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ADMINISTRATIVE INFORMATION**Support** - N/A.**Review Stage at time of this submission** - Completed but not published.**Conflicts of interest** - None declared.**INPLASY registration number:** INPLASY2025120041**Amendments** - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 11 December 2025 and was last updated on 11 December 2025.**INTRODUCTION**

Review question / Objective This study utilised meta-analysis to investigate the association between type 2 diabetes mellitus and peri-implant diseases (including peri-implantitis and peri-implant mucositis).

Condition being studied Dental implant restoration is a standard treatment for tooth loss, offering functional and aesthetic benefits. However, the rising global use of implants has brought increased focus on their biological complications, particularly peri-implantitis. This destructive, irreversible condition, defined by mucosal inflammation, bleeding/suppuration, and progressive marginal bone loss, poses the greatest threat to long-term implant survival. Its impact extends beyond clinical failure, significantly increasing treatment costs and impairing patients' quality of life through compromised function, aesthetics, and psychological well-being.

Consequently, identifying and managing risk factors, especially modifiable systemic ones, is crucial for optimizing implant prognosis.

Among systemic factors, diabetes mellitus is of major interest due to its high global prevalence and profound effects on tissue healing and immunity. Evidence regarding its association with peri-implantitis is conflicting: some studies report increased bone loss, probing depths, and inflammation risk in diabetic patients, correlated with higher HbA1c levels, while others find no significant increased risk. This inconsistency, likely due to variations in study design, size, and follow-up, creates uncertainty for clinical decision-making.

Therefore, this study aims to quantitatively synthesize the existing evidence using meta-analysis to clarify the relationship between diabetic status and peri-implant diseases, providing a foundation for personalized treatment strategies.

METHODS

Participant or population Study participants were patients with edentulism who received dental implant restoration, with implant placement sites including completely or partially edentulous mandibular or maxillary dental arches.

Intervention Not Applicable.

Comparator Not Applicable.

Study designs to be included Literature databases (PubMed, Web of Science, Cochrane Library, and Embase) were systematically searched, and studies investigating the association between diabetes mellitus and peri-implant diseases were included. The Newcastle–Ottawa Scale was used for literature quality assessment, and pooled odds ratios (ORs) with their 95% confidence intervals (CIs) were calculated based on either a random-effects model or a fixed-effects model.

Eligibility criteria The inclusion criteria were as follows: (1) studies published in peer-reviewed journals in Chinese or English; (2) study participants were patients with edentulism who received dental implant restoration, with implant placement sites including completely or partially edentulous mandibular or maxillary dental arches; (3) the exposure of interest was type 2 diabetic status; and (4) study outcomes included odds ratios (ORs) for risk factors associated with peri-implantitis and peri-implant mucositis. The exclusion criteria included (1) non-human studies; (2) study types such as conference abstracts, case reports, or systematic reviews; (3) duplicate publications; and (4) studies for which the full text could not be obtained.

Information sources Literature screening was performed independently by two researchers according to the inclusion and exclusion criteria. An initial screening was conducted based on titles and abstracts, followed by a full-text review of potentially eligible studies. In cases of disagreement between the two reviewers, a third researcher was consulted, and discussion ensued until a consensus was reached. Following the literature screening, data extraction was performed independently by the two researchers using a standardised data extraction form. Extracted information included study details (e.g. author(s), year, journal), demographic characteristics of the study population, disease status, and outcome events. For missing data in included studies (e.g. standard deviations, sample sizes, or outcome

measures), we attempted to contact the corresponding authors to request the original data.

Main outcome(s) From 1,932 initially identified records, 10 observational studies involving 2,657 patients with dental implants were included in the meta-analysis. Patient mean age ranged from 47 to 62.95 years. Diabetes prevalence varied widely (4.07%–100%) across studies.

Association with Peri-implantitis

The pooled analysis of eight studies (n=2,510) demonstrated a statistically significant association between diabetes mellitus and an increased risk of peri-implantitis. The summary odds ratio (OR) was 2.05 (95% Confidence Interval [CI]: 1.52–2.77), indicating an approximately two-fold higher risk for diabetic patients. Heterogeneity among studies was low ($I^2 = 1.8\%$; $P = 0.416$), justifying the use of a fixed-effects model.

Association with Peri-implant Mucositis

Three studies (n=928) reported on peri-implant mucositis. The meta-analysis showed a non-significant trend towards increased risk with diabetes, with a pooled OR of 1.22 (95% CI: 0.91–1.63). Heterogeneity was negligible ($I^2 = 0\%$; $P = 0.701$), and a fixed-effects model was applied.

Other Risk Factors for Peri-implantitis

Analyses confirmed smoking and a history of periodontitis as significant risk factors. The pooled OR for smoking (5 studies, n=1,826) was 1.99 (95% CI: 1.57–2.52; $I^2=0\%$). For periodontitis (7 studies, n=2,237), the association was even stronger, with a pooled OR of 3.99 (95% CI: 1.44–11.01). Significant heterogeneity was present for periodontitis ($I^2 = 93.6\%$; $P < 0.001$), necessitating a random-effects model.

Quality and Robustness

The mean Newcastle–Ottawa Scale score was 6.9 (range 6–8), indicating moderate overall quality. Formal tests did not indicate significant publication bias (Egger's/Begg's test $P > 0.05$), though statistical power was limited. Sensitivity analyses (leave-one-out) confirmed the robustness of the significant findings for diabetes, smoking, and periodontitis in relation to peri-implantitis.

Quality assessment / Risk of bias analysis The methodological quality of observational studies was assessed using the Newcastle–Ottawa Scale (NOS) [18]. This scale evaluates studies across eight items within three domains: the representativeness of the study population, the comparability of groups, and the adequacy of outcome assessment (including sufficient follow-

up time and completeness of follow-up). The maximum score is 9 points. Studies scoring 7 points or higher were considered high quality, whereas those scoring 5 points or lower were considered low quality. The Kappa value was 0.927.

Strategy of data synthesis Statistical analyses were performed using Stata software (version 16.0). Odds ratios with their corresponding 95% confidence intervals (CIs) were used to estimate the risk of developing peri-implant diseases. Heterogeneity among the included studies was assessed using the I^2 statistic and the Q test. An I^2 value 0.10 indicated acceptable heterogeneity, and a fixed-effects model was used for meta-analysis. An I^2 value $\geq 50\%$ or a Q test P-value ≤ 0.10 indicated substantial heterogeneity, and a random-effects model was thus used. If substantial heterogeneity was detected, a sensitivity analysis by excluding the included study one by one was performed to explore potential sources. Publication bias was assessed using Egger's test and Begg's test. Unless otherwise specified, the significance level (α) was set at 0.05.

Subgroup analysis Not Applicable.

Sensitivity analysis A leave-one-out sensitivity analysis was performed using Stata 16.0, where each included study was sequentially excluded to assess the robustness of the pooled estimates and to identify potential sources of heterogeneity.

Country(ies) involved China.

Keywords Diabetes mellitus, Dental implants, Peri-implantitis, Meta-analysis, Glycaemic control, Risk factors.

Contributions of each author

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