



# A randomized controlled trial comparing two techniques for unilateral cleft lip and palate: Growth and speech outcomes during mixed dentition



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## ABSTRACT

**Objective:** To study the growth and speech outcomes in children who were operated on for unilateral cleft lip and palate (UCLP) by a single surgeon using two different treatment protocols.

**Material and methods:** A total of 200 consecutive patients with nonsyndromic UCLP were randomly allocated to two different treatment protocols. Of the 200 patients, 179 completed the protocol. However, only 85 patients presented for follow-up during the mixed dentition period (7–10 years of age). The following treatment protocol was followed. Protocol 1 consisted of the vomer flap (VF), whereby patients underwent primary lip nose repair and vomer flap for hard palate single-layer closure, followed by soft palate repair 6 months later; Protocol 2 consisted of the two-flap technique (TF), whereby the cleft palate (CP) was repaired by two-flap technique after primary lip and nose repair. GOSLON Yardstick scores for dental arch relation, and speech outcomes based on universal reporting parameters, were noted.

**Results:** A total of 40 patients in the VF group and 45 in the TF group completed the treatment protocols. The GOSLON scores showed marginally better outcomes in the VF group compared to the TF group. Statistically significant differences were found only in two speech parameters, with better outcomes in the TF group.

**Conclusions:** Our results showed marginally better growth outcome in the VF group compared to the TF group. However, the speech outcomes were better in the TF group.

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## 1. Introduction

The approximate incidence of CLP is 1.3 per 1000 live births in India (Mossey and Little, 2009). There are numerous techniques described for management of patients with CLP. However, there is sparse information relating to specific management, intervention methods, and long-term outcomes in patients who have completed a strict treatment protocol. The confounding factors and inconclusive outcomes found in the available literature from around the world have led to the development of many protocols; for instance, there existed as many as 194 protocols in 205 European centers in 2001 (Shaw et al., 2001). Inter-center comparisons

have limitations in that they cannot distinguish the relationship between protocols of different centers or the elements of a center's protocol on the outcome, and the influence of the personnel delivering that protocol (Shaw et al., 2005). One possible way to overcome the above limitations is by conducting a randomized controlled trial in subjects from a single center operated on by a single surgeon.

One of the surgical protocols for patients with UCLP is using a vomer flap for the cleft of the hard palate while repairing the cleft lip. The advantages of using vomer flap include simplicity and ease of execution, without adding to surgical trauma or prolonging surgical time. This technique aids in providing an effective nasal lining in almost all types of clefts (Kobus, 1987). A debate still exists regarding the relationship between use of vomer flap as a single lining for the hard palate and defective mid-face growth (Agrawal

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and Panda, 2006). There is a deficit of randomized control trials using the vomer flap as a single layer for the hard palate repair in comparison to other techniques such as the Veau-Wardill-Kilner, Von Langenbeck, and two-flap techniques, among others.

This study was a single-center, prospective, randomized controlled study. A comparative assessment of treatment outcomes of nonsyndromic UCLP patients with two different surgical protocols, namely, the vomer flap (VF) versus the two-flap technique (TF), was carried out. Keeping in mind the large case load being operated on by a single surgeon with no prior commitment to either of the techniques, the randomized controlled trial was deemed appropriate. This design would also suggest how the techniques would compare in the hands of a single surgeon. Success in cleft lip and palate surgery cannot be judged only by the esthetic outcomes, but should also consider functional parameters such as speech and dental arch relationships (Pradel et al., 2009; Hathorn et al., 1996; Mars and Houston, 1990). The two techniques in this study were thus evaluated and compared based on the dental arch relationship, speech outcomes, and occurrence of fistula. It was hypothesized that there would be no significant differences between the two surgical protocols across these parameters.

## 2. Material and methods

After obtaining ethical clearance from Ramachandra University institutional ethics committee (Reference number- IEC/NI/03/MAY/13/33), 200 consecutive patients with nonsyndromic UCLP were included in this randomized trial from 2003 to 2005. The parents received explanations about the proposed study in understandable language. The parents were also informed that the standard of care would not be compromised if they decided to opt out of the study. None of the parents declined to join the study. Randomization was done by allocation concealment, whereby 200 chits were put in a box (100 for each group) and the parent or guardian was asked to pick one chit 1 day before the surgery. The patient was allotted to the treatment protocol as indicated in the chit. Fifteen children who did not complete the two surgeries as suggested in the protocols and 6 children operated on by more than one surgeon were excluded. Of the 179 patients who completed treatment for lip and palate repair, operated on by a single surgeon, only 85 (40 patients in the VF group and 45 patients in the TF group) came for regular follow-up through the period of mixed dentition. These patients were in the age range of 7–9 years at the time of last follow-up. Details on the mean age of intervention and follow-up of the participants is summarized in Table 1. For various reasons, speech samples were obtained from only 34 patients in the VF group and 39 in the TF group.

Two protocols were selected for randomization. In the VF group, the cleft lip was repaired using the Millard technique along with nose correction. The vomer flap was used as a single layer for hard palate closure. After 6 months, soft palate repair was carried out with sharp separation of the muscle fibers from the enveloping oral and the nasal mucosa and from the hard palatal shelves. The tensor

tendon was released just medial to the hamulus, followed by retro positioning and plication of muscle bundles along the midline. During soft palate repair, minor to major lateral releasing incision (as in the von-Langenbeck technique), either unilateral or bilateral, was needed to close the junction area in 36 of 91 patients. In the TF group, cleft lip was repaired by the Millard technique with nose correction, and anterior palate repair up to the incisor foramen. Six months later, the palate was repaired with two-flap palatoplasty. The surgeon had experience of more than 10 years in using the TF technique, whereas the VF technique was introduced in practice only 1 year before the commencement of the randomized trial.

None of the children had either preoperative or postoperative orthopedic intervention during the mixed dentition. All patients underwent routine speech evaluation between 4 and 6 years of age. Based on the profile of articulation, they were provided with three to five sessions of speech therapy at the hospital, focusing on demonstrating correction of specific articulation errors to the parents. Home training programs were recommended for correction of articulation. None of them received long-term institution-based speech therapy for correction of speech errors.

To study the maxillary growth outcomes, digital intraoral photographs were taken for all patients during mixed dentition. The set of intraoral photographs included the frontal view in occlusion, right and left buccal views, and right and left overjet views. History of palatal fistula was taken from the records. Speech samples of all patients were audio-recorded by a speech pathologist in a sound-treated room. Recognizing the need for a comprehensive speech sample (Sell, 2005; Kuehn and Moller, 2000), the recorded sample comprised a 2-min conversation, counting of numbers from 1 to 10, syllable repetition, repetition of phonetically loaded words, and sentences in the Tamil language. All children passed hearing screening (pure tone average of less than 20 dBHL) at the time when the speech samples were recorded. However, the status of the middle ear was not examined.

Mars et al. (1987) published a simple method named the GOSLON (an acronym denoting “Great Ormond Street, London and Oslo”) Yardstick to score the outcome of treatment in patients with unilateral cleft lip and palate. The outcome of treatment is viewed on occlusion and scored by experienced raters. Patients are categorized into one of the following five groups: group 1: positive overjet with average inclined or retroclined incisors with no cross-bite or open bite with excellent long-term outcome; group 2: positive overjet with average inclined or proclined incisors with unilateral cross-bite or cross-bite tendency with or without open bite tendency around the cleft site with good long-term outcome; group 3: edge-to-edge bite with average inclined or proclined incisors or reverse overjet with retroclined incisors with unilateral cross-bite with or without open bite tendency around the cleft site, with fair long-term outcome; group 4: reverse overjet with average inclined or proclined incisors, with or without bilateral cross-bite tendency with or without open bite tendency around the cleft site, with poor outcome; and group 5, reverse overjet with proclined incisors, bilateral cross-bite, and poor maxillary arch form and palatal vault anatomy with very poor outcome (Mars et al., 2006). The GOSLON Yardstick does not involve application of precise and detailed criteria, but relies on a simple method of judgment (Lilja et al., 2006).

Two examiners, a surgeon and an orthodontist, who were not members of the cleft team, scored the intraoral digital photographs on two separate occasions 2 weeks apart (Fig. 1). Each examiner was calibrated previously in the use of the GOSLON Yardstick to reduce systematic bias. The examiners were given a reference image of GOSLON score 1 to 5 as a guide to categorize the photographs during the rating (Liao et al., 2009). No conferring between examiners was allowed, and an overall GOSLON final score was

**Table 1**  
Mean age of intervention and outcomes of study

Protocol	Vomer flap (VF)	Two-flap (TF)
Mean age of lip repair	5.22 Months	6.3 Months
Mean age of palate repair	12.3 Months	12.9 Months
Mean age of follow-up for dental arch relationship evaluation	7.8 Years	8.1 Years

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