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REVIEW ARTICLE

Patient-reported outcomes in patients with severe maxillary bone atrophy restored with zygomatic implant-supported complete dental prostheses: a systematic review

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ABSTRACT

Introduction and Objective: Zygomatic implants (ZI) offer a good and predictable alternative to reconstructive procedures of atrophic maxillae. The main objetive of this systematic review was to assess the effect of rehabilitation with zygomatic implants on patient's quality of life (QLP) using Patient Reported Outcomes Measures (PROMs).

Materials and Methods: This review followed PRISMA guidelines. An automated electronic search was conducted in four databases supplemented by a manual search for relevant articles published until the end of January 2021. The Cochrane Collaboration Risk of Bias tool and the Newcastle-Ottawa Quality Assessment Scale were used to assess the quality of evidence in the studies reviewed.

Results: General findings of this systematic review showed substantial increases in Oral health-related quality of life (OHRQoL) among patients restored with ZI and high scores in terms of general satisfaction, especially in chewing ability and esthetics. An overall survival rate of ZI was 98.3% after a mean follow-up time of 46.5 months was observed. Occurrence of 13.1% biological complications and 1.8% technical complications were reported.

Conclusions: Patients rehabilitated with zygomatic implant-supported complete dental prostheses showed substantial improvements in OHRQoL and general satisfaction with the treatment received.

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KEYWORDS
Zygomatic implants; patient-reported outcomes measures; quality of life; patient satisfaction; systematic review

Introduction

Tooth loss is followed by resorption of the alveolar ridge and many studies have shown that 50% of the alveolar width is reabsorbed within the first 12 months, corresponding to an average of 5–7 mm. A reduction in the vertical dimension can also be expected, ranging from 11 to 22% (1.24 ± 0.11 mm) on the buccal side [1–3]. But this reduction of the alveolar process may be triggered by other factors besides tooth extraction, which includes periodontal disease, periapical pathology, and dental or osseous injuries. Moreover, the alveolar process may deteriorate due to local and systemic factors emanating from the patient her/himself [4].

Such factors may lead to severe atrophic situations in which rehabilitation with dental implants (DI) becomes a challenge. Commonly, atrophic maxillae require reconstructive procedures, such as bone grafting [5] or sinus floor elevation, which increase morbidity, treatment time, and surgical risk and also compromise the patient's quality of life (PQL) [6]. Moreover, it is well-known that edentulism causes functional, nutritional, and social alterations, which also reduce PQL [7].

To overcome this difficulty, zygomatic implants (ZI) offer a good and predictable alternative to reconstructive procedures, reducing treatment time. In most cases, implants can be loaded immediately, which will improve PQL directly [8].

According to the VIII European Workshop on Periodontology in 2012, Patient Reported Outcome Measures (PROMs) are defined as subjective reports of the perceptions that patients have about their oral health status and its impact on daily life and quality of life. PROMs also include outcomes regarding the patient's satisfaction with her/his state of oral health, oral health care, and other non-clinical evaluations [9].

Oral health-related quality of life (OHQoL) and satisfaction are the most commonly used PROMs in Dentistry [10]. OHRQoL is evaluated usually by the Oral Health Impact Profile-49 (OHIP-49), but also with other questionnaires, such as an abbreviated generic tool (OHIP-14) and a disease-specific tool (OHIP-EDENT) [11,12]. In some situations, Visual Analog Scales (VAS) and/or subjective self-administrated questionnaires with subjective perceptions of prosthesis retention and stability, comfort, chewing ability, and aesthetics are used to assess patient satisfaction [10].

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Several systematic reviews have analyzed PROMs results after dental implant placement [13–15], finding significant improvements in OHRQoL when comparing QLP before and after implant treatment. Clinical studies comparing conventional implant placement and zygomatic implants have been also carried out using PROMs to evaluate patients' satisfaction with treatment [16,17], obtaining positive results for both treatments.

Nevertheless, the PROMs methods used to evaluate outcomes in patients rehabilitated with zygomatic implants are heterogeneous and lack standardization [18–20]. Therefore, an analysis of the evidence on this topic is needed.

To our knowledge, no previous systematic review has analyzed PROMs data in patients rehabilitated with zygomatic implants. Therefore, the aim of this systematic review was to analyze PROMs in patients rehabilitated with zygomatic implant-supported complete dental prostheses (ZISCDP).

Materials and methods

Review development and focussed question

This systematic review was carried out according to Preferred Reporting Items for Systematic Reviews and Meta-Analysis Protocols (PRISMA-P) recommendations [21]. The following focussed PICO (population, intervention, comparison, and outcome) question was formulated:

'In edentulous patients with maxillary atrophy (P) rehabilitated with zygomatic implants supported complete dental prosthesis (I) compared, if possible, with rehabilitation with conventional dental implants (C), what is the impact of oral rehabilitation measured using different patient-reported outcome measures? (O).'

Eligibility criteria

Inclusion criteria

Inclusion criteria were: (1) human clinical studies including randomized controlled trials, controlled trials, prospective studies, retrospective studies, and case series; (2) edentulous patients rehabilitated with ZI; (3) patients rehabilitated with fixed and removable implant-supported prostheses; (4) outcome variables evaluated by PROMs (validated questionnaires); (5) number of patients $\geq$10; (6) follow-up period $\geq$1 year; (7) no restriction on publication date; (8) articles written in English, or Spanish.

Studies were selected whenever the interventions performed aimed to rehabilitate edentulous patients using ZISCDP. The selected studies compared ZISCDP with rehabilitation performed by DI. PROMs data were used to assess the effect on QLP of these procedures.

Exclusion criteria

Exclusion criteria were: (1) *in vitro* and animal studies, review articles, technical notes, and case reports; (2) patients rehabilitated with combined tooth/implant-supported prostheses; (3) PROMs evaluation in oncologic and cleft palate patients; (4) full text unavailable; (5) studies written in a language other than English or Spanish.

Assessed outcomes and term definitions

The PROMs are 'subjective' reports of the perceptions that patients have about their oral health status and the impact of it on daily life and their quality of life. Also included are reports of satisfaction in the state of oral health and oral health care and other non-clinical evaluations. In the present systematic review, the term PROMs was used to define the Oral Health of Life parameters measurements using zygomatic implants rehabilitation treatment satisfaction evaluation.

The primary outcome of the review was to assess the effect of oral rehabilitation with ZI on PQL using PROMs.

As secondary outcomes the following parameters were also evaluated: (1) PROMs comparison between patients rehabilitated with ZI and DI; (2) PROMs differences before and after treatment with ZI; (3) PROMs comparison between immediate and delayed loading; (4) PROMs comparison between patients rehabilitated with fixed and removable prostheses; (5) survival rate of the ZI placed; (6) biological and technical complications.

Sources and search strategy

An electronic search was conducted for articles published until 23 September 2021 without any restriction placed on publication date or language in four databases: (1) The National Library of Medicine (MEDLINE/PubMed) *via* Ovid; (2) Web of Science (WOS); (3) SCOPUS; and (4) Cochrane Central Register of Controlled Trials (CENTRAL). Two independent researchers (LMSA, AFL) conducted the search. The search strategy (adapted to each database) was as follows: ((zygomatic[All Fields] AND implants[All Fields]) OR (('zygoma'[MeSH Terms] OR 'zygoma'[All Fields]) AND implants[All Fields])) AND (('quality of life'[MeSH Terms] OR ('quality'[All Fields] AND 'life'[All Fields]) OR 'quality of life'[All Fields]) OR ('patient reported outcome measures'[MeSH Terms] OR ('patient'[All Fields] AND 'reported'[All Fields] AND 'outcome'[All Fields] AND 'measures'[All Fields]) OR 'patient reported outcome measures'[All Fields] OR ('patient'[All Fields] AND 'reported'[All Fields] AND 'outcomes'[All Fields]) OR 'patient reported outcomes'[All Fields]) OR ('patient satisfaction'[MeSH Terms] OR ('patient'[All Fields] AND 'satisfaction'[All Fields]) OR 'patient satisfaction'[All Fields])).

An additional manual search was performed in relevant Oral & Maxillofacial Surgery and Implant Dentistry journals as well as in the reference sections of the studies selected for review.

Data collection

After the initial electronic search, the studies were screened by the title appearing in each database by two independent reviewers (LMSA and AFL); inter-reviewer reliability was estimated by the Kappa correlation coefficient.

Inter-reviewer reliability (percentage of agreement and kappa correlation coefficient) was calculated for the initial selection process and after full-text analysis.

After duplicates and triplicates were removed, the titles and abstracts of the remaining articles were checked for adequacy, and irrelevant studies were excluded. Any disagreement in study selection was resolved by discussion with a third reviewer (JCBB). Data from each selected article was collected by the reviewers (LMSA and AFL) working together and entered on an Excel spreadsheet (Version 15.17, Microsoft Inc. 2015), recording the following parameters: authors, year of publication, study design, sample characteristics, surgical technique, intervention studied, number and brand of implants, follow-up period, type of prosthetic restoration, type of PROMs, PROMs evaluation method, results, survival rate of ZI placed, any biological and technical complications.

Risk of bias analysis

After the electronic and the manual search, the articles were analyzed by levels of evidence according to the Oxford Centre for Evidence-Based Medicine (OCEBM) from level '1' to level '5' [22].

The methodological quality of the selected studies was evaluated by two independent reviewers (LSL and FPG). Any disagreement in quality assessment was solved by a discussion with a third reviewer (JCBB).

The Cochrane Collaboration Risk of Bias tool [23] was used to perform quality assessment of randomized controlled trials (RCTs). The studies were classified as at low risk of bias (low risk of bias in all key domains), unclear risk of bias (unclear risk of bias in one or more key domains), or high risk of bias (high risk of bias in one or more key domains). The Newcastle-Ottawa Quality Assessment Scale tool was used for observational studies [24]. According to this scale, the studies were classified as good, fair, or poor quality (GQ, FQ, or PQ) following the scoring algorithm proposed by the Agency for Healthcare Research and Quality [25].

In addition, publication bias was determined visually through funnel plots generated with Stata 15 software.

Results

Inter-reviewer agreement

The inter-reviewer Kappa statistic between the two independent reviewers (LMSA and AFL) was 0.979 (95% CI: 0.986/0.972) for the title and abstract selection and 0.981 (CI 95%: 0.983/0.978) for full-text inclusion/exclusion assessment. Therefore, an inter-reviewer agreement was considered almost perfect. The intervention of a third reviewer for consensus purposes was not needed.

Study selection

The initial search yielded 752 articles, 198 after discarding duplicates and triplicates. After screening titles and abstracts, 122 articles were excluded: 108 studies for not being related to zygomatic implants, 13 because they were not written in English or Spanish, and one article because the abstract was not available. After reading the full text of the 76 selected articles, 64 were discarded for the following reasons: the studies did not include PROMs data ($n = 20$); studies had follow-up periods of <1 year ($n = 15$); studies had samples <10 patients ($n = 9$); they were case reports ($n = 7$); studies investigated oncologic or cleft palate patients ($n = 10$); they were reviews ($n = 3$). Finally, 12 articles were included in this systematic review (Figure 1).

Study characteristics

The selected studies included: one multicenter randomized controlled clinical trial ($n = 1$); one comparative clinical study ($n = 1$); prospective studies ($n = 4$); and retrospective studies ($n = 6$). All were published between 2006 and 2018. The studies were carried out in different countries: Brazil, Spain, Italy, and Turkey. All were published in Dentistry journals specializing in oral and maxillofacial surgery, implant dentistry, and prosthodontics.

The studies included a total of 306 patients, treated with 1595 implants. The characteristics of the studies, patients, and implants placed are shown in Table 1.

Of the 1595 implants placed, 628 were zygomatic implants (ZI) and 993 were conventional dental implants (DI). Several implant brands were used (Table 1).

Regarding the surgical techniques used for ZI placement, in three studies ZI was placed following the intrasinusal technique [20,26,27]; in four studies Stella and Warners' technique was performed [17,18,28,29]; in four studies ZI were placed both intrasinusally and extrasinusally [16,19,30,31]; one study did not describe the technique used [6]. Conventional drilling was used to place the ZI in all the studies, with the exception of Mozzatti et al. [31], in which ultrasonic technique was used to create the ZI beds.

Concerning the types of rehabilitation, the results reported 264 implants fixed complete dentures (IFCDs) and 13 implant-supported overdentures (IODs). In the study by Rodriguez-Chessa et al. [29] the type of rehabilitation was not mentioned. Among all the studies, immediate loading was performed in 108 patients while delayed loading was performed in 198 patients. For both groups, definitive prostheses were installed 2–11 months after implant placement.

The longest follow-up period was 10 years [20], while the shortest follow-up was 12 months [6,16,17,28].

With respect to the types of PROMs method used, seven studies analyzed PROMs through VAS scales [17,18,26–30]; two studies used the OHIP-14 questionnaire [16,19]; one study used the OHIP-EDENT [20]; one study evaluated PROMs through the Pjetursoon et al. scale [31]; and one study applied a personalized questionnaire [6].

Regarding the other secondary outcomes assessed, three studies analyzed PROMs differences between patients rehabilitated with ZI and patients rehabilitated with DI [16–18]; two studies evaluated PROMs differences before and after treatment with ZI [16,27]; differences in PROMs between

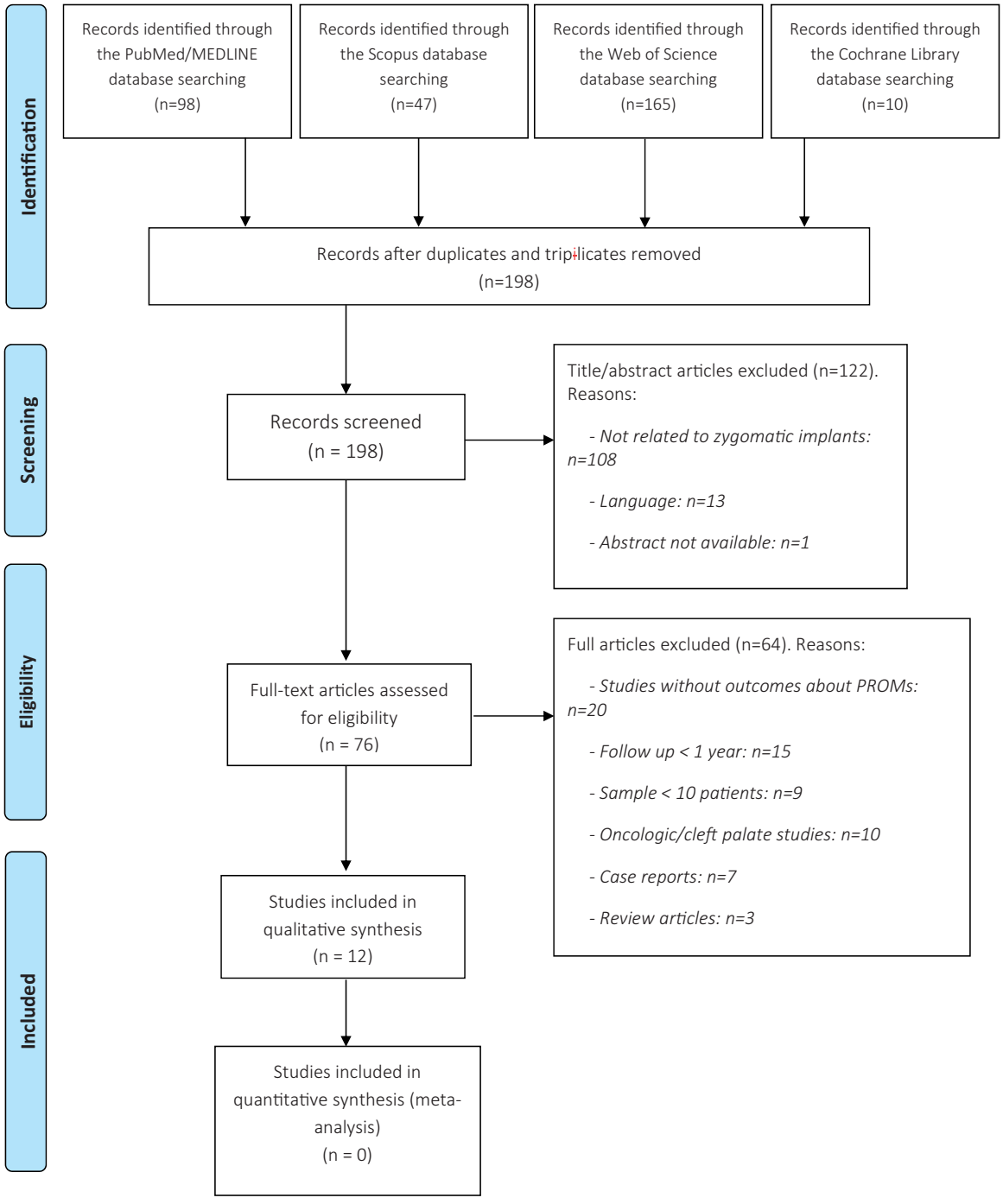

Figure 1. Flow chart with the search and selection process.

immediate and delayed loading was only recorded in one of the studies [16]; one of the studies registered differences in PROMs between patients rehabilitated with IFCDs and IODs [26].

The overall survival rate of ZI was 98.3% after a mean follow-up time of 46.5 months was observed among the included studies.

Results of individual studies (Table 2)

Level of satisfaction

Seven studies registered levels of satisfaction using VAS scales [17,18,26–30]. Considering the comparison between zygomatic and conventional implants, two of the seven studies compared differences in satisfaction between ZI and DI [17,18]. Araujo et al. [18] found significant differences (SD) between groups for all items in favour of rehabilitation with DI, while Peñarrocha et al. [17] registered higher scores in all items in the ZI group, only finding a significant difference in aesthetics (9.8 ZI group *vs.* 8.8 DI group, $p < .05$).

Levels of satisfaction before and after treatment were only recorded in one of the studies [26] in which significantly higher scores were found in chewing ability and aesthetics after treatment. Atalay et al. [26] evaluated PROMs using a VAS between patients rehabilitated with IFCDs and IODs. Results showed significant differences in favour of IFCDs in

Table 1. Information about selected studies including type of study, sample size, employed surgical technique, number and brand of implants, implant survival rate, follow-up time, surgical and mechanical complications and Oxford scale.

Author/year	Study design and LE (Oxford Scale)	Sample (*n*, sex, age)	Surgical technique	Intervention studied	Number and brand of IOI	Follow up	Survival rate	Surgical complications	Mechanical complications
Aparicio et al., 2014 [20] School of Medicine, University of Barcelona, Spain	Prospective cohort study IIb	– 22 patients (8 male, 14 female) – 48–80 years (Mean 63)	Intrasinusal	– No IL – 2nd stage 5–6 months after IOI placement	41 ZI (Nobel Biocare) 131 DI (Nobel Biocare)	10 years	ZI: 95.12% DI: 97.71%	6 acute sinusitis 6 facial haematoma 6 infraorbital paresthaesia 1 oroantral communication 2 ZI failure to extreme peri-implant infection 3 DI fail of osseointegration (90% of these complications occurred in 2 patients)	1 metal framework fracture 4 screw loosening 4 screw fracture 5 ceramic coating material fracture 2 resin coating material fracture 4 uncomfortable bulky prostheses (74% of these complications occurred in 5 patients)
Araujo et al., 2016 [18] Oral-Maxillofacial Surgery and Traumatology Sector, Onofre Lopes Univesity Hospital, Petrópolis, Brazil	Retrospective cohort study III	– 28 patients (7 males, 21 females) – 46–63 years (mean NA)	Stella and Warner technique	– Group I: 14 patients treated with ZI + DI – Group II: 14 patients treated with DI – No IL – 2nd stage 6 months after IOI placement	27 ZI (Conexão Implants) 55 DI (Conexão Implants)	15–53 months (Mean 34)	ZI: 100% DI: 100%	No complications (0%)	NM
Atalay et al., 2017 [26] Department of Oral and Maxillofacial Surgery, Istanbul University, Turkey	Retrospective cohort study III	– 16 patients (8 males, 8 females) – 23–68 years (mean 53 ± 12)	Intrasinusal	– No IL – 2nd stage 2 months after IOI placement	32 ZI (Nobel Biocare) 38 DI (Nobel Biocare and Straumann)	6–96 months (Mean 28)	ZI: 93.7%	2 ZI fail of osseointegration 1 mucositis (9.3%)	1 screw fracture (3%)
Davó et al., 2015 [19] Department of Implantology and Maxillofacial Surgery at Medimar International Hospital, Alicante, Spain	Prospective cohort study IIb	– 17 patients (7 males, 10 females) – 41–78 years (Mean 57.7)	Intrasinusal	– No IL – 2nd stage 6 months after IOI placement	68 ZI (Nobel Biocare)	5 years	NM	1 orbital haematoma 1 fistula at ZI 2 sinusitis	1 screw fracture 1 ceramic coating material fracture 1 resin coating material fracture
Davó et al., 2018 [16] Hospital Clinic in Barcelona, Spain Sant'Orsola Malpighi Polycliic in Bologna, Italy San Filippo Neri Hospital in Rome, Italy	Multicentre RCT Ib	– 71 patients (32 males, 39 females) – 36–74 years (Mean 57.94)	Intrasinusal Extrasinusal	Group 1: 35 patients with IL in ZI (definitive prostheses 4 months later) Group 1: 36 patients with DI placed 6 months after ridge augmentation (definitive prostheses 4 months later)	141 ZI 238 DI (Brand NA)	12 months	ZI: 100% DI: 100%	Group 1 (ZI): – 4 ZI fail of osseointegration – 4 sinusitis, 4 chronic fistula, 3 mayor infraorbital swelling, 1 headache, 1 dehiscence. Group 2 (DI): – 35 DI fail of osseointegration	Group 1(ZI): – 1 prosthesis failure due to ZI fail of osseointegration – 1 screw fracture – 1 resin coating material fracture Group 2 (DI): – 6 prostheses failure due to DI fail of osseointegration
Farzad et al., 2006 [27] Dpt Oral and Maxillofacial Surgery at Central Hospital, Västeras, Sweden	Prospective cohort study IIb	– 11 patients (1 male, 10 females) – 41–72 years (mean NA)	Intrasinusal	– No IL – 2nd stage 6–11 months after IOI placement	22 ZI (Nobel Biocare) 42 DI (Nobel Biocare)	18–46 months	ZI: 100% DI: 97.7%	3 sinusitis 1 DI fail of osseointegration 12 ZI and 12 DI moderate inflammation 2 ZI and 1 DI severe inflammation	NM
Lombardo et al., 2019 [30] Section of Dentistry and Maxillofacial Surgery, University of Verona, Italy	Retrospective clinical study III	– 20 patients (sex NA) – 26–86 years (62.6 mean)	Intrasinusal Extrasinusal	– IL – Definitive prostheses 6 months after IOI placement	65 ZI (Brand NA)	18.05 ± 17.23 months	98.5%	1 ZI fail of osseointegration	No complications
Mozzatti et al., 2015 [31] Private Dental Office, Torino, Italy	Prospective clinical study IIb	– 10 patients (sex NA) – 41–67 years (Mean 51.2)	Ultrasonic technique Extrasinusal (12) Intrasinusal (28)	– IL – Definitive prostheses 6 months after IOI placement	40 ZI (Nobel Biocare)	30–32 months	100%	1 discomfort due lack of keratinized gingiva	1 fracture of provisional prosthesis
Pellicer-Chover et al., 2016 [28] Oral Surgery and Implant Dentistry Division, University of Valencia, Spain	Retrospective clinical study III	– 20 patients (10 males, 10 females) – 31–77 years (mean 54)	Stella and Warner technique	– No IL – 2nd stage 3 months after IOI placement	44 ZI (Nobel Biocare) 94 DI (Brand NA)	12 months	ZI: 97.7% DI: 97.8%	1 ZI fail of osseointegration 2 DI fail of osseointegration	No complications

(*continued*)

Table 1. Continued.

Author/year	Study design and LE (Oxford Scale)	Sample (*n*, sex, age)	Surgical technique	Intervention studied	Number and brand of IOI	Follow up	Survival rate	Surgical complications	Mechanical complications
Peñarrocha et al., 2007 [17] Oral surgery and Implantology Program, Valencia University Medical and Dental School, Spain	Comparative clinical study IIb	– 46 patients (26 women 20 men) – 31–77 years (Mean 53)	Stella and Warner technique	– Group 1: Zygomatic group (23 patients with at least 1 ZI) – Group 2: non-zygomatic group (23 patients with only DI) – No IL – 2nd stage 2 months after IOI placement	44 ZI (Nobel Biocare) 277 DI (Impladent and Straumann)	12 months	NM	Group 1 (ZI): – 1 ZI fail of osseointegration – 1 pterigoid implant fail of osseointegration – 1 DI fail of osseointegration Group 2 (DI): – 1 DI fail of osseointegration	Group 1 (ZI): – 1 recurrent documentation Group 1 (DI): – 2 recurrent documentation – 1 ceramic coating material fracture
Rodríguez-Chessa et al., 2014 [29] Piracicaba Dental School, State University of Campinas, Brazil	Retrospective clinical study III	– 29 patients (18 women and 11 men) – 35–69 years (mean NA)	Stella and Warner technique	– 10 cases IL – 19 cases no IL – Definitive prostheses 6.7 ± 3.5 months after IOI placement	67 ZI (Conexão Implants) 84 DI (Conexão Implants)	10–40 months (mean 20 ± 17.23 months)	79.1%	8 ZI and DI fail of osseointegration 4 sinusitis 4 mucositis 3 persistent pain 2 externalization of ZI (31.1%)	NM
Sartori et al., 2012 [6] Latin American Institute of Dental Research and Education, Curitiba, Brazil	Prospective clinical study IIb	– 16 patients (10 women and 6 men) – 38–77 years (mean NA)	NA	– IL – Definitive prostheses loading NA	– 37 ZI (Neodent) – 58 DI (Neodent)	12 months	100%	Post-operative headache (n NA) Infraorbital paresthesia (n NA) Gingival hyperplasia surrounding ZI (n NA)	Screw loosening (n NA) Screw fracture (n NA) Coating material fracture (n NA) Need for relining (n NA)

DI: conventional dental implants; IOI: implants; IL: immediate loading; LE: level of evidence; NA: not available; NM: not mentioned; ZI: zygomatic Implants.

chewing performance, prosthesis stability, and phonetics and significant differences in favour of IODs in levels of hygiene. In two studies [28,30], high scores were found for phonetics, functionality, and aesthetics, whereas the lowest results were found in the article by Rodriguez-Chessa et al. [29] (see Table 2).

OHRQoL evaluated through OHIP-14

The multicenter RCT carried out by Davó et al. [16] evaluated differences in patients rehabilitated with ZI with immediate loading and patients with DI with delayed loading. The OHIP-14 applied after one year of follow-up showed similar results between groups. Moreover, both ZI and DI groups obtained significantly improved OHIP-14 scores compared with results before rehabilitation ($p < .001^*$). Significant differences were found in favour of ZI in terms of days of infirmity and days passed before receiving a functional prosthesis. One of the studies with a longer follow-up period [19] showed a mean OHIP-14 score of 3.8 at 5 years, a very positive result.

OHRQoL evaluated through other questionnaires

The study reporting the best long-term results in terms of PROMs was published by Aparicio et al. [20] By using the OHIP-EDENT scale, results showed that 80% of patients were satisfied with the overall treatment.

Mozzatti et al. used the Pjetursoon et al. scale [31] after performing immediate loading and ZI placed with an ultrasonic device. They found a significant increase ($p = .002^*$) in satisfaction when comparing 3- and 6-month follow-up evaluations after implant placement; 96.7% of patients were satisfied with treatment.

The study by Sartori et al. [6] used an individual and personalized questionnaire to evaluate satisfaction with treatment, reasons for dissatisfaction, complications, and the number of clinical sessions required to solve them. Half the patients were completely satisfied and the other half were satisfied but with some complaints about the prostheses or implants. Reasons for dissatisfaction, the number of clinical sessions, and the sources of complications are shown in Table 2.

ZI survival rate

Calculation of the overall ZI survival rate in the studies reviewed excluded the study by Rodriguez-Chessa et al. [29] because of its high heterogeneity compared with the other studies. Statistical heterogeneity was not detected [Cochran's Q ($df = 11$) $= 3.52$, p (value) $= .982$, $I^2 = 0.005\%$], so a fixed-effect model was chosen.

Complications (Table 1)

Among the 628 ZI placed in the studies, a total of 82 biological complications were registered (13.06%). The most frequent complication observed in 19 cases was mucositis (3%), followed by 16 cases of sinusitis (2.5%) and 15 ZI failures (2.4%). In addition, the studies reported seven orbital

Table 2. Information about selected studies including author/year, type of rehabilitation, type of employed PROMs questionnaire/scale, characteristics of evaluation methods and results of individual studies.

Author/year	Type of rehabilitation	Type of PROMs	PROMs evaluation method	Results
Aparicio et al., 2014 [20] School of Medicine. University of Barcelona, Spain	– 22 IFCD	OHIP-EDENT	19 items measuring satisfaction, ability/lack of ability to communicate, discomfort, instability of the dentures, aesthetics, pleasure when eating, level of comfort and self-assurance (code = 0–4)	80% reported being satisfied with the treatment 31, 82% reported the maximum satisfaction score (100%)
Araujo et al., 2016 [18] Oral-Maxillofacial Surgery and Traumatology Sector, Onofre Lopes Univesity Hospital, Petrópolis, Brazil	– 28 IFCD	VAS scale	7 items measuring prosthetic treatment process, aesthetics, performance when chewing, stability of prosthesis, phonetics, level of hygiene, general satisfaction (code = 0–10)	SD difference between groups in all items for group rehabilitated with DI.
Atalay et al., 2017 [26] Department of Oral and Maxillofacial Surgery, Istanbul University, Turkey	– 10 IFCD – 6 IOD	VAS scale	7 items measuring prosthetic treatment process, aesthetics, performance when chewing, stability of prosthesis, phonetics, level of hygiene, general satisfaction (code = 0–10)	– SD for IFCD *vs.* IOD in performance when chewing, stability and phonetics. – SD for IOD *vs.* IFCD in level of hygiene. – No SD in prosthetic treatment process, aesthetics and general satisfaction between groups.
Davó et al., 2015 [19] Dpt of Implantology and Maxillofacial Surgery at Medimar International Hospital, Alicante, Spain	– 15 IFCD	OHIP-14 questionnaire	14 items measuring seven different dimensions including functional, psychological and social aspects (code = 0–4)	Mean OHIP-14 score at: – 1 year: 3.4 – 3 years: 2.5 – 5 years: 3.8
Davó et al., 2018 [16] – Hospital Clinic in Barcelona, Spain. – Sant'Orsola Malpighi Polycliic in Bologna, Italy. – San Filippo Neri Hospital in Rome, Italy.	– 71 IFCD	OHIP-14	14 items measuring seven different dimensions including functional, psychological and social aspects (code = 0–4)	(a) 1-year OHIP-14: – Group 1: 3.97 ± 4.32 – Group 2: 3.93 ± 5.86 – $p = .747$ (b) Both groups had significantly improved OHIP-14 scores from before rehabilitation ($p < .001^*$ for both augmented and zygomatic patients) (c) Days of partial infirmity: – Group 1: 12.17 ± 3.82 – Group 2: 14.24 ± 4.64 – $p = .048^*$ (d) Days needed to have functional prosthesis: – Group 1: 1.34 ± 2.27 – Group 2: 444.32 ± 207.86 – $p < .001^*$
Farzad et al., 2006 [27] Dpt Oral and Maxillofacial Surgery at Central Hospital, Västeras, Sweden	– 11 IFCD	VAS scale	7 items measuring prosthetic treatment process, aesthetics, performance when chewing, stability of prosthesis, phonetics, level of hygiene, general satisfaction (code = 0–10)	Statistically significant differences ($p < .05$) were found in chewing ability and aesthetics before and after treatment.
Lombardo et al., 2016 [30] Section of Dentistry and Maxillofacial Surgery, University of Verona, Italy	– 13 IFCD – 7 IOD	VAS scale	7 items measuring prosthetic treatment process, aesthetics, performance when chewing, stability of prosthesis, phonetics, level of hygiene, general satisfaction (code = 0–10)	Significant improvement in speech, chewing ability, and aesthetics. Mean VAS score: • Chewing: 9.70 • Aesthetics: 9.70 • Phonetics: 9.20
Mozzatti et al., 2015 [31] Private Dental Office, Torino, Italy	– 10 IFCD	Pjetursoon et al. scale	9 items evaluating function and chewing comfort, phonetics, aesthetics, oral hygiene and general satisfaction (code –20 to +20)	9.7 ± 6.1 at 3 months 17.1 ± 1.9 at 6 months ($p = .002$) between3 and 6 months 96.7% of satisfied patients 77.8% highly satisfied patients
Pellicer-Chover et al., 2016 [28] Oral Surgery and Implant Dentistry Division, University of Valencia, Spain	– 20 IFCD	VAS scale	7 items measuring prosthetic treatment process, aesthetics, performance when chewing, stability of prosthesis, phonetics, level of hygiene, general satisfaction (code = 0–10)	Overall satisfaction 9.45 out of 10 (9.68 for comfort-stability, 9.36 for speech, and 9.64 for functionality) All patients gave scores of 7 or higher.

(*continued*)

Table 2. Continued.

Author/year	Type of rehabilitation	Type of PROMs	PROMs evaluation method	Results
Peñarrocha et al., 2007 [17] Oral surgery and Implantology Program, Valencia University Medical and Dental School, Spain.	– 44 IFCD	VAS scale	7 items measuring prosthetic treatment process, aesthetics, performance when chewing, stability of prosthesis, phonetics, level of hygiene, general satisfaction (code = 0–10)	All items in zygomatic group show higher score than non-zygomatic group, finding statistically difference between groups only in aesthetics (9.82 *vs.* 8.86, $p < .005$)
Rodríguez-Chessa et al., 2014 [29] Piracicaba Dental School, State University of Campinas, Brazil.	– NA	VAS scale	7 items measuring prosthetic treatment process, aesthetics, performance when chewing, stability of prosthesis, phonetics, level of hygiene, general satisfaction (code = 0–10)	Treatment satisfaction: 6.47 ($SD \pm 3.24$) Surgical trauma: 7.13 ($SD = \pm 2.68$) Occlusal function: 7.61 ($SD = \pm 2.87$) Speech and phonetic: 5.92 ($SD = \pm 3.71$) Prosthesis aesthetics: 7.86 ($SD = \pm 3.37$)
Sartori et al., 2012 [6] Latin American Institute of Dental Research and Education, Curitiba, Brazil.	– 16 IFCD	Individual, personalized questionnaire	Personalized questionnaire including: (a) Satisfaction with treatment (b) Reasons for unsatisfaction (c) Number of clinical sessions to solve problems (d) Complications source	(a) Satisfaction with treatment: – 8 patients were completely satisfied – 8 patients were satisfied with some complaints (b) Reasons for unsatisfaction – Hygiene: 2 patients – Phonetics: 2 patients – Aesthetics: 3 patients – Chewing: 1 patient (c) Number of clinical sessions to solve problems – <3:6 patients – >3:2 patients (d) Complications source – Prosthesis: 5 patients – Prosthesis and implants: 3 patients

DI: conventional dental implants; IFCD: implant supported fixed complete denture; IOD: implant supported overdenture; NA: not available; OHIP: oral health impact profile; EDENT: edentulous patient; SD: significant differences; VAS: Visual Analogue Scale.

haematomas (1.1%), six facial haematomas (0.9%), six cases of infraorbital paresthaesia (0.9%), five extraoral fistulas (0.8%), four cases of recurrent headache (0.6%), three ZI dehiscences (0.5%), and one case of oroantral communication (0.2%). In one study (Araujo et al.) [18] no biological complications were recorded.

Regarding technical complications, seven screw fractures (1.1%) and four screw loosenings (0.6%) were observed among the 628 ZIs placed. Among the 306 prostheses placed, the studies recorded seven prosthetic failures (2.3%), four cases of bulky prostheses, four cases of resin coating fracture (1.3%), three cases of recurrent documentation (1%), and one metal framework fracture (0.3%).

Risk of bias in individual studies

As shown in Tables 3 and 4, all the studies included in this systematic review showed a low risk of bias according to the Cochrane Collaboration [23] and Newcastle-Ottawa [24] quality assessment scales.

Discussion

This systematic review aimed to analyze PROMs obtained from patients rehabilitated with ZISCDP, evaluating OHRQoL and patient satisfaction, survival rates of the ZI placed, and related complications. To the best of the authors' knowledge, this is the first systematic review to evaluate these outcomes in patients restored with ZI.

A total of 306 patients treated with 1595 implants were included in the review. Of the 1595 implants placed, 628 were zygomatic implants and 993 were conventional dental implants. Several surgical techniques, types of rehabilitation, and loading protocols were found among the studies reviewed, which might have resulted in different outcomes in PROMs evaluations.

PROMs, OHRQoL, and level of satisfaction

Considering the PROMs assessment as the review primary outcome, the general findings of this systematic review pointed to substantial increases in OHRQoL among patients restored with zygomatic implants measured by OHIP-14 and OHIP-EDENT scales and high scores in terms of general satisfaction after treatment, especially in chewing ability and aesthetics.

Regarding the assessed secondary outcomes and based on the analyzed parameters, the main advantage of restorations supported by ZI lies in the possibility of performing immediate loading with a fixed restoration without the need for bone reconstruction procedures. This produces a major improvement in the OHRQoL of patients thanks to the

Table 3. Quality assessment of RCT using the Cochrane Collaboration recommendations.

	Selection bias		Reporting bias	Performance bias	Detection bias	Attrition bias	Other bias
Study	Random sequence generation	Allocation concealment	Selective Reporting	Blinding of participants and personnel	Blinding of outcomes assessment	Incomplete outcome data	Other sources of bias
Davó et al. 2018 [16]	+	+	+	+	+	+	+

+: low risk of bias; −: high risk of bias; ?: unclear.

Table 4. Quality assessment of included studies using the Newcastle-Ottawa scale.

	Selection				Comparability		Exposure			
Study	S1	S2	S3	S4	C1	C2	E1	E2	E3	Number of stars
Aparicio et al. 2014 [20]	★	0	★	★	★	0	0	★	★	6
Araujo et al., 2016 [18]	★	★	★	0	★	0	★	★	★	7
Atalay et al., 2017 [26]	★	0	★	0	★	0	★	★	★	6
Davó et al., 2015 [19]	★	0	★	★	★	0	★	★	★	7
Farzad et al., 2006 [27]	0	0	★	★	★	0	★	★	★	6
Lombardo et al., 2016 [30]	★	0	★	0	★	0	★	★	★	6
Mozzatti et al., 2015 [31]	0	0	★	★	★	0	★	★	★	6
Pellicer-Chover et al., 2016 [28]	★	0	★	0	★	0	★	★	★	5
Peñarrocha et al., 2007 [17]	★	★	★	★	★	0	★	★	★	8
Rodríguez-Chessa et al., 2014 [29]	★	0	★	0	★	0	★	★	★	6
Sartori et al., 2012 [6]	★	0	★	★	★	0	0	★	★	6

shorter period before a functional prosthesis can be received and a better post-operative period as bone grafting is not usually required [16,32,33].

In the PROMs comparison as a secondary outcome, only two studies reported results between patients rehabilitated with ZI and DI. While Peñarrocha et al. [17] registered higher scores in all VAS scale items in their ZI group compared with a DI group, Araujo et al. [18] found better results in patients rehabilitated with DI. These differences between studies might be related to different factors that affect the perception of treatment outcomes, such as varying expectations among patients, age groups, or genders [13,34–36]. Considering, only two studies were evaluating the PROMS comparing between patients rehabilitated with ZI and DI, the results contribute to assess the impact of the implant placement since the zygomatic implant technique consisted of a more aggressive surgical approach. These results should be interpreted carefully as the existing evidence from the included studies suggests that this comparison has certain methodological limitations.

Regarding loading protocols, only one of the studies compared PROMs results between immediate and delayed loading [16]. OHIP-14 scores showed significant improvements comparing pre-rehabilitation with post-rehabilitation with both immediate and delayed loading, while statistically significant differences were found in favour of immediate loading with ZI in terms of days of partial infirmity and time needed before receiving a functional prosthesis.

Similar results were observed in previous studies [14], which compared the effect of immediate loading *vs.* conventional loading in DI from the patients' perspective, obtaining higher overall patient satisfaction following immediate implant placement and immediate loading [14,37].

The type of rehabilitation is another factor that may influence patients' OHRQoL. In this context Atalay et al. [26] evaluated satisfaction levels of patients rehabilitated with ZI using VAS, comparing implant-supported fixed dentures and overdentures. They obtained better results for fixed restorations in terms of chewing, stability, and phonetics but higher scores for overdentures in terms of hygiene. Both treatments showed similar results in terms of aesthetic outcomes and general satisfaction with treatment. These findings agree with previous systematic reviews, which obtained high PROMs scores for both types of rehabilitation slightly in favour of fixed restorations over overdentures [13,38,39].

Implant and prosthesis survival rates are one of the factors that will directly affect OHRQoL. High survival rates have been related to high levels of patient satisfaction [40].

The results of the present review showed an overall survival rate of the ZI placed was 98.3% after a mean follow-up time of 46.55 months. Similar results have been observed in previous systematic reviews analyzing survival rates of ZI, ranging between 96 and 100% [8,41–43].

The high ZI survival rate may explain the substantial improvement in satisfaction levels reported by patients in the studies reviewed. Accordingly, the lowest scores for patient satisfaction were observed in the study which registered the lowest ZI survival rate (79.1%) [29].

Complications

Among the 628 ZI placed in the studies, a total of 82 biological complications (13.05%) and 11 technical complications (1.75%) were recorded. Although no studies have been found assessing the impact of the treatment complications on quality of life, the high percentage of complications reported was reflected in PROMs, whereby high complication rates led to low scores for patient satisfaction. In this way, the study carried out by Rodriguez-Chessa et al. [29], which registered the highest percentage of complications, showed the lowest satisfaction scores evaluated by VAS after

treatment. Accordingly, the study by Pellicer-Chover et al. [28], which registered a very low rate of complications, reported one of the highest satisfaction scores after treatment. The percentage of complications observed in the present systematic review concurs with previous systematic reviews analyzing complications in patients restored with zygomatic implants [9,41–46].

Limitations

The present systematic review presented certain limitations, due to the heterogeneity of the included and analyzed studies and the almost complete lack of randomized controlled clinical trials comparing patients rehabilitated with zygomatic implants with those rehabilitated with conventional dental implants. Severely atrophy maxilla implant rehabilitation is still a clinical challenging treatment, therefore several surgical techniques have been proposed due to patients' inherent characteristics. In this sense treatment randomization or direct comparison study could be a complicated option, nevertheless, new studies on direct treatment comparison are needed.

Moreover, the different surgical techniques reported may have influenced the results. Furthermore, a variety of PROMs evaluation methods were used, which may have compromised comparisons of the results. Consequently, a meta-analysis could not be performed.

Considering the high number of complications described, further studies focussed on the impact of these treatment complications on the quality of life are recommended.

Conclusions

Within the limitations of this systematic review, it may be concluded that patients with severe maxillary bone atrophy restored with ZISCDP show substantial improvements in OHRQoL and general satisfaction with the treatment received. The ZI survival rate is 98.3% after a mean follow-up time of 46.5 months.

However, the studies reviewed presented a lack of homogeneity not only regarding the surgical technique employed but also follow-up periods and the PROMs evaluation methods used. Well-designed RCTs, with longer follow-up times and standardized and comparable PROMs questionnaires, are needed to confirm the present findings.

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Disclosure statement

The authors declare no conflict of interest.

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