Characteristics, level of evidence, and impact of clinical studies on peri-implantitis

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Characteristics, level of evidence, and impact of clinical studies on peri-implantitis: 2017–2021

Authors: Yaoyu Zhao, BDS, MSc[1,2]; Qi Yan, DDS, PhD[1,2]; Xinyu Wu, BDS, MSc[1]; Fang Hua, BDS, MSc, PhD[3,4]; Bin Shi, DDS, PhD[2]

Yaoyu Zhao and Qi Yan contributed equally to this work

Correspondence to

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[1]Hubei-MOST KLOS & KLOBM, School & Hospital of Stomatology, Wuhan University, Wuhan, China; [2]Department of Oral Implantology, School & Hospital of Stomatology, Wuhan University, Wuhan, China; [3]Centre for Evidence-Based Stomatology, School & Hospital of Stomatology, Wuhan University, Wuhan, China; [4]Division of Dentistry, School of Medical Sciences, Faculty of Biology, Medicine and Health, University of Manchester, Manchester, UK.

Bin Shi, DDS, PhD, Department of Oral Implantology, School & Hospital of Stomatology, Wuhan University, 237 Luoyu Road, Wuhan, People's Republic of China 430079; E-mail: shibin_dentist@whu.edu.cn; Fax: +86-27-87873260

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One-sentence Summary: High-LOE studies on peri-implantitis tend to exert greater scientific impact, but do not have greater social impact.

Abstract

Background: The level of evidence (LOE) is an important tool in current evidence-based practice and clinical research. However, in clinical studies on peri-implantitis, the present status of LOE and its association with research impact remains to be determined. The present study aimed to gather the characteristics and level of evidence (LOE) of clinical studies on peri-implantitis conducted during 2017–2021 and to assess the association of LOE with social and scientific impact.

Materials and methods: The PubMed database was searched for retrieving clinical studies that evaluated peri-implantitis related healthcare interventions and were published between 2017 and 2021. A four-level modified Oxford 2011 LOE tool was used to determine the LOE of these studies. Citation count and Altmetric Attention Scores (AAS) were derived from Web of Science and Altmetric Explorer, respectively. Multivariate generalized estimation equation (GEE) analysis was conducted to explore relationships between LOE and citation

count, and between LOE and AAS; the publication year was considered the grouping factor for adjusting for potential clustering effects.

Results: Two hundred and thirty-five studies were considered eligible. The percentage of *level-1* to *level-4* studies was 9.8%, 35.7%, 28.9%, and 25.5%, respectively. Multivariable GEE analyses revealed that studies with higher LOE had significantly greater citation counts ($p = 0.008$). However, no significant association ($p=0.872$) was observed between LOE and AAS.

Conclusions: During 2017-2021, more than 40% of high-LOE studies on peri-implantitis were published each year. High-LOE studies showed a tendency to have larger scientific impact.

Keywords: peri-implantitis, bibliometrics, evidence-based dentistry, social impact

1. Introduction

Evidence-based medicine (EBM) is a systematic approach to medicine that integrates the optimal clinical evidence, expertise of clinicians, and preferences of patients.[1] EBM aims to promote medical decision-making based on external evidence rather than on individual clinical experience. The explosive growth of published literature has, however, impeded EBM practice because of shortage of time and extensive workload to appraise clinical studies critically.[2, 3]

The level of evidence (LOE) concept enables readers to rapidly appraise a study's quality. Presently, the popular tool for LOE assessment has been developed by Oxford Centre for Evidence-Based Medicine; the latest revision of this tool was proposed in 2011.[4] Generally, high-LOE studies show more reproducible and reliable outcomes for clinical application.[5] According to several recently published articles, LOE assessment in clinical investigations is currently gaining attention worldwide.[6-8]

Citation count, a classical bibliometrics indicator, is used to estimate an article's scientific impact. Thus, it is believed that high-LOE studies will have higher citation count. A strong relationship between LOE and citation count has been reported.[8-10] In contrast, studies in the fields of plastic surgery and orthopedics revealed no significant association with citation count,[11, 12] thus indicating an undetermined relationship between citation count and LOE.

Because of the extensive usage of social media platforms to promote scientific literature, citation count cannot accurately reflect the social impact of scientific studies.[13] Therefore, Altmetrics Attention Score (AAS) was introduced as a complementary approach to the traditional bibliometrics tool to estimate the social impact of academic research.[14] AAS is a quantitative indicator updated in real time to reflect the attention received by an academic article; the score is generated by aggregating information from online platforms, including social media, mainstream media, and online reference managers.[15] In recent years, several methodological studies have analyzed the association

between AAS and LOE; however, the outcomes are discrepant. Notably, in the fields of oral implantology and periodontology, high LOE studies tend to have significantly higher AAS.[8, 16] While in the field of surgery, no relationship was found between AAS and LOE.[17]

Following the widespread use of dental implants to replace the missing teeth, implant-related complications have gained increasing research attention. In particular, peri-implantitis, which involves peri-implant mucosal inflammation as well as progressive loss of supportive bone, is considered a major biological complication of dental implants.[18] As peri-implantitis progresses, hard and soft tissues are affected, which may ultimately cause implant failure. With an alarming prevalence rate of 22%, peri-implantitis has greatly restricted the function of dental implants.[19] In the past few decades, the number of published studies on peri-implantitis has drastically increased.[20, 21] The excessive growth in the literature on peri-implantitis has made it difficult for oral implantologists to decide the best available evidence, as limited information of LOE is presented in clinical studies on peri-implantitis. Moreover, the role of social media in recognizing high-level studies on peri-implantitis remains to be determined.

According to our understanding, a detailed investigation of characteristics, LOE, and impact of clinical studies on peri-implantitis remains to be conducted. Therefore, the objectives of this study were to (a) gather the characteristics, LOE, citation counts, and

AAS of studies on peri-implantitis published during 2017–2021 and (b) determine the potential predictors (including LOE) of social and scientific impact.

2. Materials and Methods

2.1. Search Approach

Clinical studies that evaluated peri-implantitis related healthcare interventions and were published between 2017 and 2021 were retrieved from the PubMed database. Search terms containing “peri-implantitis” and its synonyms were combined using “OR” as the Boolean operator. The last search process was conducted in August 2022, and the search approach details are given in the “See Supplementary Table 1 in online Journal of Periodontology".

2.2. Study Selection

We used the following predetermined eligibility criteria for screening the studies: (a) primary studies: case report/series, cross-sectional study, cohort studies, controlled clinical trial (CCT), randomized clinical trial (RCT), and secondary studies: systematic review, (b) studies on human patients, (c) studies involving clinical settings, and (d) studies focused on peri-implantitis related healthcare interventions. Editorials, letters, commentaries, protocols, narrative reviews, non-clinical setting studies, epidemiological,

etiology, prognosis and diagnosis studies were excluded. If screened titles and abstracts met the inclusion criteria or if further information was required, the corresponding full text was obtained for eligibility assessment. Two authors (Y.Z. and Q.Y.) completed the study selection process independently. All disagreements were discussed with two experts (F.H. and B.S.) until a consensus was achieved.

2.3. Data Extraction

Two authors (Y.Z. and X.W.) independently extracted the details from the included studies as follows: (1) article title; (2) journal name; (3) publication year; (4) study design; (5) research topic; (6) geographic origin; (7) multiple affiliations; (8) type of institution; (9) top dental school; (10) funding status; (11) open-access status; (12) citation count; and (13) AAS.

- Study design of the included studies was categorized as follows: (1) systematic review, (2) randomized controlled trial (RCT), (3) controlled clinical trial (CCT), (4) cohort study, (5) cross-sectional study, (6) case–control study, and (7) case series/report.[22, 23]
- Research topic of the published studies was categorized as follows: (1) prevention, (2) non-surgical debridement, (3) adjunctive antiseptic/antibacterial therapy, (4) laser-assisted therapy, (5) access flap surgery, (6) resective therapy, (7) augmentation

therapy, and (8) combined therapy. This categorization was modified from the previous classification schemes.[24, 25] Studies investigating the effectiveness of multiple treatment modalities, rather than a specific topic mentioned above, were categorized as "combined therapy." If a study was included in several categories, the most relevant one was considered after interaction with two experts (F.H. and B.S.).

- Type of institution was defined according to the first author's academic affiliation as follows: (1) university, (2) public health service, (3) private practice, and (4) others.
- The "top dental school" variable was dichotomized into a "yes" or "no" answer based on the 2022 QS ranking of the top 50 dental schools.[26]
- Funding status was defined as follows: (1) funding support from industries, (2) funding support from other sources, and (3) unfunded/unreported. When a study had multiple funding types, "funded by industries" was recorded in priority.
- Open-access status of the included articles was manually checked through Google Scholar, a commonly used online search engine. The complete title of an article, together with the first author's name if required, was used as search terms. After finding the targeted article, the "All Version" function was used to check for the free full text.[27]
- Citation counts of all the included studies were obtained from Web of Science in August 2022.
- An article's AAS was obtained from Altmetric sources in August 2022.

2.4. Assessment of LOE

A modified LOE rating system, which was based on the Oxford 2009 LOE tool, the Oxford 2011 LOE tool, and GRADE guidelines, was adopted in this study.[4, 28, 29] The modified LOE system has four levels. For the ease of description, "high level" was considered for *level-1* and *level-2*, and "low level" was considered for *level-3* and *level-4*. Figure 1 shows the details of the assessment tool.

For LOE assessment, the examiners were calibrated through an internal pilot study. Two authors (Y.Z. and Q.Y.) assessed 15 randomly selected studies independently, until they reached a strong agreement (based on weighed kappa statistics, $k \geq 0.75$).[30] They then examined the remaining studies independently. All disagreements were discussed with an expert (F.H.) and then resolved.

2.5. Statistical Analysis

A statistical software[1] was used to for statistical analysis. Descriptive statistics was employed to summarize the LOE and characteristics of the included studies. A generalized estimation equation (GEE) linear model was utilized to determine associations between

[1]IBM SPSS Statistics for Windows (Version 25.0), IBM Corp., Armonk, N.Y., USA

citation counts and LOE as well as between AAS and LOE, with adjustments for potential clustering effects and confounding factors. Studies without AAS were recorded as "0" in the GEE model.[31] For studies published in the same year, potential clustering effects were adjusted by setting publication year as the grouping factor. First, unadjusted univariate GEE analysis was performed to study the associations between citation counts and LOE as well as between AAS and LOE. Potential confounding variables (i.e., geographic origin, research topic, top dental school, type of institution, funding status, multiple affiliations, and open-access status) were included in a multivariate model. An exchangeable correlation matrix and a robust estimator covariance matrix were used in the GEE linear model. The dependent variables (AAS and citation counts) were log-transformed.[32] Statistical significance for all analyses was examined by a two-sided $p < 0.05$.

3. Results

3.1. Characteristics of the included studies

The literature search yielded 2149 studies, and of these studies, 235 studies were considered fit for inclusion in the present study. The flow diagram for study selection was presented in the "See Supplementary Figure 1 in online Journal of Periodontology". The kappa value between the two experts (F.H. and B.S.) was 0.83, indicating substantial agreement between the two reviewers. Table 1 shows the characteristics of the enrolled studies. Overall, the most

common study design was RCT (30.2%), followed by case report/series (23.8%) and cohort studies (22.1%). *Adjunctive antiseptic/antibacterial therapy* and *combined therapy* were the most prevalent topics, which accounted for 23.0% and 20.9%, respectively, of the total topics. Most studies were performed in Europe (45.1%), with multiple affiliations (55.3%) and in universities (81.4%). Furthermore, most studies were conducted in non-top 50 schools (76.6%). More than 50% of the studies were not funded or did not report a funding source (59.6%) and were published as open-access articles (57.9%).

During 2017 to 2021, the number of studies on peri-implantitis published per year increased gradually from 34 to 69. A considerable growth was observed in the proportion of systematic reviews (5.9–21.7%) and in the proportion of studies investigating peri-implantitis prevention (5.9–15.9%). There was an increase in the proportion of studies conducted by multiple affiliations over time (44.1–65.2%). Moreover, open-access studies increased notably from 47.1% in 2017 to 65.2% in 2021.

3.2 Assessment of LOE

Of all the included studies, *level-1 to level-4* studies were 9.8%, 35.7%, 28.9%, and 25.5% in proportion, respectively. *Level-2* was the most common LOE in each year. The proportion of *level-3* and *level-4* studies remained constant over the 5-year period, while the proportion of *level-1* studies nearly doubled from 5.9% in 2017 to 11.6% in 2021 (Figure 2A). With regard

to research topics, *adjunctive antiseptic/antibacterial therapy* was the topic for most studies with high LOE (72.2%), followed by *non-surgical debridement* (57.1%) and *laser-assisted therapy* (53.9%; Figure 2B).

3.3 Association between citation count and LOE

Overall, the included studies showed a median citation count of 4 (interquartile range [IQR]: 1–11, range: 0–148). From 2017 to 2021, the median citation count for each consecutive year was 12 (IQR: 8–20, range: 0–85), 10 (IQR: 3–26.5, range: 0–148), 9 (IQR: 2–18, range: 0–45), 4 (IQR: 2–7, range: 0–21), and 1 (IQR: 0–2, range: 0–15), respectively. In general, studies with high LOE showed greater citation counts than those with low LOE. The discrepancies in the citation count between high-LOE and low-LOE studies became greater with the increase in time after publication (Figure 3A).

The univariate GEE analysis revealed a significant association of LOE with citation count (independent variable: log-transformed; $B = 1.26$, 95% CI: 1.09–1.47, $p = 0.002$). In the multivariate GEE analysis, after making adjustment for potential clustering and confounding effects, LOE was found to be an independent predictor of citation count ($p = 0.008$). Geographical origin, research topic, type of institution, multiple affiliations, and funding status were the other predictors showing a significant association ($p < 0.05$) with citation counts (Table 2).

3.4 Association between AAS and LOE

Sixty-four studies, i.e., nearly one-third (27.2%) of the included studies, received AAS in the 5-year period. The median AAS of the 64 included studies was 1 (IQR: 1–2, range: 1–73). From 2017 to 2021, the median AAS for each consecutive year was 1.5 (IQR: 1–2.75, range: 1–73), 1 (IQR: 1–1.75, range: 1–13), 1 (IQR: 1–5.25, range: 1–8), 1 (IQR: 1–1, range: 1–14), and 1 (IQR: 1–1.75, range: 1–8; Figure 3B), respectively.

The univariate GEE analysis (independent variable: log-transformed; $B = 1.01$, 95% CI: 0.95–1.07, $p = 0.835$) as well as the multivariate GEE analysis ($p = 0.872$) did not show that LOE was significantly associated with AAS. Geographical origin, multiple affiliations, and type of institution were identified as significant predictors of AAS ($p < 0.05$; Table 3).

4. Discussion

Here, we gathered the characteristics of clinical studies on peri-implantitis over the 5-year period of 2017–2021 and evaluated whether LOE was associated with the scientific and social impact. Statistical analyses indicated that high-LOE studies were associated with a greater citation count; however, no significant relationship was observed between LOE and AAS.

4.1. Characteristics of the included studies

A steady growth of clinical literature related to peri-implantitis was observed in 2017–2021, thus indicating an increasing research activity in this field. The most prevalent research topics were adjunctive antiseptic/antibacterial therapy and combined therapy; this finding might reflect that the concept of multiple therapeutic modalities is gaining popularity in peri-implantitis treatment. The increasing number of studies on prevention implied that several researchers were exploring strategies to reduce the incidence of peri-implantitis. More than 50% of the included studies were performed in collaborations with multiple affiliations, and the most productive institution was university. These results were identical to those reported previously.[8,20]

Most of the published studies originated from Europe and Asia. The results were slightly different from those of a bibliometric study that analyzed literature reporting peri-implant diseases, which showed that the United States was the most productive nation, followed by Germany and Sweden.[20] This could be attributed to the difference in the inclusion criteria between the two studies: only those clinical studies published in the 2017–2021 period were included in the present study, while the bibliometric study included all articles published up to 2019 (limited to studies published as Article and Review).

4.2. LOE assessment

Compared to the previous LOE study that evaluated clinical research studies in oral implantology, a large proportion of high-LOE studies (45.5%) was found in the present study by using the same LOE assessment tool.[8] Additionally, more than 40% of the published studies per year were high-LOE studies (Figure 2A). In particular, more than 10 RCTs (except in 2018), which are considered the optimal study design to evaluate an intervention's effectiveness, were published per year.[33] This positive phenomenon indicated that an increasing number of scholars were focused on producing high-LOE studies related to peri-implantitis. However, it should be noted that LOE is a simplified tool for clinicians that will enable them to pre-screen clinical evidence on a particular topic, rather than the definitive recommendation for clinical decision-making.[34] A previous study showed that RCTs in oral implantology from 1996 to 2016 presented limited methodological and reporting quality.[35] Another study that evaluated the risk of bias (ROB) as well as methodological quality in systematic reviews of peri-implantitis-associated treatments reported high ROB and low-quality evidence, mainly because of the absence of head-to-head comparisons in RCTs.[36] Thus, clinicians should appraise the available evidence and decide whether to use it as clinical guidance for managing peri-implantitis.

Regarding LOE assessment based on research topics, *adjunctive antiseptic/antibacterial therapy* had the largest number of high-LOE studies at 39 with a proportion of 72.2% (Figure 2B). This can be attributed to the fact that the complexity of treatment modalities made it difficult to conduct RCTs in other research topics. In contrast, *combined therapy* had the

largest number of low-LOE studies at 31 with a proportion of 63.3%, followed by *augmentation therapy* (30 and 69.8%, respectively). In the hierarchical evidence pyramid, case series and case reports received a low ranking because of the absence of control groups, high risk of bias, and zero possibility to prove cause-effect relationship.[37] The significance of case reports, however, should not be overlooked. They are appropriate article types to report novel treatment modalities and generate hypotheses in peri-implantitis treatment. In recent years, augmentative therapy has been recommended for treating peri-implantitis with intrabony defects.[38] Additionally, several researchers have proposed the need for combined therapy in managing peri-implantitis.[25, 39] The increasing trend of case reports/series in these two research topics might reflect a shift in the concept of peri-implantitis management over the 5-year period of 2017–2021.

4.3. LOE and scientific impact

The present study results revealed a significant association of LOE with citation count in the research field of peri-implantitis. A previous study that investigated the relationship between LOE and impact of oral implantology clinical studies showed a similar conclusion.[8] In another study on bibliometrics that analyzed the 100 top-cited articles investigating peri-implant-related diseases before 2022, there were 19 systematic reviews among these articles and had the highest average citation count.[40] It is inspiring to find that researchers

recognized the importance of LOE and tended to cite high-LOE studies while preparing their scientific articles on peri-implantitis.

European studies were associated with a higher citation count than those from Asia and South America. Similarly, the bibliometric study on peri-implant related diseases reported that the majority of the most-cited authors were from Europe.[40] Moreover, in the present study, the funding status significantly influenced the citation count. A similar tendency was also observed in the previous study.[40] Some authors raised concerns regarding the presence of bias in industry-funded studies.[41, 42] However, a recent study demonstrated that significant industry sponsorship-related bias in RCTs was not found in implant dentistry, and industry-funded studies had a tendency to have a better quality of planning, conducting, and reporting.[35] Another LOE study in orthodontics reported that industry-funded studies were significantly correlated with higher LOE, as institutions were more willing to invest in RCTs rather than in nonrandomized trials.[6] As discussed earlier, whether a clinical trial is cited or not cited should be based on the objective assessment of their quality irrespective of the funding status.

No significant association was detected between open-access status and citation count in the present study. This result differed from that of a previous study, which found that open-access articles in oral implantology were associated with a lower citation count.[8] These discrepant findings could be attributed to the different sampling methods. In the present

study, clinical studies that focused on the interventions of peri-implantitis were included; in contrast, studies published only in the top oral implantology journals were selected in the previous study.

4.4. LOE and social impact

In our present study, LOE showed no significant association with AAS; this finding was different from those of previous studies.[8, 16] As shown in Figure 3B, most studies received AAS of <5. Moreover, two studies had extremely high AAS of 76 (a case report) and 32 (a cross-sectional study).[43, 44] These two studies had low LOE ranking and did not have complex scientific logic as compared to RCTs and systematic reviews. Thus, they are more readable and easier to understand, which may explain their popularity on the Internet.

Presently, the Internet has become a popular source of obtaining health information and recommendations in general public. In particular, “dental implants” was the third most common topic in dentistry on the Internet.[45] However, a previous study revealed that online information on peri-implantitis was non-patient friendly and of poor quality.[46] Online misleading information could make patients have inappropriate demand or unrealistic expectation, thereby causing unnecessary burden on clinicians.[45] Decision-making related to treatment modalities depends on the progression of peri-implantitis, which is beyond the comprehension level of general public without medical background.[46] Therefore, it may be

beneficial to encourage dental professionals to produce more high-quality and appealing information on peri-implantitis. Avoidance of the use of complex terminologies could improve the dissemination of high-level scientific evidence to the general public.

4.5. Strengths and limitations

Here, we comprehensively evaluated LOE's association with the social and scientific impact of clinical studies on peri-implantitis. Multiple articles related to peri-implantitis that were published over the 5-year period of 2017–2021 were included. Additionally, we used a modified LOE assessment tool that integrates the advantages of the Oxford LOE tool and GRADE guidelines. GEE analyses were conducted for adjusting the potential clustering impact of publication year on AAS and citation count.

The modified LOE assessment tool depends on the study design and the effect size. The methodological quality, reporting quality, and clinical significance of the included studies were not considered.[47-49] Thus, this tool is suitable for the initial assessment of research in clinical practice. The quality and clinical relevance of the studies should be appraised further if additional time is available. Moreover, it should be noted that the GEE model used in this study does not provide an overall p-value for the effect of the dependent variables. Consequently, p-values were presented per level of the dependent variables, which may increase the risk of multiple testing issues. Therefore, caution should be taken when

interpreting the results of the present study, especially regarding the significance of individual levels of the dependent variables. Furthermore, we combined levels 1 and 2 as "high" LOE, and levels 3 and 4 as "low" LOE to simplify the presentation of results. However, the combination may limit further interpretation of the unique impact of different levels of studies.

5. Conclusions

During 2017–2021, more than 40% of high-LOE studies have been published each year in the area of dental peri-implantitis. High-LOE studies showed a tendency to have greater scientific impact than low-LOE studies. However, no significant association was found between high-LOE studies and greater social impact.

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Conflict of Interest Statement

The authors declare no conflict of interest.

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Figure legends

Figure 1. The modified tool for assessing LOE. The effect size showed a dramatic effect for the following conditions: (1) a study's primary outcome was categorical and (2) risk ratio (RR) was >5 (or <0.2). Sample size and odds ratio (OR) were used to calculated RR, based on which it was decided to increase/decrease the level.

Figure 2. (A) LOE of the enrolled studies according to publication year. (B) LOE of the enrolled studies according to the research topic.

Figure 3. (A) Citation count of the enrolled studies. (B) Altmetric Attention Score (AAS) of the enrolled studies. Gray dots represent the enrolled studies. The black solid line represents the median value. The black dotted line represents the first and third quartiles.