An Evidence-Based Approach to Secondary Cleft Lip Nasal Deformity

Ross I. S. Zbar, M.D.
John W. Canady, M.D.
Montclair, N.J.; and Iowa City, Iowa

The Maintenance of Certification module series is designed to help the clinician structure his or her study in specific areas appropriate to his or her clinical practice. This article is prepared to accompany practice-based assessment of preoperative assessment, anesthesia, surgical treatment plan, perioperative management, and outcomes. In this format, the clinician is invited to compare his or her methods of patient assessment and treatment, outcomes, and complications, with authoritative, information-based references.

This information base is then used for self-assessment and benchmarking in parts II and IV of the Maintenance of Certification process of the American Board of Plastic Surgery. This article is not intended to be an exhaustive treatise on the subject. Rather, it is designed to serve as a reference point for further in-depth study by review of the reference articles presented. (Plast. Reconstr. Surg. 127: 905, 2011.)

CLINICAL SCENARIO

A 16-year-old boy consults for a unilateral cleft lip nasal deformity. In infancy, he was treated at a cleft center. At the time of lip closure, he underwent closed nasal correction with skin undermining and cartilage realignment using percutaneous sutures. He still has significant alar deformity with nasal septal deviation. What is the best evidence to guide you in managing this patient?

Secondary cleft lip nasal deformity refers to those abnormalities of the nose that persist despite primary treatment in individuals with cleft lip. Although the severity of the initial cleft deformity contributes to the ultimate outcome of the nose, improvements in primary care of cleft deformities by experienced centers have decreased the severity of these secondary deformities. Techniques such as presurgical orthopedics, nasal molding, simultaneous nasal repair at the time of cleft lip closure, and gingivoplasty have all contributed to improved primary outcomes. Nevertheless, there are many instances where revision of cleft lip nasal deformity is required to improve both functional and aesthetic outcome. The purpose of this article is to provide a summary of the best available evidence on correction of cleft lip nasal deformity that, when combined with individual clinical expertise, can assist the surgeon in the continuing evolution toward better outcomes.

METHODS FOR IDENTIFYING EVIDENCE

A literature search of PubMed, the Cumulative Index to Nursing and Allied Health Literature, and the Cochrane Library was performed to obtain the best available evidence on secondary cleft lip nasal deformity, with emphasis on preoperative assessment, treatment, and outcomes. The following search terms were combined as appropriate, and PubMed MeSH terms were used when available: “secondary cleft lip nasal deformity,” “cleft nasal deformity,” “primary cleft nasal repair,” “cleft lip nasal deformity,” “unilateral cleft lip nasal deformity,” “bilateral cleft lip nasal deformity,” “diagnosis,” “preoperative assessment,” “risk factors,” “antibiotic prophylaxis,” “anesthetics,” “premedication,” “surgical treatment plan,” “reconstructive surgical procedures,” “treatment,” “surgery,” “septoplasty,” “rhinoplasty,” “nasal correction,” “cartilage graft,” “outcome,” “complica-

Disclosure: The authors have no financial interest in any of the products, devices, or drugs mentioned in this article.
tions,” “postoperative complications,” “pain management,” and “analgesia.” The initial search was limited to human studies that were published from 1999 to 2009 and indexed as meta-analyses, randomized controlled trials, clinical trials, comparative studies, or case series; however, additional references were included if deemed necessary for discussion. Studies were excluded if the full text was inaccessible or of non-English language, as the study quality could not be evaluated. Relevant studies were appraised for quality and validity according to criteria published by the Critical Appraisal Skills Programme and assigned a level of evidence with the American Society of Plastic Surgeons Evidence Rating Scales (Tables 1 and 2). Studies included in this review are identified below by the type of clinical question (diagnosis or therapy) and level of evidence. Evidence ratings were not assigned to studies with inadequately described methods and/or worrisome biases or to references included for discussion purposes only (e.g., narrative reviews).

EVIDENCE ON PREOPERATIVE ASSESSMENT

The position of the cleft nose is determined by both the skeletal foundation and the facial soft tissues, both of which are abnormal, spanning a wide spectrum of severity in patients with cleft lip nasal deformity. Moreover, prior surgery can alter these relationships.

Fisher et al. show that experts are able to subjectively rank the severity of cleft lip nasal deformity that correspond to objective criteria (Diagnosis: Level II Evidence).2 These criteria include the columellar angle–to–nostril width ratio. As the cleft width and skeletal nasal base become progressively asymmetric, measurements of the columellar angle–to–nostril width ratio reflect these changes. Fisher et al. state that permanent records of the primary cleft lip deformity must be maintained to perform meaningful outcome studies in cleft lip repair.

A decade earlier, Fisher et al., using three-dimensional computed tomography, demonstrated four consistent findings in unilateral cleft lip: (1) the columellar base is deviated to the non-cleft side; (2) the cleft-side alar base is more posterior than the non-cleft-side alar base; (3) the non-cleft-side alar base is farther from the midline than the cleft-side alar base and; (4) the cleft-side piriform margin is farther posterior than the non-cleft-side piriform margin (Diagnosis: Level IV Evidence).3 When performing either concomitant primary cleft nasal repair at the time of lip closure or secondary rhinoplasty, the surgeon must be aware of these facts.

Kim et al. described a simple method of assessing surgical outcomes using two-dimensional digital images and regression analysis (Diagnosis: Level IV Evidence).4 This too is helpful for assessing results in an objective fashion.

EVIDENCE ON SURGICAL TREATMENT PLAN

A myriad of surgical techniques address secondary cleft lip nasal deformity, thus illustrating the complicated nature of this problem. In addition, the fact that so many techniques are espoused by various surgeons as the means of achieving successful secondary rhinoplasty belies the fact that perhaps no single approach is actually the

Table 1. American Society of Plastic Surgeons Evidence Rating Scale for Diagnosis

<table>
<thead>
<tr>
<th>Level of Evidence</th>
<th>Qualifying Studies</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>High-quality, multicenter or single-center, cohort study validating a diagnostic test (with a criterion standard as reference) in a series of consecutive patients; or a systematic review of these studies</td>
</tr>
<tr>
<td>II</td>
<td>Exploratory cohort study developing diagnostic criteria (with a criterion standard as reference) in a series of consecutive patients; or a systematic review of these studies</td>
</tr>
<tr>
<td>III</td>
<td>Diagnostic study in nonconsecutive patients (without a consistently applied criterion standard as reference); or a systematic review of these studies</td>
</tr>
<tr>
<td>IV</td>
<td>Case-control study; or any of the above diagnostic studies in the absence of a universally accepted criterion standard</td>
</tr>
<tr>
<td>V</td>
<td>Expert opinion; case report or clinical example; or evidence based on physiology, bench research, or “first principles”</td>
</tr>
</tbody>
</table>

Table 2. American Society of Plastic Surgeons Evidence Rating Scale for Therapy

<table>
<thead>
<tr>
<th>Level of Evidence</th>
<th>Qualifying Studies</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>High-quality, multicenter or single-center, randomized controlled trial with adequate power; or systematic review of these studies</td>
</tr>
<tr>
<td>II</td>
<td>Lesser quality, randomized controlled trial; prospective cohort study; or systematic review of these studies</td>
</tr>
<tr>
<td>III</td>
<td>Retrospective comparative study; case-control study; or systematic review of these studies</td>
</tr>
<tr>
<td>IV</td>
<td>Case series</td>
</tr>
<tr>
<td>V</td>
<td>Expert opinion; case report or clinical example; or evidence based on physiology, bench research, or “first principles”</td>
</tr>
</tbody>
</table>
best. There is no cookie-cutter solution to this problem. Therefore, before selecting the appropriate procedure, the surgeon must first carefully identify the distorted anatomy through either anthropomorphic or photographic analysis. This will lead to the proper diagnosis of misplaced anatomy, which subsequently allows the selection of a logical surgical intervention.

There is no doubt that better secondary outcomes are achieved by improving primary results at the time of lip closure by addressing the nose (Therapy: Level III Evidence). For years, many surgeons were concerned that intervening with the nose at the time of primary lip closure could compromise subsequent cartilage growth. However, this concept has been clearly dismissed. Therefore, all efforts are currently focused on maximizing nasal outcomes at the time of primary lip closure.

Bennun and Figueroa described the use of a presurgical splint to maximize positioning of the nasal tissues in primary repair (Therapy: Level IV Evidence). Goals of dynamic presurgical nasal splinting include straightening the columella, elevating the nasal tip, and reshaping the nasal ala. These maneuvers position the soft tissues for better primary closure and thus decrease the chances of secondary rhinoplasty.

The use of an absorbable internal nasal splint in primary cleft rhinoplasty to provide a long-term bolster effect is described by Wong et al. The theory behind this technique is that the cartilages are less likely to shift with use of a long-term bolster. Although the authors demonstrate aesthetic improvement in the postoperative period, there are minimal data regarding significantly long-term outcome (Therapy: Level III Evidence). Several years earlier, Yeow et al. also documented similar improvement in aesthetic outcomes with external nasal splinting using silicone stents. They recommended splinting for 6 months. These authors have somewhat longer follow-up data but still lack outcome into adulthood (Therapy: Level III Evidence).

The importance of diagnosing and correcting all nasal soft-tissue and skeletal bony deficiencies at the time of secondary rhinoplasty is discussed by Ahuja (Therapy: Level IV Evidence). However, because these particular cases are performed in the underdeveloped world, many of the bony and soft-tissue interventions occur simultaneously because of the economic situation of the patients.

In contrast, Cohen et al. recommend that secondary cleft rhinoplasty take place only after all orthognathic work has been performed (Therapy: Level IV Evidence). In addition, growth spurts should be completed, permitting proper development of the structures. This typically occurs in adolescence. Furthermore, fistulas should be closed before undertaking nasal work. This allows for a stable and symmetric bony platform to exist on which to execute a revision rhinoplasty without risk of oral contamination. Cohen et al. also point out that there is no single rhinoplasty technique with which to correct the various deformities encountered. Nevertheless, both airway and appearance must be addressed simultaneously.

Byrd et al. present several key concepts that help identify the anatomical deficiencies of the cleft lip nasal deformity (Therapy: Level V Evidence). These include analysis of nasal lining, nasalis muscle attachments, malposition of the lateral crus and dome, tip projection, presence of ala crease or buckling, and bony projection. Byrd et al. then describe a complex algorithm of various surgical maneuvers designed to correct each specific deficiency.

Many authors have described various cartilage grafting techniques through open rhinoplasty to address unilateral cleft lip nasal deformity (Therapy: Level IV Evidence). These are essentially well-described, standard rhinoplasty maneuvers, including grafting to the ala, columella, and/or tip, in addition to suture techniques to reposition cartilages.

Koh and Eom recommend placing the open rhinoplasty columella incision in an asymmetric fashion to account for the subsequent correction of the ala (Therapy: Level IV Evidence). Their technique involves lifting the ala on the cleft side into the ideal position with a forceps and then drawing the transverse columella incision with its intranasal extensions. This means that when the nostril is relaxed, the incision becomes asymmetric. Koh and Eom argue that this improves outcomes by accommodating for subsequent changes in the soft-tissue envelope. In addition, they stent the nose for 6 months postoperatively. Although short-term results demonstrate improvement, long-term follow-up beyond 2 years is absent.

Rather than using cartilaginous augmentation or suture repositioning to achieve improvement, Cho et al. describe using auricular composite grafts to either the columella or ala (Therapy: Level IV Evidence). The use of distant tissue imports additional soft tissue to the region, thus correcting deficiencies in their series of patients. Problems with these grafts include absorption and color mismatch, with some stepoff deformities resulting. Yonehara et al. describe using iliac bone graft in a cantilevered fashion to augment the nasal appearance (Therapy: Level V Evidence).
These authors stress the need for tight application of the bone graft, although they only dissect a subperioseal pocket without bony fixation. Disadvantages include a firm nasal tip.

Kim et al. investigated the medial crus of the lower lateral cartilage on the cleft side as a source of ala distortion from the worm’s-eye view (Therapy: Level II Evidence). These authors favor the medial crus elevation technique to improve nasal symmetry. This technique excises a crescent of tissue on the alar rim and elevates the depressed medial crus on the cleft side, improving the ala contour. There is no cartilage grafting. They note that the medial crus is not hypoplastic but rather downwardly displaced.

Using similar logic, Cho and Baik describe a combined reverse-U incision and V-Y plasty to address alar asymmetry through cartilage scoring and transfixion suturing without augmentation cartilage grafting (Therapy: Level V Evidence). However, in a follow-up study by Cho, long-term evaluation beyond 4 years demonstrated mild relapsing asymmetry (Therapy: Level IV Evidence).

Han and Choi describe a three-dimensional Z-plasty (Therapy: Level IV Evidence). These authors address the nasal cartilages in the standard and various fashions through open rhinoplasty using relocation, suspension, and/or augmentation. Their three-dimensional Z-plasty is used at the end of the procedure to achieve columellar lengthening by transposing a triangular flap of skin.

Agarwal and Chandra describe a unique cord-like structure fanning from the deflected caudal border of the septum to the anterior nasal spine in adult unilateral cleft lip patients (Therapy: Level IV Evidence). They describe this structure as the septospinal ligament and report that it must be excised while straightening the caudal septum at the anterior nasal spine during septoplasty at the time of secondary rhinoplasty. Meanwhile, Bagatain et al. describe the need to reconstitute the nasalis muscle sling around the nasal ala when closing the clefted structure in either primary or secondary rhinoplasty. Unfortunately, they experienced a significant rate of infection using permanent sutures to fixate this structure in the deep periosteum (Therapy: Level IV Evidence).

Bilateral cleft lip presents a further variable with respect to the secondary nasal deformity: shortened columellar length.

Nakajima et al. propose that, just as in unilateral cases, primary rhinoplasty at the time of lip closure for bilateral cases will lead to better outcomes (Therapy: Level IV Evidence). They use an inverted trapezoid suture technique on the nasal domes and postoperative nasal molding. They achieve excellent results with moderately long-term follow-up. McComb also supports an open tip rhinoplasty at the time of primary lip repair as a means of achieving better long-term nasal outcomes. He evaluated 10 patients after 18 years of follow-up, with compelling results (Therapy: Level IV Evidence).

Garri et al. compare the Wolfe double-arch tip rhinoplasty versus the cartilage release with tip-grafting techniques in patients undergoing secondary rhinoplasty who had a significantly shortened columella caused by bilateral clefting (Therapy: Level II Evidence). The Wolfe technique uses a columellar strut that extends beyond the native lower lateral cartilages, which then has symmetric conchal cartilages placed in an arch formation on top of the intact lower lateral cartilages. This is compared with traditional tip grafting using interdomal sutures and nonanatomical lateral and shield grafts. The authors had positive aesthetic results with the Wolfe technique and recommended that surgeons become facile with this approach.

Another technique for management of the bilateral cleft lip nasal deformity is simultaneous use of the Abbé flap and open rhinoplasty (Level IV Evidence). Once again, though, standard techniques of rhinoplasty are used with cartilage grafting and/or suturing. Nearly 20 percent of the patients required revision to the lip incisions or nasal profile. Follow-up was short term (<2 years).

Rikimaru et al. identify the paucity of columellar length as an aesthetic problem with these patients and describe a modification to the forked flap technique whereby a subcutaneous pedicle is delivered, allowing much more versatility (Therapy: Level IV Evidence). Nasal tip augmentation is performed according to routine, but the improved vascularity of the subcutaneously pedicled forked flaps reportedly preserves the increase in projection achieved by adding viable tissue. The outcomes of the five reported cases are preserved with variable follow-up (i.e., 1 to 2 years).

EVIDENCE ON POSTOPERATIVE OUTCOMES

As noted above, objectively comparing postoperative outcomes with significant long-term follow-up is difficult. The few studies that have long-term follow-up are noted above. Objectively grading these outcomes, though, remains a challenge. Moreover, because the original cleft deformity can vary significantly, as can the surgical intervention at the time of primary closure, there is
a dearth of meaningful outcome data regarding correction of cleft lip nasal deformity.

**SUGGESTED TREATMENT FOR CLINICAL SCENARIO**

When practicing evidence-based medicine, the surgeon should consider the strength of the available evidence and integrate the evidence with his or her clinical expertise and the patient’s values and preferences to develop an appropriate treatment plan. The treatment plan below is an example of how the surgeon might use the evidence to care for this particular patient.

Based on the available evidence, this patient should first undergo careful preoperative analysis of his cleft lip nasal deformity (**Level IV, V Evidence**). Open rhinoplasty technique should be used (**Level IV, V Evidence**). Cleft lip nasal deformity can be addressed with standard suture repositioning and/or augmentation as described above (**Level IV, V Evidence**).

**REFERENCES**