Presurgical orthopedics in patients with cleft lip and palate: nutrition, aesthetics and gap between maxillary segments. A systematic review

Ortopedia prequirúrgica en pacientes con fisura labio palatina: alimentación, estética y brecha entre segmentos maxilares. Revisión sistemática

Ortopedia pré-cirúrgica em pacientes con fissura labiopalatina: nutrição, estética e espaço entre os segmentos maxilares: revisão sistemática

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Abstract

Objective: To describe the results of the use of presurgical orthopedic teatments NAM, Dynacleft and nasal component in terms of esthetics, feeding, and the gap between maxillary segments.
Method: We conducted a literature review in Pubmed and SCIELO, in addition to a manual search of books and scientific articles. After applying the inclusion and exclusion criteria, 25 studies were analyzed.
Results: The literature indicates that NAM and Dynacleft improve esthetics and reduce the gap between the maxillary segments. However, more evidence is needed in relation to feeding.
Conclusion: The results of presurgical orthopedics are better if treatment begins in the first days after birth. The esthetic benefits include lip and nasal symmetry, nasal tip projection, and post primary surgical scar.

Keywords: Orthopedics, Cleft Lip, Cleft Palate.

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Resumen

Objetivo: describir los resultados que se obtienen con el uso de ortopedia prequirúrgica NAM, Dynacleft y componente nasal en relación a estética, alimentación y brecha entre segmentos maxilares.
Método: Se realizó un análisis de la literatura publicada utilizando bases de datos Pubmed y SCIELO, además de una búsqueda manual de libros y artículos científicos. Después de aplicar los criterios de inclusión y exclusión, se analizaron 25 estudios.
Resultados: La literatura indica que NAM y Dynacleft mejoran la estética y disminuyen la brecha entre los segmentos maxilares, con respecto a la alimentación se necesita mayor evidencia.
Conclusión: los resultados obtenidos con la ortopedia prequiríurgica son mejores si se empieza los primeros días de nacimiento. Dentro de la estética destaca la simetría labial y nasal, proyección de la punta de la nariz y cicatriz post operación primaria.

Palabras clave: Ortopedia; Labio fisurado; Paladar fisurado.

Resumo

Objetivo: descrever os resultados obtidos com a utilização da ortopedia pré-cirúrgica NAM, Dynacleft e componente nasal em relação à estética, nutrição e gap entre os segmentos maxilares.
Método: Foi realizada análise da literatura publicada nas bases de dados Pubmed e SCIELO, além da busca manual de livros e artigos científicos. Após a aplicação dos critérios de inclusão e exclusão, 25 estudos foram analisados.
Resultados: A literatura indica que NAM e Dynacleft melhoram a estética e diminuem o gap entre os segmentos maxilares, no que diz respeito à alimentação, mais evidências são necessárias.
Conclusão: os resultados obtidos com a ortopedia pré-cirúrgica são melhores se esta se iniciar nos primeiros dias de nascimento. Dentro da estética, simetria labial e nasal destacam-se a projeção da ponta do nariz e a cicatriz pós-operatória primária.

Palavras-chave: Ortopedia; Fenda Labial; Fissura Palatina.

Introduction

Cleft lip and palate is one of the most frequent congenital maxillofacial anomalies.[1] It ranks third according to the Latin American Collaborative Study of Congenital Malformations, and its prevalence has increased. The cleft palate rate has increased from 0.4 (1982–1994) to 0.7 (2001–2010) per 1000 births, and the cleft lip rate from 1.2 (1982–1994) to 1.4 (2001–2010) per 1000 births.[2] In Chile, cleft lip and palate prevalence is 1.7 per 1000 newborns: approximately 400 cases each year.[3] Its incidence is 1.8 per 1000 live births. Annually, this amounts to approximately 452 new cases every year.[3]
Its etiology is multifactorial, as it involves genetic and environmental factors that may interfere with the migration of neural crest cells to the first branchial arch. Genetic factors appear in 20% to 25% of cases. Additionally, 20-25% of patients present environmental factors such as vitamin A deficiency, corticosteroids, anticonvulsants, or a viral infection in the first trimester of pregnancy. No precise causes have been found in the remaining cases.[4]
Facial development of the fetus occurs between the third and twelfth week of pregnancy.[5] Between the fourth and ninth week, there is an alteration in the migration or fusion of mesenchymal cells, which gives rise to the cleft lip because the frontonasal and maxillary processes fail to fuse. Furthermore, and not necessarily at the same time, a cleft palate occurs when the

secondary palate fails to form, and the palatal shelves fail to fuse.[1]

This anomaly can be diagnosed in utero with modern technologies: an ultrasound scan in the 16th week of pregnancy or during birth.[4]

Cleft lip and palate may occur in association with other syndromic anomalies (20%) or in isolation (80%). It affects various orofacial functions such as feeding, hearing, phonation, breathing, self-esteem, esthetics, and social adaptation.[5] Therefore, this condition should be addressed from a multidisciplinary perspective to provide comprehensive and long-term rehabilitation from birth to adolescence.[4] Care guidelines have been developed to restore full rehabilitation, improve the appearance of compromised hard and soft tissues, and facilitate the patient's integration into society.[7-9]

Predental and pediatric treatment can be divided into three phases: phase 1, from birth to around 3 months of age (before any surgery); phase 2, from 3 to 12 months of age (after lip surgery); and phase 3, from 12 months onwards (after primary palatal repair).[10]

The modern school of presurgical orthopedics in cleft lip and palate treatment started in 1950 with McNeil.[11] In 1993, Grayson et al.[12] created an intraoral plate with a nasal stent for alveolar, lip, and nose modeling: nasoalveolar molding (NAM). In unilateral cleft lip and palate cases, the clinician molds the greater alveolar segment towards the mid-sagittal plane, in the direction of the lesser segment.[13] When the segments are less than 5 mm apart, the nasal component is added, which can be either a stent (acrylic projection or wire extension that runs from the plate to the nose),[13] or a conformer, which is positioned in the affected nostril.[3] Presurgical treatment is completed at the age of 5 months approximately, before the closing of the primary palate. Then, the device is removed and the first surgery is performed.[6]

Berggren et al. subsequently introduced a nasal elevator and paper tape to improve nasal morphology.[14] To avoid using of an intraoral plate and simplify the procedure, the paper adhesive tape is replaced with paper tape with an elastic band (DynaCleft ®, Canica Design Inc., Almonte, Ontario, Canada).[14] This elastic band creates muscular traction, bringing the cleft lip segments together, thus reducing the width of the bone fissure. The treatment lasts for three months in patients with unilateral or bilateral cleft lip.[3]

NAM is the most widely used technique in Chile, and it was included in the Universal Access with Explicit Health Guarantees (AUGE) program in 2005.[3]

This review aims to describe the results of NAM, Dynacleft, and a nasal component as presurgical orthopedics in terms of feeding, esthetics, and the gap between maxillary segments.

Materials and methods

Search strategy. We conducted a literature review in Pubmed (2000-2020) and SCIELO (2000-2020), in addition to a manual search of books and scientific articles.

Search terms. The following keywords were used for the search: cleft lip and palate, presurgical orthopedics, presurgical nasoalveolar molding, congenital malformations, and breastfeeding. The following MeSH terms were used: Cleft Palate, Cleft Lip, Palatal Obturators, with boolean operator AND.

Inclusion/exclusion criteria. The following filters were applied: articles in English, Spanish, and Portuguese published from 2000 to 2020, case reports, clinical trials, cross-sectional studies, systematic reviews, editorials, and clinical guidelines available in full text. Posters, letters to the editor, expert comments, and partial texts were not considered. The last search was conducted on 3 September 2020. Articles describing studies that mentioned the most commonly used preoperative orthopedic methods were considered: NAM, Dynacleft, and nasal component (nasal stent, conformer, or shaper). We also included studies where the patients had

complete uni or bilateral cleft lip and palate, who had started orthopedic treatment before the age of three months, and who had undergone orthopedic treatment for at least 100 days. We excluded articles on presurgical orthopedic methods other than NAM, Dynacleft, and nasal component (nasal stent, conformer, or shaper), studies where the patients had additional structural and functional alterations (associated syndrome) and had undergone surgery before orthopedic treatment.

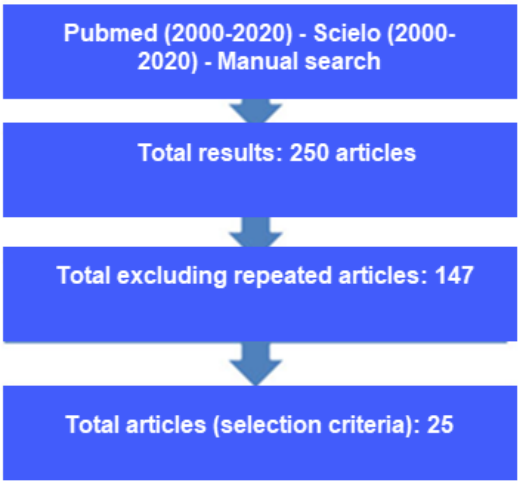
Selection process. The articles were selected independently by two reviewers. The titles were selected, and non-relevant publications were removed. The filters of each database were used by selecting the "search by date," "search for clinical trials," and "search for articles," options, mainly in PubMed and ScienceDirect. The degree of reviewer Kappa concordance was 0.96 for article selection. The disagreements between the reviewers were solved with additional discussion.

Data collection. The following variables were searched for in each article: 1. Feeding. 2. Esthetics (lip and nasal symmetry, nasal tip projection, and post-primary surgical scar). 3. Gap between maxillary segments.

Results

The search strategy yielded a total of 235 articles. Fifteen additional articles were included after the manual search. Of the total, 103 articles were eliminated because they were repeated. The complete articles were analyzed, and the inclusion and exclusion criteria were applied. This resulted in 25 studies to be analyzed, as shown in Fig. 1.

Fig. 1: Article selection flowchart



The data was collected independently using Table 1.

Table 1: Addressing each of the variables: feeding, gap between segments, and esthetics, by article

Article No.	Variables evaluated		
	Feeding	Gap between maxillary segments	Esthetics
1	Not mentioned	Presurgical orthopedics aligns the maxillary segments, reducing gap width, and facilitating primary surgery.	Nasal stent: makes it possible to model the malformed nostril.
			The use of nasal conformer in a newborn improves alar symmetry.
2	Not mentioned	Not mentioned	Not mentioned

Article No.	Variables evaluated		
	Feeding	Gap between maxillary segments	Esthetics
3	Grayson-type orthopedics improve feeding. Most children with bilateral clefts can eat correctly and show substantial improvement with the use of orthopedic plates.	Grayson-type orthopedics progressively aligns the maxillary segments, retracts the premaxilla, and approximates the alveolar ridges.	NAM uses a nasal extension to shape and reposition the deformed alar cartilage. In bilateral cleft lip cases, it lengthens the columella and supports the cleft nasal floor.
		Orthopedics aligns the three maxillary segments of patients with bilateral cleft lip and palate.	
4	Not mentioned	Preoperative orthopedics is essential and widely used. In an effort to align the three maxillary segments, lengthen the prolabium and the columella. NAM helps reduce the distance between the maxillary segments.	Not mentioned
5	NAM contributes to breastfeeding and child feeding.	NAM allows clinicians to redirect bone and soft tissues to a favorable anatomic position early. Primary lip surgery benefits from reducing the width of the palatal and alveolar cleft.	Preoperative orthopedics provides improved esthetic results, and primary lip surgery benefits from reduced soft tissue tension. NAM achieves greater symmetry of the lip, nasal cartilages,and improved nasal tip projection.
6	Presurgical orthopedics facilitates feeding.	NAM aligns the alveolar processes, narrows the alveolar gap, shapes the alar cartilages, and brings the philtrum and columella into a better position.	NAM improves nasal symmetry in unilateral cleft cases, and elongates the columella in bilateral cases.The most significant benefit is repositioning the columella from an oblique position to a vertical and midline direction. This results in better nasal tip projection, and symmetry of the alar cartilages.
		The nasoalveolar modeling plate is used in practice with good results in gaps from 3-8 mm to 14 mm.	This technique minimizes scarring, and in patients with bilateral clefts, it eliminates the need for a second surgery to elongate the columella, which causes scarring at the columella-labial junction.
7	NAM improves feeding.	NAM reduces the distance between labial segments, allows for growth stimulation and redirection in order to reposition alveolar segments in a controlled manner.	NAM improves esthetic appearance and nasal symmetry without affecting nasal growth.
			The cases presented (case 1 and 2) show minimal or almost no scarring, and almost normal anatomy of the lip and palate was achieved.
			CASE 1: patient with unilateral cleft lip and palate that has been treated with NAM for three months. The nose has not changed significantly because the child was already three months old when the condition was reported.
8	Strong evidence indicates that preoperative orthopedics does not improve the efficiency and effectiveness of breastfeeding.	Since there is no evidence in favor or against preoperative orthopedics, we suggest that the treatment be prescribed according to the surgeon's experience.	The expert committee agrees that the results of preoperative orthopedics in nasal symmetry depend on the treating professional's skills and experience.
			One study reported pressure ulcer as an adverse effect. Therefore, the authors state that no conclusions can be drawn on the usefulness of preoperative orthopedics from the studies reviewed.

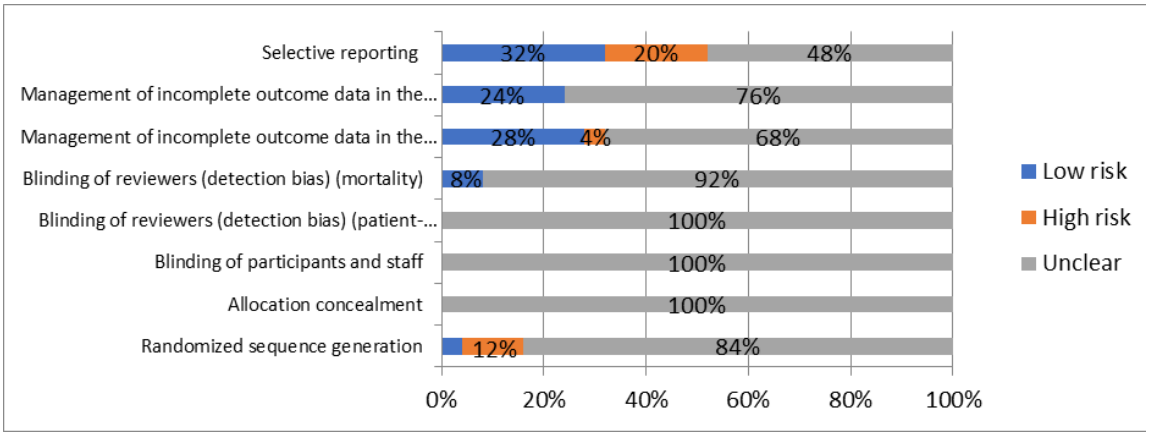
Article No.	Variables evaluated		
	Feeding	Gap between maxillary segments	Esthetics
9	Presurgical orthopedics facilitates feeding.	Presurgical orthopedics reduces the gap and repositions the maxillary segments. However, some people believe that it is not necessary and that the advantages of monitoring the cleft patient (rather than treating orthopedically) and of surgery are greater.	Further studies are needed.
10	In the first few days, the infant may need time to get used to feeding with the NAM method.	NAM reduces the severity of the initial gap between maxillary segments. Good alveolar alignment helps the surgeon to achieve a better and more predictable surgical result, in addition to a successful gingivioplasty.	Long-term studies of the NAM technique indicate improved lip and nose shape, reduction of nasal fistula and lip deformities. This technique has eliminated the need for surgical reconstruction of the columella and the resulting scar in bilateral cleft lip and palate.
			The NAM technique has been shown to significantly improve the surgical outcome in primary cleft lip and palate repair compared to other preoperative orthopedic techniques.
			Long-term studies of NAM therapy indicate that the change in nasal shape is stable with less scar tissue, and there is improved nasal and lip shape.
11	Not mentioned	One of the benefits of the NAM technique is proper alveolar, lip, and nasal alignment, which helps achieve a better and more predictable surgical result.	In unilateral cleft patients, the nasal stent used jointly with NAM straightens the deviated columella toward the noncleft side. In patients with bilateral cleft lip and palate, the nasal stent elongates the columella by stretching the tissue gradually.
			Nasal shape and esthetics in cleft patients are significantly better in patients who underwent NAM treatment.
			Long-term studies of NAM therapy indicate that the change in nasal shape is stable.
12	Some orthodontists have reported that NAM improves feeding, speech, and occlusion.	NAM can be used to approximate the alveolar segments.	NAM can improve nasal tip projection and correct alar cartilage distortion and asymmetry.
		Closing the alveolar gap with an alveolar shaper reduces the nasal deformity so that more precise nasal shaping can be implemented.	The nasal stent can be used in bilateral cleft lip and palate patients to lengthen the columella gradually. The columella thus created grows normally. This creates a nasal tip with improved projection, the lateral alar cartilage is corrected, and there is an increase in nasal mucosal surface.
13	Sixty-five percent of respondents say that the Dynacleft patch promotes infant feeding.	This new orthopedics (Dynacleft)	The nasal conformer models and corrects the malposition of the nasal cartilage and the alar base of the nose on the affected side, making the nose symmetrical.Most parents believe that the esthetic result is excellent.
		brings together the segments of the cleft lip by reducing the width of the bone fissure with muscular traction.	
14	Not mentioned	Dynacleft and Grayson's NAM: both methods significantly decrease gap width.	Both methods improve nasal asymmetry. Our findings show that both methods have similar results.

Article No.	Variables evaluated		
	Feeding	Gap between maxillary segments	Esthetics
15	With NAM, newborns can suckle without nausea or difficulty.	NAM reduces the size of the alveolar gap after molding and repositioning bone and soft tissue segments.	Using NAM, deficient tissues can be expanded, and malpositioned structures can be repositioned before surgical correction.
		Initially, the gap was 6-mm wide, and after 11 weeks with NAM, it was 1-mm wide.	NAM successfully rehabilitates the newborn by closing the oronasal communication.
16	NAM precludes traditional breastfeeding in almost all cases.	Not mentioned	Not mentioned
	How infants undergoing NAM therapy breastfeed: 75% used a Haberman feeder, and 2% used the nipple.		
17	Not mentioned	NAM improves nasal angle symmetry in patients with unilateral and bilateral cleft lip and palate, and nostril span.	Not mentioned
18	Not mentioned	The gap between maxillary segments decreases.	A significant improvement in esthetics was observed in patients who used NAM compared with those who did not.
19	Not mentioned	PNAM repositions premaxilla and alveolar processes.	In this case, the nasal width decreased, the columella length increased, and the alar cartilages were molded to a normal shape. The shape of the repaired nostril was the same as the opposite side, resulting in an appearance of facial symmetry. Post-surgery scars on the upper lip were barely identifiable.
		The results of this study show a significant decrease in the intra-alveolar gap. The alveolar segments touched, and the labial segments were closer together.	
		NAM also includes support and modeling of the nasal cartilages, correcting nasal projection, and lengthening the columella before primary surgery.	
20	Not mentioned	NAM plays an essential role in reducing the gap between segments and associated nasoalveolar and nasal deformities. Specifically, it has been argued that NAM acts as an inductive mechanism to stimulate the activity of immature nasal chondroblasts. It leads to interstitial expansion associated with improved nasal morphology.	NAM can improve several essential features like nasal cartilage deformity and nasal asymmetry. It can also stretch the nasal mucosal lining and lengthen the columella without surgery, improving appearance.
21	Not mentioned	Not mentioned	NAM minimizes wound healing disturbances and scar severity after surgery.

Article No.	Variables evaluated		
	Feeding	Gap between maxillary segments	Esthetics
22	Presurgical orthopedic treatment in children with cleft palate improves tongue function and facilitates newborn feeding.	Presurgical orthopedic treatment seeks to align the segments and reduce gap width to reduce soft tissue tension and facilitate cheiloplasty.	Presurgical orthopedic treatment aims to shape the nasal cartilages and reshape the columella. The durability of these effects is controversial.
23	Not mentioned	Intermaxillary segments in patients with NAM (CAD/CAM) and manual NAM decreased.	Not mentioned
24	Not mentioned	Not mentioned	Not mentioned
25	Not mentioned	After six months with NAM treatment, the posterior alveolar segments were aligned, and the premaxilla retracted into the oral cavity. Three alveolar segments were repositioned into their proper shape within the arch, and the lips were brought closer together.	Not mentioned

Assessing risk of bias. The risk of bias of each article was assessed according to The Cochrane Collaboration (2011) guideline: 32% of the articles were low risk for "reporting bias," while 20% of the studies were of high risk, and 48% had unclear risk (Fig. 2). The degree of bias was classified as low risk if all criteria were met, moderate risk if only one criterion was missing, and high risk if two or more criteria were missing.

Fig. 2: Risk assessment



Feeding: Ford[4] suggests that Grayson-type presurgical orthopedics initiated in the first month of life improves feeding. Santiago et al. [13] and Bravo et al.[6] agree. The latter study indicates that presurgical Orthopedics helps improve breastfeeding and feeding in general. Avhad et al. [15] state that newborns can suckle without nausea or difficulties with NAM. Hechenleitner et al. [3] conducted a survey among the guardians of patients with complete unilateral cleft treated at the Gantz Foundation, Santiago-Chile. Regarding the use of Dynacleft and its effect on feeding, 65% stated it was better, and 35% that it was neither better nor worse.[3] Alperovich et al. [16] say that routine use of NAM would not have a negative impact on breastfeeding. However, the AUGE Clinical Guide for cleft lip and palate 2015 [9] indicates that the use of presurgical orthopedics does not improve breastfeeding efficiency or effectiveness.

Esthetics: According to Bravo et al., [6] the nasoalveolar shaper allows for the early redirection of bone elements and affected soft tissues towards a favorable anatomical position. Additionally, it has better esthetic and functional surgical results, achieves greater symmetry of the lip and nasal cartilages, and improves nasal tip projection.

Santiago et al. [13] noted that nasal stents improve nasal tip projection and correct distorted and asymmetrical alar cartilage. Shetye [12] adds that they help to expand the nasal mucosal tissue lining. In patients with unilateral cleft lip and palate, the nasal stent straightens the deviated columella towards the noncleft side. In patients with bilateral cleft lip and palate, it lengthens the columella. This process takes three to four months.[12] The nasal conformer models and corrects the malposition of the nasal alar cartilage and the base of the nose on the affected side, providing good nasal symmetry.[14]

According to Nazarian et al., [17] the nasoalveolar shaper improves nostril width in both unilateral and bilateral cleft lip and palate patients.

In the study conducted by Broder et al., [18] caregivers of patients undergoing NAM therapy reported better postsurgical outcomes than caregivers of patients without a nasoalveolar shaper, especially regarding nose appearance.

Kamble et al. [19] evaluated nostril symmetry following NAM use with improved symmetry of the nose in height, width, and columella angle compared to the initial presurgical stage and with some relapse in nostril height (20%) width (10%), and columella angle (4.7%) at age 1.[19]

Gap between maxillary segments: Monasterio et al. [14] compared the two preoperative orthopedic techniques in 20 patients with unilateral cleft treated at Fundación Gantz, Santiago, Chile. Group A received treatment with the Dynacleft technique and nasal elevator for three months, before lip surgery. Group B underwent orthopedic treatment with the NAM-Grayson technique for three months before the first lip and nose surgery. All the patients were newborns. The results show that both preoperative orthopedic methods are effective. The altered nasal anatomy (increasing the angle of the columella) improves, and the width of the maxillary gap decreases in patients with complete unilateral cleft lip and palate.[14]

Table 2 shows the articles evaluated. Table 3 shows the data obtained from each article for feeding, gap between maxillary segments, and esthetics. When the article does not include these variables, "not mentioned" is entered. The articles that do not refer to any variable contextualize cleft lip and palate: its prevalence in Chile and its classification according to severity.

Discussion

The comprehensive treatment of cleft lip and palate patients is complex, and there are no rigid treatment protocols.[7] The results depend on the plasticity and moldability of the neonatal cartilaginous tissues; the earlier orthopedics

is started, the better the results.[15] The studies analyzed agree that the ideal time to start treatment is within 72 hours of birth,[6] when cartilage and bones have a high concentration of hyaluronic acid and can be easily molded.[4]

Few studies have been found on feeding; Alperovich et al. [16] mention that most cleft lip and palate patients cannot breastfeed naturally and that they generally use a Haberman feeder—a bottle for children with special needs. A survey of parents of patients undergoing NAM treatment revealed that 75% use this feeder, while 11% use another bottle. [16]

Regarding the esthetic contribution of presurgical orthopedics, thirteen of the articles studied agree that they are beneficial. This is because these corrections reduce excessive scar tissue, making the surgical scar less visible or almost invisible [6-8, 11, 15, 19-21]. However, the durability of these effects is controversial.[22] The 2015 AUGE Clinical Guide for cleft lip and palate [9] agrees that the results of preoperative orthopedics in nasal symmetry depend on the treating professional's skills and experience.

The gap between the maxillary segments would decrease according to nineteen of the articles reviewed, including those patients who used NAM created with CAD/CAM technology.[23] The other five articles do not mention this variable, and the remaining article states that there is no evidence in favor or against presurgical orthopedics.[9]

Advances in digital imaging technology, such as computer-aided design, computer-aided manufacturing and 3D printing, offer new alternatives to the orthopedic rehabilitation process.[24] The possibility of creating NAM devices with 3D technology has many benefits, such as reducing the emotional distress of patients and families due to the significant reduction in the number of adjustments and treatment time. Additionally, treatment precision improves significantly.[21] 3D facial scanners, which have a fast scanning speed compatible with the infant's movements,[25] can be used to collect valuable data on long-term growth effects, making this orthopedic process more effective and efficient. [21] Ritschl et al. [23] compared two groups of patients with cleft lip and palate: one group treated with conventional NAM and the other treated with NAM created using CAD/CAM technology. The results showed no significant clinical changes between the two groups, suggesting that CAD/CAM technology integration is as effective as the conventional approach. However, resins compatible with NAM treatment are limited since the material used for 3D printing must not be harder than the polymer used for hand-built NAMs.[21]

Presurgical orthopedics as a research topic is limited by the low number of existing randomized studies and the limited evidence on feeding. Of the twenty-five studies evaluated, only twelve analyzed this variable. Practical limitations are the low number of orthodontists trained in this procedure and its cost.[14]

Conclusion

NAM and Dynacleft improve esthetics and decrease the gap between the maxillary segments. The esthetic aspects include lip and nasal symmetry, nasal tip projection, and post-primary surgical scar. Regarding feeding, more evidence is needed. Results vary depending on treatment initiation time, which should begin within the first days of life.

Further long-term prospective clinical trials are needed to provide more evidence on the results obtained with preoperative orthopedics.

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Authorship contribution
1. Conception and design of study
2. Acquisition of data
3. Data analysis
4. Discussion of results
5. Drafting of the manuscript
6. Approval of the final version of the manuscript.

JSS has contributed in 1, 2, 3, 4, 5 and 6.
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