Received: 25 October 2021 | Revised: 30 December 2021 | Accepted: 22 January 2022

DOI: 10.1111/clr.13927

CLINICAL ORAL IMPLANTS RESEARCH WILEY

SYSTEMATIC REVIEW

Outcome measures and methods of assessment of soft-tissue augmentation interventions in the context of dental implant therapy: A systematic review of clinical studies published in the last 10 years

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This manuscript was simultaneously and jointly published in *Clinical Oral Implants Research* and the *Journal of Clinical Periodontology*

Abstract

Aim: The aim of the study was to identify and report outcome measures and methods of assessment on soft-tissue augmentation interventions in the context of dental implant therapy reported in clinical studies published in the last 10 years.

Material and Methods: The protocol of this PRISMA 2020-compliant systematic review was registered in PROSPERO (CRD42021252214). A literature search was conducted to identify articles that met the pre-established eligibility criteria. Data of interest, with an emphasis on outcome measures, were extracted. For each outcome, specific methods and timing of assessment were described in detail. Following a critical qualitative analysis of the data, outcome measures were categorized. Primary outcomes were identified and the frequency of reporting in the selected articles was calculated. Additionally, risk of bias assessments were performed for individual articles and primary outcomes.

Results: Ninety-two articles, of which 39 reported randomized controlled trials (RCTs), 20 reported non-RCTs, and 33 reported case series studies, were selected. Outcome measures were categorized into either investigator-evaluated outcome measures (i.e., clinical, digital imaging, esthetic, histologic, biomarker, and safety) or patient-reported outcome measures (PROMs). Clinical outcomes were the most frequently reported type of outcome. Considering all categories, the most frequently reported primary outcomes were facial mucosa thickness assessed with clinical methods (22.83%), facial keratinized mucosa width assessed with clinical methods (19.57%), facial mucosal margin position/recession assessed with clinical methods (18.48%), facial mucosa thickness assessed with digital imaging methods (11.96%), facial soft-tissue volume assessed with digital imaging methods (9.78%), and supracrestal tissue height assessed with clinical methods (9.78%). No distinguishable patterns of association between specific types or quality (level of bias) of clinical studies and the choice of primary outcomes were observed.

Conclusion: Clinical research on peri-implant soft-tissue augmentation has progressively increased in the last 10 years. Although clinical outcome measures were the most frequently reported outcomes in the selected literature, trends in the field are indicative of a shift from traditional clinical assessment methods to the use of digital technologies. PROMs were generally underreported but should be considered an integral methodological component in future clinical studies.

KEYWORDS
dental implant, outcome assessment, outcome measures, soft-tissue therapy

1 | INTRODUCTION

Peri-implant soft-tissue augmentation interventions are indicated prior to or after insertion of the final implant-supported prosthesis in sites presenting unfavorable structural features that are associated with or may predispose to the occurrence of inflammatory peri-implant pathosis, soft-tissue deformities, and/or suboptimal esthetics (Thoma et al., 2018). Depending on their primary therapeutic goal, peri-implant soft-tissue augmentation interventions may be broadly classified into two categories: (1) Peri-implant soft-tissue phenotype modification (Tavelli et al., 2021) and (2) Treatment of peri-implant marginal mucosa defects (PMMDs), also known as peri-implant soft-tissue dehiscences (Zucchelli et al., 2019).

The peri-implant phenotype has been defined as the morphologic and dimensional features characterizing the clinical presentation of the tissues that surround and support osseointegrated implants (Avila-Ortiz et al., 2020). The peri-implant phenotype is constituted by a soft tissue and a bone component. While the peri-implant bone phenotype is primarily determined by the bone thickness (BT), the peri-implant soft-tissue phenotype includes three key elements with different clinical and therapeutic implications: the keratinized mucosa width (KMW), the mucosal thickness (MT), and the supracrestal tissue height (STH). On the other hand, PMMDs are alterations of the peri-implant soft-tissue architecture characterized by an apical discrepancy of the mucosal margin respective to its ideal position with or without exposure of transmucosal prosthetic components or the implant fixture surface (Gamborena & Avila-Ortiz, 2021).

Over the past decade, a variety of surgical modalities for peri-implant soft-tissue phenotype modification (i.e., augmentation of KMW, MT, and/or STH) and correction of PMMDs using different techniques and graft materials have consolidated or emerged. In parallel, a plethora of true and surrogate endpoints of interest (Chambrone & Armitage, 2016) and assessment methods to monitor the results of therapy have also been developed. Research outcomes, also known as endpoints or events, are variables that are recorded during a study to assess the impact that a given intervention or exposure has on the health of a given population. Assessment and interpretation of outcomes is an essential component of research as this allows to test the validity of the hypothesis (Sanz & Vignoletti, 2014). Standardization of core research outcomes can help guiding future research, decrease potential biases, and allow for more reliable inter-study comparisons and pooled data analyses for the advancement of science and, ultimately, the enhancement of patient care.

Clinical relevance

Scientific rationale: Assessment and interpretation of outcomes is an essential component of clinical research. This systematic review was conducted as part of the Implant Dentistry Core Outcome Sets and Measurements (ID-COSM) initiative.

Principal findings: Ninety-two articles published between January 2010 and April 2021 were selected. Outcomes were categorized into clinical, digital imaging, esthetic, histologic, biomarker, safety, and patient-reported outcome measures. Clinical outcomes were the most frequently reported type of outcome measure.

Practical implications: Standardization of core research outcomes on soft-tissue augmentation interventions in the context of implant therapy can be beneficial to reducing bias in future clinical studies and contribute to optimizing the translation of scientific findings into patient care.

The primary objective of this systematic review, which was conducted as part of the Implant Dentistry Core Outcome Sets and Measurements (ID-COSM) initiative, was to identify and report outcome measures and methods of assessment on soft-tissue augmentation interventions performed in the context of dental implant therapy reported in clinical studies published in the last 10 years.

2 | MATERIALS AND METHODS

The protocol of this review was previously registered in the International Prospective Register of Systematic Reviews (PROSPERO) with the identification code CRD42021252214. This review adheres to the guidelines of the Preferred Reporting Items of Systematic Reviews and Meta-Analyses (PRISMA) 2020 statement (Page et al., 2021).

PubMed *n* = 6088 records	1. Soft-tissue augmentation OR keratinized tissue OR tissue thickness 2. Gingival graft OR connective tissue graft OR free gingival graft OR acellular dermal matrix OR dermal matrix allograft OR collagen matrix OR xenogeneic collagen matrix 3. #1 OR #2 4. Implant OR dental implant OR dental, implants OR dental implantation OR peri-implant 5. #3 AND #4
CENTRAL *n* = 3387 records	Dental implant OR peri-implant AND 'keratinized tissue' OR 'tissue thickness' OR 'connective tissue graft' OR 'free gingival graft' OR 'soft-tissue augmentation' OR 'collagen matrix' OR 'xenogeneic collagen matrix' OR 'acellular dermal matrix' OR 'dermal matrix allograft'
EMBASE *n* = 5392 records	Dental implant OR peri-implant AND 'keratinized tissue' OR 'tissue thickness' OR 'connective tissue graft' OR 'free gingival graft' OR 'soft-tissue augmentation' OR 'collagen matrix' OR 'xenogeneic collagen matrix' OR 'acellular dermal matrix' OR 'dermal matrix allograft'

TABLE 1 Search strategies used in each of the three databases. Search strategies in CENTRAL and EMBASE were modeled based on the search strategy designed for PubMed using the filters: Humans and date of publication from January 1, 2011 to April 30, 2021

2.1 | Focused research question and PICO outline

> In adult patients receiving any soft-tissue augmentation intervention prior to or after the insertion of the final implant-supported prosthesis, which outcome measures and methods of assessment have been used to monitor the results of therapy in clinical studies published in the last 10 years?

PICO outline:

- Population: Adult human subjects in need of or that have one or more dental implants.
- Intervention: Any soft-tissue augmentation intervention performed in the context of dental implant therapy prior to or after insertion of the final implant-supported prosthesis.
- Comparison: Absence of treatment or control treatment.
- Outcomes: Any outcome measures and methods of assessment reported after peri-implant soft-tissue augmentation, independently of the total follow-up time.

2.2 | Eligibility criteria

Randomized controlled trials (RCTs), non-randomized controlled trials (non-RCTs), prospective cohort studies, and pre–post case series studies (i.e., clinical studies with no control group, but involving several visits over time) in the field of implant dentistry with a minimum of 10 subjects per study group were eligible. The difference between RCTs and non-RCTs was whether randomization was used for group allocation (RCTs) or not (non-RCTs). For inclusion, studies must involve at least one peri-implant soft-tissue augmentation intervention and a subsequent outcome assessment.

2.3 | Information sources and search strategy

Three electronic databases were searched, namely the National Library of Medicine (MEDLINE/PubMed), Cochrane Central Register of Controlled Trials (CENTRAL), and EMBASE using specific strategies (Table 1). The electronic search included articles published between January 1, 2011, and April 30, 2021. Additionally, a thorough hand search was performed by screening articles published in relevant scientific journals (i.e., *Journal of Periodontology*, *Journal of Clinical Periodontology*, *Journal of Dental Research*, *Clinical Oral Investigations*, *The International Journal of Periodontics and Restorative Dentistry*, *International Journal of Oral implantology*, *Journal of Oral and Maxillofacial Surgery*, *The International Journal of Oral & Maxillofacial Implants*, *Clinical Oral Implant Research*, and *Clinical Implant Dentistry and Related Research*), as well as recent systematic reviews on this topic (Bassetti et al., 2016, 2017; Cairo et al., 2019; Lin et al., 2018; Rotundo et al., 2015; Seyssens et al., 2021; Tavelli et al., 2021; Thoma et al., 2014, 2018), published between January 1, 2011 and April 30, 2021. Per consensus agreement with the ID-COSM steering committee, the gray literature was not searched.

2.4 | Selection process

Two reviewers (E.C. and M.P.) independently performed the hand search and read the title and abstract of the entries obtained from the literature search. Inter-examiner calibration was achieved by open discussion and comparison after independent assessment of the first 200 records. After completing the screening process, both reviewers read individually through the full-text version of the potentially eligible studies. The final article selection was dictated by the eligibility criteria (see section 2.2). When disagreement regarding the inclusion of a specific article occurred, both reviewers had an open discussion. If no agreement was achieved, another co-author (G.A.) made the final decision. Following article selection, Cohen's

kappa coefficient (k) was calculated to determine the degree of inter-examiner agreement.

2.5 | Data extraction

Data extraction was preliminarily performed by two independent examiners (E.C. and M.P.). Examiners were calibrated by using a random selection of five articles to ensure consistency in the data extraction process and the terminology employed. Final data accuracy and consistency was independently verified by a third author (G.A.). Any missing information that could contribute to this review was requested from the corresponding author(s) via email communication.

2.6 | Data synthesis

Extracted data were organized into evidence tables. In addition to the reported outcome measures and their assessment methods, supplemental data included the year of publication and author(s), country(ies) and setting(s) in which the study was conducted, study design, initial and final number of participants, gender and age distribution, and description of intervention(s). For each outcome, specific methods and timing of assessment were described in detail. Following a critical qualitative assessment of the data, outcomes identified in the selected literature were categorized. The frequency of use as either primary or secondary outcome in the selected literature was calculated.

2.7 | Risk of bias assessment

The risk-of-bias analyses of each included article were independently performed by two authors (E.C. and M.P.). RCTs and non-RCTs (quasi-RCTs) were assessed with the RoB-1 Tool from version 5.1 of the Cochrane Handbook (Higgins et al., 2011), and case series were assessed using the National Institute of Health (NIH) quality assessment tool for before–after (pre–post) studies with no control group (NIH, 2021). Independently of the study type, primary outcome measures were specifically assessed using domain 4 of the RoB-2 Tool from the current version of the Cochrane handbook (Sterne et al., 2019). Additional quality aspects, such as pertinence/significance, accuracy, and reproducibility of each primary outcome measure, were taken into consideration. Disagreement between reviewers was resolved by open discussion. In case no agreement could be achieved, the final decision was made by another co-author (G.A.).

3 | RESULTS

3.1 | Article selection

The initial database search yielded a total of 14,867 entries, of which 6088 were found in PubMed, 3387 in CENTRAL, and 5392 in EMBASE. Six additional articles were identified through manual searching. Following duplicate removal, 10,572 entries remained. After title and abstract screening, 126 articles were selected for full-text review. Thirty-four of these articles were excluded after a full-text review. The list of excluded articles and reasons for exclusion are displayed in Table S1. Thus, the final selection was comprised of 92 articles (see list of selected articles online under Appendix S1). A flowchart illustrating the article selection process is depicted in Figure 1. Inter-examiner agreement kappa score for title/abstract review and for full-text review were 0.93 (95% CI: 0.855–1.0) and 0.78 (95% CI: 0.662–0.921), respectively.

3.2 | Study characteristics

Of the 92 selected articles, 4 were published in 2011, 4 in 2012, 6 in 2013, 4 in 2014, 11 in 2015, 8 in 2016, 5 in 2017, 13 in 2018, 11 in 2019, 18 in 2020, and 8 between January 1 and April 30, 2021 (Figure 2). Fifty-seven studies were conducted in an academic (university) setting, 20 were carried out exclusively in a private clinic (of which 2 were multicenter), 6 multicenter studies were conducted in both academic and private practice settings, 1 in a military setting, and in 8 articles, this information was not clearly reported. Thirty-nine studies were RCTs, 20 were non-RTCs, and 33 were case series, none of which were reported as being retrospective. For specific bibliographic details, see the list of selected articles online under Appendix S1. Although some investigations were reported by the authors as cohort studies, a critical assessment of the information provided in these articles made it evident that, technically, they were either case series or clinical trials (RCTs or non-RCTs). Hence, no proper cohort studies were present in the final article selection. Within this selection of 92 articles, a total of 81 distinct clinical studies were identified because some articles were follow-up studies of previous publications or reported additional data from an already included study.

Aside from specific data on the initial and final number of participants, as well as gender and age distribution, specific details pertaining to the type of interventions performed, details on the methods used for the measurement and timing of assessment of the outcomes reported in the selected articles, as well as additional comments, are available online in the data collection form under Appendix S1.

3.3 | Risk of bias assessment

3.3.1 | Risk of bias assessment of individual studies

RCTs: Of the 39 selected RCTs, 14 were categorized as low risk of bias, 10 as high risk of bias, and the risk of bias was unclear in the remaining 15 (Figure 3a).

Non-RCTs: All the selected non-RCTs exhibited a high risk of bias (Figure 3b).

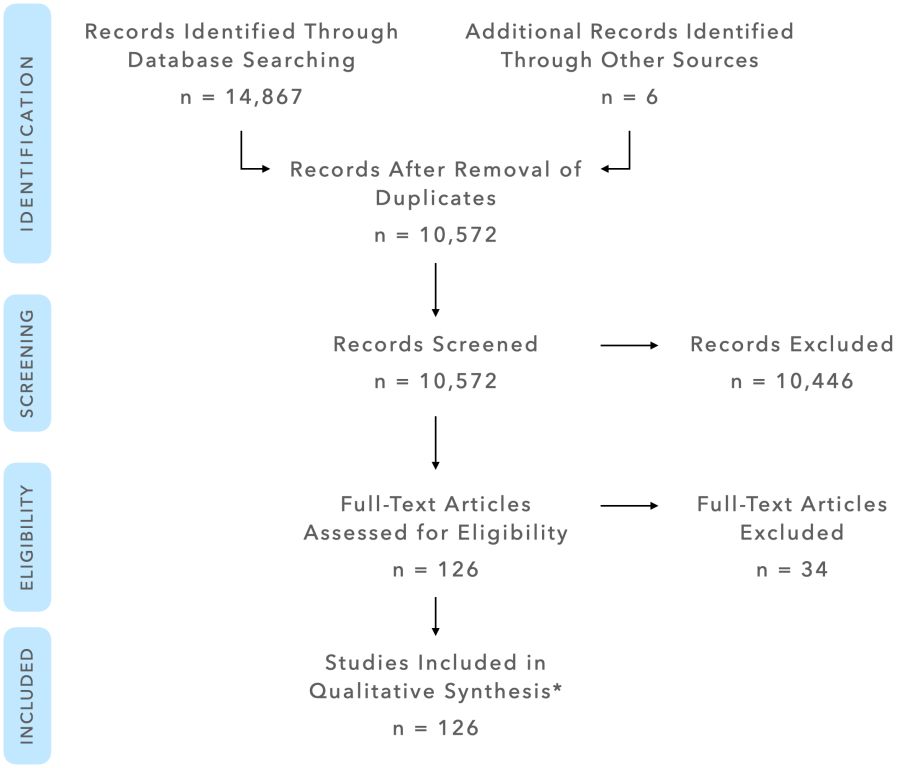

FIGURE 1 Article selection process

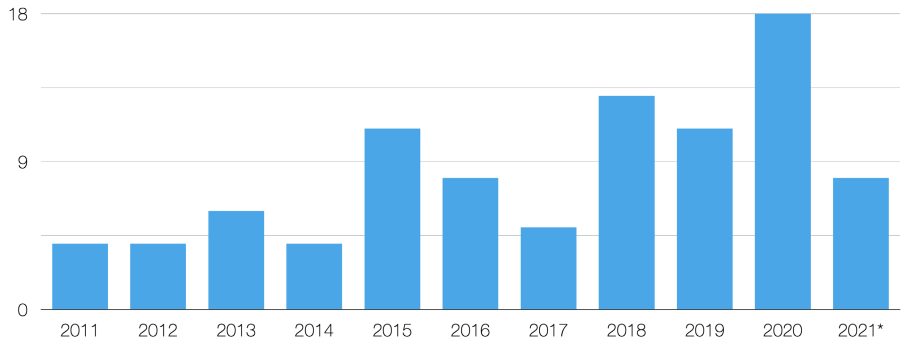

FIGURE 2 Bar graph depicting the distribution of selected articles per year of publication. *Note that only articles published between January 1 and April 30 were included in 2021

Case series: Except four studies in which the risk of bias was fair (Golmayo et al., 2021; Parvini et al., 2021; Seyssens et al., 2019; Zucchelli et al., 2013), all case series were categorized as "poor" (Figure 3c).

3.3.2 | Risk of bias assessment of primary outcomes

RCTs: The risk of bias associated with the measurement of the primary outcome was categorized as low in 25 RCTs, high in 5 RCTs, and unclear in 9 RCTs (Figure 3a).

Non-RCTs: The risk of bias associated with the measurement of the primary outcome was categorized as low in 13 non-RCTs, high in 1 non-RCT, and unclear in 6 non-RCTs (Figure 3b).

Case series: The risk of bias associated with the measurement of the primary outcome was categorized as low in 18 case series, high in 14 case series, and unclear in 1 case series (Figure 3c).

The primary outcome was clearly reported in 54 (58.70%) of the 92 selected articles. In the remaining 38 articles, the primary outcome was inferred based on the best judgment of the authors of the present systematic review (specific comments are included in the data collection form available online under Appendix S1). Interestingly, examiner calibration for the primary outcome was only reported in 28 of the selected articles (30, 43%), being 15 of them RTCs, 5 non-RCTs, and 8 case series. However, beyond that observation, no distinguishable patterns of association between specific types or methodological quality of studies and the choice of primary outcomes were observed.

3.4 | Qualitative assessment: Categorization of outcomes in selected studies

After a critical assessment of the literature selected in this systematic review, outcome measures and methods of assessment were categorized into investigator-evaluated outcome measures and patient-reported outcome measures (Sanz & Vignoletti, 2014), as follows:[1]

3.4.1 | Investigator-evaluated outcome measures

Clinical outcomes: Structural and biological assessments are performed either directly during a clinical examination (e.g., using a periodontal probe) or indirectly (e.g., using intraoral photographs or stone casts). The following clinical outcomes ($n = 40$) were identified in the selected literature (in decreasing order of frequency):

1. Facial KMW: Reported in 45 articles (48.91%). Specifically, using a periodontal probe in 44 articles (47.83%), and using intraoral photographs in 1 article (1.09%). The primary outcome in 19 articles (19.57%).
2. Plaque index (PI) (Loe, 1967) or modified plaque index (mPI) (Mombelli et al., 1987) using a periodontal probe: Reported in 45 articles (48.91%).
3. Probing depth (PD) using a periodontal probe: Reported in 45 articles (48.91%).
4. Facial mucosal margin position/recession: Reported in 33 articles (35.87%). Specifically, using a periodontal probe or a Castroviejo caliper either intraorally or on stone casts in 26 articles (28.26%) and using intraoral photographs in 7 articles (7.61%). The primary outcome in 17 articles (18.48%).
5. Bleeding on probing (BOP) using a periodontal probe: Reported in 29 articles (31.52%).
6. Facial MT via transmucosal bone sounding (e.g., endodontic file, periodontal probe, or anesthesia needle) or using a caliper: Reported in 27 articles (29.35%). The primary outcome in 21 articles (22.83%).
7. Implant survival rate: Reported in 16 articles (17.39%).
8. Interproximal papilla height: Reported in 12 articles (13.04%). Specifically, using a periodontal probe intraorally or on stone casts in 7 articles (7.61%), and using intraoral photographs in 5 articles (5.43%).
9. Gingival index (GI) (Loe, 1967) using a periodontal probe: Reported in 11 articles (11.96%).
10. STH using transmucosal bone sounding (e.g., endodontic file, periodontal probe, or anesthesia needle): Reported in 10 articles (10.87%). The primary outcome in 9 articles (9.78%).
11. Implant success rate: Reported in 9 articles (9.78%). Specifically, Smith and Zarb criteria (Smith & Zarb, 1989) were used in 3 articles (3.26%), Albretksson et al. criteria (Albrektsson et al., 1986) in 2 articles (2.17%), Buser et al. criteria (Buser et al., 1990) in 2 articles (2.17%), van Steenberghe criteria (van Steenberghe, 1997) in 1 article (1.09%), and Albretksson and Zarb criteria (Albrektsson & Zarb, 1998) in 1 article (1.09%).
12. Clinical attachment level (CAL) using a periodontal probe: Reported in 8 articles (8.70%).
13. Sulcus bleeding index (SBI) (Muhlemann & Son, 1971) using a periodontal probe: Reported in 5 articles (5.43%).
14. Surgical time: Reported in 5 articles (5.43%).
15. Full-mouth bleeding score (FMBS) using a periodontal probe: Reported in 4 articles (4.35%).
16. Full-mouth plaque score (FMPS) using a periodontal probe: Reported in 4 articles (4.35%).
17. Facial mucosa phenotype using a periodontal probe (transparency method): Reported in 3 articles (3.26%).
18. Implant stability using a technological device: Reported in 3 articles (3.26%).
19. Modified bleeding index (mBI) (Mombelli et al., 1987) using a periodontal probe: Reported in 3 articles (3.26%).
20. Facial gingival recession depth on teeth adjacent to implant site: Reported in 2 articles (2.17%).
21. Facial PMMD (recession) width using a periodontal probe or a precision gauge: Reported in 2 articles (2.17%).
22. Direct visual assessment of soft-tissue color and texture (mucosal surface structure): Reported in 2 articles (2.17%).
23. Direct visual assessment of soft-tissue healing: Reported in 2 articles (2.17%).
24. Direct visual assessment of wound healing index (WHI): Reported in 2 articles (2.17%).
25. Indirect visual assessment of alveolar process deficiency according to PES criterion using stone casts: Reported in 2 articles (2.17%).
26. Vestibular depth using a periodontal probe: Reported in 2 articles (2.17%).
27. Facial defect concavity depth and width using a periodontal probe: Reported in 1 article (1.09%).
28. Crestal KMW using a periodontal probe: Reported in 1 article (1.09%).
29. Direct visual assessment of facial contour deficiency or concavity (improved / worsened / no change): Reported in 1 article (1.09%).
30. Direct visual assessment of the convexity of the facial mucosal profile: Reported in 1 article (1.09%).
31. Graft shrinkage area using a periodontal probe: Reported in 1 article (1.09%).
32. Indirect visual assessment of soft-tissue color: Reported in 1 article (1.09%).
33. Mesiodistal length of keratinized tissue in the grafted area using a periodontal probe: Reported in 1 article (1.09%).
34. Lingual KMW using a periodontal probe: Reported in 1 article (1.09%).
35. Lingual MT via transmucosal bone sounding (e.g., endodontic file, periodontal probe, or anesthesia needle) or using a caliper: Reported in 1 article (1.09%).
36. Need for additional bone and soft-tissue augmentation procedures at the time of implant placement: Reported in 1 article (1.09%).

[1]Note that some articles included more than one primary outcome.

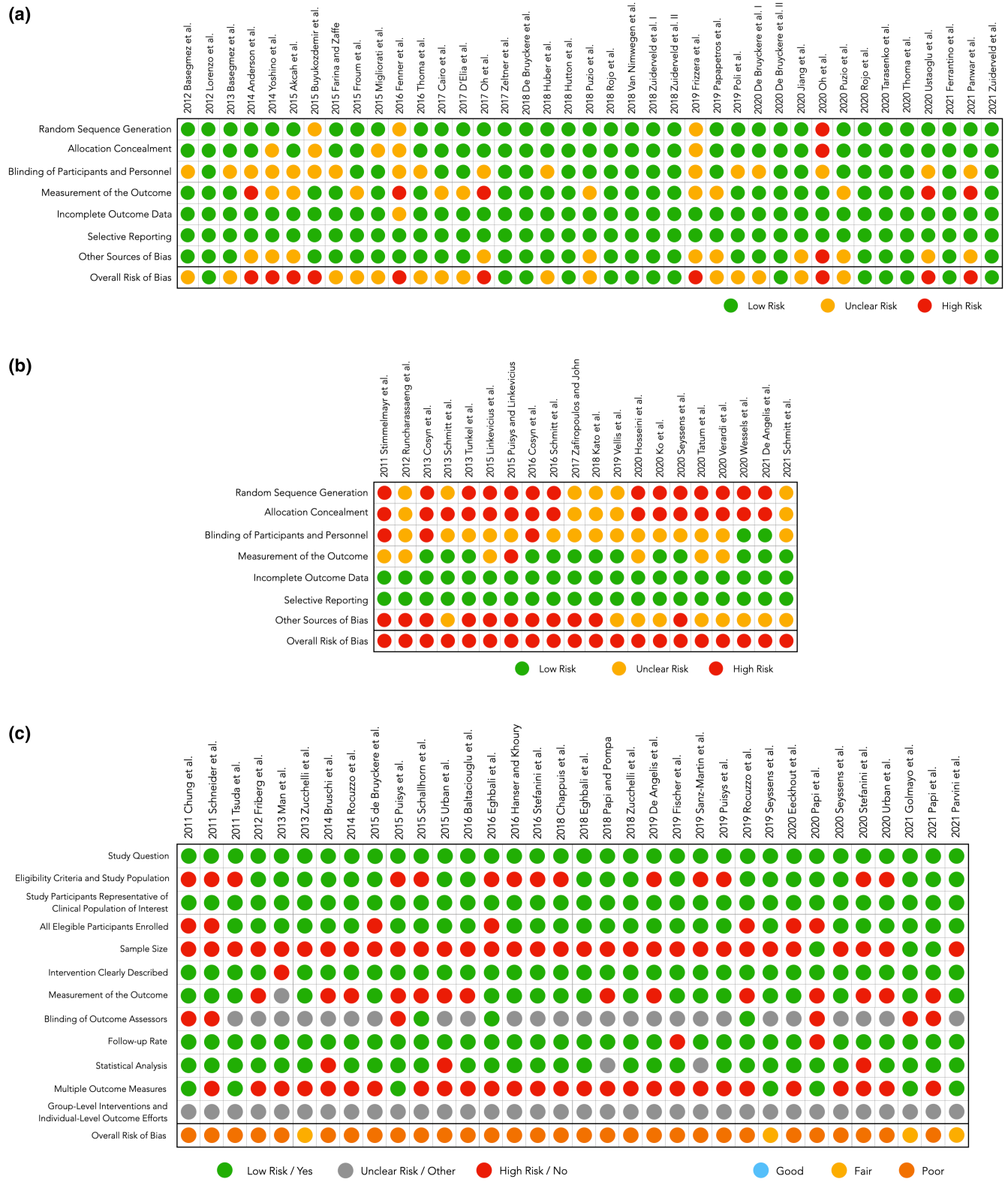

FIGURE 3 (a) Risk of bias assessment of RCTs. (b) Risk of bias assessment of non-RCTs. (c) Risk of bias assessment of case series

37. Percentage of complete correction of PMMDs: Reported in 1 article (1.09%).
38. Percentage of mucosal graft shrinkage using intraoral photographs: Reported in 1 article (1.09%).
39. Proportion of implants exhibiting peri-implant health, peri-implant mucositis, and peri-implantitis: Reported in 1 article (1.09%).
40. Suppuration (SUP) using a periodontal probe: Reported in 1 article (1.09%).

Digital imaging outcomes: Linear, profilometric, and volumetric assessments of dimensional changes of the bone and soft tissue using standard and advanced digital imaging files (e.g., radiographs or surface rendering). The following digital imaging outcomes ($n = 13$) were identified in the selected literature (in decreasing order of frequency):

1. Marginal bone loss measured using periapical radiographs: Reported in 36 articles (39.13%). The primary outcome in 1 article (1.09%).
2. Facial MT: Reported in 23 articles (25.00%). Specifically, using STL (Standard Tessellation Language) files in 11 articles (11.96%), using DICOM files in 5 articles (5.43%), using an ultrasound device in 6 articles (6.52%), and using superimposed STL and DICOM files in 1 article (1.09%). The primary outcome in 11 articles (11.96%).
3. Facial peri-implant soft-tissue volume: Reported in 12 studies (13.04%). Specifically, using STL files in 11 articles (11.96%), and using superimposed STL and DICOM files in 1 article (1.09%). The primary outcome in 9 articles (9.78%).
4. Facial BT using DICOM files: Reported in 7 articles (7.61%).
5. Facial mucosal margin position / recession: Reported in 3 articles (3.26%). Specifically, using STL files in 2 articles (2.17%), and using superimposed STL and DICOM files in 1 article (1.09%). The primary outcome in 1 article (1.09%).
6. Facial vertical bone loss using DICOM files: Reported in 2 articles (2.17%).
7. Facial bone plate integrity using DICOM files: Reported in 1 article (1.09%).
8. Facial mucosa profile assessment using DICOM files: Reported in 1 article (1.09%). The primary outcome in 1 article (1.09%).
9. Graft surface area using STL files: Reported in 1 article (1.09%). The primary outcome in 1 article (1.09%).
10. Facial KMW using STL files: Reported in 1 article (1.09%). The primary outcome in 1 article (1.09%).
11. Facial mucosal margin position / recession using DICOM files: Reported in 1 article (1.09%).
12. Papilla height changes using STL files: Reported in 1 article (1.09%).
13. Proximal bone level on the teeth adjacent to the implant site using periapical radiographs: Reported in 1 article (1.09%).

Esthetic outcomes: Assessment of esthetic outcomes either directly (e.g., clinical examination) or indirectly (e.g., using standardized intraoral photographs) by subjective evaluation or using pre-established indices or scores. The following esthetic outcomes ($n = 12$) were identified in the selected literature (in decreasing order of frequency):

1. Pink Esthetic Score (PES) assessment (Furhauser et al., 2005): Reported in 23 articles (25.00%). The primary outcome in 2 articles (2.17%).
2. Papilla Index Score (PIS) assessment (Jemt, 1997): Reported in 8 articles (8.70%).
3. White Esthetic Score (WES) assessment (Belser et al., 2009): Reported in 7 articles (7.61%).
4. Direct visual assessment of facial mucosa color: Reported in 2 articles (2.17%).
5. Direct visual assessment of color, texture, and contour of facial mucosa compared to a contralateral or adjacent site: Reported in 2 articles (2.17%).
6. Mucosa Scarring Index (MSI) assessment (Wessels et al., 2019): Reported in 2 articles (2.17%). The primary outcome in 1 article (1.09%).
7. Complex Esthetic Index (Juodzbalys & Wang, 2010): Reported in 1 article (1.09%).
8. Copenhagen Index Score (CIS) assessment (Dueled et al., 2009): Reported in 1 article (1.09%).
9. Direct visual assessment of gray show-through on the facial mucosa (yes/no): Reported in 1 article (1.09%).
10. Implant Crown Esthetic Index (ICAI) (Meijer et al., 2005): Reported in 1 article. The primary outcome in 1 article (1.09%).
11. Overall esthetic assessment using a visual analog scale (VAS): Reported in 1 article (1.09%).
12. Spectrophotometric assessment of facial peri-implant mucosa color: Reported in 1 article (1.09%).

Histologic outcomes: Descriptive histologic, histomorphometric, and immunohistochemical assessments of peri-implant soft-tissue samples. The following histologic outcomes ($n = 3$) were identified in the selected literature (in decreasing order of frequency):

1. Descriptive histologic analysis of peri-implant soft-tissue samples: Reported in 5 articles (5.43%).
2. Histomorphometric analysis (e.g., height and width, presence of residual graft material and elastic fibers, and inflammatory infiltrate) of peri-implant soft-tissue samples: Reported in 2 articles (2.17%).
3. Immunohistochemical analysis (i.e., cytokeratin 5/6, 13, and 14) of peri-implant soft-tissue samples: Reported in 1 article (1.09%).

Biomarker outcomes: Assessments of molecular markers in peri-implant sulcular fluid samples. Only one biomarker outcome was identified in the selected literature:

1. Interleukin-1β concentration: Reported in 1 article (1.09%).

Safety outcomes: Defined as assessments to monitor the occurrence of complications and adverse events. Out of the 92 selected articles, only in 20 articles (21.7%), safety outcomes were not reported. For specific details, see the data collection form under Appendix S1. It must be noted that, in most articles, information pertaining to safety outcomes was reported in the Results section, with no previous mention in the Materials and Methods section.

3.4.2 | Patient-reported outcome measures (PROMs)

Assessments performed by the patient. The following PROMs ($n = 9$) were identified in the selected literature (in decreasing order of frequency):

1. Perceived postoperative pain/discomfort using a VAS: Reported in 17 articles (18.48%).
2. Esthetic satisfaction using a VAS: Reported in 10 articles (10.87%).
3. Overall satisfaction using a VAS: Reported in 8 articles (8.70%).
4. Quality of life questionnaire (OHIP, OHIP-14, or OHIP-G14): Reported in 7 articles (7.61%).
5. Amount of postoperative inflammatory medication taken: Reported in 3 articles (3.26%).
6. Willingness to undergo the same treatment again (yes/no): Reported in 2 articles (2.17%).
7. Edema and hematoma using a VAS: Reported in 1 article (1.09%).
8. Masticatory function using a VAS: Reported in 1 article (1.09%).
9. Modified version of the complex esthetic index (Juodzbalys & Wang, 2010): Reported in 1 article (1.09%).

The top 20 most frequently reported outcome measures and all primary outcome measures reported in the selected literature are displayed in Tables 2 and 3, respectively.

TABLE 2 Top 20 most frequently reported outcome measures in the selected literature

Outcome measure	Percentage of reporting	Type of outcome measure
Facial keratinized mucosa width	48.91	Clinical
Plaque index	48.91	Clinical
Probing depth	48.91	Clinical
Marginal bone loss	39.13	Digital Imaging
Facial mucosal margin position	35.87	Clinical
Bleeding on probing	31.52	Clinical
Facial mucosal thickness	29.35	Clinical
Facial mucosal thickness	25.00	Digital Imaging
Pink esthetic score	25.00	Esthetic
Perceived postoperative pain	18.48	Patient-Reported
Implant survival rate	17.39	Clinical
Interproximal papilla height	13.04	Clinical
Facial peri-implant soft-tissue volume	13.04	Digital Imaging
Gingival index	11.96	Clinical
Supracrestal tissue height	10.87	Clinical
Esthetic satisfaction	10.87	Patient-Reported
Implant success rate	9.78	Clinical
Clinical attachment level	8.70	Clinical
Papilla index score	8.70	Esthetic
Overall satisfaction	8.70	Patient-Reported

4 | DISCUSSION

The present systematic review mainly revealed: 1. An increasing number of publications reporting the findings of clinical studies on the topic of soft-tissue augmentation in the context of implant therapy over the past 10 years; 2. The most common study type was RCT performed in a university setting; 3. Clinical outcome measures were the most frequently reported outcomes overall; 4. The most frequently reported primary outcomes were facial mucosa thickness and facial keratinized mucosa width, followed by facial mucosal margin position (recession) and supracrestal tissue height changes.

The increase in the number of investigations in peri-implant soft-tissue augmentation in the past decade is likely because of two main reasons: (1) The recognition of the critical role of the peri-implant soft tissues in the maintenance of peri-implant health and the enhancement of esthetic outcomes in implant therapy and (2) The emergence of soft-tissue graft substitutes as an alternative to autogenous grafts.

In several classic periodontal investigations on the topic of soft-tissue augmentation conducted in the late 60s and early 70s, the focus was on understanding the healing process after autogenous oral soft-tissue transplantation, as well as the development and optimization of surgical interventions (Karring, Cumming, et al., 1975; Karring, Lang, et al., 1975; Oliver et al., 1968). In the 2000s, after the consolidation of the fields of mucogingival surgery and implant dentistry had already occurred, further clinical models were introduced to assess the efficacy of novel soft-tissue graft substitutes (as alternatives to autogenous soft-tissue grafts that are commonly associated with an increased patient morbidity) for periodontal and peri-implant soft-tissue augmentation purposes (Del Pizzo et al., 2002; Griffin et al., 2006; Jung et al., 2011; McGuire & Scheyer, 2010; Thoma et al., 2012). A plethora of clinical studies has demonstrated the suitability of various soft-tissue graft substitutes as plausible alternatives to autogenous soft-tissue transplants for specific indications (Cairo et al., 2019; Fickl et al., 2021; Tavelli et al., 2021; Thoma et al., 2018).

Assessment and interpretation of outcomes are essential components of clinical research. Broadly, there are two types of clinical research outcomes: primary and secondary. The primary outcome is the most relevant variable to answer the main research question. Depending on their design, number of hypotheses, and objectives, some studies may have more than one primary outcome, as it was the case in some of the studies selected in this systematic review. The primary outcome(s) should be used *a priori* to determine the minimum number of participants required to achieve statistical power and *a posteriori* to either reject or accept the study hypothesis.

TABLE 3 Outcome measures reported as primary outcomes in the selected literature. Note that some articles included more than one primary outcome

Outcome measure	Percentage of reporting as primary outcome	Type of outcome measure
Facial mucosal thickness	22.83	Clinical
Facial keratinized mucosa width	19.57	Clinical
Facial mucosal margin position	18.48	Clinical
Facial mucosal thickness	11.96	Digital Imaging
Gingival index	9.78	Clinical
Facial peri-implant soft-tissue volume	9.78	Digital Imaging
Pink esthetic score	2.17	Esthetic
Marginal bone loss	1.09	Digital Imaging
Facial mucosal margin position	1.09	Digital Imaging
Facial mucosa profile	1.09	Digital Imaging
Graft surface area	1.09	Digital Imaging
Facial keratinized mucosa width	1.09	Digital Imaging
Mucosa scarring index	1.09	Esthetic
Implant crown esthetic index	1.09	Esthetic

Secondary outcomes are supplementary outcomes monitored to help interpret the results of the primary outcome or increase the amount of information obtained through the conduction of a study (Ferreira & Patino, 2017). Interestingly, clinical studies assessing the performance of soft-tissue graft substitutes in peri-implant soft-tissue augmentation in the past 10 years have predominantly considered gain of mucosal thickness or volume and keratinized mucosa width as primary outcomes. Management of peri-implant soft-tissue dehiscences and understanding the significance of the supracrestal tissue height around dental implants, originally referred to as "peri-implant biologic width" (Berglundh & Lindhe, 1996; Berglundh et al., 1991), have become a relevant topic of research interest in recent years. This would explain why changes in facial mucosal margin position (recession) and supracrestal tissue height were also frequently reported as primary outcomes in the selected literature.

Data analysis with a focus on primary outcome measures and methods of assessments revealed that clinical methods (e.g., use of periodontal probes, calipers, and endodontic files) were most often employed in the past 10 years. This may be associated with the fact that these traditional methods are part of daily clinical practice and have been used for decades in the field of mucogingival surgeries as part of the conventional clinical examination (Bachmann & Bernimoulin, 1980; Diedrich et al., 1972; Edel, 1974; Friedman, 1962; de Trey & Bernimoulin, 1980). Consequently, clinical assessments served as a primary outcome in approximately 60% of the articles selected in the present systematic review. However, while these methods are well established, have been validated, and are associated with low cost and simple logistics, they also are limited to some extent as they do not allow capturing the entire extent of the therapeutic effect of some surgical interventions. This is particularly critical for interventions primarily aimed at modifying the peri-implant soft-tissue contour as clinical measurements based on the use of analog instruments do not permit a reliable 3D assessment of the outcomes (e.g., volume changes).

Technological advancements have derived into the implementation of digital assessment methods, such as linear and three-dimensional analyses of STL files obtained from the digitization of casts or intraoral surface scanning (Bienz et al., 2017; Pirc et al., 2021; Windisch et al., 2007). Such analyses accounted for approximately 10% of the methods of choice to assess the primary outcome in the selected articles. The main benefits of digital assessment methods based on STL file analyses are a reduction in measurement errors, a higher reproducibility and reliability, and their non-invasiveness (Couso-Queiruga et al., 2021; Schneider et al., 2014). A progressive shift from clinical toward digital imaging methods for the assessment of outcomes can be expected in future years in this area of research.

Although PROMs were reported in 30 articles, approximately one-third of the total, in none of the selected studies, were designated as primary outcomes and, in many articles, minimal information about the methodology applied to assess PROMs was provided. Furthermore, PROMs specifically related to patient morbidity (e.g., postoperative pain and discomfort) were inconsistently investigated in studies that involved the use of a soft-tissue graft substitute.

It must be noted that the frequency of reporting of a specific method and outcome measure does not necessarily correlate with its significance in contemporary clinical research. Therefore, a highly reported clinical outcome per the findings of this systematic review (e.g., PD or PI) should not be automatically considered a core outcome and to be recommended in future research reports related to peri-implant soft-tissue augmentation. By the same token, some underreported outcomes, such as advanced digital imaging analyses and PROMs, should be considered as core outcomes given their methodological advantages and relevance in clinical practice, respectively.

Considering the result of the risk of bias analyses conducted in this systematic review, no distinguishable patterns of association between specific types or quality of clinical studies and the choice of primary outcomes were observed. It might be speculated that

properly designed studies associated with a high level of evidence (e.g., RCTs) would include a more consistent and exhaustive selection of outcomes of interest.

However, this was not observed in the selected literature. This may be attributed to individual preferences by the investigators depending on the study goal, as well as the continuous development and refinement of research methods over time.

Finally, this is the first systematic review focused on comprehensively identifying and reporting outcome measures and methods of assessment on soft-tissue augmentation interventions performed in the context of dental implant therapy. Therefore, it is not possible to compare the methods and findings hereby reported with other similar publications.

5 | CONCLUSIONS

Clinical research on soft-tissue augmentation in the context of implant therapy has progressively increased over the last decade. Although clinical outcome measures were the most frequently reported outcomes, the continuous development and refinement of assessment methods based on advanced digital imaging, as well as their high reliability and reproducibility, will likely result in an increasing number of studies incorporating the use of such tools in upcoming years. Moreover, the routine incorporation of PROMs should be recommended in future clinical investigations on this topic, particularly in clinical trials involving the use of a soft-tissue graft substitute.

CONFLICT OF INTEREST

The authors have no conflicts of interest to report pertaining to the conduction of this systematic review.

AUTHOR CONTRIBUTIONS

G.A.O. and D.S.T. conceived the idea and initial structure of the systematic review; L.C. performed the search; E.C.Q. and M.P. screened the initial entries, selected the articles, and collected the data; G.A.O. verified the validity and standardization of collected data; E.C.Q. and M.P. assessed the risk of bias; L.C contributed to the design of the final manuscript and data analysis; G.A.O. and D.S.T. led the writing; E.C.Q., M.P., and L.C. critically revised the manuscript.

DATA AVAILABILITY STATEMENT

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

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REFERENCES

Albrektsson, T., & Zarb, G. A. (1998). Determinants of correct clinical reporting. *International Journal of Prosthodontics*, *11*(5), 517–521.

Albrektsson, T., Zarb, G., Worthington, P., & Eriksson, A. R. (1986). The long-term efficacy of currently used dental implants: A review and proposed criteria of success. *International Journal of Oral and Maxillofacial Implants*, *1*(1), 11–25.

Avila-Ortiz, G., Gonzalez-Martin, O., Couso-Queiruga, E., & Wang, H. L. (2020). The peri-implant phenotype. *Journal of Periodontology*, *91*(3), 283–288. https://doi.org/10.1002/JPER.19-0566

Bachmann, A., & Bernimoulin, J. P. (1980). Free grafts of attached and papillary gingiva. *SSO: Schweizerische Monatsschrift Für Zahnheilkunde*, *90*(4), 374–380.

Bassetti, R. G., Stahli, A., Bassetti, M. A., & Sculean, A. (2016). Soft tissue augmentation procedures at second-stage surgery: A systematic review. *Clinical Oral Investigations*, *20*(7), 1369–1387. https://doi.org/10.1007/s00784-016-1815-2

Bassetti, R. G., Stahli, A., Bassetti, M. A., & Sculean, A. (2017). Soft tissue augmentation around osseointegrated and uncovered dental implants: A systematic review. *Clinical Oral Investigations*, *21*(1), 53–70. https://doi.org/10.1007/s00784-016-2007-9

Belser, U. C., Grutter, L., Vailati, F., Bornstein, M. M., Weber, H. P., & Buser, D. (2009). Outcome evaluation of early placed maxillary anterior single-tooth implants using objective esthetic criteria: A cross-sectional, retrospective study in 45 patients with a 2- to 4-year follow-up using pink and white esthetic scores. *Journal of Periodontology*, *80*(1), 140–151. https://doi.org/10.1902/jop.2009.080435

Berglundh, T., & Lindhe, J. (1996). Dimension of the periimplant mucosa. Biological width revisited. *Journal of Clinical Periodontology*, *23*(10), 971–973. https://doi.org/10.1111/j.1600-051x.1996.tb00520.x

Berglundh, T., Lindhe, J., Ericsson, I., Marinello, C. P., Liljenberg, B., & Thomsen, P. (1991). The soft tissue barrier at implants and teeth. *Clinical Oral Implants Research*, *2*(2), 81–90. https://doi.org/10.1034/j.1600-0501.1991.020206.x

Bienz, S. P., Jung, R. E., Sapata, V. M., Hammerle, C. H. F., Husler, J., & Thoma, D. S. (2017). Volumetric changes and peri-implant health at implant sites with or without soft tissue grafting in the esthetic zone, a retrospective case-control study with a 5-year follow-up. *Clinical Oral Implants Research*, *28*(11), 1459–1465. https://doi.org/10.1111/clr.13013

Buser, D., Weber, H. P., & Lang, N. P. (1990). Tissue integration of non-submerged implants. 1-year results of a prospective study with 100 ITI hollow-cylinder and hollow-screw implants. *Clinical Oral Implants Research*, *1*(1), 33–40. https://doi.org/10.1034/j.1600-0501.1990.010105.x

Cairo, F., Barbato, L., Selvaggi, F., Baielli, M. G., Piattelli, A., & Chambrone, L. (2019). Surgical procedures for soft tissue augmentation at implant sites. A systematic review and meta-analysis of randomized controlled trials. *Clinical Implant Dentistry and Related Research*, *21*(6), 1262–1270. https://doi.org/10.1111/cid.12861

Chambrone, L., & Armitage, G. C. (2016). Commentary: Statistical significance versus clinical relevance in periodontal research: Implications for clinical practice. *Journal of Periodontology*, *87*(6), 613–616. https://doi.org/10.1902/jop.2016.150554

Couso-Queiruga, E., Tattan, M., Ahmad, U., Barwacz, C., Gonzalez-Martin, O., & Avila-Ortiz, G. (2021). Assessment of gingival thickness using digital file superimposition versus direct clinical measurements. *Clinical Oral Investigations*, *25*(4), 2353–2361. https://doi.org/10.1007/s00784-020-03558-0

de Trey, E., & Bernimoulin, J. P. (1980). Influence of free gingival grafts on the health of the marginal gingiva. *Journal of Clinical Periodontology*,

7(5), 381–393. https://doi.org/10.1111/j.1600-051x.1980.tb02011.x

Del Pizzo, M., Modica, F., Bethaz, N., Priotto, P., & Romagnoli, R. (2002). The connective tissue graft: A comparative clinical evaluation of wound healing at the palatal donor site. A preliminary study. *Journal of Clinical Periodontology*, *29*(9), 848–854. https://doi.org/10.1034/j.1600-051x.2002.290910.x

Diedrich, P., Jacoby, L., & Aka, F. (1972). Studies on the width of the gingiva proper after vestibuloplasty with and without periostal fenestration. *Deutsche Zahnarztliche Zeitschrift*, *27*(4), 346–352.

Dueled, E., Gotfredsen, K., Trab Damsgaard, M., & Hede, B. (2009). Professional and patient-based evaluation of oral rehabilitation in patients with tooth agenesis. *Clinical Oral Implants Research*, *20*(7), 729–736. https://doi.org/10.1111/j.1600-0501.2008.01698.x

Edel, A. (1974). Clinical evaluation of free connective tissue grafts used to increase the width of keratinised gingiva. *Journal of Clinical Periodontology*, *1*(4), 185–196. https://doi.org/10.1111/j.1600-051x.1974.tb01257.x

Ferreira, J. C., & Patino, C. M. (2017). Types of outcomes in clinical research. *Jornal Brasileiro De Pneumologia*, *43*(1), 5. https://doi.org/10.1590/S1806-37562017000000021

Fickl, S., Therese Kroger, A., Dietrich, T., & Kebschull, M. (2021). Influence of soft tissue augmentation procedures around dental implants on marginal bone level changes-A systematic review. *Clinical Oral Implants Research*, *32*(Suppl 21), 108–137. https://doi.org/10.1111/clr.13829

Friedman, N. (1962). Mucogingival surgery: The apically positioned flap. *Journal of Periodontology*, *33*(4), 328–340.

Furhauser, R., Florescu, D., Benesch, T., Haas, R., Mailath, G., & Watzek, G. (2005). Evaluation of soft tissue around single-tooth implant crowns: the pink esthetic score. *Clinical Oral Implants Research*, *16*(6), 639–644. https://doi.org/10.1111/j.1600-0501.2005.01193.x

Gamborena, I., & Avila-Ortiz, G. (2021). Peri-implant marginal mucosa defects: Classification and clinical management. *Journal of Periodontology*, *92*(7), 947–957. https://doi.org/10.1002/JPER.20-0519

Golmayo, P., Barallat, L., Losada, M., Valles, C., Nart, J., & Pascual-La Rocca, A. (2021). Keratinized tissue gain after free gingival graft augmentation procedures around teeth and dental implants: A prospective observational study. *Journal of Clinical Periodontology*, *48*(2), 302–314. https://doi.org/10.1111/jcpe.13394

Griffin, T. J., Cheung, W. S., Zavras, A. I., & Damoulis, P. D. (2006). Postoperative complications following gingival augmentation procedures. *Journal of Periodontology*, *77*(12), 2070–2079. https://doi.org/10.1902/jop.2006.050296

Higgins, J. P. T., Altman, D. G., Gotzsche, P. C., Juni, P., Moher, D., Oxman, A. D., Savovic, J., Schulz, K. F., Weeks, L., & Sterne, J. A. C. (2011). The Cochrane Collaboration's tool for assessing risk of bias in randomised trials. *BMJ*, *343*, d5928. https://doi.org/10.1136/bmj.d5928

Jemt, T. (1997). Regeneration of gingival papillae after single-implant treatment. *International Journal of Periodontics and Restorative Dentistry*, *17*(4), 326–333.

Jung, R. E., Hurzeler, M. B., Thoma, D. S., Khraisat, A., & Hammerle, C. H. (2011). Local tolerance and efficiency of two prototype collagen matrices to increase the width of keratinized tissue. *Journal of Clinical Periodontology*, *38*(2), 173–179. https://doi.org/10.1111/j.1600-051X.2010.01640.x

Juodzbalys, G., & Wang, H. L. (2010). Esthetic index for anterior maxillary implant-supported restorations. *Journal of Periodontology*, *81*(1), 34–42. https://doi.org/10.1902/jop.2009.090385

Karring, T., Cumming, B. R., Oliver, R. C., & Loe, H. (1975). The origin of granulation tissue and its impact on postoperative results of mucogingival surgery. *Journal of Periodontology*, *46*(10), 577–585. https://doi.org/10.1902/jop.1975.46.10.577

Karring, T., Lang, N. P., & Loe, H. (1975). The role of gingival connective tissue in determining epithelial differentiation. *Journal of Periodontal Research*, *10*(1), 1–11. https://doi.org/10.1111/j.1600-0765.1975.tb00001.x

Lin, C. Y., Chen, Z., Pan, W. L., & Wang, H. L. (2018). Impact of timing on soft tissue augmentation during implant treatment: A systematic review and meta-analysis. *Clinical Oral Implants Research*, *29*(5), 508–521. https://doi.org/10.1111/clr.13148

Loe, H. (1967). The gingival index, the plaque index and the retention index systems. *Journal of Periodontology*, *38*(6), 610–616. https://doi.org/10.1902/jop.1967.38.6.610

McGuire, M. K., & Scheyer, E. T. (2010). Xenogeneic collagen matrix with coronally advanced flap compared to connective tissue with coronally advanced flap for the treatment of dehiscence-type recession defects. *Journal of Periodontology*, *81*(8), 1108–1117. https://doi.org/10.1902/jop.2010.090698

Meijer, H. J., Stellingsma, K., Meijndert, L., & Raghoebar, G. M. (2005). A new index for rating aesthetics of implant-supported single crowns and adjacent soft tissues–the Implant Crown Aesthetic Index. *Clinical Oral Implants Research*, *16*(6), 645–649. https://doi.org/10.1111/j.1600-0501.2005.01128.x

Mombelli, A., van Oosten, M. A., Schurch, E. Jr, & Land, N. P. (1987). The microbiota associated with successful or failing osseointegrated titanium implants. *Oral Microbiology and Immunology*, *2*(4), 145–151. https://doi.org/10.1111/j.1399-302x.1987.tb00298.x

Muhlemann, H. R., & Son, S. (1971). Gingival sulcus bleeding–a leading symptom in initial gingivitis. *Helvetica Odontologica Acta*, *15*(2), 107–113.

NIH (2021). *Quality assessment tool for before-after (Pre-Post) studies with no control group*. Retrieved from https://www.nhlbi.nih.gov/health-topics/study-quality-assessment-tools

Oliver, R. C., Loe, H., & Karring, T. (1968). Microscopic evaluation of the healing and revascularization of free gingival grafts. *Journal of Periodontal Research*, *3*(2), 84–95. https://doi.org/10.1111/j.1600-0765.1968.tb01908.x

Page, M. J., McKenzie, J. E., Bossuyt, P. M., Boutron, I., Hoffmann, T. C., Mulrow, C. D., Shamseer, L., Tetzlaff, J. M., Akl, E. A., Brennan, S. E., Chou, R., Glanville, J., Grimshaw, J. M., Hróbjartsson, A., Lalu, M. M., Li, T., Loder, E. W., Mayo-Wilson, E., McDonald, S., … Moher, D. (2021). The PRISMA 2020 statement: An updated guideline for reporting systematic reviews. *Journal of Clinical Epidemiology*, https://doi.org/10.1016/j.jclinepi.2021.03.001

Parvini, P., Galarraga-Vinueza, M. E., Obreja, K., Magini, R. S., Sader, R., & Schwarz, F. (2021). Prospective study assessing three-dimensional changes of mucosal healing following soft tissue augmentation using free gingival grafts. *Journal of Periodontology*, *92*(3), 400–408. https://doi.org/10.1002/JPER.19-0640

Pirc, M., Harbeck, O., Sapata, V. M., Husler, J., Jung, R. E., Hammerle, C. H. F., & Thoma, D. S. (2021). Contour changes of peri-implant tissues are minimal and similar for a one- and a two-piece implant system over 12 years. *Clinical Oral Investigations*, *25*(2), 719–727. https://doi.org/10.1007/s00784-020-03638-1

Rotundo, R., Pagliaro, U., Bendinelli, E., Esposito, M., & Buti, J. (2015). Long-term outcomes of soft tissue augmentation around dental implants on soft and hard tissue stability: A systematic review. *Clinical Oral Implants Research*, *26*(Suppl 11), 123–138. https://doi.org/10.1111/clr.12629

Sanz, M., & Vignoletti, F. (2014). Endpoints in oral and maxillofacial regeneration clinical trials. In W. V. Giannobile, N. P. Lang, & M. S. Tonetti (Eds.), *Osteology guidelines for oral and maxillofacial regeneration – Clinical research* (pp. 69–88). Quintessence Publishing.

Schneider, D., Ender, A., Truninger, T., Leutert, C., Sahrmann, P., Roos, M., & Schmidlin, P. (2014). Comparison between clinical and digital soft tissue measurements. *Journal of Esthetic and Restorative Dentistry*, *26*(3), 191–199. https://doi.org/10.1111/jerd.12084

Seyssens, L., De Lat, L., & Cosyn, J. (2021). Immediate implant placement with or without connective tissue graft: A systematic review and meta-analysis. *Journal of Clinical Periodontology*, *48*(2), 284–301. https://doi.org/10.1111/jcpe.13397

Seyssens, L., Eghbali, A., Christiaens, V., De Bruyckere, T., Doornewaard, R., & Cosyn, J. (2019). A one-year prospective study on alveolar ridge preservation using collagen-enriched deproteinized bovine bone mineral and saddle connective tissue graft: A cone beam computed tomography analysis. *Clinical Implant Dentistry and Related Research*, *21*(5), 853–861. https://doi.org/10.1111/cid.12843

Smith, D. E., & Zarb, G. A. (1989). Criteria for success of osseointegrated endosseous implants. *Journal of Prosthetic Dentistry*, *62*(5), 567–572. https://doi.org/10.1016/0022-3913(89)90081-4

Sterne, J. A. C., Savović, J., Page, M. J., Elbers, R. G., Blencowe, N. S., Boutron, I., Cates, C. J., Cheng, H.-Y., Corbett, M. S., Eldridge, S. M., Emberson, J. R., Hernán, M. A., Hopewell, S., Hróbjartsson, A., Junqueira, D. R., Jüni, P., Kirkham, J. J., Lasserson, T., Li, T., … Higgins, J. P. T. (2019). RoB 2: a revised tool for assessing risk of bias in randomised trials. *BMJ*, *366*, l4898. https://doi.org/10.1136/bmj.l4898

Tavelli, L., Barootchi, S., Avila-Ortiz, G., Urban, I. A., Giannobile, W. V., & Wang, H. L. (2021). Peri-implant soft tissue phenotype modification and its impact on peri-implant health: A systematic review and network meta-analysis. *Journal of Periodontology*, *92*(1), 21–44. https://doi.org/10.1002/JPER.19-0716

Thoma, D. S., Buranawat, B., Hammerle, C. H., Held, U., & Jung, R. E. (2014). Efficacy of soft tissue augmentation around dental implants and in partially edentulous areas: a systematic review. *Journal of Clinical Periodontology*, *41*(Suppl 15), S77–91. https://doi.org/10.1111/jcpe.12220

Thoma, D. S., Naenni, N., Figuero, E., Hammerle, C. H. F., Schwarz, F., Jung, R. E., & Sanz-Sanchez, I. (2018). Effects of soft tissue augmentation procedures on peri-implant health or disease: A systematic review and meta-analysis. *Clinical Oral Implants Research*, *29*(Suppl 15), 32–49. https://doi.org/10.1111/clr.13114

Thoma, D. S., Sancho-Puchades, M., Ettlin, D. A., Hammerle, C. H., & Jung, R. E. (2012). Impact of a collagen matrix on early healing, aesthetics and patient morbidity in oral mucosal wounds – A randomized study in humans. *Journal of Clinical Periodontology*, *39*(2), 157–165. https://doi.org/10.1111/j.1600-051X.2011.01823.x

van Steenberghe, D. (1997). Outcomes and their measurement in clinical trials of endosseous oral implants. *Annals of Periodontology*, *2*(1), 291–298. https://doi.org/10.1902/annals.1997.2.1.291

Wessels, R., De Roose, S., De Bruyckere, T., Eghbali, A., Jacquet, W., De Rouck, T., & Cosyn, J. (2019). The Mucosal Scarring Index: reliability of a new composite index for assessing scarring following oral surgery. *Clinical Oral Investigations*, *23*(3), 1209–1215. https://doi.org/10.1007/s00784-018-2535-6

Windisch, S. I., Jung, R. E., Sailer, I., Studer, S. P., Ender, A., & Hammerle, C. H. (2007). A new optical method to evaluate three-dimensional volume changes of alveolar contours: A methodological in vitro study. *Clinical Oral Implants Research*, *18*(5), 545–551. https://doi.org/10.1111/j.1600-0501.2007.01382.x

Zucchelli, G., Mazzotti, C., Mounssif, I., Mele, M., Stefanini, M., & Montebugnoli, L. (2013). A novel surgical-prosthetic approach for soft tissue dehiscence coverage around single implant. *Clinical Oral Implants Research*, *24*(9), 957–962. https://doi.org/10.1111/clr.12003

Zucchelli, G., Tavelli, L., Stefanini, M., Barootchi, S., Mazzotti, C., Gori, G., & Wang, H. L. (2019). Classification of facial peri-implant soft tissue dehiscence/deficiencies at single implant sites in the esthetic zone. *Journal of Periodontology*, *90*(10), 1116–1124. https://doi.org/10.1002/JPER.18-0616

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How to cite this article: Avila-Ortiz, G., Couso-Queiruga, E., Pirc, M., Chambrone, L., & Thoma, D. S. (2023). Outcome measures and methods of assessment of soft-tissue augmentation interventions in the context of dental implant therapy: A systematic review of clinical studies published in the last 10 years. *Clinical Oral Implants Research*, *34*(Suppl. 25), 84–96. https://doi.org/10.1111/clr.13927