Where is the Most Indicated Site for Extra-Oral Implants in the Orbit: A Systematic Review and Meta-Analysis

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Abstract

Purpose: To systematically review the current data to identify the best site for extra-oral implant placement in the orbit. Materials and Methods: Two independent reviewers performed a MEDLINE electronic search using PubMed and Web of Science databases to identify studies published in English from January 2005 until March 2017. A manual search was also performed for additional articles. The meta-analysis was based on the Mantel–Haenszel method. Results: The electronic search identified 173 studies, and the manual search revealed no additional studies (N=173). Two studies meet the eligibility criteria. A total of 271 implants was placed in the orbital rim, of which supra-orbital rim (N=134; 49.5%), infra-orbital rim (N=29; 10.7%), exhibited an implant survival of 73.9%, 72.4%, respectively. Quantitative analysis revealed no significant differences between supra and infra-orbital rims regarding implant failure (P=0.82). Conclusion: The systematic search resulted in the analysis of only two studies with short-term follow-ups and a reduced number of patients. The limited data collected indicates that there are no differences on both evaluated areas.

Key Words: Facial defects, Maxillofacial prostheses, Systematic review

Introduction

Facial defects can result from trauma, congenital disorders or surgical removal of malignant tumors [1-3]. Needles to say, patients who have such defects have their psychological condition, social behavior and quality of life negatively affected affects [1,2,4]. Fortunately, maxillofacial prostheses are a satisfactory method for treating the population with craniofacial defects when compared to irreversible surgical reconstructions [1,2,5]. However, retention is a main concerns with maxillofacial prostheses when conventional approaches are used (such as, skin adhesives, hard or soft tissue undercuts or eyeglasses), and it has been a constant challenge for clinicians and patients who undergo this method of rehabilitation [3,6].

Conventional methods for retention of maxillofacial prostheses are generally associated with patient's distress because such tools can easily result in prostheses debonding or detachment away from the skin depending on the intensity of their daily activities or involuntary movements [3,4,6]. An orbital implant may present more challenges than those in other areas because this is probably the region that is firstly observed by a third viewer. Besides, the anatomical profile of an orbital defect can accumulate body secretions which may result in skin secretions [1,2]. Furthermore, microorganism from skin may penetrate into the glue remnants of the prosthesis and negatively affect the color of prostheses [1,2]. Unfortunately, these factors decrease the overall life-span of the prosthesis [1,7].

Several studies have suggested that extra-oral implants are the clear-cut answer toward an appropriate retention of facial prostheses and became the contemporary approach for rehabilitation of orbital, auricular, nasal and multisite facial defects [1,2,8]. Unfortunately, complications vary according to the site of placement. The survival of extra-oral implants in the orbit (survival between 27%-75%) are lower and vary considerably more than at auricular region (≈95% survival) and nasal sites (survival between 71.4% to 100%) [1,2,8]. According to current published studies, the quality and volume of the bone, hygiene, radiotherapy and soft tissue thickness affect the success rates of the extra-oral oral implants [9-11]. Traditionally, 3 or 4 extra-oral implants are optimal in orbit region, being 1 or 2 in the lower lateral rim and 2 in de upper lateral rim. Medial rim are not the surgeon's first choice because this region goes toward the nose and the bone starts to be more thin and soft. In worst-case scenarios, ablative surgeries require extended margins for a safety and predictable tumor removal and avoid cancer recurrence. Therefore, the remaining anatomic profile may require surgeons to choose for the most optimal sites for implant placement.

Analysis of extra-oral implants survival rate is important to provide guidance for surgeons and prosthodontists in situations that clinicians have to choose on the best site for placement; and thus, preventing undesired problems (such as, loss of implant jeopardize) [1,2]. Moreover, information about their clinical performance is useful to provide clinicians and patients with realistic expectations about their rehabilitation treatment [1,2]. Therefore, the purpose of the present study is to systematically review the current data to identify the best site for extra-oral implant placement in the orbit. To the best of our knowledge, this is the first systematic review and meta-analysis evaluating extra-oral implant survival in the orbit according to differences regions. The null hypothesis was that there would be no significant differences regarding extraoral implant survival between supra-orbital and infra-orbital areas.

Materials and Methods

This systematic literature review was performed in accordance to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement [12,13]. The protocol for our study was registered in the International Prospective Register of Systematic Review (PROSPERO) database (registration number CRD42016035776), as required by

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PRISMA guidelines. This investigation was to determine the optimal site to place extra-oral implants in the orbit for implant-retained facial prostheses. This review question was based on the Population, Intervention, Comparison and Result (PICO) framework [14]. The definitions used were as follows: Population: Patients with orbit defects; Intervention: Population subjected to extraoral implants in the orbit; Comparison: Extra-oral implants installed in the supra- and infra-orbital rim, and; Outcomes: Implant survival.

The inclusion criteria is summarized as follows: studies published in English with at least 10 patients and studies that evaluated different sites for extra-oral implants in the orbit that displayed information about their survival. To eliminate bias in the search and results, duplicate studies, in vitro and in vivo basic and animal studies, case reports or case series and studies based on interviews or commentaries were excluded from our analysis. Two independent reviewers (A.J.V.F. and V.E.S.B.) performed a MEDLINE electronic search using PubMed and Web of Science databases to identify studies published in English from January 2005 until March 2017. The following association of medical subject headings (Mesh terms) and free-text terms were used: "orbit (Mesh) AND extraoral implants (free-text term)"; "orbit (Mesh) AND extraoral implants (free-text term) AND survival rate (Mesh)". A manual search of the following journals was also performed for articles published from January 2005 until March 2017: Journal of Prosthetic Dentistry, Journal of Oral Maxillofacial Surgery, and International Journal of Oral and Maxillofacial Surgery. After the full-text reading of the potential selected studies, their reference lists were also searched.

Initially, titles and abstracts of the identified studies were screened to determine which studies should be included in our final analysis. Any disagreement between the independent reviewers was resolved via a moderated discussion between the reviewers whereas the moderator was a third review author (M.C.G.). A data extraction form was created to collect information on the author(s), year of publication, study design, follow-up period, patient's gender and age, implant number, diameter and length, number of implants per site, irradiated patients, number of implant failures and survival (*Table 1*). The quality assessment of the methodology in the selected studies is summarized in *Table 2*. The selected studies were classified according to the Jadad scale [15]. This scale is an instrument composed of 5-point domains ranging from 0 to 5 to define the quality of the studies and assess the risk of bias through judgments of "Yes" or "No," which indicate a "low risk of bias" or a "high risk of bias," respectively. Studies classified with a score between 0 and 2 were considered to be "low quality," and studies classified with a score between 3 and 5 were considered to be "high quality."

Table 1. *Summary of the published data of the selected studies.*

Author (year)	Study design (follow-up in months)	Characteristics of patients OD (number, gender and age in years)	Implant number, diameter and length in orbit	No. of patients with OD		No. of implants per region (supra- and infra-orbital rim)	No. of failures (% of overall implant survival)
				Irradiated (mean Gy)	Non-irradiated		
Pekkan et al. [3]	Prospective, single center (mean: 60)	1 man	8 (Ø 3.3 mm/3.5mm)	2 (≈50 Gy)	0	SOR: 6	SOR: 1 (83.3)
		1 women	2 (Ø 3.3mm/5 mm)			IOR: 4	IOR: 1 (75)
		-50				AFS: NP	AFS: NP
						DFS: NP	DFS: NP
Toljanic et al. [18]	Retrospective, multi-center (mean: 52.6)	26 men	153 (NP)	NP	NP	SOR: 128	SOR: 34 (73.4)
		18 women				IOR: 25	IOR: 7 (72)
		-52				AFS: 19	AFS: 3 (84.2)
						DFS: 89	DFS: 21 (76.4)
OD = orbital defects; NP = information that were not provided; Ø = diameter of implants; Gy = grays; SOR = supra-orbital rim; IOR = infra-orbital rim; AFS = approximating frontal sinus; DFS = distant to frontal sinus.							
**It was not possible to obtain the information.							

Table 2. *Quality assessment of selected studies displayed according to year of publication.*

	Selected Studies	
	Toljanic et al. [18]	Pekkan et al. [3]
1. Was the study described as random?	No	No
2. Was the randomization scheme described and appropriate?	No	No
3. Was the study described as double-blind?	No	No

4. Was the method of double blinding appropriate?	No	No
5. Was there a description of dropouts and withdrawals?	Yes	No
Jadad scale	1	0
Quality of study	Low	Low

The meta-analysis was based on the Mantel–Haenszel method. Meta-analysis was performed to integrate the results from different studies included identified from the literature search, and the risk ratio (RR) was evaluated at a 95% confidence interval (CI), using a random-effects model to assess data from selected recent studies [16,17]. Only implant failures were analyzed for dichotomous outcomes, and only supra-orbital and infra-orbital rims (reported in the same study) were considered in this meta-analysis. The software Review Manager 5.3 (Cochrane Informatics and Knowledge Management Department) was used to generate a forest plot chart. The I2 quantity was included to express the heterogeneity across the included studies, with 25% corresponding to low-, 50% to moderate- and 75% to high heterogeneity.

Results

The electronic search identified 173 studies, and the manual search revealed no additional studies (N=173). After removing duplicate studies and after text from the remaining 13 manuscripts was read, there were 2 studies that met the eligibility criteria. *Table 1* lists general information for the selected studies. One study was prospective [3], and other retrospective [18]. The quality of study was low for both studies, according to the Jadad scale (*Table 2*), showing score 118 and 03. From the two included articles, a total of 46 patients were included, varying the age among 50 and 52 years (mean, 51 years). The follow-up period ranged from 52.6 to 60 months (mean, 56.3 months). A total of 271 implants were placed in the orbital rim. Regarding to area of implant placement, they were placed in supra-orbital rim (N=134; 49.5%), infra-orbital rim (N=29; 10.7%), approximating frontal sinus (N=19; 7%), distant to frontal sinus (N=89; 32.8%), exhibiting implant survival of 73.9%, 72.4%, 84.2%, 76.4%, respectively. The bar-clips and magnets were used to retain the prosthesis; however, the used retention system was reported only in one study3. Large variability was noted in the reported dose range of radiation delivered to sites of subsequent implant placement (range: 39.6-80.5 Gy) [3,18]. In this context, one study18 reported that no significant relationship was found between the subcategories of high-dose (≥50Gy) or low-dose (<50Gy) irradiation and implant survival (P=0.33).

Among the extracted data, it was possible to perform the comparison of two area of implant placement (*Figure 1*). Quantitative analysis revealed no significant differences between supra and infra-orbital rims regarding implant failure (P=.82; RR: 0.92; 95% CI: −0.48 to 1.80; I2: 0%).

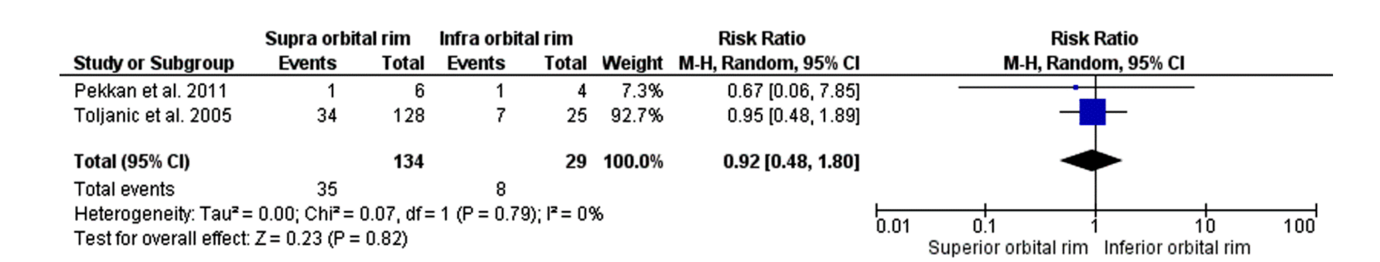

Figure 1. *Forest plot evaluating implant failure in supra-orbital and infra-orbital rims (P=0.82; RR: 0.92; 95% CI: −0.48 to 1.80; I2: 0%).*

Discussion

The meta-analysis was based on the Mantel–Haenszel method revealed no significant differences between supra-orbital and infra-orbital rims regarding extraoral implant failure. Therefore, null hypothesis was accepted.

In spite the quantitative analysis revealed no significant differences between both sites regarding implant failure, published clinical studies suggest that the survival of extra-oral implants varies according to the area of placement. For example, in the orbit survival ranges between 27%-75%, which is lower and vary considerably more than at auricular region (≈95% survival) and nasal sites (survival between 71.4% to 100%) [1,2,8]. Similar to what occurs in the oral cavity, A factor underlying this difference in survival rates may be attributed to the bone quality [4]. As revealed in a previous study, orbital bone is thinner and denser than other areas and radiotherapy may have more destructive effect on the vascularity of the orbit [4]. Unfortunately, no study did not directly compared different sites of the orbit but the mentioned hypotheses may explain why supra-orbital rim (49,5%) and infra-orbital rim (10.7%) survival differ. Interestingly, one selected study [18] reported that no significant relationship was found between the subcategories of high-dose (≥50Gy) or low-dose (<50Gy) irradiation and implant survival (P=0.33).

The irradiation factor should be more investigated in further studies because patients with advanced tumor stages, ablative surgeries require extended margins and radiotherapy is commonly associated in patients' treatment [1,2,8,9-11]. As a consequence of the tumor ablation, the remaining anatomic profile may require surgeons to choose for the most optimal sites for implant placement. Traditionally, 3 or 4 extra-oral implants are optimal in orbit region, being 1 or 2 in the lower lateral rim and 2 in de upper lateral rim. Infra-orbital rim approximating from the nasal cavity are not the surgeon's first choice because bone starts to be more thin and soft [4]. Thus, the authors of the present study risk to say that the influence of bone quality and irradiation are the most urgent factors to be investigated because these information could provide clear-cut answers to surgeons and maxillofacial prosthodontists about the possibility or not of rehabilitating patients with implant-retained.

One of the most challenging situations found in the present study was the low number of clinical studies with high bias level evaluating the most optimal area for the placement of extraoral implants in orbit. In spite the eligibility criteria used in the present systematic review have revealed clinical studies, the current published data was of low credibility and poor scientific relevance, highlighting the need for more studies about this topic. In fact, the selected studies did not have the comparison of implant survival in supra and infra orbital rims as their main purpose, but displayed such information. Therefore, the meta-analysis here presented should be carefully extrapolated to the clinical practice, before the clinical application.

Based on the findings from the articles included in this systematic review, it is not possible to identify the most optimal area for extraoral implants in orbit. Therefore, more randomized clinical trials (RCTs) comparing the implant survival in supra-orbital and infra-orbital rims in irradiated patients or not, are necessary. In addition, no information about implant surface treatment was founded. Similar to intraoral implants, modifying the surface characteristics of extraoral implants might improve implant survival and help maxillofacial prosthodontists and surgeons to improve the clinical performance of implant-retained prostheses head and neck cancer patients [4]. Finally, it is important to highlight that unexpected failures might occur even considering all the above recommendations because of some uncontrollable factors such as hygiene and soft tissue thickness. Therefore, such factors should also being considered in patients' treatment planning.

Conclusion

The systematic search for clinical studies that compared the survival of extraoral implants on supra-orbital and infra-orbital rims resulted in the analysis of only two studies with short-term follow-ups and a reduced number of patients. When choosing to rehabilitate patients with orbital defects with extraoral implants, the limited data collected indicates that there are no differences on both evaluated areas. However, information regarding irradiation is almost absent and should be considered in further studies.

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