Review Article

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Dentistry Section

Assessing Time Gap between Alveolar Cleft Repair and Dental Implant Placement: A Systematic Review

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ABSTRACT

Introduction: Orthodontic treatment is commonly undertaken in cleft patients for space closure in cleft region. However, it is only able to achieve 50-75% closure, resorting to use of dental prosthesis in form of removable or fixed partial dentures. Dental implant-based rehabilitation provides a suitable solution however, their success depends on the quality and quantity of the residual bone. Resorption of bone graft is a known scientific fact and thus, it is important to know the minimum time after which the implant can be placed so that the grafted bone is minimally lost. However, this time gap between final bone grafting and implant placement in cleft patients has not been well established.

Aim: To determine whether the clinical and/or radiological success of dental implant-based rehabilitation depends on the time elapsed between the last grafting procedure and dental implant placement in cleft region with missing permanent teeth in a unilateral or bilateral alveolar cleft patient.

Materials and Methods: The systematic review was registered in PROSPERO (International Prospective Register of Systematic Reviews) via registration number CRD42020187709. Systematic review was done at GSR Institute of Craniomaxillofacial and Facial Plastic Surgery, Hyderabad, Telangana, India, between March 2020 to July 2020 wherein articles in electronic databases (PubMed, ScienceDirect, Web of Science, (Literatura Latino-Americana de Ciencias da Saude), Cochrane Library and Google scholar, published between January 2011 to February 2020 were searched. Combination of Medical Subject Headings (MeSH) terms used included “cleft palate”, “cleft lip”, “alveolar bone grafting”, and “survival” as some of the key terms. Additional information was sought by contacting the corresponding authors. Search items included were cleft, alveolar bone grafting and dental implants. Only studies with details of time gap between last grating procedure and implant placement were included. Data extraction was done independently by two authors using pre-defined fields.

Results: Total of 12 studies were included wherein 255 dental implants were placed in 180 patients. In patients undergoing tertiary grafting, a time of 0 to 26 months was given prior to implant placement while in patients where tertiary grafting was not done, a time of 24 to 144 months was seen between two procedures. A high implant success of 95-100% was seen irrespective of the grafted bone. The JBI (Joanna Briggs Institute) tool of risk of bias assessment was used. Low level of evidence was presented by case reports and case series.

Conclusion: In case of tertiary grafting, a healing period of 3-6 months was seen to be sufficient for successful implant treatment however, a need for more comprehensive studies was recognised due to lack of mutual assessment parameters and shared information in the currently reviewed literature.

Keywords: Aesthetics, Bone grafting, Nonsyndromic clefting, Oral health, Prosthetics, Psychological assessment, Tooth agenesis

INTRODUCTION

Orthodontic treatment in cleft patients is able to achieve only 50 to 75% closure of residual space thereby, requiring remaining space closure using dental prosthesis [1]. Dental implants in grafted alveolar cleft sites provide enhanced functional and aesthetic results, improving patient’s psychological well-being and treatment acceptance [2-5]. However, they pose unique challenges that need due acknowledgment during treatment planning. Secondary bone grafting is performed prior to growth completion, while dental implants cannot be placed till patient’s craniofacial growth is complete [6]. During this duration, i.e., from secondary grafting till the patient attains skeletal maturity, there is an unavoidable loss in bone dimensions, often reaching dimensions that is unsuitable for implant placement [7,8].

This bone loss inadvertently calls for repeated bone grafting in the form of tertiary grafting to restore the lost bone [9]. However, certain patients present inhibition to the latter because of the involvement of additional surgical procedure and in such cases, dental implants have to be placed under compromised conditions [2]. Of the many factors on which success of dental implant depends, presence of foundational bone has a major influence that dictates osseointegration and implant surface coverage [1]. The currently available literature although identifies the problem of postgrafting bone resorption, they fail to comprehensively conclude about the minimum time after which implant can be placed in a grafted site so that this grafted bone is not lost [1]. The systematic review was done with an aim of determining the time elapsed between last performed bone graft surgery and dental implant placement at the alveolar cleft site in asyndromic patients. It also aimed at enumerating different sources used for grafting and probable outcomes associated with their use, characterisation of macro and micro features of the used dental implants including implant dimensions and its surface treatment, implant loading protocol used, clinical and radiographic parameters assessed, clinical success of placed dental implants, and follow-up durations.

MATERIALS AND METHODS

The presented systematic review was done after following the 27-item Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) checklist [10,11]. The review was conducted at GSR Institute of Craniomaxillofacial and Facial Plastic Surgery, Hyderabad, Telangana from March 2020 to July 2020.

The present review was done using the following patient Population, Intervention, Comparison, Outcome (PICO) guidelines [12]:

P: Unilateral or bilateral alveolar cleft patients with missing permanent tooth in cleft region.

I: Dental implant-based rehabilitation in the cleft region with single tooth prosthesis with or without tertiary bone grafting.

C: No comparison group

O: Success of dental implant based on time duration between last grafting procedure and dental implant placement, clinical and/or radiological parameters.

Final research question: For a unilateral or bilateral alveolar cleft patient, with missing permanent tooth in cleft region, is the clinical and/or radiological success of dental implant-based rehabilitation of the region dependent on the time elapsed between the last grafting procedure and dental implant placement?

Protocol and registration: The systematic review was performed following a prespecified inclusion, exclusion and analysis criteria and was registered with PROSPERO via registration number CRD42020187709 (https://www.crd.york.ac.uk/prospero/display_record.php?RecordID=187709).

Search strategy: An online search of PubMed, ScienceDirect, Web of Science, LILAC, Cochrane Library and Google Scholar electronic databases, without journal bias, was done for literature published between January 2011 and February 2020 using combination of multiple keywords. Medical Subject Headings (MeSH) terms that were used included: {"Cleft Palate" (MeSH) OR "Cleft Lip" (MeSH) OR "cleft palate" (All Fields) OR "Orofacial Cleft 1" (Supplementary Concept) OR "Cleft Lip with or without Cleft Palate, Non syndromic, 8" (Supplementary Concept)} AND {"Alveolar Bone Grafting" (MeSH) OR "Alveolar Ridge Augmentation, methods"* (MeSH)} AND {"Dental Implants" (MeSH) OR "dental implants (All fields)} OR Survival (MeSH) OR survival rate (MeSH) OR survival analysis (MeSH) OR "Aesthetics, dental" (MeSH). Search was restricted to clinical work done in humans.

Summary of search strategy, selection criterias i.e. inclusion and exclusion criterias of literature search are well-depicted in [Table/Fig-1].

Focus question	Does the clinical and/or radiographical success of dental implants in cleft region depends on the time elapsed between last grafting procedure and dental implant placement?
Search strategy	
Population	#1: {"Cleft Palate" (MeSH) OR "Cleft Lip" (MeSH) OR "cleft palate" (All Fields) OR "Orofacial Cleft 1" (Supplementary Concept) OR "Cleft Lip with or without Cleft Palate, Non syndromic, 8" (Supplementary Concept)}.
Intervention or exposure	#2: {"Alveolar Bone Grafting" (MeSH) OR "Alveolar Ridge Augmentation, methods"* (MeSH)) AND ("Dental Implants" (MeSH) OR "dental implants (All fields)}.
Comparison	No comparison group.
Outcome	#3: Survival (MeSH) OR survival rate (MeSH) OR survival analysis (MeSH) OR "Aesthetics, dental" (MeSH).
Filters	#4: "English" (language) AND "Humans" (MeSH) AND Publication year: 2011 to 2020.
Search combination #1 AND #2 OR #3 AND #4	
Database search	PubMed, ScienceDirect, Web of Science, LILAC, Cochrane Library and Google Scholar.
Electronic	PubMed, ScienceDirect, Web of Science, LILACS database, the Cochrane Library and Google Scholar.
Journals	No filters were applied for the journals.
Selection criteria	
Inclusion criteria	Full text articles published/available in English language.
	Prospective or retrospective case-series, prospective or retrospective cohort studies, case-reports, randomised/non randomised case-control trials.
	Unilateral or bilateral alveolar cleft in asyndromic patients.
	Use of dental implant for rehabilitation of a single missing permanent tooth in the affected alveolar cleft site.
	Loading of placed dental implant with a single unit crown.
	Must specify the time gap between grafting and implant placement.
Exclusion criteria	Unpublished work.
	Abstracts only, conference proceedings, letters, editorials.
	Reviews, with or without meta-analysis.
	In-vitro and animal studies.
	Studies/ case reports in which time between last grafting procedure and implant placement could not be determined.
	Use of dental implants in patients with cleft palate or cleft lip without cleft of alveolus.
	Dental implant placed in patients with cleft at sites other than the cleft region.
	Full mouth rehabilitation of patients with cleft using implant supported dentures.
	Implant based rehabilitation in syndromic patients with cleft.
	Publications discussing solely about aesthetic outcome with lack of details concerning clinical evaluation of placed implants.

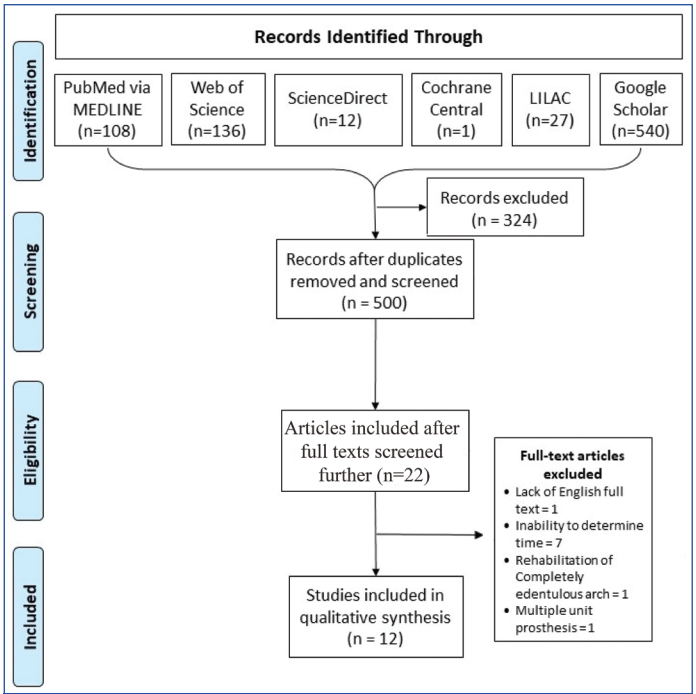
[Table/Fig-1]: Search strategy and selection criteria.

Risk of bias (quality) assessment: Two reviewers independently searched the mentioned electronic databases and decisions for inclusion or exclusion were recorded using Joanna Briggs Institute (JBI) Critical Appraisal tool [13]. In case of any disagreement, a third person was asked to independently review the publication under question and based on the decision of majority, the publication was included or excluded.

Data extraction: Patient demographics, study design, implant characteristics, assessment criteria (clinical, radiographic, or other used) were retrieved from each publication and recorded in tabular format. Parameters used by each author to determine the implant success were identified. These included any information related to recording of oral hygiene indices, plaque index, gingival index, clinical attachment loss, probing depths, bleeding index, details related to the width of attached gingiva, pain and suppuration at the implant site, mobility of the placed implant, recording of Insertion Torque (IT) values, and presence or absence of radiographic peri-implant radiolucency and bone loss. Data was individually extracted by two authors (Rizwana Mallick and Vanshika Jain) and cross-verified by two independent reviewers (Sweta Kale Pisulkar and Srinivas Gosla Reddy) and tabulated using pre-determined table headings to determine the inclusion of the study. In case of unreported data or need for additional details, the corresponding author of the published work was contacted.

Search outcomes: The search returned 824 results: 108 on MEDLINE via PubMed, 12 on ScienceDirect, 136 on Web of Science, 27 on LILAC, one on Cochrane Central and 540 on Google Scholar. After reading the titles, abstracts and removing the duplicates, 22 articles were included whose full texts were screened to ascertain their inclusion. Ten articles were excluded because of the following reasons: absence of English full text (n=1), lack of accurate determination of time between bone grafting and dental implant placement (n=7), rehabilitation of completely edentulous patients with cleft (n=1) and rehabilitation of single implant using multiple unit prosthesis (n=1). Thus, a total of 12 articles, meeting the set criteria were included for the final review and subjected to JBI risk of bias assessment [Table/Fig-2] [2-4,14-22]. This comprised of four case reports, three retrospective case series, three retrospective cohort studies, one prospective clinical trial (cohort study), and one case-control study. Owing to the heterogenicity and limited data reporting, conduction of meta-analysis was not found to be feasible. Key findings of these articles are summarised in [Table/Fig-3].

Quality and risk of bias assessment: The results of quality assessment according to the JBI checklists for retrospective and prospective cohort studies, case series, case reports, and case-control studies is presented in [Table/Fig-4a-e] respectively. Among the three restrospective [2,19,20] and one prospective cohort studies [21], no differences in the different assessment parameters were found except in statistical analysis wherein the study by



[Table/Fig-2]: Flowchart representation of literature search.

Cembranos JLC et al., did not provide details concerning the same [20]. Of the assessed case reports, two did not provide clear patient's history presented in a timeline [18,22] while case report by Jeong KI et al., also did not provide clear details of post-intervention clinical condition [18]. Among the case series, except for one by Nakata et al., all others gave clear details about the inclusion criteria of the patients [4]. Since, orofacial cleft is a congenital deformity, conditioned or valid methods for patient identification were not seen to be applicable for the studies. None of the case series provided appropriate statistical analysis.

RESULTS

Eligible studies comprised of 187 cleft patients with age range of 14 to 47 years at the time of implant placement. A total of 163 patients had unilateral cleft of either side (87.2%) and 23 patients presented with bilateral cleft (12.3%). Data findings of seven patients and their corresponding number of implants placed was excluded from current evaluation due to absence of implant in cleft region in patients with alveolar cleft (1 patient), rehabilitation using Fixed Partial Denture (FPD) (3 patients), multiunit prosthetic rehabilitation of placed implant (2 patients) and implant placed in patients without alveolar cleft (1 patient) [15,16,20,21]. Therefore, in effect, 180 alveolar cleft patients were treated with 255 dental implants. Of these implants, at least 172 implants were placed in cleft region. For the remaining implants, it could not be accurately concluded as to how many were placed in cleft sites as the same was not specified by authors and several patients received multiple implants [20].

Time between Last Bone Grafting and Implant Placement

While in majority of the cases, healing period was given prior to installation of implants, only two of the 12 reviewed literature showed evidence of simultaneous implant placement during tertiary grafting surgery [3,15]. A single patient was treated with immediate implant in one of the two studies while the number of patients in the second literature could not be identified successfully. In most cases, a healing time of at least six months was given before implant placement wherein the implant was placed after 12 or more months in a few of them [3,4,15]. Only five published works performed implants placement after less than six months of bone grafting [2,4,17,18,21]. In two papers, implants were placed in the secondary grafted bone without undertaking tertiary grafting. In these cases, a time gap of 24 to 102.3 months was seen between the two procedures [16,20].

History of Secondary Alveolar Bone Grafting (SABG)

All treated patients had surgical history of undergoing either secondary or late SABG performed between 8 to 31 years of age except in a couple of published papers which did not provide relevant details [15,19]. Age of grafting procedure could not be concluded in four papers due to lack of provided information [3,18,20,22]. All studies that elucidated details about the bone graft used for the above mentioned procedure, autologous iliac bone graft was the popularly used bone grafting material [4,16,19,20].

Tertiary Bone Grafting

All publications mentioned about the need for tertiary grafting prior to implant surgery which was performed in 99 of the total cases. Different materials were used by clinicians, however, autologous bone was the most widely used graft. Other sources of autologous bone included, iliac bone [3,20,21], mandibular bone graft [3,17,20], and cranial bone [15]. Particulate autogenous tooth bone was used in one case [18]. Some cases also utilised allogenic bone or guided bone regeneration (GBR) technique [2,15,20,22]. Only one study utilised xenogenic bone grafts for tertiary grafting [14]. Specific material used for tertiary grafting was not mentioned in one study [4]. In some cases, additional bone substitute material was used at the time of implant placement to ensure its complete coverage. Various material used included bone particles obtained during drilling for implant placement, bone material from symphysis, retromolar area or maxillary nasal spine, hydroxyapatite particles or mix of other alloplastic materials and xenograft material [4,15-17,20-22].

Implant Loading and Their Characterstics

Six papers reported implant loading with a definitive prosthesis after one to six months of osseointegration [2,3,16,18,19,21]. Two papers also mentioned about rehabilitation using provisional prothesis prior to definitive prosthesis [2,14]. These details were found to be missing in the remaining papers.

Except for two included publications [4,22], all others elucidated about dimensions and characteristics of the placed implants. Implant diameters ranged from 3 mm to 4.3 mm with 3.3 mm and 4.1 mm as the most common dimensions. Length of implants varied from 10 mm to 15 mm with 10 mm as the most used length. Most dental implants used had Sandblasted Large-grit Acid-etched (SLA) surface. Other surface treatment of implants included titanium oxide and hydroxyapatite coating.

Clinical and Radiographic Assessments and Implant Success

Implant success in terms of survival rate was a common finding reported in all papers which ranged from 95-100% [24,14-22]. Case reports were not considered eligible to comment on survival rate. Among the clinical parameters, plaque index and probing depth were the most evaluated. Other assessed parameters included, gingival index, width of keratinised gingiva, gingival recessions, pain, and suppuration at the implant site [Table/Fig-5]. Only two studies recorded implant mobility and relied either on manual judgement or use of periotest [3,21]. Additionally, two studies also commented on IT values which ranged from 15-35 cm [21,22]. No study recorded stability quotient values using Resonance Frequency Analysis (RFA). Two case reports focused on bone grafting procedure and did not comment on any recorded parameters [14,22].

Marginal Bone Loss (MBL) and periapical radiolucency on intraoral radiograph or Cone Beam Computed Tomography (CBCT) were commonly assessed radiographic parameters. Enemark scale was popularly used in three studies to radiographically check the outcome of the grafted bone [4,20,21]. Aesthetic assessment in form of pink or white aesthetic scales and patient satisfaction questionnaires were also given importance in four studies [2,15,17,19].

Author (Year)		Landes CA et al., [3] (2012)	Doh RM et al., [16] (2015)[b]	Jeong KI et al., [18] (2015)	Nakata H et al., [4] (2015)	Papi P et al., [19] (2015)	Cembranos JLC et al., [20] (2017)	Van Nhan V et al., [21] (2018)	Brauner E et al., [2] (2018)	Blume O et al., [22] (2019)	Hengjeerajaras P et al., [14] (2019)	Saint-Surin I et al., [15] (2020)[c]	Alberga JM et al., [17] (2020)
Type of study		Retrospective case series	Case report	Case report	Retrospective case series	Retrospective study	Retrospective study	Prospective clinical trial	Retrospective study	Case report	Case report	Retrospective case series	Case-control study
Patients treated (Gender)		17 (7F, 10M)	1 (M)	1 (M)	13 (8F, 5M)	25	25† (14F, 11M)	32* (23F, 9M)	14 (9F, 5M)	1 (F)	1 (M)	6 (2F, 4M)	17 (6F, 11M)
Type of Alveolar Cleft	Unilateral	14	1	1	10	23	20	32	14	1	1	6	17
	Bilateral	3	-	-	3	2	4	-	-	-	-	2	-
Age at Implant Placement (years)		15-36 24#	20	19	18 – 36 23#	21-53 34.93 ± 7.04#	14-47 24#	16-31 21.28#	18-22 19#	31	18	20.25#	17-33 21.2*
Total Implants (Implants in cleft site)		24 (24)	2 (1)	1 (1)	16 (16)	29	47	32 (29)	16 (14)	2 (2)	1 (1)	12	24 (24)
H/o SABG		3 patients	Yes	Yes	12 patients	NP	12 SABG in 11 patients 12 late alveoloplasties in 10 patients	Yes	Yes	Yes	Yes	NP	Yes
Age at SABG (years)		NP	11	Not known	11-28 19#	NP	Not known	16-31 21.28#	8-11	Not known	16	NA	11.7#
SABG grafting material		NP	Iliac bone	Not known	Iliac bone	NP	NP	NP	NP	Not known	Not known	Not known	Anterior iliac crest
Need for tertiary grafting		14 patients (done twice in 1 patient)	No	Yes	2 patients	Yes	13 patients	Yes	Yes	Yes	Yes	Yes	7 cases
Tertiary Bone Graft Source		Corticospongious bone from iliac crest or mandibular angle	-	Particulate autogenous tooth bone	NP	Iliac crest, mandibular ramus or symphysis	GBR or bone block graft from mandibular symphysis	Iliac bone	Hetrogenous cancellous particulate bone with collagen membrane	Allogenic cancellous bone of femoral head	Xenogenous graft	Autogenic (cranial or endo-oral) & Allogenic material	Retromolar area
Time to implant placement (in months)	From SABG	78-114 93#	24	-	NP	-	102.3#	-	96-144	-	-	-	11.7#
	From Tertiary grafting	0-26 8#	-	3.5	5-12	4-6 5#	25.2#	4–6	6	6	6	0–22	3
Implant dimension (diameter×length) (in mm)		3.3 or 4.1×10 or 12	3.6×10	3×11	NP	NP	3.3×10 or 12	3×10	NP	NP	4.1×13	3×11.5 = 1 3×13 = 2 3.5×10 = 1 3.5×11.5 = 1 3.5×13 = 1 4.3×10 = 1	3.25 or 3.3 or 3.5 or 4 or 4.1 or 4.3×8 or 10 or 12 or 13 or 14 or 15
Additional bone graft during implant surgery		No	Yes	No	In 12 sites	NP	Yes	In all cases	No	Yes (granular-xenogenic substitute)	No	In all cases	In 15 cases Autogenous bone chips + anorganic bovine bone with membrane
Implant Loading	Temporary Prosthesis	-	-	-	NP	-	NP	-	5-7 months	NP	3 months	NP	Healing abutment placed after 3 months
	Definitive Prosthesis	3 months	3 months	6 months		4 months#		6-8 months	6-8 months		4.5 months		NP
Success rate[a]		95.8%	-	-	100%	100%	100%	100%	100%	-	-	100%	95%
Follow-up (in months)		6-89 40#	24	6	60–156	12-56	6-153	36	24-60	6	12-120	18-84 40.3#	72.4#

[Table/Fig-3]: Key findings of reviewed literature [2-4,14-22].

a: Success rate not applicable for case reports; b: 1 patient with no implants placed in cleft region was omitted; c: Data of 2 patients rehabilitated with multi-unit prosthesis was omitted from implant success and follow-up data

†: 1 patient had cleft palate with absence of alveolar cleft; *: 3 patients were excluded as they were not treated with dental implants

#: Mean value; M: Male; F: Female; Uni: Unilateral; Bi: Bilateral; SABG: Secondary Alveolar Bone Grafting; NP: Not Provided; GBR: Guided Bone Regeneration; mm: millimetre

JBI checklist for retrospective cohort studies	Papi P et al., [19] (2015)	Cembranos JLC et al., [20] (2017)	Brauner E et al., [2] (2018)
Were the two groups similar and recruited from the same population?	NA	NA	NA
Were the exposures measured similarly to assign people to both exposed and unexposed groups?	NA	NA	NA
Was the exposure measured in a valid and reliable way?	NA	NA	NA
Were confounding factors identified?	N	N	N
Were strategies to deal with confounding factors stated?	N	N	N
Were the groups/participants free of the outcome at the start of the study (or at the moment of exposure)?	Y	Y	Y
Were the outcomes measured in a valid and reliable way?	Y	Y	Y
Was the follow-up time reported and sufficient to be long enough for outcomes to occur?	Y	Y	Y
Was follow-up complete, and if not, were the reasons to loss to follow-up described and explored?	Y	Y	Y
Were strategies to address incomplete follow-up utilised?	NA	NA	NA
Was appropriate statistical analysis used?	Y	N	Y

[Table/Fig-4a]: JBI (Joanna Briggs Institute) checklist for three retrospective cohort studies [2,19,20].
Y: Yes; N: No; NA: Not applicable; U: Unclear

JBI checklist for prospective cohort	Van Nhan V et al., [21] (2018)
Were the two groups similar and recruited from the same population?	NA
Were the exposures measured similarly to assign people to both exposed and unexposed groups?	NA
Was the exposure measured in a valid and reliable way?	NA
Were confounding factors identified?	N
Were strategies to deal with confounding factors stated?	N
Were the groups/participants free of the outcome at the start of the study (or at the moment of exposure)?	Y
Were the outcomes measured in a valid and reliable way?	Y
Was the follow-up time reported and sufficient to be long enough for outcomes to occur?	Y
Was follow-up complete, and if not, were the reasons to loss to follow-up described and explored?	Y
Were strategies to address incomplete follow-up utilised?	NA
Was appropriate statistical analysis used?	Y

[Table/Fig-4b]: JBI checklist for prospective cohort studies (clinical trial) [21].
Y: Yes; N: No; NA: Not applicable

JBI checklist for case reports	Doh RM et al., [16] (2015)	Jeong KI et al., [18] (2015)	Blume O et al., [22] (2019)	Hengjeerajaras P et al., [14] (2019)
Were patient's demographic characteristics clearly described?	Y	Y	Y	Y
Was the patient's history clearly described and presented as a timeline?	Y	N	N	Y
Was the current clinical condition of the patient on presentation clearly described?	Y	Y	Y	Y
Were diagnostic tests or assessment methods and the results clearly described?	Y	Y	Y	Y
Was the intervention(s) or treatment procedure(s) clearly described?	Y	Y	Y	Y
Was the post-intervention clinical condition clearly described?	N	N	Y	Y
Were adverse events (harms) or unanticipated events identified and described?	Y	Y	Y	Y
Does the case report provide takeaway lessons?	Y	Y	Y	Y

[Table/Fig-4c]: JBI checklist for four case reports [14,16,18,22].
Y: Yes; N: No;

JBI checklist for case series	Landes CA et al., [3] (2012)	Nakata H et al., [4] (2015)	Saint-Surin I et al., [15] (2020)
Were there clear criteria for inclusion in the case series?	Y	N	Y
Was the condition measured in a standard, reliable way for all participants included in the case series?	NA	NA	NA
Were valid methods used for identification of the condition for all participants included in the case series?	NA	NA	NA
Did the case series have consecutive inclusion of participants?	Y	U	Y
Did the case series have complete inclusion of participants?	Y	U	Y
Was there clear reporting of the demographics of the participants in the study?	Y	N	Y
Was there clear reporting of clinical information of the participants?	Y	Y	Y
Were the outcomes or follow-up results of cases clearly reported?	Y	Y	Y
Was there clear reporting of the presenting site(s)/clinic(s) demographic information?	Y	Y	Y
Was statistical analysis appropriate?	N	N	N

[Table/Fig-4d]: JBI checklist for three case series [3,4,15].
Y: Yes; N: No; NA: Not applicable; U: Unclear

JBI checklist for case-control studies	Alberga JM et al., [17] (2020)
Were the groups comparable other than the presence of disease in cases or the absence of disease in controls?	Y
Were cases and controls matched appropriately	Y
Were the same criteria used for identification of cases and controls	Y
Was exposure measured in a standard, valid and reliable way?	Y
Was exposure measured in the same way for cases and controls?	Y
Were confounding factors identified?	N
Were strategies to deal with confounding factors stated?	N
Were outcomes assessed in a standard, valid and reliable way for cases and controls?	Y
Was the exposure period of interest long enough to be meaningful?	Y
Was appropriate statistical analysis used?	Y

[Table/Fig-4e]: JBI checklist for case-control studies [17].
Y: Yes; N: No

Follow-up

All studies reported clinical follow-up in the range of 6 to 156 months [2-4,14-22] with a bulk of studies having a follow-up of at least 12 months [2,4,14-17,19,21]. Depending on the primary aim of their study, the respective authors presented various results which spanned over rate of implant success, clinical parameters and radiographical findings.

DISCUSSION

Dental implants-based rehabilitation of patients of alveolar cleft has shown positive results in improving function and aesthetics. Available literature speaks highly of its numerous advantages, however, it

Author (Year)	Landes CA et al., [8] (2012)	Doh RM et al., [18] (2015)	Jeong KI et al., [22] (2015)	Nakata H et al., [9] (2015)	Papi P et al., [21] (2015)	Cembranos JLC et al., [17] (2017)	Van Nhan V et al., [19] (2018)	Brauner O et al., [7] (2018)	Blume O et al., [23] (2019)	Hengjeerajaras P et al., [25] (2019)	Saint-Surin I et al., [20] (2019)	Alberga JM et al., [24] (2020)
Clinical parameter												
Plaque index	+										+	+
Bleeding index												+
Probing depth	+											+
Gingival index	+											
Width of keratinized gingiva	+										+	
Gingival/ mucosal recession	+											
Pain							+					
Suppuration at implant site							+				+	
Implant mobility	+						+				+	
Insertion torque												
Radiographic parameters												
Marginal bone loss	+						+				+	+
CBCT scan		+							+	+	+	
Periapical radioluceny		+	+								+	
Enemark scale				+		+	+					
Pink and white esthetic scale												
	+											+
Self-administered questionnaire												
	+				+			+				+
Criteria for implant success (as defined by respective authors)												
	In situ implant with mobility between 0 and 1, no periapical radiolucency, absence of suppuration, no persistent pain, no foreign body sensation and/ or dysesthesia					Implant survival rate						
Additional Parameters/Comments												
		Assessed parameters not elucidated	Oral hygiene	Esthetic outcome assessed based on risk factors			Fistula formation assessment	Assessed parameters not elucidated				

[Table/Fig-5]: Summary of assessed parameters.
+: Present; CBCT: Cone beam computed tomography

lacks in imparting appropriate knowledge concerning time between last grafting procedure and implant installation [2,23,24].

Assessment of Time Elapsed between Last Bone Grafting and Dental Implant Placement

The duration between final bone grafting and implant placement ranged from a value of as low as zero months (immediate implant placement) [15] to values as high as 102.3 months (in cases where implant was placed in secondary grafted bone without tertiary grafting) [20]. In all cases except one [16], 3-6 months healing period was given before proceeding for implant surgery which was comparable to that seen in healthy patients who undergo bone grafting prior to implants.

Tertiary bone grafting was invariably needed as the gap between SABG and proposed implant surgery led to gradual bone resorption, leaving inadequate bone. Although beneficial, at times patients were

not willing for tertiary grafting because of the involved additional procedure. This led to placing of implants in SABG grafted bone. All studies except one [17] reported equivalent results whether the implant was placed in the secondary or the tertiary grafted bone. This can be due to the fact that most studies are either case reports or case series and thus not a reliable means to know about the actual success rate of the treatment. Also, there was no unanimity with respect to assessed outcome parameters that can present for a good comparison baseline. Despite tertiary grafting, many cases required additional bone graft material to ensure implant stabilisation and complete bony coverage.

The reviewed literature showed evidence of successful implant placement in grafted cleft sites when placed within three to six months. There are studies which presented the same results when implants were placed after three months, however the number of these studies counts only to three [3,15,17]. In these three studies cumulatively, only a total of ten patients had implants placed after three months. A previous study evaluating graft resorption reported loss of up to 50% bone when implants were placed six months after grafting with an increased rate of resorption in the initial two years and almost complete resorption after six years [25]. In current review, no identified study with delayed implant placement commented on bone height which is an important treatment outcome.

Bone Grafts Used for Secondary and Tertiary Grafting and their Associated Findings

Alveolar grafting is associated with many postoperative complications depending on the type and side of cleft, patient's age and the type of bone graft material. It is reported that bone grafting undertaken in patients more than 12 years of age have a four times higher risk of developing complications compared to patients on the other side of the scale with significant correlation between development of postoperative complication and need for reoperation [26,27].

Autologous iliac bone is the gold standard source while cranial bone, tibia, mandibular symphysis, and rib graft are other successfully used autologous sources with no reported difference in success [26]. A previous study has also shown particulate bone to have a superior clinical performance compared to block or mixed grafts [27]. Alloplastic materials too have shown acceptable clinical results [28]. The included studies showed iliac bone as the constant donor site which was in accordance to previously published works [29]. Despite the huge success of autogenous grafts, it is important to highlight that they have a reported resorption rate of 24 to 51% after one year of function, which makes it even more important to preserve their dimensions in the earliest possible time [26].

Tertiary grafting was needed in most cases prior to implant placement even though patients have successfully undergone SABG. This can be hypothesised to the fact that SABG is done during mixed dentition period while dental implants cannot be placed until the completion of the craniofacial growth. Thus, a gradual loss of grafted bone is observed which leaves inadequate dimensions for implant. First year post SABG is shown to undergo maximum remodelling followed by relative stabilisation [8,26,30]. Prospective studies showed bone volume loss of 43.7-49.5% after one year of grafting with cumulative loss of 52% after three years with approximately an equivalent loss in vertical and labio-palatal aspects [7,8]. Reduced amount of bone loss is observed in patients subjected to orthodontic treatment for missing tooth. This can be attributed to beginning of the treatment without significant delay which enables early functional loading of grafted bone, thereby preventing resorption [31].

Bone source for tertiary grafting range from autologous source with or without enhancing factors like Platelet Rich Plasma (PRP) or Platelet Rich Fibrin (PRF) to allogenic, xenogenic and synthetic sources, all showing favourable results [14,15,22,32]. For onlay grafting, it is recommended to use corticocancellous graft over particulate bone and harvesting an oversized graft to accommodate physiologic resorption [33]. Soft tissue dehiscence which may or may not lead to loss of bone graft is a frequent complication seen with onlay grafting specially in cases which are subjected to tension closure [33,34]. In the reviewed literature, no study has addressed these issues.

Implant Characterisation (Macro and Micro Features)

Dental implant characteristics like thread design and crest module affect crestal bone loss, however these observations weren't highlighted in the reviewed literature [35]. Suzuki M et al., found that increasing implant length led to an increased amount of MBL, having a male predilection and subsequently required vestibuloplasty [36]. However, they did not find any significant difference in bone loss while comparing different implant surfaces. Authors of one paper did not believe the implant length to affect the outcome in any way [20]. No such observation was made by other authors reviewed in the current paper. With regards to surface treatment of dental implants, according to some authors, roughened surfaces are superior to machined surface [36,37]. Within the different surface roughening and their effect on MBL, a mixed bag of results has come to the fore, but all these observations have been made in healthy individuals [38-40]. Diminished bone dimensions in patients of alveolar cleft is a common finding and it is also common to encounter patients unwilling to undergo tertiary grafting procedure [2]. For such cases, it is important to have implants of shorter dimensions which can provide functionality equivalent to conventional implants. Implant characteristics also influence the implant stability which can be assessed using invasive and non invasive methods like IT measurement and periotest [41]. RFA, a non invasive method, has gained popularity in recent decade and is increasingly being used, however, in none of the reviewed literature, the device has been utilised.

Parameters Assessed to Define Clinical Success of Dental Implants

Field of implantology has seen a progressive change in the definition of implant success. In contrast to the previous ideologies which stressed on a single component as the driving force for success, the current concept views implant-prosthetic complex as a single unit, giving equal importance to clinical and radiological parameters, prosthesis, aesthetics and function [42]. The current review paper saw a lack of mutual consensus in terms of recorded parameters to define implant success. Only one study assessed all parameters encouraged by Buser while a few studies recorded only some of these parameters [3,15,17,43]. Although controversial, width of attached gingiva is often seen as an important driving factor for implant success. Per se, value of attached gingiva do not dictate patient's ability of maintaining hygiene, however, decreased values have shown to promote increased plaque accumulation, inflammation and bleeding of gingiva which adversely affect the implant health [44,45]. A width of 2mm or more is considered adequate for satisfactory peri-implant health [44]. As a mutual consensus, when evaluated, an improvement in aesthetics and soft tissue profile was noted by all authors. Implants placed in tertiary grafted bones showed better aesthetic results compared to those placed in SABG bone. This is attributed to the fact that tertiary grafting helps in compensating for the lost bone in the labial aspect which helps in avoiding the gingival lapse seen in the region [2]. In view of the authors of the presented review paper, the success criteria should be a holistic one and should follow Buser's criteria as closely as possible.

According to statement released by the American Academy of Oral and Maxillofacial Radiology, recording of Cone-beam Computed Tomography Systems (CBCT) assessment for cases planned for bone grafting and/ or implant treatment is recommended [46]. Considering the three-dimensional nature of cleft defect, it is essential that a comprehensive site evaluation be done to know about the deficit bone volume, decide optimal implant position and avoid surgical

surprises. Importance of recording CBCT has also been highlighted in previous studies which found two-dimensional (2D) assessment of cleft defect to overestimate the grafting outcomes [26,47]. The current review paper saw a lack of uniformity in terms of radiological assessments with only three scholarly works undertaking CBCT recording of which only two did so with an aim of commenting on the pre- and postoperative bone volume [16,21,22].

Clinical Success of Placed Dental Implants

Barring the case reports for assessing success of the placed implants, the included literature showed a clinical success rate of 95-100%. This was an unusually high success rate considering that alveolar cleft bone grafting is often associated with high rate of complications and such high success rate is not reported even in healthy individuals [26,27,48]. It is evident in literature that even among uncompromised individuals, implants placed in the anterior maxilla show a failure rate of 2.1 to 6.2% which is a statistically significant difference when compared to those placed in anterior mandible or posterior region of the either jaws [49,50]. With respect to immediate loading of the placed implants, again a significantly higher failure rate is reported for implants in maxillary region than those in the mandible [51]. The relatively high failure rate in anterior maxilla can also be related to the high failure rate in type III bone (3%) which is the evident bone in the anterior maxilla [50]. Thus, the authors are of the opinion that this high success rate can be due to non universal follow-up time in the reviewed papers. Even within a single study, some implants were reviewed for as short duration as six months while some were reviewed for more than double this time.

Patient Follow-Up

Although 12 months follow-up was a common finding, presence of short time of six months or long durations of 156 months made the comparison difficult. Although, it is difficult to define a follow-up protocol that can be ubiquitously followed, evidence from previously conducted literature reviews suggest that the patient should be kept on maintenance phase and recalled not later than three months for the first year. Thereafter, each patient should be kept on a lifelong follow-up spaced at six months [52]. Each of this patient visit should last for around one hour wherein extra and intraoral assessment of patient should be done including reinforcement of oral hygiene instructions [53]. These guideline recommendations are suggested based on class A rating of evidences which are directly derived from systematic review of Randomised Clinical Trials (RCTs) [52].

Limitation(s)

The presented review evaluates case reports and case series along with the single conducted case-control trial during the review period. Although providing insight into novelty detection and helping in generating hypothesis, case reports and case series generate low level of evidence and lack the ability of generalising results [54]. Also, their inclusion limits the tools that can be utilised for quality and risk of bias assessment and restricts conduction of meta-analysis. The review was also not able to comment on the size of alveolar cleft defect prior to implant placement due to lack of information concerning the same in the reviewed publications.

CONCLUSION(S)

Dental implant should not be placed before three months and not delayed beyond six months after grafting of alveolar cleft. During autologous onlay grafting for the rehabilitative management of the orofacial cleft patients, corticocancellous bone is recommended to be used with overcorrection of the defect to address the loss of graft due to bone remodelling. The soft tissue flap should be closed with minimum tension to avoid flap dehiscence and graft exposure. For implant-based rehabilitation in these patients, the authors recommend, dental implants in a grafted bone in cleft patient should not be placed before three months and should not be delayed beyond six months after bone grafting. The three dimensional recordings in form of CBCT should be undertaken instead of two-dimensional assessment, prior to grafting as well as implant placement. Universal implant-based treatment protocol for cleft patients should be developed which includes reporting of timelines, parameters assessed and complications at the time of grafting and implant placement. Further clinical studies, preferably controlled trials with implant placement done immediately, three and six months after grafting, larger sample size and longer follow-up duration should be conducted to generate substantial scientific evidence.

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