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Review

Current methods for secondary alveolar bone grafting assessment in cleft lip and palate patients — A systematic review[☆]Marcin Stasiak^{*}, Anna Wojtaszek-Słomińska, Bogna Racka-Pilszak

Department of Orthodontics, Faculty of Medicine, Medical University of Gdańsk, Al. Zwycięstwa 42c, 80-210, Gdańsk, Poland

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ABSTRACT

Introduction: The development of 3D X-ray diagnostics has led to new methods for secondary alveolar bone grafting (SABG) assessment. The aim of this study was to collect and present literature from the years 2007–2018, and review on the current treatment outcome assessment methods for SABG.

Materials and methods: A systematic review of literature from 2007 to 2018 was carried out, following PRISMA guidelines. 426 records were identified after duplicate references had been removed. 25 articles were included in the review. The Cochrane Collaboration tool or the methodological index for non-randomized studies was used for quality evaluation.

Results: Computed tomography and cone beam computed tomography were preferentially used for SABG treatment outcome verification. There were different assessment protocols. Due to the ways in which results were presented, methods were divided into five groups: linear measurements, volumetric measurements, density measurements, percentage ratios, and scales. There was only one randomized, controlled trial with high methodological quality.

Conclusions: 1. Currently, 3D X-ray imaging is a standard treatment outcome verification method for SABG. 2. It is necessary to establish the required postoperative follow-up time for best SABG treatment outcome assessment. More prospective studies to assess bone graft outcomes after 6 months and 1 year are required.

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1. Introduction

Cleft lips and palates (CLP) are the most common congenital conditions in the facial part of the cranium. A characteristic feature of clefts includes partial or complete lack of anatomical tissue continuity and tissue hypoplasia in the area of the disorder. Cleft is a developmental malformation, resulting from genetic and environmental factors (Ziemia and Karłowska, 2016). Treatment of patients with clefts is a complex process, which takes many years. The surgical treatment protocol for CLP includes autogenous alveolar bone grafting (Penkala, 2007).

Secondary alveolar bone grafts (SABG) are performed when the patient has mixed dentition. This method was first described by

Boyne and Sands in 1972 (Boyne and Sands, 1972). Depending on the timing of the procedure, there is early secondary grafting (performed before the eruption of the permanent lateral incisors) and late secondary grafting (when the roots of the canines have grown to the $\frac{1}{2}$ – $\frac{1}{3}$ of their length) (King et al., 2013). The most promising outcomes of SABG are achieved when the lateral incisors or canines have erupted through the transplant, and the bone has been functionally loaded (Dempf et al., 2002; Feichtinger et al., 2007; Tai et al., 2000).

The aim of autogenous bone grafting is to close the oronasal fistula and obtain anatomical tissue continuity in the alveolar process of the maxilla, which allows the dental arch to be stabilised (especially in bilateral clefts). Simultaneously, the transplanted bone provides bony support to the nasal alae, thus improving the symmetry of the nose (Abyholm et al., 1981).

In order to continue orthodontic treatment following alveolar grafting, bone transplant outcomes have to be known. SABG treatment outcomes affect proper tooth location in the cleft area; when a tooth is missing, they help specialists decide whether the

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^{*} Corresponding author.

E-mail addresses: marcinstasiak@gumed.edu.pl (M. Stasiak), aslom@gumed.edu.pl (A. Wojtaszek-Słomińska), bogna.racka-pilszak@gumed.edu.pl (B. Racka-Pilszak).

tooth should be restored, or the space closed. The treatment outcomes are assessed using X-ray images. In the past, two-dimensional images were used. The first scale for assessing SABG treatment outcomes was developed by [Abyholm et al. \(1981\)](#), and formed the basis of all subsequent methods using 2D images. These methods differ only in terms of degree of complexity and presentation of results ([Aurouze et al., 2000](#); [Enemark et al., 1987](#); [Hynes and Earley, 2003](#); [Kindelan et al., 1997](#); [Long et al., 1995](#); [Toscano et al., 2012](#); [Witherow et al., 2002](#)). Earlier methods used projections from one plane ([Abyholm et al., 1981](#); [Aurouze et al., 2000](#); [Bergland et al., 1986](#); [Enemark et al., 1987](#); [Hynes and Earley, 2003](#); [Kindelan et al., 1997](#); [Lilja et al., 2000](#); [Schultze-Mosgau et al., 2003](#); [Tan et al., 1996](#); [Trindade et al., 2005](#); [Witherow et al., 2002](#)), whereas the more recent ones used X-ray images from two or three planes ([Bayerlein et al., 2006](#); [Felstead et al., 2010](#); [Khalil et al., 2014](#); [Long et al., 1995](#); [Opitz et al., 1999](#); [Toscano et al., 2012](#)).

Development of 3D X-ray diagnostics has led to new methods for qualitative and quantitative assessment of bone grafting. With no studies comprehensively presenting current treatment outcome assessment methods for SABG, it was decided to use a retrospective review of the literature for this study.

The aim of this study was to collect and present literature published between 2007 and 2018, in order to review the current treatment outcome assessment methods for SABG in CLP patients. The research question chosen was: Which methods for SABG treatment outcome assessment are currently used?

2. Materials and methods

Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines were used in this study ([Liberati et al., 2009](#)).

Study characteristics

- P. At least 10 CLP patients after SABG.
- I. 3D radiological examination.
- C. Not required.
- O. Assessment method.

Inclusion criteria for papers were as follows: SABG treatment outcome assessment on the basis of 3D X-ray diagnostics; at least 10 CLP patients (required adopted study group). Publications that used only 2D postoperative images, assessed primary or tertiary bone grafting, or with a study group of fewer than 10 patients were excluded. Assessments using only the aforementioned 2D scales in 3D X-ray examinations were also excluded (the aim of the study was to present new methods). Only those papers written in English were enrolled for reviewing.

A retrospective analysis of papers published in the years 2007–2018 (last update in August) on the methods of treatment outcome assessment for SABG in CLP patients was performed. The PubMed database was searched using the following search terms: *cleft[All Fields] AND ("transplants"[MeSH Terms] OR "transplants"[All Fields] OR "graft"[All Fields]) AND (("2007/01/01"[PDAT]: "3000/12/31"[PDAT]) AND "humans"[MeSH Terms])*.

References were imported into Mendeley manager. Publications were screened on the basis of titles and abstracts. Subsequently, full-text articles were assessed for eligibility. Next, data were extracted from those records retrieved for detailed text evaluation. These procedures were conducted by the first and second authors. The third author participated in cases of disagreement. The following information was collected: study type, number and age of patients, cleft types, graft types, timing and type of pre- and postoperative X-ray tests, assessment methods.

A qualitative assessment of the studies was carried out by the first and second authors. In cases of doubt, the third author was consulted. The Cochrane Collaboration tool for assessing risk of bias was used for randomized controlled trials ([Higgins et al., 2011](#)). For non-randomized studies, the methodological index for non-randomized studies (MINORS) was used ([Slim et al., 2003](#)).

Initially, the treatment outcome assessment methods for SABG in CLP patients on the basis of 3D X-ray images were analysed. The second phase of the study involved an analysis of the methodological quality of the literature. The results of both analyses were collected in tables.

3. Results

In the first stage of selection 426 records were identified after duplicated references had been removed (some studies were repeated in the PubMed database). 42 papers were retrieved for full-text detailed evaluation. Finally, 25 articles were included in the review ([Fig. 1](#)).

[Table 1](#) presents the studies included in the qualitative analysis, and extracted data.

Most of the papers presented observational studies ($n = 20$). There were five randomized controlled trials. 56% of the studies were prospective ($n=14$) and 44% retrospective ($n = 11$). Studies were mostly cohort-based (88%, $n = 22$), rarely cross-sectional ($n = 3$).

The biggest study group consisted of 82 patients. The majority of studies evaluated SABG treatment outcomes solely in UCLP patients ($n = 18$). Papers that assessed surgical outcomes in both UCLP and BCLP patients always involved more of the former group. One of the papers assessed results by means of 2D and 3D radiographs, but did not specify the number of UCLP and BCLP patients in the 3D X-ray group ([Morselli et al., 2009](#)).

Different graft material types were used for SABG. The most popular was autogenous cancellous bone harvested from the iliac crest, and its modifications ($n = 20$). One of the studies did not specify the donor site ([Wangsrimgkol et al., 2013](#)).

According to the references, the 3D X-ray evaluation of the SABG treatment outcomes was based on images from computed tomography (56%, $n = 14$) and cone beam computed tomography (44%, $n = 11$).

There was a range of different SABG treatment outcome assessment protocols. Preoperative 3D X-ray examination was performed in 64% of the studies ($n = 16$). Single postoperative 3D radiographs were used in 56% of the studies ($n = 14$). Two postoperative X-rays were carried out in seven studies and three in four studies. The most frequent follow-up periods were 6 months ($n = 9$) and 1 year ($n = 11$). The longest prospective observation time among all cohort publications that described 3D X-ray diagnostics for assessing SABG treatment outcomes was 3 years ([Feichtinger et al., 2007](#)).

Due to the range in methods of result presentation, the 3D X-ray assessments were divided into five groups: linear ($n = 7$), volumetric ($n = 18$), and density measurements ($n = 5$); percentage ratios ($n = 18$) and scales ($n = 7$).

Volumetric measurements and percentage ratios were the most frequent SABG treatment outcome assessment methods. Linear measurements involved height, thickness, length, nasal floor height, and, in comparative analysis cases, analogous cleft defect or noncleft side parameters. Within preoperative cleft volumetric measurements, defect volume and ideal cleft volume were distinguished. The latter used the difference obtained from a superimposition of the preoperative maxilla image and an image of the maxilla after mirroring. After SABG, bone volume or resorption amount could be evaluated.

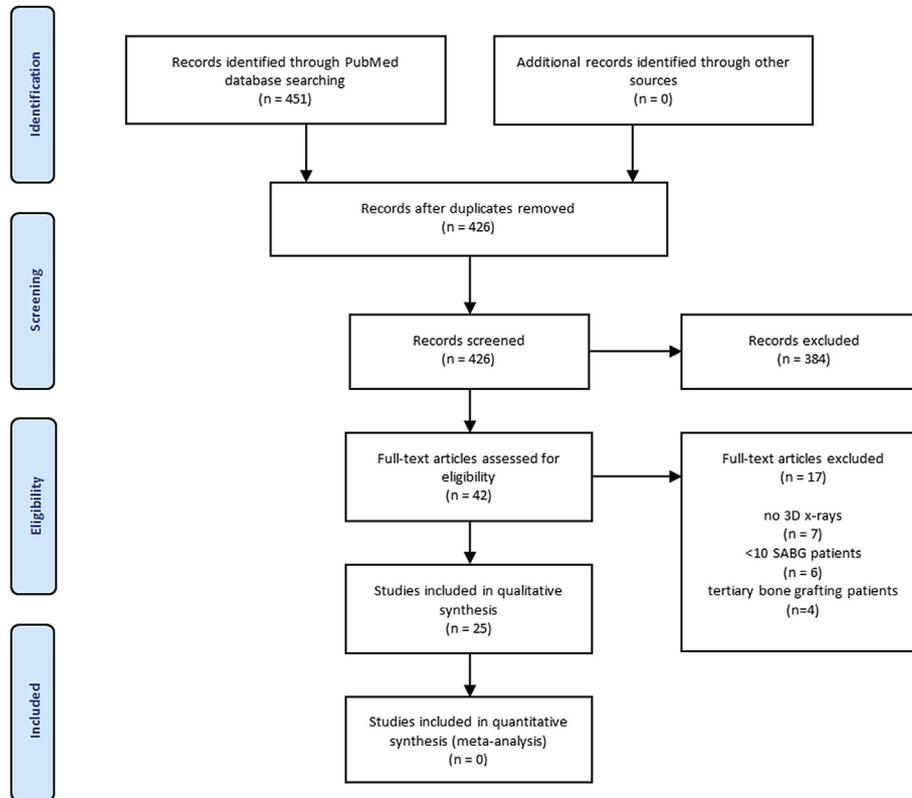


Fig. 1. PRISMA flow diagram of study selection.

Percentage ratios were divided into three groups: linear ratios (height, thickness, length, cleft/noncleft height ratio), volumetric ratios (augmentation, bone reconstruction, residual bone, resorption, graft ratio), and density ratio. The difference between augmentation and bone reconstruction ratios was that the former was assessed relative to the defect volume and the latter to the ideal cleft volume. Pre- and postoperative 3D X-rays were necessary to evaluate augmentation, bone reconstruction, and graft ratios. One of the papers was an exception to this rule, and evaluated the augmentation ratio without preoperative X-rays. The authors defined the cleft space boundaries as the continuation of the buccal and palatal bone from the cemento-enamel junction to level with the teeth apices (Liang et al., 2017). In order to assess the resorption or residual bone ratio, early postoperative and later follow-up radiographs were essential. Instead of early postoperative bone X-ray assessment, one study used the placed bone volume, measured using a syringe before defect augmentation (Oh et al., 2016). Among percentage ratios, augmentation ratio was the most popular method of evaluation (n=10).

There were four new scales for SABG outcome assessment, and two new modifications of the 2D scale, which added horizontal analyses to the vertical grading system. These measurements could be divided into three evaluation groups: vertical, horizontal, and relative to the nasal floor. Two papers used both height and thickness grading systems. Another two assessed results by means of height, thickness, and nasal floor height scores. The scale used by Oh et al. met the exclusion criteria (Oh et al., 2016).

Han et al. used Enemark grading system to categorize results obtained for cleft/noncleft height and thickness ratios (Han et al., 2017). The vertical classifications used by Morselli et al. (2009), Suomalainen et al. (2014), and Wangsrimongkol et al. (2013) were similar to those based on the 2D images. Evaluations of

grafting outcomes using the base of the nose were also 2D, and assessed the differences in nasal floor height between the cleft and noncleft sides. They differed in terms of degree of complexity and method of results presentation (Alonso et al., 2010; Morselli et al., 2009; Suomalainen et al., 2014). The thickness scale used by Morselli et al. evaluated the results at one level, using linear measurement (Morselli et al., 2009).

Although the 3D horizontal analyses presented by Wangsrimongkol et al. (2013), Suomalainen et al. (2014), and Garib et al. (2017) were similar to one another, they differed in established measurement levels and degree of complexity. The first study qualitatively evaluated bone bridge width at four different vertical levels; the other two used three levels. Garib et al. differentiated five grades, Wangsrimongkol et al. four, and Suomalainen et al. three. The first of these is the most elaborate and, like SWAG (Russell et al., 2016), takes into account the possibility of bone root coverage if a lack of bone bridge in the cleft area occurs. The grades presented by Suomalainen et al. and Garib et al. were evaluated in relation to the width of tooth roots. The method described by Wangsrimongkol et al. used the bone graft site width as the reference point.

Quality evaluation revealed that there were eight comparative and 12 non-comparative, non-randomized studies. MINORS for comparative studies obtained results from 16 to 19 (Table 2A), while those for non-comparative studies were from 7 to 12 (Table 2B). The quality of these studies was low to medium. None of the papers calculated the study size prospectively or reported adequate, unbiased assessment of the study endpoint (in three studies only 2D radiographs were blindly evaluated and no blind evaluations of 3D X-rays were performed). Only one of the randomized, controlled trials had a low risk of bias. Two presented an unclear risk of bias and two showed a high risk. A high risk of bias

Table 1
Included studies assessing the outcomes of SABG using 3D X-ray images, and extracted data.

| Study | Study type | Patient characteristics | | | | 3D radiographical examination | | | Assessment method | | | | |
|--------------------------------|------------|-------------------------|-----------|-----------------------------|------------------------------------|-------------------------------|--------------|--|-------------------|------------|-------------------|----------------|---|
| | | No. | UCLP/BCLP | Age | Graft material | Type | Preoperative | Follow-up | L | V | D | %R | S |
| Feichtinger et al. (2007) | O P C | 24 | 24/0 | 10y7m (8y2m–15y10m) | IC | CT | ib | y, 2y, 3y | | DV, BV | | AR | |
| Ozawa et al. (2007) | O P C | 25 | 15/10 | 6y10m (5–10y) | IC | CT | | ia, 6m | | BV | | RR | |
| Kim et al. (2008) | O P C | 15 | 15/0 | 10y | IC | CT | m | 3m, y | H, T | DV, BV, RA | | RR | |
| Morselli et al. (2009) | O R C | 82* | +/+ | 7–11y | Cr, IC, MS | CT | | 3m, 6m, y | H, T, NFH, HNC | | | | Own — H, T, NFH |
| Mikoya et al. (2010) | O P C | 42 | 36/6 | 6y11m (5y1m–10y1m) | MS, MB | CT | + | 6m | T | | | | |
| Alonso et al. (2010) | RCT | 16 | 16/0 | 9y6m (8y5m–11y6m) | CM + rhBMP-2, IC | CT | + | 6m, y | H | DV, BV | | HR, AR | Own — NFH |
| Canan et al. (2012) | RCT | 18 | 18/0 | 8–15y | IC, RCS + rhBMP-2, periosteoplasty | CT | + | 3m, 6m, y | H | DV, BV | HU | HR, AR | |
| Rychlik and Wójcicki (2012) | O R C | 62 | 62/0 | 11y (8–14y) | IC + PRP | CT | | 2–3d, 6m | | BV | HU | RBR, DR | |
| Benlidayi et al. (2012) | O R CS | 23 | 23/0 | 13 ± 3y9m, 10y10m ± 2y7m | IC, B-DH | CBCT | | 3.94 ± 1.15y, 5.65 ± 0.86y; at least 1.92y | | | HU | | |
| Wangrimongkol et al. (2013) | O P CS | 20 | 14/6 | 11y6m (9–17y) | | CBCT | | 3–6m | | | | | Enemark, modified Enemark — H, modified Enemark — T |
| Yoshida et al. (2013) | O R C | 12 | 12/0 | 9y10m (8y–12y6m) | IC | CT | + | 6m | | ICV, BV | | BRR | |
| Suomalainen et al. (2014) | O R C | 35 | 35/0 | 9y11m ± 1y1m | IC | CBCT | | 6m | | | | | Own — H, T, NFH |
| Nagashima et al. (2014) | O P C | 29 | 29/0 | 8–14y | IC | CT | ib | m, 6m | | ICV, BV | | RR, GR | |
| Linderup et al. (2015) | O R C | 10 | 10/0 | 9y8m (8y6m–11y2m) | MS | CBCT | m | y | | DV, BV | | AR | |
| Linderup et al. (2016) | O R C | 32 | 32/0 | 9y6m (8y1m–11y11m) | MS | CBCT | m | y | | DV, BV | | AR | |
| Shawky and Seifeldin (2016) | RCT | 24 | 24/0 | 9–14y | IC + PRF, IC | CT | + | 6m | | DV, BV | HU | AR | |
| Dissaux et al. (2016) | O R C | 28 | 23/5 | 5y2m (4–7y), 10y (8y6m–13y) | IC | CBCT | d | 6m | H, T, L | DV, BV | | HR, TR, LR, AR | |
| Takemaru et al. (2016) | RCT | 15 | 15/0 | 8y5m ± 1y, 8y8m ± 1y3m | IC, BD-HA + CC + IC | CT | ib | m, 6m, y | | ICV, BV | | | |
| Oh et al. (2016) | O R C | 40 | 40/0 | 9y2m (6y8m–12y2m) | IC | CBCT | + | y | | DV, BV | | RBR | Abyholm |
| Han et al. (2017) | O R CS | 27 | 22/5 | 9y (6–12y) | Cr | CT | | av. 6.51y (2–14.83y) | H, T, HNC, TNC | | | CNCHR, CNCTR | Enemark, modified Enemark — T |
| Sakio et al. (2017) | O P C | 29 | 29/0 | 7–9y | IC + PRP, IC | CT | + | m, y | | BV | | RR | |
| Movahedian Attar et al. (2017) | RCT | 20 | 20/0 | 9y6m (8–13y), 9y11m (8–14y) | MS + ABM + L-PRF, IC | CBCT | + | y | | DV, BV | | AR | |
| Garib et al. (2017) | O R C | 30 | 30/0 | | IC | CBCT | | 6m acot | | | | | Own — T |
| Feng et al. (2017) | O P C | 18 | 18/0 | 10y2m (8y4m–12y8m) | IC | CBCT | 1–2w | 7–10d, y | | DV, BV | | GR, AR, RR | |
| Liang et al. (2017) | O P C | 31 | 27/4 | | rhBMP-2/DBMS, IC | CBCT | | 6–9m | | DV, BV | g/cm ³ | AR | |

UCLP — unilateral cleft lip and palate, BCLP — bilateral cleft lip and palate, L — linear measurements, V — volumetric measurements, D — density measurements, %R — percentage ratios, S — scales, RCT — randomized controlled trial, O — observational study, P — prospective, R — retrospective, C — cohort, CS — cross-sectional, IC — iliac crest, Cr — cranium, MS — mandibular symphysis, MB — mandibular body, RCS — resorbable collagen sponge, rhBMP-2 — recombinant human bone morphogenetic protein-2, PRP — platelet-rich plasma, B-DH — bovine derived hydroxyapatite, PRF — platelet-rich fibrin, L-PRF — leukocyte platelet-rich fibrin, CC — collagen composite, ABM — allogenic bone material, DBM — demineralized bone matrix, CT — computed tomography, CBCT — cone beam computed tomography, d — day, m — month, y — year, acot — after comprehensive orthodontic treatment, ia — immediately after, ib ± immediately before, H — height, T — thickness, NFH — nasal floor height, L — length, HNC — noncleft height, TNC — noncleft thickness, DV — defect volume, ICV — ideal cleft volume, RA — resorption amount, BV — bone volume, HU — Hounsfield unit scale, g/cm³ — gram per cubic centimetre, HR — height ratio, CNCHR — cleft-noncleft height ratio, CNCTR — cleft-noncleft thickness ratio, AR — augmentation ratio, RR — resorption ratio, BRR — bone reconstruction ratio, RBR — residual bone ratio, GR — graft ratio, DR — density ratio, + — present but not specified, * — patients with 3D X-ray diagnostics.

after the surgery, with the volume of the graft remaining almost constant over the two subsequent years of observation. This study included the longest prospective observation time among all those included that described 3D X-ray diagnostics for assessing SABG treatment outcomes, and demonstrates that such an evaluation of treatment outcome should be performed 1 year after the operation. However, the authors noticed that the bone volume could increase after a year as a result of lateral incisor or canine eruption (Feichtinger et al., 2007). Shawky and Seifeldin found that after 6 months clinicians were able to differentiate between the newly formed bone and the native bone on the cleft side (Shawky and Seifeldin, 2016).

There were three prospective studies assessing SABG treatment outcomes after 6 months and a year (Alonso et al., 2010; Canan et al., 2012; Takemaru et al., 2016). According to Alonso et al., cancellous bone undergoes fast incorporation and vascularization and cannot be distinguished at the 6 months postoperative CT examination. In studies using rhBMP-2, similar bone integration was found to occur after 12 months (Alonso et al., 2010). Takemaru et al. found significant differences between 6- and 12-month volumes. The 12-month volume was lower than after 6 months in the iliac crest bone graft group. Reverse results were obtained for the hydroxyapatite + collagen sponge + iliac crest bone graft group (Takemaru et al., 2016). According to Canan et al., grafted bone undergoes intense resorption, presenting density loss in the first 6 months after SABG. Moreover, there seems to be a tendency to lose bone graft volume from the sixth month until the canine erupts. Autogenous grafted bone showed some stabilization after a year. However, in the group of patients treated with rhBMP-2, a significant increase in bone density occurred after the third month, and bone induction ability decreased after 6 months (Canan et al., 2012).

With regard to these findings and disagreements, it is not clear whether the follow-up period of 6 months accepted for many studies ($n = 10$) is enough. Moreover, it seems that the required follow-up period should be dependent on the graft type. There is a risk that autogenous grafted bone will not be fully integrated and matured after 6 months. It seems also that reliable assessment of SABG in cases of autogenous bone use should be performed after permanent canine eruption.

Evaluation of the effectiveness of the procedure on the basis of percentage value of the augmented or reconstructed bone defect, supported by 3D images, appears to be the best method for comparison of therapeutic effects, not least because it is one of the simplest ways of quantifying the factors involved and presenting comparative ratios. The horizontal methods suggested by Wangsrimgkol et al. (2013), Suomalainen et al. (2014), and Garib et al. (2017) seem to be suitable for spatial assessment of the graft site and the areas of the greatest bone deficit. They may be also implemented when treatment modification is evaluated.

Mesial movement of the posterior teeth after SABG to replace the missing tooth necessitates adequate bone bridge position and volume to support orthodontically guided, cleft-adjacent teeth (Lee et al., 1995). Two-dimensional vertical analysis or the assessment of the alveolar process position with respect to the base of the nasal cavity are too simple as verification criteria for treatment outcome effectiveness, and are thus inappropriate for scheduling further orthodontic and prosthetic treatment. Verification of the grafting outcomes using the base of the nose is, however, vital with respect to the symmetry of facial features, in particular the nasal alae.

In Yoshida et al. studies evaluating the bone volume on the basis of CT sections and two superimposed 3D images, higher values were obtained by means of the latter method. The authors suggest that the former method could underestimate the results (Yoshida et al., 2013).

Density is a parameter of bone quality. This measurement is a useful tool for comparing remodelling and maturation processes in different bone grafting materials (Benlidayi et al., 2012; Canan et al., 2012; Liang et al., 2017; Shawky and Seifeldin, 2016).

The study by Garib et al. was carried out solely on patients treated by mesialization of the canine to the cleft area, resulting in contact between the canine and central incisor (Garib et al., 2017). However, this procedure is not feasible in the absence of the bone bridge, with considerably disrupted cleft fragments, or when the bone bridge is of general poor quality. The results presented therefore refer to a particular group of patients, and for this reason cannot be used as a general assessment of the surgery.

Suomalainen et al. underline the fact that standardized evaluation criteria of treatment outcomes for SABG on the grounds of CBCT should be established (Suomalainen et al., 2014).

A limitation of this study is the use of just one database. For this reason, there is a risk that some eligible studies were not included in the review.

5. Conclusion

Three-dimensional X-ray diagnostics is an appropriate tool for the assessment of alveolar bone grafting outcome in patients with CLP.

The postoperative period for the assessment of SABG treatment outcome needs to be established. More prospective studies are necessary to assess the efficiency of bone grafting after 6 months and 1 year.

Declaration of interest

None.

Authors' contributions

1. Marcin Stasiak: (1) conception and design of the study, acquisition of data, analysis and interpretation of data; (2) drafting the article and revising it critically for important intellectual content; (3) final approval of the version to be submitted.
2. Anna Wojtaszek-Słomińska: (1) conception and design of the study, acquisition of data, analysis and interpretation of data, (2) drafting the article and revising it critically for important intellectual content, (3) final approval of the version to be submitted.
3. Bogna Racka-Pilszak: (1) analysis and interpretation of data, (2) drafting the article and revising it critically for important intellectual content, (3) final approval of the version to be submitted.

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