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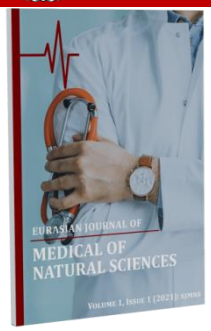

PREVENTION AND MANAGEMENT OF PERI-IMPLANT MUCOSITIS AND PERI-IMPLANTITIS: A SYSTEMATIC REVIEW OF CLINICAL OUTCOME MEASURES REPORTED OVER THE PAST DECADE

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ABSTRACT

Although dental implants generally offer favorable long-term outcomes, both technical and biological complications can still occur. A deeper understanding of the development, prevention, and treatment of peri-implant diseases is important for both patients and dental professionals. Peri-implant diseases are chronic inflammatory conditions caused by bacterial infection. Peri-implant mucositis is characterized by inflammation limited to the soft tissue surrounding the implant, whereas peri-implantitis also involves progressive bone loss that supports the implant. If left untreated, peri-implantitis often leads to implant failure due to its progressive nature.

INTRODUCTION

In 2014, two separate reviews analyzed outcome measures used in studies on implant therapy, particularly those focused on peri-implant disease management. One review found that implant survival was the most commonly reported outcome among more than 200 studies. The other identified only a small number of studies evaluating peri-implant disease treatment and highlighted inconsistent reporting and poor quality in the use of outcome measures.

At the 8th European Workshop on Periodontology held in 2014, biological complications related to dental implants were recognized as a key focus in the scientific assessment of implant therapy. To improve evaluation in this area, the use of composite outcome measures was recommended. These measures aimed to capture the key therapeutic goals—namely, the absence of inflammation and the maintenance of marginal bone stability—to enhance the clarity and relevance of study results.

Given that nearly a decade has passed since these recommendations were made regarding study design, outcome selection, and reporting standards, it is timely to reassess the current evidence on the prevention and treatment of peri-implant diseases. The Implant Dentistry Core Outcome Sets and Measurements initiative was launched to build consensus around essential outcome measures in dental implant research. As part of this effort, the goal of the present systematic review is to examine the outcome measures, assessment methods, and analytical approaches used in clinical studies focused on preventing and managing peri-implant mucositis and peri-implantitis.

MATERIALS AND METHODS

The protocol for this systematic review was registered with PROSPERO (CRD42021252851). The review process adhered to the 2024 PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines..

Methodology

This review was structured around three focused questions:

1. What outcome measures are most commonly reported in clinical studies on the prevention and/or treatment of peri-implant mucositis and/or peri-implantitis?
2. What methods (e.g., examination techniques or tools) are used to assess these outcome measures in such studies?
3. What data analysis strategies are preferred, including the primary unit of analysis, in these clinical studies?

Eligibility Criteria

Included studies had to be longitudinal in design and report either the incidence of peri-implant mucositis or peri-implantitis in patients receiving preventive care, or treatment outcomes in patients already diagnosed with these conditions. Studies addressing prevention were required to define clearly the condition being prevented and confirm its absence at baseline, while studies on management had to show that the condition was present from the start. Eligible studies were case series, cohort studies, case–control studies, or randomized controlled trials (RCTs) published from 2014 onwards, with a minimum sample size of 10 adult patients. For prevention-focused studies, a follow-up period of at least 3 years was required for peri-implantitis and at least 6 months for peri-implant mucositis. Treatment studies had to have a minimum follow-up of 6 months for peri-implantitis and 3 months for peri-implant mucositis.

Excluded studies were those with cross-sectional designs or that reported only epidemiological data without addressing prevention or management strategies. Also excluded were studies on zygomatic, blade-type, or extra-oral implants, as well as those applying inconsistent protocols for peri-implant disease prevention or treatment.

Search Methods

The electronic databases CENTRAL, MEDLINE (PubMed), and SCOPUS were searched up to April 7, 2024. Additional references were identified through hand-searching the bibliographies of included articles. Duplicates were removed after combining search results across all databases.

Study Selection

Before screening, all reviewers were calibrated through several online discussion sessions. Titles and abstracts were independently screened in duplicate by four reviewers using predefined inclusion and exclusion criteria with the help of the Rayyan platform. Inter-rater agreement was assessed using kappa statistics on the first 50 articles, achieving scores of 0.76 or higher. Full-text screening was then conducted for the selected articles, with regular team meetings to ensure consistency and resolve any uncertainties.

Data Management

Five calibrated reviewers independently extracted data from the included studies into pre-structured evidence tables. Extracted data included outcome measures, study design, setting, population, diagnostic criteria for peri-implant diseases, and details of prevention or

treatment protocols. A standardized Excel datasheet was used to ensure consistency across extractions, supported by pre-defined checklists. Regular team discussions helped maintain calibration and address any questions during data entry.

3. RESULTS

3.1 Search and Screening

The electronic database search yielded a total of 1,293 citations. After independent title and abstract screening, 229 articles were identified as potentially relevant and selected for full-text evaluation. Of these, 78 studies were excluded, primarily due to unclear diagnostic criteria (21 studies), inconsistent prevention or management protocols (17 studies), or insufficient follow-up durations (16 studies). An additional 8 articles were identified through manual reference searches, bringing the final number of included studies to 159. The screening and selection process is outlined in Figure 1.

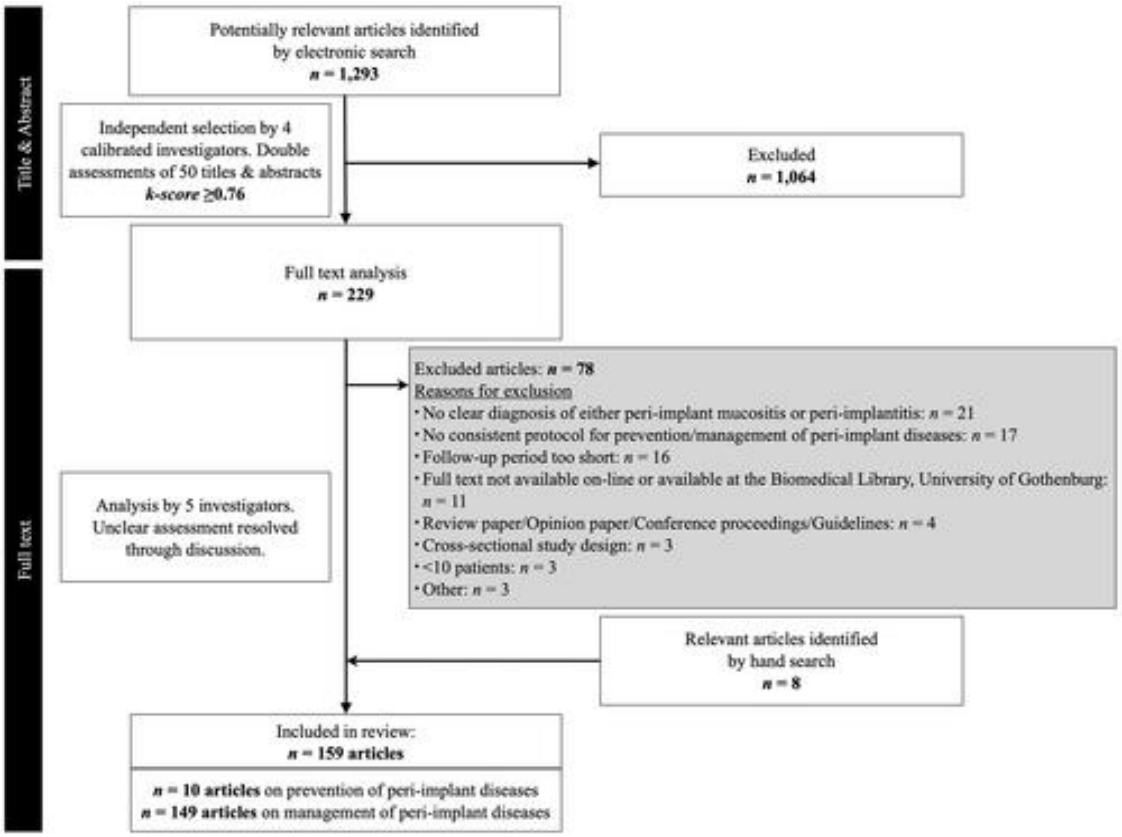

Figure 1. Flow-chart describing the process of the search and study selection

3.2 Descriptive Results

Of the 159 studies included in this review, 149 (94%) investigated the treatment of diagnosed peri-implant diseases, while the remaining 10 studies focused on prevention strategies. Most of the research was conducted in Europe (101 studies, 64%), followed by Asia (30 studies, 19%). In terms of study design, 82 publications (52%) were randomized controlled trials (RCTs), while the remaining 77 (48%) were observational studies, comprising 26 cohort studies and 51 case series.

The majority of the studies (119 out of 159, or 75%) addressed peri-implantitis. Thirty-four studies (21%) concentrated on peri-implant mucositis, while 6 studies (4%) examined both conditions. The diagnostic criteria used to define peri-implant mucositis and peri-

implantitis varied widely between studies. Among the 149 treatment-focused studies, 73 (49%) examined non-surgical approaches, 74 (50%) evaluated surgical interventions, and 2 (1%) included both.

3.3 Risk of Bias

Overall, 25 studies (16%) were considered to have a low risk of bias. Within the subset of case series and pre–post studies, only 2 studies (4%) were rated as low risk.

3.4 Focused Question 1: Outcome Measures

Across the 159 included studies, an average of 5.5 ± 2.1 outcome measures were reported per study (range: 1 to 12). The most commonly reported outcomes were probing pocket depth (PPD), noted in 89% of studies, bleeding and/or suppuration on probing (BOP) in 87%, and plaque scores in 64%. Radiographic outcomes were reported in 49% of the studies overall, with a stark contrast between peri-implant mucositis studies (10%) and those addressing peri-implantitis (62%). Measures related to soft tissue dimensions appeared in 34% of studies, while microbiological or biomarker-based outcomes were reported in 19%. Adverse events or complications were noted in only 8% of the studies, and patient-reported outcomes in just 6%.

Composite outcomes were utilized in 26% of the studies, exclusively within treatment-focused research. None of the prevention studies reported composite outcomes; however, implant loss was reported more frequently in prevention studies (70%) compared to treatment studies (13%). Further details on the outcome measures used in the included studies can be found in Figure 2, and Figure S4 provides an overview of the outcome measures reported in peri-implantitis treatment studies categorized by therapeutic approach.

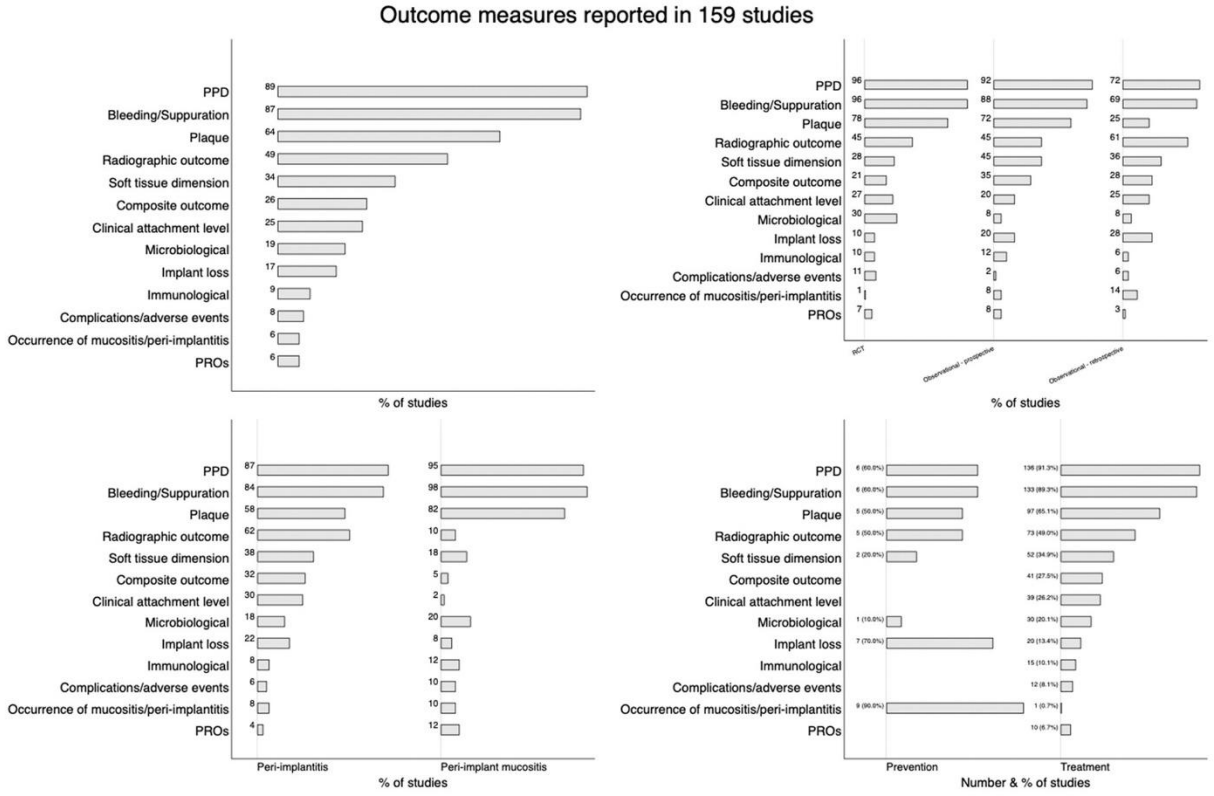

Figure 2. Outcome measures reported in 159 included studies.

No significant differences were observed in the types of outcome measures reported between studies with low risk of bias and those with unclear or high risk of bias, except for radiographic outcomes, which were less frequently included in studies classified as low risk.

Among the 41 studies (26%) that reported composite outcomes, seven distinct combinations of outcome variables were used, as detailed in Table S8. One of these studies applied multiple combinations of composite variables. Additionally, seven studies included a radiographic component within their composite outcomes but did not report radiographic results separately. As a result, these studies were not counted among the 78 articles (49% of the total) reporting radiographic outcomes independently.

In most of the studies (101 out of 159, or 64%), no primary outcome was explicitly defined. Among the remaining studies, 49 (31%) identified one primary outcome, 4 studies (3%) reported two, 2 studies (1%) specified three, and 3 studies (2%) listed four primary outcomes.

3.5 Focused Question 2: Methodology General Aspects

In 85 of the included studies (54%), outcome measures were assessed by a single examiner, while 56 studies (35%) involved multiple examiners. No significant differences were noted between prevention and treatment studies, or between those focused on peri-implantitis and peri-implant mucositis.

Examiner blinding was reported in 63 of the 82 randomized controlled trials (77%). When broken down by condition, blinding was reported in 79% of peri-implantitis studies and 72% of peri-implant mucositis studies.

Probing Pocket Depth

Probing pocket depth (PPD) was reported as an outcome in 142 studies. In most cases (60%), assessments were conducted using a standard metal periodontal probe. Pressure-sensitive probes were used in 18% of studies, while plastic probes were used in 11%. Removal of prosthetic restorations to facilitate probing was reported in only a small number of studies (6%). Calibration of examiners for probing was mentioned in 46% of the studies.

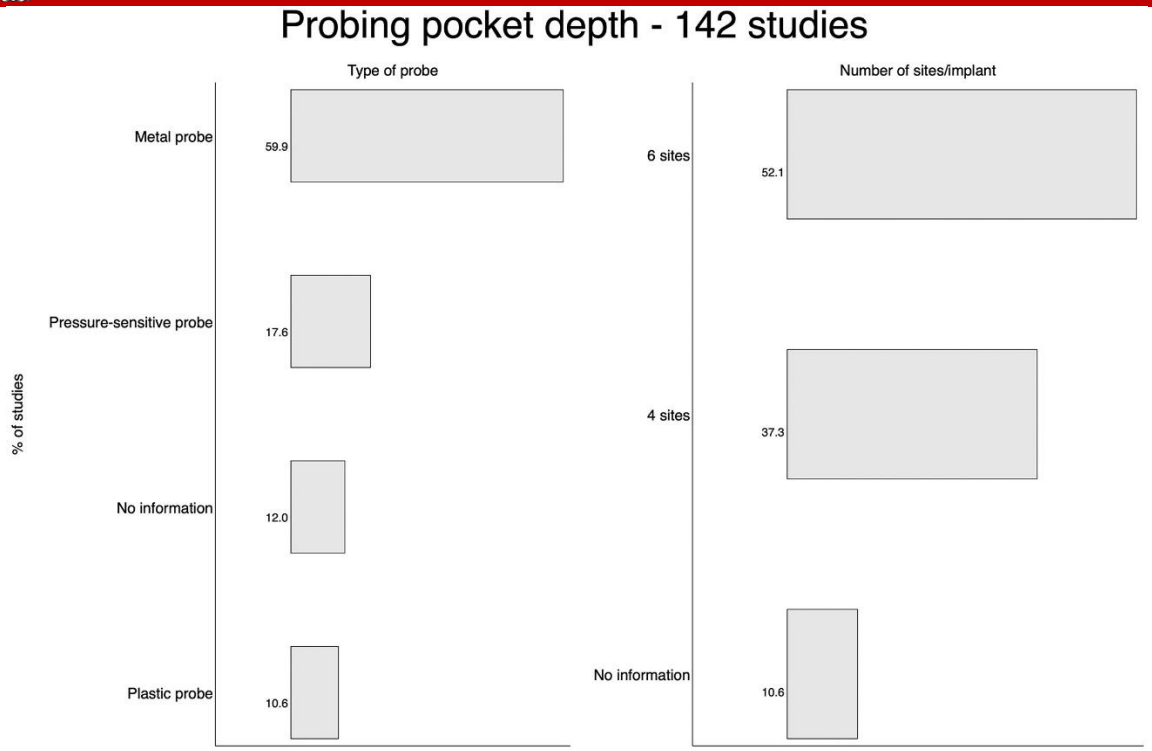

Figure 3. Details regarding assessment of probing pocket depth in 142 studies

3.5.3 Bleeding/Suppuration on Probing

Bleeding and/or suppuration on probing (BOP) was reported as an outcome in 139 of the included studies. Among these, 93 studies assessed bleeding on probing alone, while 46 evaluated both bleeding and suppuration. In most cases (56%), the evaluation was performed using a metal periodontal probe. A binary (yes/no) scoring system was used in 68% of the studies, while 15% applied an ordinal grading system (refer to Table S9). Examiner calibration for this measure was reported in 42% of studies.

3.5.4 Plaque Score

Plaque scores were included as an outcome in 102 studies. However, in the majority of cases (63%), details regarding the method of assessment were not provided. Most studies categorized plaque presence in a binary manner (51%), while fewer used an ordinal scale. Examiner calibration for plaque assessment was reported in 47% of the studies.

3.5.5 Radiographic Outcomes

Radiographic outcomes were reported in 78 studies. Nearly all of these (98%) assessed marginal bone levels, while other radiographic parameters such as defect fill, defect width, and defect angle were mentioned less frequently. The distribution of radiographic outcome selection by disease type and treatment approach is shown in Figure S9. Most studies (86%) utilized intraoral radiographs, with 79% employing a standardized radiographic holder. Use of panoramic imaging or cone beam computed tomography (CBCT) was uncommon. Reproducibility or validation of radiographic measurements was reported in 39% of the studies.

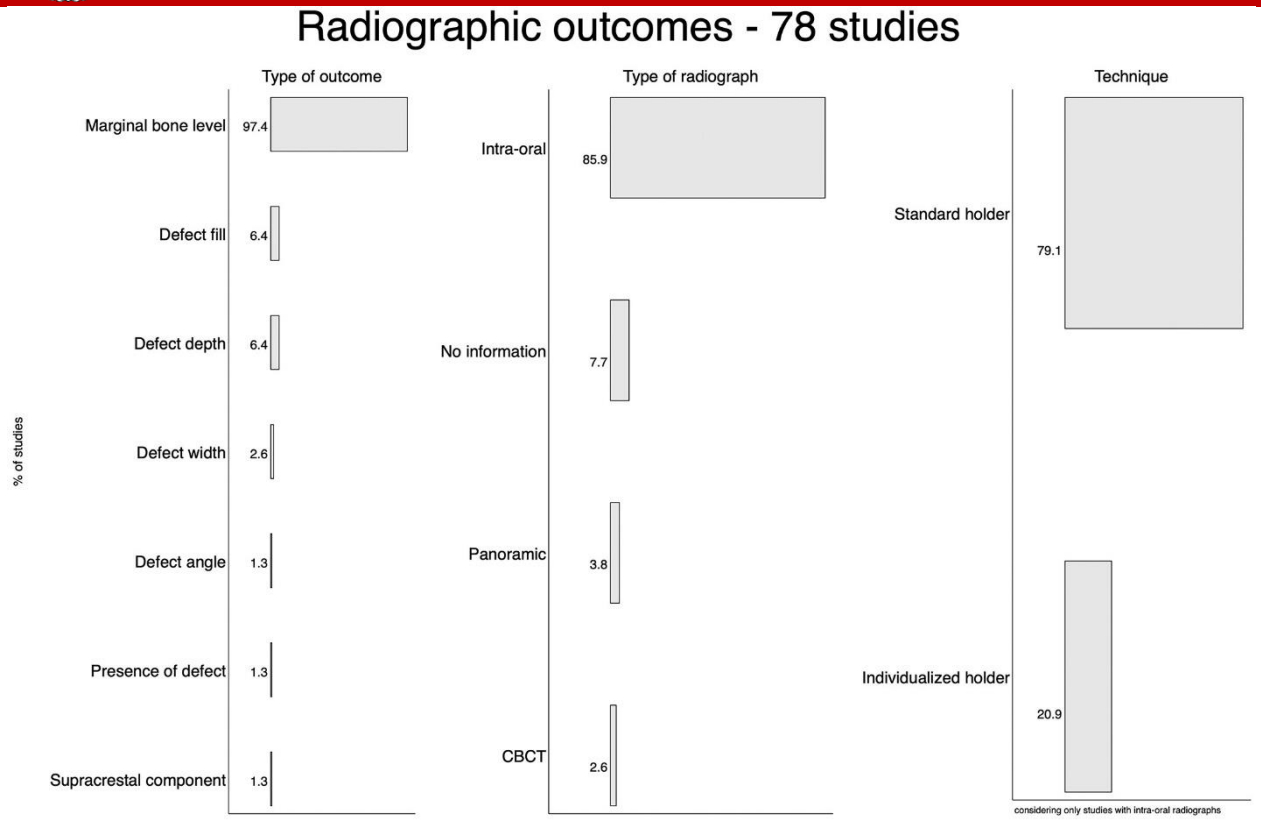

Figure 4. Details regarding radiographic assessments in 78 studies. The segment "Technique" considers only studies with intra-oral radiographs.

3.5.6 Soft Tissue Dimension Outcomes

Among the 54 studies that reported on this outcome, the majority (85%) evaluated soft tissue recession, followed by the width of keratinized mucosa (32%). Most assessments were conducted using a periodontal examination probe (83%). However, reporting on the specific aspects evaluated was inconsistent. In 35% of the studies, multiple tissue parameters were considered, while 26% focused exclusively on buccal tissue evaluation. Calibration efforts for soft tissue measurements were reported in 52% of studies.

3.5.7 Microbiological and Biomarker-Based Outcomes

Most studies that included microbiological or biomarker-related outcomes analyzed either biofilm samples alone (48%) or a combination of biofilm and peri-implant sulcular fluid (15%). In 24% of the studies, only sulcular fluid was evaluated. Sampling was commonly performed using paper strips (59%) or paper points (26%), typically at the site with the deepest probing pocket depth (44%), whereas 15% of the studies collected samples from multiple sites on the same implant.

3.6 Focused Question 3: Data Management Probing Pocket Depth

Probing pocket depth (PPD) results were commonly reported at various levels. In approximately 22% of the studies, outcomes were reported solely at the implant or site level. In 60% of the studies, the reported values represented the mean or median of measurements taken from multiple aspects around each implant. In 13% of cases, only the deepest or worst PPD per implant was reported. Most studies expressed their results as mean values, with standard deviation used as the primary measure of dispersion (Figure 5).

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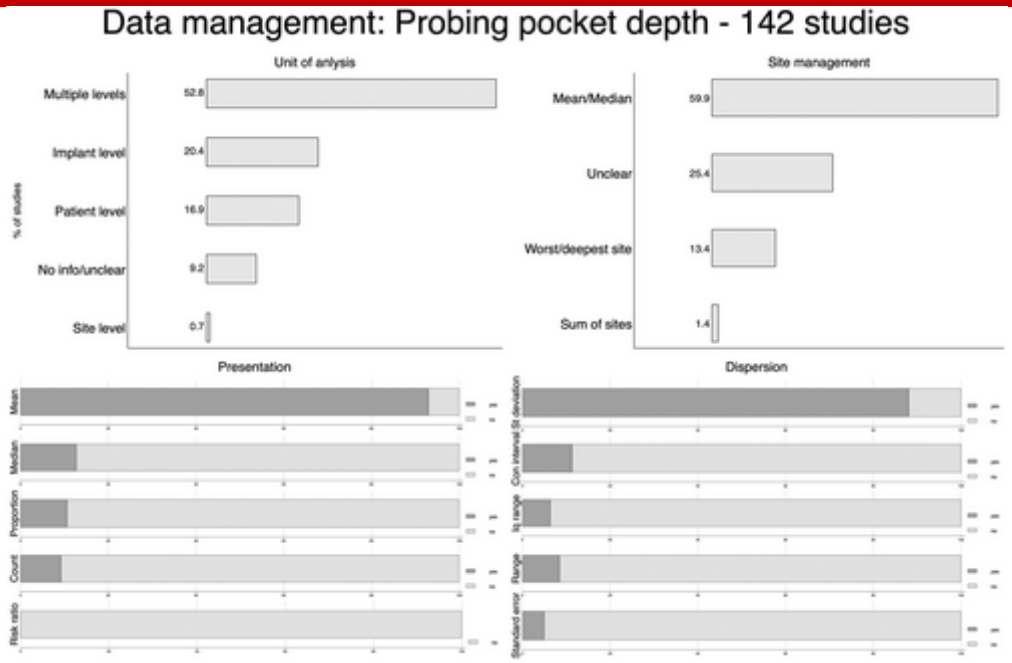

Figure 5. Details regarding data management in 142 studies reporting on probing pocket depth.

3.6.2 Bleeding/Suppuration on Probing

The analysis unit for bleeding on probing (BOP) followed a similar distribution pattern as that of probing pocket depth (PPD). However, a greater number of studies employed either the worst-site method alone or a combination of reporting mean/median values alongside the worst-site approach. Consequently, over 60% of the studies reported results as proportions, while just under 50% presented mean values (see Figure 6).

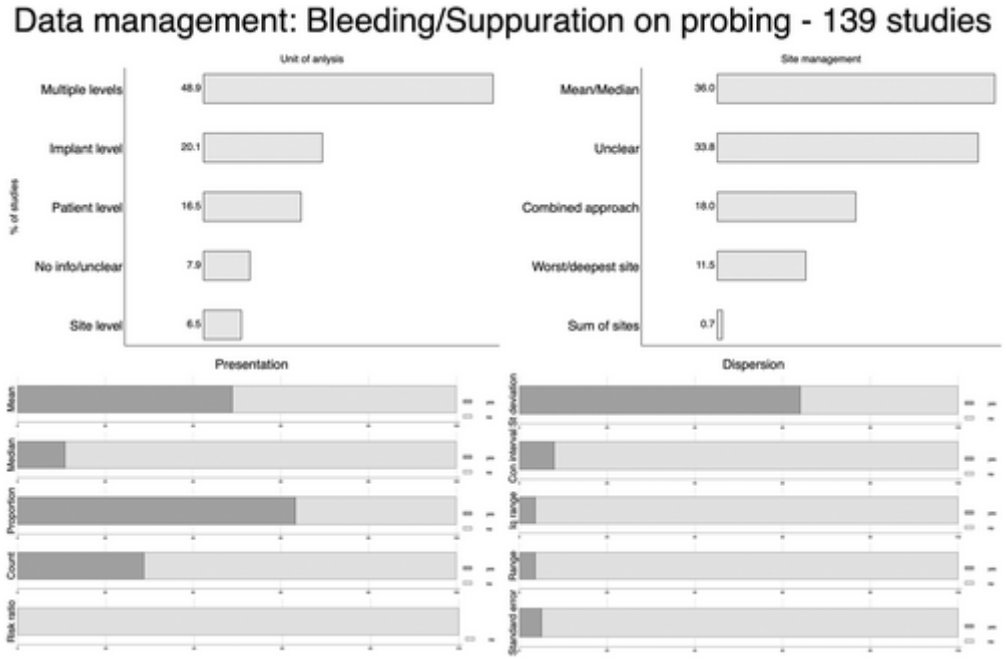

Figure 6. Details regarding data management in 139 studies reporting on bleeding/suppuration on probing.

3.6.3 Plaque Score

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Plaque scores were commonly reported either across multiple levels (41%) or solely at the patient level (23%). In 41% of studies, the method for site-level analysis—whether using mean, median, worst, or total scores—was not clearly specified. Among the studies that provided such details, data were typically aggregated from multiple implant surfaces using mean or median values. Presentation of plaque score outcomes was evenly split between mean values and proportions, with standard deviation being the most frequently used measure of variability.

3.6.4 Radiographic Outcomes

As with probing pocket depth (PPD), radiographic outcomes were reported at multiple or patient levels in 64% of studies. In 60% of cases, results reflected mean or median values, whereas only 8% of studies based their analysis on the worst individual implant reading. Nearly 90% of studies presented results as mean values, accompanied by standard deviations as the measure of dispersion. Fewer than 20% reported outcomes as frequency distributions or proportions (see Figure 7).

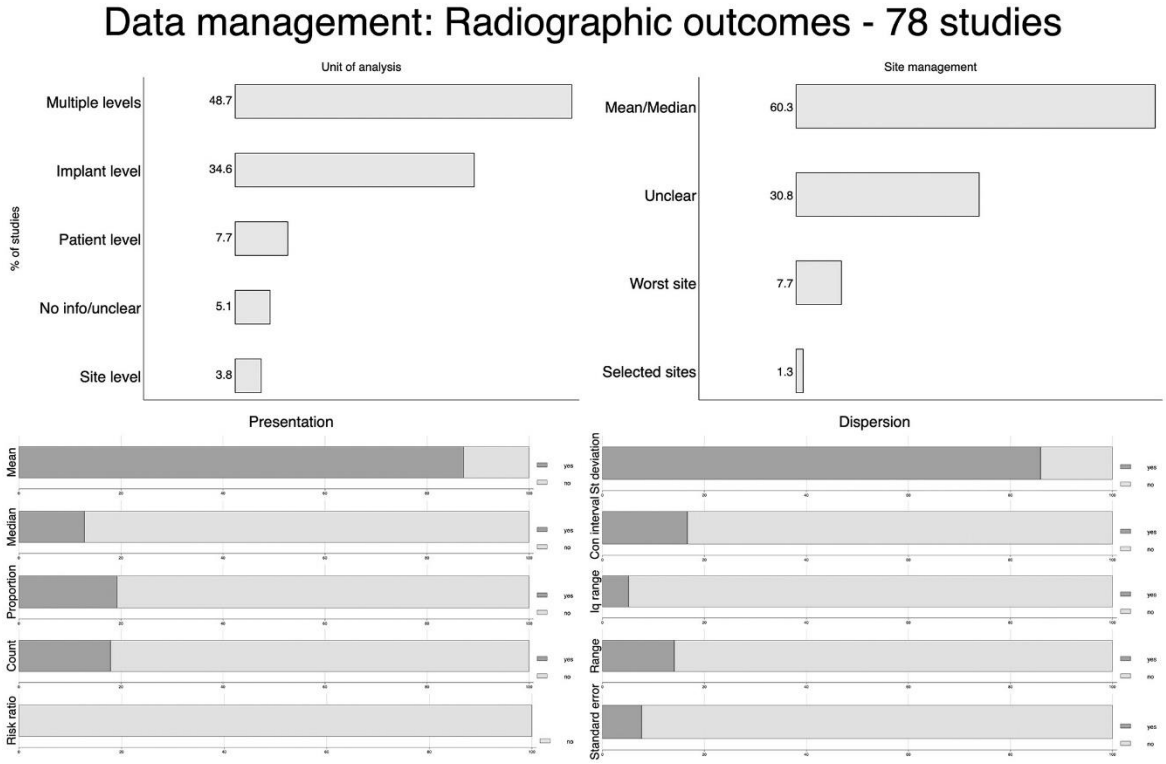

Figure 7. Details regarding data management in 78 studies reporting on radiographic assessments

3.6.5 Outcomes Related to Soft Tissue Dimensions

Unlike other outcome measures, data on peri-implant soft tissue dimensions were most often analyzed at the implant level. In 19% of studies, specific implant aspects—typically the buccal surface—were selected as target sites, while 35% provided aggregated estimates based on multiple assessments per implant. As with other parameters, the most frequently used format for data presentation was mean values alongside standard deviations.

3.6.6 Microbiological and Biomarker-Based Outcomes

A relatively small number of studies reported microbiological and biomarker-based outcomes at the implant level. More commonly, the patient served as the primary unit of analysis, either on its own or within a multi-level framework. The site with the deepest probing pocket depth (PPD) was typically selected to represent the implant. Study results were fairly evenly distributed across formats, including mean/median values, proportions, and counts.

4. DISCUSSION

This systematic review examined outcome measures and their assessment in clinical studies focused on the prevention and management of peri-implant mucositis and peri-implantitis published between 2011 and 2021. From the 159 included studies, probing pocket depth (PPD) and bleeding on probing (BOP) were reported in 89% and 87% of cases, respectively. Other outcomes such as plaque scores (64%), radiographic assessments (49%), soft tissue dimensions (34%), and composite outcomes (26%) were reported less frequently. Adverse events (8%) and patient-reported outcomes (6%) were rarely documented. Only 36% of studies clearly identified their primary outcomes. When reported, PPD, radiographic outcomes, and soft tissue dimensions were typically presented as mean values rather than in categorical formats (e.g., yes/no). Notably, for radiographic and soft tissue-related outcomes, the unit of analysis was often either the implant or not clearly defined.

It is notable that nearly 90% of the reviewed studies—focused on either prevention or treatment—reported on PPD and BOP. This aligns with long-standing clinical recommendations. The 8th European Workshop on Periodontology (2012) had already established the resolution of mucosal inflammation and reduction in PPD as key indicators of successful treatment outcomes (Sanz & Chapple, 2012). Similarly, the 2018 World Workshop emphasized the diagnostic importance of PPD and BOP at implant sites (T. Berglundh et al., 2018). Despite widespread acceptance, the predictive value of these parameters has only recently been confirmed through larger cohort studies (Carcuac et al., 2017; Karlsson et al., 2019; J. Berglundh et al., 2020; Carcuac et al., 2020; Romandini et al., 2020).

Several recent studies have explored the relationship between peri-implant soft tissue dimensions and peri-implant health (e.g., Puisys & Linkevicius, 2015; Lim et al., 2019; Monje & Blasi, 2019; Oh et al., 2020; Ravidà et al., 2020; Obreja et al., 2021; Solonko et al., 2022). Nevertheless, most of the included studies failed to consistently report on this domain. When soft tissue dimensions were considered, the focus was mainly on soft tissue recession, while parameters such as width of keratinized mucosa or mucosal thickness were often overlooked. Furthermore, advanced volumetric tools such as intraoral scanning (e.g., Parvini et al., 2021) remain underutilized in this field.

Both the 2012 and 2019 European Workshops (Sanz & Chapple, 2012; Jepsen et al., 2019) recommended the use of composite outcomes—combining the absence of soft tissue inflammation and bone level stability—as a more comprehensive treatment endpoint. Despite this, the current review found that only about 25% of studies incorporated composite outcomes. Moreover, considerable variability existed in the variables and thresholds used in such assessments. Definitions of peri-implant mucositis and peri-implantitis also varied significantly across studies. It is important to note, however, that treatment studies may adopt

stricter inclusion criteria than those used in general case definitions, especially when targeting specific stages of disease or therapeutic approaches.

Another important observation was the limited reporting of complications, adverse events, and patient-reported outcomes—despite their recognized significance in implant research as highlighted during the 8th European Workshop (Tonetti & Palmer, 2012). Although the majority of studies used patient-level data for PPD and BOP, this was not always the case for radiographic and soft tissue outcomes. The inconsistency in reporting units of analysis is problematic, as clear identification of the analysis level is essential for proper interpretation and statistical handling (Elm et al., 2008; Schulz et al., 2010). While in some instances patient-level and implant-level data may align closely—making hierarchical analysis unnecessary—clarity in reporting remains crucial.

Whether clinical studies are interventional or observational, reporting guidelines (e.g., CONSORT, STROBE) emphasize the need to specify primary outcomes to reduce selective reporting bias, ensure statistical power, and underscore clinical relevance (Elm et al., 2008; Schulz et al., 2010). Yet, over 60% of the studies failed to meet this standard. While our assessment relied on explicit labeling of "primary" outcomes or power calculations, it's possible that some studies were appropriately designed but lacked detailed reporting. Still, the inconsistent application of reporting standards over the past decade is evident, echoing concerns already raised by Graziani et al. in 2012.

Another trend identified was the predominant reporting of continuous measures (e.g., mean values) for core outcomes like PPD, radiographic parameters, and soft tissue dimensions, rather than categorical indicators such as "pocket closure." This approach conflicts somewhat with the broader trend in periodontal research advocating for more defined clinical endpoints (Loos & Needleman, 2020; Sanz et al., 2020). Given the limited long-term follow-up data in peri-implant disease treatment, establishing and using clinically meaningful thresholds remains a challenge but is essential for future studies.

This review included 159 studies, 82 of which were randomized controlled trials (RCTs), meeting inclusion criteria based on minimum follow-up periods derived from peri-implantitis onset data (Derks et al., 2016) and common observation periods in therapeutic studies (e.g., Heitz-Mayfield et al., 2011; Philip et al., 2022; de Waal et al., 2015; Cha et al., 2019; de Tapia et al., 2019). In contrast to the 21 RCTs identified in a similar review a decade ago (Graziani et al., 2012), this indicates notable growth in the evidence base. However, two concerns persist: (1) most studies targeted treatment rather than prevention, and (2) less than 20% of studies were judged to have a low risk of bias (RoB). Thus, while the quantity of research has increased, high-quality evidence—particularly regarding prevention—remains limited.

5. CONCLUSIONS

In clinical studies addressing the prevention and management of peri-implant mucositis and peri-implantitis over the past decade, the following key findings were observed:

- PPD was consistently reported, typically measured using a metal probe at six sites per implant, with prostheses in place.
- Bleeding/Suppuration on Probing was also routinely assessed at six sites per implant, categorized as present/absent.

- Radiographic Evaluations largely focused on bone levels assessed via standardized intraoral imaging.
- Composite Outcomes were seldom employed.
- Adverse Events and Patient-Reported Outcomes were rarely addressed.
- Primary Outcomes were infrequently identified.
- Outcome Reporting for PPD, radiographic data, and soft tissue dimensions primarily relied on mean values.
- Unit of Analysis was most often at the patient level for core outcomes, though radiographic and soft tissue-related data often lacked clarity or remained implant-focused.

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