

Presurgical Orthodontic Preparation Of Newborns With Complete Bilateral Cleft Lip And Palate

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Abstract

Background: Bilateral cleft lip and palate (BCLP) can present quite a few challenges in management, especially due to pronounced premaxillary protrusion and displacement of the alveolar segments. While the traditional method of nasoalveolar molding (NAM) and removable appliance has been popular, its limitations in more severe cases have led us to explore alternative approaches. This study aims to evaluate how effectiveness of presurgical appliance fixation with mini-screws with partial vomer osteotomy when compared to the usual removable appliances.

Methods: In this retrospective case-control study, we included 57 infants with complete BCLP. They were divided into two groups: a case group of 27 treated with mini-screws-fixed appliances and partial vomer osteotomy, and a control group of 30 who received removable appliances. We assessed outcomes such as the reduction in cleft width, treatment duration, surgical parameters (like operative time and revision rates), postoperative recovery, and any complications.

Results: Patients who received microimplants showed significantly better cleft reduction ($22.0 \pm 0.74\text{mm}$ to $9.0 \pm 0.3\text{mm}$, $p < 0.001$) compared to those in the control group ($21.5 \pm 0.86\text{mm}$ to $12.1 \pm 0.95\text{mm}$, $p = 0.02$). The treatment was also much shorter, lasting 20-25 days for cases versus 7 months for controls. Surgical outcomes were better for the case group, with shorter operative times (98 ± 12 vs. 135 ± 18 minutes, $p = 0.01$), lower revision rates (7.4% vs. 25%, $p = 0.04$), and faster recovery from oral feeding (14 ± 3 vs. 21 ± 5 days, $p = 0.03$). In contrast, 33.3% of control patients developed ulcers, whereas none occurred with the case group. **Conclusion:** Combining mini-screws-fixed appliances and partial vomer osteotomy significantly outperforms traditional methods in managing BCLP, offering rapid cleft reduction, improved surgical feasibility, and better postoperative outcomes. This approach shows promise for severe cases, but further long-term studies on growth are needed.

Keywords: bilateral cleft lip and palate, presurgical orthopedics, microimplants, vomer osteotomy, nasoalveolar molding

INTRODUCTION

Bilateral cleft lip and palate (BCLP) is one of the most difficult and complicated congenital craniofacial abnormalities. To achieve the best functional and aesthetic results, a multidisciplinary approach must be meticulously coordinated [1]. As the most severe phenotypic expression of orofacial clefts, BCLP represents special anatomical challenges. These include nasal deformity, which includes a short columella, horizontally oriented nostrils [2], and flattened lower lateral cartilages, significant premaxillary protrusion from unrestrained growth at the vomero-premaxillary suture, which complicates surgical closure of the lip and palate, and alveolar segment displacement [3]. Despite the fact that the treatment of these patients has changed significantly in the last few decades, there are still significant differences over the best presurgical orthodontic preparation and its long-term effects on craniofacial development. Conventional methods, such as passive removable plates and nasoalveolar molding (NAM), have shown some promise in narrowing clefts and enhancing surgical results. Passive plates often lead to alveolar segment collapse after discontinuation, as seen in studies where lateral segments relapsed once appliance therapy ended [4]. Nevertheless, the fundamental limitations of these methods stem from their reliance on soft tissue anchoring, necessitating extended treatment periods. Furthermore, their effectiveness is significantly compromised in cases of severe deformity, where the elastic memory of displaced tissues often leads to incomplete correction and relapse [5,6]. Treatment options for BCLP have expanded since the introduction of skeletal anchoring in orthodontics,

which has completely changed the way complicated craniofacial abnormalities are managed. Orthopedic forces can be directly applied to maxillary bone segments due to the absolute anchoring provided by mini-screws, which normally have a diameter of 1.2 to 1.6 mm and have demonstrated dependable anchoring reliability in various clinical scenarios [7, 8]. When fixing appliances with mini-screws with partial vomer osteotomy, which separates the premaxilla from its vomerine attachment, this method enables controlled three-dimensional realignment of the maxillary components that have been displaced [16]. In addition to facilitating oral hygiene and nutrition, rigid internal fixation, which includes the fixation of orthodontic appliances, also speeds up bone repair, permits immediate mandibular function, and lessens complications like maxillomandibular lock [9]. These factors all help to improve post-surgical stability and patient acceptance. Additionally, during the crucial postoperative healing phase, fixation minimizes both vertical and horizontal relapse by maintaining the maxilla in its proper position [10, 11]. Despite these theoretical advantages, the literature contains limited comparative data on the efficacy of microimplant-assisted presurgical orthopedics versus conventional methods. Existing studies are predominantly case reports or small case series, with few controlled comparisons of treatment outcomes [12 - 14]. This retrospective case-control study was designed to provide a comprehensive evaluation of microimplant-assisted presurgical orthopedic treatment for complete BCLP, with specific attention to its comparative effectiveness versus traditional approaches.

METHOD

Study Design and Setting

This retrospective case-control study was conducted at the Department of Pediatric Dentistry and Orthodontics, the Research Institute of Pediatrics, and the Department of Maxillofacial Surgery at Morozov Children's City Clinical Hospital. The study included 57 neonates with bilateral complete cleft lip and palate (BCLP). The aim was to evaluate the efficacy of presurgical orthodontic preparation (fixation of a maxillary orthodontic appliance using mini screws combined with partial vomer osteotomy).

Participants and Intervention

Participants were divided into a case group (27 patients) who underwent presurgical orthodontic preparation and a control group (30 patients) who did not. Inclusion criteria included age ≤ 3 years, a BCLP diagnosis, and complete medical records. Patients with significant comorbidities or incomplete data were excluded. The case group received presurgical orthodontic preparation involving partial vomer osteotomy and fixation of a maxillary orthodontic appliance with titanium mini-screws (Absoanchor, Korea; 1.2–1.3 mm diameter, 5–6 mm length), allowing them to be installed in many areas of the upper jaw that were previously inaccessible. In contrast, the control group used removable orthodontic appliances and underwent surgery without presurgical preparation. All patients underwent comprehensive preoperative evaluations, including clinical blood and urine tests, chest X-rays, abdominal ultrasounds, ECG, and assessments by neonatologists, pediatricians, ENT surgeons, and anesthesiologists. Diagnostic maxillary models were created before and after presurgical preparation, with AutoCAD software used to measure cleft dimensions, palatal defect parameters, and intermaxillary bone angles.

Determining the Degree of Deformation of the Jaw

We observed children with bilateral cleft lip and palate before primary cheiloplasty surgery. In connection with the need to manufacture an orthodontic appliance, we were interested in the following parameters for choosing the design of the appliance: the dimensions and sizes of the protrusion of the intermaxillary bone, the angle of deviation of the intermaxillary bone from the midline of the face, and the distance between the anterior points of the alveolar processes of the lateral fragments of the upper jaw.

Outcomes

We aimed to evaluate the difference between presurgical fixation of a maxillary orthodontic appliance using mini screws with partial vomer osteotomy versus removable appliance in terms of: cleft width reduction,

treatment duration, reported complications, surgical outcomes represented as operative time and rate of revisions, and recovery duration .

Statistical Analysis

We used SPSS software for statistical analysis to compare treatment outcomes between the case and control groups. Paired t-tests were applied to assess changes within each group, such as cleft width reduction, which showed significant improvements in both groups. Independent t-tests were conducted to evaluate intergroup differences. Chi-square tests assessed categorical variables. Normally distributed data was presented as Mean \pm SD.

RESULTS

Patient Characteristics and Demographics

The study included 57 patients, with 27 in the case group and 30 in the control group. The majority of patients were male (68.5%), and regional referrals (61.8%) accounted for most cases (Table 1) .

Treatment Outcomes

Treatment outcomes were compared between traditional removable appliances and microimplant-fixed appliances with partial vomer osteotomy. The control group required an average treatment duration of 7 months and achieved cleft width reduction from 21.5 ± 0.86 mm to 12.1 ± 0.95 mm ($p=0.02$), but failed to attain complete bony contact .

Complications, including mucosal ulcers (33.3%) and high treatment discontinuation rates (23.3%), were observed. Conversely, the case group demonstrated superior outcomes, achieving cleft width reduction from 22.0 ± 0.74 mm to 9.0 ± 0.3 mm ($p<0.001$) within a 20–25-day active treatment period, followed by 15-30 days of retention. Complete bony contact was attained in severe cases ($P<0.05$) .(Table 2) .

Surgical outcomes also favored the case group, with reduced operative time (98 ± 12 minutes vs. 135 ± 18 minutes in controls, $P=0.01$) and lower revision rates (7.4% vs. 25%, $p=0.04$). Additionally, the case group achieved faster recovery to full oral feeding (14 ± 3 days vs. 21 ± 5 days in controls, $p=0.03$) and exhibited no mucosal damage. Imaging with CT-guided planning ensured accurate microimplant placement and optimized device fitting. Cheiloplasty was performed earlier in the microimplant group (average age: 4 months) compared to the control group (2+ years), contributing to 80-85% success in achieving stable rehabilitation outcomes and reducing secondary deformities.

Table 1: Demographic characteristics

| Characteristic | Number (N=57) | Percentage (%) |
|--|---------------|----------------|
| Gender | | |
| Male | 39 | 68.5 |
| Female | 18 | 31.5 |
| Age | | |
| Newborn to 3 years | 57 | 100 |
| Residence | | |
| Moscow | 22 | 38.2 |
| Regions | 35 | 61.8 |
| Type of Cleft | | |
| Complete Bilateral Cleft Lip and Palate (BCLP) | 57 | 100 |

Table2: Comparison of Treatment Outcomes Between Case and Control Groups

| Outcome | Case Group (n = 27) | Control Group (n = 30) | p-value |
|-------------------------------------|------------------------|---------------------------|-----------------|
| Initial cleft width (mean \pm SD) | 22.0 ± 0.74 mm | 21.5 ± 0.86 mm | - |
| Post-treatment cleft width | 9.0 ± 0.3 mm | 12.1 ± 0.95 mm | Case: < 0.001 |

| | | | |
|------------------------------------|-----------------------|------------------|---------------|
| | | | Control: 0.02 |
| Complete bony contact achieved | Yes (in severe cases) | No | < 0.05 |
| Duration of active treatment | 20 – 25 days | ~7 months | - |
| Retention period | 15 – 30 days | Not specified | |
| Mucosal complications | None | Ulcers in 33.3% | |
| Treatment discontinuation rate | 0% | 23.3% | - |
| Surgery duration (cheiloplasty) | 98 ± 12 minutes | 135 ± 18 minutes | 0.01 |
| Surgical revision rate | 7.4% | 25% | 0.04 |
| Time to resume full oral feeding | 14 ± 3 days | 21 ± 5 days | 0.03 |
| Age at cheiloplasty | 4 months | >2 years | - |
| Stable rehabilitation success rate | 80-85% | Lower | - |
| CT-guided implant/device fitting | Yes | No | - |

DISCUSSION

The findings of this study demonstrate significant advantages of presurgical miniscrew-fixed appliances combined with partial vomer osteotomy over traditional removable appliances in the management of bilateral cleft lip and palate (BCLP). Our results align with the growing body of evidence supporting bone-anchored techniques for severe craniofacial anomalies while addressing several limitations of conventional approaches that have persisted since the early days of cleft care [15, 16]. The most notable result was the greater reduction in cleft width that the case group ($22.0 \pm 0.74\text{mm}$ to $9.0 \pm 0.3\text{mm}$) produced in comparison to removable appliances ($21.5 \pm 0.86\text{mm}$ to $12.1 \pm 0.95\text{mm}$). The elastic memory of misplaced tissues, which frequently causes recurrence with traditional treatments, may be prevented by direct skeletal pressures via microimplants, according to our findings. The significant reduction in treatment length (20–25 days active phase compared to 7 months for controls) signifies a paradigm shift in presurgical preparation and is consistent with earlier research suggesting that orthodontic treatment time can be shortened by combining osteotomy and miniscrew anchoring [17]. Surgical outcomes provided additional support for the microimplant strategy. It is probable that the 27% decrease in operating time (98 ± 12 vs. 135 ± 18 minutes, $p=0.01$) is due to less tissue strain during closure. The 70% relative reduction in revision rates (7.4% vs 25%, $p=0.04$) suggests that microimplants combined with osteotomy may help address complications of the cleft surgery, and this aligns with previous studies [17, 18]. The 80-85% long-term success rate suggests this approach may mitigate secondary deformities, though longitudinal follow-up is needed to confirm this potential advantage over conventional methods. Limitations are worth taking into account. Although the groups' demographic matching improves comparability, the retrospective design may create selection bias. The small sample size ($n=27$ microimplant cases) indicates that prospective multicenter collaboration with a larger population is necessary for future research because full BCLP is uncommon. These findings have important clinical implications for surgeons; the demonstrated reduction in operative difficulty and complications supports microimplants as a valuable adjunct, particularly for wide clefts. For orthodontists, the technique offers a predictable way to achieve bony alignment without prolonged treatment.

CONCLUSION

This study shows that in every measured parameter—treatment effectiveness, surgical feasibility, postoperative recovery. presurgical miniscrew-fixed appliance implantation combined with partial vomer osteotomy performs noticeably better than conventional removable appliances. By using bone anchoring to provide regulated three-dimensional alignment, this technology overcomes the basic drawbacks of traditional techniques and allows for quicker, more predictable recovery.

DECLARATION

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Ethical Considerations

This study was approved by the Institutional Ethics Review Board. Prior to data collection, written informed consent was obtained from the parents of the participating children, in full compliance with the Helsinki Declaration principles. The data were used solely for scientific research purposes and were kept strictly confidential, with no identifying information included. Parents had the right to withdraw their children from the study at any time without any consequences.

Conflict of Interest

The researcher declares no conflict of interest related to this study.

Data Availability

The data and materials related to this study are available upon request.

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