Early functional outcome of two surgical protocols used in the repair of complete unilateral cleft lip palate: a comparative study

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Background and objective **The outcome of different treatment protocols for primary management of patients with complete unilateral cleft lip palate (UCLP) may vary considerably. This study aimed to compare the results of quality of speech and velopharyngeal sphincter mechanism between two surgical protocols used in the repair of complete UCLP.**

Patients and methods **This study was conducted in Zagazig University Hospitals from February 2009 to April 2012 on 30 patients. The patients were categorized into two groups: group A, which consisted of 15 patients who underwent cleft lip repair and cleft hard palate repair with a vomer flap in same sitting; and group B, which consisted of 15 patients who underwent only cleft lip repair at first sitting. At the age of 12 months in both groups, repair of the remaining cleft palate was performed.**

Results **A significant difference between groups A and B at all postoperative comparisons was found in terms of grade of nasality, grade of closure of the velopharyngeal valve, and nasal emission of air.**

Conclusion **Early repair of the hard palate with simultaneous cleft lip repair can be considered as a reliable alternative procedure to one-stage palatoplasty and appeared to have better early functional results in the treatment of complete UCLP. *Ann Pediatr Surg* 10:99–106**

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Keywords: cleft lip, cleft palate, velopharynx, vomer flap

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Introduction

A wide range of cleft lip and palate management protocols currently exists throughout the world. The outcomes of different treatment protocols for primary management of patients with complete unilateral cleft lip palate (UCLP) may vary considerably. The ideal technique of palatoplasty is the one that gives complete closure, having an intact hard and soft palate with normal velopharyngeal mechanism and perfect speech, without affecting the maxillofacial growth and hearing [1]. Determining the optimal timing and sequence of cleft lip and palatal surgery has long raised a major controversy.

The Norwegian center at the Rikshospitalet (Oslo, Norway), used a sequence of initial repair of the hard palate with a vomer flap and simultaneous lip repair at the age of 3–4 months. This was followed by soft palate repair at the age of 12 months. There are many reports with the assessment of cephalometric data of Oslo protocol that showed excellent mid facial growth [2–4]. In our hospital, we usually used the sequence of lip repair at 3 months followed by one-stage palatoplasty at the age of 12 months.

The aim of this study was to early assess and compare speech outcome in terms of the grade of nasality, nasal emission of air, and grade of closure of velopharyngeal valve (VPV) between these two surgical protocols used in the repair of complete UCLP.

Patients and methods

This prospective study was conducted in the Pediatric Surgery Unit, General Surgery Department, and Otorhinolaryngology Head and Neck Surgery Department, Zagazig University Hospitals, from February 2009 to April 2012, on 30 patients who were diagnosed as complete UCLP.

The patients were categorized into two groups: group A, which consisted of 15 patients who underwent simultaneous cleft lip repair and cleft hard palate repair with a vomer flap in the same sitting at the age of 3–4 months; and group B, which consisted of 15 patients who underwent only cleft lip repair at the first sitting. At the age of 12 months, repair of the remaining cleft palate was performed in both groups. A formal consent had been taken from parents of the children or their relatives.

All these patients were subjected to evaluation by detailed history, routine systemic, head and neck, and otorhinolaryngological examination. Syndromic children and children with a history of previous surgical repair were excluded from the study.

Each patient was subjected to examination by the otolaryngologist and phoniatrician before and after surgery. Proper treatment of any nasal or upper respiratory tract infections was done preoperatively.

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Postoperatively, patients were followed up initially at 1-week intervals for 1 month, and then at monthly intervals for 1 year. Data were collected and statistically analyzed.

Surgical procedures

(1) For closure of the lip, a Millard procedure was performed.
(2) Posterior palate closure in group A and one-stage palatoplasty in group B were based on Von Langenbeck's procedure.
(3) Vomer flap technique for early hard palate closure:

The incision for the vomer flap was made up to the bone. On the medial side of the lateral palatal segment, the incision followed the border between the oral and nasal mucosa. The oral mucoperiosteum on the hard palate on the cleft side was bluntly undermined. The vomer flap was mobilized sufficiently to allow the flap to be turned, like a book page, across the cleft and tucked beneath the undermined oral palatal flap to be sutured to mobilized nasal mucosa. Then the oral palatal flap was sutured to the other incisional side of the vomerine tissues to cover the vomerine bone (Fig. 1).

Speech assessment

Every patient of both groups was subjected to the protocol of assessment that is applied in the Phoniatric Unit, Zagazig University Hospitals. This protocol was structured in the Phoniatric Unit, Ain-Shams University [5]. Postoperative assessment was repeated three times for every patient, after 1 month (age of 13 months), 6 months (age of 18 months), and 1 year (age of 2 years) after the second stage of repair to assess the results of the surgery. It includes subjective as well as objective measures of evaluation.

Postoperative assessment comprises three levels:

(1) Elementary diagnostic procedures:
   (i) Patient and parents' interview: it includes personal data, developmental milestones, detailed history of operative intervention, and its outcome.
   (ii) Auditory perceptual assessment (APA) of the patient's cry and speech: The grade of nasality was assessed auditorily during patient's speech or cry if the language and speech could not been assessed at the time of assessment. Assessment of nasality is graded along a five-point scale in which 0 is normal and 4 is the most severe affection.
   (iii) Visual assessment of the vocal tract, using simple clinical examination tools that include visual assessment of the lip, teeth, alveolar margin, tongue, hard palate, soft palate, the presence or absence of fistula, uvula, movement of palatal muscles, and pharyngeal walls.
(2) Clinical diagnostic aids:
   (iv) Documentation of APA (audio recording): amples of patient's cry were recorded digitally by the computer in a sound-treated room and assessed by three judges for analysis and given a score that is graded along a five-point scale, in which 0 is normal and 4 is the most severe affection.
   (v) Video nasoendoscopy: all the patients were examined using a flexible fiberoptic nasopharyngeal endoscope from Xion Medicals (Berlin, Germany). The VPV movement was recorded while the patient was crying. The movement of the velum and lateral pharyngeal walls was traced on the monitor and given a score from 0 to 4 as follows: 0 is the resting (breathing) position or no movement; 2 is half the distance to the corresponding wall; 4 is the maximum movement reaching and touching the opposite wall. Pattern of closure of the VPV was specified whether circular, coronal, sagital, or others.

Statistical analysis

Results of both the groups were compared statistically using the following tests from the SPSS program version 17.0 (Chicago, Illinois, USA). The χ^2-test was used as a nonparametric test to compare between qualitative data. When *P*-value is less than 0.05, it is considered statistically significant.

Results

This study included 30 patients, 19 male (63.3%) and 11 female (36.7%), who were diagnosed as having complete UCLP. The age of these patients at the time of first stage of surgery was 3–4 months, whereas the age of the patients at time of second stage of surgery was 12 months.

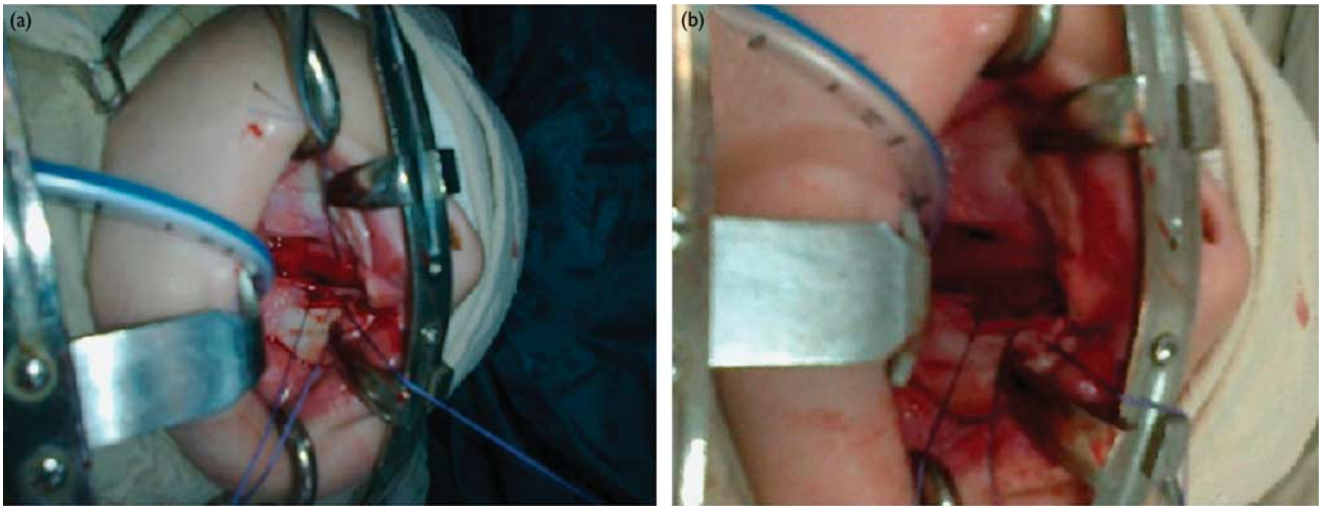
Intraoperative hemorrhage was acceptable in all patients of both groups. The use of epinephrine lignocaine solution reduced blood loss. No blood transfusion was needed. No patient in group A developed oronasal fistula, whereas two (13.3%) patients in group B developed oronasal fistula.

The cases who underwent one-stage palatoplasty showed statistically more hypernasality and higher nasalance scores in comparison with two-stage palatoplasty. No major differences regarding articulation and voice characteristics were found. As expected, significant differences were found between the speech intelligibility and resonance characteristics in individuals who underwent a palatoplasty and the normative data.

Table 1 and Fig. 2 demonstrate the comparison between groups A and B in the preoperative and postoperative results of APA of patient's speech or cry if speech has not been developed yet, during the following periods: preoperative, 1, 6 months, and 1 year, which revealed improvement in all postoperative comparisons. This improvement is more obvious in group A than in group B. Preoperative comparison between groups A and B revealed nonsignificant difference, whereas all postoperative comparisons between both groups revealed significant difference in favor of group A.

Table 2 and Fig. 3 demonstrate comparison between groups A and B in nasal emission of air. Results showed improvement in the degree of emission in all

Fig. 1



Vomer flap technique.

Table 1 Preoperative and postoperative comparison between groups A and B in auditory perceptual assessment of the grade of nasality

Variables	Grade of nasality	Group A ($n=15$) [n (%)]	Group B ($n=15$) [n (%)]	χ^2	P
Preoperative at the age of 1 year	0	0 (0)	0 (0)	0.19	>0.05 (NS)
	1	0 (0)	0 (0)		
	2	2 (13)	2 (13)		
	3	4 (27)	3 (20)		
	4	9 (60)	10 (67)		
One month postoperative at 13 months of age	0	6 (40)	0 (0)	15.8	<0.05 (S)
	1	8 (53.3)	4 (27)		
	2	1 (6.7)	8 (53)		
	3	0 (0)	3 (20)		
	4	0 (0)	0 (0)		
Six months postoperative at 1.5 years of age	0	4 (27)	0 (0)	14.5	<0.05 (S)
	1	9 (60)	3 (20)		
	2	2 (13)	9 (60)		
	3	0 (0)	3 (20)		
	4	0 (0)	0 (0)		
One year postoperative at the age of 2 years	0	4 (27)	0 (0)	14.6	<0.05 (S)
	1	9 (60)	3 (20)		
	2	2 (13)	8 (53)		
	3	0 (0)	4 (27)		
	4	0 (0)	0 (0)		

S, significant.

postoperative comparisons. This improvement is more clear in group A. Preoperative comparison between groups A and B revealed nonsignificant difference, whereas all postoperative comparisons between both groups revealed significant difference in favor of group A.

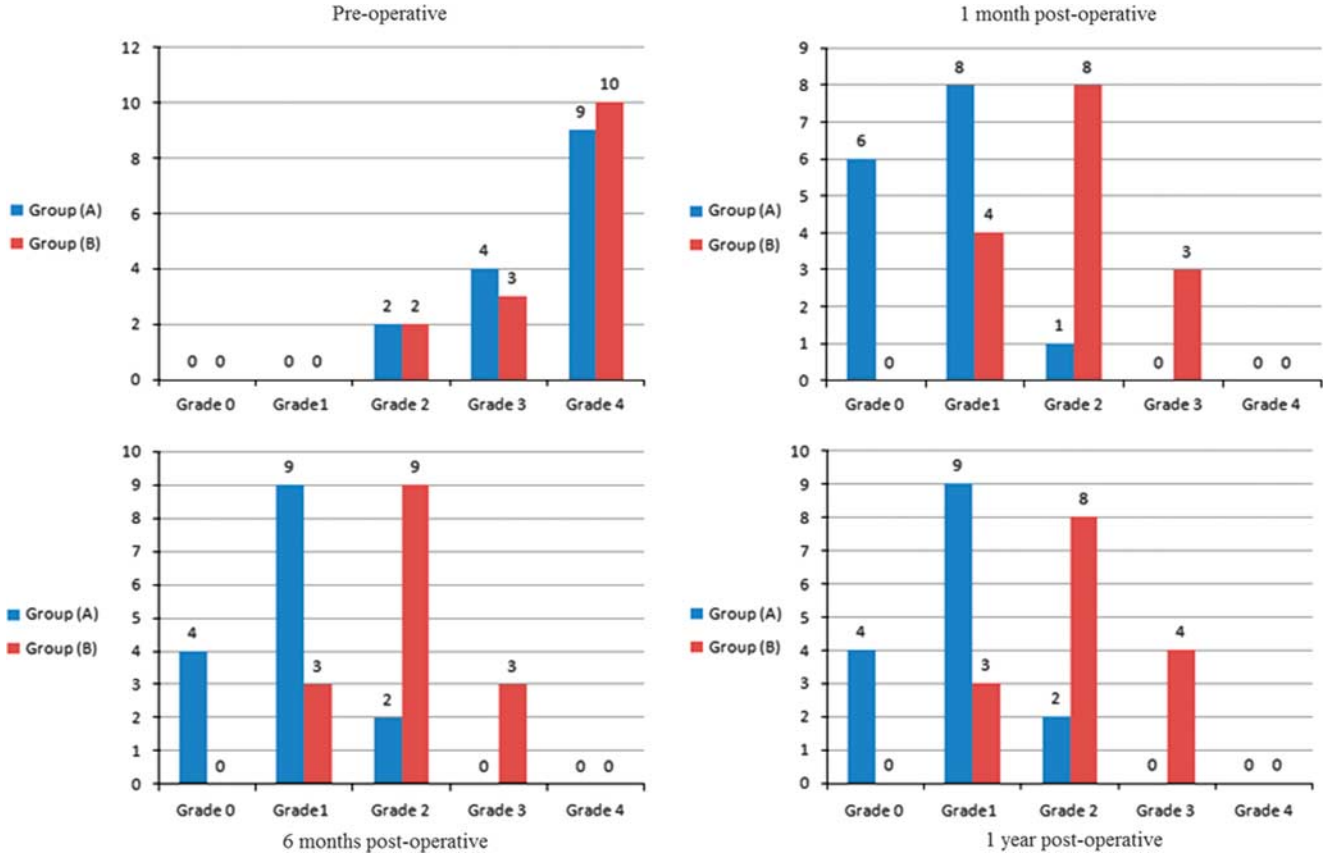
Table 3 demonstrates that comparison between groups A and B in grade of closure of VPV showed improvement in the closure in all postoperative comparisons. This improvement is more clear in group A. Preoperative and 1-month postoperative comparisons between groups A and B revealed nonsignificant difference, whereas the rest of the postoperative comparisons between both groups revealed significant difference in favor of group A (Figs 4–8).

Discussion

Treatment of the cleft palate has evolved over a long period. Various techniques of cleft palate repair practiced today are the results of principles learned through many years of modifications. The effectiveness of various treatment protocols has been challenged by controversies concerning speech and maxillofacial growth [6].

In the management of patients with complete palatal clefts, early repair of the soft palate (before 1 year of age) and delayed repair of the hard palate (after 5 or 6 years of age) has advocated on the basis that good speech will develop following soft palate closure, and that avoidance of trauma to the hard palate will obviate maxillary growth disturbance. In addition, it is said that many of the remaining hard palate fistulas will close spontaneously, and that residual hard palate openings will be easy to close. However, the majority of patients treated as before failed to develop speech spontaneously and a very high percentage suffered both anterior and posterior air escape, and a high proportion required pharyngeal flaps. Spontaneous complete closure of the hard palate was infrequent. The hard palate openings

Fig. 2



Bar graph shows the results of the grade of dysphonia in groups A and B.

Table 2 Preoperative and postoperative comparison between groups A and B in the auditory perceptual assessment of audible nasal air emission

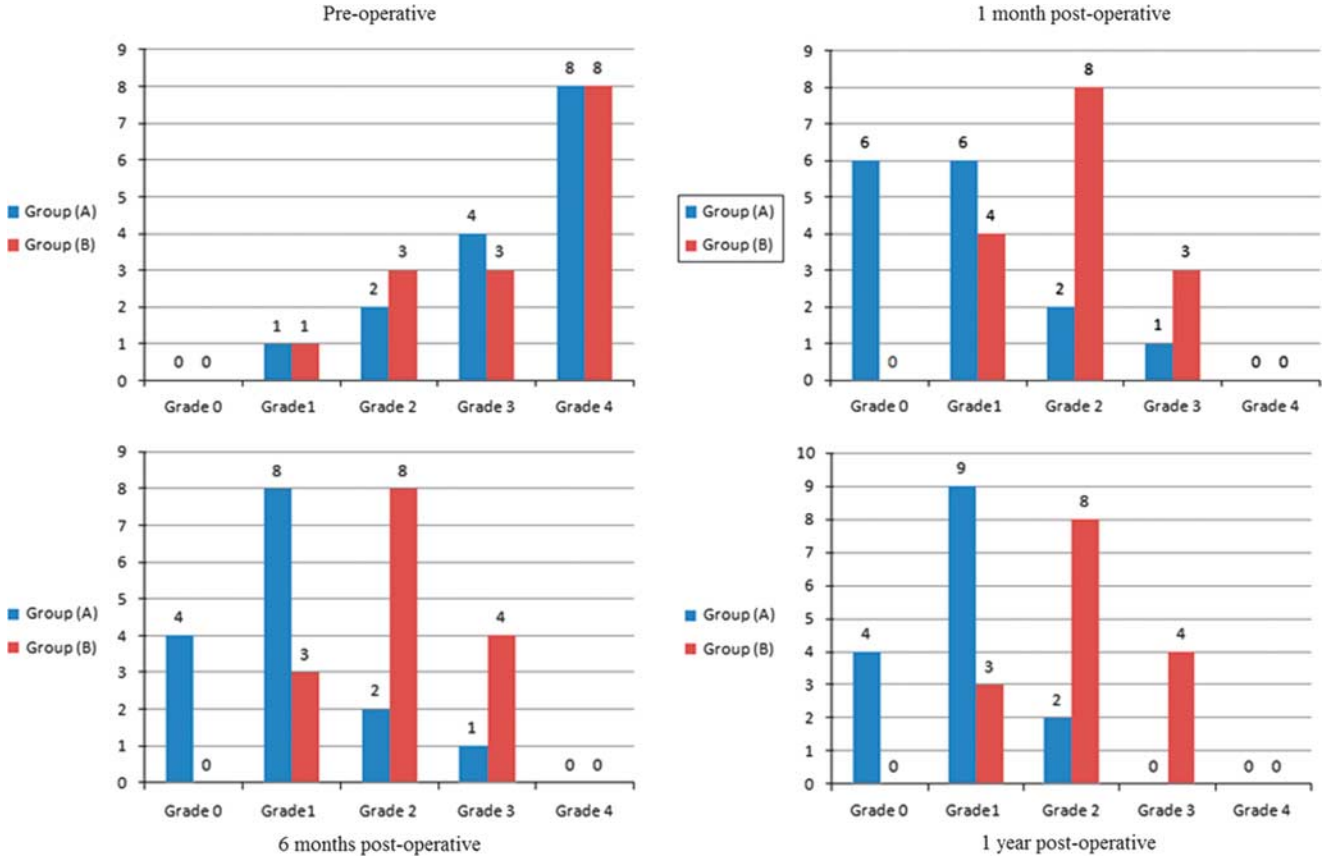
Variables	Audible nasal air emission	Group A ($n=15$) [n (%)]	Group B ($n=15$) [n (%)]	χ^2	P
Preoperative at the age of 1 year	0	0 (0)	0 (0)	0.34	>0.05 (NS)
	1	1 (7)	1 (7)		
	2	2 (13)	3 (20)		
	3	4 (27)	3 (20)		
	4	8 (53)	8 (67)		
One month postoperative at 13 months of age	0	6 (40)	0 (0)	11	<0.05 (S)
	1	6 (40)	4(27)		
	2	2 (13)	8 (53)		
	3	1 (7)	3 (20)		
	4	0 (0)	0 (0)		
Six months postoperative at 1.5 years of age	0	4 (27)	0 (0)	11.7	<0.05 (S)
	1	8 (53)	3 (20)		
	2	2 (13)	8 (53)		
	3	1 (7)	4 (27)		
	4	0 (0)	0 (0)		
One year postoperative at the age of 2 years	0	4 (27)	0 (0)	14.6	<0.05 (S)
	1	9 (60)	3 (20)		
	2	2 (13)	8 (53)		
	3	0 (0)	4 (27)		
	4	0 (0)	0 (0)		

S, significant.

were not easy to close. The speech deficiencies associated with this technique are obvious, whereas the possible advantages in relation with maxillofacial growth remain difficult to prove [7].

Shaw *et al.* [8] reported 194 different treatment protocols in different cleft centers in Europe. Oslo protocol has popularized closure of the lip and hard palate with vomer flap first, followed by closure of the soft palate 3 months later [2,9]. Oslo protocol has received considerable attention in the latter part of the 20th century because of a high proportion of patients achieved good maxillary forward growth with a low requirement for maxillary osteotomy [4,10]. At our hospital, the commonly used surgical

Fig. 3



Bar graph shows the results of the audible nasal air emission in groups A and B.

Table 3 Preoperative and postoperative comparison between groups A and B in the endoscopic overall closure of the velopharyngeal valve

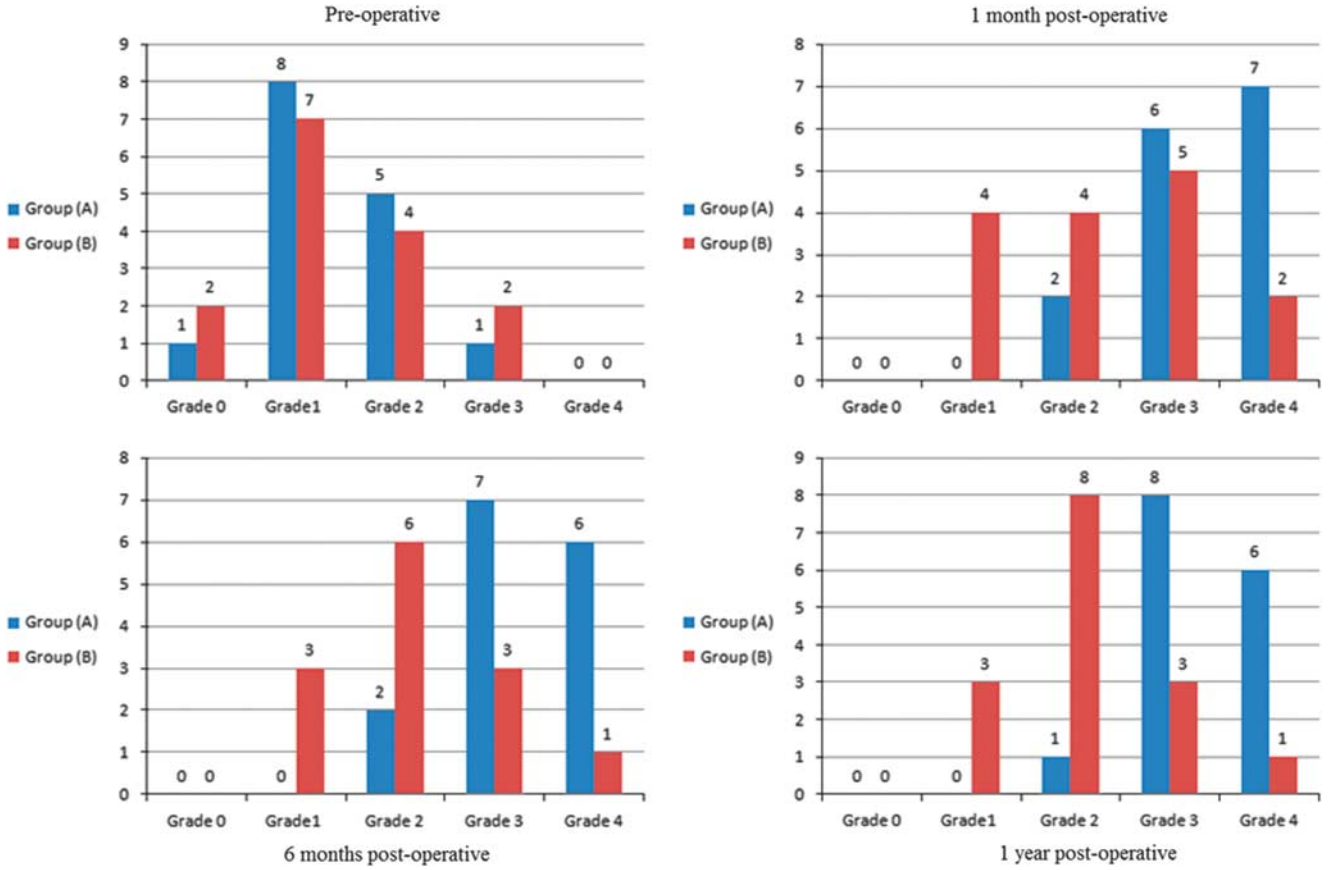
Variables	Closure of VPV	Group A ($n=15$) [n (%)]	Group B ($n=15$) [n (%)]	χ^2	P
Preoperative at the age of 1 year	0	1 (7)	2 (13)	0.84	>0.05 (NS)
	1	8 (53)	7 (47)		
	2	5 (33)	4 (27)		
	3	1 (7)	2 (13)		
	4	0 (0)	0 (0)		
One month postoperative at 13 months of age	0	0 (0)	0 (0)	7.5	>0.05 (NS)
	1	0 (0)	4 (27)		
	2	2 (13)	4 (27)		
	3	6 (40)	5 (33)		
	4	7 (47)	2 (13)		
Six months postoperative at 1.5 years of age	0	0 (0)	0 (0)	8.9	<0.05 (S)
	1	0 (0)	3 (20)		
	2	2 (13)	6 (40)		
	3	7 (47)	5 (33)		
	4	6 (40)	1 (7)		
One year postoperative at the age of 2 years	0	0 (0)	0 (0)	14.3	<0.05 (S)
	1	0 (0)	3 (20)		
	2	1 (7)	8 (53)		
	3	8 (53)	3 (20)		
	4	6 (40)	1 (7)		

S, significant; VPV, velopharyngeal valve.

protocol is the Linköping protocol with repair of the cleft lip alone at the age of 3 months followed by one-stage palatoplasty at the age of 12 months. The main purpose of this current study was to compare early functional results of speech assessment in these two protocols.

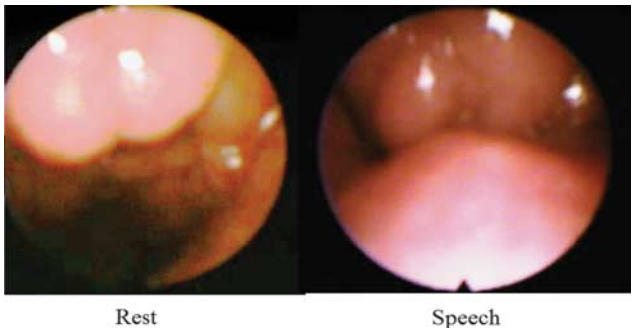
Repair of the cleft lip alone in UCLP needs extensive dissection during subsequent palatoplasty; however, with simultaneous repair of the cleft lip and the cleft hard palate by vomer flap, subsequent palatoplasty does not need extensive dissection. For this reason, the chances of oronasal fistula decrease in the latter group [11–13]. Ferdous *et al.* [13] reported that repair of the cleft lip simultaneously with the hard palate by using vomer flap in patients with UCLP is a suitable and effective procedure. This procedure is easy to perform and does

Fig. 4



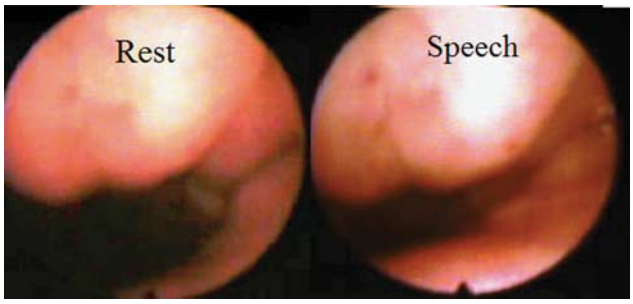
Bar graph shows the results of the VPV closure in groups A and B. VPV, velopharyngeal valve.

Fig. 5



Endoscopic closure of VPV in a case of group A (preoperative assessment): it shows moderate incompetence of VPV during speech (grade II closure). VPV, velopharyngeal valve.

Fig. 6

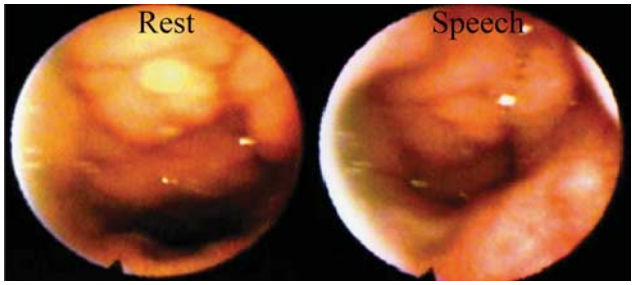


Endoscopic closure of VPV of the same case of group A (6-month postoperative assessment): it shows competent closure of VPV during speech (grade IV closure). VPV, velopharyngeal valve.

not need blood transfusion. It reduces the cleft alveolar and cleft soft palatal gap significantly, thus making it easy for cleft soft palate repair and reducing the chance of oronasal fistula formation. With regard to surgical complication, no patient in group A developed oronasal fistula similar to the result of the study by Ferdous *et al.* [13], whereas two patients (13.3%) in group B developed oronasal fistula within the fistula rate reported in the literature [12].

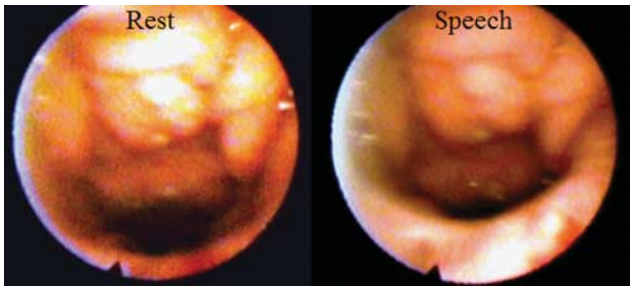
In the experimental study by Cupero *et al.* [14], it was found that resection of vomer does not affect facial growth. Freng [15], reported that the growth of the nasal septum/vomer, at least at its basal parts, is not involved in facial development during the period from infancy to adulthood. Moreover, in more recent studies, safe extensive resection of the vomerine septum was performed safely by McLeod *et al.* [16] with no clinical facial growth disturbance. Even all vomer could be

Fig. 7



Endoscopic closure of VPV in a case of group B (preoperative assessment): it shows moderate incompetence of VPV during speech (grade II closure). VPV, velopharyngeal valve.

Fig. 8



Endoscopic closure of VPV of the same case of group B (6-month postoperative assessment): it shows mild incompetence of VPV during speech (grade III closure). VPV, velopharyngeal valve.

removed safely by Romeh and Albirmawy [17] over their 13 years of work. Therefore, it is established that vomer flap or even resection does not affect facial growth and could be used safely.

Regarding velopharyngeal incompetence, there was a statistically significant difference in the results of post-operative comparisons between both groups in favor of group A in terms of improvement in the grade of nasality, nasal emission of air, and grade of closure of VPV.

Although there was a nonsignificant difference in preoperative comparison between groups A and B in APA of speech or cry, and in audible nasal air emission, there was a significant difference in all postoperative comparisons in favor of group A. This indicates that the early closure of the hard palate prepares for better results of later soft palate closure, which in turn improves nasal tone and nasal emission of air during speech and cry.

The results of comparison between both groups in the overall closure of VPV confirms the same opinion as the preoperative and early 1-month postoperative comparisons showed nonsignificant difference, whereas significant differences started to appear in the successive 6 months and 1-year postoperative comparisons (Figs 2–5). The presence of nonsignificant difference of the 1-month postoperative comparison can be considered a short-term result, which may still be affected by postoperative edema. This edema can help competent closure of the VPV. On the other side, the presence of significant difference in the later on comparisons in favor of group A may be because of more tension on the site of incision in group B, which increases more with time owing to growth of the tissues. This revealed that the long-term results of repair of the cleft lip simultaneously with the hard palate by vomer flap are good and reliable. To prove these possibilities, further assessments and comparisons are still needed to confirm the stability of results with increase in age and after complete development of speech.

Postoperatively, at the end of this study, there was improvement in nasal tone, audible nasal emission of air, and in the grade of closure of the VPV in patients of group A to a degree better than group B, which is statistically significant.

Conclusion

Simultaneous cleft lip and hard palate repair can be considered as a reliable procedure alternative to one-stage palatoplasty. It appears to have better early functional results in the treatment of complete UCLP in terms of the grade of nasality, the nasal emission of air, and the grade of closure of VPV.

Acknowledgements

Conflicts of interest

There are no conflicts of interest.

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