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ORIGINAL RESEARCH ARTICLE

The Swedish National Cleft Registry as a tool for long-term outcome evaluation: secondary alveolar bone grafting as an example

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ABSTRACT

National quality registries provide valuable opportunities for prospective, standardised follow-up of clinical outcomes over long periods. In cleft care, such long-term data remain limited internationally, particularly beyond childhood. The Swedish National Cleft Lip and Palate (CL/P) Registry, established in 1999 with predefined variables and standardised follow-ups, enables longitudinal evaluation of treatment outcomes across centres.

The primary aim was to demonstrate the long-term usability of the Swedish National CL/P Registry for outcome assessment. As a clinical example, long-term outcomes after secondary alveolar bone grafting (SABG) from a single centre with complete historical registry coverage were analysed. National analyses of SABG outcomes are currently constrained as the first complete nationwide cohorts became available in 2025. To enable a longer observation period, data from a centre with consistent documentation since the registry's initiation were therefore examined.

Since April 2006, 167 patients had documented SABG outcomes at a standardised 16-year follow-up. Outcomes were assessed using a nationally agreed bone height scoring system based on two-dimensional dental radiographs, where a bone height of ≥ 3/4 of the root length was considered successful. Successful grafting was observed in 84% of unilateral and 71% of bilateral clefts. Higher age at first SABG and the need for complementary grafting were associated with poorer outcomes.

This study illustrates how a national quality registry with predefined variables and long-term follow-up can identify clinically relevant patterns and challenges. The presented SABG outcomes exemplify registry-based quality evaluation and provide a structured basis for continuous discussion, adjustment and improvement of cleft care.

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Introduction

National quality registries play an increasingly important role in modern healthcare by enabling systematic documentation, comparison and evaluation of clinical practice over time. In Sweden, more than 100 national quality registries collect prospective data on predefined variables with the primary aim of monitoring outcomes, improving quality of care and ensuring equity in treatment [1]. In addition to their role in quality assurance, such registries also offer valuable opportunities for clinical research, particularly when long-term follow-up is required.

The Swedish National Registry for Cleft Lip and Palate (CL/P) was established in 1999 as a collaboration between the six cleft centres in Sweden. The primary goal was a structured evaluation and comparison of treatment methods and outcomes over time, ensuring consistent and equal care as well as improving treatment for children with CL/P across all six centres. After its initiation, the registry was designed with predefined variables and standardised outcome assessments, determined through repeated national consensus meetings involving orthodontists and clinicians from all participating centres. The registry was formally recognised as a national quality registry in 2016 and achieved the highest certification level in 2023 [2]. All children born with CL/P in Sweden are offered inclusion in the registry. Background data such as cleft type, heredity, associated syndromes, and malformations are collected at birth. Treatment data such as surgical and orthodontic procedures are continuously recorded, whilst treatment outcomes are recorded at standardised follow-ups at five, 10, 16, and 19 years of age. The average coverage rate of the registry is 95.1% for children born from 2009 to 2018 with a reporting rate of 92.4% for cleft-related surgeries [3].

One of the most distinctive strengths of the Swedish CL/P Registry is the inclusion of outcome assessments at 16 years of age. Internationally, long-term follow-up of cleft treatment beyond early childhood remains uncommon. To date, only one national registry worldwide reports outcomes at this age, the Norwegian cleft registry, although data at 16 years have not yet been published. The large British cleft registry (CRANE) currently reports outcomes only up to 5 years of age [3, 4]. Consequently, standardised long-term outcome data during adolescence – a period when most orthodontic rehabilitation has been completed and surgical interventions such as secondary alveolar bone grafting (SABG) can be fully evaluated – are largely lacking.

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Although SABG has become standard for closing the alveolar cleft in most centres, uncertainties remain regarding the optimal timing of the procedure and other factors that may influence its outcome. Previous studies have suggested that an early SABG has a better chance for success than a late SABG while other potential influencing factors include sex, cleft laterality, cleft type, and the need for complementary surgery (Enemark et al. [5]; Fahradyan et al. [6]; Najar Chalien et al. [7]; Wiedel et al. [8] Padwa et al 2023 [9]). Many published studies are however retrospective, limited in size, or based on short follow-up periods, often evaluating outcomes within the first year after surgery [7–9]. However, as bone remodelling, tooth eruption and orthodontic treatment may influence the final outcome over several years, assessment at a later, standardised age may provide additional clinically relevant information.

The Swedish CL/P Registry was established in 1999, however the usage of the CL/P was not standardised between the six national CL/P centres until 2009 where all centres agreed to adhere to the registry. As a result, national analyses of outcomes at 16 years of age are currently limited, since the first complete nationwide cohorts for patients born 2009 onwards will have available 16-year follow-ups from 2025 onwards. This temporal limitation restricts the possibility of analysing long-term outcomes across all centres at present. However, individual centres that have consistently reported data since the initiation of the registry, such as Malmö Cleft centre offer an opportunity to explore the long-term usability of the registry and to examine outcome patterns over extended periods.

This study includes patients who underwent SABG at our cleft-centre in Malmö, where continuous data reporting in the CLP/P registry has been standard procedure since the registry's initiation in 1999. The primary aim was to illustrate the long-term usability of the Swedish National CL/P Registry for outcome assessment over time, using SABG as a clinical example. A secondary aim was to evaluate long-term outcomes of SABG at our centre, thus to determine the proportion of patients with healed bone grafts at 16 years determine the number of SABG surgeries performed per patient; examine the influence of factors such as age at first grafting, sex, cleft laterality and adoptive or foreign-born status. The intention was not to compare centres, but to demonstrate how registry-based data can be used to identify patterns, challenges and areas for continued discussion and quality improvement in cleft care.

At our cleft centre at Skåne University Hospital in Malmö, patients with complete CL/P follow a protocol established in the early 2000s: primary lip repair at 4 months, primary palatal repair at 12 months, and SABG in the mixed dentition, commonly at 7–10 years of age. Lip plasty techniques follow Cutting [10] and by Fisher [11] while palatal repair follow Langenbeck [12] with careful intravelar muscle repair as described by Sommerlad [13]. According to Åbyholm [14] SABG is performed using cancellous bone from the iliac crest and mucoperiosteal flaps. Bilateral alveolar clefts are treated in a one-step procedure, except in rare anatomically complex cases. The SABG protocol is initiated at 7 years of age with an orthodontic clinical evaluation and two-dimensional dental radiographs. Timing is determined by dental development and need for orthodontic measures. Any dental appliances are removed the day before surgery and repositioned at the end of the procedure. Patients are instructed to rinse with chlorhexidine daily for 2 weeks, consume only fluids for 3 days and soft foods for 4 weeks postoperatively. Penicillin is administered intravenously on the day of surgery and orally for 1 week after. A clinical follow-up is performed after 2 weeks and bone graft healing is evaluated after 6 months using two-dimensional dental radiographs, which is supplemented with cone beam computed tomography (CBCT) when needed.

Methods

Data from the CL/P Registry

All patients born with CL/P from 1999 to 2006 and registered by our centre were identified. All available variables and data points are pre-determined and fixed in the registry. In the registry cleft extension is documented by the involvement of the lip, hard and soft palate as well as the presence of an alveolar cleft. Of the 704 patients, 385 had alveolar clefts, corresponding to a prevalence of approximately 55%. From April 2006 to June 2024, 168 patients had a documented 16-year follow-up, although extensive missing data (>2 missing data points/variable entries) were encountered in one case. Consequently, 167 patients remained for analysis. A flowchart of the patient selection is shown in Figure 1. In cases of less than two missing data points, data were supplemented or adjusted based on their medical records by author M.B. If bone height assessments were missing, author A-P. W., who is one of the two orthodontists assessing bone grafts in the registry, used the two-dimensional dental radiographs from the 16-year follow-up to determine the bone height score. The CL/P Registry was corrected accordingly.

Cleft type was observed and categorised based on the registered primary International Classification of Diseases (ICD)-10 code: unilateral cleft lip/alveolus (Q36.9); bilateral cleft lip/alveolus (Q36.0); cleft soft palate with unilateral cleft lip/alveolus (Q37.3); bilateral cleft hard and soft palate with cleft lip/alveolus (Q37.4); and cleft hard and soft palate with unilateral cleft lip/alveolus (Q37.5). Adoption status, and born in Sweden or abroad, are simply 'yes' or 'no' questions in the registry, and foreign country of birth is not further specified. Surgery abroad is noted as 'none', 'partial', or 'complete'.

Age at the first SABG was observed, as well as the number of SABG procedures for each patient. Both unilateral and bilateral clefts were included. In bilateral cases, bone heights were recorded for each side separately.

In the CL/P registry, bone height assessment is documented by orthodontists at each individual centre. Two-dimensional dental radiographs taken at 16 years age of the grafted clefts are assessed according to a pre-determined bone height scoring system. The scoring system available in the registry is based on three-quartile assessments adhering to the Bergland index [15], based on measuring the height of the bone graft in relation to root length of the mesial tooth related to the cleft. However, in the CLP registry the scoring system is simplified by removing the intermediate category of a bone height between $>3/4$ and $<3/4$. This results in three scores: a bone height of $\geq 3/4$, a bone height of $<3/4$, and no bone bridge. A successful graft is defined as a bone height of $\geq 3/4$, and complete graft failure as no bone bridge. This yardstick was established nationally by orthodontists to facilitate straightforward comparisons by employing a limited number of scoring categories, with the goal simplifying data registration time efficiency. The mering of the two highest Bergland scores in the registry were motivated by that they clinically have the same implications and are often jointly considered as a successful outcome. At our centre, two orthodontists were responsible for the assessment of bone grafts, assessing these separately.

Calculations and statistics

The CL/P Registry data were processed in Microsoft Excel. Statistical analyses were conducted using International Business Machines (IBM) Statistical Package for the Social Sciences (SPSS) Statistics Version 28.0.2.0. Descriptive statistics included frequencies, medians, and percentages. Tables and graphs were generated in SPSS and adjusted in Microsoft Excel.

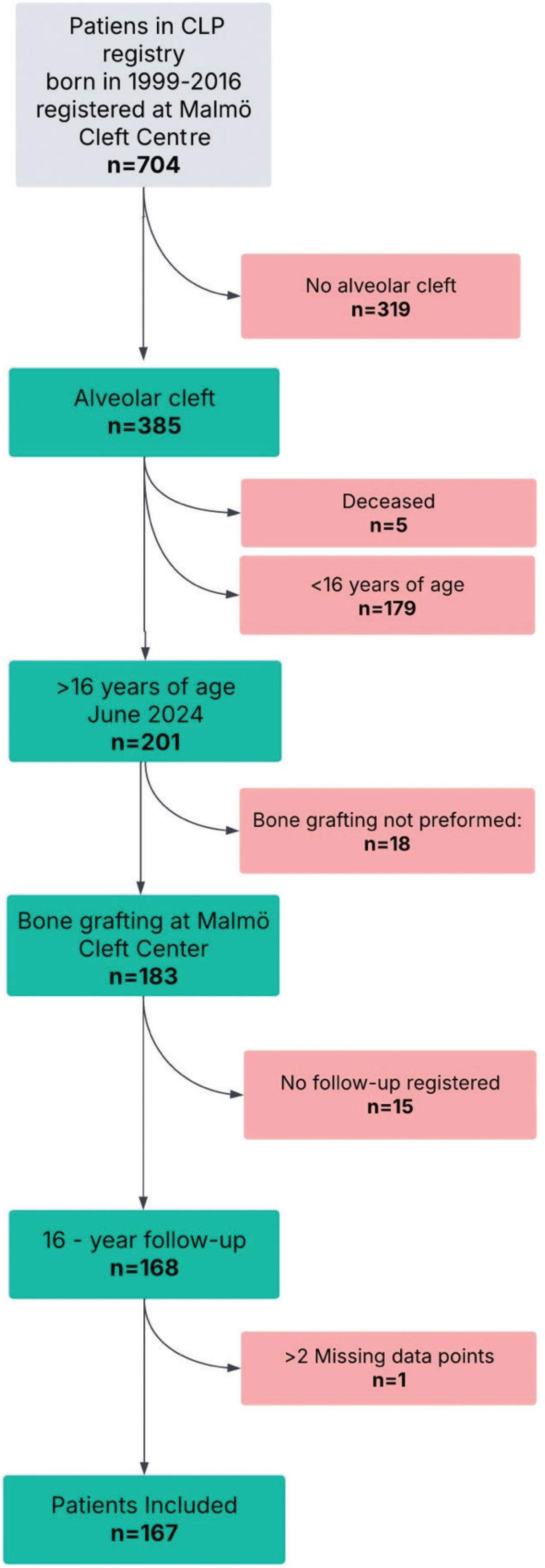

Figure 1. Flowchart of patient selection from the CL/P registry. Legend: Selected patients (*n*) in green (to the left) at each stage. Excluded patients in red with age < or >16 to the right. CL/P: Cleft Lip and/or Palate.

A multivariate analysis using binary logistic regression was attempted, but was found unstable due to few events in the group with bone height $<3/4$. Therefore, a separate univariate binary logistic regression for each variable was performed. The Mann–Whitney U-test was used to compare the number of SABG surgeries between unilateral and bilateral clefts. A *p*-value of <0.05 was considered to indicate a statistically significant difference.

Only four patients (2.4%), two with unilateral and two with bilateral clefts, had no bone bridging. They were therefore included in the bone height $<3/4$ group in the statistical analysis. Some bilateral clefts had different bone height scores on either side. A bone height of $<3/4$ on one or both sides was categorised as a bone height of $<3/4$.

Ethics

The study was approved by the Swedish Ethical Review Authority (diary number 2024-02114-01). Access to data from the CL/P Registry was approved by its steering committee.

Results

Data were easily extractible from the registry into an Excel file with all available data points and variables for each patient included. In 30 of the selected patients, a few data points with descriptive data were either missing or contradictory in the CL/P registry. Bone height assessments were missing in 12 of these patients (Table 1).

The characteristics of the 167 patients included in this study are shown in Table 2. All patients were operated on either by author M.B. or by author H.S, with a mean follow-up period of 7 years, ranging from 6 months to 10 years. Of these, 66% were male and 34% were female. Unilateral clefts were observed in 116 cases (69%), and bilateral clefts in 51 (31%). Among the unilateral clefts, 64% were left-sided and 36% were right-sided. Forty patients were born abroad, of whom 31 were adopted from foreign countries. Another two patients were adopted within Sweden. A slightly higher proportion of adopted patients (36%) had bilateral clefts compared with the overall study population. Notes on surgical procedures abroad were fragmentary in the CL/P Registry and thus not considered further.

Grafting with a final bone height $\geq 3/4$ was present in 98 of 116 unilateral clefts (84%), and in 36 of 51 (71%) of bilateral clefts (Table 3). As a result, 18 unilateral clefts and 15 bilateral clefts had a bone height $<3/4$. Four patients (2.4%) had no bone bridging. In patients with unilateral clefts, SABG was registered as a single operation in 105 (91%) of the cases, where 92 patients (79%) achieved a bone height of $\geq 3/4$. Nine patients underwent two bone grafting procedures, and two patients had a third. For the bilateral clefts, grafting was accomplished by a single operation in 32 (63%) of the cases, of which 26 (52%) achieved a bone height of $\geq 3/4$. Thirteen

Table 1. Missing data – the number of cases reviewed per data category.

Missing data – Reviewed cases	
Type of missing data	Cases reviewed (*N*)
Bone height	12
Date of first SABG surgery	9
Cleft laterality	5
Cleft side	4
Total	30
Percentage of cases	18%

The type and frequency of patients (*N*) with missing data in the CL/P registry reviewed against medical records. Percentage of cases with missing data relative to the total cohort (*N* = 167). CL/P: Cleft Lip and/or Palate; SABG: Secondary Alveolar Bone Grafting.

Table 2. Patients' characteristics of the cohort from the Cleft Lip and/or Palate (CL/P) registry.

Patient data		All clefts		Unilateral clefts		Bilateral clefts	
		N	%	*N*	%	*N*	%
Total number of patients		167	100	116	100	51	100
Patient sex	Male	111	66	76	66	35	69
	Female	56	34	40	34	16	31
Cleft laterality	Unilateral	116	69	-	-	-	-
	Bilateral	51	31	-	-	-	-
Cleft side	Left	74	44	74	64	-	-
	Right	42	25	42	36	-	-
	Bilateral	51	31	-	-	-	-
Cleft type	Unilateral cleft lip	27	16	27	23	-	-
	Unilateral cleft lip, soft and hard palate	82	49	82	71	-	-
	Unilateral soft palate	1	1	1	1	-	-
	Bilateral cleft lip	7	4	4	3	3	6
	Bilateral cleft lip, soft and hard palate	50	30	2	2	48	94
Adopted	Yes	33	20	21	18	12	24
	No	134	80	95	82	39	76
Born in Sweden	Yes	126	75	86	74	40	78
	No	40	24	30	26	10	20
	Unknown	1	1	-	-	1	2

Number (*N*) and percentage (%) are reported within the cleft category for each variable. Dotted lines indicate non-applicable or already presented values. CL/P: Cleft Lip and/or Palate.

patients had a second SABG surgery, three had a third, and another three had a fourth. The number of patients needing additional surgery was significantly higher ($p < 0.001$) in the bilateral cleft group. A bone height of < 3/4 was associated with more than one SABG. This finding was significant in the unilateral cleft group ($p = 0.016$) and close to significant in the bilateral cleft group ($p = 0.051$). Thirteen patients (11%) with unilateral clefts and six patients (12%) with bilateral clefts had only one surgery and a final bone height of < 3/4.

Figure 2 shows the age distribution regarding the first SABG. Most patients had their first SABG between 7.5 and 10.5 years of age, with a peak at 9 years. Figure 3 shows the success rate (bone height ≥ 3/4) related to the age at the first SABG. A higher age at the first SABG significantly decreased the likelihood of a bone height ≥ 3/4 in both unilateral and bilateral clefts ($p = 0.021$ and $p = 0.046$, respectively). On average, patients with a bone height of < 3/4 were 1 year older (9.96, 9.77) than those with a bone height of ≥ 3/4 (8.95, 8.80) in the case of both unilateral and bilateral clefts.

No significant differences in SABG outcomes were observed in relation to sex, cleft type, or cleft side. In bilateral clefts, the likelihood of a successful graft (bone height ≥ 3/4) was considerably lower in adopted (33%) and in foreign-born patients (40%) compared to non-adopted (82%) and patients born in Sweden (80%). These differences were statistically significant ($p = 0.004$ and $p = 0.025$, respectively), but the small sample sizes of the adopted and foreign-born groups limit estimation precision.

Discussion

The Swedish quality CL/P Registry collects data consecutively in real time. Its reporting rate exceeds 90% for cleft-related surgery [3], and the registry´s coverage rate is compatible with prospective cohort studies in which a dropout rate of approximately 10% can be expected [16], thus minimizing risk of selection bias. As mentioned, data from only one CL/P centre was used to allow for a longer observation period, since the first nationwide 16-year follow up cohorts became available in 2025. The Malmö cleft centre has in internal registry monitoring consistently shown high reporting completeness, comparable

Table 3. Patients' outcomes after Secondary Alveolar Bone Grafting (SABG).

SABG results		Unilateral clefts		Bilateral clefts	
		N	%	*N*	%
Number of surgeries	1	105	91	32	63
	2	9	8	13	25
	3	2	2	3	6
	4	0	0	3	6
Bone level: all sides	≥ 3/4*	98	84	36	71
	< 3/4 one side, ≥ 3/4 one side	-	-	7	14
	< 3/4*	16	14	6	12
	Bone missing	2	2	2	4
Bone level: left side	≥ 3/4	63	85	40	78
	< 3/4	11	15	9	18
	Bone missing	0	0	2	4
Bone level: right side	≥ 3/4	35	47	36	71
	< 3/4	5	7	13	25
	Bone missing	2	5	2	4
Bone level categorised	≥ 3/4	98	84	36	71
	< 3/4	18	16	15	29

Percentages are rounded to whole numbers. Totals may therefore not sum to 100%. The number of SABG surgeries and bone height results at the 16-year follow-up. Bone height categorised < 3/4 indicates < 3/4 on at least one side or no bone bridge. Unilateral ($N = 116$) and bilateral ($N = 51$) clefts presented separately, with counts (*N*) and percentages (%). SABG: Secondary Alveolar Bone Grafting. Bone height ≥ 3/4/< 3/4 = bone height of ≥ 3/4 or < 3/4 of the root length of the mesial tooth related to the cleft. *Score includes one side for unilateral and both sides for bilateral.

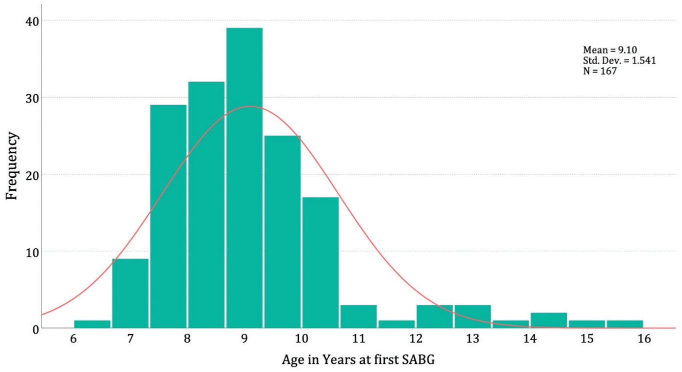

Figure 2. Age at first SABG. Histogram based on registered ages at first SABG with a normal distribution line. The mean, standard deviation, and total number of patients (*N*) included in the upper right corner. SABG: Secondary Alveolar Bone Grafting.

to national averages. However, formally published centre-specific coverage rates are currently not available.

Of the patients included, 18% had one missing data point. Corrections of these have its clear limitation with the risk for assessments deviating from the scores of non-corrected patients. Nonetheless, using the same assessor as well as the same radiographs reduces the risk for substantial deviations of bone height assessments in these patients. Missing data are often unavoidable in both clinical and registry-based research, but it is of importance to minimise it. Continued systematic validations, such as this study, are an important way forward. Since 2009, the stringency of data registrations in the national CL/P registry has improved greatly. At present, an obligatory annual registry intervention is conducted at each centre intended to reduce the risk of exclusion of patients and incomplete or missing data. These ongoing measures are expected to improve overall data completeness over time. Nevertheless, the extent to which this objective is achieved remains to be demonstrated by future studies.

The results of SABG are rather frequently reported in the scientific literature. However, studies are often retrospective, or the number of patients is limited. Many studies evaluate grafts at about 6 months postoperatively [7, 8, 17], although research indicates that bone resorption may proceed further [18–20]. Furthermore, eruption of cleft-adjacent teeth and orthodontic treatment of various durations may also increase the bone height over time. A study performed by Padwa et al. 2024 [9], evaluated a notable 722 patients, finding similar trends as our results with a higher age and previous failed bone graft as risk factors. However the median follow up period was 8 months. From this perspective, an advantage of this study, using the CL/P registry is the longer follow-up period, ranging from 6 months to 10 years, with a mean of 7 years.

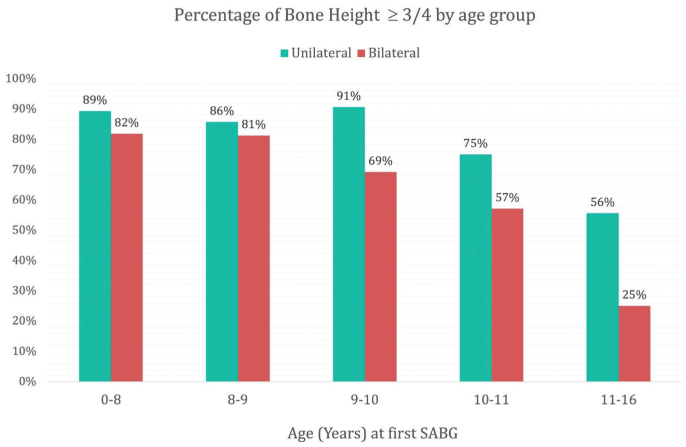

Figure 3. Bone height ≥ 3/4 by age at first SABG. The percentage of patients with a bone height ≥ 3/4 by age at first SABG divided into age intervals. Unilateral clefts (green) and bilateral clefts (red). SABG: Secondary Alveolar Bone Grafting. Bone height ≥ 3/4 = bone height of ≥ 3/4 of the root length of the mesial tooth related to the cleft.

Systematic reviews of the literature may provide greater estimates of SABG outcomes. Guo et al. [21] included prospective randomised clinical trials, which only generated two studies, both with a high risk of bias. A systematic review by Fahradyan et al. [6], mainly focusing on the timing of SABG, generated eight studies, four of which were retrospective. A more recent review of 15 studies was presented by Mundra et al. [22]. In summary, the concept of preoperative orthodontics for central incisor alignment and SABG in the early mixed dentition (6–8 years) appears to increase the likelihood of a favourable outcome. An early SABG was recommended, for instance, by Chalien et al. [7], who found that SABG failure was correlated with a higher age. Kimia et al. [17] reported an overall 86% success rate and advocated SABG before the age of 9 years. The results of this study support these findings, as a successful grafting with a bone height of ≥ 3/4 achieved in more than 80% of unilateral clefts and over 70% of bilateral clefts, although complementary grafting was necessary in quite a few cases, especially in bilateral clefts. Furthermore, our study shows a higher age to correlate with a lower success rate. Based on our results, our clinical recommendation aligns with previous studies, suggesting that SABG should ideally be performed before the age of 10, as that is associated with more favourable outcomes. Nonetheless, one should not blindly consider age as the sole biological determinant for SABG; a late operation may also indicate a later developed ability to carry out the various stages of the occlusion rehabilitation. Furthermore, tooth eruption should presumably continue to be the primary determinant factor for SABG timing, however this identified age-threshold could serve as an important practical checkpoint when planning treatment.

A study by Lundberg et al. [23] may stand out in this context. They found a success rate of over 90% in both unilateral and bilateral clefts, and this was independent of age. Tentative explanations for these divergences are the exclusion of syndromic patients, a dropout rate of 30%, and the inclusion of only nine patients with bilateral clefts. In addition, only 18% of the SABGs were performed to enable lateral incisor eruption. According to our experience from the perspective of occlusion rehabilitation, the lateral incisor, when present, should be taken care of whenever possible. Bone grafting is then advised when a thin shell of bone still covers the descending tooth [24]. In addition, in our study, seven patients with bilateral clefts had different outcome scores on either side. These patients were categorised in the < 3/4 outcome group despite having a bone height ≥ 3/4 on one side. This highlights the difficulties in comparing results from individual centres and speaks for the use of registries with well-defined inclusion criteria as well as clear outcome measures.

Sixteen patients with unilateral clefts (14%) and 13 with bilateral clefts (26%) had a bone height of < 3/4. Although a bone height of ≥ 3/4 is the main goal, a lower bone height can be considered satisfactory in some patients where the bone bridge can provide sufficient stability of the maxilla, even enabling possible orthodontic space closure. In other instances, a satisfactory prosthetic rehabilitation of the dental occlusion can be accomplished, in some cases with the use of dental implants. This reasoning is supported by the observation that 13 of our patients (11%) with unilateral clefts and six patients (12%) with bilateral clefts had no complementary bone graft despite a bone height < 3/4.

In a long-term perspective, only 2.4% of the patients had no bone bridging. Similar low failure rates are reported, for instance, by Chalien et al. [7]. Graft failure presents an additional challenge for achieving a satisfactory dental occlusion and poses a barrier for patients who would benefit from an orthognathic surgical correction of the upper jaw in the late teens. However, no clear outcome variables were identified in this group, and it was not evident that our four patients without a bone bridge underwent SABG later than the rest of the patients, as their ages were within the reported mean.

The first SABG is crucial for achieving a bone height ≥ 3/4, or slightly below, if an orthodontic occlusion rehabilitation is manageable. In unilateral clefts, a bone height of ≥ 3/4 after one surgery was achieved in 79% of cases, and in bilateral clefts in 52% of cases. In the long term, the need for complementary bone grafts was significantly associated with a bone height < 3/4 in unilateral cases ($p = 0.016$). In bilateral clefts, the interpretation of the registry data are more uncertain as we routinely perform SABG in one step at our centre, with few individual exceptions. In any case, the need for complementary bone grafts seems to predict a higher probability of achieving a lower bone level (< 3/4) in bilateral cases as well. What was not achieved by the first SABG seems to be even more difficult to achieve in a complementary SABG. Scarring and altered blood supply to the tissues may represent obstacles in such conditions.

Our results show that bilateral clefts pose a particular challenge when it comes to SABG. However, we found no statistically significant differences in results that could be attributed to gender, cleft type or to the left or right side in unilateral cases. All this is in line with previously reported results [9, 17, 23].

Regarding adoption, we found a slightly higher proportion of patients with bilateral clefts, most of whom were born abroad, compared to non-adopted patients. Furthermore, being adopted and foreign-born was associated with a reduced likelihood of a bone height ≥ 3/4. Previous research has recognised that internationally adopted children with CL/P present an additional challenge, which is further supported by our findings [25, 26]. An absence of, delayed or unsatisfactory repairs of the lip and palate in the countries of origin, particularly in complex clefts, may be one contributing factor to treatment challenges in this group and a lack or deficiency in terms of primary holistic care of a child with a cleft may be another. While it would be of interest to investigate this further, information in this area is often scarce. Adding reliable data to the register in this regard would therefore not be feasible.

As mentioned, this yardstick was established nationally with the purpose to facilitate time-efficient and straightforward comparisons. In studies using the Bergland index, a score of I (normal bone height) and II (≥ 3/4) is typically considered a successful graft, equivalent to the definition of a successful graft in our study (≥ 3/4), arguably enabling comparisons with these studies. Furthermore, a normal bone height and ≥ 3/4 have the same clinical implications and fewer scoring categories facilitates consistency and agreement between assessors. However, as with the Bergland index, the scoring system itself lacks a nuanced picture of bone graft healing due to it being based on 2D imaging, and does not consider functional outcomes which may not be fully represented by the bone graft height.

During the 16 year follow up, radiographs are preformed following a standardised protocol. Patients who have undergone SABG have either completed their occlusion rehabilitation or, in a few cases, are undergoing orthognathic surgical correction of their jaws. CBCT has shown to be useful, or even preferred, for evaluating the healing of the graft after SABG [9, 17, 27] due to more accurate results. For this purpose, a low-dose CBCT seems to be a promising option for evaluating SABG outcomes [28]. Nevertheless, radiation exposure should be limited whenever possible. So far, CBCT as a standard, has not been deemed necessary in a quality registry setting [29]. Since conventional two-dimensional dental radiographs are standard at the 16 year follow up in Sweden [30], an outcome variable not depending on regular CBCT usage may be preferred. Consensus on how to evaluate SABG outcomes such as the usage of imaging methods and outcome definitions and breakpoints is yet to be achieved. Taken together, out study underscore the need for a more refined and updated scoring system for evaluating SABGs in our registry as well as in the CLP research field.

A national quality registry serves primarily as a tool to monitor care and outcomes. In some research contexts, these data are also sufficient to answer questions from a scientific perspective. To date, the registry has formed the basis for 18 publications in international scientific journals and has supported four PhD theses, two of which have been completed, while two are currently in progress. However, registry data must be interpreted and handled with caution. For example, this study required supplementation of registry data with medical records in 18% of the included patients.

Using registry-based data presents further challenges that need to be considered when conducting research based on these types of data sets. The way the CL/P registry is structured, all data registered are assessed only once by one person, meaning that intra- or inter-rater reliability cannot be evaluated. A second assessor control would significantly improve the reliability of our bone height assessments. However, it is important to address that this may not be realistically feasible for a registry setting, adding to the constant trade-off in registry-based studies. In addition, data are usually recoded by the centres own medical personnel, where a directional overestimation bias cannot be excluded, which in turn limits external comparison with previous studies. However, the overall trends and observed risk factors may still maintain valuable insights, being less affected by an overall directional bias.

Compliance with a registry is thus a key issue. Although the reporting rate of the CL/P Registry is over 90%, there is room for improvement. For instance, the addition of variables such as adoption conditions and surgical procedures performed abroad would be of great interest. However, this must be weighed against the extra work required and consequently, the potential impact on the registry's reporting rates. Regarding our secondary aim, we found the CL/P Registry in its current form to be helpful and feasible for evaluating our long-term SABG results but should be viewed as complementary to, rather than superior to, other study designs. The next step, involving the compilation of SABG results from all units participating in the registry, is currently ongoing.

Conclusions

This study demonstrates how a national quality registry with predefined variables and long-term follow-up can be used to identify clinically relevant patterns and challenges over time. Using the registry, a higher age, the need for additional surgery and in bilateral clefts, adoptive and foreign-born status were identified as risk factors for poorer SABG results. The presented SABG outcomes serve as an example of registry-based quality evaluation rather than centre-to-centre comparison, and provide a structured basis for continuous discussion, adjustment and improvement of cleft care.

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Data availability statement

The datasets generated and/or analyzed during the current study are not publicly available due to ethical restrictions. However, they are available from the corresponding author upon reasonable request

Declaration of interest statement

The authors have no conflicts of interest to declare.

Declaration of contribution

- **Magnus Becker**: Principal investigator; responsible for study conception, ethical approval, study design, local patient responsibility, extensive data registration, registry development and stewardship, and manuscript revision.
- **Sofia Larsson**: Conducted the study analyses and prepared the initial manuscript draft.
- **Henry Svensson**: Former clinical lead for the patient group; contributed to data interpretation and manuscript revision.
- **Anna-Paulina Wiedel**: Orthodontist; performed several outcome assessments, reviewed cases with missing data and evaluated unassessed radiographs.
- **Mia Stiernman**: Contributed to data analysis and manuscript preparation.

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