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Original Article

Outcomes of Presurgical Nasoalveolar Molding using Modified Nostril Retainers in Patients with Unilateral Cleft Lip and Palate at an Average Follow-up of 2 Years

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Main Points

- Nasal molding was started without decreasing the cleft width to 5 mm.
- No patient developed a mega nostril.
- Treatment outcomes were stable for a mean of 2.2 years after surgery.

ABSTRACT

Objective: Presurgical nasoalveolar molding (PNAM) using a modified nostril retainer is a new treatment approach. This study aimed to evaluate the outcomes of early nasal molding using this approach with an average follow-up of 2 years in patients with severe unilateral cleft lip and palate.

Methods: This retrospective study included 18 patients with unilateral cleft lip and palate without genetic syndromes who underwent PNAM with modified nostril retainers. The Grayson technique was employed with an intraoral plate to approximate cleft segments. Nasal molding was initiated before reducing the cleft width to 5 mm. Measurements, including alar base height ratio (ABHR), nasal floor width ratio (NFWR), columellar length ratio (CLR), columellar angle (CA), and nostril axis inclination on the cleft and non-cleft sides (NAI-C and NAI-NC, respectively), were calculated from standard photographs taken before PNAM (T1), after PNAM (T2), after an average of 1.81 months post-surgery (T3), and after an average of 2.2 years after T3 (T4). Pairwise comparisons of values at the four time points were conducted.

Results: NFWR, CLR, CA, NAI-C and NAI-NC significantly increased after PNAM ($p<0.05$). However, no significant change was observed in ABHR ($p>0.05$) from T1 to T2. These outcomes were maintained at T4, and no patient developed a mega nostril.

Conclusion: The use of a modified nostril retainer for nasal molding appears to provide stability during the high probability of relapse reported in the literature.

Keywords: Unilateral, cleft palate, nostril retainers, presurgical molding

INTRODUCTION

Unilateral cleft lip and palate are one of the most common congenital craniofacial anomalies, often associated with various dentoalveolar anomalies, such as midface deficiency, distortion, displacement, and tissue deficiency of nasal structures.[1,2] Therefore, presurgical nasoalveolar molding (PNAM) is crucial, particularly in severe cases. Maternal estrogen passing through the placenta elevates the hyaluronic acid level in the fetal blood during pregnancy. Hyaluronic acid alters cartilage and connective tissue elasticity by breaking down the intercellular matrix; thus, increased plasticity and decreased elastic deformation of the cartilage lead to cartilage molding.[3-5]

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After birth, infants no longer receive maternal estrogen, causing a gradual decrease in hyaluronic acid levels in their blood. Consequently, cartilage can be more easily shaped within the six weeks following birth.[3]

Grayson recommended that nasal molding should start after achieving the laxity of the nasal soft tissue.[1,2] Inserting a nasal stent before achieving the laxity of the alar rim is sometimes impossible when the body of the nasal stent is rigid because the tension of the tissues reduces the space available for inserting the body of the stent. However, the modified nostril retainer is manufactured using soft acrylic; thus, it can enter the nose without any irritation before achieving the laxity of the nasal soft tissue. Therefore, the cleft width need not be decreased to 5 mm to achieve the laxity of the nasal soft tissue and start nasal molding.[6,7] This study aimed to evaluate the outcomes of this new approach in which nasal molding is started earlier than in the conventional method at an average follow-up of 2 years in patients with unilateral severe cleft lip and palate.

METHODS

This retrospective study received approval from the Clinical Research Ethics Committee of Uşak University Faculty of Medicine (approval no: 117-117-13, date: 02.06.2021). Informed consent was obtained from the parents of each patient after a detailed explanation of the procedures. The study protocol complied with the tenets of the Declaration of Helsinki. Patients treated consecutively Mersin and Uşak University selected based on the following criteria: (1) complete unilateral cleft lip-cleft palate with a cleft width exceeding 5 mm, (2) undergoing PNAM between 2017 and 2020, (3) absence of genetic syndromes or other congenital deformities, and (4) availability of clinical records and photographs suitable for analysis at four defined time points. Data were collected at the following time points: within two weeks of birth before the initiation of nasoalveolar molding (T1), after PNAM (T2), within an average of 1.81 months postsurgery (T3), and within an average of 2.2 years after T3 (T4). All surgeries were performed [Hacettepe University] by the same surgeon. The 18 patients (11 boys and 7 girls) included in this study met all the inclusion criteria.

Treatment Protocol

Nasal molding was carried out using a modified nostril retainer that was manufactured from soft acrylic (Vertex Soft, Vertex-Dental B.V., Soesterberg, The Netherlands), and cleft reduction was performed with an intraoral plate according to the Grayson technique (Figure 1A). In the initial session, an L-shaped tape was affixed to the alar groove of the non-cleft nose and lip, and then the tape was stretched until the columella was as upright as possible, and the band was attached to the cleft lip. The appliance was inserted and then secured in the mouth using rubber bands and tape.

Finally, the modified nostril retainer was placed on the nose and attached to the cheek using tapes. Weekly activation was performed adding soft acrylic to the cleft side of the modified nostril retainer. If columella lengthening was needed, soft acrylic was applied to the noncleft side as well (Figure 1B). The intraoral plate was selectively ground in areas expecting movement, while soft acrylic was added to regions requiring molding to reduce the cleft width. If the nose was asymmetrical after the greater and lesser alveolar segments touched each other, nasal molding was continued. When the modified nostril retainer is appropriately used, a reduction in tissue tension due to activation is expected after approximately one week. There might be two reasons for continued tension in the soft tissue: irregular use or the end of plastic deformation in the nasal cartilage. If no changes were observed in soft tissue tension, cleft and noncleft nostril heights were recorded, and the modified nostril retainer was not activated. If no changes were observed in soft tissue tension nostril heights during three subsequent visits, and family cooperation was ensured, it was concluded that the nasal cartilage's moldability was lost. All patients used modified nostril retainers as nasal stents for 3-6 months. Standardized digital photographs of all patients (frontal and basal views) were obtained, as recommended by Titiz and

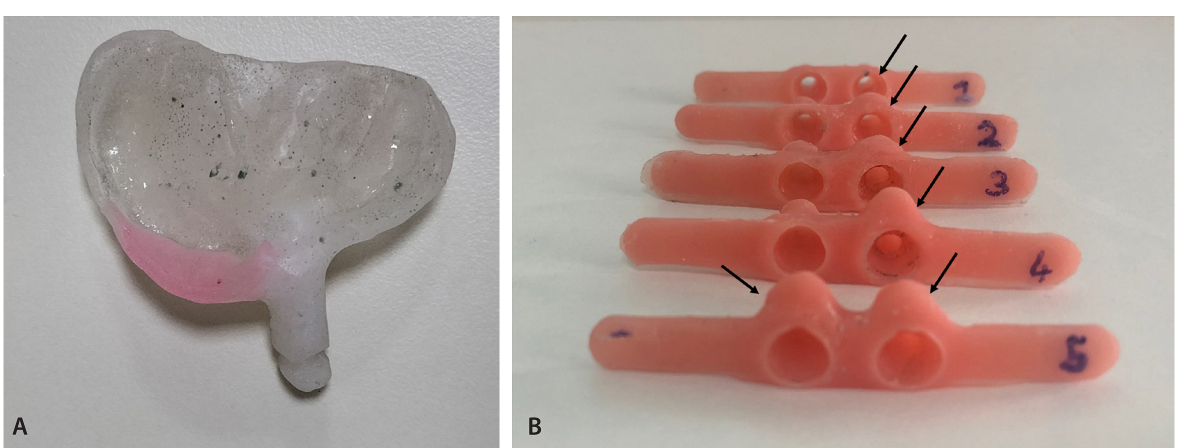


Figure 1. A: Intraoral appliance B: Modified nostril retainer activation: In the first visit, the non-activated appliance (1) is attached to the nose, and the appliance is activated using soft acrylic at each visit. If columella lengthening is required, bilateral activation is performed (5). One modified nostril retainer is used for each patient. For a better understanding of the method, each step is shown using a different modified nostril retainer

Aras.[8] From frontal view photographs, the alar base height ratio (ABHR)[9] was calculated. From basilar oblique view photographs, the columellar angle (CA),[10] nostril axis inclination on the cleft and noncleft sides (NAI-C and NAI-NC, respectively),[11] nasal floor width ratio (NFWR),[9] and columella length ratio (CLR)[9] were calculated (Figure 2).

Statistical Analysis

The minimum number of patients needed to compare pre-and post-treatment measurement values with a 95% confidence level was calculated using G Power analysis. (Version 3.1.9.2; Heinrich-Heine-Universität Düsseldorf, North Rhine-Westphalia, Germany). The effect size reported in a previous study, was 0.79.[12] Because of the analysis (α=0.05), the standardized effect size was 0.79. The minimum sample size was determined to be 15, with a theoretical power of 0.80.

Statistical analysis was performed using IBM SPSS version 25.0 (IBM Corp., NY, USA). The normality assumption was checked using the Shapiro-Wilk test in the first step of data analysis. Pearson's chi-square correlation analysis was performed when data were determined to be normally distributed to determine measurement error and similarity between measurements. Spearman rank difference correlation analysis was performed in cases in which the normality assumption was not met. The two-way Friedman test was applied to analyze the difference between the means of variables that were nonnormally distributed and had three or more dependent groups. The adjusted Bonferroni test was used to determine whether the groups were distinct. P-values <0.05 were considered statistically significant.

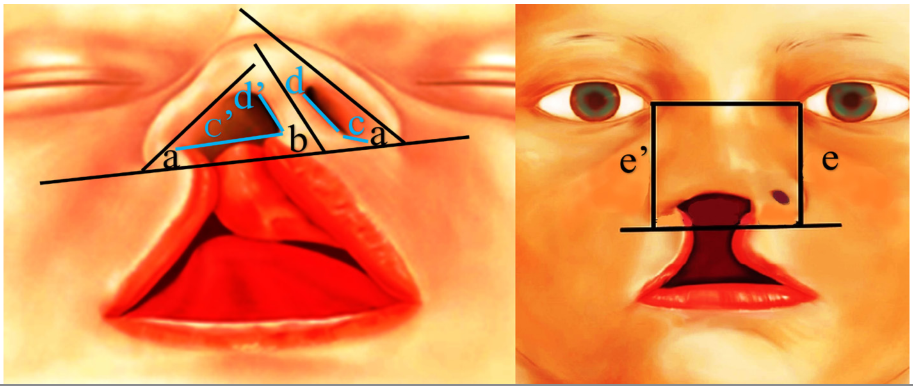
Method Error

Measurements were repeated by the same researcher using 10 randomly selected facial photographs at 1-month intervals under standard conditions to facilitate intraobserver reliability testing. Correlation coefficients between measured values were 0.85, which suggested that the method error was clinically acceptable.

RESULTS

The alveolar cleft width varied between 7 and 16 mm, with a mean of 10.6 mm. The timing of the treatment stages is shown in Table 1. During the examination of patient clinical follow-up cards, no information was found regarding soft tissue nasal problems such as large nostrils, nasal epithelial compression, columellar deformation, or bleeding. However, band-induced irritation was observed on the cheeks in some patients. The progressive stages of modified PNAM in an infant are illustrated in Figure 3. Columellar angle (CA) increased after PNAM (Table 2, T1-T2, p<0.05), approached a right angle after primary lip surgery (T2-T3, p<0.05), and remained stable at T4 (Table 2, T3-T4, p>0.05). Nostril axis inclination on the cleft (NAI-C), nostril axis inclination on the noncleft side (NAI-NC) nasal floor width ratio (NFWR), and columella length ratio (CLR) increased after PNAM (Table 2, T1-T2, p<0.05) and were found to be stable at T4 (Table 2, T3-T4, p>0.05). Treatment did not result in an improvement in alar base height ratio (ABHR), as the mean ABHR remained similar at all time points (T1, T2, T3, T4).

A



B

Figure 2. Measurements used in the study. A: a. Nostril axis inclination cleft (NAI-C) and noncleft (NAI-NC), angular measurement between the longitudinal plane of the nostril and the nasal width plane; b. columellar angle (CA), angular measurement between the columellar axes and nasal width plane at the subnasale; c/c': nasal floor width ratio (NFWR), nasal floor width on the non-cleft side/nasal floor width on the cleft side; d'/d: columellar length ratio (CLR), columellar length on the cleft side/columellar length on the non-cleft side. B: e/e' alar base height ratio (ABHR), alar base height on the noncleft side/alar base height on the cleft side

Table 1. Timing of treatment

Timepoint	n	Minimum	Maximum	Mean	Standard deviation
T1 (days)	18	2.00	12.00	6.38	3.01
T2 (months)	18	2.00	4.00	2.97	0.55
T3 (months)	18	3.00	5.00	4.02	0.52
T4 (years)	18	1.50	3.00	2.20	0.68

T1: Within 2 weeks of birth, before initiation of nasoalveolar molding; T2: After presurgical nasoalveolar molding; T3: Within an average of 1.81 months after primary lip surgery; T4: Within an average of 2.2 years following T3 time point

Figure 3. Progressive stages of modified presurgical alveolar nasoalveolar molding treatment. A: Pre-treatment basal view (10 days); B: during PNAM treatment; C: post-treatment basal view (6 weeks); D: Post-treatment basal view 1.5 months after primary lip surgery; E: Post-treatment basal view 3 years after primary lip surgery.

Table 2. Comparison of measurements assessed at T1-T4 timepoints

	T1 SD	T2 SD	T3 SD	T4 SD	T1/T2	T1/T3	T1/T4	T2/T3	T2/T4	T3/T4
CA	29.66±13.68	79.05±6.28	85.72±3.46	85.77±3.05	0.012*	0.000*	0.000*	0.033*	0.0367*	1.00
NAI-C	16.88±9.83	45.72±4.19	48.61±4.88	47.77±4.50	0.001*	0.000*	0.000*	1.000	0.639	1.00
NAI-NC	38.72±9.24	46.16±3.14	47.61±3.92	46.83±3.91	0.000*	0.000*	0.001*	1.000	1.000	1.00
NFWR	31.50±6.34	74.94±8.43	89.88±3.77	89.61±4.13	0.05*	0.000*	0.000*	0.005*	0.027*	1.00
ABHR	91.66±2.42	91.72±2.19	91.55±2.09	91.33±2.37						
CLR	32.33±9.75	76.72±7.10	84.22±6.94	84.66±6.38	0.012*	0.000*	0.000*	0.233	0.059	1.00

*Significant difference ($p<0.05$). The two-way Friedman test was applied to analyze the difference between the means of the variables. The adjusted Bonferroni test was used to identify the group or groups that made the difference. No statistically significant differences were found between the average ABHR values over time. For this reason, no pairwise comparisons were made

CA: columellar angle; NAI-C and NAI-NC: Nostril axis inclination on the cleft and non-cleft sides respectively; NFWR: nasal floor width ratio; ABHR: alar base height ratio; CLR: columella length ratio; T1: within 2 weeks of birth, before initiation of nasoalveolar molding; T2: after presurgical nasoalveolar molding; T3: within an average of 1.81 months after primary lip surgery; T4: within an average of 2.2 years after T3

DISCUSSION

High-quality photographs are essential for evaluating treatment outcomes. In patients with CLP, two-dimensional (2D) facial photographs are commonly employed for documentation. However, the utilization of three-dimensional photographs is increasing. Digital stereophotogrammetry is a noninvasive technology with several advantages, including accurate measurements, reproducibility, and quick image acquisition.[13] However, the restricted portability and high cost of the system restrict its use as a recording standard; therefore, 2D photographs remain important for evaluating treatment outcomes.

Photogrammetry is the art, science and technology of obtaining reliable information about objects and their immediate surroundings through measurement on photographs.[14] The mathematical model of photogrammetry is based on central prospective projection, with the photograph serving as the projection plane. Titiz[15] determined the effects of positioning errors on ratio and angle measurements in patients with unilateral CLP. The study showed that using 2D photographs acquired according to the central projection rules specified by photogrammetry can yield reliable results for ratio and angle measurements.

A nasal molding device not attached to an intraoral plate offers several advantages. Some patients with cleft lip and palate may be fed using a specialized bottle system designed to help babies with serious sucking difficulties, such as a cleft palate. This may lead to poor parental compliance with the use of an intraoral appliance. Moreover, the use of intraoral plates may occasionally lead to sores or fungal infections, requiring the removal of the intraoral plate for some time. To overcome these limitations, a modified nostril retainer was manufactured using a special mold, enabling nasal molding independent of an intraoral appliance. In our previous work, we only used modified nostril retainers for patients with UCLP, without maxillary collapse, and with a cleft width of less than 6 mm.[16] However, in severe cleft cases, intraoral plates are necessary for properly aligning the alveolar segments because uncontrolled forces are more likely to occur without an intraoral plate.[17] In this study, the cleft width was from 7 to 16 mm (mean 10.6 mm); thus, an intraoral plate manufactured according to the Grayson alveolar aligning technique was preferred to reduce the cleft width.

The Grayson technique is a well-known method that has undergone several modifications. Grayson recommends adding a nasal stent when the width of the cleft is reduced to 5 mm to achieve laxity of the nasal soft tissues and to avoid increasing the nostril circumference.[1,2] In 2009, Southmedic produced a ready-made nasal elevator with a special flexible tape called Dyna-Cleft protocol (Canica Design Inc., Ottawa, Canada). In the Dyna-Cleft protocol, both alveolar and nasal molding were initiated from the first day without waiting for the reduction of the cleft width to 5 mm, which is similar to our technique. No study has reported the occurrence of a mega nostril using the Dyna-Cleft protocol[17,18] as a result of early shaping, as claimed by Grayson. Jahanbin et al.[19] evaluated the effect of immediate versus delayed addition of the nasal stent to the nasoalveolar molding plate on the nose shape in infants with unilateral cleft lip and palate. In the early treatment group, nasal molding was started without reducing the cleft width to 5 mm. In the late-onset group, nasal molding was initiated after the cleft width was reduced to 5 mm. The results showed that early use of nasal stents provided more desirable results concerning decreasing the width of the nostrils, increasing their height, and correcting the angle of the columella without any adverse effects on the nostrils after treatment. However, nasal stents fabricated using orthodontic acrylic, even if it has a soft acrylic outer surface, may increase the risk of mucosal injury in cases with wider clefts. The stretched soft tissue reduces the space available for inserting the stent body. Therefore, a modified nostril retainer fabricated using only soft acrylic may lead to fewer complications in the nasal soft tissue in patients with severe clefts.

Similar to our study, Matsuo et al.[3] and Matsuo and Hirose[5] reported the use of symmetrical or asymmetrical silicone nostril retainers for nasal molding. However, our technique used nostril retainers made of soft acrylic that had wings that facilitated taping. These wings ensured that the modified nostril retainer remained stable within the nose without requiring support from the nasal base. In contrast, Matsuo et al.[3] used silicone nostril retainers that did not have wings. In such silicone nostril retainers, the resistance from the nasal soft tissue must be overcome by the anchorage support provided by the nostril floor.[3] The size of the cleft may lead to an inability of the nostril base to provide adequate support. Additionally, maintaining the position of silicone nostril retainers might be problematic.[20] Also, the addition of silicone for activation is more difficult than that of soft acrylic. Furthermore, tape adheres to soft acrylic more easily than to silicone.[7,8]

Doruk and Kiliç[21] and Larson et al.[22] introduced external devices to improve alveolar position and nasal septum symmetry. In both techniques, the nostril molding device was attached to a head cup. Although these systems separate the intraoral plate from the nasal molding device, anchoring the nasal molding device on the infant's head may disturb the baby's comfort and sleep patterns.

In PNAM, the modified nostril retainer provides some advantages for the physician and the family. Family cooperation is critical to the success of PNAM. According to our clinical observations, the motivation of families increased when they observed visual changes in their children in a short time as nasal molding was started in the first visit. The air holes in the modified nostril retainers also reduced the anxiety of the families regarding proper breathing of the infants. In the Grayson method, adding a nasal stent to the intraoral plate requires a sensitive laboratory step. The fit of the nasal stent is crucial for the correct molding force and stability of the intraoral plate. Manufacturing the modified nostril retainer does not involve a sensitive laboratory step.

The columella is located centrally at the base of the nose, is a prominent aesthetic component of the nasal midline, and has a pivotal role in determining the shape of the nasal base. Deviations in the columella and variations in its width and height lead to distortion of the nostril shape and frequently compromise function.[23] In patients with unilateral cleft lip and palate, deformation is observed not only on the cleft side of the nose but also on the noncleft side. Another advantage of PNAM using a modified nostril retainer is that it can lengthen the columella if necessary. Ruíz-Escolano et al.[24], Titiz and Aras[8], Abhinav et al.[17], and Monasterio et al.[25] reported a correction of columella deviation of 23.68°, 28.5°, 22°, and 25.9°, respectively, in patients with unilateral cleft lip and palate treated using the Grayson technique. In this study, correction of the columella deviation was 49.84°. In the Grayson technique and in our technique, an L-shaped tape is attached from the alar groove of the noncleft nose and lip to the cheek of the cleft side until the axis of the columella is corrected to the maximum extent permitted by the soft tissues. Taping from the noncleft side to the cleft side applies rotational force to the columella at the rotational center of the nasal stent in the nostril. In the Grayson technique, this force is mostly absorbed by the soft tissue of the noncleft nostril; however, with the presented technique, the modified nostril retainer in the noncleft nostril transmits the force generated by the tape and pushes the columella to the midline. In this study, more effective transmission of the force generated by the tape may have resulted in more uprighting of the columella than that with the classical method.

Previous studies recommended using a nasal stent to retain the corrected nostril shape after primary lip surgery. In our clinic, patients use the modified nostril retainer as a nasal stent after primary lip surgery, potentially contributing to long-term stability. However, as this is a retrospective study, conducting a prospective study were to be planned, it would be unethical to recommend not using a nasal stent to evaluate the efficacy of nasal molding with a modified nostril retainer. Cartilage memory and scar contraction are key factors in the long-term deterioration of the cleft nose.[26] Cartilage memory is defined as a tendency of cartilage to revert to its original position over time due to elasticity.[27] Starting nasal cartilage molding as early as possible might achieve more long-lasting molding of the relatively plastic immature cartilage and avoid the elastic deformation that occurs in the older, more mature, and less plastic cartilage. Early cartilage shaping reduces cartilage memory.[27] Thus, early shaping may have a more significant effect on stability than using a nasal stent after primary lip surgery.

According to Roux's concept of orofacial orthopedics and the functional matrix theory put forward by Melvin L. Moss in the 1960s, there is an intimate relationship between shape, structure, and function. Modified nostril retainers used during PNAM may enhance nasal breathing, aligning with the functional matrix theory, where evolving function contributes to the permanence of molding and more normal development of the nasal airway.

Chang et al.[28] observed varying degrees of relapse in nasal cleft deformity after primary rhinoplasty. Tang et al.[29] found significant asymmetry in the nose nine months after primary lip repair. In this study, with an average follow up of 2.2 years after primary lip surgery, no relapse was observed. Initiating nasal molding with modified nostril retainers before reducing the cleft width to 5 mm is likely advantageous for maintaining symmetry, especially in patients with large clefts.

Study Limitations

First, being a retrospective study, we could only investigate routinely collected data, limiting the scope of data collection. More data could be obtained from 3D photographs. Feasibility issues in the clinic prevented their inclusion. Another method for evaluating the nasolabial region is impressions of the nasoalveolar region. However, obtaining such impressions requires general anesthesia for the infant and the use of unpressurized techniques.[30] The ethical concerns and impracticality of sedating infants solely for impressions at the initial stage limit their use to primary lip surgery. Moreover, recording impressions without applying pressure to the soft tissues, which can cause distortion, is challenging.[30] Another limitation is the evaluation period of approximately 2.2 years for treatment outcomes. Future studies with longer follow-up periods are necessary. Further studies with a control group, including patients treated with the Grayson technique, will offer valuable evidence to precisely determine the effectiveness of early nasal molding before reducing the cleft width to 5 mm in patients with severe cleft lip and palate.

CONCLUSION

No relapse occurred within a maximum of one year after primary lip surgery, which is reported in the literature as the period with a high probability of relapse. Moreover, early treatment did not lead to the formation of meganails.

Ethics

Ethics Committee Approval: The study was approved by the the Clinical Research Ethics Committee of Uşak University Faculty of Medicine (approval no: 117-117-13, date: 02.06.2021).

Informed Consent: Informed consent was obtained from the parents of each patient following a detailed explanation of the procedures.

Peer-review: Externally peer-reviewed.

Author Contributions: Concept - S.T., E.O., İ.E.G.; Design - S.T., E.O., İ.E.G.; Data Collection and/or Processing - S.T., E.O., İ.E.G.; Analysis and/or Interpretation - S.T., E.O., İ.E.G.; Literature Review - S.T., E.O., İ.E.G.; Writing - S.T., E.O., İ.E.G.

Declaration of Interests: The authors have no conflicts of interest to declare.

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