Premaxillary Setback With Posterior Vomerine Ostectomy: Outcomes of Single-Stage Repair of Complete Bilateral Cleft Lip With a Severely Protruding Premaxilla

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Abstract

Objective: Evaluating the safety and outcomes of premaxillary setback with posterior vomerine ostectomy in single-stage repair of complete bilateral cleft lip (CBCL) with severe premaxillary protrusion.

Design: Retrospective case series.

Setting: Multiple outreach surgical sites.

Patients/Participants: From 2012 to 2016, 41 patients with CBCL and severe premaxillary protrusion underwent posterior vomerine premaxillary setback (PVPS) by a single surgeon in Brazil, Ecuador, and Peru. Patients 4 months to 18 years old undergoing primary or revision CBCL surgery were eligible for inclusion in the study. Patients with diagnosed syndromes were excluded.

Interventions: Posterior vomerine premaxillary setback.

Main Outcome Measures: Postoperative complications and postoperative aesthetic outcomes.

Results: The mean age at surgery was 3.7 ± 3.8 years, with an average follow-up time of 17.0 ± 13.9 months. Patients underwent their procedures in Brazil (71%), Ecuador (22%), and Peru (7%). The majority of patients were aged 2 years or less (56%), were males (54%), had undergone prior surgery (56%), and had not undergone preoperative surgical orthopedics (95%). None of the patients developed major complications. All patients were able to undergo PVPS with concomitant required procedures and had good aesthetic outcomes.

Conclusions: Few reports have evaluated single-stage CBCL repair or revision with severe premaxillary protrusion using PVPS. Our study shows that this technique is safe and results in good aesthetic outcomes. Further follow-up with anthropometric patient data is needed to evaluate long-term postoperative outcomes.

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Introduction
A prominent premaxilla can be found in many children with complete bilateral cleft lip (CBCL) and complicates their surgical management. Premaxillary retropositioning is frequently indicated in primary or revisional CBCL surgery to avoid wound tension, which can significantly increase the risk of complications including dehiscence and infection. Existing appliances for premaxillary setback include extraoral head caps, elastic straps, tapes, nasoalveolar molding (NAM), Latham appliances, and Burston plates (Burston, 1958; Burston, 1960; Latham et al., 1976; Millard and Latham, 1990). Some of those techniques are effective and are commonly used for patients with wide unilateral or bilateral cleft lips, but require lengthy therapy, may be associated with various complications, and do not adequately address cases with a locked-out premaxilla. Their success can also heavily depend on patients’ compliance and access to care, further complicating their use. Unilateral or bilateral lip adhesion may be performed to close very wide clefts at the time of primary surgery but involves the need for secondary surgery. It also may not successfully mold the premaxillary and vomer bones and can lead to scarring of the orbicularis oris muscle, all of which add complexity to the definitive repair (Wallace, 1963). All of these factors make single-stage premaxillary setback a valuable surgical option in this patient population.

The purpose of a vomerine ostectomy is to allow premaxillary retropositioning into the maxillary arch. Considering the premaxillary blood supply, an osteotomy anterior to the vomero-premaxillary suture (VPS) may potentially be associated with premaxillary necrosis. It may also limit the extent of concurrent rhinoplasty and lead to thinning of the philtrum at the time of repair while potentially damaging septal segments that are important for facial growth. All of those factors combined may result in a poor aesthetic outcome.

A premaxillary setback technique with a vomerine ostectomy posterior to the VPS, avoiding some of the pitfalls described above, is presented here. Our series highlights the outcomes of this surgical procedure and its applicability in tertiary centers as well as in outreach settings.

Methods
This retrospective study includes cases performed between September 2012 and September 2016 in Brazil, Ecuador, and Peru. Inclusion criteria consisted of the presence of a CBCL deformity and a severely protruding premaxilla. Patients with diagnosed syndromes were excluded from the study. The series included primary and revision procedures for all patients aged 4 months to 18 years. Patients who met inclusion criteria underwent premaxillary setback with posterior vomerine ostectomy.

All procedures were performed by the same surgeon (F.A.). Patients were followed through local multidisciplinary cleft clinics. Patient charts were reviewed, and data were extracted for age, gender, use of presurgical orthopedics, surgical history, concurrent gingivoperiosteoplasty (GPP), length of the setback, postoperative complications, and length of follow-up.

The study’s primary outcome was the development of postoperative clinical complications. Postoperative aesthetic results constituted the study’s secondary outcome, specifically defined as the following:

1. Restoration of symmetry of Cupid’s bow in relation to the lip with the 2 high points being equidistant from the low point.
2. Alignment of Cupid’s bow with the nose with matching of the 2 high points in relation to the nostrils’ base.
3. Restoration of continuity of the orbicularis oris muscle throughout the upper lip without residual deficiency or notching.
4. Symmetry of the philtral ridges and adequate fullness of the philtral tubercle.
5. Adequate support and projection of the tip of the nose, symmetrical outflaring of the medial crural footplates, and symmetrical width and shape of the nostrils.

Institutional review board approval was obtained from the ethics and research committee of São Judas Tadeu Hospital. Written informed consent including consent for publication of patient information and images was obtained for all patients from their legally authorized representative. The authors are members of a nongovernmental organization providing comprehensive cleft care and follow-up in outreach settings, including Brazil, Ecuador, Lebanon, El Salvador, and Peru. Descriptive analysis was performed using SPSS v 21.0 (IBM, Armonk, New York).

Surgical Technique
The extent of the desired premaxillary setback is determined prior to surgery. A premaxillary protrusion of ≥ 10 mm is used as the cutoff for the need to perform a setback in a setting where other options are not available. The remainder of the clinical examination is also crucial to the planning process, specifically the premaxillary anatomy in relation to the palate. The size of the ostectomy is dictated by the extent of the protrusion for the setback to achieve continuity of the maxillary arch.

The single-stage procedure is performed under general anesthesia, with the patient in supine position with minimal extension of the neck and stabilization of the head. Nasal and infraorbital nerve blocks are performed. The local anesthesia technique has been previously described by the senior author.
An equal mixture of volumes of 0.5% lidocaine with epinephrine 1:200 000 and 0.25% bupivacaine with epinephrine 1:200 000 is injected first at the infraorbital foramen. A total of 0.25 mL is injected into each side. The same mixture and volume is then injected at the external nasal nerve (a branch of the ophthalmic nerve), which is located beneath the compressor nasi and supplies the integument of the ala and the tip of the nose. The vomer and premaxilla are then infiltrated with 1 mL of the same anesthetic mixture. Prior to the incision, 12 minutes are fully allowed to elapse in order to maximize the vasoconstrictive effect of epinephrine. The nasolabial markings used by the authors for cleft lip repair adhere to those described by Mulliken (2009). Although the premaxillary setback is expected to affect the configuration of the cleft lip and the position of the prolabium, the anatomical reference points remain the same.

The incision used by the authors is a “cojoined double Y” incision, which consists of a vertical midline incision made along the caudal crest of the vomer, extended in a Y-shaped configuration at both ends. This is comparable to the incision made for a superiorly based vomer flap for palatoplasty. After incision of the mucosa, bilateral flaps are raised, and the VPS is identified. The 2 created mucoperiosteal flaps are reflected laterally. The tissues are elevated only enough to perform the osteotomy (Figure 1). Atraumatic flap elevation and dissection are necessary to prevent compromising mucosal blood supply or affecting the nasal septal cartilage and midface growth center. For patients with an intact or previously repaired palate, the vomer is accessed intranasally: For patients with an intact palate, access to the vomer is gained through one of the alveolar gaps of the CBCL. This is easier done after performing the lip dissection. A horizontal incision is made along the vomerine mucosa only on that side of the cleft. The incision is made posterior to the VPS, to avoid disrupting the blood perfusion to the area. The size of the incision is dictated by the size of the planned setback. A mucoperiosteal flap is raised superiorly to provide the exposure to perform osteotomies. For patients with a repaired complete bilateral cleft palate, an incision is made at the anterior margin of the secondary palate, going from the level of the first molar on one side to the level of the first molar on the contralateral side. The size of the incision is dictated by the size of the planned setback. A mucoperiosteal flap is then

Figure 1. Vomerine ostectomy steps. A, A cojoined double Y-shaped incision marking is made posterior to the vomero-premaxillary suture (VPS). B, The cojoined double Y-shaped incision is made along the caudal crest of the vomer, and bilateral mucoperiosteal flaps are raised and reflected laterally, exposing the vomer. C, The osteotomies are made parallel to the caudal end of the premaxilla. Dashed markings show the edges of the reflected mucoperiosteal flaps and the markings for the vomerine osteotomies. D, The ostectomy is completed.
raised, and the vomer is visualized. The premeasured ostectomy length is marked on the vomer, starting at 5 mm posterior to the VPS. Care is taken to stay exclusively on the vomer, which is located in a relatively more posterior position in older patients (Verwoerd and Verwoerd-Verhoef, 2010).

Osteotomies are done with a reciprocating saw. The superior aspect of the new premaxillary unit is gently separated from the vomer to bring more mobility to the premaxilla and avoid nasal stenosis. In order to maximize bony contact and stability and avoid excision of cartilaginous septum, the osteotomy needs to be roughly parallel to the caudal end of the premaxilla (Figures 1 and 2). The osteotomies are done in keeping with the principles of pediatric septal anatomy, avoiding growth centers as much as possible. Care is taken to avoid compromising the vascularity of the philtrum and premaxilla.

Premaxillary retropositioning is performed with digital pushback (Figure 2). In patients with anterior bite, semirigid fixation with no. 1 steel wire is used to stabilize the premaxilla in line with the maxillary arch. The wire is attached to the canine pillar, crossing through the anterior nasal spine, and anchored on the contralateral canine pillar in a figure of 8 fashion. After completion of the premaxillary setback, the vomerine mucosa is closed over the ostectomy site with 4.0 Vicryl on RB-1 needle. Gingivoperiosteoplasty is performed to stabilize the premaxilla in its new position and to achieve closure of the alveolar gap bilaterally. For patients without deciduous teeth, stabilization is performed with GPP only, without wire stabilization. Primary bilateral cleft lip repair or cleft lip revision is then done in standard Mulliken technique (Mulliken, 2009; Rogers et al., 2013). At this juncture, cleft lip rhinoplasty is performed, completing the procedure. In patients presenting with unrepaired cleft lip and palate, the setback, cheiloplasty, and rhinoplasty are performed, leaving the palatal repair for a later stage. If a wire is used, it is removed when the palate repair is performed at 12 to 16 months. If the patient has an intact palate, the wire is removed at the time of alveolar bone grafting at 8 to 12 years of age.

**Postoperative Care and Follow-Up**

Postoperatively, patients are placed on a progressive liquid to mashed diet for 3 weeks following which a regular diet can be resumed with no restrictions. Postoperative instructions are the same regardless of the age of the patient. Patients are placed on a 3-day postoperative course of azithromycin.

All patients should ideally be followed by a surgeon as well as an orthodontist at 7, 30, and 90 postoperative days and yearly thereafter. Postoperative physical examination focuses on...
viability of the GPP flaps, integrity of the suture lines, and stability of the premaxilla with gentle manual pressure. Whenever available, pre- versus postoperative cephalometric X-rays can be obtained to monitor the position of the premaxilla. Computed tomography scan can be obtained to monitor bone growth and healing. In outreach settings, patients were followed postoperatively by our surgical team with physical examination at 7 days and 1 year.

Results

Between September 2012 and September 2016, 42 patients underwent premaxillary setback with vomerine ostectomy. One patient was lost to follow-up after moving to another state and was excluded from the analysis.

Table 1 depicts general patient characteristics. The patients underwent their procedures in Brazil (71%), Ecuador (22%), and Peru (7%). The mean age at surgery was 3.7 ± 3.8 years, while the average follow-up time was 17.0 ± 13.9 months. The majority of patients were aged 2 years of less (56%), were males (54%), underwent prior surgery (56%) including bilateral cleft lip repair (17%) or bilateral cleft lip and palate repair (39%), and did not undergo preoperative surgical orthopedics (95%). Patients with prior surgical history had not undergone premaxillary setback and presented with unsatisfactory aesthetic results including premaxillary protrusion and/or exposure, lip necrosis, and lip dehiscence. The 23 patients with prior surgical history underwent bilateral cleft lip revision with concomitant premaxillary setback, GPP, and rhinoplasty. Out of the 23 patients, 17 patients also underwent palatal revision surgery. Most patients (90%) underwent GPP at the time of the premaxillary setback, those who did not were older with teeth already erupted. The extent of premaxillary setback ranged between 7 and 16 mm.

All 41 patients with long-term follow-up underwent successful premaxillary setback with the concomitant procedures described, resulting in good aesthetic outcomes. Minor complications related to minimal premaxillary mobility (<1 mm with gentle manual pressure) and superficial surgical site infection were encountered in 7 (17%) patients and are detailed in Table 2. No major complications were encountered.

Representative Cases

Case 1. The first patient is an 8-year-old female who presented to the Global Smile Foundation Multidisciplinary Cleft Care Center in Guayaquil, Ecuador, in March 2015 (Figure 3). She had undergone 4 prior surgical procedures with poor outcomes (Figure 3A): primary bilateral cleft lip repair with secondary dehiscence, cleft palate repair with residual palatal fistula, and 2 subsequent cleft lip/nose revisions. Her outcomes were unsatisfactory based on the following findings: lack of continuity of the orbicularis oris muscle, asymmetry of Cupid’s bow in relation to the lip, asymmetry of Cupid’s bow in relation to the nose, asymmetry of the philtral ridges, inadequate fullness of the philtral tubercle, inadequate nasal tip and projection, asymmetry of the width and shape of the nostrils, and a poor aesthetic result. The patient showed signs of severe social withdrawal, attributed by herself and her family to her residual lip deformity.

After clinical evaluation and interdisciplinary planning, the patient underwent a single-stage surgery including premaxillary setback with posterior vomerine ostectomy, palatal fistula repair, GPP, and septrhinohiocheioplasty. At 2-year postoperative follow-up, she presented with significant improvement in facial appearance and social integration (Figure 3B). The patient now has Cupid’s bow symmetry and alignment with the nose, continuity of the orbicularis oris muscle, symmetry of the philtral ridges, adequate fullness of the philtral tubercle, and adequate nasal tip support and projection. She also demonstrated marked improvement in social behavior and reported better social integration.

Case 2. The second patient is a 7-year-old female whose parents sought care for at our Multidisciplinary Cleft Care Center in Macapá, Brazil, in October 2016 for bilateral cleft lip and palate repair (Figure 4). The patient had not undergone prior therapy. On physical examination, she had significant projection of the premaxilla in relation to the midface and was not a candidate for safe primary lip/nose repair without premaxillary setback. A single-stage premaxillary setback was performed along with primary bilateral cleft lip repair, GPP, and primary rhinoplasty. No complications were noted at 1-year follow-up; her premaxilla was healthy and stable without any mobility in the maxillary arch. Premaxillary setback allowed for an
excellent aesthetic outcome. The single-stage procedure had accomplished the following: restoration of symmetry of Cupid’s bow in relation to the lip with the 2 high points being equidistant from the low point, and alignment with the nose with matching of the 2 high points in relation to the nostrils’ base. Furthermore, continuity of the orbicularis oris muscle throughout the upper lip without residual deficiency or notching, symmetry of the philtral ridges, and adequate fullness of the philtral tubercle was also achieved. The nose demonstrated adequate support and projection of the tip, symmetrical outflaring of the medial crural footplates, and symmetrical width and shape of the nostrils.

Discussion

Correct growth of the maxillary arches, nasal septum, and premaxilla require a fine balance between the circumoral musculature, the tongue, and continuous bony and soft tissue boundaries anteriorly. In patients with bilateral cleft lip with a protruded premaxilla, these relationships are altered, which leads to the unrestrained projection of the premaxilla and relative hypoplasia of the maxillary arches (Mulliken, 2009). In patients with repaired bilateral cleft lip, a significantly protruded premaxilla may result in ongoing functional problems beyond the risk of immediate postoperative complications including the absence of proper anterior occlusion, lateral mobility of the premaxillary segment, and labial or palatal oronasal fistulae (Mulliken, 2009). Problems with speech, oral hygiene, and the bearing of facial differences may lead to significant psychosocial problems and social stigma during childhood. Correction of the prominent and rotated premaxilla by orthodontic treatment is not available in many centers, especially in outreach settings. Furthermore, orthopedic treatment alone is prone to failure in the setting of poor compliance or device malfunction and is unlikely to be effective in children who are referred late, after 10 months of age when the VPS is stiff and the maxillary elements are rigid (Mulliken, 2003). In our series of 41 patients, our single-stage technique for bilateral cleft lip repair and premaxillary setback with an ostectomy performed posterior to the VPS proved to be safe and allowed for cosmetic results that would have not been otherwise possible in an isolated bilateral cleft lip repair procedure. Our series also shows that this technique can be safely performed in select outreach settings with adequate postoperative support and long-term follow-up.

The risk of jeopardizing premaxillary perfusion is a serious consideration driving operative strategy (Vyas et al., 2016). Published reports on the technique are relatively scant and we argue that posterior vomerine ostectomy is safer from a vascularity perspective, especially for a surgeon novice to the technique. Our technique also allows adequate primary or secondary rhinoplasties at the time of lip repair, which is especially important in outreach settings and revision cases. This is a significant advantage compared to previous publications on anterior VPS ostectomy that note limitations to performing simultaneous rhinoplasty at the time of lip repair (Fakih-Gomez et al., 2015).

In patients with CBCL, the septopremaxillary ligament is the only attachment of the premaxilla to the nasal septum at the VPS (Latham, 1970; Burdi, 1971; Fakih-Gomez et al., 2015). The premaxilla is carried forward at the same rate as that of the growing septum, and the tension at the VPS creates the

<table>
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<tr>
<th>Patient</th>
<th>Age at Surgery</th>
<th>Gender</th>
<th>Orthopedics</th>
<th>Surgical History</th>
<th>GPP</th>
<th>Complications</th>
<th>Follow-Up (Months)</th>
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<tr>
<td>Patient 1</td>
<td>12 months</td>
<td>Female</td>
<td>No</td>
<td>None</td>
<td>Yes</td>
<td>Minimal premaxillary mobility</td>
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<td>Patient 2</td>
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<td>No</td>
<td>None</td>
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<td>Minimal premaxillary mobility</td>
<td>36</td>
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<td>Patient 3</td>
<td>13 months</td>
<td>Male</td>
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<td>None</td>
<td>Yes</td>
<td>Skin infection</td>
<td>36</td>
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<td>Patient 4</td>
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<td>Bilateral CLPR</td>
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<td>None</td>
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<td>Minimal premaxillary mobility</td>
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<td>No</td>
<td>Bilateral CLPR</td>
<td>No</td>
<td>Skin infection</td>
<td>32</td>
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Abbreviations: CLPR, cleft lip and palate repair; GPP, gingivoperiosteoplasty.

*Seven (17%) patients developed minor complications including minimal premaxillary mobility and surgical site infection.
condition for bone formation (Latham et al., 1973; Delaire and Precious, 1986). Previous reports of a cartilaginous epiphysis in this area having a role in osteogenesis have been refuted by anatomical studies (Monroe, 1959; Burdi, 1971). Whether this procedure affects facial growth has been debated in the literature (Friede and Pruzansky, 1985). Progressive ossification of the cartilaginous septum happens during childhood and expands the perpendicular plate toward the vomeral alae in a craniocaudal direction. Traumatic or surgical disruptions of the anatomical relationships in this area can lead to septal deviation, while loss of cartilage can lead to a growth impediment in the nose and maxilla over time (Verwoerd and Verwoerd-Verhoef, 2010). Thus, when one is performing a vomerine ostectomy, the patient’s age must be carefully considered and should affect the angle and positioning of the osteotomy/ostectomy. The intact presence of a basal zone of septal cartilage between the sphenoid and the anterior nasal spine seems to be the most crucial step in guaranteeing a normal increase in length of the premaxilla and maxilla (Verwoerd et al., 1980). This seems to be due to the ongoing ossification of the cartilaginous septum starting in childhood but also due to ongoing mitotic activity and expansion of the intercellular matrix at this site (Vetter et al., 1984). However, it has been argued, as animal studies also seem to indicate, that the residual gap between the cut segments of vomer or cartilage, when cuts are made anterior to the VPS, affects midfacial growth proportionately (Verwoerd and Verwoerd-Verhoef, 2010). An adequate pushback and approximation helps address this issue, although it is possible that the subsequent growth is not in line with the rest of the growing nose, leading to septal deviation and facial changes later on in life (Trenite Nolst, 2005).

Studies comparing unrepaired to repaired adult patients with cleft lip and palate have shown that unrepaired maxillae have a normal to slightly protrusive upper jaw, protruded maxillary anterior dentition, and a normal or slightly hypoplastic mandibular relation (Will, 2000). Fried and Pruzansky (1985) noted in one article that most of their patients had a concave profile from maxillary retrusion following premaxillary setback. However, studies by Padwa and Freihofer have shown that the effects of premaxillary setback on facial growth are minimal after 6 to 8 years of age (Freihofer et al., 1991; Padwa et al., 1999).

Many argue that in the end, achieving a good lip repair is what matters most, as some element of midfacial hypoplasia is to be expected for many patients with bilateral cleft lip and palate, with most of them eventually needing maxillary advancement. Reasons for the decreased midfacial growth can be numerous such as soft tissue scarring, tension across the lip, decreased intrinsic growth potential, and cleft palate repair technique. Although results with preoperative NAM or other presurgical orthopedics when possible and available have been overall positive, some argue that they can also lead to midfacial growth deficits in a way that is similar to the one attributed to premaxillary setback (Berkowitz et al., 2004). We agree that for many patients on whom premaxillary setback is performed, alternative available options and suboptimal outcomes are not good options either, making the facial growth arguments obsolete in that setting.

Limitations of this study are related to its retrospective nature. It is difficult to control for many of the patient variables, as each case of protruding premaxilla, especially in revision cases, is unique in presentation. Our length of follow-up is also relatively short and longer follow-up periods will be required to determine the true effects of the technique on facial growth. A prospective longitudinal study comparing anthropometric data over 10 to 15 years for patients undergoing premaxillary setback by different surgeons with ostectomy anterior versus posterior to the VPS may better elucidate the effect of different technical factors on facial growth.

**Conclusion**

Premaxillary setback with posterior vomerine ostectomy and septorhinocheiloplasty as a single-stage procedure is a viable option for the treatment of children with CBCL and a protruded premaxilla with or without any preoperative orthopedic treatment. Successful single-stage primary lip and nose repair or revision is feasible with the described technique. Further analysis of this surgical technique with long-term follow-up

**Figure 4.** Case 2. Seven-year-old female. A and B, Preoperative pictures showing complete bilateral cleft lip with significant projection of the premaxilla in relation to the middle third of the face. C and D, Postoperative outcome at 1-year follow-up after single-stage premaxillary setback with primary bilateral cleft lip repair, gingivoperiosteoplasty, and primary rhinoplasty.
including both anthropometric and patient-reported outcomes during childhood and adolescence is important.

Authors’ Note
All authors contributed to the conception and design of the work. F.A., V.C., and U.H. performed data acquisition. F.A., V.C., and R.S.K. performed data analysis. All authors performed data interpretation and participated in drafting and critically revising the manuscript and approved the final version submitted and are accountable for all aspects of the work. The abstract for this manuscript was presented at the American Cleft Palate-Craniofacial Association (ACPA)’s 75th Annual Meeting, April 10-14, 2018 in Pittsburgh, PA.

Acknowledgments
The authors would like to thank Elaine Dong and Rayan Beckdache for the illustrations.

Declaration of Conflicting Interests
The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Funding
The author(s) received no financial support for the research, authorship, and/or publication of this article.

Supplemental Material
Supplemental material for this article is available online.

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