific effects vary according to treatment protocol, type of anchorage, and factors related to cleft severity and surgical history. Orthopedic protraction of the maxilla has positive aesthetic, skeletal, and functional effects. Early treatment and the use of skeletal anchorages enhance these effects. Large studies are needed to determine the best protocol for optimal results.

Keywords: Maxillary protraction; Orthodontic; Cleft lip; Growing patients.

RESUMO

O manejo terapêutico de pacientes com fissura labiopalatina é desafiador, e fissuras bilaterais completas são as mais difíceis de tratar. Esses pacientes apresentam déficit de crescimento relacionado a procedimentos reconstrutivos precoces. O objetivo deste estudo é revisar a literatura sobre protocolos de protração maxilar e seus efeitos em pacientes em crescimento com fissura labiopalatina bilateral. As bases de dados utilizadas foram PubMed, Science Direct, Cochrane Library e Virtual Health Library (VHL), Scopus, usando as seguintes palavras-chave "protração maxilar", "fenda bilateral" e "ortodôntico" com o operador booleano "AND". Três protocolos para protração em pacientes com fissura labiopalatina bilateral são relatados: protração com máscara facial com ancoragem dentária, protração com máscara facial com ancoragem esquelética e tração intermaxilar com ancoragem esquelética. Os resultados sugerem que tanto as terapias de protração de ancoragem dentária quanto esquelética são eficazes em pacientes com hipoplasia maxilar, embora os efeitos específicos variem de acordo com o protocolo de tratamento, o tipo de ancoragem e fatores relacionados à gravidade da fissura e histórico cirúrgico. A protração ortopédica da maxila tem efeitos estéticos, esqueléticos e funcionais positivos. O tratamento precoce e o uso de uma ancoragem esquelética aumentam esses efeitos. Grandes estudos são necessários para determinar o melhor protocolo para resultados ideais.

Palavras-chave: Protração maxilar; Ortodontia; Fissura de lábio; Pacientes em crescimento.

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INTRODUCTION

Cleft lip and palate represent one of the most common congenital malformations (1). The annual prevalence of infants born with cleft lip with or without cleft palate is 10 per 10,000 (2). Patients with cleft lip and palate have typical facial features such as maxillary hypoplasia, skeletal Class III pattern, and abnormalities in the number and position of their teeth (3). The psychological consequences of this malformation are very serious because they affect the facial region. The therapeutic management of cleft patients is demanding, and complete bilateral clefts are the most difficult to treat (4), due to intrinsic growth deficits that affect facial morphology later in life, and extrinsic growth deficits related to early reconstructive surgery (5).

According to Tellez-Conti et al. (6), orthopedic treatment at an early age is recommended to compensate for growth deficits in the middle third of the face, to avoid the scarring effects of surgery, and to achieve a better facial, skeletal, and dental relationship at the end of the growth period. Although orthopedic maxillary protraction has received wide attention and has been shown to effectively treat patients with normal and unilateral cleft lip and palate (UCLP), few studies have focused on its effect on bilateral cleft patients (7). This review aimed to investigate the protocols for maxillary orthopedic protraction and the extent of dentoskeletal and soft tissue change in growing patients with bilateral cleft lip and palate (BCLP).

MATERIAL AND METHOD

A non-systematic electronic search was performed on PubMed, ScienceDirect, Cochrane Library, Virtual Health Library, and Scopus using the following English descriptors: “maxillary protraction”, “bilateral cleft”, “orthodontic”, and the Boolean operator “AND”. Inclusion and exclusion criteria are listed in Figure 1. The initial search retrieved 212 articles and, after applying the inclusion and exclusion criteria, eight articles were selected for this literature review. The flowchart for article selection, in accordance with PRISMA guidelines is shown in Figure 2 (8). Searches were conducted November 10, 2024. The reference lists of all included articles were searched for additional studies.

Inclusion criteria	Exclusion criteria
• (BCLP) treated with orthopedic maxillary protraction alone or combined with other treatments; • Languages: English and French; • Clinical studies.	• Patients with syndromic cleft lip and palate; • Normal or cleft patients not treated by maxillary protraction; • Duplicates; • Literature review, books, thesis, abstracts, and letters to the editor.

Figure 1 - Inclusion and exclusion criteria.

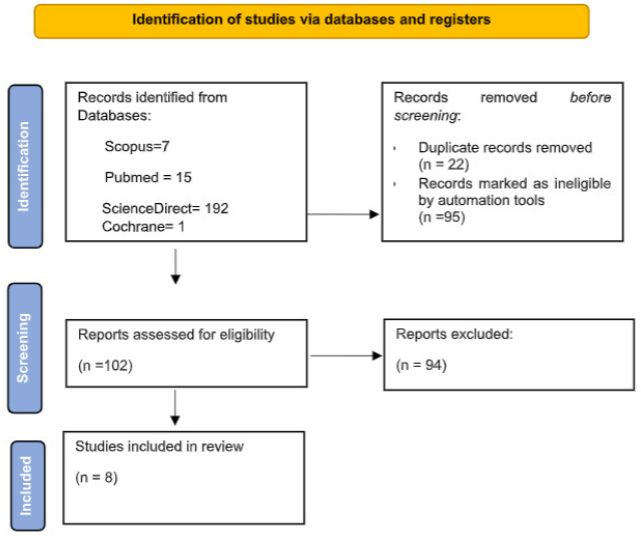

Figure 2 - Article selection flow chart.

RESULTS

Characteristics of the included articles

This review extracted information on the anchorage type, authors, year of publication, study design, studied sample, device used and orthopedic protraction protocol, age at initial treatment, the duration of treatment, and the outcomes from its chosen articles (Table 1). The publication years of the studies ranged from 1993 to 2022, seven of the analyzed articles were retrospective studies, and one study was a clinical trial.

The total sample evaluated by all articles totaled 210 patients, 82 of whom had bilateral cleft lip and palate; 113, unilateral cleft lip and palate; 15, no clefts. Patients’ ages varied from four to 12 years.

Regarding anchorage type and traction method, four studies (9-12) used a face mask for traction in conjunction with dental anchorage (either a quad helix, palate expander, or transpalatal arch). These dental anchorages also used for maxillary expansion. Overall, three studies (13-15) used a face mask in conjunction with infrazygomatic mini-plates for skeletal anchorage. Another study (16) used intermaxillary traction with elastics on infrazygomatic miniplates as skeletal anchorage.

Table 1 - Selected articles

Anchorage type	Author, year	Study design	Sample	Orthopedic protraction appliance	Orthopedic protraction protocol (Wearing time, amount of force, the traction force direction)	Age of protraction	Duration of treatment	Outcomes
Dental Anchored Face Mask Therapy	Mutluol et al. 2022 (9)	Retrospective study	-30 patients; -15 non cleft; -15 BCLP.	Petit face mask + hyrax expander	- 24 hours per day (excluding meals); - 500 g of force on each side; - Forward and 30°-45° downward to the maxillary occlusal plane	BCLP: 10.8 years Non-cleft patients: 11.4 years	BCLP 6 months Non-cleft patients: 6 months	Rapid maxillary expansion, combined with face mask, induced improvement in both groups: - Soft tissue: decreased profile concavity - Hard tissue: maxillary protrusion, mandibular retraction, - Increased upper incisor proclination more important in BCLP group
	Kobayashi et al. 2015 (10)	Retrospective study	- 7 BCLP	Delaire type face mask + palatal arch	- 8-12 hours per day - 150-250 g of force on each side; - 10° downward from the occlusal plane.	- 4-5 years	- 6-12 months	Maxillary growth at 10 years was good after the use of maxillary protraction appliance for postoperative retardation of maxillary growth cases. A treatment protocol based on presurgical orthopedics, gingivoperiosteoplasty, Furlow's palatoplasty, and maxillary protraction may be an option, but long-term growth is unknow
	Tindlund and Rygh 1993 (11)	Retrospective study	- 87 patients; - 63 UCLP; - 24 BCLP.	Delaire-type face mask + Quadhelix	- 11 hours per day; - 350 g of force on each side; - Forward and 15° downward to the maxillary occlusal plane.	- 6 years - 11 months	- 12-15 months	The effect of protraction on soft tissue: the convexity of the soft tissue profile(SS-NS-SM angle) increased significantly in both groups (especially the BCLP group).
	Tindlund and Rygh 1993 (12)	Retrospective study	- 87 patients; - 63 UCLP; - 24 BCLP.	Delaire-type face mask + Quadhelix	- 11 hours per day; - 350 g of force on each side; - Forward and 15° downward to the maxillary occlusal plane.	- 6 years 11 months	- 12-15 months	Effects in hard tissue are: For BCLP group - 90% dentoalveolar; - 10% skeletal For UCLP group - 55% dentoalveolar - 45% Skeletal -Advancement of point A BCLP < UCLP -Counterclockwise rotation of the palatal plane in both groups; - Clockwise rotation of the occlusal plane significantly greater in the BCLP group

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Anchorage type	Author, year	Study design	Sample	Orthopedic protraction appliance	Orthopedic protraction protocol (Wearing time, amount of force, the traction force direction)	Age of protraction	Duration of treatment	Outcomes
Mini-Plates-Anchored Face Mask Therapy	Kim JE et. al. 2020 (13)	Retrospective study	- 24 patients; - 11 BCLP; - 13 UCLP.	Petit-type face mask + infrazygomatic miniplates	- 12-4 hours per day; - 500 g of force on each side; - ND.	- 12 years	- 57 months	The amount of maxillary protraction with the face mask and infrazygomatic miniplates was significantly correlated with the improvements in airway spaces
	Woon On et al. 2018 (14)	Retrospective study	- 21 patients; - 16 UCLP; - 5 BCLP.	Petit-type face mask + infrazygomatic miniplates	- 12-14 hours per day; - 500 g of force on each side; - Forward and 30° downward to the maxillary occlusal plane.	- 11 years	- 57 months	Long-term use of face mask and infrazygomatic miniplates is effective on maxillary protraction in adolescent cleft patients without clockwise rotation of the mandible. Dental inclination change in the maxillary and mandibular incisors was minimized during long-term use.
	Ahn HW et al. 2012 (15)	Retrospective study	- 30 patients; - 15 UCLP; - 15 BCLP.	Petit-type face mask + infrazygomatic miniplates	- 12-14 hours per day - More than 500 g of force on each side; - Forward and 30° downward to the maxillary occlusal plane.	- 11 years	- 24 months	The effect of protraction on hard tissue: - Point A advance BCLP < UCLP; - Minimal counterclockwise rotation of the palatal plane in two groups; - No difference in the degree of vestibuloversion of the maxillary incisors or on the linguoversion of the mandibular incisors between the two groups. - No difference was observed regarding clockwise rotation of the mandible.
Mini-Plates-Anchored Intermaxillary elastics traction therapy	Jahanbin A et al. 2016 (16)	Clinical Trial	- 11 patients Group 1 (3 UCLP; 3 BCLP); Group 2 (3 UCLP; 2 BCLP)	Group 1: Intermaxillary elastics traction to infrazygomatic miniplates + w-arch expander Group 2: Mini-Plate-Anchored face mask Therapy + w-arch expander.	Group 1: - 12-14 hours per day; - 500 g of force on each side; - Forward and 15° downward to the maxillary occlusal plane; Group 2: - 24 hours. - The elastic force until 250 g per side; - CL III elastics.	Group 1: 10 years; Group 2: 8 years.	Group 1: - 7 months; Group 2: - 5 months.	Bone-anchored intermaxillary elastics had similar effects to the miniplate-anchored face mask on maxillary protraction. Also, both of the applied methods showed similar results on the lip and chin soft tissue contour. No significant difference was found between the two treatment groups regarding the type of cleft.

**ND: no detail*

The treatment period varied from six to 24 months and wearing time, from 11 to 24 hours (excluding meal times). Moreover, the vector force was directed forward and 10-45 degrees downward to the maxillary occlusal plane. The amount of force ranged from 150 to 350 g per side for patients aged under six years and 500 g per side for older ones.

Overall, three studies compared treatment between patients with unilateral or bilateral cleft lip and palate (11,12,15), one study compared

treatment between patients with bilateral or no cleft (9), and one study evaluated the protraction protocol in a group of children with bilateral clefts and compared their growth with a group of normal untreated children (10). The remaining three studies evaluated protraction in patients with bilateral or unilateral clefts, without comparing these two types of cleft (13,14,16).

The authors used several cephalometric analyses to assess treatment outcomes. To interpret the results, they compared similar measurements:

- (ua.is-n.ss) or (U1-NA): assessment of the upper incisor proclination;
- (L1- NB) or (la.ii-nsm) or IMPA: assessment of the lower incisor proclination;
- (GOGNSN) or (ML-NSL): assessment of mandibular divergence.

Results of the chosen studies

Results suggest that dental and skeletal anchorage protraction therapies successfully treat patients with BCLP and maxillary hypoplasia, although the specific effects may vary depending on the treatment protocol and treatment duration. Table 2 presents the studies that reported identical skeletal cephalometric measurements (SNA, SNB, ANB, and GoGn-SN) before and after orthopedic protraction.

Hard tissue effects: maxillary advancement constitutes a relevant outcome in most studies: SNA=+2.19° (9), SNA=+0.45° (15), SNA=+0.1°(12) (SNA-SNA difference measured before and after protraction). The UCLP group showed a greater point A advance than the BCLP group (12,15). Rotation of the occlusal plane: some studies observed rotation, particularly clockwise rotation of the occlusal plane in cases of dental anchorage (9,12).

Table 2 - Quantitative analysis of included studies

	Sample BCLP	SNA (T2 - T1)	SNB (T2 - T1)	ANB (T2 - T1)	GOGNSN (T2 - T1)
Quadhelix+ Delaire face mask (12)	24	+0.1	−1.8	+1.8	+0.7
Miniplates + Petit face mask (15)	15	+0.45	−0.82	+1.27	+0.46
Expander (dental anchorage) + Petit face mask (9)	15	+2.19	−0.52	+2.33	+0.81

Soft tissue effects: face mask therapies (with miniplates or dental anchorage) significantly changed soft tissue, decreasing profile concavity (SS-N-SM=+2.5°) and significantly increasing gnathion, subnasale, and upper lip thickness (9,11).

Dental effects: dentoalveolar Class III compensation occurred, particularly in dental anchorage and longer treatment protocols (9,12,13). Functional effect: the amount of maxillary protraction with the face mask and miniplates was significantly related to the improvements in this airway on the oropharyngeal and nasopharyngeal airway spaces. Maxillary advancement: point A advancement to the vertical reference plane is positively correlated with increases in superior posterior airway space, middle airway space, and upper nasopharynx (13).

DISCUSSION

The reviewed studies provided a comprehensive overview of orthopedic traction protocols for patients with BCLP, their efficacy, their impact on skeletal structures and soft tissues, and their long-term outcomes. Variability in outcomes is influenced by multiple factors such as anchorage type, protraction method and protocol, bilateral cleft type characteristics, and alveolar bone graft.

Regardless of the type of anchorage, advancement of point A is a common outcome across all studies. To enable quantitative comparisons, only three studies (9,12,15) showed identical skeletal cephalometric measurements (SNA, SNB, ANB, GOGNSN) before and after orthopedic protraction. Quantitative Analysis (Table 2) showed a greater point A advance in the study that treated patients with dental anchorage protraction and palatal disjunction (9), better controlling the vertical direction in the study in which patients with BCLP received miniplates (15), making them an interesting therapeutic option in hyperdivergent cases. It also found better control of the incisal axes and rotation of the palatal and occlusal planes with skeletal anchorage (14, 16).

These results agree with Baek et al. 2010, which confirms that skeletal anchorage better controls secondary effects such as labial inclination of the maxillary incisors, extrusion of the maxillary molars, and clockwise rotation of the mandibular plane (17).

Faco et al. 2019, found that face mask bone anchorage therapy in patients with UCLP showed a significant orthopedic maxillary

protraction, improved Class III skeletal pattern, a counterclockwise rotation of the palatal plane, and improved molar relations (18). Han et al. have also shown better esthetic results and stability with miniplate anchorage (19). Therefore, the use of a skeletal anchorage would be an advantage, except that miniplates can only be placed after the age of 10 years. The reduced height of the maxillary alveolar bone and the eruption of the mandibular canines would complicate surgery before this age (20). The potentiation of the effect of protraction by disjunction is a result to be interpreted with caution as it contradicts the meta-analysis of Zhang et al. 2015, which states that the result of maxillary orthopedic protraction is similar with or without rapid palatal disjunction (21).

The facial profile changed from a concave to more orthognathic profile for all samples in the selected studies. This finding agrees with Shamlan et al. 2015, who investigated the canonical correlation between hard and soft tissues in facial profiles and found that 84% of the soft tissue variation stems from hard tissue variation (22).

According to these results, maxillary protraction with skeletal anchorage has skeletal and aesthetic effects in the treatment of patients with BCLP and long-term functional effects, increasing pharyngeal airspace (13). This result agrees with Steegman et al. 2023 (23), who confirm that 1.5 years of treatment with skeletal anchorage significantly increased total airway volume and nasopharynx ($P<0.01$).

The included studies in this review used face mask traction (Delaire or Petit) or intermaxillary elastics traction. According to Jahanbin et al. 2016, intermaxillary traction on miniplates can offer an alternative to maxillary protraction in patients with unilateral and bilateral cleft lip and palate (16) as it is easier for patients to cooperate in the absence of an extraoral appliance, as in Tiwari et al. 2024 (24).

Overall, three studies investigated the effects of orthopedic maxillary protraction on hard and soft tissues considering cleft type (11,12,15). They reported greater maxillary advancement in patients with unilateral clefts both under the conventional tooth-anchored masks and skeletal-anchored masks, despite the difference in effects (skeletal for the UCLP and mainly dentoalveolar for the BCLP). Tindlund and Rygh (11) showed that the changes in the soft tissue profile were more or less the same. Before we can say that protraction works better in unilateral than in bilateral clefts, we must consider the surgical history and severity of the cleft.

Each study used a specific surgical protocol. However, the protocol was the same in UCLP and BCLP (11,15). According to Naqvi et al. (25), surgery avoids directly damaging bone but the fibrous scar tissue formed near bone growth sites may prevent normal downward and forward maxillary remodeling and development. As patients with BCLP generally have more scar tissue than those with UCLP, the amount of scar tissue and their tension may explain the difference in maxillary advancement between them. Further studies are needed to assess the influence of cleft scar tissue on maxillary protraction outcomes.

These studies ignored the severity of the cleft at the start of treatment or cervical vertebral maturation, an indicator of patients' growth potential. The GOSLON Yardstick index is the most widely used to assess the efficacy of treatment and treatment outcomes (26). According to Harila et al. (27), this useful method can assess the relation between dental arches and treatment prognosis in cleft patients. They found that patients with BLCP have the poorest prognosis because the initial size of their cleft is usually the largest and most severe. Therefore, such poor outcome confirms that the initial severity of the cleft affects the prognosis of the occlusion and the required orthodontic treatment and methods.

Tellez-Conti et al. (28) found a difference in craniofacial growth and development in patients with cleft lip and palate. Patients with unilateral cleft had predominantly Class III malocclusions, whereas patients with bilateral cleft had Class II malocclusions at an early age. During the prepubertal period, these values became progressively negative until the end of the growth period, implying Class III. Therefore, early orthopedic treatment is strongly recommended to compensate for growth deficits in the midface and to avoid the scarring effects of surgical procedures (28,29). It is advisable to re-examine patients with bilateral clefts in the prepubertal period as this is when Class III malocclusion tends to develop.

According to Ahn et al. 2020 (30), the severity of the cleft and whether alveolar bone grafting is performed can influence the position of the maxillary center of resistance. Studies show that combining protraction and grafting can correct alveolar clefts well, but the timing of grafting remains controversial (9,10,31,32).

In our review, Kobayashi et al. 2015 (10) performed alveolar bone grafting after orthopedic protraction in most patients to correct residual alveolar bone insufficiency. This is consistent with the timing suggested by Meazzini et al. (31), who state that in growing patients with wide unilateral or bilateral

clefts, preoperative orthopedic protraction could be an effective method to reduce alveolar and cleft width, minimizing the risk of post-graft fistulae and reducing the need for additional surgery. However, Yang et al. 2012 (32) found, in their three-dimensional finite element analysis, that it would be more advantageous to perform maxillary protraction with a skeletally anchored face mask and after alveolar bone grafting, regardless of cleft type.

Despite the relevance of its results, this study has several limitations: a small number of included studies, limited sample size of patients with bilateral clefts, protocol heterogeneity, and the compared groups prohibited a meta-analysis. Future research should focus on prospective randomized controlled trials to better assess the efficacy of treatment methods and their long-term results.

CONCLUSION

Several maxillary protraction protocols can treat growing patients with bilateral clefts. They generally produce positive skeletal, aesthetic, and functional results. The studies in this review reported a decrease in profile concavity, Class III dentoalveolar compensation (particularly with dental anchorage), and longer treatment protocols. The UCLP group showed greater A-point advancement than the BCLP group. The use of a skeletal anchorage is possible from the age of 10 years, providing better vertical control and minimizing dentoalveolar effects.

The following factors can optimize protraction results:

- Early restorative surgery: perform conservative surgical procedures close to the suture areas to minimize the negative impact on maxillary growth.
- Age of orthodontic treatment: start treatment at an early age to compensate for growth deficits due to scar tissue tension.
- Follow-up is important during the pre-pubertal period.
- Anchorage: Use of skeletal anchorage in patients over 10 years of age.

No competing interests have been declared.

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