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Early secondary alveolar bone grafting in cleft lip and palate patients – personal experience

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Abstract

Introduction and Objective. Alveolar cleft is present in 75% of cleft patients. Alveolar bone grafting can be divided according to time of the procedure into primary, early secondary, secondary and tertiary.

Materials and Method. A retrospective analysis of 41 children with early secondary alveolar bone grafting was performed. Qualification for autologous bone grafting (ABG) was performed during orthodontic consultation. The presence of a symptomatic oronasal fistula and/or a bone defect within the alveolar process that could hinder orthodontic treatment and prosthetic rehabilitation in the cleft area was also assessed. Prior to the procedure, a dental examination was required, and, if necessary, treatment of carious lesions or inflammatory conditions within the oral cavity completed. In children over the age of 5, qualification for surgery was based on an orthodontic assessment of Cone Beam Computed Tomography (CBCT) imaging of the cleft area.

Results. Early secondary autologous bone grafting (eSABG) was carried out in 7 children with cleft lip (3 with left-sided cleft lip, 2 with right-sided cleft lip, and 2 with bilateral cleft lip) and in 34 children with cleft lip and palate (20 with left- sided cleft lip and palate, 8 with right-sided cleft lip and palate, and 6 with bilateral cleft lip and palate). In 1 case, loss of bone graft was observed. No other serious complications were reported.

Conclusions. The results suggest that early secondary alveolar bone grafting using iliac crest bone in alveolar cleft associated with cleft lip or cleft palate, is a safe procedure with a low rate of serious complications.

Key words

bone graft, cleft lip, cleft palate, alveolar cleft

INTRODUCTION

An alveolar cleft is present in 75% of patients with cleft lip (CL) or cleft lip and palate (CLP) [1]. In each of these patients, a bone graft to the alveolar process of the maxilla (ABG) is necessary to achieve both satisfactory aesthetic and functional outcomes. The first reports of ABG date back to 1901, when Von Eiselsberg used a skin-bone flap to reconstruct the alveolar process of the maxilla. In 1914, Drachter performed the first successful ABG using a fragment of tibial bone along with its periosteum [2].

The surgical techniques, timing of alveolar bone grafting (ABG), and the choice of graft material continue to be subjects of considerable controversy [3]. With respect to the patient's age at the time of ABG, 2 principal approaches are recognised: primary ABG, performed in children under the age of 2, and secondary ABG (SABG), performed in patients with mixed dentition. Within the secondary group, 3 subcategories are distinguished: early secondary ABG (eSABG), carried out in patients aged between 2–5; secondary ABG, performed between 6–12, and late (tertiary) ABG, performed after the age of 12 (Fig. 1) [4]. In Poland, the most common procedures are early secondary and secondary alveolar bone grafting. ESABG are often performed simultaneously with lip or palate reconstructions, while secondary procedures are part of multi-stage reconstructions.

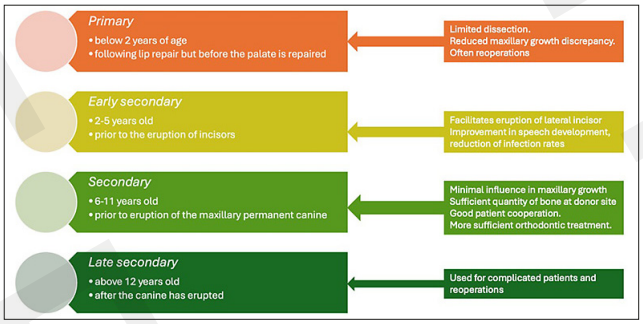

Figure 1. Timing of ABG according to patients' age and dental development

Autogenous bone remains the material of choice for ABG, most commonly harvested from the iliac crest, and less frequently from the tibia, ribs, or calvaria. Both cancellous and cortical bone may be used; however, cancellous bone offers several advantages, including superior integration and facilitation of tooth eruption. Bone substitutes are also employed and are considered a promising alternative for the future, such as allogenic freeze-dried bone and recombinant human bone morphogenetic protein-2 (rhBMP-2), among others. Their principal advantage lies in the elimination of

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the donor site, which significantly enhances post-operative patient comfort.

The objective of ABG is to achieve stability and continuity of the maxillary arch, providing support both for the teeth adjacent to the cleft and for the alar base of the nose. A properly integrated bone graft establishes a foundation for future dental implantation, or spontaneous tooth eruption. In some cases, closure of an oronasal fistula is performed simultaneously and, occasionally, corrections of the lip or nose are also carried out [5].

The aim of this study was to describe a single-centre experience in eSABG.

MATERIALS AND METHOD

A retrospective analysis of clinical data was conducted between 2016–2021. A total of 58 ABG procedures were performed at the East Centre for Burn Treatment and Reconstructive Surgery in Łęczna, eastern Poland: 41 early secondary ABG, 10 secondary ABG, and 7 late ABG procedures.

Inclusion criteria. The study group consisted of patients with CL or CLP who underwent early secondary alveolar bone grafting and were controlled in Clinic of Congenital Deformities, Department of Jaw Orthopaedics at the Medical University in Lublin, eastern Poland.

Qualification for ABG was performed during orthodontic consultation. The presence of a symptomatic oronasal fistula and/or a bone defect within the alveolar process that could hinder orthodontic treatment and prosthetic rehabilitation in the cleft area, was also assessed. Prior to the procedure, a dental examination was performed and, if necessary, treatment of carious lesions or inflammatory conditions within the oral cavity completed. In children over the age of 5 years, qualification for surgery was based on an orthodontic assessment of CBCT imaging of the cleft area.

The follow-up of the operated group was a minimum of 5 years. Onset of the orthodontic treatment was understood as the endpoint.

Ethical statement. The data used in the study were obtained from a single-centre, non-randomized, uncontrolled retrospective clinical analysis, approved by the Ethics Committee at the Medical University of Lublin (Ref. No: KB-0024/148/11/2025)). The principles outlined in the Declaration of Helsinki were respected.

Surgical procedure. The patient is admitted to the ward either the day before the procedure or on the morning of the procedure. Standard pre-operative laboratory tests are performed, including blood typing, complete blood count, and coagulation profile. Immediately prior to surgery, the patient undergoes a full-body wash using surgical soap and oral hygiene appropriate to their age performed (in children, preparations containing chlorhexidine are used). Pre-operative infection prophylaxis is initiated with clindamycin.

All the procedures are performed by one experienced, board certified paediatric and plastic surgeon (MB).

The procedure is performed under general anaesthesia with intubation using a reinforced endotracheal tube. In addition, both the donor and recipient sites are locally anaesthetised with a mixture of 0.5% lignocaine, 0.25% bupivacaine, and adrenaline at a dilution of 1:200,000. The surgical field is disinfected with an alcohol-based preparation for the skin and iodine-derivative preparations (Braunol, B. Braun Melsungen AG, Germany) for the oral mucosa.

An initial assessment of the width of the alveolar cleft is performed, and in the case of bilateral clefts, the feasibility of performing bilateral ABG is also evaluated. This allows for an estimation of the amount of donor material required to fill the defect.

An incision is made parallel to and approximately 1–2 cm lateral to the iliac crest. The incision measures approximately 2–3 cm and begins at the level of the anterior superior iliac spine. The soft tissues are then dissected to expose the iliac crest, and the external portion, primarily cartilaginous, is separated as a flap to access the cancellous bone (Fig. 2). Cancellous bone is separated from the cortical bone on both the external and internal surfaces, and a block of cancellous bone is harvested, which is subsequently placed in saline solution. The empty cavity is filled with a haemostatic sponge (Spongostan™, Ethicon, USA), and the previously separated portion of the iliac crest repositioned. The cartilage and muscles are sutured to achieve optimal reconstruction of the donor site and to prevent future irregularities of the iliac crest. Absorbable sutures, such as PDS or Maxon™ (Covidien, Irland) 3–0 or 4–0, are used for this purpose. The subcutaneous tissue is then closed with an absorbable monofilament suture (Monocryl 4–0), which is also used for placing the intradermal suture. Finally, Steri-Strips (3M, USA) and a sterile dressing are applied to the wound.

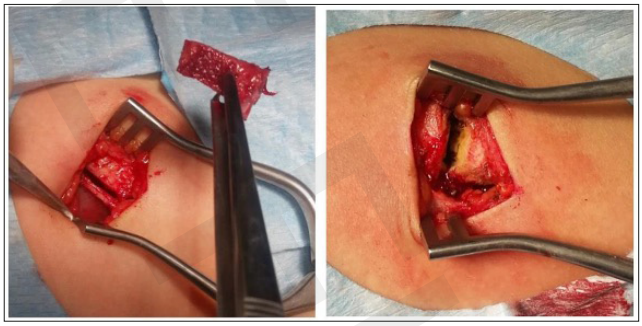

Figure 2. Donor side. Harvesting iliac cancellous bone

Following local anaesthesia of the oral mucosa, an incision is made along the medial and lateral walls of the alveolar cleft. The incision is extended laterally towards the region of the first premolar (tooth 4) in such a way as to create a mucoperiosteal flap necessary to cover the graft and reconstruct the external surface of the alveolar process (Fig. 3). The periosteum is then elevated, and the presence of an oronasal fistula is assessed. In most cases, the presence of an oronasal fistula is established based on the medical history and pre-operative examination. However, in the case of very narrow, slit-like fistulae, the fistula may not produce clinical symptoms. If an oronasal fistula is identified, it must be closed by incising the mucosa at the apex of the alveolar cleft and suturing it into the nasal passage. The mucoperiosteal flaps from the internal surface of the alveolar process are sutured using single interrupted stitches (Vicryl™ 4–0 or 3–0 [Ethicon, USA]) from the palatal side, creating a bed for the bone graft. The cancellous bone is shaped on the surgical table to fill the entire previously prepared site, fitting tightly against the maxillary bone. In

Figure 3. Preparation of the gingivomucosal flap; a bilaterial lip and palate cleft

young children, the bone is highly pliable, and shaping it does not present difficulties. The bone graft is then covered with the mucoperiosteal flaps, which are sutured along their external edges and anchored to the palate. For mucosal suturing, Vicryl™ (Ethicon, USA) 5–0, 4–0, or 3–0 sutures are used (Fig, 4). The oral cavity is irrigated with a solution containing iodine-based preparations.

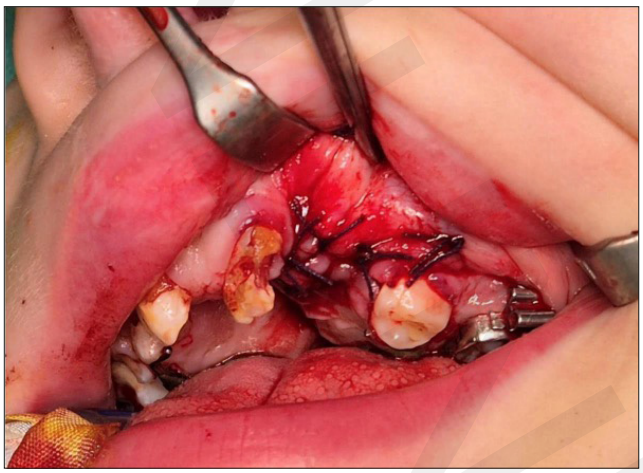

Figure 4. Sutures after gingivoplasty. Elements of the orthodontic appliance visible

In cases of bilateral clefts, if the width, stability, and degree of projection of the premaxillary bone permit, bilateral ABG is performed, with the surgical procedure carried out analogously on both the right and left sides.

Occasionally, teeth are present within the cleft; in sEABG, these are most often deciduous teeth. The decision to extract or preserve them is made pre-operatively following an orthodontic consultation.

Following surgery, the patient is not given food or fluids for approximately 8–12 hours. Thereafter, a liquid and pureed diet is introduced, and oral rinsing after each meal is initiated using a chlorhexidine preparation or a chamomile infusion. Post-operatively, analgesics are administered. Patients typically experience more pronounced pain at the donor site, which may occasionally cause difficulty with ambulation during the first or second post-operative day. Antibiotic therapy is continued, and cold compresses applied locally to the upper lip. Hospitalisation lasts 2–3 days. The liquid and pureed diet is maintained for 1 month, after which the diet is expanded to include soft, unprocessed foods. A regular, unrestricted diet is introduced 3 months after surgery. Antibiotic therapy is maintained for 5–7 days post-operatively. The first follow-up visit at the surgical outpatient clinic takes place 1 week after surgery, and the second visit occurs 1 month post-operatively. The first orthodontic follow-up is scheduled 3 months after surgery.

The following complications may occur post-operatively: swelling of the upper lip, haematoma, infection of the donor or recipient sites, deformation of the iliac crest, displacement of the graft due to mechanical trauma, poor graft integration, or complete graft resorption.

RESULTS

Early secondary ABG was performed in 30 boys and 11 girls. The mean age of the children operated on in this group was 3 years (standard deviation 1). eSABG was carried out in 7 children with cleft lip (3 with left-sided cleft lip, 2 with right-sided cleft lip, and 2 with bilateral cleft lip), and in 34 children with cleft lip and palate (20 with left- sided cleft lip and palate, 8 with right-sided cleft lip and palate, and 6 with bilateral cleft lip and palate). The clinical characteristics of the group are summed in Table 1. In all children with bilateral cleft lip or cleft lip and palate, bilateral ABG was performed simultaneously.

Table 1. Characteristics of the study group; eSABG- early secondary alveolar bone grafting. In all cases the iliac bone was used

Procedure	No. of cases	Gender F/M	Mean Age	Cleft lip / Cleft lip+ palate
eSABG Left	8	2/6	3	2/6
eSABG Right	3	2/1	3,5	0/3
eSABG Left+Right	2	0/2	3,5	0/2
eSABG Left+Lip Reconstruction	11	5/6	3	2/9
eSABG Right+Lip Recontruction	6	1/5	3	1/5
eSABG Left+ Right+Lip Recontruction	1	0/1	3	0/1
eSABG Left+Lip Reconsruction+ Palate Fistula Closure	2	0/2	2,5	0/2
eSABG Right+Lip Reconsruction+ Palate Fistula Closure	1	0/1	2	0/1
eSABG Left+ Lip Reconstrution +Nose Reconstruction	7	0/7	4	2/5

In 30 children, scar revision of the upper lip was performed concurrently with ABG; in 3 children, closure of palatal fistulae was carried out; in 3 children, frenotomy for a short lingual frenulum was performed; and in 5 children, correction of post-cleft nasal deformities was undertaken.

The mean hospital stay was 2.39 days (standard deviation 0.49). The first follow-up visit occurred 1 week post-operatively, followed by subsequent visits at 1 month and 1 year after surgery.

All children received antibiotic therapy (clindamycin), with the first dose administered immediately prior to surgery. Antibiotic treatment was continued at home orally for a total of up to 7 days.

For analgesia, nalbuphine was administered during the first two 2 post-operative days in combination with paracetamol and ibuprofen. At home, children received paracetamol for pain management for a total of 5–7 days.

Oral fluids were introduced, on average, 12 hours after surgery. At home, a liquid and pureed diet was maintained for 1 month, after which it was expanded to include soft foods. A regular, unrestricted diet was introduced from the third month post-operatively.

To facilitate dissolution of the sutures in the oral vestibule, mouth rinsing with chlorhexidine preparations was used; in cases of intolerance, a chamomile infusion was employed.

Children began ambulating 1 day after surgery.

All children exhibited swelling of the upper lip and cheek on the operated side. No wound infections were observed at either the donor or recipient sites.

During follow-up (ranging from 4–8 years), only 1 case (1/41, 2,44%) was recorded of graft failure requiring repeat ABG prior to orthodontic treatment. This concerned a girl with bilateral cleft lip and palate who had undergone simultaneous bilateral ABG; re-operation was necessary only on one side (the side with the wider alveolar defect).

In 12 cases, minor contour deformities of the iliac crest were observed.

DISCUSSION

Alveolar bone grafting is a standard procedure in the management of alveolar clefts [6, 7]. The goals to reconstruct the bony arch are both aesthetic and functional. It is indisputable that the most important and expected outcomes are improvements in speech development, articulation, as well as reduction of infection rates [8]. The main purposes of bone grafting are reconstruction of the dental arch and providing efficient eruption of lateral incisors, obliteration of oronasal fistulas, and creating nasal and alar base [6, 8, 9]. Secondary ABG has become the gold standard among the treatment options for alveolar cleft; however, there are some controversies in terms of ABG, such as timing of the surgery and grafting material.

The discussion regarding the optimal timing of ABG is strongly related to the maxilla growth and dental maturation. Early secondary ABG aims to prevent maxillary growth disorders and when performed before lateral incisor eruption, improves bone survival to a greater extent than in secondary procedures [10]. Closure of the maxillary arch at the early ages, in comparison to secondary reconstructions, improves proper speech development and articulation [7]. What is more, early secondary ABG prevents caries, one of the risk factors of graft loss [7].

In the study, 41 children underwent early secondary alveolar grafting with a low rate of complications – 2.44% of graft loss. The results are superior to the outcomes of the primary ABG described by Bardan et al., where complete bone ossification was reported in 50% of operated cases [11], and comparable to secondary ABG with a mean graft loss of approximately 2.75% [7, 12]. In only 1 case, a serious adverse event – graft loss – occurred. In other cases, mild and transient complications were present. In the recipient site, there was upper lip and cheek swelling. No wound infections were observed at either the donor or recipient sites.

In this study, in all cases an autologous bone graft from the iliac crest was used. Even though donor site morbidity is low – 2% of complications [13], it is one of the rationales to seek for a synthetic or allogenic materials for bone augmentation. The alternatives for autologous bone in eSABG can be demineralized bone matrix [5], a mixture of DBX, bone morphogenic protein (rhBMP-2) [2], and freeze-dried bone chips (FDBC) [14], or human bone morphogenetic protein-2 (rhBMP-2) [15]. The threats emerging from allogenic materials under discussion are the risk of malignancies or heterotopic ossification [14]. Although allogenic materials reduce hospital stay and use of resources, they can be expensive to purchase [14].

The literature regarding use of synthetic grafting material in eSABG is very limited. Al-Rawee et al. compared material consisting of hydroxyapatite and tricalcium phosphate to autologous graft used for secondary ABG. The obtained results are satisfactory and comparable to autologous bone [16] which are consistent with a meta-analysis by Putri et al. Three randomized control studies (RCT) were taken into consideration [17]. In all 3 secondary or late secondary ABG was performed (Sakamato et al. secondary ABG [18]; Bezzera et al. mean age of participants 15,6 [19]; [Kumar et al. patients aged 7–16 [20]). No serious adverse events were reported in the aforementioned observations. In 2 RCTs hydroxyapatite was used, in 1 platelet rich plasma (PRP) to hydroxyapatite was added to improve ossification [19], while in another a complex of hyaluronic acid and collagen [18]. PRP or plateklet rich fibrin (PRF) are believed to increase bone density and volume [21]. In a case report by Vemagiri et al., PRF was added to autologous iliac crest bone graft in a secondary ABG [22].

All patients in the current study were under orthodontic supervision in the pre- and post-operative periods. Chang et. al. proved that orthodontic treatment before the ABG has positive influence on graft survival and central incisor positioning [23], but in the current study, in children under age of 2, orthodontic treatment was not performed. eSABG enable all teeth eruption trough grafted bone which can improve SWAG (The Standardized Way to Assess Grafts) scores in the coronal third prior to orthodontics, according to conclusions of Lowry at al. [24].

In the clinic referred to in the current study, bone grafts are assessed with CBCT examination in children over the age of 5 years. As soon as cooperation with a child is achieved, slow palatal expansion and elastic appliances are used. When narrowing of the maxilla is observed Rapid Palatal Expansion (RPE) is implemented, but not in children under the age 6 years. There was no compromising the alveolar grafted region as presented by Garib et al [25]. Orthodontic expansion is often accompanied with face mask maxillary protraction according to cephalometric indication.

CONCLUSIONS

The obtained results suggest that early secondary alveolar bone grafting using iliac crest bone in alveolar cleft associated with cleft lip or cleft palate, is a safe procedure with a low rate of serious complications. The analysis was focused of the personal experience in a single centre with a mean follow-up of 5 years. It would be beneficial to directly compare the 2 most common procedures – early secondary and secondary bone grafting, which would require a multi-centre study of at least 2 experienced centres with different operating protocols.

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