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Cleft Lip and Palate Correction: The Utah Protocol

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Background: Cleft repair remains a contentious issue in craniofacial surgery, especially regarding the optimal timing and techniques. This study aims to present our institutions' current protocol for cleft lip and palate repair, including alveolar bone grafting (ABG).
Methods: A total of 17 patients (20 clefts) treated with the latest protocol from 2016 to 2023 were evaluated. Demographic and clinical data were obtained from electronic charts. The protocol includes lip repair at 3 months, soft palate repair at 1 year, and hard palate closure with concurrent ABG at 2 years.
Results: Mean graft height and thickness scores were 2.3 and 2.2, respectively. Three clefts showed scores marginally below the threshold for thickness, potentially requiring regrafting. Malocclusion was minimal with no significant crossbites or velopharyngeal insufficiency.
Conclusions: Our modified protocol, emphasizing early hard palate closure with ABG, yields satisfactory outcomes in terms of graft height and thickness. Although long-term follow-up is warranted, our approach seems safe and efficient, potentially improving outcomes compared with traditional methods. *(Plast Reconstr Surg Glob Open 2024; 12:e6298; doi: 10.1097/GOX.0000000000006298; Published online 8 November 2024.)*

INTRODUCTION

Cleft repair is one of the most debated topics in craniofacial surgery, with constant changes ranging from the type of surgery to the materials and procedural adjuncts used. The optimal timing for reconstruction remains the most contested. The most common protocol followed by many centers in the United States is delineated later. The cleft lip, nasal, and alveolar deformities are addressed with nasoalveolar molding (if necessary) starting soon after birth. Surgical correction of the lip and nasal deformity is done at 3–6 months of age. The cleft palate correction, which can be done in 1 or 2 stages, is generally performed between 9 and 18 months of age. Correction of the alveolar cleft with secondary bone grafting is done between 6 and 9 years of age.

Alveolar bone grafting (ABG) is one the most controversial procedures in the management of cleft lip and palate deformity in terms of timing, materials, and surgical technique. The evolution of ABG is punctuated by numerous historical milestones. The first documented attempt of correction dates back to 1901, when Von Eiselsberg[1] used a small finger pedicled flap that included both bone and soft tissue. A few years later, Lexer[2] and Drachter[3] described the use of nonvascularized bone grafts. Later on, Axhausen[4] highlighted the importance of maxillary osseous arch stabilization and dental preservation. He was then followed by Schmid,[5] who drastically changed the surgical technique by describing the closure of the nasolabial fistula and using small iliac crest bone grafts. The modern approach to treating alveolar clefts was introduced by Boyne et al,[6] who described the current timing and materials used for addressing alveolar deformities. Finally, Cohen et al[7] described the goals of alveolar cleft repair, seeking to mitigate functional deficits while restoring aesthetics. The authors placed a particular focus on maxillary arch stabilization, permanent teeth eruption support, and their movement with orthodontics. In addition, they used bone augmentation at the piriform rim for improved maxillary contour, dental arch, and nose shape.[8–11]

Several studies shaped the current consensus regarding the timing of ABG. In 1958, Schrudde and Stellmach[12] proposed ABG before 2 years of age (primary repair). However, follow-up studies showed significant inhibition

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of the midface growth, which led to this technique being abandoned.[13,14] The current treatment protocol consists of treating alveolar clefting between 6 and 9 years of age during the mixed-dentition stage before the eruption of the canines. This is based on the fact that the sagittal and transverse growth of the anterior maxilla is essentially complete at this age. The remaining maxillary growth is based on the vertical component, associated with the eruption of the permanent teeth.[6,15] Delayed ABG after the canine eruption has consistently been associated with a low success rate, both in graft take and tooth stabilization and for this reason, it has been largely abandoned.[16–22] On the other hand, bone grafting just before the mixed-dentition stage, although thought to be detrimental to maxillary growth, seems to be safe.[23–25] Furthermore, even earlier grafting, in the first years of life, seems not to have a negative impact on maxillary growth.[26–30] In 2018, Siegenthaler et al[31] demonstrated that patients undergoing early ABG at ages 2–4 have similar dental arch morphology to the ones treated at the age of 10.

Significant debate has focused on the difference between grafting materials used in ABG. To date, the gold standard remains autologous bone grafting, with the iliac crest regarded as the best donor site for harvesting cancellous bone grafts. This is followed by calvarian, tibial, rib, and mandibular bone, in decreasing order.[32] The success rate of autologous bone grafting has been reported to be greater than 80%, with some variation reported in the literature. The success rate has been traditionally quantified with either clinical evaluation (ie, canine eruption) or with imaging studies (maxillary x-ray, assessing the amount of bone height).[16–19] Shortcomings of autologous bone grafting are significant postoperative pain, limited donor site availability, functional problems (ie, ambulation issues), infections, and prolonged hospitalization.[33,34] These prompted the use of alternative grafting materials. Bone growth factors (primarily recombinant human bone morphogenetic protein- 2 [rhBMP-2]) and cadaveric bone products have been the most extensively used, either alone or in combination; rhBMP-2 is a potent inducer of bone and cartilage formation and belongs to the TGF-β family.[35,36] In the United States, it is currently approved in adults for spinal fusion, tibial nonunion reconstruction, and maxillary sinus augmentation. However, mixed with the demineralized bone matrix (DBX), an allograft bone void filler consisting of collagen and bone growth factors responsible for actively stimulating bone formation and regeneration, rhBMP-2 has been used off-label for alveolar bone regeneration. No evidence of higher infection rate, heterotopic ossification, malignant transformation, or airway compromise has been reported when the mixture of the 2 components has been used for ABG compared with iliac bone grafting.[37–39]

In light of these findings, our institution has evolved its cleft protocol. Traditionally, a 2-stage palate repair has been used, with the soft palate repaired at 1 year of age and the hard palate 1 or 2 years later. The alveolar closure was subsequently performed with cancellous iliac bone grafting at 6–9 years of age. More recently, the protocol was changed, and simultaneous closure of the hard palate and alveolus with bone grafting of both structures at around 2 years of age was implemented. In addition to timing, the bone grafting materials used have also evolved. The changes were made to improve outcomes because traditional protocols did not yield, at our institution, the consistent satisfactory results that the authors were expecting.

The authors present here the institution's current protocol that has been used consistently for the past 8 years and report short- and medium-term outcomes.

Takeaways

Question: To evaluate the efficacy of the Utah protocol including simultaneous closure of the hard palate and alveolus with bone grafting of both structures at around 2 years with demineralized bone matrix, bone morphogenetic protein, and bone chips.

Findings: Our findings demonstrated minimal malocclusion and no significant crossbites or velopharyngeal insufficiency, along with clinically acceptable graft height and thickness, suggesting the efficacy and reproducibility of our approach.

Meaning: Our protocol offers a safe and efficient method for managing cleft lip and palate deformities, potentially improving outcomes compared with traditional protocols.

MATERIALS AND METHODS

The authors evaluated all cleft patients treated by a single surgeon (B.G.) from 2016 to the end of 2023. All information was obtained from the electronic chart of each patient. For every patient, the demographic and clinical data were recorded. This study was approved by the institutional review board (IRB_00131670).

The Current Utah Cleft Protocol

Starting in 2016, based on various shortcomings in long-term outcomes seen with our previous protocols in the treatment of cleft lip and palate patients, the authors implemented several changes in our protocol. In the next few paragraphs, the current protocol for treating cleft patients is described.

Cleft Lip Repair

A few days after birth, if indicated, lip taping, nasal activator reshaping, and oral alveolar molding are initiated. Adjustments are done every week by our team of orthodontists. Surgery is performed starting at 3 months of age, using a modified Mohlers technique. At the end of the surgery, a palatal prosthesis (if a concomitant cleft palate is present) is placed at the level of the hard palate, to improve breathing, oral feeding, and separating the tongue from the palatal cleft. Postoperatively, nasal stents are used for at least 6 months if tolerated. These stents are upsized based on facial/nose growth.

Soft Palate Repair

The soft palate is repaired at around 1 year of age using a modified Furlow palatoplasty. Bilateral large alveolar relaxing incisions are made to allow medialization of the palatal flaps.

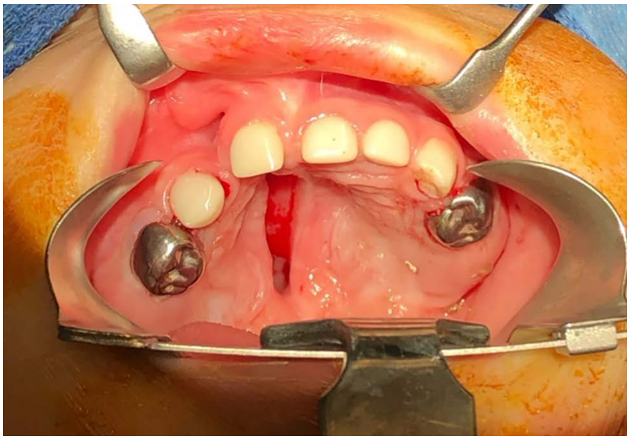

Fig. 1. Intraoperative picture of the palate of a 2-year-old boy, 1 year after soft palate repair. The 2 palatal shelves are nicely approximated, making the subsequent watertight closure of the hard palate and alveolus over the bone graft feasible.

At the end of the procedure, a new custom palatal prosthesis is fabricated and applied over the residual hard palate opening, replacing the previous prosthesis applied at the time of cleft lip repair. [**See figure, Supplemental Digital Content 1**, which displays, on the left, a custom palatal prosthesis. It is used to improve breathing, oral feeding, and separating the tongue from the palatal cleft, preserving maxillary width (by preventing maxillary collapse), while allowing the palatal shelves to migrate toward each other in the midline, under the forces exerted by the repaired soft palate. On the right, it is possible to see the prosthesis applied over the residual hard palate opening, after the soft palate repair, **http://links.lww.com/PRSGO/D620**.] The aims of this prosthesis, in addition to the benefits provided by the first splint applied at the time of cleft lip repair, are preserving maxillary width by preventing maxillary collapse. At the same time, it allows the palatal shelves to migrate toward each other in the midline, under the forces exerted by the repaired soft palate. The medialized palatal shelves facilitate an easier watertight closure of the hard palate and alveolus at the time of bone grafting (Fig. 1). In the rare instance in which alveolar collapse is still present at this time, the palatal prosthesis is fabricated with a transverse expansion screw. Transverse expansion is undertaken slowly to re-establish a normal palatal width.

Hard Palate Repair with Concurrent ABG

The hard palate is closed around 2 years of age. Concomitantly, alveolar cleft closure is performed with bone grafting of both the alveolus and hard palate. This re-establishes the normal anatomy of the soft tissues and maxillary bone.

Marcaine with epinephrine is infiltrated at the level of the alveolar cleft, the entire hard palate, and the anterior portion of the previously repaired soft palate. With a cold knife, an incision is performed at the junction between oral and nasal mucosa, along the entire length of the palate cleft (starting from the closed soft palate). This incision is continued along the margin of the alveolar cleft. Two opposing oral mucoperiosteal palatal flaps are dissected and elevated, with the blood supply coming from the greater palatine vessels. Medially, vomer flaps are elevated extending to the mucosa of the premaxilla. Laterally, palatal nasal mucosal flaps are elevated. The dissection is extended in continuity with alveolar nasal mucosal dissection. Lateral nasal mucosa flaps are sutured with the homolateral medial vomer flaps. The closure is performed in continuity with the alveolar nasal mucosa. Watertight closure is achieved, fully separating oral and nasal cavities. The integrity of the repair is assessed by nasal saline irrigation under pressure.

Two opposing lateral-based mucoperiosteal gingival flaps are elevated from the alveolus and are pulled together to evaluate the tension along the edges. The periosteum of the flaps is scored transversally to allow for increased movement. A back cut in the lateral flap (in front of the parotid duct) is performed, to further increase the flap mobility. Removal of any scar tissue, deciduous or supernumerary teeth, present in the alveolar cleft is performed. The cortical bone on both edges of the alveolar cleft is injured with a *rongeur* until bleeding is seen, to simulate an acute fracture site and stimulate bone healing. The alveolar and hard palate cleft are progressively filled with a combination of cadaveric bone chips (MTF, Edison, N.J.), bone morphogenetic protein (BMP)-2 (Infuse Medtronic Sofamor Danek), and DBX Inject, Depuy Synthes, Solothurn, Switzerland), in an approximate 80–10–10 ratio. A small amount of DBX is used, to stabilize the bone chips and fully obliterate the dead space. The BMP-2 carrier sponge is cut out into very small pieces (1 mm diameter), which are distributed throughout the graft site. This last maneuver aims at reducing the edema and inflammation associated with BMP-2 while minimizing the dead space that the cellulose carrier may create inside the alveolar defect. The oral hard palate flaps are sutured to each other and placed over the hard palate bone graft. At the level of the alveolus, the previously raised gingival mucoperiosteal flaps are advanced and sutured to each other and the palatal flaps. The closure is done with minimal tension in a watertight fashion.

A mold of the repair is taken, and a custom protective splint is fabricated and applied over the alveolar and hard palate repair. The splint is retained in place using the denture glue for 6 weeks[40] (Fig. 2). The splint aims to stabilize the bone graft and protect the suture line during the healing process.

Prophylactic oral antibiotic therapy is prescribed for 1 week postoperatively. The patients are placed postoperatively on a full liquid diet for 2 weeks, followed by a pureed regiment for 4 additional weeks.

At a minimum of 6 months after the procedure, a maxillary computed tomography (CT) scan with 3D reconstruction is performed to assess alveolar graft height (GH) and graft thickness (GT). The authors developed a standardized scoring system to quantify graft take with criteria described in Table 1 (Figs. 3, 4) The GH and GT scores of at least 2 were deemed clinically sufficient (Fig. 5).

Fig. 2. Postoperative picture of the palatal splint, 6 weeks after the hard palate and ABG.

RESULTS

A total of 17 patients (20 clefts) were treated with the latest version of our protocol (completing the first 3 major operations) for complete cleft lip and palate, as delineated above. None of the patients required any additional procedures. Patient characteristics can be found in Table 2.

The mean GH and GT for the entire cohort were 2.3 and 2.2, respectively (Table 3). Three of 20 clefts (15%) showed scores just marginally below the set minimal threshold of 2 for GT (all 3 had a score of 1.5) and can be considered for regrafting. One graft out of 20 clefts (5%) was a complete failure with scores of GH 0 and GT 0 and required regrafting.

To this point, of all the patients, only 4 have been identified with moderate class III malocclusion (<4 mm negative overjet), with none having severe class III malocclusion. Six patients displayed on examination very mild class III malocclusion (<1 mm negative overjet), with the rest having normal occlusion. In addition, only 2 patients in the entire group were identified to have small crossbites. The rest of the patients have normal palate width, with no crossbite. In addition, none of the patients in this group was noted to have significant velopharyngeal insufficiency requiring early surgical correction.

DISCUSSION

Cleft lip and palate management is still evolving. To date, there is no universal consensus regarding the type of operative intervention to be adopted, the materials to be used, and the optimal timing to intervene. Furthermore, the literature on cleft repair outcomes tends to focus only on isolated metrics (ie, velopharyngeal insufficiency, speech, and fistula rate), neglecting how different measurable parameters evolve and affect each other over time. Numerous protocols have been proposed by different craniofacial groups around the world for the treatment of cleft deformities. Some of them show significant overlap, while others display quite substantial differences. Regarding cleft palate repair, these protocols can be divided into those that support the 1-stage palatal correction[41–43] and those that support initial soft palate repair followed by delayed repair of the hard palate.[44–47] Alternative approaches to this general trend are also being used.[48,49] Systematic reviews evaluating the optimal procedure and timing of palate repair failed to identify this.[50,51] The need to evolve our protocol came from the need to improve and standardize our results in the treatment of cleft patients. This shift happened in parallel with the availability of new surgical materials, which allowed for the introduction of new surgical techniques and/or new concepts that slightly challenged some of the dogmas of the past (ie, the midface growth impairment associated with early ABG).

Regarding cleft lip repair, what distinguishes our protocol from others is postoperative patient management. Indeed, the authors implemented consistently long-term postoperatively nasal molding (at least 6 months postoperatively), to optimize the lower nose shape. The majority of the patients tolerate this, with only a minority requiring premature discontinuation due to either difficulty with nasal breathing or periprosthetic nasal erosion.

More variability exists in the modality of cleft palate repair. The Utah cleft program has evolved the management of cleft palate closure, in a constant quest to improve outcomes and reproducibility of results. At first, just like many centers in the United States, the approach has been to correct the cleft palate in one stage between 9 and 18 months. This protocol did not yield satisfactory results because our rate of palatal fistulas was too high. For this reason, a 2-stage closure was adopted. The closure of the alveolar cleft was initially performed around 7 years of age. Despite improvement in the results, a significant number of

Table 1. Scoring System Used to Quantify Graft Take by Measuring Alveolar GH and GT

Score	Criteria
GH	
0	Bone gap in the alveolar process cleft without any bone bridges in the alveolar cleft
1	One-third of normal alveolar height anywhere from the nasal floor to the cementoenamel junction
2	Two-thirds of the normal alveolar height anywhere from the nasal floor to the cementoenamel junction
3	Normal height of alveolar ridge from the nasal floor to the cementoenamel junction
Graft thickness	
0	Inadequate thickness of bone throughout the entire alveolar cleft height
1	Adequate thickness of one-third of the normal alveolar height
2	Adequate thickness of two-thirds of the normal alveolar height
3	Adequate thickness of the entire normal alveolar height

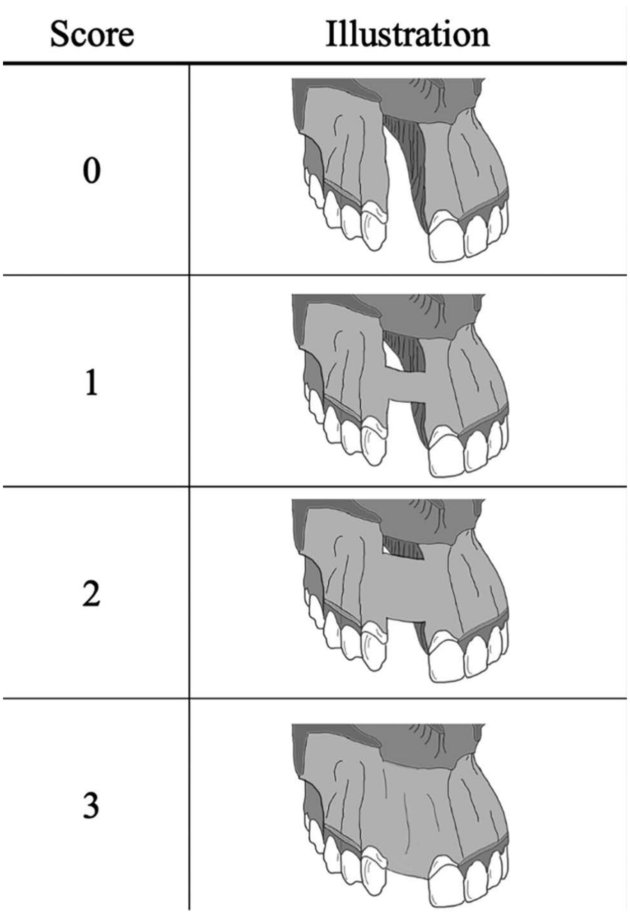

Fig. 3. Standardized scoring system to evaluate the bone take height after an ABG.

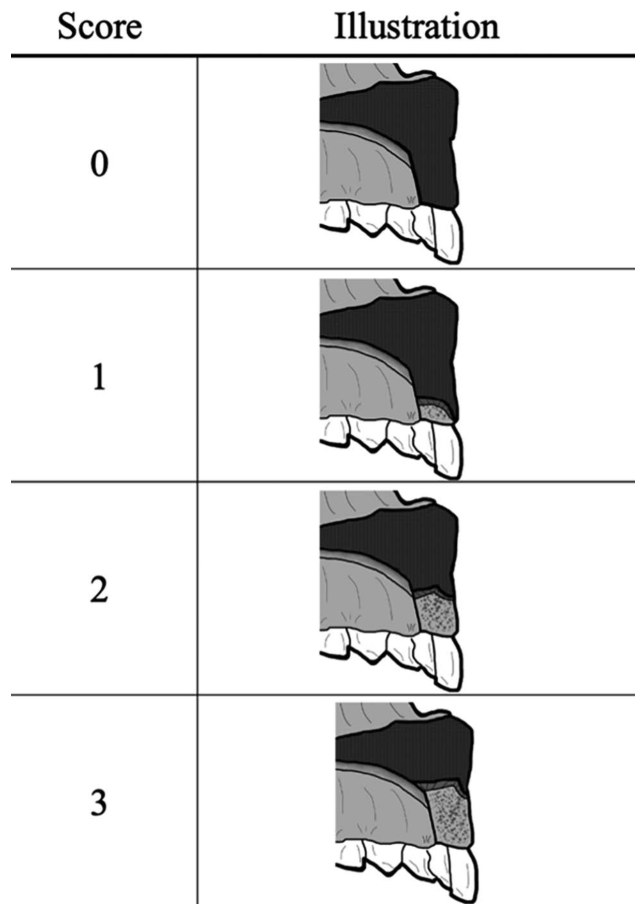

Fig. 4. Standardized scoring system to evaluate the bone take thickness after an ABG.

patients later required additional secondary orthognathic corrections (ie, surgically assisted rapid palatal expansion) due to transverse maxillary deficiency with a clinically significant crossbite. This was a driving force for a significant modification of the protocol. Simultaneous closure of the hard palate and the alveolar cleft with bone graft of both structures at 2 years of age was implemented. Besides the beneficial effect of the stabilization of the maxillary arch, additional advantages of this approach are potentially better graft take (due to the relatively small size defect and absence of permanent teeth within the alveolar cleft) and better tooth eruption, in normalized maxillary anatomy.

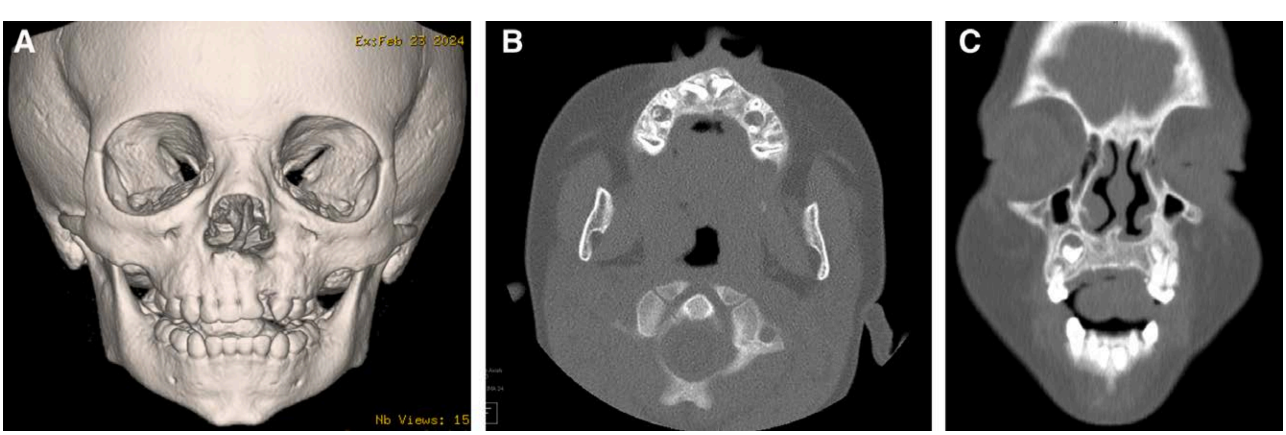

Fig. 5. Typical excellent CT scan result of (A) 3D reconstruction, (B) axial view, and (C) coronal view to evaluate GH and GT in patients who underwent concomitant repair of the alveolar cleft and hard palate using DBX, BMP, and FDBC.

Table 2. Patient Characteristics

	Early Concomitant Hard Palate and Alveolar Cleft Repair
No. patients	17
No. clefts	20
Age at surgery, mo, median (range)	26.5 (19– 33)
Male, n (%)*	11 (65)
Laterality, n (%)*	
Unilateral	14 (70)
Bilateral	6 (30)
Mean follow-up to CT, mo*	11.5

*Numbers were generated by cleft.

Table 3. GH and GT of Patients Undergoing Early Concomitant Hard Palate and Alveolar Cleft Repair

	Early Concomitant Hard Palate and Alveolar Cleft Repair
GH	2.3
GT	2.2

The bone grafting technique has also evolved based on advances made in the clinical literature. Traditionally, cancellous iliac bone was the only material used. Due to constraints in the availability of autologous bone for grafting at an early age, alternatives were sought. Initially, following the concepts presented by other centers, the authors used a combination of BMP-2 and DBX.[37] Because the results were not fully satisfactory based on 6-month postoperative CT scans, cortical allograft was added to the bone graft mixture, with significant improvement in outcome.[38,52–55] The addition of cortical allograft followed the positive experience reported in neurosurgical and orthopedic spinal fusion literature. The main advantages of using the 3-product bone graft mixture over cancellous iliac bone are less postoperative pain; no need for a donor site; and thus, no donor site morbidity. To date, the authors have not identified any disadvantages of using this mixture. Just like other articles have described previously, our group has also not identified a higher infection rate, heterotopic ossification, malignant transformation, or airway compromise.

After 8 years of using the aforementioned practice, our group is satisfied with the short- and medium-term results obtained so far. To date, no significant complications or negative outcomes have been encountered to prompt further modifications or discontinuation of the protocol. Performing a CT scan with 3D reconstruction at least 6 months after bone grafting has given us an excellent tool to measure the amount of bone and its density. This allows for the identification of significant bone graft loss so that these patients can be referred for alveolar bone regrafting. Unlike other methods used in the past (ie, plain x-rays or clinical judgment), the CT scan is an objective measurement that can identify not only whether the ABG was successful, but also how much bone was successfully integrated. With this information, the surgeon can easily understand whether regrafting is warranted. Our results demonstrate consistent clinically acceptable GH and GT, suggesting that our method could be widely used.

The main limitation of our study is the lack of follow-up until facial maturity is completed. Continued evaluation of the effects of our protocol on the management of cleft patients will be required.

CONCLUSIONS

Our institution's approach to cleft lip and palate care has been continuously modified in an attempt to improve outcomes in the management of this difficult patient population. Although follow-up to facial maturity is needed, at this time, the authors conclude that our approach is safe, efficient, and reproducible, with potential improvement in outcomes compared to traditional protocols.

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DISCLOSURE

The authors have no financial interest to declare in relation to the content of this article.

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