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Evaluation Of Furlow Z-Plasty Technique With Addition Of Buccinator Myomucosal Flap On Palatal Lengthening For Primary Cleft Palate Repair

Mahmoud Khodir[1]* *BDs*, Mahitab M. Soliman[2] *PHD*, Mamdouh M. Aboulhassan[3] *PHD*

ABSTRACT

INTRODUCTION: Cleft palate is considered as one of the most frequent congenital abnormalities of the face. Short palates with misoriented musculature is always a problem affecting speech. These considerations have pushed surgeons to modify palatoplasty techniques to get better speech outcomes.
AIMS: To assess the significance of the buccinator myomucosal flap use combined with Furlow double z palatoplasty on lengthening of the palate in primary cleft palate.
METHODS: Forty cleft palate patients were done using classical furlow z-plasty operation without suturing the right sided anteriorly based mucosal flap to the edge of the hard palate. This space was further filled with a left posteriorly based buccinator myomucosal flap.
RESULTS: Among 40 patients with an age range of 9-18 months, the palatal lengthening was of a mean 29.65 (±4.72) compared to preoperative mean of 21.65 (±4.25).Paired t-test was used showing significant difference of pre and postoperative ($P<0.001$).
CONCLUSION: Buccinator myomucosal flaps are effective and safe for palatal lengthening in primary cleft palate repair. they provide length and further more attachment by soft pliable tissue to the hard palate making it more mobile . however long term follow up is needed to validate this effect on speech.
KEYWORDS: Furlow z-plasty, buccinator myomucosal, palatal lengthening.
RUNNING TITLE: palatal lengthening using buccinator myomucosal flaps with z-plasty.

1 Instructor of oral and maxillofacial surgery , faculty of dentistry , Alexandria university.
2 Professor of oral and maxillofacial surgery , faculty of dentistry , Alexandria university.
3 Professor of plastic surgery , faculty of medecine , Cairo university.

* *Corresponding Author:*
Email: mahmoudakram@hotmail.com

INTRODUCTION

Cleft palate is a congenital malformation as a result of abnormal facial development during intra-uterine life(1).Disturbances can occur at any period during palatal development, as faulty shelf growth of the palate, delayed or failed elevation and blocked fusion, may result in cleft palate (CP) without or with cleft lip (CL/P) . Clefts of the palate occurs in variable forms, such as isolated cleft palate, associated with unilateral or bilateral cleft lip. It may involve soft palate, soft and part of the hard palate or completely transverse the palate(2). Cleft palate and lip may alter many functions as digestion, feeding, speech, middle-ear functions, respiration, hearing and dental and facial development can be impaired because of the organs involved. Those problems can also result in emotional, educational and psycho-social difficulties. Worldwide, the prevalence of CL/P occurs in about one in every 1000 live births(3).

Functionally, the palate is formed of the hard palate, that offers mechanical support and is a growth center of the maxilla, and the soft palate, that provides velopharyngeal competency. The levator veli muscles are the main motors of the velar element of velopharyngeal competence. Normally they take a forward, downward and medial course which facilitates a cranial, lateral, and posterior movement of the soft palate while velopharyngeal closure. While in the cleft palate patients they are located sagittally, running postero-anteriorly and inserted onto the hard palate at its posterior edge. This alignment prevents the muscle from applying its upward, lateral and posterior pull(4).

while the indexed literature describes various modalities that was refined over the past 30 years. Over the years, cleft surgeons appreciated the significance of dissection and retro-positioning of the levator muscle on refining speech outcomes(5). The objectives of palatal repair include oral and nasal cavities separation, providing normal anatomic velopharyngeal apparatus for better speech development, Eustachian tube function and minimizing maxillary growth inhibition(6).

Bernard von Langenbeck in the 19th century invented a method of palatal repair using mucoperiosteal flaps to repair of the hard palate area. He preserved the anterior attachment of the mucoperiosteal flap to the alveolar margin to make it bipedicled flap.This technique was later on modified by Bardach in 1967 and then refined by Salyer et al in the 80s of the past century with superb structural and anatomical results but with inconsistent speech outcomes owing to velopharyngeal insufficiency due to short palate (1).

Velopharyngeal incompetency is defined as the incomplete closing of the sphincter, resulting in air escape from the nose and/or hyper-nasality (1). Disturbed speech resonance from velopharyngeal insufficiency is considered a major problem associated with palatoplasty, with about one third of the patients that suffer from abnormal resonance caused by anatomical abnormalities and pharyngeal flap as a second surgery is commonly needed with this treatment modality to treat this attained insufficiency (7-10). That's why Velopharyngeal competence is needed for the proper production of sounds to close the velophayngeal sphincter intimately and totally (11).

Furlow was the first surgeon to report a palatal repair technique, where the levator veli palatini muscle is dissected and released free from its position attached to the hard palate and retro-positioned in a Z-plasty lengthening procedure without using of releasing incisions (12). Primarily Furlow's technique aims at constructing a correct palatal muscular sling and an increasing in velar length (13). Moreover it produces minimal scar with no raw area in the hard palate (12).

However , among the problems related to the applying the Furlow palatoplasty is its limitation of the procedure in wide clefts. furthermore, possibility of higher fistula rate associated with the technique's use (13).

This has led toward the thinking of the use of the buccinator myomucosal flaps to lengthen the palate. It was described in 1989 for the wide cleft palatal repair by Bozola recording a great improvement in nasality (14).

In 1997 , Robert Mann described the addition of buccal flaps to the double Z-plasty for closure of wider clefts with minimal tension and the rare need for lateral relaxing incisions along the alveolus. These merits decrease scar formation and maximize blood supply to the alveolus (15).

The origin of the buccinator muscle is from the alveolar processes of the mandible and maxilla.The posterior half of the muscle is supplied by the buccal artery which is a branch of the internal maxillary artery.(16) The facial artery sends several branches to the buccinator muscle, the posterior buccal is the largest branch, that supplies the posterior half of the buccinator muscle. The parotid gland duct has a significant anatomical relation to the muscle and enters the buccinator muscle opposite the upper second molar.(17–21) Some modifications were made to increase the mucosal flaps vascularity were stated by Maeda et al., that also stated buccal 'myomucosal' flaps for cleft palate repair.(22)

Bozola et al. was the first to describe a posteriorly based axial myomucosal flap on the buccal artery. The buccal mucosa and the buccinator muscle were incised to the buccopharyngeal fascia level, and the flap was then elevated in the antero-posterior direction in the area of the loose areolar plane between the buccopharyngeal fascia and the buccinator muscle. The dissection continues in the posterior direction before reaching the pterygomandibular raphe, where the main neurovascular bundle pierces the flap.(14)

The aim of this study is to assess the significance of the use of buccal myomucosal flap combined with Furlow double z palatoplasty on lengthening of the palate in primary cleft palate.

Methods

Study design and setting:

One arm clinical trial was held in the Oral and Maxillofacial Surgery department operative theatre, faculty of Dentistry, Alexandria University and department of plastic surgery, Cairo university. This study was reported according to CONSORT guidelines (23) and registered on clinical trials.gov PRS with ID NCT04346173.

Participants:

A minimum sample size of 25 children was required based on assuming 95% confidence level and 80% study power. Velar closing ratio was used as indication for primary cleft palate repair (24).The mean difference in velar ratio after Furlow palatoplasty was 0.21 mm with pooled SD of 0.26 (25).

Elgibilty criteria

Patients included in the study were in the age frame between 9 and 18 months, have not done any previous palatal repair. Their Haemoglobin level was above 10 grams and weight above 10 pounds (4.5 kilograms). Syndromic patients and medically compromised patients contradicting operation were excluded.

Informed consents were gained from the parents and guardians of the patients to ensure and confirm their understanding of the outcome of the operation and the risks they might be subjected to during the intervention.

Preoperative assessment

Full Personal data in details were obtained including name, age and gender. In addition to name, address and telephone number of parents. Patients were asked if they had underwent any previous operations for the treatment of the palatal cleft. General health state was examined .Haemoglobin level and bleeding profile laboratory investigations were done.

Operative procedure

All patients were treated under general anaesthesia.Inhalational induction using Sevofluorane .Intravenous access obtained by inserting a cannula then Atropine injection of 0.02 mg/kg followed by Propofol of 2 mg/kg.Endotracheal intubation then shifting from Sevofluorane to Isofluorane.

The surgical field was scrubbed with povidone-iodine (Betadine, Purdue Products L.P), followed by draping of the patient with sterile towels exposing only the area of surgery. Insertion of a Dingman mouth retractor to allow good exposure of operating field, followed by infiltration of local anaesthetic with Adrenalin for its haemostatic effect (1:200000 Adrenalin with xylocaine) (Figure 1). The parotid duct is marked with a coloured suture and the donor site of the future Buccinator flap is also infiltrated with local anaesthetic.

Designing the Double Opposing Z-Plasty:

Refreshing of the edges of the uvula was first done and sutured together using 6-0 PDS suture. Then the classical Furlow z palatoplasty technique is made without suturing the anteriorly based right side oral mucosa flap to the edge of the hard palate leaving L-shaped defect which would be filled the next step by the Buccinator flap.

Designing the Buccinator Myomucosal Flap:

The left buccinator myomucosal flap was outlined inferior to the parotid duct with average 3.5 to 5.0 cm in length and 1.2 cm in width. Its position on the buccal mucosa is 2 mm anterior to the base of the retromolar trigone and extends anteriorly to within 6 to 8 mm of the oral commissure. First, the mucosa was incised along the full length of the flap on the markings revealing the buccinator muscle below, followed by dissection through the buccinator muscle at the tip of the flap to the level of the buccal fat. The flap was then rotated such that its mucosa faces orally and sutured into the L-shaped defect as far forward

into the hard palate defect. Finally, the buccal flap cheek donor areas will be then loosely closed using 4-0 vicryl sutures (Figure 2).

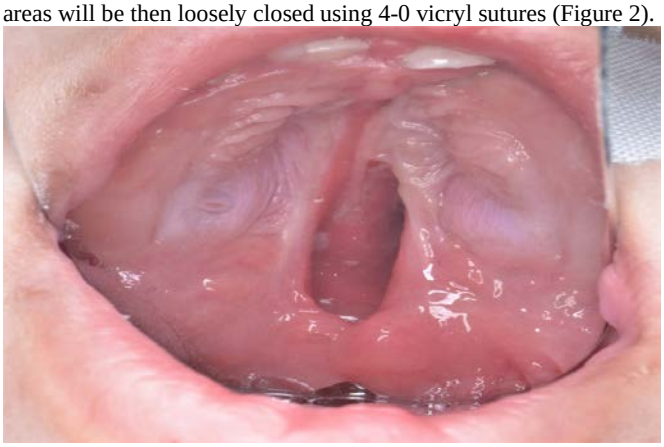

Figure (1): Preoperative photograph showing left complete unilateral cleft palate

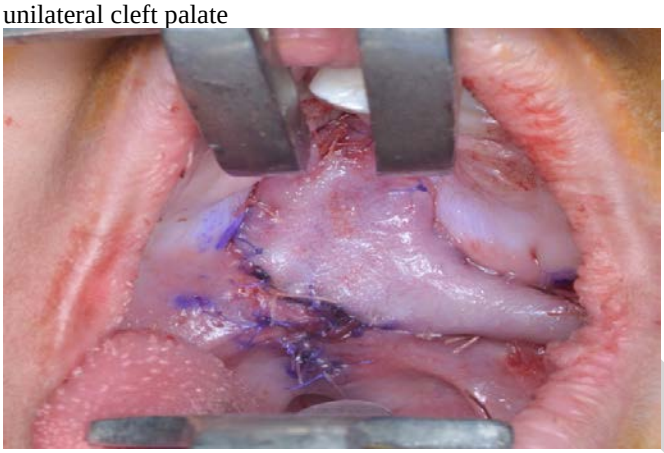

Figure (2): Immediate Postopeartive photograph showing combined left buccinator myomucosal flap with double opposing z-plasties.

Postoperative phase

Special attention was given for the early postoperative care as airway may be compromised in the early postoperative period. Soft,fully liquid diet was instructed for all patients for 4 weeks postoperatively Solid foods have to be of a pureed consistency.Arm restraints were used to prevent the patient disrupting the repair with fingers or thumb.

Postoperative medications

All patients were given Intravenous IM Cefotaxime (Cefotax, E.I.P.I.C.O, Egypt) 25mg/kg/12 hours daily for the next 5 days, Miconazole (Daktarin gel, Johnson & Johnson, Ireland) gel 2cc three times/ day, Xylometazoline (Otrivin nasal drops, GlaxoSmithKline Ltd, United Kingdom) Nasal drops three times/ day and Paracetamol (Calpol drops, Johnson & Johnson, Ireland) 2.5 cc as needed with maximum 4 times /day.

Clinical Outcomes

Palatal lengthing outcome was recorded by comparing the immediate postoperative measurments with the preopeartive ones. The measurments were performed in curved dimension using a flexible paper ruler while the patients were anesthesised with a Dingman retractor placed. The point connecting the hard and soft palate were determined as a starting point, while the uvula base was set as an end point.(16) (Figure 3)

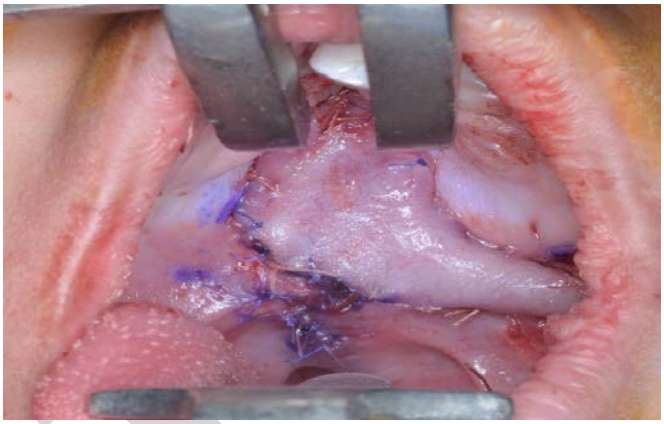

Figure (3): immediate postoperative photograph showing measurement of palatal lengthening from point of junction between soft and hard palate and base of uvula using flexible paper ruler.

Reliability

The intraexaminer reliability for the palatal length was calculated using intra class corelation (ICC). ICC value revealed good reliability (ICC=0.89)

Statistical analysis

Palatal length was presented using mean and standard deviation and compared using paired t test. Signficance level was set at p value ≤0.05. Data was analyzed using SPSS version 25.

RESULTS

The study was conducted on forty patients selected based on the inclusion criteria from those admitted to the Oral and Maxillofacial Surgery Department, Faculty of Dentistry, Alexandria University and plastic surgery department, Cairo university. They consisted of twenty five males and fifteen females; with a ratio of 5:3.

Out of the forty patients of this study; twenty eight patients had complete unilateral cleft(twenty two in the left side and six in the right one) , nine with incomplete cleft while three with bilateral cleft lip and palate.

Among 40 patients with an age range of 9 - 14 months, the palatal lengthening was of a postoperative mean 29.65 (±4.72) compared to preoperative mean of 21.65 (±4.25).Paired t-test was used showing significant difference of pre and postoperative (P<0.001). (Table 1)

Table (1): Comparison between the two periods according to the palatal length.

Palatal length	Pre (n = 40)	Post (n = 40)	t	p
Min. – Max.	12.0 – 32.0	20.0 – 40.0		
Mean ± SD.	21.65 ± 4.25	29.65 ± 4.72	19.948*	<0.001*
Median	21.0	30.0		

t: Paired t-test

p: p value for comparing between pre and post

*: Statistically significant at p ≤ 0.05

DISCUSSION

Among various problems conducted with different techniques of cleft palate repair , speech problems remains the cleft surgeons' main concern(26-29).Our concern here is directed towards double opposing z-plasty of the palate which is first described by Furlow in 1986(30) with addition of buccinator myomucosal flap to assess the significance of their use on lengthening of the palate in primary cleft palate repair and enhancement of speech results.(15)

Our sample has shown increased male to female prevalence in all cleft palate types, this is in contrast to Antoszewski and Fijałkowska in their study in 2016 in isolated cleft palate type and in accordance with them in unilateral cleft lip and palate patients. They cited that the most common type of cleft was the isolated cleft palate whilst in our results it was the unilateral cleft lip and palate type (31). Gatti GL et al in 2017 stated that the unilateral cleft lip and palate type is most prevalent in their study followed by isolated cleft palate type and these results are in accordance with ours (32). Left unilateral type was most frequent in our study compared to right type , this was agreed by Begum F et al in 2019 whom had same results and the bilateral is the least frequent type.(33)

Timing of surgery is always a controversial topic between surgeons , it has a major effect on speech scores; however, this was caused by persistent compensatory articulation errors. This finding highpoints the significance of doing palatal repair before the acquisition of language. Shaw et al in 2019 supported the range of six to twelve months(34). Shi and Losee in 2015 has proved that operating in earlier stages affect maxillary growth and they recommended delayed palatal closure till fifteen years of age.(35)

However koberg and koblin in 1973 has reported that the effect of the technique of repair used is more significant on maxillary growth despite the timing , where they found that Veau's pushback and Langenbeck's technique with relaxing incisions were most damaging to growth.(36)

Jackson et al in 2013 reported better results when operating using furlow double z-plasty technique,(37) and chate et al in the year 1997 cited excellent growth results using intravelar palatoplasty without lateral relaxing incisions as well (38). In our study we aspire good results of growth when using furlow z-plasty technique along with addition of buccinator flap at nine to eighteen months. Having a long active palate with normal musculature position is always the main concern of surgeons , in our study combining furlow z plasty technique with buccinator myomucosal flap showed us significance elongation of the palate , this was also cited by Mann in 2017. Moreover adding an anatomical tissue between hard and soft palate decreased significantly its shrinkage and rebound giving healthy nourished palate .(15)

Furlow z-plasty is believed to form a tight pharyngeal sphincter as the levator veli muscles are mobilized fully each time, regardless the operator, and are significantly overlapped at the posterior soft palate.(30) This technique is opposite to the intravelar veloplasty that is based on the midline suture repair. Moreover, it preserves an intact musculomucosal layer in each of the flaps improving vascularity and thus decreasing scarring and consequent stiffness of the soft palate. Another surgeon named Jackson et al. published a large series on speech results after repairing using the Furlow technique. According to the findings, three quarter of the patients had a competent velopharyngeal mechanism, 85.3 percent showed no or inaudible nasal emission, and 8.1 percent of the patients underwent secondary surgeries to correct velopharyngeal incompetence.(37)

However, crticisms have reprted high fistula rates when the Furlow method is used in wider clefts without the use of relaxing incisions, and the fear for damaging effects on facial growth when the operator uses relaxing incisions (39). Mann in the year 2017 used bilateral buccinator flaps , one facing nasal cavity and the other facing oral cavity , he assumed that this technique releases tension along all palatal planes and decreased fistula occurence.(15) In our study we used only the left buccinator myomucosal flap, posteriorly based on buccal artery in an L-shape pattern facing only oral cavity. It fill in the space between hard and soft palate with anatomical tissue preventing muscle relapse with no contracture , increasing palatal tissue vascularity and eliminating dead spaces. We believe to leave a backup right flap if we need it in the future in secondary surgeries whether fisulation or dehiscence occurs.

The overall results of this study necessitated the acceptance of the hypothesis that there is no effect of using buccinator myomucosal flaps on palatal lengthening .

CONCLUSION

Within the limitation of this study, using buccinator myomucosal flap along with furlow z plasty technique is of a great advantage on lengthening the palate , decreasing tension and contracture and nourishing palatal vascularity. However long term follow up is needed to validate this effect on speech.

Conflict of Interest

The authors declare that they have no conflict of interest.

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REFERENCES

1. Agrawal K. Cleft palate repair and variations. Indian J Plast Surg. 2009;42:S102-S9.
2. Mossey PA, Little J, Munger RG, Dixon MJ, Shaw WC. Cleft lip and palate. The Lancet. 2009 Nov 21;374:1773-85.
3. Ogata H, Sakamoto Y, Kishi K. Cleft Palate Repair without Lateral Relaxing Incision. Plast Reconstr Surg Glob Open. 2017;5:e1256.
4. Smith DM, Losee JE. Cleft palate repair. Clin plast surg. 2014;41:189-210.
5. Nguyen DC, Patel KB, Skolnick GB, Skladman R, Grames LM, Stahl MB, et al. Progressive Tightening of the Levator Veli Palatini Muscle Improves Velopharyngeal Dysfunction in Early Outcomes of Primary Palatoplasty. Plast Reconstr Surg. 2015;136:131-41.
6. Pigott RW. Objectives for cleft palate repair. Ann Plast Surg. 1987;19:247-59.
7. Sell D, Sweeney T. Percent consonant correct as an outcome measure for cleft speech in an intervention study. Folia Phoniatrica et Logopaedica. 2020;72:143-51.
8. Marsh JL. Management of velopharyngeal dysfunction: differential diagnosis for differential management. J Craniofac Surg. 2003;14:621-8.

9. LaRossa D, Jackson OH, Kirschner RE, Low DW, Solot CB, Cohen MA, et al. The Children's Hospital of Philadelphia modification of the Furlow double-opposing z-palatoplasty: long-term speech and growth results. Clinc Plast Surg. 2004;31:243-9.
10. Witt PD, Wahlen JC, Marsh JL, Grames LM, Pilgram TK. The effect of surgeon experience on velopharyngeal functional outcome following palatoplasty: is there a learning curve? Plast Reconstr Surg. 1998;102:1375-84.
11. Andrades P, Espinosa-de-los-Monteros A, Shell DHt, Thurston TE, Fowler JS, Xavier ST, et al. The importance of radical intravelar veloplasty during two-flap palatoplasty. Plast Reconstr Surg. 2008;122:1121-30.
12. Abdel-Aziz M. Speech outcome after early repair of cleft soft palate using Furlow technique. Int J Pediatr Otorhinolaryngol. 2013;77:85-8.
13. Williams WN, Seagle MB, Pegoraro-Krook MI, Souza TV, Garla L, Silva ML, et al. Prospective clinical trial comparing outcome measures between Furlow and von Langenbeck Palatoplasties for UCLP. Ann Plast Surg. 2011;66:154-63.
14. Bozola AR, Gasques JA, Carriquiry CE, Cardoso de Oliveira M. The buccinator musculomucosal flap: anatomic study and clinical application. Plast Reconstr Surg. 1989 Aug;84:250-7.
15. Mann RJ, Martin MD, Eichhorn MG, Neaman KC, Sierzant CG, Polley JW, et al. The Double Opposing Z-Plasty Plus or Minus Buccal Flap Approach for Repair of Cleft Palate :A Review of 505 Consecutive Cases. Plast Reconstr Surg. 2017;139:735e-44e.
16. Zhao Z, Li S, Yan Y, Li Y, Yang M, Mu L et al. New buccinator myomucosal island flap: anatomic study and clinical application. Plast Reconstr Surg 1999;104:55 – 64.
17. Tezel E. Buccal mucosal flaps: a review. Plast Reconstr Surg 2002;109:735– 41.
18. Tipton JB. Closure of large septal perforations with labialbuccal flap. Plast Reconstr Surg 1970;46:514– 15.
19. Jackson IT. Closure of secondary palatal fistulae with intra-oral tissue and bone grafting. Br J Plast Surg 1972; 25:93 –105.
20. Kaplan EN. Soft palate repair by levator muscle reconstruction and a buccal mucosal flap. Plast Reconstr Surg 1975;56:129– 36.
21. Rayner CR. Oral mucosal flaps in midfacial reconstruction. Br J Plast Surg 1984;37:43 – 7.
22. Maeda K, Ojimi H, Utsugi R, Ando S. A T-shaped musculomucosal buccal flap method for cleft palate surgery. Plast Reconstr Surg 1987;79:888– 96.
23. Schulz KF, Altman DG, Moher D; CONSORT Group. CONSORT 2010 statement: updated guidelines for reporting parallel group randomised trials. BMJ. 2010 Mar 23;340:c332.
24. Cheng X, Bo Z, Yin H, Yang K, Li J, Shi B. Age and Preoperative Velar Closure Ratio Are Significantly Associated With Surgical Outcome of Furlow Double-Opposing Z-Plasty in Palatal Re-Repair. J. Oral Maxillofac. Surg. 2019 .
25. Ng ZY, Young SE, Por YC, Yeow V. Results of primary repair of submucous cleft palate with furlow palatoplasty in both syndromic and nonsyndromic children. Cleft Palate-Cran J. 2015;52:525-31.
26. Sell D, Grunwell P, Mildinhall S, Murphy T, Cornish TA, Bearn D, et al. Cleft lip and palate care in the United Kingdom--the Clinical Standards Advisory Group (CSAG) Study. Part 3: speech outcomes. Cleft palate Craniofac J. 2007;3:30-3.
27. Marsh JL. Management of velopharyngeal dysfunction: differential diagnosis for differential management. J Craniofac Surg. 2003;14:621-8.
28. LaRossa D, Jackson OH, Kirschner RE, Low DW, Solot CB, Cohen MA, et al. The Children's Hospital of Philadelphia modification of the Furlow double-opposing z-palatoplasty: long-term speech and growth results. Clinc Plast Surg. 2004;31:243-9.
29. Witt PD, Wahlen JC, Marsh JL, Grames LM, Pilgram TK. The effect of surgeon experience on velopharyngeal functional outcome following palatoplasty: is there a learning curve? Plast Reconstr Surg. 1998;102 :1375-84.
30. Furlow LT Jr. Cleft palate repair by double opposing Z-plasty. Plast Reconstr Surg. 1986 Dec;78 :724-38.
31. Antoszewski B, Fijałkowska M. Prevalence of cleft lip and/or palate in children from L odz between years 1981–2010. Congenital anomalies. 2016 Mar;56 :60-4.
32. Gatti GL, Freda N, Giacomina A, Montemagni M, Sisti A. Cleft lip and palate repair. Journal of craniofacial surgery. 2017 Nov 1;28 :1918-24.
33. Begum F, Iqbal M, Nahar N, Akter S, Zisa RS, Rahman KS. Frequencies of Different Types of Cleft Lip, Cleft Lip with Palate and Cleft Palate in Bangladeshi Children. Mymensingh medical journal: MMJ. 2019 Oct 1;28 :833-38.
34. Shaw W, Semb G, Lohmander A, Persson C, Willadsen E, Clayton-Smith J, Trindade IK, Munro KJ, Gamble C, Harman N, Conroy EJ. Timing Of Primary Surgery for cleft palate (TOPS): protocol for a randomised trial of palate surgery at 6 months versus 12 months of age. BMJ open. 2019 Jul 1; 9: 250-71.
35. Shi B, Losee JE. The impact of cleft lip and palate repair on maxillofacial growth. International journal of oral science. 2015 Mar;7:14-7.
36. Koberg W, Koblin I. Speech development and maxillary growth in relation to technique and timing of palatoplasty. J Maxillofac Surg 1973; 1: 44–50
37. Jackson O, Stransky CA, Jawad AF et al. The Children's Hospital of Philadelphia modification of the Furlow double-opposing Z-palatoplasty: 30-year experience and long-term speech outcomes. Plast Reconstr Surg 2013; 132: 613–22
38. Chate R, DiBiase D, Ball J . A comparison of the dental occlusions from a United Kingdom sample of complete unilateral cleft lip and palate patients with those from the Eurocleft Study. Transactions of the 8th International Congress on Cleft palate and Related Craniofacial Anomalies. Singapore: Stamford Press, Academy of Medicine, 1997: 371– 76.

39. Williams WN, Seagle MB, Nackashi AJ . A methodology report of a randomized prospective clinical trial to assess velopharyngeal function for speech following palatal surgery. Control Clin Trials 1998;19:297–312.