Success Rate of Mid-Secondary Alveolar Cleft Reconstruction Using Anterior Iliac Bone Grafts: A Retrospective Study

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Abstract

Introduction: Bony reconstruction of the alveolar process and its adjacent platform largely represents the final step in surgical achievement of functionality and aesthetics in cleft patients. Throughout the years, the success of this procedure has been investigated. The aim of this study was to assess the success rate of autogenous mid-secondary alveolar bone grafting in this setting. Methods and Material: A retrospective cohort study was performed. All cleft patients receiving secondary alveolar bone grafts between 1990 and 2020 were reviewed. Criteria for assessing success were long-term preservation of alveolar bone stock, ability of spontaneous or orthodontic-guided eruption and periodontal health of permanent lateral incisors and canine teeth, absence of exposed root structures of neighbouring teeth, absence of fistula and successful placement of implants. Failure of alveolar bone grafts was indicated by radiographically demonstrable total or near-total graft loss requiring reintervention. Results: A number of 124 patients were included and grouped as those primarily operated following our (two-staged palatoplasty) protocol and those receiving cheilorhinoplasty and palatoplasty (one-staged) at other centres. Given the limited cohort size, no complex statistical analysis was performed. In the first group of 64 patients 12 experienced complications (Veau III, eight/36; Veau IV, four/18). In the second group of 60 patients, 12 experienced complications (Veau III, six/37; Veau IV, six/17). Discussion: Our surgical protocol using anterior iliac bone grafts for secondary alveolar reconstruction achieved good results, comparing favourably with previous literature.

Keywords: Alveolar cleft, bone grafting, bone transplantation, cleft palate, iliac crest

Introduction

Bony reconstruction of the alveolar process and its adjacent platform largely represents the final step in surgical achievement of functionality and aesthetics in our patients with Veau III or IV cleft palates. Throughout the years, the success of this procedure has been investigated in conjunction with timing and graft origin. Secondary alveolar bone grafting is now a well-established approach, owing to the formative work of Boyne and Sands.[1] The most widely used source is cancellous iliac bone, although tibia, mandible, rib, and calvarium may serve as other options.

We hypothesised that the outcomes of our alveolar bone grafting are comparable with the ones from the literature. The aim of this study was to assess the subsequent success rate of autogenous mid-secondary alveolar bone grafting in this setting.

Subjects and Methods

Study design

A retrospective cohort study of our own case series was undertaken on approval of the Institutional Research Ethics Board of Universitair Ziekenhuis Brussel, Vrije Universiteit Brussel (B. U. N. 143201836187, 02/05/2018) and conducted in accordance with the ethical principles mentioned in the Declaration of Helsinki (2013). Informed consent was obtained.

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Selection of patients
All cleft patients receiving secondary alveolar bone grafts between 1990 and 2020, that met the inclusion criteria were potential candidates for investigation. As such, no sample size was determined beforehand.

Inclusion criteria were as follows: (a) alveolar bone grafts performed by the same surgeon; (b) cleft lip and alveolus, with or without the involvement of palate; (c) full availability of patient records and follow-up accounts at least 1 year after bone grafting procedure.

Surgical protocol and approach
The protocol we devised for primary cleft surgery first entailed lip/nose repair at 3 months of age, definitive lip and palate repair according to Millard–Mohler–Asensio and primary Millard–McComb rhinoplasty at 4 months of age for unilateral complete clefts and Millard–Mulliken cheilorhinoplasty for bilateral complete clefts. The soft palate was repaired according to Widmaier-Perko (1991–1993) and according to Furlow (1993-present) between 9 and 12 months of age (depending on speech developmental status); hard palate repair was undertaken at age of 4 years by pairing of the edges of any narrow residual palatal cleft (usually in incomplete unilateral clefts) or otherwise by raising hinge-door flaps in combination with a flip-over flap.\(^{[3]}\) For wider unilateral complete clefts, a single transpositional palatal flap sufficed (with or without relaxing incision), using two such flaps if bilateral.

Alveolar repair through iliac bone graft took place as warranted at 8–11 years of age to accommodate canine eruption and development, along with premaxillary repositioning osteotomy of bilateral complete clefts. In some cases, early bone grafting was performed prior to the eruption of cleft-side lateral incisors. Presurgical orthodontics (fixed or removable Hyrax or Haas expander) served to expand and align the maxillary arch in advance of these grafts.\(^{[3]}\)

As of 2012, a collagen biomatrix (TissuDura; Baxter AG, Vienna, Austria) was applied at times (not routinely) below the repaired nasal layer (Vicryl 5-0; Ethicon, Somerville, NJ, USA) and stabilised by adding fibrin sealant (Tissueel; Baxter). Bone marrow was aspirated from the iliac crest using a 50-mm Jamshidi needle (Handlex; Medax, Poggio Rusco, Italy). Cancellous bone was harvested through a medially based trap-door technique from the anterior iliac crest with the use of Champy 8 mm and 5 mm Bone Biopsy Instruments (KLS Martin Group, Tuttlingen, Germany). The harvested bone was particulated using a bone mill and mixed with bone marrow aspirate\(^{[4]}\) afterward, was syringe-condensed into the alveolar cleft and manually molded. After suturing of oral mucosa (Vicryl 4/0), fibrin sealant was employed to affix the mucoperiosteal flaps onto the transplanted bone. A nasal packing with an inner airway tube (Ivalon; First Aid Bandage Company, New London, CT, USA) was inserted and remained in place until hospital discharge (average, 2 days). At the donor site, a continuous anaesthetic elastomeric pump (Baxter International Inc, Deerfield, IL, USA) was placed. Patients were discharged wearing the pump as a pouch, which we removed 3 days’ postoperatively (on average).

In patients with bilateral clefts, the Dautrey arch bar (Stryker Leibinger, Freiburg, Germany) helped immobilise premaxilla intraoperatively and postoperatively. However, a resin-bonded titanium arch bar, patient-specific and three-dimensional (3D)-printed [Figure 1], has since (2016) replaced the above. Arch bars were retained for 68 weeks and removed during ambulatory visits.

Perioperative protocol
Patients were asked to begin tooth brushings on postoperative day 1, with dietary restrictions for 7 days (full liquid) and for another 2 weeks (soft/mixed) thereafter. Nose blowing was prohibited for 3 weeks. Intravenous antibiotics administered at induction were followed by a 5-day oral broad-spectrum regimen. Paracetamol was given intravenously, generally every 6 h (adjusted as needed), converting to an oral equivalent once oral intake was adequate to effect stable analgesia. Intravenous opioids were also available at request, and a 1-week supply of oral paracetamol and ibuprofen was prescribed according to weight at the time of discharge. All patients received a nasal spray of saline solution (Sterimar; Sofibel, Levallois-Perret, France) and a mouthwash containing Chlorhexidine 0.12% (Perio-Aid; BCM Ltd Nottingham, UK).

Assessment criteria
Evaluations of bone grafting success that appear in the literature are based on clinical and/or radiographic assessments. A number of criteria for clinical evaluation of grafts have been proposed, including periodontal insertion level, adequate width of attached gingiva in the cleft vicinities, eruption of permanent central and lateral incisors (for early secondary bone grafting) and canine teeth into grafted bone, absence of exposed root structures adjacent to clefts,\(^{[9]}\) aesthetic results conferred by bony support of alar base, closure of any existing palatal fistula,\(^{[10]}\) and stabilisation of premaxilla in conjunction with bilateral clefting.\(^{[7,8]}\)

Imaging methods commonly used to assess corrective alveolar bone grafts are radiographs (periapical, occlusal), computed tomography (CT), and cone-beam CT (CBCT). The two-dimensional (2D) processes involve a grading system, measuring interalveolar septal height after the eruption of canine teeth (Bergland scale\(^{[11]}\) or gauging bone tissue position in relation to teeth bordering clefts (Chelsea scale\(^{[12]}\)). A 3D approach determines bone fill by volumetric assessment.

Unfortunately, CBCT was not readily available 20 years ago, so volumetric evaluations of all grafted patients in this study were not feasible. Our clinical evaluations of bone grafts relied on the protocol formulated by Precious.\(^{[9]}\) Criteria for success were as follows: long-term preservation of alveolar bone stock, ability of spontaneous or orthodontic-guided eruption and periodontal health of permanent lateral incisors and canine teeth, absence of exposed root structures for teeth adjacent to clefts, absence of fistula, and successful placement...
of osseointegrated implants as warranted. Failure of alveolar bone grafts was indicated by radiographically demonstrable total or near-total graft loss requiring reintervention.

**Statistical analysis**

The study used descriptive statistics consisting of means and percentages of the presenting participants of the study along with standard deviations in the data analysis; P values were calculated to determine statistical significance. A P < 0.05 was considered statistically significant. Analysis of variance and Bonferroni post hoc tests were carried out. The following covariates were used: gender, type of clefting, primarily operated patients and those receiving primary surgical treatment of the cleft lip and palate, other centres, and frequency of complications following alveolar bone grafting.

**Results**

Complete files of the 146 patients who underwent alveolar bone grafting were retrieved for analysis. In case of missing information, the patients were contacted through e-mail and post. Given the limited cohort size, results were presented numerically, rather than in percentages. A number of patients (n = 22) who underwent late secondary or tertiary bone grafting (iliac, 19/22; calvarial, 3/22) were ultimately excluded. The remaining 124 patients were grouped as those primarily operated on following our standardised (two-staged palatoplasty) protocol and those receiving primary surgical treatment of the cleft lip and palate in other centres.

In the first group of 64 patients (females, 27; males, 37), 36 had Veau III clefts, and 18 had Veau IV clefts. There were 10 patients with unilateral lip and alveolar clefts, without the involvement of palate. Three syndromic patients (Van der Woude, Opitz, and cerebro-costo-mandibular, one each) were represented. Average age at the time of surgery was 9.7 years.

Twelve of these 64 patients experienced complications (Veau III, eight/36; Veau IV, four/18). Complete graft loss in two patients called for surgical revisions [Figure 2a and b]. Partial graft loss, with a lack of spontaneous or orthodontic-guided canine eruption, was observed in two instances; and two patients developed dehiscence with graft contamination. Root resorption, lateral incisor loss, and periodontal problems were noted in two patients [Figure 2c and d]. Three patients required additional bone grafting prior to implant placement. In one patient, suboptimal implant osteointegration was evident. No postoperative fistula (Pittsburgh V-VII) was registered.

In the second group of 60 patients (female, 21; male, 39; all operated before alio loco), 37 had Veau III clefts, and 17 had Veau IV clefts. Five patients had unilateral lip and alveolar clefts and one bilateral lip and alveolar clefting, without palatal involvement. Average age at time of surgery was 11.5 years.

Twelve patients experienced complications (Veau III, 6/37; Veau IV, 6/17), including complete graft loss (n = seven) requiring surgical revision. Partial graft loss was observed in two patients after dehiscence and graft contamination. Root resorption of a lateral incisor was noted in one patient. Four of these patients presented an oronasal fistula (Pittsburgh VII, two/four, Pittsburgh V, two/four). One Pittsburgh VII fistula required an additional retromolar bone grafting for closing; one Pittsburgh V fistula was closed with a cartilaginous auricular graft. The two remaining fistulas presented no reflux or other functional impairment and were spontaneously closed by soft-tissue growth.

There was a slightly higher association between males and frequency of complications (17% vs. 12% in females). The overall average across both genders was 15%. Bilateral clefts presented a higher rate of complications (19%) than unilateral clefts (13%) (P < 0.05). Patients receiving primary surgical treatment of the cleft lip and palate in other centres had a slightly higher rate of postoperative complications (16% vs. 13% in primary operated cases) but the difference proved statistically not significant.
**DISCUSSION**

Proper grafting of an alveolar cleft allows eruption of teeth into the cleft, orthodontic movement, and ultimately the achievement of arch continuity. Quantifying the success of such grafts is seemingly a broad and onerous task. Diagnostic imaging has proven essential in determining outcomes of alveolar graft procedures by evaluating the extent to which defects are filled, the eruption status of neighboring teeth, and the adequacy of bony substrate for endosseous implant placement.

In 1986, Bergland introduced a 2D-evaluation scale based on interdental septal height. It was later pointed out by Feichtinger et al.\[11,12\] that the 2D approach (relative to 3D assessment) resulted in overestimates due to sagittal graft resorption patterns. As mentioned, not all patients in our study had opportunities for pre- and post-operative 3D evaluations. We subsequently focused our retrospective analysis on palpable outcomes objectified through tooth eruption within grafts, allowance of orthodontic movements, and nonrequirement of surgical revisions in alveolar cleft region.

This study did not evaluate nasal morphology, symmetry, and nostril support following alveolar bone grafting. Even though positive effects of bone graft on nasal symmetry and support have been reported in several studies,\[13-15\] a contrary publication suggested that mixed-dentition alveolar bone grafting appears to have no significant long-term effect on nasal morphology, symmetry, or nostril shape.\[16\]

Our efforts were met with an 81% iliac bone graft success rate. Twenty-four of the 124 patients included developed postgraft complications. Although our limited patient population may be a source of bias, these findings are aligned with outcomes detailed in a previously published report.\[17\]

Past investigations seem to confirm that bone grafts of alveolar clefts during mixed dentition (vs. primary or tertiary states) yield more reliable outcomes.\[18,19\] Some centres have thus decided to graft earlier, either before or during the eruption of lateral incisors. This strategy is known as early secondary bone grafting, and it is considered an acceptable option.\[18,20\] In our group, alveolar clefts were grafted before canine eruption but rarely before eruption of lateral incisors (mostly diminutive, with hypoplastic or absent root formation) because of the higher success rate anticipated.\[20,21\]

In literature, the overall success rate of such procedures correlates with short-and long-term complications.\[22\] Loss of grafts is usually the result of early wound dehiscence, leading to graft exposure and contamination. Common long-term complications are periodontal pocket formation and severe resorption of transplanted bone.

We are firm advocates of presurgical orthodontics.\[3\] Expanding the maxillary dental arch, de-rotating lateral incisors (if present and useful), and aligning the teeth are necessary steps to provide space for tooth eruption at recipient sites. In a recent systematic review,\[23\] the integration of presurgical orthodontics into alveolar bone graft procedures was associated with a higher postoperative rate of bone formation and a lower complication rate. Grafted clefts clearly benefitted from this approach (83.9% vs. 54.9% average success rate).

In our clinic, we now use particulate cancellous bone grafts from the anterior iliac crest, harvested by a minimally invasive technique. Given the ease of harvesting, reduced morbidity, and higher concentration of osteogenic cells, cancellous bone is considered superior to a cortical block. Unlike cancellous bone only, a mix of cortical and cancellous iliac bone is thought to promote less bone resorption and higher bone density.

In 2016, we began mixing grafts with bone marrow aspirate. Despite the unproven utility of this practice in alveolar cleft repair, prior articles have emphasised the distinct advantageous effects of bone marrow-derived cells on bone regeneration and soft tissue wound healing.\[24\] Nonetheless, this retrospective analysis of our own patient series did not find a difference in outcomes of iliac bone grafting, with or without bone marrow aspirates.

There are no evidence-based guidelines yet for antibiotic prophylaxis during repairs of cleft lip, palate, and alveolus. We use a standard 5-day broad-spectrum regimen (amoxicillin + clavulanic acid, 50 mg/kg), based on the lack of control over oral hygiene in our young patients. A current systematic review and meta-analysis\[24\] have produced insufficient evidentiary support for antibiotic prophylactic prevention of postoperative infections in intraoral bone graft placement procedures; however, it is unclear if this pertains to paediatric patients with clefts.

Iliac bone remains the gold standard in grafting alveolar clefts, although related morbidities (e.g., donor-site pain, gait disturbances, nerve lesions with chronic pain, suboptimal scarring, haematoma, seroma, and infection) have prompted a search for bone substitutes. One of the most promising substances is bone morphogenetic protein (BMP-2).\[25\] This topic is sadly devoid of larger investigations, as highlighted in a Cochrane review.\[26\] Several studies have demonstrated the role of BMP-2 in tumour angiogenesis.\[27,28\] Our previous work has shown that pain at donor sites may be effectively managed through a multitude of accessible protocols, without increasing the burden of care.\[29\]

Finally, it is worth mentioning that in 18% of our patients with complications (4/22), endosseous implants were involved. There is presently a dearth of randomised controlled trial data available in this regard. On a short-term basis (<5 years), the implant survival rate in grafted alveolar clefts is 91%; but it is apparent that other factors, such as marginal bone loss, functionality, and aesthetics, are not taken into account.\[30\] Considering the suboptimal results that young patients display and the need for additional bone grafting, our preference is diastema closure with segment osteotomy at the same time as orthognathic surgery.
As the treatment of cleft patients, our surgical protocol using anterior iliac bone grafts for mid-secondary alveolar reconstruction achieved good results, comparing favourably with previously elaborated outcomes in the literature.

Declaration of patient consent
The authors certify that they have obtained all appropriate patient consent forms. In the form, the patients have given their consent for their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published, and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

Registration of research studies
This trial was registered on www.isrctn.com. (Unique ISRCTN24136967; Registration Date: March 30, 2022).

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Nil.

Conflicts of interest
Dr. Maurice Mommaerts is associated as a section editor of this journal and this manuscript was subject to this journal's standard review procedures, with this peer review handled independently of this section editor and their research group.

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