

Radiographic outcome of secondary alveolar bone grafting in patients with alveolar clefts

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Abstract

Objective: To determine the outcome of secondary alveolar bone grafting (SABG) in a series of consecutive patients with clefts involving the alveolus.

Design and Setting: Retrospective cohort study of consecutive operations performed between June 2011 and September 2016 by a single surgeon at a single United Kingdom cleft center.

Participants: A total of 160 patients with a cleft/s involving the alveolus, inclusive of syndromic patients and those with atypical facial clefts.

Interventions: A standard protocol involved an oral hygiene program, pre-surgical orthodontics where necessary and autologous bone grafting from the iliac crest.

Main Outcome Measure(s): The Kindelan bone-fill index was used to evaluate success using occlusal radiographs. Weighted Cohen's kappa coefficient was used as a measure of intra- and inter-rater agreement. Fisher's exact test was used to examine the effects of type of cleft, pre-surgical orthodontics or age at time of SABG on radiographic outcome.

Results: There were 200 SABGs assessed. Mean age at time of SABG was 9.1 years old (SD 1.1) with 99% (n = 198) of grafts deemed successful. There were two failures where re-graft was performed successfully during the study period. A grade 1 outcome was achieved for 92.5% (n = 185) of grafts and this did not appear to be affected by type of cleft ($P = .290$), pre-surgical orthodontics ($P = .380$) or age at time of SABG ($P = .081$).

Conclusions: The high success rate reported in this study supports the favorable outcomes of a high-volume cleft surgeon. These findings can be used for comparative audit with similar units providing cleft care.

KEYWORDS

alveolar bone grafting, cleft lip, cleft palate, orthodontics

1 | INTRODUCTION

Patients born with clefts involving the alveolus require bone grafting as part of surgical cleft repair, with this procedure being used since at least the mid-20th century.¹ Secondary alveolar bone grafting (SABG),

described by Boyne & Sands² in 1972, is carried out in the mixed dentition. This is often around the ages of 8 to 12, prior to canine tooth eruption, which enables the development of further alveolar bone as the permanent canine erupts into position through the graft site.^{3,4} This is now accepted practice, but timing of surgery can also be influenced by



patient-specific factors, such as the presence of an unerupted cleft side lateral incisor. Some centres advocate for earlier bone grafting, prior to the age of 8, reporting no adverse effects on maxillary growth⁵ whilst aiding eruption of the cleft side maxillary central and lateral incisors.⁶

The most common donor site chosen for autologous SABG in the United Kingdom is iliac crest.⁷ The goals of SABG are to stabilize the maxillary segments and provide sufficient bone through which the developing permanent canine can spontaneously erupt.^{2,3,8} Additional alveolar support for teeth adjacent to the cleft and closure of any oronasal fistulas will also be desirable. Prosthetic rehabilitation at the cleft site, if required, can be facilitated and there is improved support for the alar base of the nose.⁶ An orthodontic appliance may be required prior to grafting to align anterior teeth, correct crossbites and create space for surgical access, whilst potentially increasing the volume of bone which can be grafted into the recipient site.^{9,10}

Multiple outcome measures have been developed for the assessment of SABG¹¹ and these often involve the use of two-dimensional radiographs, frequently upper occlusal and periapical views.⁷ These may be supplemented or alternated with a dental pantomogram and three-dimensional cone beam computed tomography (CBCT). Amongst UK cleft centres, 81% will image the cleft site at 6 months post-operatively.⁷ Two-dimensional radiographic assessment measures include the Bergland scale to assess the height of bone between teeth immediately adjacent to the cleft site³ and the Chelsea scale.¹² These measures rely on the eruption of the maxillary canine to assess the outcome of the graft. Another internationally accepted measure of SABG outcome includes the Standardized Way to Assess Grafts (SWAG) scale.¹³

More commonly in the UK, the Kindelan bone-fill index¹⁴ is used. This index uses a percentage and graded assessment of bone infill between pre- and post-operative views. Grade 1 is considered an ideal outcome, with >75% bone fill across the cleft. Grade 2 is still considered a successful outcome with 50%-75% bone infill. Anything less than 50% (grades 3 and 4) would likely necessitate re-grafting and be considered a failure. The benefit of the Kindelan index is that it can be used in the early post-operative phase as well as at later follow-up and does not rely upon eruption of the maxillary canine to make an assessment. This may mean earlier detection of graft failure and more expedient revision surgery.¹⁵

The aim of this study was to measure the outcome of SABGs performed by a single cleft surgeon at a UK tertiary care cleft center using radiographic assessment with the Kindelan bone-fill index. Secondary aims were to evaluate the effects of cleft type, pre-surgical orthodontics, and age at SABG on radiographic outcome.

2 | MATERIALS AND METHODS

2.1 | Population

Retrospective cohort of consecutive SABG operations performed between June 2011 and September 2016 was completed. This date

range involved the first 200 bone grafts performed by the operating surgeon on appointment to the cleft service. The sample was inclusive of patients with both unilateral cleft lip and palate (UCLP), bilateral cleft lip and palate (BCLP) and those with cleft lip and alveolus (CL+A). Patients who were diagnosed as syndromic or had atypical facial clefts were also included in the sample. Exclusion would only be based on incomplete records that would prevent radiographic outcome assessment.

2.2 | Setting

All treatment was carried out at a tertiary care cleft center in the United Kingdom. Patients were treated by a single cleft surgeon and cleft orthodontist. All treatment was funded by the United Kingdom National Health Service.

2.3 | Intervention

Local protocol for SABG involved multidisciplinary team assessment at age 8, with agreement to perform grafting dependent on when the maxillary canine root is between one and two-thirds formed. A further 6-month review was arranged for patients with delayed dental development. Early grafting (<8 years) was completed for patients with a missing cleft lateral incisor but with the presence of a favorable unerupted supernumerary tooth distal to the cleft to provide sufficient bone for its eruption. Patients also underwent an oral hygiene program with a dental therapist under the guidance of a paediatric dentist. This included supervised toothbrushing and provision of disclosing tablets for two weeks pre-operatively. Telephone follow-up with a dental therapist was provided one week post-operatively to support this.

Pre-surgical orthodontic expansion was completed with a quad helix or removable appliance if required to correct posterior crossbites or at the request of the surgeon to improve access to the surgical site in very constricted archforms. Orthodontic alignment was provided with a sectional pre-adjusted edgewise labial fixed appliance for the correction of anterior crossbites and to create space for surgical access when necessary. All patients underwent autologous bone grafting from the iliac crest. Patients with BCLP underwent simultaneous grafting of both cleft sites. The local surgical protocol for iliac bone harvest and subsequent grafting has previously been described.¹⁶

2.4 | Outcomes

Data were extracted retrospectively from patient clinical records, including the age at time of SABG and type of cleft. The primary outcome measure was the Kindelan bone-fill index to evaluate radiographic success. Pre- and post-operative upper oblique occlusal radiographs centered over the cleft/s were used, at times

supplemented by periapical views. Radiographs were taken at the SABG assessment, normally at age 8, and at the 6-month post-operative review. For patients with BCLP, both graft sites were scored. Images were downloaded from Caresteam Vue PACS imaging software (Caresteam Health Inc) into an anonymized slideshow file for scoring. Radiographs were assessed digitally by two experienced cleft clinicians with scoring completed remotely to prevent collusion. Following this, where scoring differed for a particular set of radiographs, a third consensus score was generated for the purposes of a definitive audit score and subsequent secondary analyses. Success of SABG was determined as being grades 1 or 2, as defined by Kindelan et al (1997)¹⁴ and detailed in Table 1. Information on the type of orthodontic appliances used, number of visits and duration of orthodontic treatment were also extracted.

2.5 | Data management

Data collection was completed using a pre-piloted Microsoft Excel® (Microsoft, Redmond, WA) spreadsheet. The principles of the Declaration of Helsinki were observed. Data analyses were completed independent of the outcome assessors.

2.6 | Ethical approval

This project was undertaken for quality improvement purposes using existing patient records as part of the annual audit of cleft unit outcomes. Registration was completed with the regional cleft audit team and reporting of these outcomes form part of the national clinical governance for cleft care in the United Kingdom.

2.7 | Statistical analyses

Reproducibility of the Kindelan index was assessed by asking the outcome assessors to re-score the first 30 radiographs two weeks later. The level of intra- and inter-rater agreement was determined using weighted Cohen's kappa coefficient due to the ordinal nature of the Kindelan index. Fisher's exact test was used to examine whether outcomes were affected by the type of cleft and use of pre-surgical orthodontics. The age at time of bone grafting was also assessed by converting age at operation into a dichotomous variable of <11 and ≥11 years old. This age was chosen as a cut-off point

TABLE 1 Grading and definition of SABG success. Kindelan et al (1997)¹⁴

Grade	Bone-fill score	Outcome
1	>75%	Success
2	50%-75%	Satisfactory (Success)
3	<50%	Unsatisfactory (Failure)
4	No complete boney bridge	Failure

above which the majority of patients would have advanced root development of unerupted maxillary canines and would therefore be considered a 'late' graft with respect to local protocol. For patients with BCLP, the graft site with the lowest score was used for statistical testing. *P* values were calculated at the 0.05 significance level.

3 | RESULTS

There were 200 consecutive SABGs performed in 160 patients. All patients had radiographs of sufficient quality to undergo scoring and so no exclusions were made. This sample comprised of 98 (61.25%) males and 62 (38.75%) females. There were 102 (63.75%) patients with UCLP, 38 (23.75%) patients with BCLP and 20 (12.5%) patients with CL+A. Three patients were included with formal diagnoses of CHARGE, Patau's and 22q11 deletion syndrome, respectively. There were also two cases of patients with a Tessier number 3 and a mid-line facial cleft.

Of the 200 grafts assessed, 198 were deemed successful (99%), having either a grade 1 or grade 2 outcome. An example of a successful outcome is provided in Figure 1. Two SABGs failed and were subsequently re-grafted prior to canine tooth eruption within the study period with a successful outcome. One graft was also a revision procedure, with the first attempt undertaken by a different surgeon and resulted in a successful outcome. Table 2 details the Kindelan index scores for all grafts assessed by cleft type. Mean age at time of bone grafting was 9.1 years old (SD 1.1, range 7-19.9). There were 65 (40.63%) patients who underwent pre-surgical orthodontics. Types of appliances used included a quad helix (*n* = 57), often in combination with a sectional labial fixed appliance (*n* = 64). An upper removable appliance was used for 4 patients. Pre-surgical orthodontic treatment had a mean duration of 10.9 months (SD 4.60, range 5-28) over a mean of 10 visits (SD 3.65, range 5-22).

Intra-rater agreement was near perfect¹⁷ for both clinicians, as detailed in Table 3. Inter-rater agreement was substantial using a weighted kappa coefficient. Both failures were in patients with UCLP, however, type of cleft did not appear to affect outcome of the SABG with any statistical significance in terms of both success rate (*P* = 1.000) and percentage deemed to have a grade 1 'ideal' outcome (*P* = .290). There was also no statistically significant difference in Kindelan score when pre-surgical orthodontics was undertaken (*P* = 1.000). Age at time of bone grafting did not appear to influence overall success (*P* = 1.000) or when comparing the percentage of grade 1 outcomes (*P* = .081). There were 31 grafts performed in patients ≥11 years old (*n* = 22) with 81.81% of these being deemed grade 1 compared with 93.57% in patients grafted prior to age 11, as detailed in Table 4.

4 | DISCUSSION

The radiographic outcomes in this report compare well with the literature, although there is some heterogeneity in the measures



FIGURE 1 An example of pre- (A) and post-operative (B) radiographs with a successful SABG outcome for a patient with UCLP

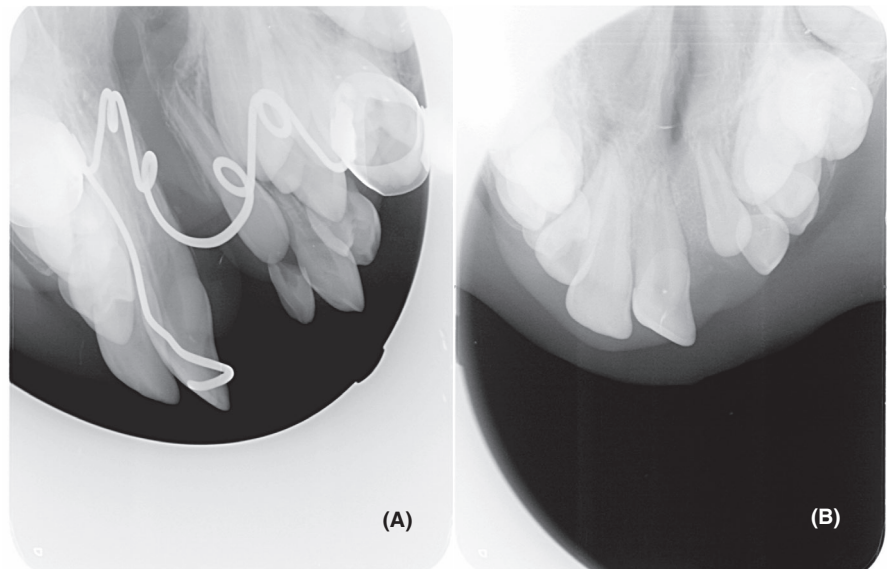


TABLE 2 Outcome and Kindelan index score by cleft type (n = 200)

Grade	Outcome	UCLP (%)	BCLP (%)	CL+A (%)	Total (%)
1 (>75%)	Success	93 (89.42)	72 (94.74)	20 (100)	185 (92.5)
2 (50%-75%)	Success	9 (8.65)	4 (5.26)	0	13 (6.5)
3 (<50%)	Failure	1 (0.96)	0	0	1 (0.5)
4 (no bone bridge)	Failure	1 (0.96)	0	0	1 (0.5)

TABLE 3 Intra- and inter-rater agreement with weighted kappa values and 95% confidence intervals

	Rater 1	Rater 2
Rater 1	0.845 (0.636-1) ^c	0.664 (0.449-0.880) ^b
Rater 2	0.664 (0.449-0.880) ^b	0.845 (0.636-1) ^c

Note: $P = <.001$ for all kappa statistics.

Agreement¹⁷:

^aModerate.

^bSubstantial.

^cNear perfect.

used and the definition of success. The 1998 Clinical Standards Advisory Committee (CSAG) report into cleft care in the United Kingdom found a 58% success rate of SABG using the Kindelan bone-fill index.¹⁸ This was much lower when compared to Northern European centers and encouraged a framework for continuous audit of clinical outcomes and the eventual centralization of UK cleft services. The Scottish managed clinical network for cleft (CLEFTSiS) found that for SABGs carried out in 2000-2004, 76% of grafts were successful.¹⁹ Success rates of 81% and 85% were later reported for both individual and UK national cleft outcome studies^{20,21} and repeated CLEFTSiS audit for 2007-2010 showed significant improvement to a 99% success rate.²² These studies have demonstrated the benefits of centralization and the importance of continuous audit and appraisal of treatment outcomes in cleft care.

Comparable results from North American cleft centers have indicated that the level of expertise and volume of the operating surgeon may similarly be related to the quality of outcome.¹³ This single-center outcome report finds a 99% success rate, with 92.5% (n = 185) having a grade 1 outcome. Although we did not examine aspects such as surgical morbidity, previous retrospective evaluation of 100 SABGs performed by the same cleft surgeon found a low complication rate for this procedure, with 92% of patients being discharged the following day.¹⁶ This evaluation covered a substantial proportion of the operations for which the radiographic outcomes are reported here.

There is some variation in what is considered a late graft, however, for patients undergoing SABG after the age of 11 the overall success rate was not reduced but there was a reduction in the proportion of grade 1 outcomes, albeit not to a statistically significant extent. This trend is consistent with previous reports in the literature.²³⁻²⁵ As this study was primarily conducted for audit purposes, we did not seek to examine other indicators of success which could provide a more holistic measure of SABG outcome. Successful eruption of the canine through the graft site is an important clinical outcome. So too are the absence of negative sequelae, such as invasive cervical root resorption or recurrence of oronasal fistulae, which require more long-term follow-up to assess.

There were 22 patients who underwent SABG after the age of 11. Reasons for this included several late presentations to the cleft service, mostly transfer cases or patients who were recent arrivals to the United Kingdom (n = 6). This meant that assessment for SABG was in some cases much older than age 8 and therefore individual



	% Success rate	P Value	% Kindelan Grade 1	P Value
UCLP	98 (102/104)	1.000	89.42 (93/104)	.290
BCLP	100 (38/38)		94.74 (36/38)	
CL+A	100 (20/20)		100 (20/20)	
Pre-surgical orthodontics	98.48 (65/66)	1.000	89.39 (59/66)	.380
No orthodontics	98.95 (95/96)		94.79 (91/96)	
Age at time of ABG <11	98.57 (138/140)	1.000	93.57 (131/140)	.081
Age at time of ABG ≥11	100 (22/22)		81.81 (18/22)	

Note: Lowest graft score used for patients with BCLP (n = 38). Two grafts were repeated within the study period with 162 grafts assessed with statistical testing.

decisions to proceed with grafting were a deviation from the ideal protocol. Some patients underwent later SABG due to delayed dental development or other medical concerns (n = 13). Late grafts also included the 3 revision procedures. It is important to ensure timely assessment and operation for SABG, but similar issues have been reported in other cleft units.^{18,24} We chose to still include the outcome of these operations as part of service evaluation and to identify if these 'late' grafts contributed to poorer outcomes. We also chose to include the small number of syndromic patients and those with atypical facial clefts to be representative of operator case mix and ensure outcomes were applicable to all patients treated within our unit.

The Kindelan bone-fill index uses two-dimensional imaging so may also not reflect the true degree of success and architecture of the regenerated bone. It cannot make detailed volumetric assessments as only the vertical dimension of bone bridge formation can be visualized and is therefore likely not a sensitive enough measurement tool to assess the effects of variables like pre-surgical orthodontics on SABG outcome. However, two-dimensional imaging is acceptable for evaluating and comparing patient outcomes at the population scale,²⁶ with three-dimensional imaging more suited to individual patient assessment and planning. Due to the homogeneity of outcomes in this sample, the proportion of grade 1 outcomes was assessed in secondary analyses. The Kindelan bone-fill index is an inherently subjective assessment tool and attempts to increase sensitivity have included modification with a visual analogue scale.²³ Radiographic indices of this kind all have seemingly comparable reproducibility²⁷ but in future, three-dimensional imaging modalities may be used more widely as radiation doses reduce.¹¹ It has been suggested that the SWAG scale may overcome some of the deficiencies of the Kindelan index by localizing any residual alveolar defects.⁴ Currently, SWAG is not widely used in the United Kingdom but validation of results with this method could be carried out in future.

Most bone resorption can be expected to occur in the buccopalatal dimension, with reports suggesting a mean volumetric bone loss of 49.5% at one-year post-surgery²⁸ and minimal change thereafter. Likewise, radiographic outcome of SABG does not appear to change significantly between assessment carried out at both short and longer-term follow up.²⁹ Imaging within the one-year post-operative period is therefore likely to be an appropriate reflection of the final result, as carried out in this study. A further investigation

TABLE 4 Effect of cleft type, pre-surgical orthodontics and age at time of SABG on % success and Grade 1 outcome

could be considered using radiographs at the start of definitive orthodontic treatment, which is usually about 2 or more years post-SABG. The use of CBCT imaging for individual patients following SABG has in some cases been found to increase the rate of revision surgery.³⁰ As most SABGs occur between the ages of 8 to 12, the increased sensitivity of children to X-radiation must also be considered. Recent research has estimated that undertaking two CBCTs in a 10- to 14-year-old female would equate to a 1 in 10 000 risk of developing cancer.³¹ From a clinical perspective, if there is a sufficient bone bridge to facilitate orthodontic tooth movement for function and esthetics, CBCT is not indicated for routine assessment.

The standardization of pre- and post-operative imaging can also be challenging, with previous audit within this cleft unit finding a high standard of diagnostic occlusal radiography.³² Despite the common limitations of retrospective studies, records were available for all patients in this cohort with all radiographs of sufficient quality to undergo scoring. A further strength of this study is the large and consecutive sample, with good consistency in the implementation of the Kindelan bone-fill index. As would be expected, the intra-rater agreement was higher than that for between raters. Further calibration and training exercises may have helped to improve the degree of inter-rater agreement. The 40% of patients reported to have undergone pre-surgical orthodontics is also in line with UK national findings.⁷

Overall, cleft care within the United Kingdom has benefited greatly from the shift towards centralization of services, producing high-volume operators and improved standards of care.³³ We only report the outcomes for one such cleft center and surgeon. Regional and national multicenter audit remains important to monitor clinical outcomes.

5 | CONCLUSION

The high success rate of 99% reported in this study supports the favorable outcomes of a high-volume cleft surgeon. Type of cleft, pre-surgical orthodontics, and age at time of SABG did not appear to affect radiographic outcome in this cohort. These findings can be used for comparative audit with similar units providing cleft care and demonstrate the importance of high-quality record keeping for continuous appraisal of treatment outcome.



CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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