Prediction of outcomes of secondary alveolar bone grafting in children born with unilateral cleft lip and palate

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SUMMARY The aim of this cross-sectional clinical outcome study using retrospective data capture of treatment histories was to examine the characteristics of children born with unilateral cleft lip and palate (UCLP) in the United Kingdom (UK) who were not grafted at the appropriate age or who had an unsuccessful secondary alveolar bone graft.

The subjects were born with complete non-syndromic UCLP between 1.4.82 and 31.3.84 and were aged between 12.0 years and 14.7 years at the time of data collection under the care of 48 cleft teams.

The success of secondary alveolar bone grafting was assessed using a modification of the Bergland index.

There were no independent predictors for unmet bone grafting need. The outcome of secondary alveolar bone grafting was assessed for 164 subjects; 90 (55%) had a successful first graft. Non-Caucasian (P = 0.037) and increasing age at grafting (P = 0.007) were risk factors for poor outcome. After adjustment for other risk factors, increased age at grafting was independently associated with having a seriously deficient or failed graft (OR = 1.03; 95% Cl 1.01–1.06 P = 0.036). All the non-Caucasians in this sample had an unsatisfactory graft.

Increasing age in months at grafting and ethnicity are predictors for poor outcome of secondary alveolar bone grafting in children born with UCLP in the UK.

Introduction

The Clinical Standards Advisory Group (CSAG), 1996, commissioned a national study of the process and outcome of cleft care in the United Kingdom (UK). The results showed that the outcomes of secondary alveolar bone grafting in the UK were poor, with less than 60 per cent of children having a successful graft (Williams *et al.*, 2001). Moreover, a substantial number of children had not been grafted at the optimal age of 9–11 years (Bergland *et al.*, 1986). The reasons behind these poor results were not immediately apparent.

A number of factors are believed to influence the outcome of alveolar bone grafting. Several studies (Bergland *et al.*, 1986; Lee *et al.*, 1995; Kalaaji *et al.*, 1996; Enemark *et al.*, 1997) have shown that dental development at the time of the graft is important. The best results are achieved if the graft is undertaken before the eruption of the canine. Recently it has been suggested that bone grafting may be undertaken earlier in some cases to give bony support to the erupting lateral incisor (Enemark *et al.*, 2001).

Other factors, the donor site, the pre-operative health of the graft site, the procedure at operation, and the incidence of post-operative complications (Lilja *et al.*, 1987; Sindet-Pederson and Enemark, 1990; Cohen *et al.*, 1993; LaRossa *et al.*, 1995; Tan *et al.*, 1996; McCanny and

Roberts-Harry, 1998) have been shown to influence the outcome of bone grafting. Sample sizes, however, have been too small to examine the effect of confounders, such as age at grafting, on these associations.

The experience of the cleft team may also affect outcomes in some aspects of cleft care. Previous reviews of the literature (Nuffield Institute of Health, 1996) suggest that hospitals treating high volumes of patients achieve better outcomes than those dealing with smaller volumes. The relationship between hospital volume and outcome of bone grafting has not been examined. The experience and training of the surgeon could also be important. Kalaaji et al. (1996) demonstrated that surgeons with greater cumulative experience of secondary alveolar bone grafting had higher success rates than less experienced surgeons. There is an association between the annual operating experience of the surgeon and speech outcomes of primary repair in cleft patients (Williams et al., 1999). It is not known whether this is also true for secondary procedures such as alveolar bone grafting.

As a result of the CSAG (1998) study, cleft services in the UK are currently being reorganized. In the future, primary and secondary surgery, including alveolar bone grafting, will be undertaken at regional cleft centres (Health Services Circular, 1998). Long-term treatments, A. WILLIAMS ET AL.

such as orthodontics, will continue to be delivered locally under the clinical direction of the regional cleft team. The main aim of centralization is to increase surgical expertise and improve the outcomes of surgical correction. The CSAG (1998) report showed that there is also an urgent need to improve the quality of delivery of other aspects of UK cleft care, in particular secondary alveolar bone grafting.

The aim of the present study was to examine the demographic and treatment characteristics of children in the CSAG cleft study who had an unsuccessful first bone graft or who were not grafted at the optimal age, and to identify predictors for poor outcome.

Methods

The CSAG (1998) study was based on two age cohorts, the '5 year-olds' (aged 5–7), who were included to assess the outcome of primary repair, and the '12 year-olds' (aged 12–14), who were selected to examine, amongst other aspects, the outcome of secondary alveolar bone grafting. The study was restricted to non-syndromic children born with complete bony unilateral cleft lip and palate (UCLP). To increase the sample size each age cohort covered a two-year birth period. The present study was based on the 12 year-old cohort, which consisted of children born with UCLP between 1st April 1982 and 31st March 1984, who were aged 12.0–14.7 years at the time of data collection.

The methods used in the CSAG study for identifying the sample and collecting the outcomes have been described previously (Sandy *et al.*, 1998). To summarize, children identified for the study were invited to attend data collection days, which were held at cleft centres around the UK during 1996. A series of standardized outcome records was collected for each child who attended. An anterior oblique radiograph directed through the

cleft was taken for each 12 year-old who had been grafted, unless a good quality radiograph taken during the past 18 months was already available.

Independent observers (selected from a panel of plastic surgeons and oral and maxillofacial surgeons) examined each subject's clinical notes. The observers ascertained whether the child had been grafted and, if so, whether the first graft had been successful or had to be repeated. Details of the child's age at the first bone graft, the grade and speciality of the surgeon who undertook this graft, the donor site, whether teeth had been removed at the time of grafting, and whether there were any post-operative complications were also recorded. The number of bone grafts undertaken by each surgeon for the 12 year-olds was calculated from the Research Team database.

The Research Team Registrar recorded the ethnic group of each child who attended a data collection day. Since the majority of children were white Caucasian (Table 1) they were divided into white Caucasian and others (Asian, Afro-Caribbean, and other) for the analysis. Socio-economic status was determined from the postcode of the child's current address using the Carstairs Index (Carstairs and Morris, 1989). The Carstairs Index scores were divided into quintiles for the analysis. The lowest two quintiles represented low socioeconomic status. The distance between each subject's home and the hospital where their cleft team was based was determined using a Geographic Information System (Arc View 3.2 GIS Software, ESRI (UK) Ltd, Aylesbury, Bucks). To gain an indication of the number of annual referrals currently being received by the cleft team, the number of 5 year olds identified for the study was calculated from the database. The teams were divided into 'high volume' (10 or more 5 year old UCLP cases identified) and 'low volume' (less than 10 5 year old UCLP cases identified) for the analysis.

Table 1 Demographic characteristics of 12–14 years olds with UCLP who had received an alveolar bone graft compared with children who had not been grafted.

Baseline characteristic	Grafted $(n = 239)$		Not grafted $(n = 36)$		Chi-squared test	
	Frequency	% (95%CI)	Frequency	% (95%CI)	P	
Male	153/239	64 (58–60)	22/36	61 (45–78)	0.905	
High socio-economic group (Carstairs 1–3)	129/218	59 (52–66)	13/31	42 (25–59)	0.170	
Caucasian	178/189	94 (91–97)	21/23	91 (80–100)	0.781	
Under the care of a 'high volume' cleft team (≥5 UCLP per year)	114/239	48 (42–54)	21/36	58 (42–74)	0.296	
Median travelling distance from home to cleft team base	19.7 km range 1.5–498 interquartile 9.9–39.5 km n = 220		24.8km range 2.5–109 interquartile 13.0–45.6 km <i>n</i> = 30	range	Mann–Whitney <i>U</i> -test 0.374	

Assessment of outcome

Two experienced orthodontists (WS and GS) examined all the anterior radiographs and classified the oral and nasal aspects of the grafts according to the system outlined in Figure 1. As the majority of canines were unerupted, classification of the oral aspect was based mainly upon the distal aspect of the central incisor.

Four categories of outcome and a fifth category, 'unreadable', were used to rate the radiographs. The inter-examiner agreement was calculated using the weighted kappa statistic. Where any disagreement occurred the film was re-read by both examiners and the category agreed by consensus. The final results were grouped as 'successful' [perfect (grade A) or minor deficiency of the interdental bone (grade B)], 'seriously deficient' [a graft where there was sufficient bone for the canine to erupt but insufficient for successful tooth movement (grade C)], or 'failed' (grade F). If there was a deficiency of bone on the nasal aspect [around the root apex of the canine (grade G)] the graft was ranked as 'severely deficient'.

Analysis

For the first part of the analysis, the subjects were divided into those who had been grafted and those who had not received a bone graft. The demographic characteristics of the two groups were compared. To examine the data for selection bias, the demographic characteristics of children with details of bone grafting available were compared with the characteristics of children for whom no details were available. Similarly, the demographic and treatment characteristics of children for whom the outcome of bone grafting was assessed were compared with those of subjects with no outcomes available. Chi-squared tests were used to compare the distribution of categorical variables between the two

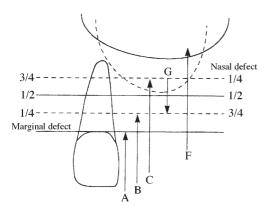


Figure 1 Diagram showing the modified Bergland Index used for assessing the quality of secondary alveolar bone grafting in UCLP. A, 'perfect' bone graft; B, marginal defect up to 1/4 of root length; C, marginal defect more than 1/4 of root length; F, failure; G, nasal defect more than 1/4 of root length.

outcome groups. Student's *t*-tests were used to examine the distribution of normally distributed continuous data and non-parametric Mann–Whitney *U*-tests to describe the distribution of skewed continuous data.

For the second part of the study, the subjects were divided into those who had a successful first bone graft and those who had an unsuccessful (failed or seriously deficient) graft. Subjects who had undergone a repeat graft were included in the latter group. The demographic and treatment characteristics of the two groups were compared. Crude odds ratios were calculated for the association between each characteristic and unsuccessful outcome. Mantel–Haenszel tests were used to examine the strength of each association.

Backward-stepwise logistic regression modelling was used to examine the association between important risk factors ($P \le 0.200$ as recommended by Maldonado and Greenland, 1993) and poor outcome, adjusted for the simultaneous effect of other risk factors. Likelihood ratio tests (LRT) were used to identify the models with the best fit. The data were also examined for interaction between risk factors for poor outcome by fitting the models with interactive terms. LRT were used to compare each model constructed with and without interactive terms.

Results

A total of 319 12 year-olds were identified from the CSAG (1998) study. Details of alveolar bone grafting were available for 275 (86%) children. There were no statistically significant differences in the demographic characteristics [sex (P = 0.771), socio-economic status (P = 0.611), ethnic group (P = 0.658), distance from the cleft team base (P = 0.787), volume of referrals received by cleft team caring for the child (P = 0.313)] of subjects with information available on bone grafting compared with those for whom no data were collected.

Unmet need for bone grafting and demographic factors

Thirty-six children (13%) had not received an alveolar bone graft by the optimal age of 9-11 years (Bergland et al., 1986; Enemark et al., 1987). Table 1 shows the demographic characteristics of children who had been grafted compared with those who had not received a bone graft. There was no association between sex, ethnic group, travelling distance from the child's home to the hospital base of the cleft team, being under the care of a high volume cleft team, and unmet need for alveolar bone grafting in this sample. Children from low socio-economic backgrounds (Carstairs Index 4 and 5) were at increased risk of not having received a secondary alveolar bone graft compared with children from more privileged backgrounds. This association, however, was not statistically significant at the 5 per cent level (Table 1).

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A total of 239 children (87% of those with records available) had been grafted. Ten of these children had a repeat bone graft; one child had been grafted three times (Table 2). The mean age at grafting was 10 years 3 months. Details of the surgeon who performed the graft were collected for 201 (84%) children. Table 2 shows that the number of grafts undertaken by plastic surgeons compared with maxillofacial surgeons were almost equal. Nearly all the grafts were taken from the iliac crest.

Anterior oblique radiographs were collected for 183 (77%) of the 239 children who had a secondary alveolar bone graft. Twenty-six radiographs were considered to be unreadable due to poor tooth position or film quality.

Table 2 Details of secondary alveolar bone grafting for 12–14 year-old children born with UCLP in the UK.

	12 year-olds $n = 319$	
	Frequency	%
Number of bone grafts		
0	36	13
1	229	83
2	9	3
3	1	1
Total	275 (86%)	
Not recorded	44	
	Subjects who	
	had been grafte	ed
	n = 239	
Grade of surgeon who undertook first graft		
Consultant	171	85
Trainee	29	15
Total	200	
Not recorded	39	
Speciality of surgeon		
Plastic	95	47
Maxillofacial	105	52
Plastic and maxillofacial	1	1
Total	201	
Not recorded	38	
Donor site		
Iliac crest	194	98
Tibia	4	2
Chin	1	1*
Total	199	
Not recorded	40	
Teeth removed at the time of the graft		
Yes	71	43
No	96	57
Total	167	
Not recorded	72	
Post-operative complications at graft site		
Yes	31	18
No	139	82
Total	170	
Not recorded	69	
Mean age in years at first bone	10.3 (SD = 1.3)	
graft $(n = 195)$	Range 7.2–14.0)
Median number of bone grafts undertaken		
by each surgeon for the 12 year-olds	3	
Interquartile range 2–8	Range 1–16	

In total, 157 (86%) radiographs were assessed. Only 59 per cent (n = 92) of bone grafts were ranked as successful. Twelve per cent (n = 19) of grafts had failed, and 29 per cent (n = 46) were considered to be seriously deficient (Williams *et al.*, 2001).

Demographic and treatment factors and unsuccessful bone grafting

The surgical details collected related to the first alveolar bone graft. Table 2 shows that 10 12 year-olds had received a repeat bone graft. Two of these children had a successful repeat graft, therefore 90 children (i.e. 92–2) were categorized as having a successful first alveolar bone graft. Seven subjects who had a repeat graft had no outcomes available. Since the first graft had to be repeated these children were also included in the 'unsuccessful' group for the analysis. In total 74 (45%) of the 164 12 year-olds for whom the outcome could be assessed had an unsuccessful first graft.

Tests for selection bias showed no differences in the demographic characteristics [sex (P = 0.247), socioeconomic status (P = 0.772), ethnic group (P = 0.451), number of referrals received by the cleft team (P = 0.292)or treatment characteristics (grade of surgeon who undertook bone graft, P = 0.364), speciality of surgeon (P = 0.168), volume of repairs undertaken by the surgeon (P = 0.568), age at bone grafting (P = 0.155) of subjects with outcomes available compared with those for whom the outcome of bone grafting could not be determined. From the study by Enemark et al. (1987) the baseline exposure to being grafted at the optimal age of 10 years in subjects with an unsuccessful bone graft (Bergland Index score of 2-4) was 9 per cent based on a ratio of three controls to two cases. The sample size in this study of 254 cases gives a precision of ±20 per cent with 95 per cent confidence to detect an odds ratio of 3.00.

Table 3 shows the crude and adjusted odds ratios for the associations between demographic and treatment risk factors and unsuccessful alveolar bone grafting in this sample. The number of bone grafts undertaken by each surgeon was skewed to the right. The statistical tests used assume normality, so log transformations were therefore used to improve the distribution of the number of bone grafts undertaken per surgeon for this part of the analysis. There was a strong association between age at operation and success of alveolar bone grafting. Non-Caucasian patients were also at increased risk of having an unsuccessful graft. Since outcomes were only collected for 11 non-Caucasians it is difficult to reach firm conclusions about the association between ethnicity and success of bone grafting. Children operated on by plastic surgeons were at increased risk of poor outcome. Surprisingly, trainee surgeons achieved better outcomes than consultants. No association was

Table 3 Crude and adjusted odds ratios for the association between demographic and treatment risk factors and unsuccessful secondary alveolar bone grafting in 12–14 year-old children born with UCLP in the UK.

Risk factor	12 year-olds		
	Crude odds ratio (95%CI)	Mantel– Haenszel test (P)	
Non-Caucasian	5.42		
versus	(1.11-26.41)	0.037	
Caucasian	n = 156		
Low socio-economic group	1.39		
(Carstairs 4 + 5)			
versus	(0.72-2.69)	0.323	
High socio-economic group	n = 147		
(Carstairs 1–3)			
High volume cleft team			
versus	1.00	1.000	
Low volume cleft team	(0.54-1.85)		
Plastic surgeon	1.97		
versus	(0.98-3.95)	0.055	
Maxillofacial surgeon	n = 132		
Consultant surgeon	2.36		
versus	(0.78-7.13)	0.128	
Trainee	n = 132		
Post-operative complications at graft site	2.78		
versus	(0.94-8.15)	0.063	
No complications	n = 105		
Teeth removed at operation	0.66		
versus	(0.31-1.40)	0.274	
No teeth removed	n = 112		
Per natural log increase in number	0.90		
of bone grafts for 12 year-olds	(0.72-1.14)	0.377	
undertaken by the surgeon	n = 153		
Per monthly increase in age at	1.04	0.007	
bone grafting	(1.01-1.07)		
	n = 123		
Per monthly increase in age at bone	1.03		
grafting adjusted for ethnic group,			
post-operative complications, speciality	(1.01-1.06)	0.036	
of surgeon, and grade of surgeon	n = 98		

found between the number of grafts undertaken by the surgeon and the success of grafting. There was a weak association between post-operative complications at the graft site and subsequent failure of the bone graft. Details of complications were only available for 170 (71%) of the subjects, which makes it difficult to reach firm conclusions on this association (Table 2).

Logistic regression model

An LRT was constructed to examine the association between age at bone graft adjusted for ethnic group, grade and speciality of the surgeon. Complete data were available for 98 subjects.

The model predicted the outcome for the seven non-Caucasians perfectly, and because of this the rest of the analysis was confined to Caucasians. After adjustment for the grade and speciality of the surgeon, there was a significant association between monthly increase in age at bone grafting and poor outcome in Caucasian patients (Table 3). The sequential removal of variables for post-operative complications at the graft site (P=0.527), grade of the surgeon (P=0.310), and speciality of the surgeon (P=0.340) made no significant difference to the model. Removal of age in months at first bone graft, however, significantly altered the model (P=0.027). This suggests that increased age at operation is an independent risk factor for unsuccessful bone grafting in this sample. No evidence of an interaction between age at grafting and ethnicity was found (P=0.500).

Discussion

The results of this study suggest that there is an inverse relationship between increasing age in months at bone grafting and the success of the procedure. This association appears to be independent of other treatment risk factors, although this sample size lacked the statistical power to confirm this. In addition, bone grafts were less successful in non-Caucasian patients. Closer examination of the data revealed that the ethnic minority children who had an unsuccessful graft were all operated on later than 10 years of age. However, whilst the sample is too small to reach definite conclusions on this aspect, it would appear that for some reason these children were not grafted at the optimal time. Alternatively there may be some genetic explanation as to why grafting failed in non-Caucasians.

It was also found that those from low socio-economic backgrounds tended to be less likely to have received a bone graft by the optimal age of 9-11 years than children from more privileged backgrounds. Again, the sample size was too small to confirm this, but the data suggest that, as for many other conditions (Whitehead, 1992), there may be inequalities in the provision of cleft care to different social groups. The families of children born with a cleft lip and palate need to attend hospital appointments for assessment and treatment on a regular basis over a long period. Some families find it impossible to maintain this degree of commitment (Glaun et al., 1998) and this could result in their child being lost to follow-up. Some parents may also be satisfied with the results of the primary repair and unaware that their child requires another operation for bone grafting. Cleft teams need to ensure that parents are informed about long-term care pathways and appreciate the importance of bone grafting to the overall result that can be achieved for their child.

The decision to graft is usually made by the orthodontist and surgeon together. After centralization, cleft care in England will be delivered on a 'hub and spoke' model (Health Service Circular, 1998). This model envisages that all the surgical treatment is

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undertaken at a regional centre ('hub'); however, longterm treatments such as orthodontics will be delivered locally at 'spoke' hospitals under the direction of the regional team. There is increased potential under these new arrangements for children requiring bone grafting to become lost to follow-up due to poor communication between the orthodontist at the local ('spoke') centre and the surgeon at the regional ('hub') cleft team base. Cleft team members will need to make great efforts to ensure that children from deprived backgrounds and ethnic minority groups in particular receive regular care and treatment such as bone grafting at the optimal time.

This study and others have shown that the age at which bone grafting is undertaken is probably the most important predictor of success (Enemark *et al.*, 1987; Lee *et al.*, 1995; Kalaaji *et al.*, 1996; CSAG, 1998). It is therefore not appropriate for children to be placed on a long waiting list for grafting. Adequate surgical staff and operating time need to be made available at the regional centre so that children who require bone grafts are not left on long waiting lists. Since most children with clefts involving the lip and alveolus will require grafting, it should be possible to predict the demand for grafting at least 10 years in the future.

The results of the present study support the findings of Lilja *et al.* (1987) of an association between post-operative complications at the graft site and poor outcome. The association was weak and not independent of other factors. Details of operative procedure were only available for 71 per cent of the subjects in the present study and this may explain why a stronger association was not shown. Moreover, the outcome measures were not directly comparable. Lilja *et al.* (1987) assessed the quantity of bone in the graft site, whereas this investigation assessed inter-proximal alveolar bone levels.

The findings of some studies (LaRossa et al., 1995) suggest that grafts taken from the iliac crest are more successful than those from other sites. It was not possible to examine the relationship between graft site and outcome in this study because the vast majority of cases (97%) had iliac crest grafts. Interestingly, none of the grafts taken from sites other than the hip in this study were successful. It has also been suggested that the initial tissue quality and periodontal health (McCanny and Roberts-Harry, 1998) of the graft site may affect the outcome of alveolar bone grafting. It was not possible to test these within a cross-sectional study design. A prospective study is required to examine how these factors may influence the success of bone grafting.

Some oral and maxillofacial surgeons argue that they are best trained to undertake primary and secondary cleft surgery because they are more experienced in handling alveolar tissues. In this study equivalent numbers of bone grafts were undertaken by plastic surgeons and maxillofacial surgeons. Maxillofacial surgeons achieved a slightly higher success rate (57%) than plastic

surgeons (43%), although this was not statistically significant. The outcome of bone grafting was generally poor and there is no convincing evidence that either surgical speciality produced good results in this sample (Brennan *et al.*, 2001).

It has also been suggested (Kalaaji et al., 1996) that the cumulative operating experience of the surgeon is an important determinant of outcome. As this investigation was cross-sectional, it was not possible to examine this, but the association between the number of grafts undertaken for children by individual surgeons and outcome was assessed. Since bone grafts were carried out over a number of years in this sample this could act as a proxy for cumulative surgical operating experience. In contrast to the outcome of primary repair in this sample (Williams et al., 1999), no association was found between the volume of bone grafts undertaken by individual surgeons and the results achieved. The majority of surgeons undertook three or less grafts. It is possible that there is a threshold for operating experience which has to be achieved to improve outcomes, and that none of the surgeons in this sample reached this. The results failed to demonstrate a relationship between the number of referrals received by the cleft team and the results achieved. All the cleft teams operating in the UK at the time of the CSAG (1998) study in 1996 were low volume operators. Again it is possible that a threshold for improving outcomes was not reached.

If cumulative operating experience were related to improved outcomes one might expect that consultant surgeons would achieve better results than trainees. In this study however there was a tendency for trainees to achieve better outcomes of grafting than consultant surgeons. This may be a reflection of difficulty of care mix; however, it is impossible to confirm this in a restrospective study such as this based on a small sample.

The outcome of alveolar bone grafting in the CSAG (1998) study was very poor, particularly when compared with the results achieved by cleft teams in Scandinavia (Bergland *et al.*, 1986). The results suggest that the crucial factor in determining outcome is ensuring that the graft is undertaken at the optimal time rather than the characteristics of the surgeon or the technique that is used at operation. Orthodontists at both the local and regional cleft centres should take responsibility for ensuring that cleft patients under their care are grafted at the optimal time. This will need good liaison between all members of the cleft teams.

Conclusions

Increasing age in months at grafting and non-Caucasian ethnicity group are predictors for unsuccessful secondary alveolar bone grafting in children born with UCLP in the UK.

Children from low social backgrounds appear to be at increased risk of not being grafted by the age of 12 years, although the present sample size was small. Other European countries may find these predictors of use in analysing outcomes of alveolar bone grafting.

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