Repair of the complete cleft lip and hard palate with vomerine flap versus cleft lip repair only in unilateral complete cleft lip and palate
Hossam Abd Alhay, Aboubakr El Shafie, Salah Nasser, Ahmed Shehata, Ahmed Alhewity

Aim
The aim of the work was to study the effect of repair of cleft lip alone and repair of cleft lip with simultaneous repair of cleft hard palate with vomerine flap in unilateral complete cleft lip and palate (UCCLP).

Patients and methods
This study was carried out on 20 patients with UCCLP. Patients were classified into two groups: group A included 10 patients treated with simultaneous repair of the cleft lip with repair of alveolus and anterior portion of hard palate with vomerine flap, and after 12 weeks patients underwent repair of cleft soft palate; group B included 10 patients treated with cleft lip repair only, and after 12 weeks patients underwent repair of entire cleft hard and soft palates.

Results
Patient’s age in group A ranged from 3 to 7 months (mean age: 4.65 months), whereas patient’s age in group B ranged from 3 to 6 months (mean age: 4.55 months), with male predominance of about 65% (13) patients in the study. The mean operation time for group A was 81 min, whereas for group B it was 46.5 min. The mean reduction of the cleft alveolar gap between first and second operation in group A was 3.95 mm, whereas in group B it was 2.25 mm. Group A developed two cases of minor hemorrhage stopped with compression, one case of oronasal fistula of small size, and a case of whistle deformity, whereas in group B there was one case of massive hemorrhage stopped with cauterization and two cases of large oronasal fistula.

Conclusion
This study found that simultaneous repair of cleft lip and hard palate using vomerine flap in patients with UCCLP is a suitable and effective procedure, as it reduces cleft alveolar gap significantly and reduces the chance of complications and oronasal fistula formation.

Keywords:
simultaneous repair, unilateral complete cleft lip and palate, vomerine flap

Introduction
The most common congenital malformations occurring in the craniofacial region are cleft lip and/or palate. Major population differences have been reported, with the highest rates in Asians and Native Americans (1/500 births) and the lowest rate in Africans (1/2500 births) [1]. Historical reference to the cleft lip deformity dates back to the Greek physician Hippocrates who referenced the presence of this condition but not its repair in his writings. Around 150 AD, the Roman physician Galen used the term ‘lagochellos’ to describe a similar condition. Chinese physicians are credited as the first to repair the cleft lip deformity around 390 AD. They performed their repair by simply bringing the cleft segments together toward the midline and securing them with silk ties and resin [2]. Unilateral cleft lip and palate is much more than an alteration of the lip and palate; it is a defect of the middle one-third of the face. In treating this deformity, it is essential to address the different elements of the problem: the bony defect of the maxilla, the nasal deformity, and the dynamic force of the lip – the muscle – which is responsible for much of the distortion of the nose and maxilla [3-7]. The orbicularis muscle has a very significant effect on the growth of the maxilla. Muscular reconstruction is a key to balancing the forces acting on the maxilla, the nasal tip, and the lip. The lip has to be symmetrical not only at rest but also on animation, and it has to grow symmetrically. Usually when reference is made to the orbicularis oris muscle of the upper lip only the
horizontal bands of muscle are mentioned. This muscle also comprises oblique fibers (orbicularis externus) that are of very great importance in lip movements. The balance of the lip derives from the activity of the two types of muscle fiber [8–11]. Repair of cleft lip alone in unilateral complete cleft lip and palate (UCCLP) needs extensive dissection during palatoplasty and more time for operation. There may be more chances of oronasal fistula formation and, if cleft palate repair was done earlier, also mid-facial growth disturbance. However, after simultaneous repair of cleft lip and cleft hard palate by vomer flap, during subsequent palatoplasty, extensive dissection is not needed, it takes less time, has less chance of oronasal fistula formation, and does not have an effect on mid-facial growth [12].

**Patients and methods**

This study was carried out on 20 patients with UCCLP, recruited from the Otorhinolaryngology Outpatient Clinic at Benha University Hospital and Benha Specialized Hospital of Pediatrics during the period from November 2015 to October 2016, and after approval of the medical ethics committee.

**Inclusion criteria**

The inclusion criteria were as follows:

1. Children with UCCLP.
2. Children aged 3–9 months.

**Exclusion criteria**

The exclusion criteria were as follows:

1. Patients with previous surgery of cleft lip and palate.
2. Unilateral cleft with other deformities of face.
3. Patients with poor general condition not fit for surgery.

The patients were classified into two groups:

**Group A:** this group included 10 patients with UCCLP treated with repair of the cleft lip with the Millard technique simultaneous with repair of alveolus and anterior portion of hard palate with vomerine flap, and then after 12 weeks the patients underwent repair of cleft soft palate.

**Group B:** this group included 10 patients with UCCLP treated with cleft lip repair only with the Millard technique, and then after 12 weeks the patients underwent repair of the entire cleft hard and soft palates.

For each patient the following was done:

**Preoperative assessment**

Preoperative assessment included the following:

1. Adequate history taking including perinatal history and family history:
   - Complaint by the family.
   - Related symptoms.
   - Other nonrelated symptoms to diagnose syndromic patients with other birth defects.

2. General examination of the patient as regards vital signs, growth, and developmental milestones.

3. Complete ENT examination:
   - Examination of the ear: ears were examined on a regular basis, as children with cleft lip and palate are susceptible to many conditions such as otitis media with effusion and structural abnormalities such as microtia and anotia.
   - Examination of the nose and throat, dental examination, and adequate assessment of the airway were also performed.

4. Patient counseling: helping the parents to understand the deformity and aim of surgery, as well as discussing the benefits, risks, and complications of surgery.

5. Consent: written informed consent was taken from parents, and photographic consent was also taken.

6. Investigations:
   - Laboratory: complete blood count, bleeding profile, erythrocyte sedimentation rate.
   - Radiological: computed tomography to exclude other associated craniofacial anomalies.
   - Audiological: auditory brainstem response and tympanometry.

**Operative details**

Group A was surgically corrected with the Millard procedure (rotation advancement technique) for cleft lip repair with simultaneous repair of anterior palate with vomerine flap.

**Surgical technique**

General anesthesia was used with the nasal endotracheal tube, and the operation time and measurement of the cleft alveolar gap (CAG) using a caliper under anesthesia was recorded. The rotation advancement repair begins with careful marking using methylene blue of the anatomic landmarks of the cleft lip deformity. After meticulous and careful marking, the lip is injected with local anesthetic containing epinephrine 1/200 000. The operation begins using a number 15 blade scalpel to make a careful incision in the gingival labial sulcus anteriorly across the cleft. The number 15 blade is used to carry out supra peristeal dissection releasing the muscle fibers of the cleft from...
the maxilla. This provides significant increase in flap mobility and will serve to take tension off the closure line. After this, a sharp small scalpel is used to perform the skin incisions. Full-thickness incision is carried from point 3 to point 5 plus X. This incision is slightly beveled to preserve more orbicularis oris musculature for closure. After this, a scalpel is used to provide 1–2 mm of release of the skin from the underlying orbicularis oris muscle. This facilitates a three-layer closure of the mucosa, orbicularis oris muscle, and dermis; next, a small curved scissors is inserted superficial to the alar cartilages, and the orbicularis oris muscle. This facilitates a three-layer closure of the mucosa, and the vomerine flap is elevated. All of the oral mucosa is preserved. Mucoperiosteum is elevated for 3–5 mm to allow interdigitation of the vomerine flap, and thus this creates double-layered closure of the oral cavity. Group B underwent cleft lip repair only with the Millard procedure. The same technique was used as regards general anesthesia, the operation time and measurement of the CAG were recorded under anesthesia using the same landmark incisions without use of vomerine flap (cleft lip repair only). After 12 weeks, the entire hard and soft palates were repaired.

Postoperative management

(1) The patient was discharged after first or second postoperative day according to general condition.

(2) Plain water was given 4–6 h orally postoperatively.

(3) Topical antibiotic, analgesic, and liquid diet was given for 2 weeks.

(4) Postoperative follow-up was performed after 1, 3, and 6 months:

(a) Aesthetic appearance and parent satisfaction.

(b) Occurrence of complications, including oronasal fistula.

(c) Audiological assessment by tympanometry and auditory brainstem response after 6 months.

Results

Regarding age in this study, age in group A ranged from 3 to 7 months (mean: 4.65 months), whereas age in group B ranged from 3 to 6 months (mean: 4.55 months), and showed no significant difference between the two groups (P=0.87) (Table 1). As regards sex in this study, group A had seven boys and three girls, whereas group B had six boys and four girls. There was a male predominance of about 65% in the study (Table 2).

In group A, the operation time ranges from 70 to 90 min (mean: 81 min). In group B, the operation time ranges from 35 to 55 min (mean: 46.5 min). It showed a significant difference between the two groups (P=0.001) (Table 3).

In group A, reduction in the CAG between first and second operation ranges from 2 to 6 mm (mean: 3.95 mm), whereas in group B reduction in the CAG between first and second operation ranges from 1 to 3.5 mm (mean: 2.25 mm). It showed a significant difference between the two groups (P=0.002) (Table 4).

As regards complications, in group A two cases had minor hemorrhage that resulted from vomerine flap bed, which was controlled by mild compression and there was no need for blood transfusion. Group B showed no immediate complications during lip repair, but one case showed significant hemorrhage during palatoplasty controlled by cautereization, and then the patient needed blood transfusion.
In addition, group A showed only one case of minute oronasal fistula after 1 month postoperatively, with no increase in size in subsequent follow-up. There was another case of whistle deformity. Group B showed two cases of oronasal fistula after 1 month postoperatively, which increased in size in subsequent visits (Figs 1–8).

**Discussion**

The treatment of a UCCLP has changed considerably over the past decades, and techniques are still continuously evolving. The ideal technique results in perfect speech and a low fistula rate without affecting the maxillofacial growth. Inferior speech outcomes were reported with delayed hard palate repair, suggesting early closure to be beneficial. Furthermore, the use of vomer flaps to accomplish early hard palate closure produced acceptable or even favorable mid-facial morphology and a low fistula rate was noted [12].

With regard to age in this study, we reported that patient age in group A ranged from 3 to 7 months (mean: 4.65 months), whereas patient age in group B ranged from 3 to 6 months (mean: 4.55 months). These results coordinated with the results obtained by other studies in this area, such as by Kirschner et al. [13], in which the age ranged from 3 to 7 months. However, these results do not match with the study conducted by Ferdous et al. (2010) on 43 patients of UCCLP, in which the age of the patients of the study ranged from 4 to 108 months (9 years) (mean: 28.5 months).

Concerning sex in this study, group A had seven boys and three girls with a male to female ratio of 2.3 : 1, whereas group B had six boys and four girls with a male to female ratio of 1.5 : 1, and thus male predominance found in this study accounts for 65% of the whole study (P=NS), and this matched with other studies as the study conducted by Li et al. [7], in which the male to female ratio in both groups was 2.1 : 1 and 1.9 : 1, respectively, whereas in the study conducted by Ferdous et al., 2010, on 43 patients of UCCLP the male to female ratio in both groups was 2.2 : 1 and 1.5 : 1, respectively. In addition, in the study conducted by Kazi et al. (2013) on 35 patients a male predominance of ratio 1.7 : 1 was found.

Table 3 Comparison between groups A and B regarding duration of the operation

<table>
<thead>
<tr>
<th>Variable</th>
<th>Groups</th>
<th>Means±SD</th>
<th>Range</th>
<th>Student’s t-test</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Duration of operation</td>
<td>Group A</td>
<td>81.0±6.58</td>
<td>70–90</td>
<td>11.63</td>
<td>0.001**</td>
</tr>
<tr>
<td></td>
<td>Group B</td>
<td>46.5±6.69</td>
<td>35–55</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Table 4 Comparison between groups A and B regarding reduction in cleft alveolar gap

<table>
<thead>
<tr>
<th>Variable</th>
<th>Groups</th>
<th>Means±SD</th>
<th>Range</th>
<th>Student’s t-test</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reduction in CAG</td>
<td>Group A</td>
<td>3.95±1.21</td>
<td>2–6</td>
<td>3.62</td>
<td>0.002**</td>
</tr>
<tr>
<td></td>
<td>Group B</td>
<td>2.25±0.86</td>
<td>1–3.5</td>
<td></td>
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</table>

CAG, cleft alveolar gap.

Concerning the duration of the first operation in group A ranged from 70 to 90 min (mean: 81 min). In group B, the operation time ranged from 35 to 55 min (mean:...
46.5 min) (P=0.001, highly significant), and we took much less time than the study conducted by Ferdous et al. (2010) on 43 patients with UCCLP in which the mean time of the first operation on his first group managed by simultaneous repair of cleft lip and anterior hard palate with vomerine flap was 89.57 min and also the mean time of the first operation in the second group managed by only cleft lip repair and later on repair of the entire cleft hard and soft palates was 65.25 min, but in the study conducted by Kazi et al. (2013) on 35 patients with UCCLP the mean time for the first operation was shorter than our study, which was 80.25 min. We found that CAG in this study in group A showed a reduction between first and second operation, which ranged from 2 to 6 mm (mean: 3.95 mm), and in group B the reduction of CAG between first and second operation ranged from 1 to 3.5 mm (mean: 2.25 mm);
CAG was reduced in both groups, but reduction was highly significant in group A ($P=0.002$). The results of the study conducted by Ferdous et al. (2010) on 43 patients with UCCLP reduction of CAG was found to be better than our results, as reduction of CAG in the first group managed by simultaneous repair of cleft lip and anterior hard palate with vomerine flap ranged from 3 to 8 mm (mean: 5.3 mm) and reduction of CAG on the second group managed by only cleft lip repair and later on repair of entire cleft hard and soft palates ranged from 1.5 to 8.5 mm (mean: 4.42 mm); in addition, in the study conducted by Kazi et al. (2013) on 35 patients with UCCLP, it was found that mean reduction of CAG in this studied group was 5.3 mm. The study conducted by Johanna et al. (2014) on 47 patients with UCCLP had shown a significantly higher reduction of CAG width (average: 5.0 vs. 1.5 mm) after early closure of the hard palate using a vomer flap when compared with lip closure only, and this matches with our results.

As regards oronasal fistula formation, in our study we found in group A only one case of minute oronasal fistula after 1 month postoperatively, with no increase in size in subsequent follow-up, whereas in group B we found two cases of oronasal fistula after 1 month postoperatively, with an increase in size in subsequent visits; in a study conducted by Agrawal and Panda [14], it was found that the use of vomerine flap on palatoplasty showed no oronasal fistula in the anterior palate, but 2.95% of fistulas were found at the junction of the hard and soft palate. In the study conducted by Ferdous et al. (2010) on 43 patients of UCCLP, no patient developed oronasal fistula in the first group where repair of cleft lip is associated with repair anterior hard palate with vomerine flap, but in the second group where cleft lip repair is done first and later on repair of entire hard and soft palates was done, two cases of oronasal fistula were found on the seventh postoperative day.
Figure 3

(a) Unilateral complete cleft lip and palate preoperatively. (b) Markings before lip closure. (c) Infiltration of diluted adrenaline 1/200,000. (d) Measurement the cleft alveolar gap before lip closure. (e) Dissection of the orbicularis oris muscle. (f) Nasal layer closure. (g) Final closure of the lip.

Figure 4

Examples for aesthetic results on both groups.
With regard to the occurrence of complications, in group A we found two immediate complications in the form of minor hemorrhage due to elevation of vomerine flaps, which was stopped by compression with saline-soaked cotton, without need of blood transfusion, and also one delayed complication of vermillion notching. In group B, we found no immediate complications during first operation but only one case of significant hemorrhage during palatoplasty, which was stopped by cauterization; also, the patient needed blood transfusion. In the study conducted by Ferdous et al. (2010) on 43 patients of UCCLP, it was found that, in his studied group of simultaneous cleft lip repair and anterior palate repair using vomerine flap, five patients had mild hemorrhage from elevation of vomer flap, which was stopped by application of gelatin foam, which matched with our study as no patient needed blood transfusion; another five patients with mild respiratory difficulty were observed, and a case of vomer flap disruption and a case of vermillion notch were found the second group, which was managed by cleft lip repair only and later on repair of cleft hard and soft palates. Six patients showed significant hemorrhage during subsequent palatoplasty and needed blood transfusion, and seven patients showed mild respiratory difficulty. In the study conducted by Gaurav et al. (2015), he found on his study on 101 patients treated with lip repair and anterior palate repair that failed vomer flaps increased the risks of complications in the subsequent palate repair so he abandoned use of vomerine flaps.

Conclusion
We found that simultaneous repair of cleft lip and hard palate using vomerine flap in patients with UCCLP is a suitable and effective procedure, as there is less chance of maxillary hypoplasia, and it can also done at an early age with the cleft lip repair. The procedure decreases the need of extensive dissection in subsequent palatoplasty and does not need blood transfusion. It reduces CAG significantly and reduces the chance of oronasal fistula formation.

Recommendation
It is recommended to conduct more studies in the simultaneous repair of cleft lip and hard palate using vomerine flap in patients with UCCLP and to compare...
the results among a large number of patients, to study its effect on duration of the operation, postoperative complications, oronasal fistula formation, impact on feeding, and to exclude any growth disturbance of the mid-face.

**Financial support and sponsorship**
Nil.

**Conflicts of interest**
There are no conflicts of interest.

**References**


Author Queries???

AQ1: A running head short title was not provided; please check if this one is suitable and, if not, please provide a short title of up to 40 characters that can be used instead.

AQ2: Please provide permission letters for publication of Figs 4, 7, 8.

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AQ4: Please provide significance of ‘*’ which is marked in the Tables 3 and 4.

AQ5: Please check whether the insertion of Dochead as ‘Original article’ is appropriate.

AQ6: Please check the initialized middle name of the author ‘Hossam A. Alhay’ is correct.

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