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SYSTEMATIC REVIEW OPEN ACCESS

Patient- and Clinician-Reported Outcomes and the Outcome Measures in Studies Reporting on Rehabilitation of the Edentulous Maxilla With Implant-Supported Fixed Prosthesis Using Short, Standard-Length and/or Zygomatic Implants: A Systematic Review of Clinical Studies Published in the Last 10 Years

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ABSTRACT

Objectives: To identify patient-reported outcomes (PROs), clinician-reported outcomes (ClinROs) and patient-reported outcome measures (PROMs) in studies evaluating the rehabilitation of the edentulous maxilla with implant-supported fixed prosthesis using short and/or standard-length and/or zygomatic implants.

Materials and Methods: A systematic search was conducted in MEDLINE/PubMed, EMBASE, Scopus, Web of Science, Cochrane Central Register of Controlled Trials, and National Clinical Trial Register for articles published between January 1, 2014, and March 24, 2024. Studies reporting both PROMs and ClinROs related to implant therapy in patients with fully edentulous maxillae were eligible for inclusion. Study characteristics, PROMs, and ClinROs were extracted from each article. Study quality was appraised using Cochrane's Risk of Bias 2 tool, Newcastle-Ottawa Scale, or the Joanna Briggs Institute Critical Appraisal Tool according to the study design.

Results: The electronic search identified 1981 titles after removing duplicates. Fourteen publications, reporting both ClinROs and PROMs based on 12 studies (14 publications). These studies evaluated a total of 575 participants and 3367 implants. Eight publications focused exclusively on one type of implant design: seven evaluated standard-length implants and one examined zygomatic implants. The remaining six publications assessed two implant types: four compared zygomatic and standard-length implants, while two compared short and standard-length implants. The most frequently used PROMs among the publications ($n = 14$) were Oral Health-Related Quality-of-Life using OHIP questionnaires (7/14) and patient satisfaction using unstandardized questionnaires (7/14). The most frequently reported objective ClinROs were complication (14/14), marginal bone loss (10/14) assessed using standardized

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periapical radiographs, implant mobility/stability/failure (7/14), and implant survival (4/14). Subjective ClinROs related to the clinician's perception were reported in only one study (1/14) and focused on swelling after treatment.

Conclusions: PROMs and objective ClinROs are often reported together in clinical trials involving short, standard-length or zygomatic implants for implant-supported fixed prostheses in edentulous maxillae. However, the frequent use of unstandardized questionnaires for PROMs hinders sound comparisons across studies. Subjective ClinROs based on clinician perception are rarely reported.

1 | Introduction

Implant therapy is widely regarded as a highly successful treatment option for a wide range of clinical indications, from single-tooth replacements to full-arch restorations (Branemark et al. 1977; Gallucci et al. 2016; Messias et al. 2023). This success is largely due to high survival rates at both the implant and restorative levels. Traditionally, the success of implant treatments is assessed using standard outcome measures (Tonetti, Heitz-Mayfield, et al. 2023), which include implant and restoration survival rates, changes in marginal bone levels, probing depth values, plaque indices, and assessments of the peri-implant tissues, in addition to aesthetic outcomes (Avila-Ortiz et al. 2023; Thoma et al. 2018).

Given the expanding access of edentulous patients to implant therapy, new treatment options have been developed to restore the mandible or maxilla with fixed full-arch prostheses (Messias et al. 2023). These implant-supported fixed full-arch prostheses vary significantly in invasiveness and clinical complexity compared to single-tooth implants in partially edentulous patients, thereby impacting the patient's quality of life more substantially (Yao et al. 2018). The treatment options generally differ in the number, dimension, and location of the implants placed. These include standard-length implants (>6 mm), short dental implants (≤6 mm), and zygomatic implants, all of which utilize the available bone following tooth extraction (Jung et al. 2018). For a completely edentulous maxilla, clinicians must choose among these options based on the patient's individual needs and the clinician's expertise to ensure successful outcomes (Messias et al. 2021).

Traditionally, mid- to long-term outcomes of implant therapy with implant-supported fixed full-arch prostheses have been evaluated using objective clinician-reported outcomes (ClinROs) (US Food and Drug Administration 2021a), such as survival rates, marginal bone levels and various clinical parameters based on radiographic and clinical assessments. However, these research outcomes have not always reflected the aspects that patients consider most important (Chalmers and Glasziou 2009). Recently, there has been a growing trend toward capturing subjective measures, the so-called patient-reported outcomes (PROs) using patient-reported outcome measures (PROMs), which are questionnaires designed to assess PROs (Calvert et al. 2013; Calvert et al. 2018; Weinfurt and Reeve 2022), to gain deeper insights into challenges associated with treatment and the aesthetic outcomes of implant therapy (Cosyn et al. 2024; Thoma et al. 2024).

PROs have significantly altered treatment approaches by capturing information about patients' experiences with their treatment that cannot be captured any other way (Thoma and Strauss 2022). PROMs in general are quicker, less burdensome, and less costly to collect than traditional clinical measures (Feine et al. 2018).

The selection of implant placement protocols is largely influenced by the clinician's preference and expertise (Tonetti et al. 2019) highlighting the importance of considering subjective ClinROs based on clinicians' perceptions (Cosyn et al. 2024; Thoma et al. 2024). These subjective ClinROs are particularly relevant, as treatment options for the edentulous maxilla often involve invasive procedures requiring advanced expertise and clinical skills, which less experienced practitioners may lack.

Incorporating clinicians' perceptions alongside patient-reported outcomes could significantly enhance the decision-making process, particularly for less experienced clinicians. Decisions for specific treatment plans rely on the clinician's knowledge, skills, attitudes, available resources, and the patient's values and preferences (Thoma et al. 2021). However, while there is an increasing emphasis on patient-reported outcomes in treatment decisions, ClinROs based on clinicians' perceptions remain underrepresented in clinical research (Cosyn et al. 2024; Thoma et al. 2024).

Insufficient consideration in selecting outcomes for clinical trials has led to inefficiencies in both the conduct and reporting of research (Chalmers and Glasziou 2009). Numerous studies have shown that inconsistencies in reported outcomes create significant challenges for those utilizing healthcare research. Such inconsistencies hinder the ability to synthesize findings from different studies and effectively apply them in practice. Recently, there has been a growing interest in developing agreed standardized sets of outcomes, known as core outcome sets (COS) that should be measured and reported as a minimum in all effectiveness trials for a specific health area (Clarke 2007; Williamson et al. 2017). Given the ongoing interest in clinician- and patient-reported outcomes for the edentulous maxilla, it is crucial to identify and summarize current assessment methods. This may provide a more holistic view of treatment and patient satisfaction, ultimately leading to better-informed clinical decisions and improved patient care.

The aim of the present study was, therefore, to identify patient-reported outcomes and clinician-reported outcomes and their respective assessment methods in studies evaluating the rehabilitation of the edentulous maxilla with implant-supported fixed prostheses using short, standard-length and/or zygomatic implants.

2 | Materials and Methods

2.1 | Protocol and Registration

This systematic review is reported according to the guidelines of the Preferred Reporting Items of Systematic Reviews and Meta-Analyses (PRISMA) 2020 statement (Page et al. 2021). A detailed protocol was designed prospectively and registered on PROSPERO (CRD42024523563; March 23, 2024) prior to the start of this study.

2.2 | Terminology

Due to the heterogeneity in the terminology reported in the literature, the following definitions were employed to classify outcome measures:

Patient-reported outcome (PRO): any report of the status of a patient's health condition that comes directly from the patient without interpretation of the patient's response by a clinician or anyone else (US Food and Drug Administration 2021b).

Patient-reported outcomes measures (PROMs): instruments that are used to measure the PROs, most often self-reported questionnaires (Powers III et al. 2017).

Clinician-reported outcomes (ClinROs): A measurement based on a report that comes from a trained healthcare professional after observation of a patient's health condition (US Food and Drug Administration 2021a). Most ClinROs involve a clinical judgment or interpretation of the observable signs, behaviors, or other manifestations related to a disease or condition (FDA-NIH Biomarker Working Group; BEST (Biomarkers, EndpointS, and other Tools)). ClinROs cannot directly assess symptoms that are known only to the patient. In the present systematic review, the scope of ClinROs was broadened to include *subjective* factors related to the clinician's perception such as the observable signs related to treatment (swelling), ease of performing surgical and restorative procedures with different implant options (short, standard-length, or zygomatic implants), and their perceptions regarding the maintenance of the prosthesis. This expanded definition reflects the understanding that the terminology will be periodically updated to include additional terms and clarifications from a wide range of stakeholders, including the scientific and medical communities, patients, providers, industry, and regulators (FDA-NIH Biomarker Working Group 2016; BEST (Biomarkers, EndpointS, and other Tools)).

Implant-supported fixed dental prosthesis: A prosthesis that is fixed to and supported by more than one dental implant(s) and the prosthesis cannot be removed by the patient (Morgano et al. 2023).

2.3 | Eligibility Criteria

The eligibility criteria for this systematic review were organized using a modified PICO framework (PIOS), excluding the "comparison" element. The focused question was as follows: "In adult patients with a fully edentulous maxilla undergoing implant therapy with short (≤6 mm), standard-length (>6 mm), and/or zygomatic implants and fixed dental prostheses, which types and methods of assessment are commonly used to report patient- and clinician-reported outcomes?"

Population (P): Adult (≥18 years) patients with fully edentulous maxilla in need of implant therapy.

Intervention (I): Implant therapy using short (≤6 mm), standard-length (>6 mm), and/or zygomatic implants supporting a fixed dental prosthesis.

Outcome (O): Patient-reported outcomes measures (PROMs) assessing pain, edema, hematoma, aesthetic satisfaction, treatment satisfaction, patient likelihood to repeat surgery, oral health impact profile, quality of life, and surgery time simultaneously with ClinROs measures including clinical outcomes (e.g., survival and marginal bone level changes), as well as subjective ClinROs based on clinicians' perceptions such as swelling, ease of treatment, feasibility of treatment and clinician's satisfaction.

Study (S): randomized controlled trials (RCTs), nonrandomized controlled trials (non-RCTs), prospective cohort studies, observational studies, and case series with a minimum of 10 subjects per study group were eligible since the aim of the present review was to assess outcome measures.

Study eligibility criteria were assessed based on the PIOS framework (Table 1). All decisions regarding the eligibility criteria were made by the group of review authors, including dentists with professional experience in prosthetic and implant dentistry.

2.4 | Search Strategy

Four electronic databases and two trial registers were searched, namely, the National Library of Medicine (MEDLINE/PubMed), EMBASE, Scopus, Web of Science, Cochrane Central Register of Controlled Trials (CENTRAL), and National Clinical Trial Register using specific adapted strategies (Table 2). The electronic search was performed in duplicate by two review authors (S.S. and J.Y.P.) and included articles published between January 1st, 2014, and March 24th, 2024. No language restrictions or search filters were applied. The summary of search strategy is reported in Table 1. The electronic search was supplemented by forward and backward reference checking from reviewed papers and relevant systematic reviews on the topic (Abdunabi et al. 2019; Brennand Roper et al. 2023; Estrin et al. 2023; Gonçalves et al. 2022; Kwon et al. 2014; Messias et al. 2023; Sáez-Alcaide et al. 2022; Yao et al. 2018). In addition, the search strategy was optimized by refining the search terms using the software "SearchRefinery" (Clark et al. 2020).

2.5 | Study Selection

Based on the inclusion and exclusion criteria (Table 1), two calibrated reviews (S.S. and S.P.) independently performed titles, abstracts, and keywords screening using the Rayyan Online Software (Qatar Computing Research Institute). Inter-examiner

TABLE 1 | Summary of review search strategy and eligibility criteria.

Databases	**1. National Library of Medicine (MEDLINE/PubMed), 2. Embase, 3. Scopus, and 4. Web of Science**
Registers	1. National clinical trial register 2. Cochrane Central Register of Controlled Trials (CENTRAL)
Other sources	Forward and backward reference checking from reviewed papers and relevant systematic reviews on the topic
Key terms	*Population*: (jaw, edentulous OR mouth, edentulous OR edentulous OR tooth loss) AND (maxilla OR upper jaw OR maxillary); *Intervention*: (dental implant OR Dental Prosthesis, Implant-Supported OR Denture, Partial OR full-arch); *Outcome*: (visual analog scale OR quality of life OR patient satisfaction OR patient reported outcome measure* OR PROM* OR OHIP OR questionnaire* OR patient centered outcome OR patient-reported outcome OR patient related)
Limits	
Dates	January 1st, 2014—March 24th, 2024
Language	English, German, Spanish, Russian, or Korean
Location	International
Article type	Academic
Eligibility criteria	
Types of studies	Randomized clinical trials, controlled clinical studies, prospective studies, observational studies, and case series ($\geq$ 10 patients)
Inclusion	1. Systemically healthy adult patients with fully edentulous maxilla or both maxilla and mandible in case of two-arms studies; 2. Patients with implant-supported fixed restorations.
Exclusion	1. Unsuitable population (not evaluating systemically healthy adult patients in need of implant therapy on the edentulous maxilla); 2. Inadequate exposure (not evaluating implant therapy with short ($\leq$ 6 mm), standard-length (> 6 mm), or zygomatic conventional implants and fixed partial dentures); 3. Inadequate outcomes (absence of simultaneous reporting of PROMs and ClinROs); 4. Articles did not publish the implant length; 5. Inadequate study type (not RCT, controlled studies, prospective studies, observational studies, and case series with at least 10 patients per group); 6. Articles reported not in English, German, Spanish, Russian, or Korean; 7. Trial registered, not yet published.

calibration was achieved through open discussion and comparison between two reviewers (S.S. and J.P.) after independently assessing the first 100 records (approximately 5% of the total). Articles with unclear PROM information in the abstract, but with the potential for relevant data in full text were included for full-text analysis. No restrictions were made in terms of length of follow-up period, as this review did not focus on treatment efficacy. However, at this stage, the language of included studies was restricted to English, German, Korean, Russian, and Spanish. Subsequently, both reviewers independently assessed the full-text version of potentially eligible studies, after calibrating their assessment on five articles. When disagreement regarding the inclusion of a specific article occurred, both reviewers had an open discussion. If no agreement was achieved, another co-author (D.S.T.) made the final decision. Following article selection, Cohen's kappa coefficient (k) was calculated to determine the degree of interexaminer reliability.

2.6 | Data Extraction and Management

Data from the included studies were extracted using a pilot-tested data extraction table (Excel Microsoft Corporation) after calibration and validation by discussion of two first articles. One reviewer (S.P.) performed data extraction, and another (S.S.) checked all the information. Final data accuracy and consistency were independently verified by another co-author (F.J.S.). Any missing information that could contribute to this project was kindly requested from the corresponding author(s) via email communication. In case of no answer or unsatisfactory explanation, the respective article was ultimately excluded from the review.

For each of the eligible studies, the following data were recorded: bibliographic information: first author, publication year, and country of origin; study design; participants

TABLE 2 | Search strategies.

Databases	
PubMed	#1 (jaw, edentulous OR mouth, edentulous OR edentulous OR tooth loss) AND (maxilla OR upper jaw OR maxillary) #2 (dental implant OR Dental Prosthesis, Implant-Supported OR Denture, Partial OR full-arch) #3 (visual analog scale OR quality of life OR patient satisfaction OR patient reported outcome measure* OR PROM* OR OHIP OR questionnaire* OR patient centered outcome OR patient-reported outcome OR patient related) #4 #1 AND #2 AND #3
Embase	#1 ("jaw, edentulous" OR "mouth, edentulous" OR edentulous OR "tooth loss") AND (maxilla OR "upper jaw" OR maxillary) #2 ("dental implant" OR "dental prosthesis, implant-supported" OR "denture, partial" OR "full mouth") #3 ("visual analog scale" OR "quality of life" OR "patient satisfaction" OR "patient reported outcome measure*" OR "PROM*" OR "OHIP" OR "questionnaire*" OR "patient centered outcome" OR "patient-reported outcome" OR "patient related") #4 #1 AND #2 AND #3
Scopus	#1 TITLE-ABS-KEY (("jaw, edentulous" OR "mouth, edentulous" OR edentulous OR "tooth loss") AND (maxilla OR "upper jaw" OR maxillary)) #2 TITLE-ABS-KEY(("dental implant" OR "Dental Prosthesis, Implant-Supported" OR "Denture, Partial" OR full-arch)) #3 TITLE-ABS-KEY (("visual analog scale" OR "quality of life" OR "patient satisfaction" OR "patient reported outcome measure*" OR prom* OR ohip OR questionnaire* OR "patient centered outcome" OR "patient-reported outcome" OR "patient related")) #4 #1 AND #2 AND #3
Web of Science	#1 TS = (("jaw, edentulous" OR "mouth, edentulous" OR "edentulous" OR "tooth loss") AND ("maxilla" OR "upper jaw" OR "maxillary")) #2 TS = ("dental implant" OR "Dental Prosthesis, Implant-Supported" OR "Denture, Partial" OR "full-arch") #3 TS = ("visual analog scale" OR "quality of life" OR "patient satisfaction" OR "patient reported outcome measure*" OR PROM* OR OHIP OR questionnaire* OR "patient centered outcome" OR "patient-reported outcome" OR "patient related") #4 #1 AND #2 AND #3
Register	
Cochrane Central Register of Controlled Trials (CENTRAL)	#1 MeSH descriptor: [Jaw, Edentulous] explode all trees #2 MeSH descriptor: [Mouth, Edentulous] explode all trees #3 MeSH descriptor: [Tooth Loss] explode all trees #4 (jaw edentulous OR mouth edentulous OR edentulous OR tooth loss) #5 #1 OR #2 OR #3 OR #4 #6 MeSH descriptor: [Maxilla] explode all trees #7 (maxilla OR upper jaw OR maxillary) #8 #6 OR #7 #9 #5 AND #8 #10 MeSH descriptor: [Dental Implants] explode all trees #11 MeSH descriptor: [Dental Prosthesis, Implant-Supported] explode all trees #12 MeSH descriptor: [Denture, Partial] explode all trees #13 (dental implant OR Dental Prosthesis Implant-Supported OR Denture Partial OR full-arch) #14 #10 OR #11 OR #12 OR #13 #15 MeSH descriptor: [Visual Analog Scale] explode all trees #16 ("visual analog scale" OR "quality of life" OR "patient satisfaction" OR ("patient reported outcome" NEXT measure*) OR PROM* OR OHIP OR questionnaire* OR "patient centered outcome" OR "patient-reported outcome" OR "patient related") #17 #15 OR #16 #18 #9 AND #14 AND #17
ClinicalTrials.gov	Condition or disease: Jaw Edentulous AND Maxilla Intervention or treatment: Dental Implants OR Implant-supported denture

Abbreviation: MeSH, Medical Subject Headings.

characteristics: gender and age; implants characteristics: type, loading protocol, location and number of implants overall and per patient, length, diameter, and brand; PROMs: utilized scale, domain, scale range, number of evaluated questions and interpretation; ClinROs: evaluated timepoints, objective; utilized scale, reported parameters, number of evaluated questions, and complications: intraoperative, postoperative, biological and technical.

2.7 | Quality Assessment

All included articles were independently evaluated by two reviewers (S.S., F.J.S.) for overall risk of bias using the corresponding scale according to the study design. RoB 2 Tool (Sterne et al. 2019) was used for RCTs, the Newcastle–Ottawa Scale (NOS) was utilized for nonrandomized controlled and observational studies, and the Joanna Briggs Institute Critical Appraisal tool (Moola et al. 2017) for case series and cross-sectional studies. Disagreement between reviewers was resolved by open discussion. In case no agreement could be achieved, the final decision was made by another co-author (D.S.T.).

2.8 | Data Synthesis

A narrative synthesis was employed for this review, as a meta-analysis was deemed inappropriate due to the focus of the study and the significant heterogeneity among the studies. The aim of the present systematic review was not to compare interventions or their efficacy. The synthesis process started with a preliminary analysis, during which data were extracted and the outcomes organized into tabular form. This method provided a comprehensive summary of the findings and facilitated the identification of potential patterns within the data.

3 | Results

3.1 | Study Selection

Figure 1 presents the flow of studies through the systematic review. The initial electronic search yielded a total of 1981 entries, of which 662 were retrieved in PubMed, 436 in EMBASE, 349 in Scopus, 302 in Web of Science, 215 in CENTRAL, and 17 in the National Clinical Trial Register. Following duplicate removal, 1051 articles remained. After title and abstract screening, 69 articles were selected for full-text analysis. Fifty-five of these articles were excluded after full-text review, ending up with 14 publications. The list of excluded articles and reasons for exclusion are displayed in Table S1. No further manuscripts were found through cross-reference checking. Inter-examiner agreement kappa score amounted to 0.862 for the screening phase and to 0.776 for the full-text analysis, demonstrating a good agreement between the reviewers.

Overall, 14 publications reporting on 12 studies with unique patient populations were included, and a total of 575 participants and 3367 implants were evaluated in this systematic review (Agliardi et al. 2014; Agliardi et al. 2017; Ayna et al. 2021; Davó et al. 2018; Davó and Pons 2015; Ebinger et al. 2016; Esposito et al. 2015; Esposito et al. 2018; Felice et al. 2020; Fernández-Ruiz et al. 2021; Mozzati et al. 2015; Peñarrocha-Oltra et al. 2014; Yamada et al. 2015; Zhang et al. 2016).

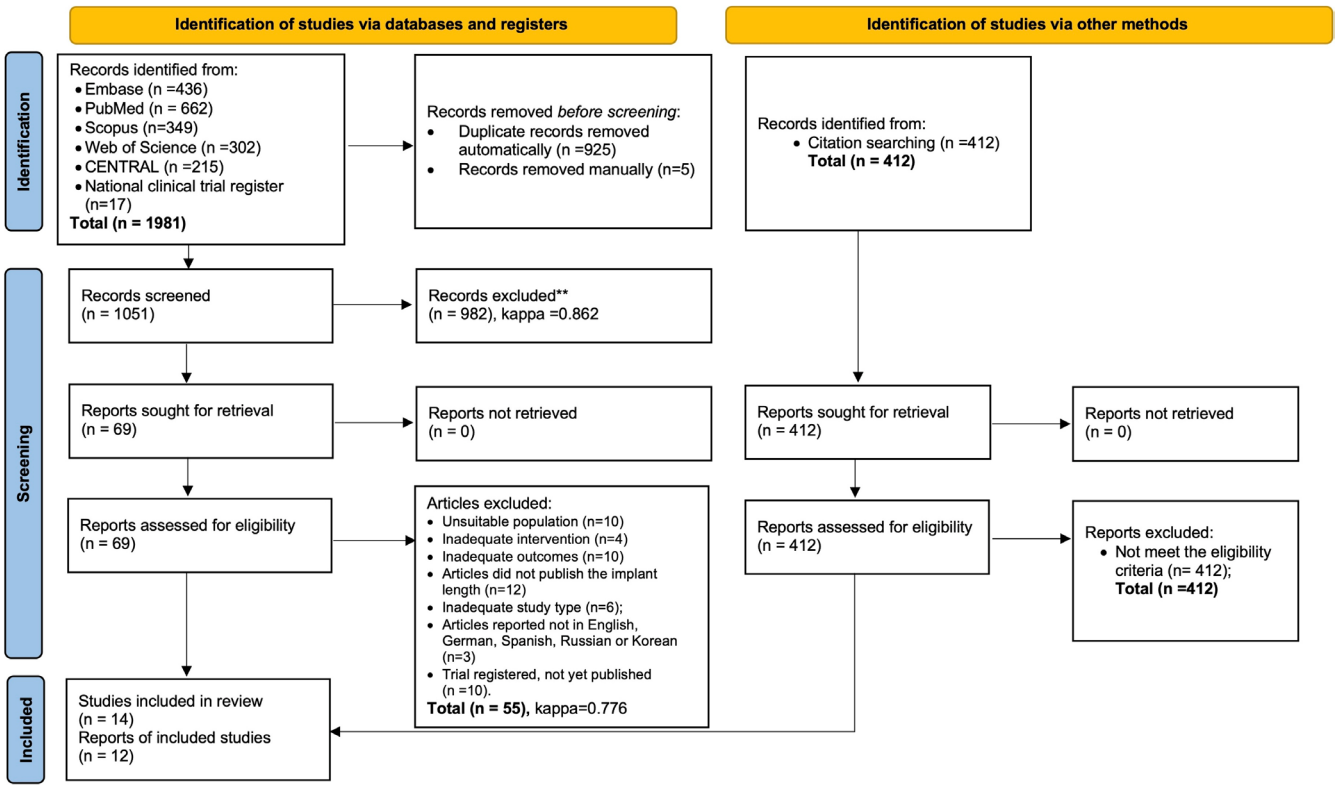

FIGURE 1 | PRISMA 2020 flow diagram for new systematic reviews which included searches of databases, registers, and other sources.

3.2 | Study Characteristics

Table 3 summarizes the general details, participant information, and implant characteristics of the included studies. Further details of each study are provided in Supporting Information S2. Of the 14 selected articles, 2 were published in 2014, 4 in 2015, 2 in 2016, 1 in 2017, 2 in 2018, 1 in 2020, and 2 in 2021. Among these studies, five were RCTs, one was a non-RCT, six were prospective cohort studies, and two were case series. The sample sizes ranged from 10 participants (40 implants) to 80 participants (396 implants). For the edentulous maxilla, the number of implants per patient ranged from 4 to 8, with one study focusing on zygomatic implants. Nine articles evaluated immediate loading, one study utilized an early loading protocol, three trials used conventional loading, and one study investigated several loading protocols.

Six articles evaluated two types of implants: four compared zygomatic and standard-length implants, while two compared short (≤6 mm) and standard-length implants (>6 mm). Eight articles analyzed only one type of implant design, with seven focusing on standard-length implants and one article on zygomatic implants. Ten articles reported the exact implant lengths and their respective distributions, while four provided only the range of implant lengths used.

Thirteen studies reported implant diameter information. Among these, eight detailed the diameters and their distributions, four specified only the exact diameters of the evaluated implants, and one case series provided only the range of implant diameters assessed.

Thirteen articles evaluated implants from a single brand. Of these, eight analyzed Nobel Biocare implants, two RCTs evaluated MegaGen implants, one assessed Straumann implants, one examined Galimplant systems, and one focused on Sweden and Martina implants. Additionally, one study evaluated implants from two brands: Nobel Biocare and Straumann (Supporting Information S2).

3.3 | Patient-Reported Outcomes (PROs) and Patient-Reported Outcome Measures (PROMs)

The identified PRO constructs in the selected literature were measured/assessed with the following PROMs:

1. **PRO:** Oral health-related quality-of-life ($n=7$).
- **PROM**: OHIP-14 (5/7), OHIP 11–16 (1/7), OHIP-J54 (1/7).

2. **PRO:** Satisfaction with specific domains ($n=7$).

- **PRO domain:** Aesthetics/appearance ($n=7$).
  - **PROM**: Unstandardized questionnaire (6/7), VAS (1/7).
- **PRO domain:** Chewing function/masticatory function ($n=7$).
  - **PROM**: Unstandardized questionnaire using categoric scales (4/7), 5-point Likert scales (2/7), and VAS (1/7).
- **PRO domain:** Comfort/chewing discomfort ($n=3$).
  - **PROM**: Unstandardized questionnaire using categoric scales (2/3), VAS (1/3).
- **PRO domain:** Ease of cleaning/oral hygiene ($n=2$).
  - **PROM**: Unstandardized questionnaire using categoric scales (1/2), VAS (1/2).
- **PRO:** Speech function/phonetics ($n=4$).
  - **PROM**: Unstandardized questionnaire using categoric scales (3/4), VAS (1/4).
- **PRO**: Treatment duration ($n=1$).
  - **PROM**: VAS (1/1).
- **PRO**: Self-esteem ($n=1$).
  - **PROM**: VAS (1/1).

3. **PRO:** General satisfaction ($n=2$).
- **PROM**: Unstandardized questionnaire using categoric scales (1/2), VAS (1/2).

4. **PRO**: Likelihood to repeat surgery ($n=2$).
- **PROM**: Unstandardized questionnaire using categoric scales (2/2).

5. **PRO**: Postoperative swelling ($n=1$).
- **PROM**: VAS (1/1).

6. **PRO:** Days of impaired activity ($n=2$).
- **PROM**: Unstandardized questionnaire (2/2).

7. **PRO:** Pain ($n=1$).
- **PROM**: VAS (1/1).

Table 4 summarizes the characteristics of the patient-reported outcome measures (PROMs) utilized across the included studies. A variety of instruments were employed to evaluate satisfaction and quality of life following treatment. Some studies (e.g., Agliardi et al. 2014 and 2017) utilized unstandardized questionnaires based on 5-point Likert scales, assessing satisfaction with aesthetics, masticatory function, and phonetics, with higher scores consistently indicating better outcomes. Other studies, such as those by Esposito et al. (2015, 2018) and Felice et al. (2020), applied custom scales ranging from binary options to six-grade responses, with higher scores again corresponding to more favorable results. OHIP instruments (e.g., OHIP-14, OHIP-11–16, and OHIP-J54) were used in several studies to assess oral health-related quality of life, where lower scores generally indicated better-perceived quality of life. Visual analog scales (VAS), as used by Peñarrocha-Oltra et al. (2014), were applied to assess satisfaction and postoperative symptoms. The interpretation of VAS scores varied by domain; higher scores indicated greater satisfaction in most areas, while lower scores represented less pain or swelling for postoperative symptoms. Overall, the most frequently evaluated outcomes across studies were satisfaction with function, aesthetics, and quality of life. The PROMs used to assess these domains varied considerably in their format, the type of response scales applied, and the interpretation of the resulting scores.

TABLE 3 | Characteristics of the included publications ($n = 14$) corresponding to the included studies ($n = 12$)—participants and implants.

		Participants		Implants				
Authors/ country	**Study design**	**Number of patients (M/F)**	**Mean age (y)**	**Number implants**	**Implant type (numbers of implants in case of several types)/loading protocol**	**Number of implant pro-patient, location (posterior–anterior–anterior–posterior)**	**Implant length in mm, [number of implants]**	**Diameter of implant [number of implants]**	**Implant system**
Agliardi et al. 2014/PT	Cohort	32 (15/17)	58	192	Standard/ Immediate loading	6; 2–1–1–2	**Anterior:** 11.5 [12] 13.0 [34] 15.0 [18] **Posterior:** 11.5 [2] 13.0 [77] 15.0 [9]	4.0 [192]	Nobel Biocare
Agliardi et al. 2017/PT	Cohort	15 (2/13)	62	60	Standard (Davó et al. 2018) Zygomatic (Mozzati et al. 2015)/ Immediate loading	4; 1–1–1–1	**Anterior standard:** 10.0 [8] 11.5 [8] 13.0 [2] **Anterior zygomatic:** 35.0 [2] 40.0 [2] 45.0 [2] 50.0 [6] **Posterior zygomatic:** 35.0 [3] 40.0 [11] 42.5 [1] 45.0 [10] 50.0 [5]	3.3 [2] 4.0 [16] 5.0 [42]	Nobel Biocare
Ayna et al. 2021/DE	Cohort	34 (17/17)	61	136	Standard/ Immediate loading	4; 1–1–1–1	**Mesial implants:** 13.0 [68] **Distal implants:** 16.0 [68]	4.0 [NR]	Nobel Biocare

(Continues)

TABLE 3 | (Continued)

		Participants		Implants				
Authors/ country	**Study design**	**Number of patients (M/F)**	**Mean age (y)**	**Number implants**	**Implant type (numbers of implants in case of several types)/loading protocol**	**Number of implant pro-patient, location (posterior–anterior–anterior–posterior)**	**Implant length in mm, [number of implants]**	**Diameter of implant [number of implants]**	**Implant system**
Davó and Pons 2015/ES	Case series	17 (7/10)	57.7	68	Standard/ Immediate loading	4; 1–1–1–1	At least 8.5 mm	At least 3.3 mm	Nobel Biocare
Davó et al. 2018/ES	RCT	71 (32/39)	57.5 (Standard group) 58.3 (Zygomatic group)	379	Standard (248) Zygomatic (131)/ Immediate loading	4 (Zygomatic group); NR 6–8 (Standard group); NR	**Standard:** 8.5 [40] 10.0 [84] 11.5 [46] 13.0 [50] 15.0 [28] **Zygomatic:** 35.0 [7] 40.0 [25] 42.5 [13] 45.0 [28] 47.5 [17] 50.0 [32] 52.5 [9]	3.4 [1] 3.5 [157] 3.75 [2] 4.0 [131] 4.3 [87] 5.0 [1]	Nobel Biocare
Ebinger et al. 2016/CH	Cohort	33 (NR)	NR	204	Standard/ Conventional loading	5–6 impl; NR	8.0–13.0 mm	3.5 [NR], 4.5 [NR] (Straumann) 3.5 [NR], 4.3 [NR] (Nobel Biocare)	Nobel Biocare; Straumann
Esposito et al. 2015/IT	RCT	28 (16/12)	56 (Shortgroup) 52 (Standard group)	178	Short (NR) Standard (NR)/ Conventional loading	4–8 impl; NR	**Short:** 5.0–8.5 mm **Standard:** at least 11.5 mm	4.0 [NR] 5.0 [NR] 6.0 [NR]	MegaGen

(Continues)

TABLE 3 | (Continued)

		Participants		Implants				
Authors/ country	**Study design**	**Number of patients (M/F)**	**Mean age (y)**	**Number implants**	**Implant type (numbers of implants in case of several types)/loading protocol**	**Number of implant pro-patient, location (posterior–anterior–anterior–posterior)**	**Implant length in mm, [number of implants]**	**Diameter of implant [number of implants]**	**Implant system**
Esposito et al. 2018/ES	RCT	71 (32/39)	58.3 (Zygomatic group) 57.5 (Standard group)	379	Standard (248) Zygomatic (131)/ Immediate loading	4 (Zygomatic group); NR 6–8 (Standard group); NR	**Standard:** 8.5 [40] 10.0 [84] 11.5 [46] 13.0 [50] 15.0 [28] **Zygomatic:** 35.0 [7] 40.0 [25] 42.5 [13] 45.0 [28] 47.5 [17] 50.0 [32] 52.5 [9]	3.4 [1] 3.5 [157] 3.75 [2] 4.0 [131] 4.3 [87] 5.0 [1]	Nobel Biocare
Felice et al. 2020/IT	RCT	28 (16/12)	56 (Short implant group) 52 (Augmented group)	178	Short (NR) Standard (NR)/ Conventional loading	4–8 impl; NR	**Short:** 5.0–8.5 mm **Standard:** at least 11.5 mm	4.0 [NR] 5.0 [NR] 6.0 [NR]	MegaGen

(Continues)

TABLE 3 | (Continued)

		Participants		Implants				
Authors/ country	**Study design**	**Number of patients (M/F)**	**Mean age (y)**	**Number implants**	**Implant type (numbers of implants in case of several types)/loading protocol**	**Number of implant pro-patient, location (posterior–anterior–anterior–posterior)**	**Implant length in mm, [number of implants]**	**Diameter of implant [number of implants]**	**Implant system**
Fernández-Ruiz et al. 2021/ES	RCT	80 (41/39)	60.1 (Zygomatic group) 60.9 (All-on-4 group)	396	Standard (257) Zygomatic (139)/ Immediate loading	Zygomatic group: 4–8 impl; NR All-on-4 group: 4 imps; 1–1–1–1	**Standard:** 10.0 [64] 12.0 [154] 14.0 [39] **Zygomatic:** 35.0 [13] 37.5 [6] 40.0 [40] 42.5 [25] 45.0 [28] 47.5 [8] 50.0 [11] 52.5 [2] 55.0 [3] 60.0 [3]	3.5 [106] 4.0 [151] 4.2 [139]	Galimplant
Mozzati et al. 2015/IT	Case series	10 (NR)	51.2	40	Zygomatic/ Immediate loading	4; 1–1–1–1	30.0 [2] 35.0 [7] 40.0 [11] 45.0 [7] 47.5 [6] 50.0 [7]	NR	Nobel Biocare
Peñarrocha-Oltra et al. 2014/ES	Nonrandomized controlled study	29 (13/16)	55.4	193	Standard/ Immediate and conventional loading	6–8; NR	10.0 [39] 11.5 [61] 13.0 [51] 15.0 [15]	3.8 [24] 4.25 [146] 5.0 [23]	Sweden and Martina
Yamada et al. 2015/JP	Cohort	48 (26/22)	56.0	278	Standard/ Immediate loading	4–6; NR	8.5 [3] 10.0 [27] 11.5 [37] 13.0 [101] 15.0 [108] 18.0 [2]	3.5 [48] 4.3 [217] 5.0 [13]	Nobel Biocare

(Continues)

TABLE 3 | (Continued)

Authors/country	Participants: Study design	Participants: Number of patients (M/F)	Participants: Mean age (y)	Implants: Number implants	Implants: Implant type (numbers of implants in case of several types)/loading protocol	Implants: Number of implant pro-patient, location (posterior–anterior–anterior–posterior)	Implants: Implant length in mm, [number of implants]	Implants: Diameter of implant [number of implants]	Implants: Implant system
Zhang et al. 2016/CN	Cohort	12 (4/8)	56.3	91	Standard/Early loading	6–8; NR	6.0 [1] 8.0 [4] 10.0 [48] 12.0 [38]	3.3 [4] 4.1 [72] 4.8 [15]	Straumann

Abbreviations: Impl., implant; mm, millimeter; NR, not reported; RCT, randomized controlled trial; Short implants, implants with a length of 6 mm or less; Standard implants, implants with a length of more than 6 mm.

3.4 | Clinician-Reported Outcomes (ClinROs)

The identified objective ClinROs in the selected literature were the following:

- Bleeding on probing/bleeding index/modified bleeding index ($n = 5$)

Five of the included studies evaluated bleeding on probing (2/5), bleeding index (2/5), or modified bleeding index (Mombelli et al. 1987) (1/5) as an outcome. Among measuring methods, the type of periodontal probe was specified in two studies, and three articles assessed the measure in a binary way (yes/no). None of the studies mentioned the calibration procedure.

- Implant failure/Implant mobility/Implant stability ($n = 7$)

Implant failure, mobility, or stability were evaluated in seven articles. Among measuring methods of current ClinROs, three articles defined implant failure as implant mobility, removal of stable implants due to progressive marginal bone loss or infection, or mechanical failures rendering the implant unusable, such as implant fractures or deformation of the implant-abutment connection. One article defined implant failure as rotational mobility, infection necessitating implant removal, or mechanical complications making the implant unusable. Another article considered an implant stable if it demonstrated a minimum torque of 15 Ncm. The remaining studies did not provide detailed definitions or criteria.

- Implant success ($n = 3$)

Implant success was assessed in three studies. The measures were defined as follows: one study evaluated the success of zygomatic implants using the Malo criteria (Malo et al. 2014). One article defined implant success as a stable implant confirmed by tightening the screw of the abutment at 15 Ncm torque. Another study defined implant success as the absence of clinically detectable mobility, no pain or subjective discomfort, and no continuous radiolucency around the implant.

- Implant survival ($n = 4$)

Implant survival was reported in four articles. Among ClinROs, one article evaluated the survival of zygomatic implants by van Steenberghe criteria (van Steenberghe 1997) and three studies utilized subjective evaluation.

- Implant torque ($n = 1$)

Insertion torque was evaluated in one study. It was measured using a torque wrench.

- Marginal bone loss ($n = 10$)

Marginal bone loss was evaluated in 10 studies. Of these, eight studies assessed marginal bone levels using standardized periapical radiographs, while one multicenter study used either orthopantomograms or periapical radiographs, depending on the center. One study did not provide specific information about the evaluation method. Six studies specified that marginal bone level changes were assessed by a blinded examiner.

- Number of treatment sessions ($n = 2$)

TABLE 4 | Characteristics of the included studies—patient-reported outcome measures.

	PROMs			
Authors/country	**Utilized scale**	**Domain**	**Number of evaluated items; scale range (min/max)**	**Interpretation**
Agliardi et al. 2014/IT	Unstandardized questionnaire using a 5-point Likert scale	Satisfaction with: • Aesthetics • Masticatory function • Phonetics	3 Items rated with a 5-point Likert scale (Abdunabi et al. 2019; Agliardi et al. 2014; Agliardi et al. 2017; Albrektsson et al. 1986; Avila-Ortiz et al. 2023)	Higher score = better satisfaction in every domain
Agliardi et al. 2017/PT	Unstandardized questionnaire using a 5-point Likert scale	Satisfaction with: • Aesthetics • Masticatory function • Phonetics	3 Items rated with a 5-point Likert scale (Abdunabi et al. 2019; Agliardi et al. 2014; Agliardi et al. 2017; Albrektsson et al. 1986; Avila-Ortiz et al. 2023)	Higher score = better satisfaction in every domain
Ayna et al. 2021/DE	OHIP11-16	Oral health-related quality of life	14 Items rated 0–4; (0/56)	Lower value represents higher quality of life
Davó and Pons 2015/ES	OHIP-14	Oral health-related quality of life	14 Items rated 0–4; (0/56)	Lower value represents higher quality of life
Davó et al. 2018/ES	OHIP-14	Oral health-related quality of life	14 Items rated 0–4; (0/56)	Lower value represents higher quality of life
Ebinger et al. 2016/CH	OHIP-14	Oral health-related quality of life	14 items rated 0–4; (0/56)	Higher score = better function in every domain
Esposito et al. 2015/IT	Unstandardized questionnaire with separately analyzed questions	Satisfaction: • Aesthetics • Function Likelihood of repeat therapy	Function, aesthetics: 1 item each, 6 grades from "yes, absolutely" to "absolutely not" Undergoing same therapy again: "yes" or "no"	"Yes, absolutely", "yes" = better function in every domain
Esposito et al. 2018/ES	OHIP-14	Oral health-related quality of life	14 items rated 0–4; (0/56)	Lower value represents higher quality of life
Felice et al. 2020/IT	Unstandardized questionnaire with separately analyzed questions	Satisfaction with: • Aesthetics • Function Likelihood of repeat therapy	Function, aesthetics: 1 item each, 6 categories from "yes, absolutely" to "absolutely not" Undergoing same therapy again: "yes" or "no"	"Yes, absolutely", "yes" = better function in every domain

(Continues)

TABLE 4 | (Continued)

	PROMs			
Authors/country	**Utilized scale**	**Domain**	**Number of evaluated items; scale range (min/max)**	**Interpretation**
Fernández-Ruiz et al. 2021/ES	OHIP-14 Unstandardized questionnaire with one question (5 grades)	Oral health-related quality of life Satisfaction with prosthesis	OHIP-14: 14 items rated 0–4; (0/56) Level of satisfaction: 1 item with 5 grades from "dissatisfied" to "extremely satisfied"	OHIP-14: Lower score corresponds to better oral quality of life Satisfaction: higher score = better satisfaction
Mozzati et al. 2015/IT	Unstandardized questionnaire with 9 items	Satisfaction with: • Aesthetics • Chewing comfort • Function • Oral hygiene • Phonetics	9 Items rated using a 5-grade categorizing scale −2 to 2; (each item presented as a sum of 10 patients' scores; −20/20)	Higher score = better satisfaction in every domain
Peñarrocha-Oltra et al. 2014/ES	VAS	General satisfaction Satisfaction with: • Aesthetics • Chewing function • Comfort • Easy of cleaning • Postoperative pain and swelling • Speech function • Self-esteem • Treatment duration	10-cm VAS	Postoperative pain and swelling: lower score = less pain and swelling The other domains: higher score = better satisfaction
Yamada et al. 2015/JP	OHIP-J54	Oral health-related quality of life	54 items rated 0–4; (0/216)	Lower value represents higher quality of life
Zhang et al. 2016/CN	Unstandardized questionnaire with separately analyzed questions	Satisfaction with: • Appearance • Comfort • General satisfaction • Masticatory function	Each item 4 grades, from "excellent" to "poor"	"Excellent" suggesting higher patient satisfaction

Abbreviations: NR, not reported; OHIP, oral health implant profile; OHRQoL, oral health-related quality of life; VAS, visual analog scale.

Treatment time with clinicians was reported in two studies. One study measured treatment time as the number of dental visits, while the other measured and reported the surgical time for implant placement in minutes.

- Occlusal forces ($n = 1$)

Occlusal forces were evaluated and measured in one study, with their distribution analyzed using a pressure-sensitive film and its accompanying analyzer. Measurements were taken both before implant insertion, using the existing dentition or dentures, and after the delivery of the implant-supported prosthesis.

- Plaque index/modified plaque index ($n = 5$)

Plaque accumulation was reported in five studies. The assessment methods included the modified plaque index (Mombelli et al. 1987) in one article, using an ordinal scale (0–3) in two studies and a percentage-based approach (yes/no) in another two studies. None of the studies reported any calibration methods.

- Probing depth (PD) ($n = 3$)

PD was reported in three of the included studies; however, the measuring instrument and type of periodontal probe used were specified in only two of them. None of the studies mentioned calibration procedures or indicated whether the prosthesis was removed for probing purposes.

- Prosthesis success ($n = 4$)

Prosthesis success was reported in four of the included studies, with slightly varying definitions. The measures were defined as "a prosthesis in function, without mobility or pain, even if one or more implants were lost", "a clinically stable prosthesis that had not been removed for 2 weeks or more during the study period", or "a prosthesis that remained unchanged and required no intervention during the observation period". The remaining study referenced the California Dental Association (CDA) rating system but did not provide specific details regarding the evaluation process.

- Prosthesis failure ($n = 4$)

Four studies used prosthesis failure as an outcome and defined it as "a prosthesis that could not be delivered because of implant failures, or prosthesis replacement because of any reasons."

- Prosthesis survival ($n = 2$)

Two studies reported on prosthesis survival. The measures were defined as one study referencing the CDA rating system to define survival, while the other did not provide any details on how survival was assessed.

- Time to function ($n = 2$)

Two studies reported on the time to function, defined as the number of days from the initial surgical intervention to the delivery of the implant-supported provisional prosthesis.

- Complications ($n = 14$)

This review identified various types of complications across studies:

- Technical complications were reported in 13 studies, including provisional prosthesis fractures, mobility at the abutment connection, screw loosening, veneering material chipping or tooth fracture, and recementation (Supporting Information S2).
- Biological complications were observed in 11 trials, with peri-implantitis reported in three studies. Heterogeneity existed in the peri-implantitis definitions, with one study using the 2011 European Workshop on Periodontology criteria (Lang et al. 2011), another using the 2014 guidelines for the diagnosis and treatment of peri-implant diseases (Padial-Molina et al. 2014), and one study not specifying its definition. Other biological complications included lack of keratinized gingiva, implant mobility, and implant migration into the nasal cavity.
- Postoperative complications were reported in 12 articles. Sinusitis, associated with zygomatic implants, was detected in five studies. Implant mobility/insufficient primary stability was observed in three trials, and implant loss due to infection occurred in three articles. Other postoperative complications included fistulas, massive swelling, pain, and soft tissue dehiscence or recession.
- Intraoperative complications were reported in eight studies, with sinus membrane perforation during zygomatic implant placement being the most frequent.

The identified subjective ClinROs in the selected literature were the following:

- Postoperative swelling rated by the clinician ($n = 1$)

One study assessed the level of postoperative swelling with an unstandardized scale from 0 (no swelling) to 4 (severe swelling affecting the eyelid and facials muscles) (Yamada et al. 2015).

Table 5 provides both qualitative and quantitative information on objective and subjective ClinROs, including evaluated time points and complications. Maximum follow-up periods varied from 1 to 10 years. Objective ClinROs were reported in 14 articles. The most frequently reported ClinROs were complications (14 articles) followed by marginal bone loss, reported in 10 articles. Nine studies analyzed marginal bone levels by standardized periapical radiographs, one multicenter study by both orthopantomogram and periapical radiographs, depending on the center, and one article did not report current information. Six articles specified that a blinded examiner performed evaluation of marginal bone level changes. Implant, prosthesis, or combined survival rates were assessed in nine studies, while success rates were reported in five trials. Bleeding-related measures (bleeding index, modified bleeding index, or bleeding on probing) were included in five studies, and the plaque index was evaluated in five studies. Probing depth was analyzed in three articles. Subjective ClinROs were reported in only one study (Yamada et al. 2015), which examined postoperative patient swelling as subjectively assessed by clinicians.

TABLE 5 | Characteristics of the included studies—clinician-reported outcomes (ClinROs), including complications, and evaluated timepoints.

		ClinROs				Complications			
			Subjective (clinician's perception) ClinROs						
Authors/ country	**Evaluated time points**	**Objective ClinROs**	**Utilized scale**	**Evaluated parameter**	**Number of evaluated items**	**Intraoperative**	**Postoperative**	**Biological**	**Technical**
Agliardi et al. 2014/IT	• Baseline • 6 m after impl. placement • 12 m • 18 m • 24 m	Bleeding index Implant failure Implant survival MBL Plaque index Prothesis success Prothesis survival	NR	NR	NR	NR	Yes • Impl. lost due to infection	No	No
Agliardi et al. 2017/PT	• Baseline • 6 m after impl. placement • 1 y • 3 y • 6 y	Bleeding index Implant success MBL Plaque index Probing depth Prosthetic success	NR	NR	NR	Yes • Sinus membrane perforation	Yes • Sinusitis	No	No
Ayna et al. 2021/DE	• Immediately after impl. placement • 1 y • 2 y • 3 y • 4 y • 5 y • 6 y	BOP Implant survival MBL Occlusal forces Plaque index Prosthesis survival	NR	NR	NR	NR	No	NR	Yes • Detachment of veneering material • Dislodgement of teeth • Loosening of multiunit abutment screw

(Continues)

TABLE 5 | (Continued)

Authors/ country	Evaluated time points	ClinROs				Complications			
			Subjective (clinician's perception) ClinROs						
		Objective ClinROs	Utilized scale	Evaluated parameter	Number of evaluated items	Intraoperative	Postoperative	Biological	Technical
Davó and Pons 2015/ES	• 6 m after definitive prosthesis • 1 y • 3 y • 5 y	Implant success Prosthetic success	NR	NR	NR	Yes • Orbital penetration	Yes • Fistula • Sinusitis	Yes	Yes • Abutment screw fracture • Definitive prostheses fractures "Sleeping" implant due to unfavorable position
Davó et al. 2018/ES	• Baseline • 4.5 m after loading • 1 y	Days of impaired activity Failure of augmentation Implant failure MBL Number of sessions with clinicians Prosthesis failure Time to function	NR	NR	NR	Yes • Sinus membrane perforation	Yes • Chronic fistula • Headache • Impl. lost due to infection • Major swelling • Mucosa recession • Sinusitis • Tumefaction	Yes • Impl. migration to nasal space • Impl. mobility	Yes • Fracture of resin • Fracture of abutment screw • Mobility at abutment connection
Ebinger et al. 2016/CH	6.5 ± 2.7 y (average)	BOP Implant survival Probing depth Plaque index	NR	NR	NR	NR	No	NR	NR
Esposito et al. 2015/IT	• 5 m after loading • 1 y	Implant failure MBL Prosthesis failure	NR	NR	NR	No	Yes • Soft tissue Dehiscences • Pain at donor site	No	No

(Continues)

TABLE 5 | (Continued)

		ClinROs				Complications			
			Subjective (clinician's perception) ClinROs						
Authors/ country	**Evaluated time points**	**Objective ClinROs**	**Utilized scale**	**Evaluated parameter**	**Number of evaluated items**	**Intraoperative**	**Postoperative**	**Biological**	**Technical**
Esposito et al. 2018/ES	• Baseline • 4.5 m after loading	Days of impaired activity Failure of augmentation Implant failure MBL Number of sessions with clinicians Prosthesis failure Time to function	NR	NR	NR	Yes • Sinus membrane perforation	Yes • Chronic fistula • Headache • Impl. lost due to infection • Major swelling • Mucosa recession • Sinusitis • Tumefaction	Yes • Impl. migration to nasal space • Impl. mobility	Yes • Mobility at abutment connection
Felice et al. 2020/IT	• Baseline • 5 m after loading • 1 y • 5 y	Augmentation failure Implant failure MBL Prosthesis failure	NR	NR	NR	No	Yes • Pain at donor site • Soft Tissue dehiscence	Yes • Peri-implantitis	No
Fernández-Ruiz et al. 2021/ES	• 1 y after loading	Implant mobility MBL	NR	NR	NR	No	Yes • Maxillary sinusitis • Orbital cellulitis	Yes • Peri-implantitis	Yes • Excessive food accumulation apical to the prostheses • Prosthetic fracture
Mozzati et al. 2015/IT	• 3 m after impl. placement • 6 m	Implant stability Infection Inflammation Pain	NR	NR	NR	NR	NR	Yes • Lack of keratinized gingiva	Yes • Teeth fracture of provisional prosthesis

(Continues)

TABLE 5 | (Continued)

Authors/ country	Evaluated time points	ClinROs				Complications			
			Subjective (clinician's perception) ClinROs						
		Objective ClinROs	Utilized scale	Evaluated parameter	Number of evaluated items	Intraoperative	Postoperative	Biological	Technical
Peñarrocha-Oltra et al. 2014/ES	• Baseline • 3 m after impl. placement • 12 m	Implant stability	NR	NR	NR	NR	Yes • Insufficient primary stability	NR	NR
Yamada et al. 2015/JP	• Baseline • After provisional placement • After definitive placement (4–7 m after imp. placement)	Implant survival Insertion torque MBL Operation time Postoperative pain Postoperative swelling	NR	NR	NR	No	Yes • Implant mobility	No	Yes • Provisional prosthesis fracture • Screw loosening in provisional prostheses
Zhang et al. 2016/CN	• 1 y after loading • 3 y • 5 y • 10 y	Implant success MBL Modified bleeding index Modified plaque index Probing depth Prosthesis success	NR	NR	NR	NR	Yes • Implant mobility	Yes • Peri-implantitis	Yes • Abutment loosening • Minor porcelain chipping • Recementation

Abbreviations: BOP, bleeding on probing; Impl., implant; m, months; MBL, marginal bone loss; NR, not reported; y, years.

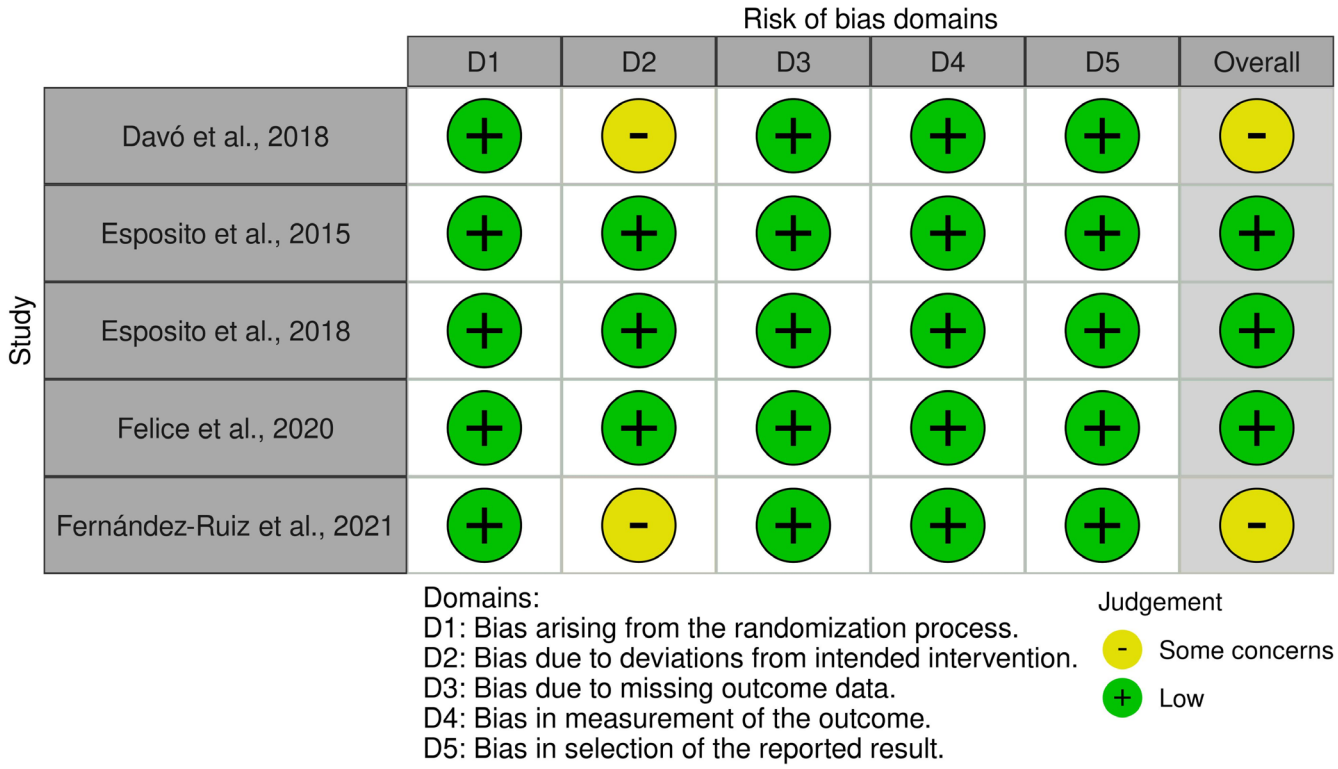

FIGURE 2 | Risk of bias assessment for randomized controlled trials.

3.5 | Risk of Bias Assessment

The quality assessment of the included RCTs by the ROB2 risk of bias assessment tool is illustrated in Figure 2. The complete risk of bias assessment for the remaining studies is displayed in Tables 6 and 7.

4 | Discussion

The present systematic review aimed to identify PROs and ClinROs with their respective assessments methods, reported simultaneously in trials using short (≤6 mm), standard-length (>6 mm) or zygomatic implants for the rehabilitation of the edentulous maxilla with implant-supported fixed full-arch prostheses.

The present systematic review predominantly revealed:

I. Ongoing efforts to report PROMs alongside traditional objective ClinROs.

II. Significant heterogeneity in the evaluation of PROs, with a frequent reliance on unstandardized PROMs or questionnaires.

III. A lack of reporting of subjective ClinROs assessing clinician's perceptions.

A PROM is a questionnaire designed to assess a patient-reported outcome (Calvert et al. 2013; Calvert et al. 2018; Weinfurt and Reeve 2022). Some PROMs are intended to measure only a single domain (e.g., a visual analog scale (VAS) for measuring pain), whereas others are designed to measure multiple domains (e.g., OHIP-14, which measures various aspects of oral health impact). A patient's score on a domain is estimated by their answers to one or more questions using standardized response options for the PROM (Weinfurt and Reeve 2022). Although readers might be familiar with this terminology, these concepts are infrequently defined in the dental literature, potentially causing confusion among practitioners.

The present review revealed an ongoing trend toward reporting PROMs in studies evaluating implant-supported fixed full-arch prostheses in the edentulous maxillae. These findings are well in line with previous systematic reviews indicating a growing interest in PROMs in implant dentistry (De Bruyn et al. 2015; Feine et al. 2018; Yao et al. 2018). It has been hypothesized that the completion of PROMs by patients, and the subsequent feedback of these data to clinicians, can support communication between patients and clinicians, thereby improving processes and outcomes (Guyatt et al. 1997; Nelson et al. 2015; Sutherland and Till 1993). For example, PROMs may prompt patients to identify what is important to them and are more likely to be understood than traditional outcomes, empowering patients to raise issues with clinicians (Feldman-Stewart and Brundage 2009; Santana and Feeny 2014).

The included studies generally showed heterogeneity in PROMs in line with previous reviews on the topic, highlighting persistent issues of variability and inconsistency in outcome reporting, especially in studies focused on the edentulous maxilla (Yao et al. 2018). This heterogeneity is problematic

TABLE 6 | Risk of bias assessment for nonrandomized controlled and observational studies.

Newcastle–Ottawa Scale										
	Selection domain				Comparability domain	Outcome domain				
References	Representativeness of the exposed cohort (0. 0 stars; 1. 1 star; 2. 2 stars)	Selection of the nonexposed cohort (0. 0 stars; 1. 1 star)	Assessment of the exposure (0. 0 stars; 1. 1 star; 2. 2 stars)	Demonstration that the outcome of interest was not present at the start of study (0. 0 stars; 1. 1 star)	Comparability of cohorts on the basis of the design or analysis controlled for confounders (0. 0 stars; 1. 1 star; 2. 2 stars)	Assessment of outcome (0. 0 stars; 1. 1 star)	Was follow-up long enough for outcomes to occur (0. 0 stars; 1. 1 star)	Adequacy of follow-up of cohorts (0. 0 stars; 1. 1 star; 2. 2 stars)	Total	Quality
Agliardi et al. 2014	1	0	1	1	1	0	1	1	6	Good
Agliardi et al. 2017	1	0	1	1	1	0	1	1	6	Good
Ayna et al. 2021	1	1	1	1	1	0	1	1	7	Good
Ebinger et al. 2016	1	0	1	1	1	0	1	1	6	Good
Peñarrocha-Oltra et al. 2014	1	1	1	1	1	1	0	1	7	Good
Yamada et al. 2015	1	0	1	1	1	1	0	1	6	Good
Zhang et al. 2016	1	0	1	1	1	0	1	1	6	Good

TABLE 7 | Risk of bias assessment for case series.

JBI critical appraisal checklist for case series											
References	Question 1 (yes; no; unclear; not applicable)	Question 2 (yes; no; unclear; not applicable)	Question 3 (yes; no; unclear; not applicable)	Question 4 (yes; no; unclear; not applicable)	Question 5 (yes; no; unclear; not applicable)	Question 6 (yes; no; unclear; not applicable)	Question 7 (yes; no; unclear; not applicable)	Question 8 (yes; no; unclear; not applicable)	Question 9 (yes; no; unclear; not applicable)	Question 10 (yes; no; unclear; not applicable)	Overall appraisal (include; exclude; seek further info)
Davó et al. 2018	Yes	Yes	Unclear	Unclear	Yes	Yes	Unclear	Yes	Unclear	Unclear	Include
Mozzati et al. 2015	Yes	Yes	Unclear	Unclear	Yes	No	Yes	Yes	Unclear	Yes	Include

because systematic reviews and meta-analyses aim to synthesize evidence from diverse studies within the field on specific interventions. The variability in outcome reporting significantly complicates the comparison of these studies, leading to an inefficient use of resources and time dedicated to research. For example, some studies failed to provide baseline pretreatment assessments, a major limitation because it does not offer the effect size of the intervention's benefit. Posttreatment assessments often reflect healing or recovery rather than the actual benefit of the dental treatment itself. Pretreatment assessments are necessary to evaluate and judge the effect of the intervention accurately.

The review also revealed that the number of assessments, study durations, and follow-ups varied among studies. Studies with short or limited follow-up periods may capture an initial positive effect that might seem more pronounced than the outcomes observed over the long term. To determine sustained and reliable outcomes, longer follow-ups are needed. With the increasing use of more robust statistical models (e.g., general linear mixed models), understanding the trajectory of outcomes over an extended period can inform appropriate time points for assessment in specific research.

Most included studies evaluated the oral health-related quality of life using a validated instrument (e.g., questionnaire), such as OHIP (Slade 1997) in their different forms (OHIP-14, OHIP 11–16, and OHIP-J54). However, as for patient satisfaction, many studies applied ad hoc clinician-generated questionnaires using different scales, complicating the comparison among studies. The use of nonstandardized data collection using ad hoc clinician-generated questionnaires may make it uncertain if they are truly measuring what they intend to measure. For example, an ad hoc patient satisfaction question may be more related to the process of care than the outcome itself, which may partly explain the reported ceiling effect when using these ad hoc questions.

A major issue is the ongoing lack of a clear, standardized definition of "satisfaction," which is often assumed to be "common sense" (Yao et al. 2018). Some studies asked about overall satisfaction, while others focused on specific aspects such as chewing or speaking. These different approaches can lead to significantly different results. Broad, general questions may elicit overly positive responses, while more targeted questions encourage more thoughtful and accurate feedback (Feine et al. 2018).

One proposed solution to this inconsistency is the adoption of a COS, which defines the essential outcomes that should be collected and reported (Clarke 2007). In implant dentistry, a recent attempt has been made to standardize the minimum set of outcomes (Tonetti, Sanz, et al. 2023). Using a COS does not mean that outcomes in a particular trial are restricted to only those in the set. It only means that these core outcomes are expected to be consistently collected and reported, but researchers can include additional outcomes relevant to their specific studies and aims (Williamson et al. 2017). In fact, it is expected that these set core outcomes evolve over time. For instance, the concept of "implant success" has long been identified as an area requiring a standardized set of outcome measures (Carr et al. 2011). However, despite the recent efforts to establish a minimum set

of standardized outcomes in implant dentistry (Tonetti, Sanz, et al. 2023), the issue of defining "success" remains unresolved. As a result, variations in the definition of implant success continue to pose challenges.

This review adopted a focused approach by specifically examining patients with implant-supported fixed full-arch prostheses in the edentulous maxilla. The primary objective was to identify instances where both PROMs and ClinROs were reported concurrently. This information will serve as a foundation for future assessments and potential improvements in outcome measurement.

Clinician decision-making involves making clinical decisions about an individual patient. This process is influenced by a complex interplay of factors, including clinician's knowledge, skills, attitudes, and personal preferences (Thoma et al. 2021; Thoma et al. 2024). The present study revealed the lack of reporting of subjective ClinROs assessing clinician's perceptions such as ease or difficulty of the procedure. The only identified subjective ClinROs were related to postoperative patient swelling, which was subjectively assessed by clinicians (Yamada et al. 2015). This finding is unsurprising, given the historical underreporting of clinician perspectives and preferences in research. Many of the included studies involved experienced clinicians, which may not necessarily reflect the realities of clinical practice for general practitioners. A recent consensus suggested that clinician preferences heavily influence implant placement protocol selection (Tonetti et al. 2019). The systematic collection of subjective ClinROs assessing clinician's perceptions such as ease of the procedure, could be particularly valuable for less experienced clinicians, helping them to select one treatment over another (Cosyn et al. 2024; Thoma et al. 2024).

4.1 | Limitations

A sensitive search strategy was employed to identify as many potentially relevant studies as possible. However, inconsistent indexing may have resulted in the omission of some relevant studies, especially those that did not simultaneously report PROMs and ClinROs. Additionally, while this review did not focus on the efficacy of the included studies, it is worth noting that seven were nonrandomized controlled trials or observational studies, and two were case series. This highlights the need for further research with robust study designs such as RCTs.

4.2 | Future Perspective

This systematic review shows that PROMs are frequently reported alongside traditional objective ClinROs in studies evaluating full-arch implant-supported fixed dental prostheses in the maxilla. However, the types, scales, and specific questionnaires used to assess PROs vary widely, complicating the comparison across studies. Furthermore, the impact of subjective ClinROs, such as ease of treatment, treatment feasibility, and clinician satisfaction, remains unclear. To address these limitations, the research community should prioritize:

- Standardization of PROMs: Utilize standardized questionnaires and scales for consistent and comparable PROMs across studies.
- Reporting of subjective ClinROs: Subjective ClinROs such as ease of treatment, treatment feasibility, and clinician satisfaction should be evaluated and reported.
- Electronic Data Collection: Implement electronic records (ePROMs/iPROMs based on big data) for consistent data collection across studies, facilitating data analysis and informed decision-making.

5 | Conclusion

PROMs and objective ClinROs are often reported together in clinical trials involving short, standard-length, or zygomatic implants for fixed dental prostheses in edentulous maxillae. However, the frequent use of unstandardized questionnaires for PROMs hinders sound comparisons across studies. Subjective ClinROs assessing the clinician's perspectives are rarely reported.

Author Contributions

Daniel S. Thoma: conceptualization, funding acquisition, writing – review and editing, supervision, resources. **Sofya Sadilina:** data curation, project administration, investigation, visualization, writing – original draft. **Ronald E. Jung:** conceptualization, writing – review and editing. **Seung-Hyun Park:** investigation, validation, formal analysis, writing – review and editing. **Jin-Young Park:** methodology, software, writing – original draft. **Ui-Won Jung:** conceptualization, funding acquisition, software, writing – review and editing. **Franz J. Strauss:** formal analysis, validation, visualization, writing – review and editing.

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Ethics Statement

Ethical approval was not required for this systematic review.

Conflicts of Interest

The authors declare no conflicts of interest.

Data Availability Statement

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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Supporting Information

Additional supporting information can be found online in the Supporting Information section.