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SYSTEMATIC REVIEW

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Single and partial tooth replacement with fixed dental prostheses supported by dental implants: A systematic review of outcomes and outcome measures used in clinical trials in the last 10 years

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Abstract

Aim: To evaluate outcome measures, methods of assessment, and analysis in clinical studies on fixed single- and multiple-unit implant restorations.

Materials and Methods: Three independent electronic database searches (MEDLINE, EMBASE, and Cochrane) were done to identify prospective and retrospective clinical studies published from January 2011 up to June 2021 with ≥20 patients and minimum 1-year follow-up period on technical and clinical outcomes of implant-supported single crowns (SCs) and partial fixed dental prostheses (P-FDPs). An entire data extraction was performed to identify primarily the most reported outcome measures and later to define the choice of assessment methods of those outcome measures. The outcomes were analysed descriptively, and the strength of association was evaluated using the Pearson chi-square test ($p \leq .05$).

Results: In a total 531 studies, 368 on SCs (69.3%), 70 on P-FDPs (13.1%), and 93 on both restoration types (17.5%) were included; 56.3% of all studies did not clearly define a primary outcome. The most frequent primary outcome was marginal bone level (MBL) (55.2%) followed by implant survival (5.3%), professional aesthetic evaluation (3.4%), and technical complications (2.1%). Peri-implant indices were the most reported secondary outcome (55.1%), followed by implant survival (39.9%), MBL (36%), and implant success (26.4%). Prosthetic failure (seven studies [3.9%]) was one of the least reported outcome measures.

Conclusions: Outcome measures and their assessment methods showed high heterogeneity among studies. Primary outcomes were not often defined clearly, and the most frequently selected primary outcome was marginal bone loss. Prosthetic outcomes, implant survival, and patient-related outcomes were only infrequently reported.

KEYWORDS
dental Implant, extraction, oral rehabilitation, outcome reporting, partial fixed prosthesis, periodontal pocket

Clinical Relevance

Scientific rationale for study: Implant-supported fixed dental prostheses (FDPs) have become a well-documented and established treatment option for the replacement of missing teeth. Numerous prospective and retrospective clinical studies have been performed in the last decade to document the survival rates and the biological and technical outcomes of implant-supported FDPs, both focusing on single crowns and multiple-unit partial FDPs. It remains difficult, however, to interpret the outcomes of the published studies because of the heterogeneity of assessed outcome measures and reporting. This review elaborates which outcomes and outcome measures were used in the scientific literature published in the last 10 years, with the aim to provide suggestions for the design and the reporting of future studies.

Principal findings: Large heterogeneity of assessing and reporting the outcomes of the implant-supported FDPs was found, with marginal bone levels being the most frequently reported outcome.

Practical implications: Future studies should address more the biological and technical outcomes of the restorations supported by implants.

1 | INTRODUCTION

Fixed dental prostheses (FDPs) supported by dental implants have been the subject of numerous clinical studies in the last decades. The myriad of published data on the survival rates and the general clinical outcomes of the implant-supported FDPs has resulted in several systematic reviews (SRs) and meta-analyses in the literature (Pjetursson et al., 2007; Jung et al., 2012). All in all, implant-supported FDPs have performed well and can be considered a very well-documented treatment option for the replacement of single or multiple missing teeth (Pjetursson et al., 2007; Jung et al., 2012).

Nevertheless, during the review procedures, some limitations of the current scientific literature on implant-supported FDPs were recognized (Schumann, 1992; Pjetursson et al., 2007; Jung et al., 2012). A large heterogeneity of study designs and differences in reporting of data were found, often hampering the interpretation of the outcomes for further evaluation. The reported clinical outcomes of the restorations included their survival, that is, whether the restorations were still in place at time of the follow-up examination, and their success, that is, whether the restorations were still perfect, without any problems at the follow-up visit.

In this case, some authors have used the term "complication-free" instead of "success" (Pjetursson et al., 2012).

One of the main difficulties of review procedures was that definitions of these terms could be different between studies or were missing in the manuscripts. While some authors clearly discriminated survival from success, others reported success rates while evaluating the survival of restorations, or vice versa. Hence, a clear differentiation of survival and success was highly recommended during recent consensus conferences for better standardization of reporting (Cairo et al., 2012; Pjetursson et al., 2014).

Another difficulty when evaluating the literature for inclusion or exclusion in an SR was the heterogeneity of the reporting on FDP complications. Complications included technical problems, biological problems, and/or aesthetic problems. These problems were reported as single parameters, separate parameters, or combined. Furthermore, in some studies standardized indices were used for the assessment, while in others self-developed, non-standardized criteria were applied.

For the assessment of technical outcomes of the implant-supported restorations as an example, in some studies well-defined criteria such as the United States Public Health Service (USPHS) criteria (Zembic et al., 2015) or the Californian Dental Association criteria (Díez-Quijano et al., 2020) were used, mostly modified for the evaluation of implant restorations. These standardized assessment methods helped the reviewers to compare the outcomes of different studies, while self-developed criteria were frequently difficult to interpret and compare with other literature.

One very common technical problem that is assessed and reported in several different ways in studies on implant-supported FDPs is chipping or extended fracture of the veneering ceramic. While some studies report chipping of the veneering ceramic in a very meticulous way, discriminating small superficial chippings from large ones, others report generically on the chippings (Pjetursson et al., 2014). A comparison of these different studies is very difficult, though it is unknown whether a detailed discrimination is of relevance for the overall outcomes (Pjetursson et al., 2014). The same applies to the different outcome measures used for the assessment of the biological and the aesthetic results of the implant-supported FDPs. Studies reporting on well-defined indices can be compared and can well be used for meta-analyses of the literature. However, which indices and criteria are of primary and secondary clinical relevance is not defined yet. One example is the widely used Pink Aesthetic Score for the assessment of the aesthetics of implant-supported FDPs (Furhauser et al., 2005). The evaluation encompasses a rating of several well-defined parameters with scores and a mean score is calculated for the aesthetics of a respective restoration. The score can be used for statistical comparison of test and control sites, yet its clinical interpretation and relevance for daily clinical practice remain questionable.

Numerous different outcome measures have been published in the last decade to assess implant-supported FDPs, and a standardization is desirable for better interpretation of the results of different studies.

Therefore, it was the aim of the present SR to analyse all possible outcome measures for assessing health and disease conditions, including evaluation of complications and aesthetic outcomes, of implant-supported single crown (SC) and partial multiple-unit fixed dental prostheses (P-FDPs) reported in the literature of the last 10 years.

2 | MATERIALS AND METHODS

2.1 | Study design

The Preferred Reporting Items for Systematic Reviews and Meta-analyses guidelines (PRISMA [Page et al., 2021]) were applied in designing and reporting this review. Furthermore, the protocol of the present review was registered at PROSPERO (Reg. ID: CRD42021278459).

The PICOS for the present review were as follows:

- (P) Types of participants: Adult patients with single and partially edentulous conditions rehabilitated with implant-supported fixed restorations;
- (I) Types of interventions: Any type of prosthetic treatment for single and/or partial tooth replacement with implant-supported SCs or multiple-unit, P-FDPs, made out of metal–ceramics or all ceramics, and veneered or monolithic;
- (C) Comparison between interventions: All types of comparative or non-comparative treatments with implant-supported SCs and P-FDPs;
- (O) Type of outcomes measures: All types of outcomes measures differentiated as primary and secondary outcomes, and their methods of assessment;
- (S) Types of studies: Randomized controlled clinical trials (RCTs), controlled prospective studies (CPS), prospective cohort studies (PCS), retrospective studies (RS), and pre- and post-case series (PPCS).

The following PICOS questions were addressed:

PICOS question 1

In clinical studies on outcomes of (1) single-unit and/or (2) multiple-unit implant-supported P-FDPs, what are the outcome measures commonly reported for the assessment of health or disease of implant-supported restorations?

PICOS question 2

In clinical studies on outcomes of (1) single-unit and/or (2) multiple-unit implant-supported P-FDPs, what methods are used in the assessment of the reported outcome measures?

PICOS question 3

In clinical studies on outcomes of (1) single-unit and/or (2) multiple-unit implant-supported P-FDPs, is there a difference in reporting outcomes comparing studies of different design?

2.2 | Information sources and search strategy

A literature search was performed using different electronic databases (MEDLINE by PubMed, EMBASE, and The Cochrane Oral Health Group Trials Register) to identify studies published in the last 10 years. A detailed search strategy and the respective combinations of search terms are reported in Appendix 1.

Furthermore, the reference lists of previous SRs and of the included studies were checked to hand-search articles (Pieralli et al., 2018; Pjetursson et al., 2018, 2021; Rabel et al., 2018; Sailer et al., 2018).

The search results were imported to a reference management software (EndNote X9: Thomson Reuters).

2.3 | Inclusion criteria

The following studies were included:

1. Human studies
2. Type of studies: RCT, CPS, PCS, RS, and PPCS. A minimum of 20 patients at the final follow-up was considered for PCS, RS, and PPCS
3. Published from 1 January 2011 to 23 June 2021
4. A follow-up time of at least 1 year after insertion of the final restoration
5. SCs and P-FDPs supported by root form dental implant and made of metal–ceramic or ceramic materials, monolithic or bi-layered, namely zirconia with/without veneering, glass–ceramic, polymer-infiltrated ceramic network, and SC with directly veneered ceramic implant abutment.

2.4 | Exclusion criteria

1. Technical reports and case reports
2. Studies not declaring outcomes a priori
3. Unclear reporting on dropouts/number of patients at final follow-up per group.

2.5 | Selection of studies and data collection process

Two investigators (Luigi Barbato and Lapo Serni) performed the title/abstract screening and the full-text eligibility process based on the inclusion/exclusion criteria. Any disagreement was discussed with a third author (Umberto Pagliaro).

A specific extraction dataset was prepared and used for qualitative assessment and statistical analysis. The data extraction encompassed first author name, year of publication, country of publication origin, journal, setting (university, private clinics, etc.), study type, follow-up time, number of patients, number and type of implant restoration (SCs and P-FDPs), and number of implants. Additionally, all the outcomes related to the implant-supported restoration were registered. In case of multiple publications on the same patient cohort, all manuscripts were reviewed and data were retrieved from earlier manuscripts when needed.

2.6 | Data items and outcomes

Since the aim of the SR was to identify outcome measurements, no specific variables could be defined a priori. An entire data extraction of all enclosed manuscripts was performed, and outcomes were clustered for the following:

- *Implant variables*: any outcome related to the implant (e.g., implant survival, success and failure; biological outcome measures such as peri-implant periodontal indices, presence or absence of peri-implant mucositis, and/or peri-implantitis; implant technical problems such as implant fractures; implant stability measurements);
- *Prosthetic variables*: any outcome related to the restoration (e.g., restoration survival, success and failure; technical complications such as chippings or fractures of veneering material, fractures of restorations, fractures of abutments, fractures of screws, loosening of screws, de-cementations);
- *Peri-implant hard and soft tissue variables*: any outcome related to hard and soft tissue assessment (e.g., marginal bone level [MBL] at x-ray, soft tissue thickness, soft tissue level, width of keratinized tissue, and 3D volumetric assessment);
- *Patient-related outcome measurement*: any outcome related to patient satisfaction (e.g., general satisfaction, aesthetic or functional satisfaction);
- *Aesthetic evaluation*: any outcome related to the aesthetic evaluation of the implant-supported restoration rated by clinicians (e.g., PES/WES and other composite indices, inter-dental papilla assessment, discoloration);
- *Economic aspects*: any outcome related to the economic evaluation of the restoration in terms of time and costs.

After the extraction of the data, a grouping of the data into domains, such as implant-related outcomes (domain 1), implant prosthetic outcome measures (domain 2), or similar, was foreseen.

The definition of the domains could be made only after data extraction, however.

2.7 | Risk-of-bias assessment

The risk-of-bias (RoB) assessment had two steps. Initially, the overall RoB assessment was performed using different tools in relation to study design:

- The Cochrane RoB-1 tool was used for RCTs.
- The Newcastle–Ottawa Scale was used for CPS and PCS.
- The National Institute of Health's quality assessment tool for before–after studies with no control group was used for RS and PPCS.

Then, to describe the RoB of the outcome measurements for all study types, a specific assessment for the outcomes was performed using the domain 4 from the Cochrane RoB-2 tool. Briefly, five questions [(1) Was the method of measuring the outcome inappropriate? (2) Could measurements of the outcome have differed between groups? (3) Were the examiners aware of the intervention received by participants? (4) Could the assessment of the outcome have been influenced by knowledge of the intervention received? and (5) Is it likely that assessment of the outcome was influenced by knowledge of the intervention received?] were answered and a specific algorithm was used to rate the study at low, unclear, or high RoB (Higgins et al., 2021).

2.8 | Statistical analysis

The data were analysed using the SPSS statistical package (IBM SPSS Statistics version 26 [IBM Corp.]).

Descriptive analysis was performed, and strength of association was evaluated using the Pearson chi-square test. Data reported on a scale were not normally distributed, and median and interquartile range (IQR) were reported. However, the means and SDs or the confidence intervals (CIs) were also reported for ease of interpretation. The level of significance was set at $p \leq .05$. As all p-values were either very small or non-significant, no correction for multiple testing was performed.

To illustrate graphically the relationship between all the variables, an analysis of multiple correspondence was performed.

3 | RESULTS

3.1 | Literature search outcomes

The extensive literature search in the three scientific databases (MEDLINE [PubMed], EMBASE, and the Cochrane Trials Register) led to the identification of 11,662 titles. After elimination of duplicates, 8138 titles were screened, out of which 1147 were pursued for further evaluation of eligibility for the present review. After further hand-searching, 58 additional studies were included for evaluation. After the evaluation of the titles, selected abstracts, and full-text manuscripts, 531 studies were considered for this review. The reasons for exclusion of studies from this review were reporting on full-arch implant-supported restorations ($n = 176$), follow-up period less than 1 year or not reported ($n = 143$), no detailed reporting of the type of restoration ($n = 89$), unclear dropout rate and reported data ($n = 38$), outcomes not clearly defined/study design unclear ($n = 37$), cross-sectional study ($n = 24$), less than 20 patients in final follow-up

($n = 20$) (applied to all study types except RCTs), and mixed data on teeth and implants ($n = 6$).

Figure 1 shows the details of the literature search as well as the inclusion and exclusion of the studies during the review process.

3.2 | Descriptive results

Of the 531 included studies, 167 were RCTs (31.5%), 18 were CPS (3.4%), 33 were PCS (6.2%), 174 were retrospective studies (32.8%), and 139 were pre- and post-case series (26.2%).

As only a few CPS and PCS were found, the two study types were merged and the following evaluation was done on the level of prospective studies (CPS and PCS).

Considering the type of implant-supported restorations, 328 studies (61.8%) reported on implant-supported SCs, 54 studies (10.2%) reported on P-FDPs, and 149 studies (28.1%) reported on both treatment options.

The follow-up time in the included literature ranged from 1 to 22 years. The median follow-up was 3.5 years (IQR 3.5) (Figure 2).

An overview of the countries in which the research was performed and the years of publication is given in Figure 3a,b. The year of publication was evenly distributed around 2016.

The majority of studies included 100 or less patients at baseline ($n = 434$). In 91 studies, between 100 and 1000 patients were included, and in 3 studies, more than 1000 patients were included at baseline. The mean number of included patients at baseline in the present review was 88.3 (95% CI: 68.4–108.2) (Figure 3c).

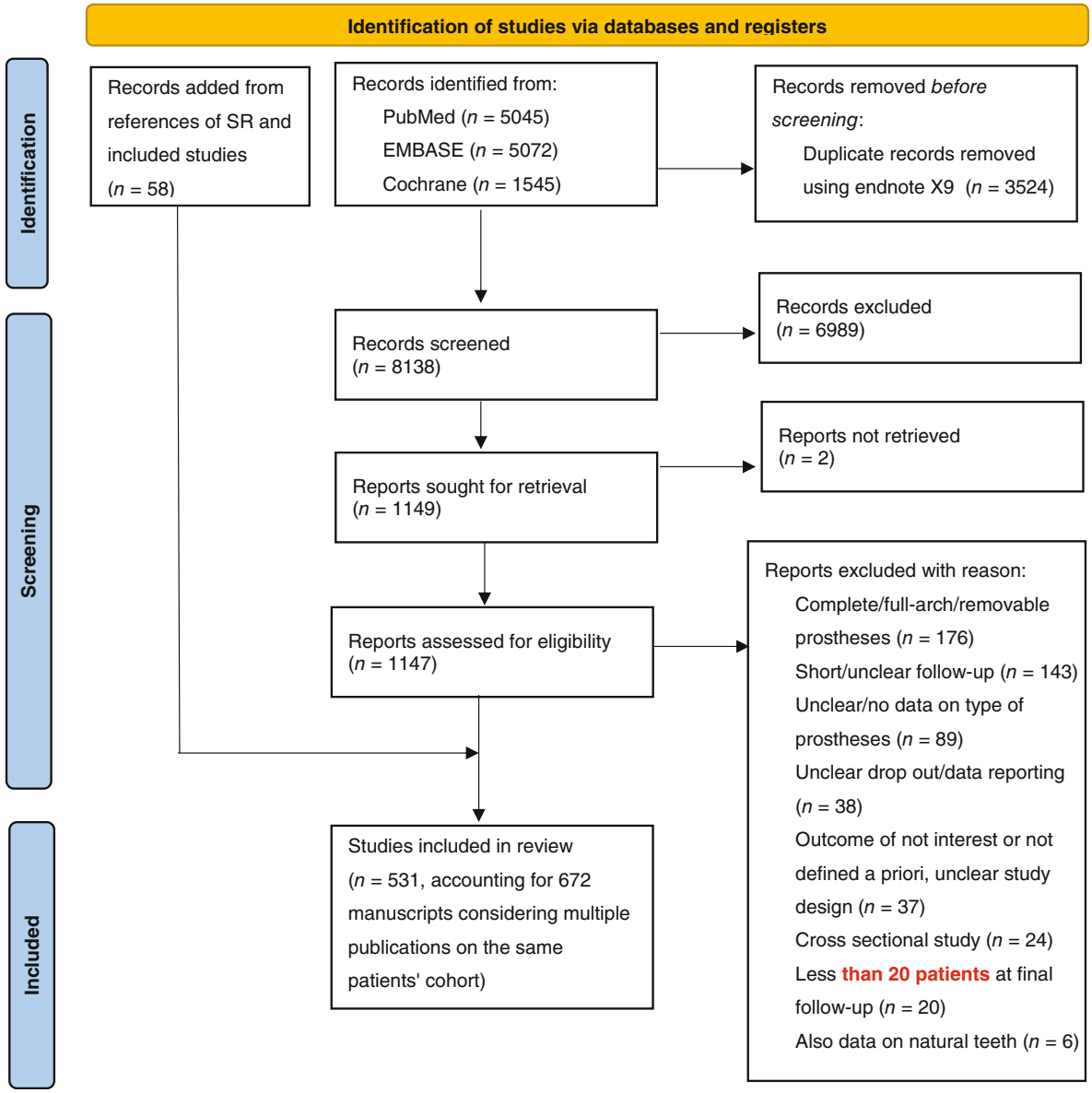

FIGURE 1 PRISMA 2020 flow diagram for new systematic reviews, which included searches of databases and registers only. SR, systematic review. Adapted from Page et al., 2021

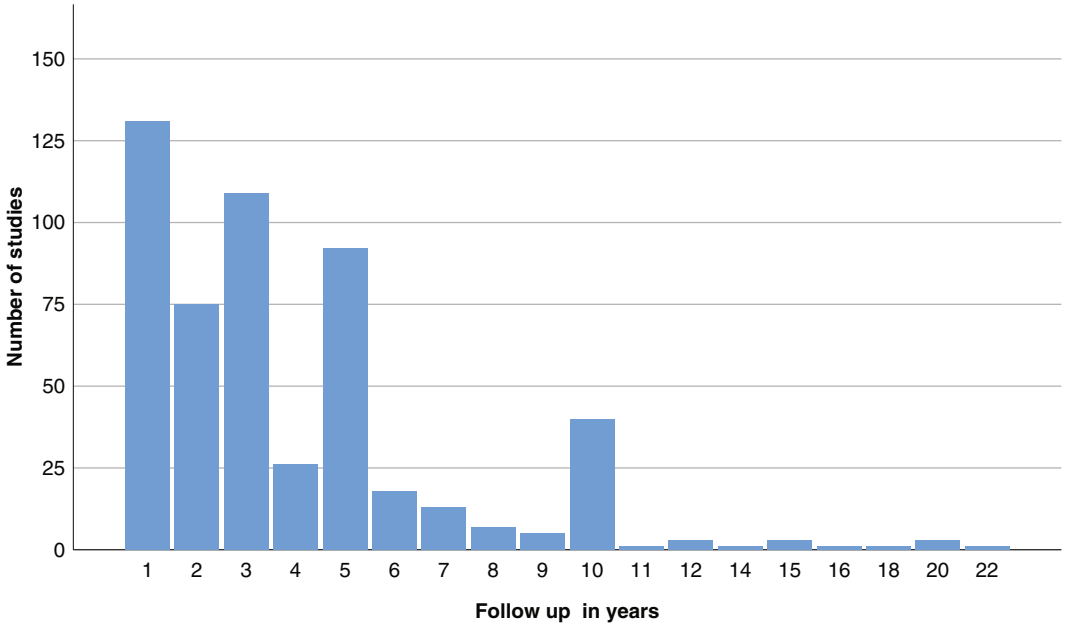

FIGURE 2 Follow-up times in the included literature [Colour figure can be viewed at wileyonlinelibrary.com]

The frequency distribution of implants evaluated in the studies was as follows: 336 studies reported on the number of implants between 11 and 100 and 169 studies on the number of implants between 101 and 1000. Six studies reported more than 1000 implants. The mean number of implants was 150 (95% CI: 107.2–192.2) (Figure 3d).

In total, 368 implant-supported SCs were examined in the included literature. Two-hundred and ninety-two studies reported on up to 100 SCs, 73 studies on up to 1000 SCs, and 3 studies on more than 1000 SCs. The mean number of SCs was 102 (95% CI: 71.8–131.6).

Seventy studies reported on implant-supported P-FDPs. Fifty-six studies reported on up to 100 P-FDPs and 14 studies reported on up to 1000 P-FDPs. The mean number of P-FDPs in the studies was 68.7 (95% CI: 42.3–95).

Table 1 gives an overview of the median amount of baseline patients and implants included in the different studies as well as the number of implant-supported SCs and P-FDPs and the median follow-up in years.

3.3 | Risk-of-bias

Considering the overall RoB, 54 studies (10%) were considered as low, 83 studies (15.7%) as unclear, and 394 (74.3%) studies as high.

Considering the specific assessment of RoB for outcome (RoB-2), 230 studies (43.3%) were at low, 284 (53.5%) at unclear, and 17 (3.2%) at high RoB. The examiner of the outcome was not blinded, or no information was reported on this in 329 studies (62%) (Question 3). Outcome assessment could have been influenced by knowledge of the intervention received by participants in 291 studies (54.8%) (Question 4), while the outcome assessment was likely influenced in 10 studies (1.9%).

3.4 | PICOS question 1: Outcome measures

3.4.1 | Outcomes reported in the studies (result of individual studies)

Six main domains were identified during the evaluation of the literature, and some additional parameters not directly related to the implant-supported restoration outcomes were attributed to a seventh domain.

Overall, the data extraction included domains focusing on implant-related outcomes, such as implant survival, success, and failure; implant biological outcome measures (domain 1) such as peri-implant periodontal indices, presence or absence of peri-implant mucositis, and/or peri-implantitis; implant technical problems such as implant fractures; and implant stability measurements.

The extracted domains on implant prosthetic outcome measures (domain 2) included implant restoration survival, success, and failure; implant restoration technical complications (chippings or fractures of veneering material, fractures of restorations, fractures of abutments, fractures of screws, loosening of screws, de-cementations).

The domain on peri-implant tissue stability-related outcome measures (domain 3) encompassed MBL measurements, and soft tissue stability assessments (marginal soft tissue level/recession, soft tissue thickness, width of keratinized tissues, 3D volumetric assessments).

Furthermore, the domain of patient-related outcome measures (PROMs) on the overall satisfaction and the satisfaction with the aesthetics and the function of the implant-supported restorations were

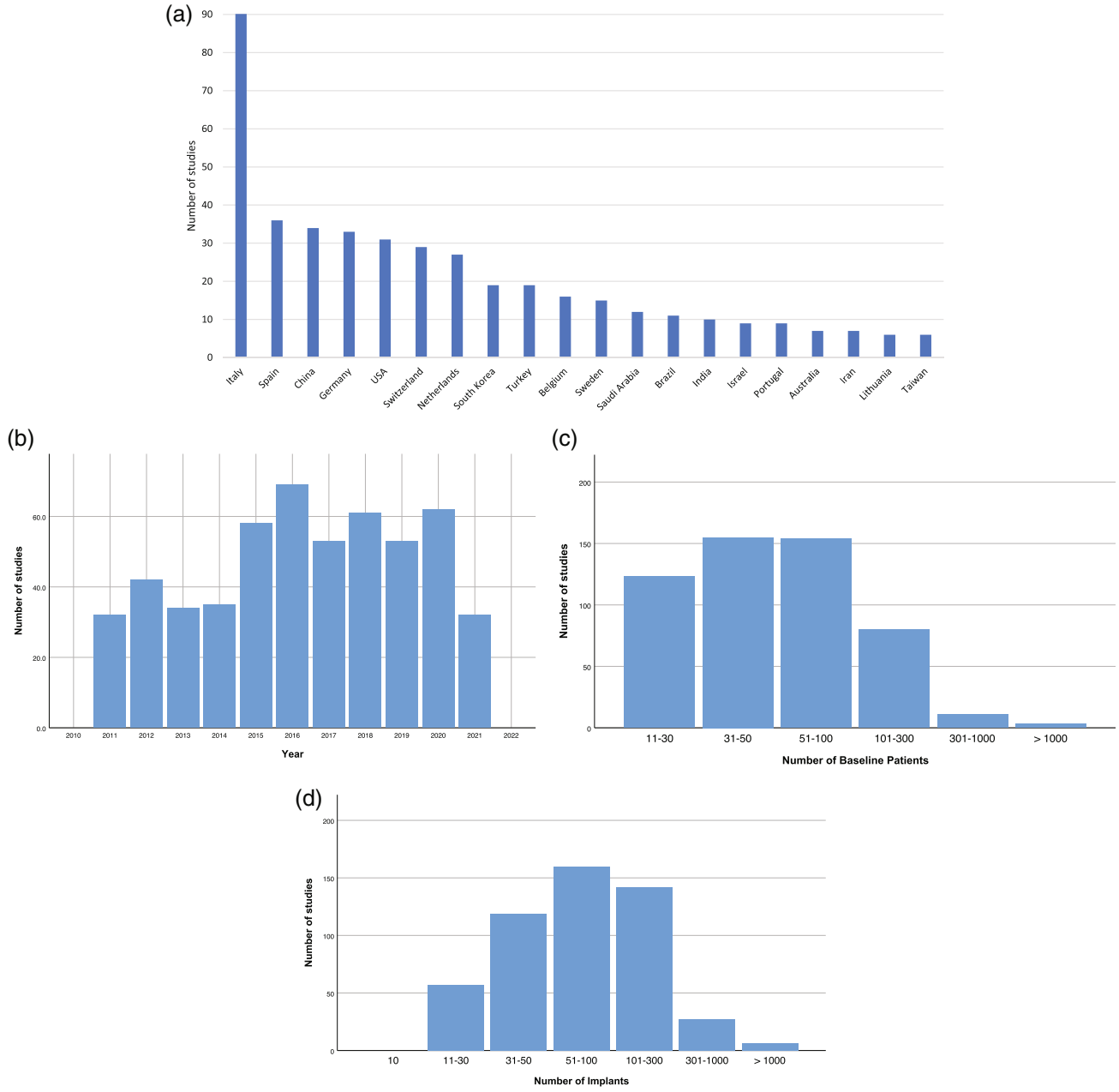

FIGURE 3 (a, b) Overview of the countries in which the research was performed and the years of publication. (c) Mean number of included patients at baseline. (d) Mean number of implants in the included studies [Colour figure can be viewed at wileyonlinelibrary.com]

assessed using questionnaires, with or without the visual analogue scales (VAS) (domain 4).

The aesthetic outcomes of the implant-supported restorations were assessed with aid of composed indices (e.g., PES/WES [Furhauser et al., 2005; Belser et al., 2009]; ICAI [Vaidya et al., 2015]) and by evaluating the inter-dental papilla presence or absence (Papilla Index [Jemt, 1997] and papilla recession), and the assessment of the mucosal discoloration (domain 5).

Finally, the economic aspects were assessed by evaluating the total cost of the treatment and the cost of management of complications (domain 6).

Additional outcomes, not attributed to the above domains, encompassed the crown length ratio and the periodontal outcomes of natural teeth adjacent to implants (domain 7).

A detailed description of the outcomes for type of studies and RoB for the outcome is given in Table 2.

MBL assessment at x-ray was the most frequently reported outcome, described in 453 articles (85.3%) (199 low, 242 unclear, and 12 high RoB) (Figure 4).

Implant survival was assessed in 214 studies (40.3%) (89 low, 121 unclear, and 4 high RoB), success was assessed in 145 studies (27.3%) (63 low, 77 unclear, and 5 high RoB), and failure in 107 studies

TABLE 1 Overview of the mean and median number of baseline patients and implants included in the different types of studies

	RCT				CPS + PCS			
	Mean	SD	Median	IQR	Mean	SD	Median	IQR
Baseline P. (*N*)	43.43	16.36	47	31	111.00	67.88	111	—
Implants (*N*)	86.57	23.75	96	36	188.00	165.46	188	—
Single crown rest (*N*)	37.29	10.31	33	14	140.50	130.81	141	—
Implant with FPD (*N*)	22.57	9.48	21	19	14.50	4.95	15	—
Follow-up (years)	1.83	0.96	1.30	2.00	3.00	2.83	3.00	—
	RS				PPCS			
Baseline P. (*N*)	121.85	79.76	95	122	40.71	12.59	40	26
Implants (*N*)	244.00	153.89	231	289	88.29	38.46	68	58
Single crown rest (*N*)	88.00	65.01	86	95	42.86	16.35	45	13
Implant with FPD (*N*)	84.31	48.68	97	76	20.43	15.82	12	27
Follow-up (years)	7.16	3.78	7.00	5.70	3.61	1.88	3.00	3.00

Abbreviations: CPS, controlled prospective studies; FPD, fixed dental prostheses; IQR, interquartile range; PCS, prospective cohort studies; PPCS, pre- and post-case series; RCT, randomized controlled clinical trial; RS, retrospective studies.

(20.1%) (53 low, 52 unclear, and 2 high RoB). Peri-implant mucositis was reported in 38 (7.2%) studies and peri-implantitis in 62 (11.7%).

Prosthetic survival was assessed in 37 studies (7%) (14 low and 23 unclear RoB), success in 41 studies (7.7%) (19 low, 21 unclear, and 1 high RoB), failure in 38 studies (7.2%) (19 low, 18 unclear and 1 at high RoB). Technical complications were assessed in 138 studies (26%) (60 at low, 74 at unclear, and 4 at high RoB).

PROMs were evaluated in 95 studies (17.9%) (45 low, 48 unclear, and 2 at high risk).

Peri-implant soft tissue assessments were reported in 135 studies (25.4%) (73 low, 58 unclear, and 4 at high RoB), while professional aesthetic evaluation was done in 137 studies (25.8%) (79 low, 52 unclear, and 6 at high risk).

The economic aspects represent the less investigated outcome, being reported by only 11 studies (2.1%) (Table 2).

3.4.2 | Primary and secondary outcomes

Of 531 studies included, 299 did not report which was the primary outcome, or reported two or more primary outcomes and were not included in this evaluation.

Thus, 232 studies (43.7%) defined a single primary outcome. Among these studies, 54 (10.2%) had a single outcome, and therefore, secondary outcomes were assessed in 178 studies (33.5%). An opposite statement (e.g., "the primary outcome was" or similar) was used only in 155 studies (29.2%).

The most frequently used primary outcome was, by far, MBL (128 studies, 55.2%) followed by implant survival (28 studies, 5.3%), professional aesthetic evaluation (18 studies, 3.4%), and technical complications (11 studies, 2.1%).

Considering secondary outcomes, peri-implant indices were the most used (98 studies, 55.1%), followed by implant survival (71 studies, 39.9%), MBL (64 studies, 36%), and implant success (47 studies, 26.4%). The least used were prosthetic failure (7 studies, 3.9%), 3D soft tissue volume assessment (6 studies, 3.4%), and economic aspect (4 studies) (Table 3, Figure 4).

3.5 | PICOS question 2: What was the method to assess the outcome?

3.5.1 | Outcome measures (percentages are related to the total number of studies reporting a specific outcome)

The included studies presented a huge heterogeneity in outcome measurements (Appendix 2).

Implant and prostheses survival/success/failure were measured using both a specific definition provided by the same author of the manuscript or widely accepted definition/criteria.

Implant survival was defined as an implant in situ with or without complication in 25.2% of the studies and, quite surprisingly, was not defined in 36.4% of the studies reporting this outcome (214 studies). The most frequently adopted criteria for implant success were Albrektsson and Zarb 1986 (Albrektsson et al., 1986) (27.6%) followed by Buser 1990 (Buser et al., 1990) (16.6%). Implant failure was defined as loss or removal of the implant for any reason (e.g., mobility, infection, fracture) in 69.2% of the studies reporting this outcome.

Prosthetic survival was defined as original prostheses in situ with or without modifications in 43.2% of the studies, while the USPHS criteria were used in 21.6% of the studies. More than 50% of the studies defined prosthetic success as a stable restoration in function with no complications, while 71.1% of the studies defined prosthetic failure as loss/removal/replacement of the restoration.

TABLE 2 Outcome reported in the studies included in the SR

Outcome	Total number of studies	Type of study				Risk of bias (outcome)		
		RCT	CCT-PCS	RS	PPCS	Low	Unclear	High
Implant survival/success								
Implant survival	214	58	26	71	59	89	121	4
Implant success	145	34	11	54	46	63	77	5
Implant failure	107	40	12	28	27	53	52	2
Prostheses survival/success								
Prosthetic survival	37	7	5	12	13	14	23	–
Prosthetic success	41	14	3	13	11	19	21	1
Prosthetic failure	38	22	2	7	7	19	18	1
Implant biological complications (any type)	116	44	7	39	26	54	60	2
Mucositis	38	10	6	13	9	18	20	–
Peri-implantitis	62	17	9	23	13	24	37	1
Prostheses technical complications (any complication)	138	49	6	46	37	60	74	4
Chipping	34	10	–	15	9	9	22	3
Prosthesis/framework fracture	53	17	1	21	14	17	32	4
Veneering fracture	41	21	1	13	15	17	21	3
Fracture of the abutment	39	17	–	14	8	16	22	1
Fracture of the screw	38	14	–	17	7	16	21	1
Screw loosening	67	22	–	17	18	21	43	3
Loss of retention	33	10	–	15	8	10	20	3
Decementation	25	9	1	10	5	8	22	3
Peri-implant indices (CAL, PD, BoP, PI, and GI)	266	94	31	65	76	133	127	6
Peri-implant bone level on x-ray	453	147	43	135	128	199	242	12
Implant stability	40	21	8	3	8	19	21	–
Patient-related outcomes	95	42	7	18	28	45	48	2
Peri-implant soft tissue assessment	135	54	15	24	42	73	58	4
Gingival margin position (e.g., recession, facial tissue level)	91	35	12	18	26	47	41	3
Soft tissue thickness, volume	30	14	1	2	13	19	11	0
KT assessment	64	30	6	9	19	41	21	2
Aesthetic evaluation by clinician	137	56	14	32	35	79	52	6
Index on photo (e.g., PES/WES, ICAI)	93	34	10	27	22	52	38	3
Papilla Index (e.g., Jemt)	70	34	6	10	20	42	25	3
Economic aspects	11	6	1	4	–	5	5	0

Abbreviations: BoP, bleeding on probing; CAL, clinical attachment level, GI, gingival index; ICAI, implant crown aesthetic index; KT, keratinised tissue; PCS, prospective cohort studies; PD, probing depth; PES, pink esthetic score; PI, plaque index; PPCS, pre- and post-case series; RCT, randomized controlled clinical trial; RS, retrospective studies; SR, systematic review; WES, white esthetic score.

Measurements of peri-implantitis and mucositis were very heterogeneous. The majority of the authors used widely accepted definition for plaque, bleeding, and gingival index around the implant.

Almost all (98%) of the studies used linear measurements on periapical x-rays for MBL assessment.

PROMs were frequently assessed using the VAS (60%) and the Likert scale (21.1%).

Aesthetic evaluation was often assessed using validated index/score on photo (e.g., PES/WES [Furhauser et al., 2005; Belser et al., 2009], ICAI [Vaidya et al., 2015]) and the Papilla Index (Jemt, 1997).

3.6 | PICOS question 3: Influence of study design and the RoB on outcome measures

3.6.1 | Outcomes measures in different study types

Tables 4 and 5 display the comparison of the reporting of the respective outcome measures in the different study types.

Nine out of the 16 outcome measures (implant stability, prosthetic failure, peri-implant indices, soft tissue recession, soft tissue thickness, KT assessment, MBL, PROMs, and Papilla Index) included in

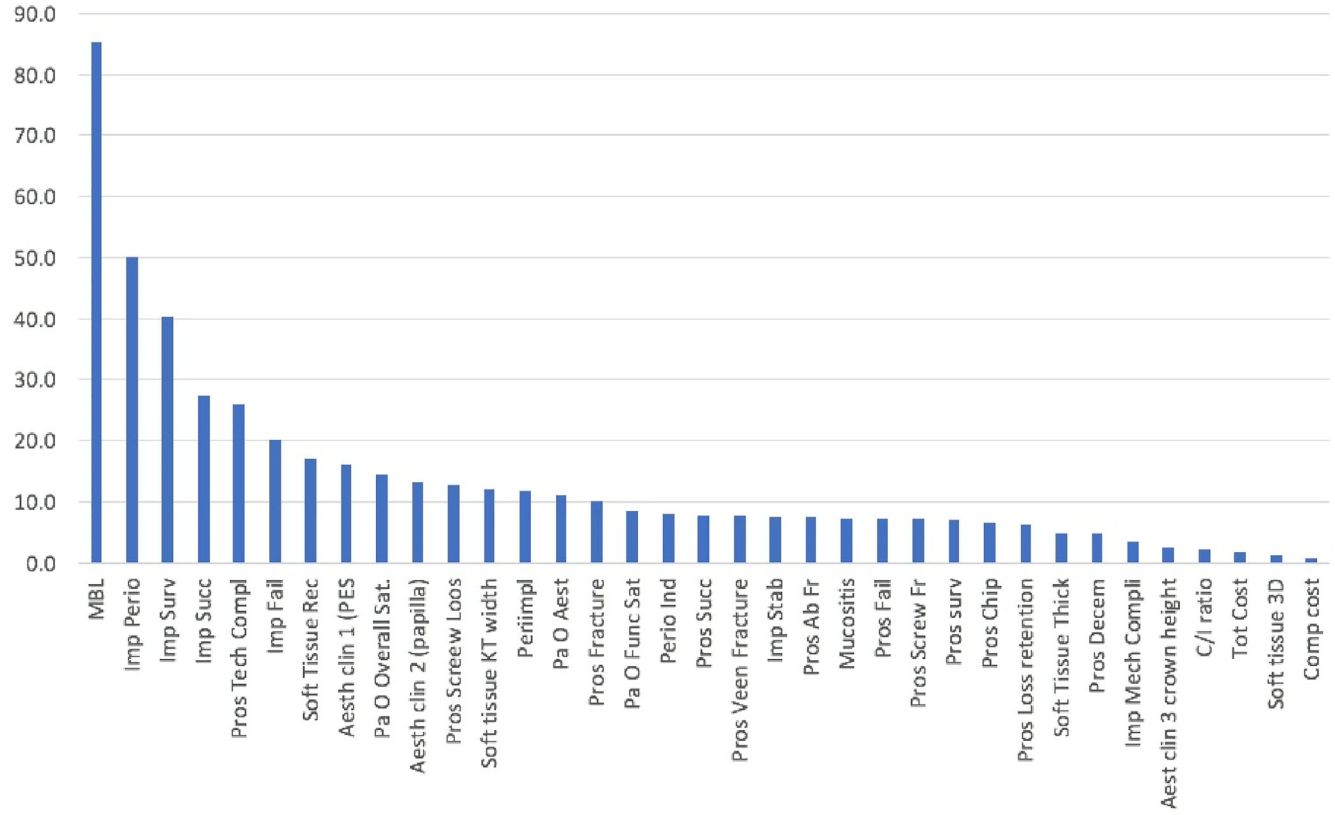

FIGURE 4 Overview of the outcomes evaluated in the included literature and the amount of literature addressing the respective outcome (%); 100% corresponds to the 531 included studies [Colour figure can be viewed at wileyonlinelibrary.com]

this analysis were significantly more often reported in RCTs than in other types of studies. Retrospective studies more frequently reported on implant success and on screw loosening than the other types of studies (Table 4).

The reporting focused more often on the domains of implant-related outcomes, such as the peri-implant periodontal indices, or the presence or absence of peri-implant mucositis and/or peri-implantitis, or the assessment of peri-implant hard and soft tissue stability-related outcomes and the implant stability, than on the implant restoration-related outcomes.

Finally, PROMs were significantly more often reported in RCTs than in the other types of studies ($p < .01$); the same applies to the aesthetic outcomes ($p = .02$).

Even grouping the outcomes, all the domains of outcomes measures tended to be most frequently addressed in RCTs compared to the other types of studies. The difference was significant for peri-implant tissue-stability-related outcome measures (domain 3), patient-related outcomes (domain 4), and aesthetic outcomes (domain 5) ($p < .01$) (Table 5).

No significant differences between study types were found with respect to whether or not primary outcomes were defined. Among 232 studies (43.7%) defining the primary outcome, 35.3% were RCTs, 8.6% were prospective studies (CPS and PCS), 32.3% were RS, and 23.7% were PPCS.

3.6.2 | Outcome measures and RoB-2

The reporting on the different domains was not correlated with the RoB of the studies, with one exception, namely the analysis of aesthetic outcomes ($p < .05$) (Table 5).

Chipping of the veneering material and de-cementation (domain 2) were significantly more often reported in literature of unclear bias than in studies with obviously low or high bias. The assessment of keratinized tissues (domain 3) was predominantly reported in the literature of low bias. The same applies to the aesthetic indices and the assessment of inter-dental papillae (domain 5) (Table 6).

3.6.3 | RoB-2 in different study types

Overall, significant differences of RoB were found for the study type. RCTs exhibited significantly more often a low RoB than the other study types, while RS were more often of unclear or high RoB ($p < .01$). Prospective studies (CPS and PCS) had an unclear or low RoB, and PPCS were frequently of unclear RoB.

Sample size computation, however, was mainly performed in RCTs, with a significantly higher frequency than at all other types of studies ($p < .01$).

TABLE 3 Studies clearly defining primary and secondary outcome

	Primary outcome (232 studies)		Secondary outcome (178 studies)	
	Frequency	Percent within studies	Frequency	Percent within studies
Peri-implant bone level	128	55.2%	64	36%
Implant survival	28	5.3%	71	39.9%
Implant success	7	1.3%	47	26.4%
Implant failure	8	1.5%	29	16.3%
Peri-implant indices	2	0.4%	98	55.1%
Mucositis/peri-implantitis	4	0.8%	36	20.2%
Prosthetic survival	5	0.9%	13	7.3%
Prosthetic success	3	0.6%	13	7.3%
Prosthetic failure	1	0.2%	7	3.9%
Technical complications	11	2.1%	42	23.6%
PROMs	1	0.2%	37	20.8%
Aesthetic outcomes (PES/WES; ICAI)	18	3.4%	19	10.7%
Papilla Index Jemt	—	—	26	14.6%
Gingival margin position (e.g., recession)	10	1.9%	29	16.3%
Implant stability	1	0.2%	9	5.1%
Soft tissue thickness	3	0.6%	10	5.6%
Keratinized tissue	—	—	25	14%
Perio outcomes (FMPS, FMBS)	—	—	21	11.8%
3D soft tissue volumetric analysis	1	0.2%	6	3.4%
Economic aspect	1	0.2%	4	2.2%

Abbreviations: FMBS, full mouth bleeding score; FMPS, full mouth plaque score; ICAI, implant crown aesthetic index; PES, pink esthetic score; PROMs, patient-related outcome measures; WES, white esthetic score.

3.6.4 | Type of restoration, setting, and funding in different study types

Overall, significant differences were found regarding which type of restorations were tested in the different study types. Implant-supported SCs were significantly more often evaluated in RCTs than in the other types of studies ($p < .01$), while implant-supported P-FDPs were mostly tested in PPCS ($p < .01$). RS studies most frequently tested both types of restorations, namely SCs and P-FDPs, in the same study.

No significant differences were found with respect to the setting of the studies; the studies were performed either in private or public settings or mixed in both in the same study (Table 7).

Of the 98 studies (18.5%) not reporting the setting, 34.7% were RCTs, 9.2% prospective studies (CPS and PCS), 30.6% RS, and 25.5% PPCS.

A significant difference was, however, observed for the sources of funding supporting the different types of studies. Private sources (such as company support) were mostly attributed to RCTs (56.1%) or PPCS (21.2%), while public funding (such as independent grants) was primarily attributed to retrospective studies (50.7%), followed by RCTs (24%) ($p < .01$). Furthermore, a mix between private and public funding was mostly applied to RCTs (50%), followed by PPCS (28.6%) (Table 7). Finally, regarding the funding, most studies of low bias were supported by private funding, while studies of unclear bias most frequently received public funding ($p < .01$).

4 | DISCUSSION

The aim of the present SR was to assess the outcome measures to evaluate health and disease conditions, including assessment of complications and aesthetic outcomes, of implant-supported single (SC) and partial multiple-unit fixed dental prostheses (P-FDPs) reported in the literature on the last 10 years.

A total of 531 studies were included in the SR, of which 31.5% was RCTs, thus confirming a positive trend in the modern implant literature to publish an increasing number of clinical trials to evaluate the efficacy of treatments (Cairo et al., 2012). Interestingly, this overwhelming amount of data mainly come from a small number of countries. Considering the 20 most prevalent nations, Italy, Spain, China, Germany, the United States, and Switzerland accounted almost 70% of the published studies. Possible reasons to explain this finding may be related to some specific conditions including economics, interest for this research topic, and request of treatment by patients, favouring the clinical research in the specific area. Interestingly, Italy was the country with the highest number of clinical studies in the last 10 years. Possible reasons may be the high use of dental implants in

TABLE 4 Comparison of the reporting of the respective outcome measures in the different study types: 100% corresponds to the total number of studies (*N*) reporting the respective outcome

Specific outcomes						
Study type	**Domain**	**RCT**	**CPS + PCS**	**RS**	**PPCS**	***p*-Value**
Implant survival *N* = 214	1	27.1%	12.1%	33.2%	27.6%	NS
Implant success *N* = 145	1	23.4%	7.6%	37.2%	31.7%	.04
Implant failure *N* = 107	1	40.2%	7.5%	32.7%	19.6%	NS
Implant stability *N* = 40	1	52.5%	20.0%	7.5%	20.0%	<.01
Prosthetic survival *N* = 37	2	18.9%	13.5%	32.4%	35.1%	NS
Prosthetic failure *N* = 38	2	57.9%	5.3%	18.4%	18.4%	<.01
Prosthetic fracture *N* = 53	2	32.1%	1.9%	39.6%	26.4%	NS
Screw loosening *N* = 67	2	32.8%	0.0%	40.3%	26.9%	.03
Implant periodontal measur. *N* = 266	3	35.3%	11.7%	24.4%	28.6%	<.01
Soft tissue recession *N* = 91	3	38.5%	13.2%	19.8%	26.6%	.03
Soft tissue thickness *N* = 26	3	46.2%	3.8%	7.7%	42.3%	.01
Keratinized tissue *N* = 64	3	46.9%	9.4%	14.1%	29.7%	<.01
Marginal bone level *N* = 453	3	32.5%	9.5%	29.8%	28.3%	<.01
Patient-related outcomes (overall, aesthetic, function)	4	Significantly more often reported in RCT				<.05
Aesthetic indices *N* = 85	5	38.8%	10.6%	28.2%	22.4%	NS
Aesthetic papilla *N* = 70	5	48.6%	8.6%	14.3%	28.6%	<.01

Abbreviations: CPS, controlled prospective studies; NS, not significant; PCS, prospective cohort studies; PPCS, pre- and post-case series; RCT, randomized controlled clinical trial; RS, retrospective studies.

TABLE 5 Influence of study design and risk-of-bias (RoB) on the reporting of outcomes in the six main domains

Outcomes 1–7 and type of studies						
Study type	**Domain**	**RCT**	**CPS + PCS**	**RS**	**PPCS**	***p*-Value**
Implant outcome *N* = 507	1	31.0%	9.9%	32.7%	26.4%	NS
Implant prosthetic *N* = 194	2	36.6%	6.7%	29.9%	26.8%	NS
Peri-implant outcome *N* = 494	3	32.4%	10.1%	30.8%	26.7%	<.01
Patient related outcome *N* = 97	4	44.3%	8.2%	18.6%	28.9%	<.01
Aesthetic outcome *N* = 137	5	40.9%	10.2%	23.4%	25.5%	.02
Economic aspects outcome *N* = 11	6	54.5%	9.1%	36.4%	0.0%	NS
Additional outcomes *N* = 52	7	36.5%	17.3%	21.2%	25.0%	NS
Outcomes 1–7 and bias assessment (RoB-2)						
Bias assessment, overall	**Domain**	**Low**	**Unclear**	**High**		***p*-Value**
Implant outcome *N* = 507	1	42.8%	54.2%	3.0%		NS
Implant prosthetic *N* = 194	2	40.7%	55.2%	4.1%		NS
Peri-implant outcome *N* = 494	3	44.3%	52.6%	3.0%		NS
Patient-related outcome *N* = 97	4	47.4%	50.5%	2.1%		NS
Aesthetic outcome *N* = 137	5	57.7%	38.0%	4.4%		<.01
Economic aspects outcome *N* = 11	6	45.5%	54.5%	0.0%		NS
Additional outcomes *N* = 52	7	51.9%	46.2%	1.9%		NS

Abbreviations: CPS, controlled prospective studies; NS, not significant; PCS, prospective cohort studies; PPCS, pre- and post-case series; RCT, randomized controlled clinical trial; RS, retrospective studies.

that country and the interest in implant research by numerous private and university groups.

Among the outcomes of this SR, information on funding frequently was not reported or not clearly stated, most specifically in retrospective studies and case series. Information on funding was significantly related to the study design: randomized clinical trials more frequently showed a company funding compared to retrospective and not randomized trials. This may imply a potential problem in the assessment of possible conflict of interest in clinical research. A previous SR evaluated the quality of implant literature published between 1993 and 2008 exploring the possible association between industry sponsorship and annual implant failure rate (Popelut et al., 2010). Interestingly, the funding source was not reported in 63% of the trials. The authors reported that both industry-associated and unknown funding source trials showed lower annual failure rates compared with non-industry-associated trials (Popelut et al., 2010). Findings from the present SR corroborate the importance of clear funding disclosure in dental implant research in order to minimize the possible RoB in the clinical scenario for single patient treatment and general healthcare policy definition.

When assessing reporting of outcomes, the primary outcome was well defined only in one-third of the RCTs, the retrospective studies, and the pre-and post-case series, and even less frequently in the prospective cohort studies. This finding is critical because the primary outcome is the outcome considered in the investigation as the most important (target of the study), and it should be used for a priori sample size calculation and the definition of statistical analysis. The lack of a well-defined primary outcome may raise important problems in data interpretation, thus highlighting a strong limitation in modern dental implant research.

Sample size calculation was not frequently reported in clinical trials in the last 10 years; this was more frequent in RCTs than in non-randomized trials. Sample size calculation is a critical issue when assessing the quality of clinical literature since it allows us to make proper inferences from a selected sample of population, and it is critical for study design for both prospective and non-prospective studies. In a previous SR assessing the quality of RCTs published between 1989 and 2011 focusing on dental implants, sample size calculation was reported in a very limited number of RCTs (12%) (Cairo et al., 2012). Outcomes from the present SR suggest that there is a positive trend in the last decade in performing proper sample size calculation for RCTs. This may be related to a number of reasons, including the high popularity of quality checklists for RCTs in protocol preparation (e.g., adherence to CONSORT statement) and the higher interest of dental journals in improving article quality. Conversely, it should be taken into account that sample size is very frequently omitted in non-randomized trials, thus implying that this type of study may be frequently underpowered. It also is to be considered that in a high number of studies where power calculations are performed, the conditions for the calculations may not be correct in situations, for example, when the primary outcome is very seldom in the literature, resulting in unrealistically high numbers of patients needed for a specific study.

The present SR showed a consistent heterogeneity among possible outcome measurements. Among the reported outcomes, MBL was the most frequent one (85% of included studies). This finding was not related to the study quality, meaning that MBL was the most

TABLE 6 Influence of study design and risk-of-bias (RoB) on the reporting of the detailed outcomes

Bias assessment RoB-2, overall	Domain	Low	Unclear	High	*p*-Value
Implant survival $N = 214$	1				NS
Implant success $N = 145$	1				NS
Implant failure $N = 107$	1				NS
Implant stability $N = 40$	1				NS
Prosthetic survival $N = 37$	2				NS
Prosthetic failure $N = 38$	2				NS
Prosthetic fracture $N = 53$	2				NS
Screw loosening $N = 67$	2				
Chipping $N = 34$	2	26.5%	64.7%	8.8%	.03
Decementation $N = 25$	2	16.0%	72.0%	12.0%	<.01
Implant periodontal measur. $N = 266$	3				NS
Soft tissue recession $N = 91$	3				NS
Soft tissue thickness $N = 26$	3				.06
Keratinized tissue $N = 64$	3	64.1%	32.8%	3.1%	<.01
Marginal bone level $N = 453$	3				NS
Patient-related outcomes (overall, aesthetic, function)	4				NS
Aesthetic indices (PES) $N = 85$	5	56.5%	42.4%	1.2%	.02
Aesthetic papilla $N = 70$	5	60.0%	35.7%	4.3%	<.01

Abbreviations: NS, not significant; PES, pink esthetic score.

TABLE 7 Comparison of the methodological parameters reported in the different study types

Outcome	RCT	CPS + PCS	RS	PPCS	*p*-Value
	31.5%	9.6%	32.8%	26.2%	
Setting					NS
Private	23.2%	10.4%	42.4%	24.0%	
Public	33.3%	9.9%	30.4%	26.4%	
Mixed	37.1%	5.7%	22.9%	34.3%	
Not reported	34.7%	9.2%	30.6%	25.5%	
Funding					<.01
Private	56.1%	10.6%	12.1%	21.2%	
Public	24.0%	6.7%	50.7%	18.7%	
Mixed	50.0%	7.1%	14.3%	28.6%	
Not reported	20.6%	10.1%	39.2%	30.1%	
Pros treatment					<.01
Single crown	35.4%	9.8%	26.5%	28.4%	
FPD	31.5%	5.6%	27.8%	35.2%	
Both	22.8%	10.7%	48.3%	18.1%	
Sample size computation	65.6%	9.2%	17.6%	7.6%	<.01

Abbreviations: CPS, controlled prospective studies; FPD, fixed partial denture; NS, not significant; PCS, prospective cohort studies; PPCS, pre- and post-case series; RCT, randomized controlled clinical trial; RS, retrospective studies.

frequently reported outcome irrespective of the study design. Furthermore, RoB-2 analysis suggests that the quality of measurement collection was not related to the type of study. Possible reasons to explain the high popularity of MBL among clinical studies may be related to the relative simplicity in clinical recording considering the first implant threshold and the adjacent bone level as reference point on x-ray. Conversely, it should be taken into account that MBL does not necessarily reflect soft tissue margin stability at the buccal site and the occurrence of gingival recession may jeopardize patient satisfaction irrespective of the relative MBL stability (Cairo, Nieri, et al., 2020). Furthermore, a recent international workshop on peri-implant diagnosis strongly suggests the use of peri-implant indices as critical to monitoring peri-implant health in the long term along with x-ray evaluation to confirm diagnosis of peri-implantitis (Berglundh et al., 2018). Very interestingly, peri-implant indices were the most used secondary outcomes in the included studies.

Among the possible outcome measurements, implant survival was reported only in 40.3% of the studies, while implant failure was reported in 20.1% of the studies. These findings may surprise the reader since they are probably the most important outcomes at both patient and operator levels. Additionally, a clear definition was not provided in more than 30% of the studies reporting implant survival. Possible reasons to explain this outcome may be related to some potential factors such as confusion in the definition among different studies (e.g., implant survival vs. implant failure), the relative short time of observation of the selected studies (mean duration 3.9 years), and the huge heterogeneity among the different studies. Along with implant survival/failure, surprisingly, prosthetic outcomes (survival, success, failure, and technical complications) were assessed in very few studies (35.6%). Some technical complications were more often reported in studies at the lower quality level. Implant success criteria were reported only in 27.3% of studies, with two possible options (Albrektsson et al., 1986; Buser et al., 1990). These findings corroborate the urgent need to use a clear data form for collecting data in implant research.

Patient-related outcomes were detected only in 18% of studies and were more frequently reported in RCTs. Patient satisfaction and morbidity assessment are currently considered critical to understanding the outcomes of surgical procedures (Cairo, Barootchi, et al., 2020). A recent consensus highlighted the importance of incorporating PROMs into clinical trials, using specific questions for evaluating patients' anxiety, discomfort, preference, and aesthetics (Tonetti & Jepsen, 2014). Current outcomes seem to suggest that implant literature is less familiar to PROMs compared to periodontal literature, but their evaluation appears critical for an adequate assessment of the perception of outcomes at the patient level.

Not surprisingly, RCTs were significantly associated with low risk for the assessment and reporting of the outcome (RoB-2). Additionally, the outcomes related to the peri-implant soft tissue (PES/WES and Papilla Index) were mostly reported by studies at low RoB. This suggests that well-designed RCTs at low RoB usually perform also aesthetic evaluation of the implant-supported restoration.

Limitations of the present SR may be related to the high heterogeneity of the included studies and the limitation in selecting only manuscripts in the English language. Furthermore, the follow-up of the included studies ranged between 1 year and more than 20 years, providing a very heterogeneous amount of data. This finding may have influenced the reported outcomes. Finally, both single and partial restorations were merged and the reported related outcomes were combined.

5 | CONCLUSIONS

Data from the present SR show that:

- there is high heterogeneity in reporting outcomes among clinical studies in implant dentistry;
- primary outcomes are very often not clearly defined;
- sample size calculation is frequently not performed apart from RCTs;
- among the reported outcomes, marginal bone loss is the most frequent reported outcome; and
- important outcomes such as prosthetic variables, success criteria, implant survival/failure, and patient-related outcomes are often not reported.

In conclusion, there is urgent need to improve reporting outcomes in studies dealing with implant dentistry. Furthermore, it is critical to provide a standardized approach for data collection for the most important variables at patient and clinical levels.

AUTHOR CONTRIBUTIONS

Francesco Cairo, Irena Sailer, Luigi Barbato, Duygu Karasan, and Philippe Mojon contributed to study conception and design. All authors contributed to electronic and hand search. Luigi Barbato, Umberto Pagliaro, and Lapo Serni performed the data extraction. Philippe Mojon, Francesco Cairo, and Luigi Barbato contributed to data analysis and interpretation. All authors contributed to drafting and critically revising the manuscript.

CONFLICT OF INTEREST

The authors declare no conflict of interest in regard to the present work.

DATA AVAILABILITY STATEMENT

Data available on request from the authors.

ETHICS STATEMENT

This study is a systematic review and doesn't need an approval from an ethical comitee.

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SUPPORTING INFORMATION

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