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Systematic Review
Dental Implants

Effectiveness of dental implants placed in bone graft area of cleft Patients

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Abstract. The purpose of this study was to determine the effectiveness of dental implants placed in the bone graft area of cleft patients. Electronic databases and relevant journals were searched to the end of August 2018. A total of 11 articles were eligible for systematic review considering the previously established inclusion and exclusion criteria, and then underwent risk of bias assessment. A total of 483 implants were placed and showed a survival rate of 93% after a mean follow-up of 60.5 months. The iliac bone was the most used for the reconstructive surgery in cleft patients, followed by the mandible. There is a high survival rate of dental implants placed in areas of bone grafts in patients with alveolar clefts. However, more studies with high methodological quality and with a longer follow-up are needed to offer more safety for practitioners and patients regarding the placement of dental implants in areas of alveolar clefts with bone grafting.

Key words: dental implants; cleft palate; cleft lip; bone grafting.

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Oral rehabilitation is an essential part for the treatment of patients with cleft lip and palate. These patients may present unilateral or bilateral alveolar clefts, causing changes in shape and bone thickness. This influences the normal process of tooth eruption and causes tooth agenesis in many cases, especially in lateral upper incisors[1,2]. Alveolar cleft is a congenital malformation, common in patients with cleft lip and palate. Its incidence ranges from 1.8 to 2.5 in every 1000 live births and occurs in approximately 75% of patients with clefts[3,4].

Alveolar cleft is usually surgically treated with bone grafting, which provides support for the canine tooth eruption, facilitates orthodontic movement, and allows the placement of dental implants[1,3,4]. Although there are several protocols to perform grafting, secondary bone grafting presents the best results and the autogenous bone, especially the iliac bone, is considered as the gold standard for this reconstruction[1,5,6].

When grafting is not performed, fixed or removable prostheses may be used; however, both feature disadvantages, especially regarding adjacent tooth wear and aesthetic defficiencies[7].

The advent of osseointegration and the development of rehabilitation techniques using dental implants meant not only an improvement in masticatory function but also in patient's self-esteem by enhancing aesthetics of the smile and the face. Dental implants in patients with alveolar clefts

represent an excellent treatment option, because it is a safe procedure that features good prognosis and low morbidity, and there is no need for tooth wear and allows a rehabilitation with fixed teeth[8–12].

Although dental implantation provides unarguable advantages in the treatment of patients with alveolar clefts, it also shows some issues. The major issue concerns osseointegration, because these implants are usually placed on grafted areas, which presents lower volume and density in many cases, which may decrease the survival rate[8,12,13]. This fact often calls for additional surgeries to increase bone volume[14], which increases complexity, costs, and morbidity of procedures.

Previous systematic reviews that addressed this theme showed several methodological flaws, such as the inclusion of case series, short follow-ups (less than 12 months)[15], inclusion of studies published only in the English language, and search on only one database[16]. These methodological flaws may be interpreted as sources of bias and, hence, make these studies less relevant to be considered and followed by researchers and practitioners.

The present systematic review was conducted to answer the following focused question: what is the effectiveness of dental implants placed in sites of bone grafting in patients with alveolar clefts?

Materials and Methods

The study protocol was registered on the International Prospective Register of Systematic Reviews (PROSPERO, registration number: CRD42018092209) and was performed following the recommendations of the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA Statement)[17].

Search Strategy

The online search was performed on Medline via PubMed (1966–2018), Lilacs (1982–2018), Central Cochrane (up to 2018), and Sigle via Open Grey (1980–2018). The following search strategy was performed on these databases using MeSH terms: (''cleft palate''[MeSH Terms] OR (''cleft''[All Fields] AND ''palate''[All Fields]) OR ''cleft palate''[All Fields]) AND (''dental implants''[MeSH Terms] OR (''dental''[All Fields] AND ''implants''[All Fields]) OR ''dental implants''[All Fields]). A manual search was also performed of the references of eligible articles and in author's personal files.

Study Selection

The search process was conducted by two reviewers (P.H.H.S. and F.J.C.L.), and a third reviewer (O.B.O.N.) was consulted in cases of disagreement in which a consensus was not achieved between the two first reviewers. Titles and abstracts of initial hits were screened by these reviewers and potentially eligible papers were read fully to assess their eligibility. Methodological quality assessment was performed for included articles. Clinical studies were sought, including randomized or non-randomized clinical trials and prospective or retrospective observational studies.

Inclusion Criteria

Inclusion criteria were as follows: randomized clinical studies and observational studies (prospective and/or retrospective) that assessed the effectiveness of dental implants placed in areas of bone grafting in patients with alveolar clefts; studies performed in humans with no restrictions of age, gender, or ethnicity; alveolar clefts reconstructed unilaterally or bilaterally; there was no restriction of language.

Exclusion Criteria

The following were excluded: case reports, systematic reviews, patients with syndromes or with any other comorbidities; studies with less than 1 year of follow-up; duplicated publications; papers that did not report results after the end of research; experimental studies with animals or with cell cultures; papers in which data regarding study follow-up was incomplete or with poorly described interventions.

Outcomes

The primary outcome was the survival rate of dental implants placed in areas of bone grafting in patients with alveolar clefts. Secondary outcomes were: bone graft donor site for alveolar cleft reconstruction; clinical attachment loss; and level of peri-implant bone loss.

Statistical Analysis

A descriptive statistical approach was used to present data. The implant survival rates were described as percentages; peri-implant bone loss and clinical attachment loss were presented in millimetres. The other outcomes were presented as reported in primary studies and a weighted arithmetic mean was calculated to relate the survival rate of dental implants in different bone graft donor sites.

Methodological quality and risk of bias assessments

In order to determine the risk of bias, and, consequently, the quality of included studies, the items of the Newcastle–Ottawa Scale (NOS) were used. This tool determines the risk of bias of prospective and retrospective observational studies using a score that varies from 0 to 9 stars and classifies the study as follows: zero to three stars represent a very high risk of bias; four to six stars indicate a high risk of bias; and seven to nine stars determine a low risk of bias. This scale especially considers criteria related to the selection process of the sample, comparison between analysed groups, and exposure to risk factor. Nine items were assessed, and one star was given when the item was properly reported on articles.

Results

The search yielded 215 results: 197 on Medline via PubMed, 15 on Lilacs, two on Cochrane Central and one on Sigle via Open Grey. Of these, 198 publications were excluded after reading the title and abstract, and after exclusion of duplicates. The 17 remaining articles were read fully and six more papers were excluded for the following reasons: implant success rate was not reported ($n = 1$); less than 1 year of follow-up ($n = 1$); implants were not placed in an area of cleft ($n = 1$); emphasis on bone reconstruction ($n = 1$); duplicated by the same author ($n = 1$); literature review ($n = 1$). Finally, 11 articles were eligible for systematic review considering the previously established inclusion and exclusion criteria, and then underwent risk of bias assessment. Cohen's Kappa was calculated and showed an agreement rate between reviewers of 88.2%. Details regarding selection process are shown in Fig. 1.

Quality assessment

Of the 11 articles that underwent quality assessment, nine were of retrospective studies and two were of prospective studies. Only three studies presented a control group, and because these control groups were very heterogenous amongst themselves, a meta-analysis was not possible. Studies were assessed using the items from the NOS. Of the 11 studies assessed, three presented low risk of bias and eight

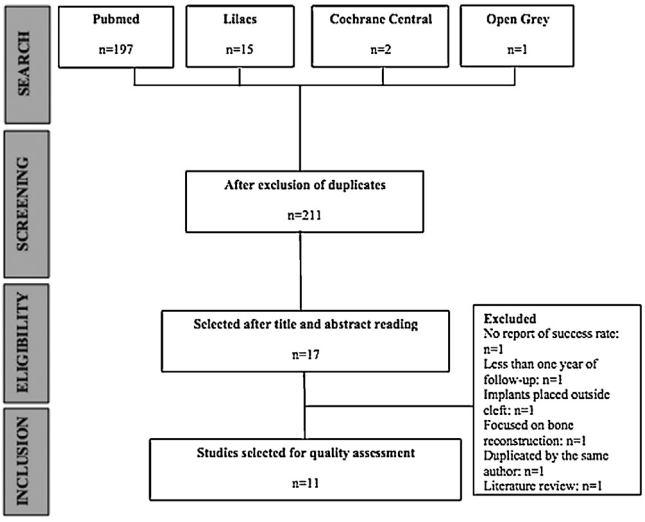

Fig. 1. Flowchart of the study selection process.

showed a very high risk of bias. These results are shown in Fig. 2.

Patients and implants

Eligible studies comprised a total of 361 patients with mean age of 20.6 years. A total of 483 implants were placed (mean of 1.34 implants per patient) and showed a survival rate of 93% after a mean follow-up of 60.5 months. Two hundred and seventy-three cases (76.3%) were of unilateral clefts and 85 cases (23.7%) were of bilateral clefts. Three cases were not identified in the literature. One article did not report how many men and women participated in the research[18] and one study[19], after participant exclusion, did not report the gender of the remaining patients. The other nine studies showed 54.4% of men and 45.6% of women.

Bone grafts

Only one study[20] quantified the bone graft donor sites; this article reported nine donations from the iliac bone and one donation from the mental region. However, considering only the origin of donor areas for cleft grafting, there were six reports for iliac bone[7,11,13,19–21], mandible[20,21], tibia and skullcap[11]. Four articles[9,10,12,17] did not report this information.

The use of additional grafts was reported for 55 occasions, being 67% from the iliac bone in four articles[7,12,18,19] and 18.2% from the mandible (15 occasions, with 10 of them specifically from the mental region). These additional grafts were reported in four articles[7,12,19,20]. Donor areas were also found for additional grafts from the mouth, tibia, ulna and lyophilized bone[11,18]; however, five articles[9,10,13,20,22] did not report or did not clarify the origin of the grafting material. Moreover, two articles[9,13] reported the use of additional grafting but did not specify the donor area. Additional grafting was placed before implant placement in most articles to fill the previously occurred bone loss[7,9,11,12,18,19]. Nevertheless, five studies did not report whether an additional bone graft was placed before, after or during implant placement[10,13,20–22].

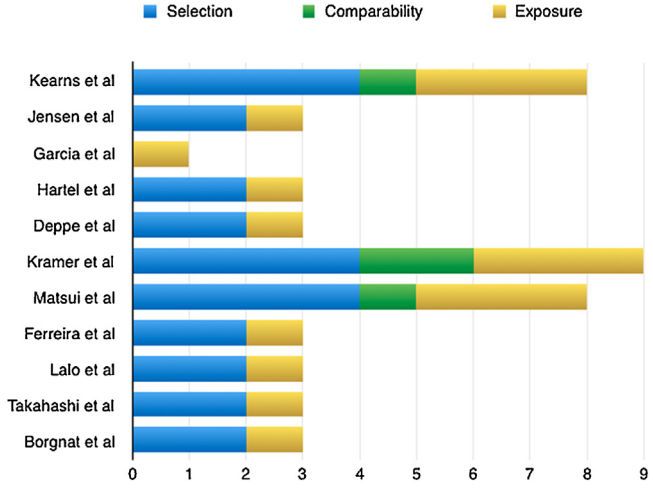

Fig. 2. Risk of bias and quality of studies through the Newcastle–Ottawa Scale.

Effectiveness of implants on different types of bone graft

Six studies did not report which donor site was used for implant osseointegration[9,10,12,13,17,19], comprising a total of 399 implants (82.6% of the total). Studies that did report the success rates on different types of bone graft (84 implants; 17.4% of total)[7,11,20,21,22], showed that 45 used iliac bone with two non-osseointegrated implants (4.44%; 2.4% of the total) and 29 used grafting from the mental region, also with two non-osseointegrated implants (6.9%; 2.4% of the total). Other donor sites such as tibia as well as the use of lyophilized bone graft were reported[10], showing 100% of osseointegration.

Time between implant placement and prosthetic loading

Most studies described a period of 6 months between implant placement and prosthetic loading[7,11–14,22]. One article described that the prosthetic loading occurred after 3 months (14 weeks), another article reported immediate or early prosthetic loading (13 days)[20], and three did not describe it[9,10,18].

Peri-implant bone loss

Only four articles reported peri-implant bone loss, however, it was expressed in different forms: means[12], minimum, mean and maximum[18], and using percentage of bone loss[19,20]. Only one study reported clinical attachment loss[18].

Considering the two articles[12,18] that reported the mean bone loss in millimetres, with a total of 79 individuals (21%) and 106 implants (21.7%), a mean bone loss of 2.75 mm was obtained; nevertheless, there were reports of bone losses up to 6 mm[18]. Two other articles[19,21] reported bone loss in percentages; still, their results were reported differently, which made it impractical to use data from different studies.

These data are shown in Table 1.

Table 1. Primary and secondary variables and study design of selected articles.

Author and year	Type of study	No. of patients	Gender	Mean age (years)	No. of implants	Type of cleft	Bone graft donor site	Additional bone graft and donor site	Follow-up (months)	Level of peri-implant bone loss	Loss of clinical attachment	Prosthesis installation after implant	Implant survival rate
Kearns, 1997	Retrospective	14	9 M/5 F	22.2	20	9 Un/5 Bi	Iliac	3 Iliac 3 Mental region	28.5	Not reported	Not reported	6 months	90%
Jensen, 1998	Retrospective	16	11 M/5 F	19	20	14 Un/2 Bi	Chin	Not reported	48	Not reported	Not reported	6 months	90%
Garcia et al., 2011	Retrospective	09	4 M/5 F	21.4	10	9 Un/0 Bi	9 Iliac 1 Chin	Not reported	58	Not reported	Not reported	9-Immediate 1–13 days	100%
Hartel et al., 1999	Retrospective	11	Not accounted after exclusions	17	17	8 Un/7 Bi	Iliac	7 Iliac 2 Mental region	28	4 with 2/3, 7 with 1/3, 2 with1/2 and 4 with 1/4	Not reported	3 months	94%
Deppe et al., 2004	Retrospective	32	Not reported	17	35	29 Un/3 Bi	Not reported	3 Iliac 6 Mouth	76	Min: 1.8 mm; max: 6.0 mm; mean: 3.5 mm	Min: 1.5 mm; max: 5.5 mm; mean: 2.9 mm	Not reported	86.2%
Kramer et al., 2005	Prospective	45	33 M/12 F	25.9	75	24 Un/21 Bi	Iliac	6 Cases, site not reported	66	Not reported	Not reported	6 months	82.2%
Matsui et al., 2007	Prospective	47	21 M/26 F	23.3	71	32 Un/15 Bi	Not reported	42 Iliac 5 Mandible	60	2 mm	Not reported	6 months	98.6%
De Barros Ferreira et al., 2010	Retrospective	120	55 M/65 F	21	123	106 Un/7 Bi	Not reported	Yes, but with no report of where and how many	26	Not reported	Not reported	Not reported	94.3%
Lalo et al., 2007	Retrospective	08	5 M/3 F	21.5	11	6 Un/2 Bi	Iliac, tibia, and skullcap	Tibia, ulna and lyophilized graft	66	Not reported	Not reported	6 months	100%
Takahashi et al., 2008	Retrospective	16	8 M/8 F	19.1	23	13 Un/3 Bi	Iliac	5 Mental region	103	10 with 25–50% 3 with 50–75% 3 with 0–25%	Not reported	6 months	90.9%
Borgnat et al., 2015	Retrospective	43	27 M/16 F	19	78	23 Un/20 Bi	Not reported	Not reported	106	Not reported	Not reported	Not reported	97.4%

Bi, bilateral; F, female; M, male; Un, unilateral.

Discussion

Oral rehabilitation with dental implants is a well-established reality in important healthcare centres for patients with alveolar clefts. Despite studies showing good survival rates for dental implants in these patients, there is a lack of studies with low risk of bias in the literature, which is addressed by the present study and by other reviews regarding the focused theme[15,16]. One may see a high risk of bias in several publications, which makes it impractical to obtain a robust scientific evidence.

Regarding survival rate of dental implants, eligible studies showed 93% of success, which corroborates similar results found in previous studies[15,16]. Only studies in which dental implants were placed in areas of bone grafting in patients with alveolar clefts were considered for analysis, regardless of bone graft donor sites. An adequate follow-up of at least 1 year is also fundamental. Thus, a couple of studies that were considered in other reviews were not included on the present study[23,24].

Although the analysis of the bone grafting used was not the primary outcome of the present study, we consider it an important topic to address on alveolar cleft reconstruction. Iliac bone was the most used donor site, probably because it is more well addressed in the literature and it shows more availability. This bone is compatible with several types of alveolar clefts and has abundant medullar bone, although it is associated with postoperative locomotion problems[6,25]. Nevertheless, two other donor areas were used and the mandibular symphysis stands out as a proper donor area for reconstruction with higher effectiveness than the iliac bone[26], although there are limitations regarding the availability of bone volume[27–30]; this leads to a need for additional bone grafting, which is stated in most studies. One must highlight that no eligible study used the Recombinant Bone Morphogenetic Protein 2 (RhBMP-2), which we believe to be an excellent option because it eliminates the need for a donor site, which decreases morbidity, complexity, and duration of surgery[31,32].

It is worth mentioning that the ideal analysis would be performed if the effectiveness of dental implants could be divided in groups regarding different bone graft donor sites, such as iliac, mental region or tibia. This is supported by the fact that these donor sites present different morphological structures as well as different embryological origins, which may influence the reconstructed area and, consequently, osseointegration. The present study intended to collect such data, however, eligible studies failed to report this item (about 82.4% of the sample). This shows the need for new primary studies with this endpoint, which would improve scientific evidence regarding this topic.

Additionally, four articles analysed peri-implant bone loss and clinical attachment loss[12,18,19,21], with similar data reported in the literature[16]. The small number of articles that analysed these outcomes attracts attention, because peri-implant clinical outcomes may indicate an early risk of implant loss.

Regarding statistical analysis, it was not possible to perform meta-analysis because only three[7,12,13] of the 11 eligible studies used control groups; however, the authors used different controls and assessed different outcomes, which made it impractical to perform any comparisons or to perform statistical analysis. This situation reveals the need for future researches to include control groups in order to compare the effectiveness of dental implants in areas of alveolar clefts with implants outside the alveolar cleft area.

It is of the utmost importance that future studies on the focused theme are performed with the highest methodological rigor to increase the level of scientific evidence and to reduce the risk of bias so that dental implants placed in areas of alveolar clefts present higher safety and predictability.

In conclusion, according to the best available evidence, there is a high survival rate of dental implants placed in areas of bone grafts in patients with alveolar clefts. However, there is a clear need for studies with high methodological quality and with a longer follow-up to find scientific evidence not yet verified, offering more safety for practitioners and patients regarding the placement of dental implants in areas of alveolar clefts with bone grafting.

Conflict of Interest

The authors declare that there was no conflict of interest.

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Patient Consent

Not Required.

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