

The size of palatal cleft and surgical outcome in palatal cleft patients treated with and without feeding plate

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ABSTRACT

Background and aim: Cleft lip and cleft palate are among the most common congenital anomalies in the head and facial area. With a goal of detaching the oral cavity from the nose and helping baby's feeding, a palate appliance named the feeding plate was provided for patients. Study was conducted to investigate the effect of the feeding plate on the cleft features and the resulting surgical outcomes. **Materials and Methods:** 14 neonates with cleft palate were entered into the present study. They were distributed into case and control groups (n = 7). For the case group, the feeding plate was provided during the first week after the birth, and they were visited at least three times before surgery. The control group included patients who did not receive a feeding plate who were prepared for surgery. Surgery outcomes (end-flap necrosis, hematoma, and fistula) were evaluated one week and one month after the surgery. Data were analyzed by SPSS-20 using a paired t-test. **Findings:** The width of alveolar ridge in the anterior, medial and posterior regions increased in the case group after using the feeding plate (during surgery), the increase was significant in the anterior and posterior regions (p = 0.001 and p = 0.006, respectively). The width of the cleft palate in the case group decreased after using the feeding plate in all three areas, the decreases was statistically significant in the anterior region (p = 0.045). Examining the width of the cleft palate during surgery between the two case and control groups, it was concluded that in each of the anterior, medial and posterior regions, the width of the cleft palate was lower in the control group, the difference was not significant though. Examining the ratio of the width of the cleft palate to that of the alveolar ridge between the case and control groups during the production of the feeding plate and during the surgery in the anterior, medial and posterior regions showed that the ratio of the cleft palate width to the alveolar ridge width decreased during surgery in all three regions. This reduction was significant in the anterior and posterior regions (0.0012 and p = 0.006 respectively). **Conclusion:** The results of the present study showed that utilizing feeding plate was effective in reducing the size of the cleft palate and decreasing ratio of cleft palate width to that of the alveolar ridge in the case group. Using feeding plate did not affect the surgery outcome.

Keywords: Feeding plate, cleft palate, end flap necrosis, hematoma, fistula



1. INTRODUCTION

Cleft palate and cleft lip are among the most common congenital anomalies in the head and facial area, occurring in one out of every seven hundred births (Yu et al., 2009; Fisher et al., 2011). The incidence etiology of the cleft is unknown; however, both environmental and genetic factors can be responsible for the defect (Yu et al., 2009). Poor nutrition, tobacco and alcohol consumption, viral infection, and some drugs are among the major environmental risk factors (Yu et al., 2009). There are a number of complications associated with the cleft palate and lip, including eating difficulties, speech problems, otitis media, hearing loss, passage of nasal discharges into one's mouth, and unpleasant odor, among which the baby's nutrition is the major concern. There is also evidence concerning growth retardation of babies with cleft palate and palate lip in comparison to normal babies (Fisher et al., 2011; Harville et al., 2005; Tse et al., 2012). Feeding plate is a prosthetic device designed to block the site of cleft palate, separating the oral cavity from the nasal cavity (Yu et al., 2009). It should be constructed in the early days of the baby's birth, since the level of hyaluronic acid is high in the first 6 weeks, and it allows breakage of the intercellular matrix, resulting in the plasticity and formability of the soft tissue and bone tissue. Furthermore, the adaptation of the baby to the device is high in that period (Tse et al., 2012). Surgical interventions are required after growth of the baby. Many clinicians prefer to carry out cleft lip surgeries during infancy at 3-6 months of age (Hoghoughi et al., 2019).

A palatoplasty surgery is performed when the infant is 10 months old. In the meantime, it is still unknown whether the use of feeding plate is helpful in facilitating the surgical process and whether it can affect surgical outcomes (the probability of a flap necrosis, or the occurrence of fistula) (Scapoli et al., 2005; Ripa et al., 1993; Carinci et al., 2007; Fonseca, 2017; Shkoukani et al., 2013). Although the probability of post-palatoplasty flap necrosis is unknown, this would be unpleasant for both the patient and the surgeon (Scapoli et al., 2005). The incidence rate of forming a fistula after the initial palatoplasty is reported to be between 1 and 70 percent. A new systematic review has reported this to be 8.6 percent. Various factors including the type of cleft and its severity, the age of the patient, the surgical approach, and the surgeon's expertise are considered in assessing the occurrence of post-palatoplasty complications (Fonseca, 2017).

In a study, Bongaarts et al., (2006), (the Netherlands) indicated that the orthopedic appliances of the newborns have no effect on the size of the maxillary arch in the deciduous teeth period in a child with a cleft palate and one-sided lip. Nao kinouchi et al., (2018) have reported several benefits of Pre-surgical nasoalveolar molding such as: reduced need for secondary bone graft and minimized extent of primary nasal surgery and scar tissue. Rossell Perry et al., (2017) studied mucoperiosteal flap necrosis following the first palatal plastic surgery in cases with cleft palate. In general, palatal flap necrosis was seen in 4 of 1174 cases. They identified the causes of major post-surgical defects as tension of wound closure, infection, hematoma, and flap necrosis, being the most frequent reason for post-surgical defect.

In cases with cleft palate, Perry et al., (2017) investigated the risk factors of mucoperiosteal flap necrosis following initial palatoplasty. This retrospective study concluded that being female, being over 15 years old, type of cleft (bilateral and incomplete), and the intensity of cleft palate are related to an increased risk of flap necrosis. Bauer et al., (2017), (Germany) conducted a study to determine the dentoalveolar and palatine growth in the first months of birth. Molds were made from maxilla of 32 neonates with cleft palate on both the first day of birth, and then on a monthly basis for 5 consecutive months, and a feeding plate were produced every month for each baby. Longitudinal, transverse, and vertical growth of palate and dento-alveoli was measured. The variation of the longitudinal growth was significant for the first three months. The variation of the transverse growth was significant on all monthly intervals. The variation of vertical growth was not significant between the monthly intervals. The analysis of the growth results concerning the feeding plate showed that making a larger feeding plate per month would help the extension of alveoli each month.

Therefore, the present study was carried out based on the probability of the effect of the feeding plate on the post-palatoplasty complications and its effect on the size of the cleft palate and the alveolar ridge width.

2. MATERIALS AND METHODS

In this study, 14 cleft palate patients referring to Babol medical centers (children aged 9 to 18 months with cleft palate who had initially undergone palatoplasty surgery and had no syndromic problems) were studied (January 2019 –December 2019 with ethical approval number: MUBABOL.HRI.REC.1396.217). For seven patients (50%) who referred at birth the production of casts and feeding plate was conducted (case group). The width of Alveolar ridge and cleft palate at birth was measured from the cleft palate casts in anterior, medial and posterior regions of the patients in the case group. Seven patients (50.0%) did not receive feeding plate as they did not refer at birth (control group).

The casting was done with the purpose of making a feeding plate with a heavy silicone body (Panacil, Germany), and the thickness of the cleft in the three anterior, medial, and posterior sections of the cleft palate was measured on the cast (Shkoukani et al.,2013; Nalabotho et al., 2020). Before performing the, the cleft width was measured from three anterior, medial, and posterior sections with the aim of investigating the effect of feeding plate on the size of the cleft by producing a cast (with the same material). The size of the cleft in the control group was also measured before the surgery bypanasil silicon casting and preparation of the casts.

All patients in the case and control groups underwent palatoplasty with Langenbeck Von technique. The needed information was collected through examination and clinical measurements. Surgical complications including hematoma, flap end necrosis, and fistula were investigated both a week and a month following the surgery. Data were analyzed by SPSS -20 and using T-test, and the results were reported.

3. RESULTS

Alveolar ridge width and the cleft palate width, at birth, were measured in anterior, medial and posterior regions of the patients in the case group. The alveolar ridge width and the cleft palate in anterior, medial and posterior regions of both case and control groups were also measured before surgery (Table 1).

Table 1 Quantitative variables’ mean and standard deviation for the two groups: case and control

Variables	Case group Mean (standard deviation)	Control group Mean (standard deviation)
Alveolar ridge width during the production of feeding plate (mm)		
Anterior region	17.57(2.37)	-
Medial region	29.14(4.41)	-
Posterior region	33.86(2.96)	-
Cleft palate width during the production of feeding plate (mm)		
Anterior region	7.00(2.30)	-
Medial region	10.43(2.44)	-
Posterior region	11.57(3.30)	-
Alveolar ridge width during surgery (mm)		
Anterior region	19.71(2.13)	20.29(2.75)
Medial region	32.14(2.79)	30.14(2.34)
Posterior region	37.71(2.81)	35.86(2.11)
Cleft palate width during surgery (mm)		
Anterior region	6.14(2.85)	5.86(2.73)
Medial region	9.29(3.03)	8.71(3.25)
Posterior region	10.71(3.77)	10.00(3.65)
Posterior wall of pharynx distance to Cleft palate (mm)	12.00(9.86)	9.86(3.62)

The alveolar ridge width of the anterior and posterior regions increased significantly after using the feeding plate (during surgery) (p <0.02 and p = 0.006 respectively) (Table 2, Chart 1).

Table 2 Comparison of the width of alveolar ridge in the case group before and after using the feeding plate in the anterior, medial and posterior regions

Regions	The width of the alveolar ridge in the case group (mm)		P value*
	Before using feeding plate Mean (standard deviation)	After using feeding plate Mean (standard deviation)	
Anterior region	17.57(2.37)	19.71(2.13)	0.027
Medial region	29.14(4.41)	32.14(2.79)	0.24
Posterior region	33.86(2.96)	37.71(2.81)	0.006
P value	<0.01	<0.01	

* Using paired t-test before and after using the feeding plate in each area separately

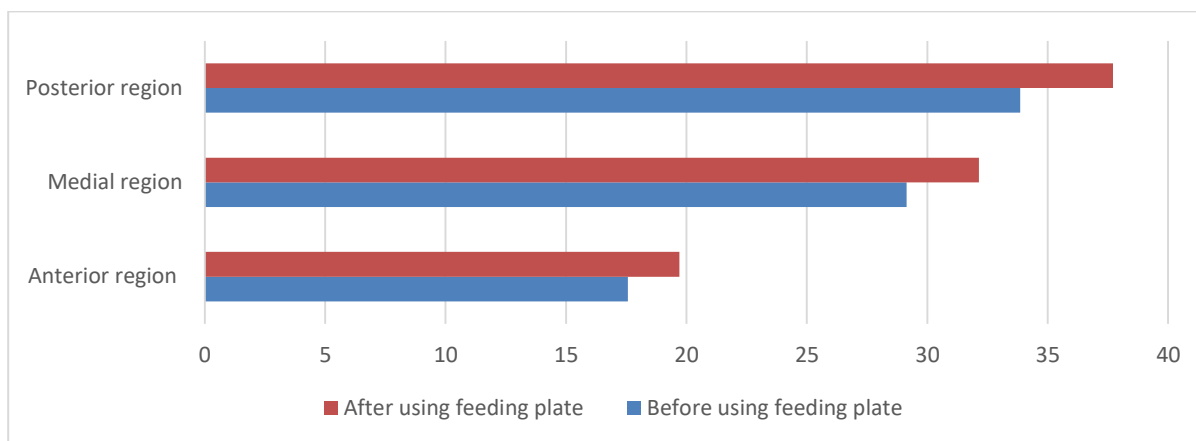


Chart 1 Comparison of the width of alveolar ridge in the case group before and after using the feeding plate

In the anterior region, the cleft palate width decreased significantly after using the feeding plate ($p = 0.04$). As for the medial and posterior regions, the cleft palate width decreased after using the feed plate, but this difference was not statistically significant ($p = 0.13$ and $p = 0.14$, respectively) (Table 3, Chart 2).

Table 3 Comparison of the cleft palate width in the case group before and after using the feeding plate in anterior, medial and posterior regions

Regions	Cleft palate width in the case group (mm)		P value*
	Before using feeding plate Mean (standard deviation)	After using feeding plate Mean (standard deviation)	
Anterior region	7.00(2.30)	6.14(2.85)	0.045
Medial region	10.43(2.4)	9.29(3.03)	0.13
Posterior region	11.57(3.30)	10.71(3.77)	0.14
P value	0.01	0.04	

* Using paired t-test before and after using the feeding plate in each area separately

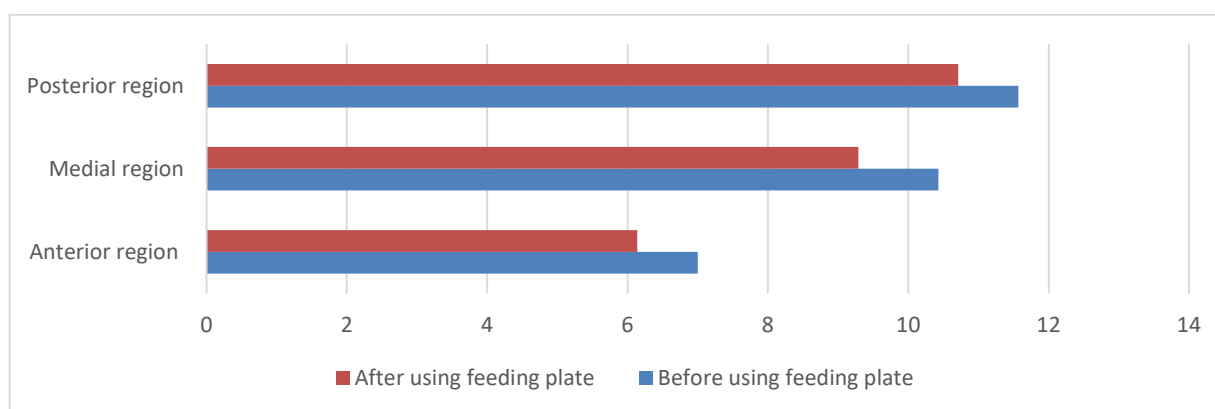


Chart 2 Comparison of the cleft palate width in the case group before and after using the feeding plate

According to the investigation of alveolar ridge width during surgery between the two case and control groups, no significant difference was observed between the two groups in terms of alveolar ridge width in anterior, medial, and posterior regions. In addition, the width of the alveolar ridge in the posterior region was significantly higher in both case and control groups ($p < 0.001$) (Table 4, Chart 3).

Table 4 Comparison of alveolar ridge width during surgery between the two cases and control groups in anterior, medial and posterior regions

Regions	Alveolar ridge width during surgery (mm)		P value*
	Case group Mean (standard deviation)	Control group Mean (standard deviation)	
Anterior region	19.71(2.13)	20.29(2.75)	0.67
Medial region	32.14(2.79)	30.14(2.34)	0.17
Posterior region	37.71(2.81)	35.86(2.11)	0.18
P value	0.001>	0.001>	

* Using paired t-test before and after using the feeding plate in each area separately

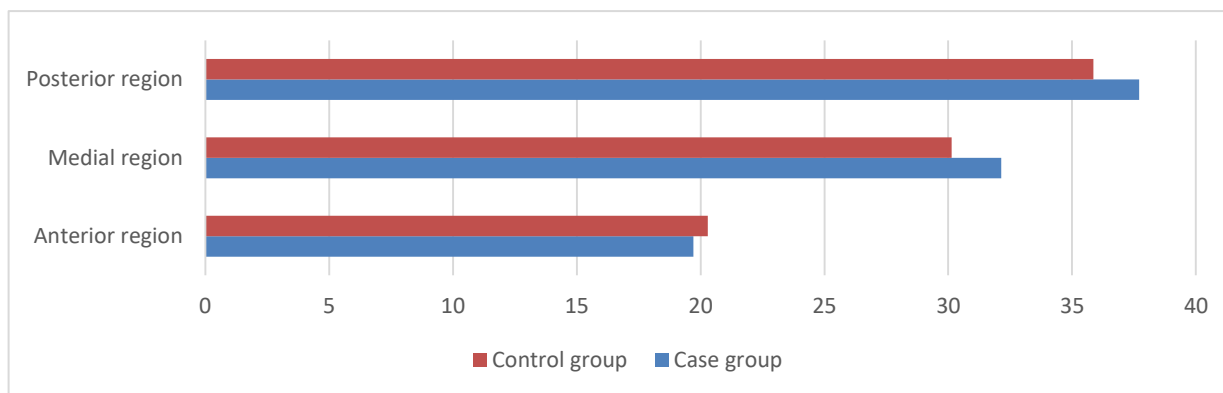


Chart 3 Comparison of alveolar ridge width during surgery between the two case and control groups

Based on the study of alveolar ridge width during surgery between the two groups, no significant difference was observed between the two groups in terms of alveolar ridge width in anterior, medial, and posterior regions. In addition, the width of the alveolar ridge in the posterior region was significantly higher in both case and control groups ($p = 0.04$) but this difference was not significant in the control group ($p = 0.07$) (Table 5, Chart 4).

Table 5 Comparison of the cleft palate width during surgery between case and control groups in anterior, medial and posterior regions

Regions	Cleft palate width during surgery (mm)		P value*
	Case group Mean (standard deviation)	Control group Mean (standard deviation)	
Anterior region	6.14(2.85)	5.86(2.73)	0.85
Medial region	9.29(3.03)	8.71(3.25)	0.74
Posterior region	10.71(3.77)	10.00(3.65)	0.72
P value	0.04	0.07	

* Using paired t-test before and after using the feeding plate in each area separately

The mean and standard deviation of the distance between posterior wall of pharynx and the cleft palate was 12.00 ± 2.44 mm in the case group and 9.86 ± 3.62 mm in the control group. This difference (being higher in the case group than the control group) was not statistically significant, though ($p = 0.21$). None of the patients in the case and control groups had complications including hematoma, flap end necrosis, and fistula one week after the surgery, but one month after surgery, only 1 patient from the case group (7.1%) was reported to have anterior fistula. Examining the ratio of the cleft palate width to that of the alveolar ridge in the case group; during the production of the feeding plate and at the time of surgery in the anterior, medial, and posterior regions showed that the ratio of cleft palate width to that of the alveolar ridge during the surgery decreased in all three regions. This reduction was reported to be significant in the anterior and posterior regions (Table 6, Chart 5).

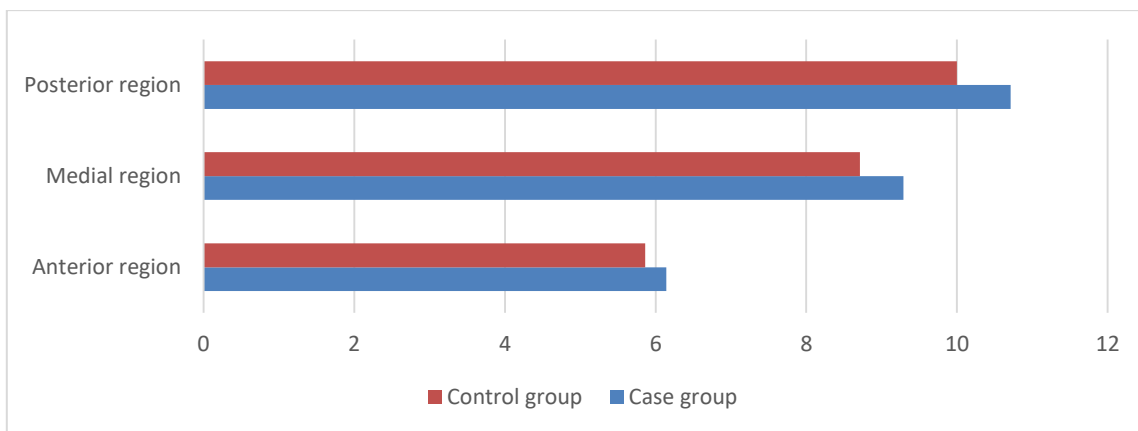


Chart 4 Comparison of the cleft palate width during surgery between case and control groups

Table 6 Comparison of the ratio of the cleft palate width to that of the alveolar ridge in the case group during the production of the feeding plate and during surgery in anterior, medial and posterior regions

Regions	Cleft palate width / Alveolar ridge width		P value*
	During production of feeding plate Mean (standard deviation)	During surgery Mean (standard deviation)	
Anterior region	0.4(0.06)	0.32(0.10)	0.006
Medial region	0.36(0.08)	0.28(0.08)	0.123
Posterior region	0.33(0.06)	0.27(0.09)	0.012

* Using paired t-test before and after using the feeding plate in each area separately

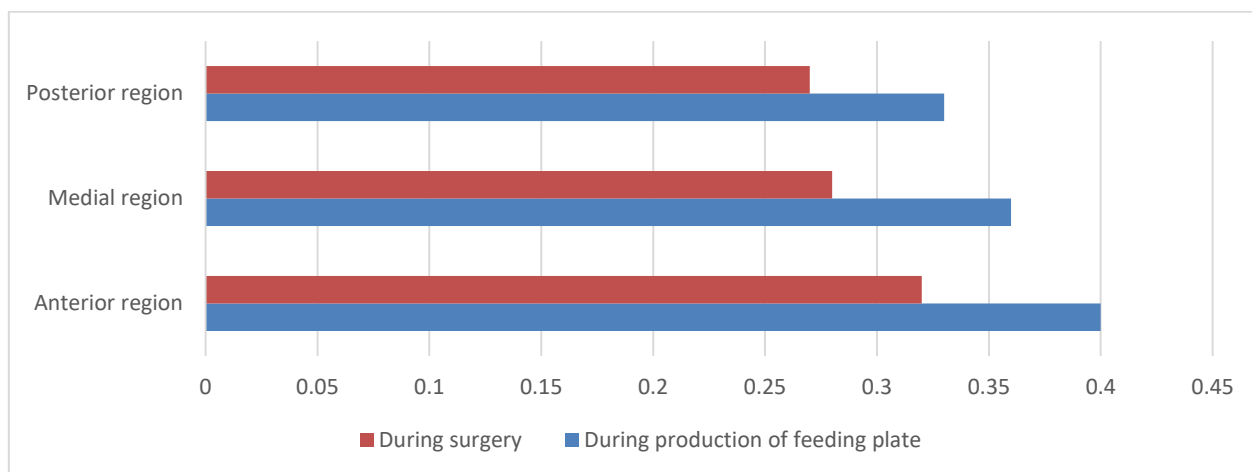


Chart 5 Comparison of the ratio of the cleft palate width to that of the alveolar ridge in the case group during the production of the feeding plate and during surgery

Table 7 Comparison of the cleft palate width ratio to that of the alveolar ridge in the case and control groups during surgery in the anterior, median, and posterior regions

Regions	Cleft palate width / Alveolar ridge width		P value*
	Case group Mean (standard deviation)	Control group Mean (standard deviation)	
Anterior region	0.32(0.10)	0.28(0.12)	0.7
Medial region	0.28(0.08)	0.28(0.11)	0.98
Posterior region	0.27(0.09)	0.29(0.09)	0.98

* Using t-test, two groups of case and control in each area separately

Comparing the ratio of cleft palate width to that of the alveolar ridge in the two cases and control groups during in anterior, medial and posterior regions showed that the ratio of the cleft palate width to that of the alveolar ridge in the case group was greater than that of the control group in the anterior region. In addition, it was equal in the median and posterior regions, but this difference was statistically insignificant in all three regions (Table 7, Chart 6).

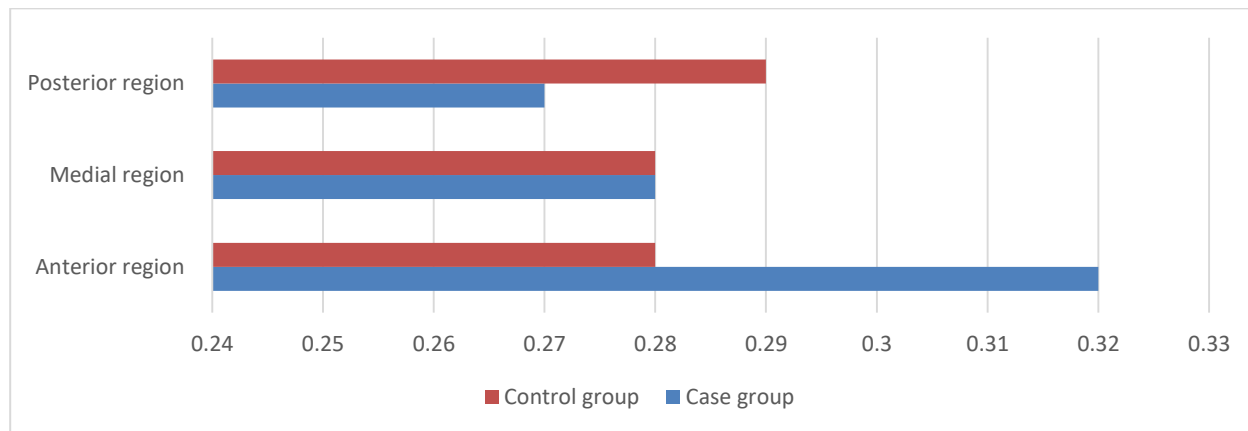


Chart 6 Comparison of the cleft palate width ratio to that of the alveolar ridge in the case and control groups during surgery

4. DISCUSSION

One of the ways to control the complications of cleft palate is to use prostheses that cover the cleft (Nalabotho et al., 2020). Since using covering prostheses of the cleft palate such as the feeding plate allows the child to suck and feed normally, it is necessary to implement various studies on the effect of this method on decreasing the cleft palate width and improving the separation of the nasal area and oral cavity. In addition, information on the benefits and disadvantages of using the feeding plate and its use in all newborns with cleft palate will be obtained. In this study, we paid more attention to the effect of the feeding plate on the width of the cleft palate and the alveolar ridge in the anterior, medial and posterior regions.

This research aimed to study the size of cleft palate and surgery results in orofacial cleft patients treated with and without the feeding plate. Conducting different analyzes and examining the width of the alveolar ridge and orofacial cleft in the two case and control groups showed that the use of feeding plate in patients with orofacial cleft reduces not only the cleft palate width but also the ratio of the cleft palate width to that of the alveolar ridge in the case group. Although the cleft palate width in patients using the feeding plate significantly reduced in the anterior region, this difference was not significant between the two groups. In addition, the incidence of complications one week and one month after the surgery was not different among the two groups significantly. In many case studies, the use of feeding plate has led to facilitated eating, guided growth, developed maxillary regions, and normalized lingual function (Kinouch et al., 2018).

Prasandnalabothu et al., (2020) declared that pre surgical orthopedics in unilateral cleft lip and palate might result in reduced cleft width especially at anterior regions based on three dimensional analyses. It was concluded in the present study that the feeding plate could reduce the cleft palate width in the anterior region. This finding suggests that the feeding plate has a slight effect on the size of the cleft palate in the anterior region, and this reduction in the cleft width is beneficial for decreasing the distance between parts of the palate for better surgery results. A decrease in the cleft palate width in the middle and posterior regions has also been observed, but the significance of these differences depends on several factors. Tomita et al., (2010) investigated the association of alveolar cleft severity with the outcome of neonatal orthodontic treatment in patients with complete and one-sided cleft palate. They concluded that severity of the cleft width significantly affects the orthopedic performance of the newborn, and its efficacy in patients with severe cleft palate was higher than those with minor clefts.

The reduction in ratio of the width of the cleft palate to that of the alveolar ridge in the case group showed that the use of the feeding plate helps the placement of tongue in the correct position and facilitation of the alveolar width extension far from the cleft palate. Thereby, it is beneficial in reducing the complications during future orthodontic treatments. In this study, there was no correlation between the width of the cleft palate and that of the alveolar ridge between the two groups; this may be due to the failure to calculate this ratio in the control group, because this group's patients did not refer at birth. Bauer et al., (2017) indicated that producing a larger feeding plate, for each month, helps the development of alveolar ridge.

One of the important issues in the first months of life in newborns with orofacial cleft is achieving the right weight by proper nutrition and preparing the child for the future surgery. These appliances are not only for separating oral cavity and nasal area, but

for achieving the highest therapeutic efficacy (Nalabotho et al., 2020; Mossey et al., 2009). Considering these, it may be concluded that receiving a feeding plate is effective on the cleft palate in improving surgical treatment. Moreover, it improves the nutrition process, prevents choking and reversal of food, and provides the necessary physical conditions for the baby that are essential for a successful surgery. In the case study of Ali et al., (2017) they reported that using a feeding plate was effective in nutrition and weight gain of the baby and it helps the reduction of mothers' anxiety as well. This is also reported in the study conducted by Erkan et al., (2013). They have argued that the Feeding plate would result in the increased quality of the baby's swallowing and nutrition.

However, some other studies concluded that these measures were not significantly different among the group using the feeding plate and the group who did not use it; its usage did not have any disadvantages, though. For example, Masarei et al., (2007) performed a randomized controlled trial among 50 cases with orofacial cleft to evaluate the effects of the feeding plate on the nutrition of 3-to-12-month-old babies. According to their results, no significant difference was observed in height growth, head perimeter, or body mass index. In addition, no significant difference was observed among the groups in terms of physiological measurements, including the length of suction, suction speed, peak-to-peak intervals, percentage of positive pressure generation, and ingestion rates at the time of using the feeding plate. Therefore, the effects of this prosthesis on the improvement of the nutritional status and growth of the newborn, and ultimately the positive effect on the process of correction of orofacial cleft surgery were not negative in the studies, if they have not been positive.

Prahl et al., (2005) showed that the orthopedic of the neonates with orofacial cleft can temporarily affect the dimensions of the maxillary arch, and its effect will not continue until the closure of soft palate. On the other hand, Bongaarts et al., (2006) reported that the effect of lip and palate surgery is much greater than using neonatal orthopedic appliances. The results of the aforementioned studies are consistent with those of the present study. Moreover, to examine the other roles of this prosthesis, its effects have been investigated on some disorders such as flap necrosis, fistula, and hematoma. Post-palatoplasty palatine necrosis in cases with cleft palate is an infrequent, yet remarkable, problem that has been investigated by few studies, and this complication's prevalence is still unknown. The occurrence of severe fistulas resulting from palate flap necrosis can be a major challenge for any surgeon. Therefore, considering the importance of these postoperative complications, we compared their incidence between the infants who received the feeding plate and the ones who did not. Results showed that in one out of seven infants receiving the feeding plate, a fistula was developed, but this could not determine any relationship between the presence of the feeding plate and the occurrence of the fistula.

Perry et al., (2017) examined the factors affecting flap necrosis and other complications of palatoplasty in cases with cleft palate. They reported that the occurrence of flap necrosis was 0.3% in their study. In the present study, there was no case of flap necrosis, but in 1 case (1.7%), fistula was reported. The patient had a bilateral and wide open cleft palate (compared with other patients); it can be thus said that the occurrence of fistula in this patient was associated with the wide open cleft. Dentino et al., (2016) reported palatal fistula in 19% of patients. The reason for this difference can be associated with the difference in sample size, severity of cleft palate, or patients' age at the surgery time.

5. CONCLUSION

The results of this study showed that the use of feeding plate in the case group reduced the size of cleft palate in all three regions, and it was significant in the anterior region. No significant difference was observed between case and control groups. Using a feeding plate reduced the ratio of the cleft palate width to the alveolar ridge width in the case group in all three regions, and it was significant in both anterior and posterior areas. No significant difference was observed between case and control groups. In addition, the use of the feeding plate did not affect the surgery outcomes. It is suggested to conduct a similar study to evaluate the weight gain of newborns in the same period in both groups. A study with greater sample size and using data from other centers would be helpful as well.

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Author Contributions

Dr Mansoure Mohammadi contributed of all palatoplasty surgery. Dr Amin alavi contributed manuscript work & production. Dr Afaghovakhti contributed manuscript work & production and also was made all of feeding plates for the case group.

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This study has not received any external funding.

Conflict of Interest

There are no conflicts of interests.

Ethical approval

The study was approved by the Medical Ethics Committee of BABOL University (ethical approval code: MUBABOL.HRI.REC.1396.217).

Data and materials availability

All data associated with this study are present in the paper.

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