Received: 26 November 2020 | Revised: 8 February 2021 | Accepted: 24 April 2021

DOI: 10.1111/clr.13767

REVIEW ARTICLE

CLINICAL ORAL IMPLANTS RESEARCH WILEY

Patient-reported outcome measures following soft-tissue grafting at implant sites: A systematic review

Martina Stefanini[1] | Lorenzo Tavelli[2] | Shayan Barootchi[2] | Matteo Sangiorgi[1] | Giovanni Zucchelli[1,2]

[1]Department of Biomedical and Neuromotor Sciences, University of Bologna, Bologna, Italy

[2]Department of Periodontics & Oral Medicine, University of Michigan School of Dentistry, Ann Arbor, MI, USA

Correspondence
Martina Stefanini, Department of Biomedical and Neuromotor Sciences, University of Bologna, Bologna, Italy.
Email: martinastefanini3@gmail.com

Abstract

Objectives: To review the available literature on patient-reported outcome measures (PROMs) following soft tissue augmentation at implant sites.

Materials and Methods: A comprehensive electronic and manual search was performed to identify clinical studies that involved soft tissue augmentation around dental implants and reported PROMs, including post-operative morbidity, painkillers intake, quality of life, aesthetics and satisfactions.

Results: Nineteen articles were included in the qualitative analysis. Autogenous grafts (free gingival graft and connective tissue graft), acellular dermal matrix and xenogeneic collagen matrix were utilized, either with a bilaminar- or an apically positioned flap approach. PROMs reported in the literature included perceived hardship of the procedure and pain during the surgery, post-operative morbidity, painkillers intake, number of days with discomfort, satisfaction, aesthetic evaluation, quality of life and willingness to undergo the treatment again. Most of the included studies showed similar PROMs between autogenous grafts and substitutes, in terms of post-operative morbidity, painkillers intake, quality of life, aesthetic assessment and satisfaction. Nevertheless, a trend towards lower post-operative discomfort was observed for graft substitutes. High scores for patient satisfaction and aesthetic evaluation were observed in all the interventions compared to non-grafted sites.

Conclusions: PROMs represent a crucial endpoint of clinical studies evaluating the outcomes of soft tissue grafts at implant sites. Most of the studies did not find significant differences in terms of patient morbidity and painkillers between autogenous grafts and substitutes. Soft tissue grafting can enhance patient satisfaction and aesthetic evaluation compared to non-grafted sites.

KEYWORDS
acellular dermal graft, autogenous grafts, collagen matrix, dental implant, patient-reported outcome measures

1 | INTRODUCTION

Dental implants are predictable treatment options for the rehabilitation of single and multiple edentulous areas (Buser et al., 2017). Although the most frequently reported success criteria for implant therapy include mobility, pain, radiolucency, peri-implant bone loss, suppuration and bleeding (Papaspyridakos et al., 2012), the importance of assessing patients' subjectively reported outcomes has progressively gained interest in the scientific community. A recent consensus report from the International Team for Implantology concluded that PROMs, such as patient satisfaction and quality of life, should be included in every implant-related clinical study (Feine et al., 2018).

Nowadays implant therapy is often driven by patients' aesthetic demands that are becoming more stringent by day (Mazzotti et al., 2018; Roccuzzo et al., 2014; Zucchelli et al., 2019). Nonetheless, most of the indices that have been proposed for assessing the aesthetic outcomes of dental implants are based on professional evaluation and not on patients' perspectives (Belser et al., 2009; Juodzbalys & Wang, 2010; Stefanini et al. 2018). Among the techniques that have been performed for improving the aesthetic conditions at implant sites, soft tissue augmentation with autogenous grafts or substitutes have shown great outcomes and predictability (Bianchi & Sanfilippo, 2004; Cairo et al., 2017; Tavelli et al., 2021; Zucchelli et al., 2013, 2020). In particular, Hosseini and co-workers evaluated the 5-year tissue changes in the anterior maxilla around implants that were placed with or without a connective tissue graft (CTG) (Hosseini et al., 2020). A spectrophotometer and a computer software were used for the professional aesthetic evaluation that led the authors to conclude that grafted sites had better colour compared to non-grafter sites (Hosseini et al., 2020). It has been shown that CTG is able to significantly increase peri-implant soft tissue thickness and this may have contributed to the stability of the soft tissue margin up to 5 years (Roccuzzo et al., 2018; Zucchelli et al., 2018). CTG has also the property of augmenting peri-implant papilla height (Stefanini et al., 2020). Other authors have supported the notion that CTG can improve the aesthetic outcomes of dental implant therapy, with higher mean pink aesthetic scores compared to non-grafted sites (Migliorati et al., 2015; Wiesner et al., 2010). However, these observations should not only be based upon the clinician's perspective, especially when comparing the outcomes of CTG vs. soft tissue graft substitutes, such as the collagen matrix (XCM) or acellular dermal matrix (ADM). Avoiding a second surgical site (the palate), the unlimited availability and the reduction in the overall surgical time are among the main advantages that have been attributed to graft substitutes compared to autogenous soft tissue grafts. Results from several studies investigating patient-related outcomes have shown strong patients' preference towards soft tissue graft substitutes when compared with autogenous grafts, mainly due to the reduction in post-operative morbidity (Aroca et al., 2013; McGuire et al., 2014; Tavelli, McGuire, et al., 2020; Tonetti et al., 2018).

In this scenario, there is no doubt that the outcomes of peri-implant soft tissue augmentation, either with autogenous grafts or alternative materials, should take into account the patient's own perspective of the treatment, not including only aesthetics but also morbidity, satisfaction, quality of life, among others.

A recent randomized clinical trial (RCT) investigating peri-implant soft tissue augmentation with CTG vs. XCM concluded that the autogenous graft should be preferred when increasing mucosal thickness is the primary goal, while XCM can be considered as a viable alternative when the reduction in patient morbidity is a primary aim of the therapy (Cairo et al., 2017). Other studies have compared PROMs of autogenous grafts vs. substitutes, and reached either similar or conflicting results (Anderson et al., 2014; Huber et al., 2018; Lorenzo et al., 2012; Thoma et al., 2016; Vellis et al., 2019). However, a comprehensive review focusing on PROMs following peri-implant soft tissue grafting procedures has not yet been performed. Therefore, the aim of the present study was to review the available literature on PROMs following soft tissue augmentation (including all the interventions intended for increasing keratinized mucosa width, attached mucosa, soft tissue thickness or soft tissue contour) at implant sites.

2 | MATERIAL AND METHODS

2.1 | Protocol registration and reporting format

The protocol of the present review was registered in the PROSPERO database, hosted by the National Institute for Health Research, University of York, Center for Reviews and Dissemination (CRD42020182021). This manuscript was prepared following the Cochrane Collaboration guidelines (Higgins et al., 2011).

2.2 | Focused question

The goal of this review was to address the following focused question: What is the impact of soft tissue augmentation around dental implants relative to PROMs?

2.3 | PICOT question

The following population, intervention, comparison, outcomes and time (PICOT) framework (Stillwell et al., 2010) was used to guide the inclusion and exclusion of studies for the above-mentioned focused question:

Population (P): Patients requiring soft tissue augmentation for a single or multiple dental implant(s) (either metallic or ceramic implants).

Intervention (I): Soft tissue augmentation at implant sites either with autogenous grafts (free gingival graft [FGG] and connective tissue graft [CTG]) or substitutes (collagen matrix [XCM] and allogeneic acellular dermal matrix [ADM]), including bilaminar techniques or apically positioned flap approach.

Comparison (C): Grafted vs. non-grafted sites or grafted sites with different soft tissue grafts (FGG, CTG, XCM and ADM)

Outcome (O): Patient-related outcome measures (PROMs), including morbidity, satisfaction, self-reported aesthetics and willingness to retreat.

Time (T): Minimum follow up of 3 months after the surgical intervention.

2.4 | Search strategy

A detailed systematic literature search was conducted using the following electronic databases: The National Library of Medicine (MEDLINE via PubMed); EMBASE via OVID; the Cochrane Central Register of Controlled Trials; Latin American & Caribbean Health Sciences Literature (LILACS); Web of Science and Scopus. For examining unpublished trials, the grey literature, non-profit reports, government research or other materials were also electronically explored through searching in ClinicalTrial.gov and OpenGrey. The search strategy was primarily designed for the MEDLINE database with a string of medical subject headings and free-text terms, and then modified appropriately for other databases. No restrictions were set for date of publication, journal or language. The search results were downloaded to a bibliographic database to facilitate duplicate removal and cross-reference checks. Details regarding the search strategy and the development of the search key terms for the databases are displayed in the Appendix.

To ensure a thorough screening process, the electronic search was complemented with a manual search in the following journals: *Journal of Dental Research*, *Journal of Clinical Periodontology*, *Journal of Periodontology*, *Clinical Oral Implants Research*, *Clinical Implant Dentistry and Related Research*, *The International Journal of Oral & Maxillofacial Implants*, *Journal of Oral and Maxillofacial Surgery*, *International Journal of Oral Implantology*, *Clinical Oral Investigations and International Journal of Periodontics* and *Restorative Dentistry*. The manual search period was from January 1, 2000, to March 26, 2020. Additionally, reference lists of the retrieved studies for full-text screening and previous reviews in the topic of peri-implant soft tissue (plastic) surgery were screened (Bassetti, Stahli, Bassetti, & Sculean, 2016, 2017; Cairo et al., 2008, 2019; Gargallo-Albiol et al., 2019; Gobbato et al., 2013; Lin et al., 2013, 2018; Poskevicius et al., 2017; Rotundo et al., 2015; Suarez-Lopez Del Amo et al., 2016; Tavelli, Barootchi, Avila-Ortiz, et al., 2020; Thoma, Buranawat, Hammerle, Held, Jung, 2014, Thoma, Muhlemann, Jung, 2014; Thoma et al., 2018 Wennstrom & Derks, 2012).

The last electronic search was conducted on May 1, 2020, and the manual literature search was updated until November 21, 2020.

2.5 | Inclusion criteria

- Soft tissue augmentation at implant sites using CTG, FGG, ADM or CM
- Prospective interventional human studies
- Evaluation and reporting of clinical outcomes of interest (PROMs) over a minimum follow-up period of 3 months.

2.6 | Exclusion criteria

- Retrospective clinical studies, case reports or animal studies
- Inclusion of implants with a diagnosis of peri-implantitis (Berglundh et al., 2018)
- Soft tissue augmentation around natural teeth
- Simultaneous hard and soft tissue augmentation
- Studies recruiting only smoking individuals.

2.7 | Selection of studies

Two calibrated examiners (LT and SB) screened the titles and abstracts (if available) of the entries identified in the search, in duplicate and independently. Next, the full-text version of all studies that potentially met the eligibility criteria or for which there was insufficient information in the title and abstract to make a decision was obtained. Any article considered as potentially relevant by at least one of the reviewers was included in the next screening phase. Subsequently, the full-text publications were also evaluated in duplicate and independently by the same review examiners. The examiners were calibrated with the first 10 full-text, consecutive publications. Any disagreement on the eligibility of the studies was resolved through open debate between both reviewers until an agreement was reached or through settlement by an arbiter (MS). All articles that did not meet the eligibility criteria were excluded and the reasons for exclusion were noted. Inter-examiner agreement following full-text assessment was calculated via kappa statistics. Disagreement on the inclusion of the studies at any point was resolved in the same manner as previously mentioned.

2.8 | Data extraction and management

Two examiners (LT and SB) independently retrieved all relevant information from the included articles using a data extraction sheet specifically designed for this review. At any stage, disagreements between the reviewers were resolved through open discussion and consensus. If a disagreement persisted, a third person (SB) settled the discussion. Aside from the outcomes of interest (PROMs), the following study characteristics were retrieved:

- Study design, number of centres, geographic location, setting (university vs. private practice) and source of funding

- Population characteristics, age of participants, number of participants and treated sites (baseline/follow up), singular/multiple treated sites and follow-up period
- Type of intervention, utilization of soft tissue grafting materials and techniques
- Timing of soft tissue augmentation: whether it was at the time of the implant placement, at second stage or delayed.

According to the aim of the current review to comprehensively evaluate the PROMs associated with peri-implant soft tissue grafting, including non-randomized reports, qualitative analysis of the obtained and gathered data was planned for detailed description of the results grouped per category of PROMs.

2.9 | Quality assessment, risk of bias and data analysis

The risk of bias for the included studies was assessed independently and in duplicate by two authors (LT and MS). For RCTs, it was performed according to the recommended approach by the Cochrane collaboration group (Higgins et al., 2011). For non-randomized cohort studies included in the qualitative analysis, the ROBINS-I tool (Sterne et al., 2016) was used to determine the potential risk of bias. For case series, the Joanna Briggs Institute Critical Appraisal tool (Moola et al. 2017) was utilized for quality assessment (Appendix). Any disagreement was discussed between the same authors. Another author (GZ) was consulted in case no agreement was reached. However, no study was excluded on the basis of the risk of bias within a study.

2.10 | Data analysis

Due to the expected various heterogeneity and limited sample size per outcome, the results of the current systematic review were expressed qualitatively and without quantitative assessment. The descriptive analysis was performed per type of patient-subjective outcomes measured in each study and presented as stated in the original report. Reviewer reliability (Kappa) in the screening and search process was assessed with the KappaGUI (Santos, 2018) package in Rstudio (Version 1.3.959).

3 | RESULTS

3.1 | Search results and study selection

The literature search process is shown in Figure 1. Following removal of duplicates, 1889 records remained for screening by titles and abstracts. The full-text assessment was performed for 66 studies. Based on predetermined inclusion criteria, 19 articles were included in the qualitative analysis (Anderson et al., 2014; Baldi et al., 2020; Bianchi & Sanfilippo, 2004; Cairo et al., 2017; De Bruyckere et al., 2020; Fenner et al., 2016; Froum et al., 2015; Huber et al., 2018; Hutton et al., 2018; Lorenzo et al., 2012; Roccuzzo et al., 2016, 2019; Schallhorn et al., 2015; Thoma et al., 2016, 2020; Vellis et al., 2019; Wiesner et al., 2010; Zucchelli et al., ,2013, 2018). The reason for exclusion of the 47 records is reported in the Appendix (Table 1). The inter-reviewer reliability in the screening and inclusion process, as assessed with Cohen's k, corresponded to 0.89 and 0.94 for assessment of titles and abstracts and full-text evaluation respectively.

3.2 | Description of studies

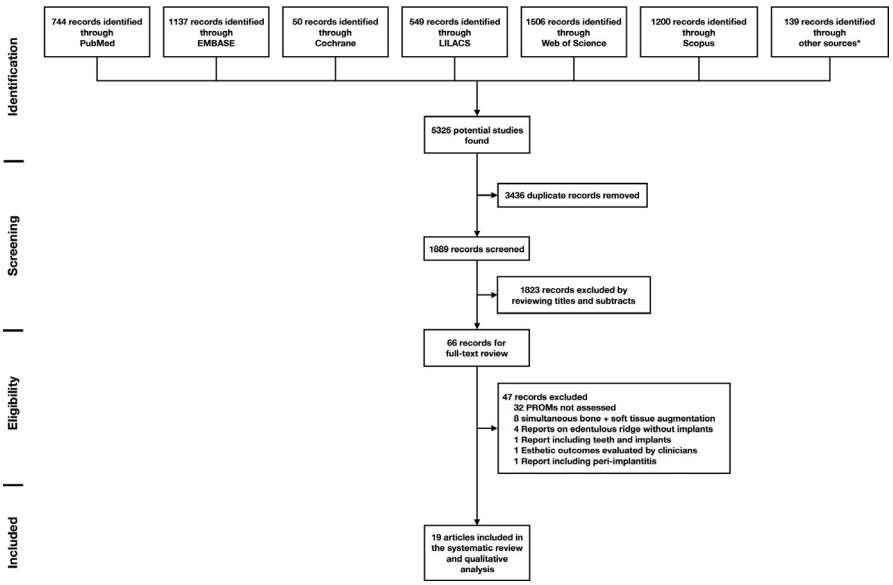
Thirteen studies were RCTs (Anderson et al., 2014; Baldi et al., 2020; Bianchi & Sanfilippo, 2004; Cairo et al., 2017; De Bruyckere et al., 2020; Froum et al., 2015; Huber et al., 2018; Hutton et al., 2018; Lorenzo et al., 2012; Thoma et al., 2016, 2020; Vellis et al., 2019; Wiesner et al., 2010), two were non-randomized studies (Fenner et al., 2016; Roccuzzo et al., 2016) and four were case series (Roccuzzo et al., 2019; Schallhorn et al., 2015; Zucchelli et al., 2013, 2018).

Three studies reported PROMs on the same cohort of patients of a previous published article with a longer follow up (Huber et al., 2018; Thoma et al., 2020; Zucchelli et al., 2018). One RCT compared soft tissue grafting with guided bone regeneration and, therefore, only one arm was considered in the qualitative analysis (De Bruyckere et al., 2020).

Three studies investigated PROMs of soft tissue grafting with an apically positioned flap approach (APF) (Lorenzo et al., 2012; Roccuzzo et al., 2016; Vellis et al., 2019), while the others used soft tissue grafts in combination with bilaminar techniques (Table 1).

PROMs following soft tissue augmentation with CTG were investigated in 15 studies (Anderson et al., 2014; Baldi et al., 2020; Bianchi & Sanfilippo, 2004; Cairo et al., 2017; De Bruyckere et al., 2020; Fenner et al., 2016; Huber et al., 2018; Hutton et al., 2018; Lorenzo et al., 2012; Roccuzzo et al., 2019; Thoma et al., 2016, 2020; Wiesner et al., 2010; Zucchelli et al., ,2013, 2018). In particular, nine of them harvested a sub-epithelial CTG (Anderson et al., 2014; Bianchi & Sanfilippo, 2004; De Bruyckere et al., 2020; Huber et al., 2018; Hutton et al., 2018; Lorenzo et al., 2012; Thoma et al., 2016, 2020; Wiesner et al., 2010), two articles reported the outcomes (on the same cohort of patients) of CTG obtained from the de-epithelialization of a free gingival graft (FGGs) (Zucchelli et al., 2013, 2018), one study utilized a CTG obtained from the de-epithelialization of a gingival graft from the maxillary tuberosity (Roccuzzo et al., 2019), one trial utilized either sub-epithelial CTG or a CTG obtained from the de-epithelialization of a FGG (Cairo et al., 2017) and two studies did not specify the harvesting technique (Baldi et al., 2020; Fenner et al., 2016). PROMs of FGG were evaluated in two studies (Roccuzzo et al., 2016; Vellis et al., 2019), while three trials reported on acellular dermal matrix (ADM) (Anderson et al., 2014; Baldi et al., 2020; Hutton et al., 2018) and eight studies assessed the PROMs of xenogeneic collagen matrix

FIGURE 1 PRISMA flowchart



(XCM) (Cairo et al., 2017; Froum et al., 2015; Huber et al., 2018; Lorenzo et al., 2012; Schallhorn et al., 2015; Thoma et al., 2016, 2020; Vellis et al., 2019). Five studies compared PROMs of grated vs. non-grafted sites (Baldi et al., 2020; Bianchi & Sanfilippo, 2004; Froum et al., 2015; Roccuzzo et al., 2016; Wiesner et al., 2010).

Regarding the time of the soft tissue augmentation, five trials performed soft tissue grafting at the time of implant placement (Bianchi & Sanfilippo, 2004; De Bruyckere et al., 2020; Froum et al., 2015; Hutton et al., 2018; Wiesner et al., 2010), three studies at the second stage (Baldi et al., 2020; Cairo et al., 2017; Schallhorn et al., 2015), seven studies after implant loading (delayed) (Anderson et al., 2014; Lorenzo et al., 2012; Roccuzzo et al., ,,2016, 2019; Vellis et al., 2019; Zucchelli et al., 2013, 2018), while four articles did not report this information (Fenner et al., 2016; Huber et al., 2018; Thoma et al., 2016, 2020). Table 1 described study characteristics, their intervention and their PROMs.

PROMs evaluated in the included studies involved hardship of the surgery, pain during the surgery, post-operative morbidity, painkillers intake, number of days with discomfort, self-reported complications (e.g., oedema, haematoma, bleeding, etc.), satisfaction, aesthetic evaluation, willingness to retreatment, quality of life and discomfort during brushing.

Due to the inclusions of non-randomized studies and inadequate findings for conducting statistical comparisons, it was decided not to perform a quantitative analysis for this review, rather to discuss the results in a quantitative manner.

3.3 | Assessment of the risk of bias

Six RCTs were considered as low risk of bias (Cairo et al., 2017; De Bruyckere et al., 2020; Froum et al., 2015; Hutton et al., 2018; Lorenzo et al., 2012; Wiesner et al., 2010), while six were rated as having moderate risk of bias (Anderson et al., 2014; Baldi et al., 2020; Bianchi & Sanfilippo, 2004; Huber et al., 2018; Thoma et al., 2016, 2020). One trial was considered at high risk of bias (Vellis et al., 2019). Four non-RCTs were categorized as having low risk of bias (Roccuzzo et al., 2016, 2019; Zucchelli et al., 2013, 2018), while two non-RCTs were considered at moderate risk of bias (Fenner et al., 2016; Schallhorn et al., 2015). Details can be found in the Appendix.

3.4 | Hardship of the surgery and pain during the surgery

Hardship of the surgery and pain during the procedure were evaluated only in one trial (Cairo et al., 2017). The authors used a visual analogue scale (VAS) from 0 to 100 after the surgery to evaluate these two PROMs. Patients reported a statistically significant higher hardship of the surgery for CTG compared to XCM (35 ± 23 vs. 17 ± 13, respectively). No significant difference was described for perceived pain in the two groups (Cairo et al., 2017).

3.5 | Post-operative morbidity

Post-operative morbidity was evaluated using a VAS from 0 to 10 or from 0 to 100 in eight trials (Anderson et al., 2014; Cairo et al., 2017; De Bruyckere et al., 2020; Froum et al., 2015; Hutton et al., 2018; Lorenzo et al., 2012; Thoma et al., 2016; Vellis et al., 2019). Five studies assessed the post-operative pain in the first 7–14 days (Cairo et al., 2017; De Bruyckere et al., 2020; Lorenzo et al., 2012; Thoma et al., 2016; Vellis et al., 2019), while others extended the evaluation of this outcome up to the last follow up (Anderson et al., 2014; Froum et al., 2015; Hutton et al., 2018).

Among the studies performing an apically positioned flap approach, Vellis and co-workers found an average VAS of 19 and 29.7

TABLE 1 Characteristics of the included studies and their interventions

Publication	Study design	No. of centres, Country, Setting, Funding	Treatment	Timing of intervention	Participant age (years), No. Male/Female, Inclusion of smokers
Anderson et al. (2014)	RCT	Single centre, USA, University, sponsored	ADM–bilaminar	Delayed	49, NA, yes
			CTG–bilaminar	Delayed	49, NA, yes
Baldi et al. (2020)	RCT	Multicentre, Italy, University, sponsored	ADM–bilaminar	At second stage	51.1, 3/9, yes
			CTG–bilaminar	At second stage	47.5, 7/5, yes
			No soft tissue augmentation	At second stage	53.9, 5/7, yes
Bianchi and Sanfilippo, (2004)	RCT	Single centre, Italy, University, NA	CTG–bilaminar	At implant placement	45.4, 58/58, yes
			No soft tissue augmentation	NA	
Cairo et al., (2017)	RCT	Single centre, Italy, University, sponsored	XCM–bilaminar	At second stage	50.3, 10/20, yes
			CTG–bilaminar	At second stage	48.3. 6/24, yes
De Bruyckere et al., (2020)	RCT	Single centre, Belgium, University, self-supported	CTG–bilaminar	At implant placement	48, 12/9, no
Fenner et al., (2016)	Non-RCT	Single centre, Switzerland, University, self-supported	CTG–bilaminar	NA	48, NA, yes
			No soft tissue augmentation	NA	
Froum et al., (2015)	RCT	Single centre, USA, University, sponsored	XCM–bilaminar	At implant placement	NA, NA, yes
			No soft tissue augmentation	NA	NA, NA, yes
Huber et al., (2018)	RCT	Single centre, Switzerland, University, sponsored	CTG–bilaminar	NA	43.4, 4/6, yes
			XCM–bilaminar	NA	44.1, 3/7, no

Follow up time (months)	Patients (n), Implants (n)	Morbidity (VAS) (mean ± SD)	SAT (mean ± SD)	EST (mean ± SD)	Quality of life	Other PROMS assessed
3, 6	6,6	93.4 (2 weeks) 40 (6 weeks) 36.6 (3 months)	NSSD between groups	NSSD between groups and NSSD change from baseline to the last recall	Slight reduction but NSSD between the two groups (Questionnaire)	Painkillers intake in the first 2 weeks (greater use in the CTG group but NSSD)
3, 6	7,7	88.6 (2 weeks) 0 (6 weeks) 0 (3 months)			Slight increase but NSSD between the two groups	
6	12, 12	NA	VAS 92.1 ± 8.3	VAS 92.1 ± 8.3	NA	NA
6	12, 12		VAS 97.5 ± 4.1	VAS 94.1 ± 4.9		
6	12, 12		VAS 92.5 ± 8.6	VAS 92.9 ± 7		
12 - 108	96, 96	NA	NA	Higher for CTG group	NA	NA
	20, 20	NA	NA		NA	
3, 6	30, 30	13 ± 10*	VAS 95 ± 5*	VAS 90 ± 8	NA	Hardship of the surgery, pain during the surgery, painkillers intake after 1 week, number of days with discomfort, complications and presence of oedema
3, 6	30, 30	37 ± 15	VAS 91 ± 9	VAS 90 ± 9	NA	
12	21, 21	30.8 ± 11.5 (day1) 17.7 ± 10.6 (day3) 5.7 ± 2.1 (day7) 4.9 ± 1.3 (day14)	NA	VAS 87 ± 15	From an overall OHIP-14 of 28.76 ± 8.95 to 15.71 ± 2.31 1 years after the treatment	Painkillers intake, presence of oedema, haematoma, painkillers, bleeding and willingness to retreatment
86.4	14, 14	NA	97	NA	NA	NA
	12, 12	NA		NA	NA	
3	17, 17	12.1 ± 20.3 (1–2 weeks) 0.9 ± 1.5 (4 weeks) 0.7 ± 0.7 (8 weeks) 0.8 ± 0.9 (3 months)	VAS 97.7 ± 5	NA	NA	NA
3	14, 14	5.5 ± 7.9 (1-2 weeks) 2.2 ± 3.8 (4 weeks) 3.3 ± 6 (8 weeks) 2 ± 3.2 (3 months)	VAS 96.7 ± 4.9	NA	NA	
12	10, 10	NA	NA	NA	Change from baseline to 1 year 0.5 ± 1.6 (OHIP-14)	NA
12	10, 10	NA	NA	NA	Change from baseline to 1 year 1 ± 2.6 (OHIP-14)	

(Continues)

TABLE 1 (Continued)

Publication	Study design	No. of centres, Country, Setting, Funding	Treatment	Timing of intervention	Participant age (years), No. Male/Female, Inclusion of smokers
Hutton et al., (2018)	RCT	Single centre, USA, University, sponsored	ADM–bilaminar	At implant placement	59.7, 6/4, no
			CTG–bilaminar	At implant placement	51.2, 5/5, no
Lorenzo et al., (2012)	RCT	Single centre, Spain, University, supported	CTG–APF	Delayed	63, 3/8, yes
			XCM–APF	Delayed	62. 2/8, yes
Roccuzzo et al., (2019)	Non-RCT	Single centre, Italy, Private Practice, self-supported	CTG	Delayed	53.1, 2/11, yes
Roccuzzo et al., (2016)	Non-RCT	Single centre, Italy, Private Practice, self-supported	FGG–APF	Delayed	52.4, 52/76, yes
			No soft tissue augmentation (implants with KM)	NA	
			No soft tissue augmentation (implants without KM)	NA	
Schallhorn et al., (2015)	Non-RCT	Multicentre, USA, University, sponsored	XCM–bilaminar	At second stage	NA, NA, NA
Thoma et al., (2016)	RCT	Single centre, Switzerland, University, sponsored	CTG–bilaminar	NA	42.7, 4/6, yes
			XCM–bilaminar	NA	43.8, 3/7, yes
Thoma et al. (2020)	RCT	Single centre, Switzerland, University, sponsored	CTG–bilaminar	NA	43.4, NA, yes
			XCM–bilaminar	NA	44.1, NA, no
Vellis et al., (2019)	RCT	Single centre, USA, Private practice, sponsored	XCM–APF	Delayed	NA, NA, yes
			FGG–APF	Delayed	NA, NA, yes
Wiesner et al., (2010)	RCT	Single centre, Austria, Private practice, NA	CTG	At implant placement	39, 3/7, no
			No soft tissue augmentation	NA	39, 3/7, no
Zucchelli et al., (2013)	Non-RCT	Single centre, Italy, University, self-supported	CTG–bilaminar	Delayed	NA, 6/14, yes
Zucchelli et al. (2018)	Non-RCT	Single centre, Italy, University, self-supported	CTG–bilaminar	Delayed	NA, NA, yes

Abbreviations: ADM: acellular dermal matrix. APF: apically positioned flap. CTG: connective tissue graft. EST: aesthetic evaluation of the treatment. FGG: free gingival graft. KM: keratinized mucosa. NA: not available. NSSD: not statistically significant. OHIP-14: Oral Health Impact Profile. RCT: randomized controlled trial. SAT: satisfaction of the treatment. VAS: visual analogue scale (from 0 to 100). XCM: xenogeneic collagen matrix.

*SSD better compared to the other treatment group.

Follow up time (months)	Patients (n), Implants (n)	Morbidity (VAS) (mean ± SD)	SAT (mean ± SD)	EST (mean ± SD)	Quality of life	Other PROMS assessed
4	10, 10	10.1 ± 7.8 (2 weeks) 4.40 ± 4.25 (4 weeks) 4.5 ± 8 (8 weeks)	VAS 94.8 ± 7.31	NA	NA	NA
4	10, 10	23.6 ± 24.7 (2 weeks) 10.4 ± 16.5 (4 weeks) 9.7 ± 15.5 (8 weeks)	VAS 98.3 ± 2.26	NA	NA	NA
3, 6	11, 11	< 30	NA	NA	NA	Painkillers intake (NSSD between the two groups)
3, 6	11, 11	< 30	NA	NA	NA	
60	13, 13	NA	NA	VAS 95 ± 8	NA	NA
120	NA, 11	NA	NA	NA	NA	Soreness/discomfort referred during oral hygiene procedures
	NA, 63	NA	NA	NA	NA	
	NA, 24	NA	NA	NA	NA	
6	30, 35	NA	VAS 90 ± 20	NA	NA	NA
3	10, 10	Slightly higher than XCM but NSSD	NA	NA	Baseline 5.2 ± 6.1 Follow up 4.4 ± 5.6 (OHIP-14)	Painkillers intake (NSSD between the two groups)
3	10, 10	Slightly lower than XCM but NSSD	NA	NA	Baseline 5.6 ± 9.5 Follow up 4.6 ± 5.9 (OHIP-14)	
36	9, 9	NA	NA	NA	0 ± 0 (OHIP-14) *	NA
36	7, 7	NA	NA	NA	1 ± 1.3 (OHIP-14)	
3, 6	30, 30	19 ± 26	NA	NA	NA	NA
3, 6	30, 30	29.7 ± 29	NA	NA	NA	NA
12	10, 10	NA	10/10 patients satisfied	6 pts preferred the aesthetics of the CTG sites*, 4 no preference (VAS not used)	NA	Willingness to retreatment
12	10, 10	NA	9/10 patients satisfied		NA	
12	20, 20	NA	NA	VAS 87.55 ± 10.2	NA	NA
60	19, 19	NA	NA	VAS 89.5 ± 9.1	NA	NA

(out of 100) for XCM and FGG, respectively (Vellis et al., 2019), while Lorenzo et al. reported that the average VAS was <30 (of 100) in both the CTG and XCM groups (Lorenzo et al., 2012).

In the first two post-operative weeks, only one study found a higher patient morbidity for CTG compared to a graft substitute (XCM) (37 ± 15 vs. 13 ± 10 VAS value, respectively) (Cairo et al., 2017), while five trials did not find a significant differences between CTG and graft substitutes (XCM or ADM) (Anderson et al., 2014; Hutton et al., 2018; Lorenzo et al., 2012; Thoma et al., 2016; Vellis et al., 2019). Froum and co-workers showed that patients allocated in the XCM group reported similar discomfort compared to patients who did not received soft tissue augmentation (Froum et al., 2015).

Interestingly, Anderson and co-workers observed that patients in the CTG group did not report pain after the second week, while patients who received ADM described pain also at week 6 (mean VAS 40) and 3 months (mean VAS 36.6). Although these data showed a clinical impact, statistical differences were not found between the two groups (Anderson et al., 2014). On the other hand, Hutton et al. did not observe significant differences in perceived discomfort between ADM and CTG at 2, 4, 8 and 16 weeks (Hutton et al., 2018).

3.6 | Painkillers intake

Four studies reported painkillers intake (Anderson et al., 2014; Cairo et al., 2017; Lorenzo et al., 2012; Thoma et al., 2016). Among the studies performing a bilaminar approach, Cairo et al. showed that CTG was associated with significantly higher painkillers consumption compared to XCM (3.9 ± 0.7 vs. 2.2 ± 0.8 ibuprofen 600 mg tablets respectively) (Cairo et al., 2017), while Thoma et al. did not find significant difference between painkillers intake following CTG or XCM, even though the pain medication consumption was (non-significantly) higher in the CTG group (Thoma et al., 2016). Anderson et al. reported a higher trend for painkillers use in the CTG group compared to the ADM group, although this finding was not statistically significant (Anderson et al., 2014). Lastly, the only study reporting painkillers intake following apically positioned flap, either with CTG or XCM, failed to find significant differences between the two treatment groups (Lorenzo et al., 2012).

3.7 | Satisfaction

Patient satisfaction was assessed in six articles using VAS (Baldi et al., 2020; Cairo et al., 2017; Fenner et al., 2016; Froum et al., 2015; Hutton et al., 2018; Schallhorn et al., 2015) and in two studies using questions and predetermined answers (Anderson et al., 2014; Wiesner et al., 2010). Three RCTs did not observe a significant difference for patient satisfaction between ADM and CTG (Anderson et al., 2014; Baldi et al., 2020; Hutton et al., 2018). In particular, Hutton et al. reported a satisfaction of 98.3 ± 2.26 and 94.8 ± 7.31 for CTG and ADM respectively (Hutton et al., 2018). On the other hand, Cairo et al. found significant superior VAS values for XCM compared to CTG (95.5 ± 5 vs. 91 ± 9) (Cairo et al., 2017).

Two trials comparing grafted vs. non-grafted sites did not report differences in terms of patient satisfaction (Froum et al., 2015; Wiesner et al., 2010). Fenner et al. showed a mean value of 97 on the VAS, without distinguishing between patients who received and those who did not receive CTG (Fenner et al., 2016).

3.8 | Aesthetic evaluation

Nine articles investigated patient aesthetic evaluation (Anderson et al., 2014; Baldi et al., 2020; Bianchi & Sanfilippo, 2004; Cairo et al., 2017; De Bruyckere et al., 2020; Roccuzzo et al., 2019; Wiesner et al., 2010; Zucchelli et al., 2013, 2018). Among the articles that performed soft tissue augmentation primarily for increasing tissue thickness (Baldi et al., 2020; Cairo et al., 2017; De Bruyckere et al., 2020; Wiesner et al., 2010), the mean VAS value ranged from 87 to 94.1 (Baldi et al., 2020; Cairo et al., 2017; De Bruyckere et al., 2020). In a split-mouth design, Wiesner et al. observed that the patients significantly preferred the aesthetic of the grafted (CTG) site compared to the non-grafted site (Wiesner et al., 2010).

Three studies evaluated patient aesthetic evaluation following the treatment of peri-implant soft tissue dehiscences/deficiencies (PSTDs). While Anderson et al. failed to detect a significant change from baseline to 6-month post-op or even significant differences between the two groups (CTG and ADM), Roccuzzo et al. and Zucchelli et al. showed a significant improvement following the treatment of PSTDs with CTG (Roccuzzo et al., 2019; Zucchelli et al., 2013, 2018). In particular, Zucchelli et al. reported a patient aesthetic evaluation of 29.5 ± 13.2 at baseline, that became 89.5 ± 0.91 at the 5-year follow up (Zucchelli et al., 2018).

Bianchi and Sanfilippo stated that a good aesthetic assessment was reported by patients who received immediate implant with or without CTG, with better results for the CTG group (Bianchi & Sanfilippo, 2004). However, the method used for assessing the patient-reported aesthetic evaluation and its score were not described in the article (Bianchi & Sanfilippo, 2004).

3.9 | Quality of life

The assessment of the impact of the treatment on patient's quality of life was reported in five articles (Anderson et al., 2014; De Bruyckere et al., 2020; Huber et al., 2018; Thoma et al., 2016, 2020), with three of them referring to the same cohort of patients (Huber et al., 2018; Thoma et al., 2016, 2020). Four trials used the Oral Health Impact Profile (OHIP-14) (De Bruyckere et al., 2020; Huber et al., 2018; Thoma et al., 2016, 2020), while one RCT evaluated the quality of life based on a revised version of the Kiyak Post-Surgical Patient Questionnaire (Kiyak et al., 1984).

Thoma et al. showed similar results between CTG and XCM at suture removal and at the 3-month follow up. They also observed

that at suture removal, median overall scores for CTG were higher (although not statistically significant) than for XCM. The authors highlighted that there was a trend for more physical pain and social disability for CTG compared to XCM within the first 7–10 days (Thoma et al., 2016). At the 1-year follow up, no significant differences were observed between the two groups, with median overall OHIP scores of 0 at all time points and in both groups (Huber et al., 2018). Interestingly, at the 3-year recall, the median overall OHIP scores for the CTG group remained 0, while a median overall score of 1 ± 1.3 was found in the XCM group, with this difference being statistically significant (Thoma et al., 2020). The authors stated that this finding was surprising since the tissues in the "outlier" patient were healthy and no complications occurred. They also specified that the patient reported that the scores were due to personal issues and not the treatment (Thoma et al., 2020).

When evaluating the effect of CTG to re-establish buccal convexity at the time of implant placement, De Bruyckere et al. found an improvement in all the investigated OHIP-14 domains between baseline and the 1-year recall (De Bruyckere et al., 2020).

Anderson et al. reported a slight reduction in the quality-of-life index for the CTG group over time, while a slight increase was observed in the ADM group. However, no significant differences were found between groups (Anderson et al., 2014).

3.10 | Other PROMs assessed

Cairo et al. evaluated the number of days with discomfort between XCM and CTG, showing that subjects allocated in the XCM group experienced a significant lower number of uncomfortable days compared to the CTG group (1.2 ± 0.7 vs. 2.4 ± 0.7 days respectively) (Cairo et al., 2017). They also evaluated post-operative soft tissue complications, such as oedema and bleeding. After 2 weeks, the only significant difference was related to the number of sites with oedema in the CTG group compared to the XCM group (20 vs. 7 respectively) (Cairo et al., 2017). Similarly, De Bruyckere et al. evaluated the self-assessment of oedema, haematoma and post-operative bleeding by means of VASs (De Bruyckere et al., 2020). The mean VAS on oedema was 32 at day 1, 22 at day 3 and 4 at day 7, with overall lower value compared to the control group (guided bone regeneration). The mean VAS on haematoma was 10 at day 3 and 1 at day 7. Ten per cent of the patients reported post-operative bleeding. The willingness to undergo the treatment again was 81% for patients who received CTG, with the remaining subjects (19%) who answered "maybe" (De Bruyckere et al., 2020).

Wiesner et al. also investigated the willingness to undergo the CTG augmentation again. One patient replied "definitely yes", two patients "yes", two patients were "uncertain", four subjects "no" and one subject "absolutely no" (Wiesner et al., 2010).

Roccuzzo et al. assessed the presence of self-reported soreness/discomfort during oral hygiene procedures, in terms of "yes" or "no" (Roccuzzo et al., 2016). Interestingly, 42.9% of patients with implants lacking keratinized mucosa reported discomfort during brushing, while no patients in the implants with keratinized mucosa group described soreness during oral hygiene procedures. In 11 patients with implants lacking keratinized, a FGG was performed to facilitate plaque control. At the 10-year follow up, 9.1% patients who received FGGs because of lack of peri-implant keratinized mucosa reported soreness/discomfort during brushing (Roccuzzo et al., 2016).

Figure 2 summarizes the studies favouring autogenous grafts or substitutes for the investigated patient-reported outcome measures.

Autogenous vs. Substitutes

PROM	Favors autogenous	Comprable	Favors substitutes
Hardship of the surgery (VAS)			Cairo et al. 2017
Post-operative morbidity (VAS)		Anderson 2014*; Hutton 2018; Lorenzo 2012; Thoma 2016*; Vellis 2019**	Cairo et al. 2017
Numbers of day with discomfort			Cairo et al. 2017
Painkillers intake		Anderson 2014*; Lorenzo 2012; Thoma 2016*	Cairo et al. 2017
Post-operative complications			Cairo et al. 2017
Quality of life	Thoma 2020*	Anderson 2014*; Huber 2018*; Thoma 2016*	
Esthetics		Baldi 2020*; Cairo 2017	
Satisfaction		Anderson 2014*; Hutton 2018	Cairo et al. 2017

FIGURE 2 Summary of the studies favoring autogenous grafts or substitutes for the investigated patient-reported outcome measures. * Study with a moderate risk of bias. ** Study with a high risk of bias

3.11 | Funding

Among the 13 RCTs included, 10 were sponsored by the companies manufacturing the investigated soft tissue graft substitute (Anderson et al., 2014; Baldi et al., 2020; Cairo et al., 2017; Froum et al., 2015; Huber et al., 2018; Hutton et al., 2018; Lorenzo et al., 2012; Thoma et al., 2016, 2020; Vellis et al., 2019). The three trials assessing the outcomes of ADM vs. CTG were sponsored (Anderson et al., 2014; Baldi et al., 2020; Hutton et al., 2018), as well as the five studies comparing XCM vs. CTG (Cairo et al., 2017; Huber et al., 2018; Lorenzo et al., 2012; Thoma et al., 2016, 2020). The two RCTs comparing CTG vs. non-augmented sites were self-supported (Bianchi & Sanfilippo, 2004; Wiesner et al., 2010). Among the non-RCTs, only one study was sponsored (Schallhorn et al., 2015). Table 2 illustrates the source of funding of the included articles.

4 | DISCUSSION

4.1 | Main findings

PROMs have become a crucial endpoint of clinical studies. The present systematic review aimed at assessing PROMs following soft tissue augmentation at implant sites. It has been advocated that one

TABLE 2 Source of funding group per intervention and study design

	RCTs		Non-RCTs	
Treatments assessed	**Sponsored**	**Self-sponsored**	**Sponsored**	**Self-sponsored**
ADM vs. CTG	Anderson et al. (2014), Baldi et al. (2020), Hutton et al. (2018)			
XCM versus CTG/FGG	Cairo et al. (2017), Huber et al. (2018), Lorenzo et al. (2012), Thoma et al. (2016, 2020), Vellis et al. (2019)			
XCM versus non-grafted sites	Froum et al. (2015)			
XCM			Schallhorn et al. (2015)	
CTG/FGG versus non-grafted sites		Bianchi and Sanfilippo (2004), Wiesner et al. (2010)		Fenner et al. (2016), Roccuzzo et al. (2016)
CTG		De Bruyckere et al. (2020)[a]		Roccuzzo et al. (2019), Zucchelli et al. (2013, 2018)

Abbreviations: ADM, acellular dermal matrix; CTG, connective tissue graft; FGG, free gingival graft; RCT, randomized controlled trial; XCM, xenogeneic collagen matrix.
[a]RCT comparing CTG to guided bone regeneration.

of the main advantages of graft substitutes is the reduction in patient morbidity (McGuire et al., 2014; Tavelli, Barootchi, et al., 2019; Tavelli, McGuire, et al., 2020; Tonetti et al., 2018). Interestingly, we observed that only one study found a statistically significant higher post-operative reported pain and painkillers intake for CTG compared to XCM (Cairo et al., 2020). Other studies have reported a trend towards higher morbidity and painkillers intake for autogenous grafts compared to XCM or ADM, however, without reaching statistically significance (Anderson et al., 2014; Hutton et al., 2018; Lorenzo et al., 2012; Thoma et al., 2016; Vellis et al., 2019). It can be speculated that the lower patient morbidity associated with graft substitutes is more prominent for multiple than single sites. Indeed, ADM and XCM are largely used for the treatment of generalized multiple gingival recessions, while their indication for single site seems to be more limited in periodontal plastic surgery (Pietruska et al., 2019; Tavelli, Barootchi, et al., 2019; Tonetti et al., 2018). However, the size of the harvested autogenous grafts, as well as the dimensions of graft substitutes were not reported, and their influence on the surgical site on patient morbidity could not have been explored.

In addition, it has also to be mentioned that several approaches have been suggested for minimizing patient morbidity following palatal harvesting (Tavelli et al., 2018; Tavelli, Ravida, et al., 2019; Zucchelli et al., 2010) and this may have played a role for the PROMs. On the other hand, the increased surgical time and the need for a second surgical site that characterized autogenous grafts can affect patient's perception of the procedure, with Cairo et al. who reported a better perception of the surgery in patients treated with XCM compared to CTG (Cairo et al., 2020). Interestingly, a recent article showed that patients can remember the discomfort during and following the soft tissue grafting procedure even after a decade (Tavelli, Barootchi, Di Gianfilippo, et al., 2020).

To what extent perceived hardship of the surgery and patient morbidity could affect the final treatment satisfaction is unknown. While one trial found higher satisfaction for XCM compared to CTG (Cairo et al., 2020), two studies did not observe significant differences between ADM and CTG (Anderson et al., 2014; Hutton et al., 2018). Interestingly, a similar satisfaction was also reported between grafted and non-grafted sites (Froum et al., 2015; Wiesner et al., 2010), leading to speculate that soft tissue augmentation at implant sites may not contribute to patient's perception of the treatment. Nevertheless, the benefits of soft tissue phenotype modification on peri-implant health have been demonstrated and clinicians should be aware that the rational for increasing mucosal thickness or keratinized mucosa at implant sites is promoting lower plaque and inflammatory indices, lower pocket depth and stable marginal bone loss over time (Tavelli, Barootchi, Avila-Ortiz, et al., 2020; Thoma et al., 2018), rather than patient satisfaction.

On the other hand, Wiesner and co-workers observed a significantly higher preference towards the aesthetic outcomes of grafted (CTG) vs. non-grafted sites (Wiesner et al., 2010). Similarly, patients receiving immediate implants, with or without CTG, indicated better aesthetic outcomes for grafted sites (Bianchi & Sanfilippo, 2004).

Using a subjective method, Hosseini et al. demonstrated that implant sites that received CTG showed a better mucosal colour match with adjacent sites compared to non-grafted implants (Hosseini et al., 2020). This is probably due to the fact that thin soft tissue phenotype is more prone to discoloration due to the abutment or implant components (Jung et al., 2007; Lops et al., 2017; Thoma, Muhlemann, et al., 2014). CTG, CM and ADM have been found effective in increasing mucosal thickness (Tavelli, Barootchi, Avila-Ortiz, et al., 2020), with results stable over time (Hosseini et al., 2020; Thoma et al., 2020). The increased mucosal thickness and colour match with the adjacent sites may have been one of the reasons for the higher aesthetic outcomes reported for grafted vs. non-grafted sites.

PSTDs are conditions that can negatively affect aesthetics and patient perception of implant therapy (Mazzotti et al. 2018; Stefanini et al., 2020; Zucchelli et al., 2019). Therefore, it is not surprising that questionnaires assessing aesthetic outcomes are often used for the treatment of PSTDs. Anderson et al. did not observe significant improvement in the patient-reported aesthetics from baseline to 6 months (Anderson et al., 2014), which is probably due to the limited mean dehiscence coverage obtained. On the other hand, Zucchelli et al. described a pre-operative aesthetic evaluation of 29.5 on a 1-100 VAS, with a significant improvement at 1 and 5 years after PSTD treatment with CTG (mean VAS 87.5 and 89.5 respectively) (Zucchelli et al., 2013, 2018). The authors advocated that the use of CTGs obtained from the de-epithelialization of FGGs may be one of the reasons for the significant increase in keratinized tissue width and soft tissue thickness from the 1- to 5-year follow up (Zucchelli et al., 2018), which may have also contributed to the slight improvement in the patient-reported aesthetics. The differences among the CTG harvesting technique (sub-epithelial vs. free gingival graft), the surgical approach (traditional CAF vs. combined surgical–prosthetic approach) and the amount of mean dehiscence coverage (40% vs. 96%–99%) may explain the discrepancy in the effect of PSTD treatment observed in the studies of Anderson et al. and Zucchelli et al. respectively (Anderson et al., 2014; Zucchelli et al., 2013, 2018).

5 | LIMITATIONS

Despite this being the first attempt in the literature to systematically evaluate PROMs following soft tissue augmentation at implant sites, a limited number of articles with the predetermined inclusion criteria was available.

In addition, readers have to bear in mind that several of the included studies were sponsored. In particular, all the RCTs investigating the outcomes of graft substitutes compared to autogenous grafts or non-grafted sites declared funding from the companies manufacturing the graft substitutes. On the other hand, RCTs and non-RCTs evaluating PROMs after soft tissue augmentation with autogenous grafts only were self-supported. Furthermore, several studies were considered to have moderate or high risk of bias.

Additionally, the heterogeneity observed in the treatment arms, outcomes of interest and method of assessing PROMs prevented from performing a statistical analysis. Lastly, although a thorough search strategy was employed, it may still be possible that some relevant literature was not identified in the search process.

6 | RECOMMENDATION FOR FUTURE RESEARCH

Given the importance of incorporating PROMs in clinical studies, the present review can provide recommendations for future studies. Questionnaires including dichotomous questions and 1–10 VASs are advocated to evaluate PROMs. VAS represents a valid tool for capturing patient perception of the treatment, allowing also the comparison of the outcomes of interest among different studies. Similarly, the use of OHIP-14 has also been suggested to measure the impact of the treatment on quality of life (Slade, 1997), with several recent trials that have incorporated this questionnaire in periodontal and peri-implant plastic surgeries (De Bruyckere et al., 2020; Huber et al., 2018; Thoma et al., 2020; Tonetti et al., 2018).

For further uniformity and standardization of subjective patients-reported outcomes with specific to soft tissue procedures, we recommend using questionnaire depicted in Figure 3. Aesthetic is evaluated prior to the surgical procedure and at the last follow up (at least 6 months) using a 1–10 VAS. Post-operative pain is evaluated in the first 10 days after the surgical procedure using a 1–10 VAS. Presence of swelling, bruising/haematoma and the number of days with swelling are also assessed. The number of days for recovery is defined as the days with post-operative pain >0. At the last follow-up visit (at least 6 months), aesthetics is evaluated both using a 1–10 VAS and also asking the patient the following question: "How much do you think that your aesthetics has improved compared to baseline?" Lastly, treatment satisfaction and quality of life are assessed using a 1–10 VAS. The proposed recommended methods for assessment of soft tissue grafting procedures-related subjective outcomes measures can be utilized alone or in combination with the OHIP-14 questionnaire.

Based on the available evidence, the following conclusions can be drawn:

1. PROMs represent a crucial endpoint of clinical studies evaluating the outcomes of soft tissue grafts at implant sites and can be captured with questionnaires including dichotomous or open questions, VAS or OHIP-14.
2. Most of the studies did not find significant differences in terms of patient morbidity and painkillers between autogenous grafts and XCM/ADM. Nevertheless, a trend towards lower post-operative discomfort was observed for graft substitutes.
3. High scores for patient satisfaction and aesthetic evaluation were observed in all the interventions. Weak evidence suggests that CTG-treated sites may be rated by patients with higher aesthetic outcomes compared to non-grafted sites.

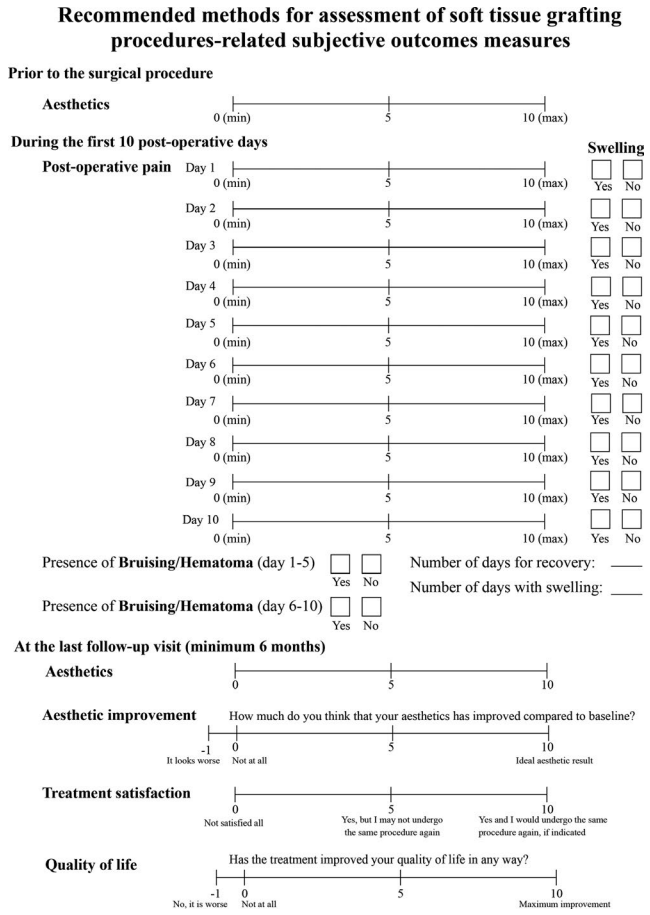


FIGURE 3 Recommended methods for assessment of soft tissue grafting procedures-related subjective outcomes measures

4. Limited evidence supported the observation that soft tissue grafting at implant sites has a positive impact on oral health-related quality of life
5. Further studies investigating peri-implant soft tissue augmentation incorporating PROMs are needed to validate these findings and to further compare different graft materials.

CONFLICT OF INTEREST

The authors do not have any financial interests, either directly or indirectly, in the products or information enclosed in the paper.

AUTHOR CONTRIBUTIONS

M. Stefanini: Design of the study, study registration, interpretation of data, manuscript preparation and the initial draft and final review of the work; accountable for all aspects of the work. **L. Tavelli:** Design of the study, study registration, acquisition and interpretation of data, manuscript preparation and the initial draft and final review of the work; accountable for all aspects of the work. **S. Barootchi:** Acquisition and interpretation of data, manuscript preparation and the initial draft and final review of the work; accountable for all aspects of the work. **M. Sangiorgi:** Design of the study, study registration, interpretation of data, manuscript preparation and the initial draft and final review of the work; accountable for all aspects of the work. **G. Zucchelli:** Design of the study, critical review of the draft and contribution to the writing of the manuscript. Final approval of the version to be published and accountable to the accuracy or integrity of the work.

ORCID

Martina Stefanini https://orcid.org/0000-0002-9154-637X
Lorenzo Tavelli https://orcid.org/0000-0003-4864-3964
Shayan Barootchi https://orcid.org/0000-0002-5347-6577

REFERENCES

Anderson, L. E., Inglehart, M. R., El-Kholy, K., Eber, R., & Wang, H. L. (2014). Implant associated soft tissue defects in the anterior maxilla: a randomized control trial comparing subepithelial connective tissue graft and acellular dermal matrix allograft. *Implant Dent*, *23*(4), 416–425. https://doi.org/10.1097/id.0000000000000122

Aroca, S., Molnar, B., Windisch, P., Gera, I., Salvi, G. E., Nikolidakis, D., & Sculean, A. (2013). Treatment of multiple adjacent Miller class I and II gingival recessions with a Modified Coronally Advanced Tunnel (MCAT) technique and a collagen matrix or palatal connective tissue graft: a randomized, controlled clinical trial. *Journal of Clinical Periodontology*, *40*(7), 713–720. https://doi.org/10.1111/jcpe.12112

Baldi, N., Buti, J., Mensi, M., Alfonsi, F., Cinquini, C., Tonelli, P., & Barone, A. (2020). Xenogeneic dermal matrix versus autologous connective tissue graft versus no graft at abutment connection for improving aesthetics: 6-month outcomes of a randomised controlled trial. *Clinical Trials in Dentistry*, *02*(2), 49–62.

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. *Clin Oral Investig*, *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., Armitage, G., Araujo, M. G., Avila-Ortiz, G., Blanco, J., Camargo, P. M., Chen, S., Cochran, D., Derks, J., Figuero, E., Hämmerle, C. H. F., Heitz-Mayfield, L. J. A., Huynh-Ba, G., Iacono, V., Koo, K.-T., Lambert, F., McCauley, L., Quirynen, M., Renvert, S., … Zitzmann, N. (2018). Peri-implant diseases and conditions: Consensus report of workgroup 4 of the 2017 World Workshop on the Classification of Periodontal and Peri-Implant Diseases and Conditions. *Journal of Clinical Periodontology*, *45*(Suppl 20), S286–S291. https://doi.org/10.1111/jcpe.12957

Bianchi, A. E., & Sanfilippo, F. (2004). Single-tooth replacement by immediate implant and connective tissue graft: a 1–9-year clinical evaluation. *Clinical Oral Implants Research*, *15*(3), 269–277. https://doi.org/10.1111/j.1600-0501.2004.01020.x

Buser, D., Sennerby, L., & De Bruyn, H. (2017). Modern implant dentistry based on osseointegration: 50 years of progress, current trends and open questions. *Periodontology 2000*, *73*(1), 7–21. https://doi.org/10.1111/prd.12185

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

Cairo, F., Barbato, L., Tonelli, P., Batalocco, G., Pagavino, G., & Nieri, M. (2017). Xenogeneic collagen matrix versus connective tissue graft for buccal soft tissue augmentation at implant site. A randomized, controlled clinical trial. *Journal of Clinical Periodontology*, *44*(7), 769–776. https://doi.org/10.1111/jcpe.12750

Cairo, F., Barootchi, S., Tavelli, L., Barbato, L., Wang, H. L., Rasperini, G., Graziani, F. & Tonetti, M. (2020). Esthetic- and patient-related outcomes following root coverage procedures: A systematic review and network meta-analysis. *Journal of Clinical Periodontology*, *47*(11), 1403–1415. https://doi.org/10.1111/jcpe.13346

Cairo, F., Pagliaro, U., & Nieri, M. (2008). Soft tissue management at implant sites. *Journal of Clinical Periodontology*, *35*(8 Suppl), 163–167. https://doi.org/10.1111/j.1600-051X.2008.01266.x

De Bruyckere, T., Cosyn, J., Younes, F., Hellyn, J., Bekx, J., Cleymaet, R., & Eghbali, A. (2020). A randomized controlled study comparing guided bone regeneration with connective tissue graft to re-establish buccal convexity: One-year aesthetic and patient-reported outcomes. *Clinical Oral Implants Research*, *31*(6), 507–516. https://doi.org/10.1111/clr.13587

Feine, J., Abou-Ayash, S., Al Mardini, M., Santana, R. B., Bjelke-Holtermann, T., Bornstein, M. M., Braegger, U., Cao, O., Cordaro, L., Eycken, D., Fillion, M., Gebran, G., Huynh-Ba, G., Joda, T., Levine, R., Mattheos, N., Oates, T. W., Abd-Ul-Salam, H., Santosa, R., … Zubiria, J. P. V. (2018). Group 3 ITI Consensus Report: Patient-reported outcome measures associated with implant dentistry. *Clinical Oral Implants Research*, *29*(Suppl 16), 270–275. https://doi.org/10.1111/clr.13299

Fenner, N., Hammerle, C. H., Sailer, I., & Jung, R. E. (2016). Long-term clinical, technical, and esthetic outcomes of all-ceramic vs. titanium abutments on implant supporting single-tooth reconstructions after at least 5 years. *Clinical Oral Implants Research*, *27*(6), 716–723. https://doi.org/10.1111/clr.12654

Froum, S., Khouly, I., Tarnow, D., Froum, S., Rosenberg, E., Corby, P., Kye, W., Elian, N., Schoor, R., & Cho, S.-C. (2015). The use of a xenogeneic collagen matrix at the time of implant placement to increase the volume of buccal soft tissue. *International Journal of Periodontics and Restorative Dentistry*, *35*(2), 179–189. https://doi.org/10.11607/prd.2226

Gargallo-Albiol, J., Barootchi, S., Tavelli, L., & Wang, H. L. (2019). Efficacy of xenogeneic collagen matrix to augment peri-implant soft tissue thickness compared to autogenous connective tissue graft: A systematic review and meta-analysis. *International Journal of Oral and Maxillofacial Implants*, *34*(5), 1059–1069. https://doi.org/10.11607/jomi.7497

Gobbato, L., Avila-Ortiz, G., Sohrabi, K., Wang, C. W., & Karimbux, N. (2013). The effect of keratinized mucosa width on peri-implant health: A systematic review. *International Journal of Oral and Maxillofacial Implants*, *28*(6), 1536–1545. https://doi.org/10.11607/jomi.3244

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*, https://doi.org/10.1136/bmj.d5928

Hosseini, M., Worsaae, N., & Gotfredsen, K. (2020). Tissue changes at implant sites in the anterior maxilla with and without connective tissue grafting: A five-year prospective study. *Clinical Oral Implants Research*, *31*(1), 18–28. https://doi.org/10.1111/clr.13540

Huber, S., Zeltner, M., Hämmerle, C. H. F., Jung, R. E., & Thoma, D. S. (2018). Non-interventional 1-year follow-up study of peri-implant soft tissues following previous soft tissue augmentation and crown insertion in single-tooth gaps. *Journal of Clinical Periodontology*, *45*(4), 504–512. https://doi.org/10.1111/jcpe.12865

Hutton, C. G., Johnson, G. K., Barwacz, C. A., Allareddy, V., & Avila-Ortiz, G. (2018). Comparison of two different surgical approaches to increase peri-implant mucosal thickness: A randomized controlled clinical trial. *Journal of Periodontology*, *89*(7), 807–814. https://doi.org/10.1002/JPER.17-0597

Jung, R. E., Sailer, I., Hammerle, C. H., Attin, T., & Schmidlin, P. (2007). In vitro color changes of soft tissues caused by restorative materials. *International Journal of Periodontics & Restorative Dentistry*, *27*(3), 251–257.

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

Kiyak, H. A., Hohl, T., West, R. A., & McNeill, R. W. (1984). Psychologic changes in orthognathic surgery patients: a 24-month follow up. *Journal of Oral and Maxillofacial Surgery*, *42*(8), 506–512. https://doi.org/10.1016/0278-2391(84)90009-0

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

Lin, G. H., Chan, H. L., & Wang, H. L. (2013). The significance of keratinized mucosa on implant health: A systematic review. *Journal of Periodontology*, *84*(12), 1755–1767. https://doi.org/10.1902/jop.2013.120688

Lops, D., Stellini, E., Sbricoli, L., Cea, N., Romeo, E., & Bressan, E. (2017). Influence of abutment material on peri-implant soft tissues in anterior areas with thin gingival biotype: a multicentric prospective study. *Clinical Oral Implants Research*, *28*(10), 1263–1268. https://doi.org/10.1111/clr.12952

Lorenzo, R., Garcia, V., Orsini, M., Martin, C., & Sanz, M. (2012). Clinical efficacy of a xenogeneic collagen matrix in augmenting keratinized mucosa around implants: a randomized controlled prospective clinical trial. *Clinical Oral Implants Research*, *23*(3), 316–324. https://doi.org/10.1111/j.1600-0501.2011.02260.x

Mazzotti, C., Stefanini, M., Felice, P., Bentivogli, V., Mounssif, I., & Zucchelli, G. (2018). Soft-tissue dehiscence coverage at peri-implant sites. *Periodontology 2000*, *77*(1), 256–272. https://doi.org/10.1111/prd.12220

McGuire, M. K., Scheyer, E. T., & Gwaltney, C. (2014). Commentary: incorporating patient-reported outcomes in periodontal clinical trials. *Journal of Periodontology*, *85*(10), 1313–1319. https://doi.org/10.1902/jop.2014.130693

Migliorati, M., Amorfini, L., Signori, A., Biavati, A. S., & Benedicenti, S. (2015). Clinical and aesthetic outcome with post-extractive implants with or without soft tissue augmentation: A 2-year randomized clinical trial. *Clinical Implant Dentistry and Related Research*, *17*(5), 983–995. https://doi.org/10.1111/cid.12194

Moola, S., Munn, Z., Tufanaru, C., Aromataris, E., Sears, K., Sfetcu, R., Currie, M., Lisy, K., Qureshi, R., Mattis, P., & Mu, P.-F. (2017). Systematic reviews of etiology and risk. In E. Aromataris, & Z. Munn (Ed.). *JBI Manual for evidence synthesis*. Joanna Briggs Institute Reviewer's Manual. The Joanna Briggs Institute.

Papaspyridakos, P., Chen, C. J., Singh, M., Weber, H. P., & Gallucci, G. O. (2012). Success criteria in implant dentistry: A systematic review. *Journal of Dental Research*, *91*(3), 242–248. https://doi.org/10.1177/0022034511431252

Pietruska, M., Skurska, A., Podlewski, L., Milewski, R., & Pietruski, J. (2019). Clinical evaluation of Miller class I and II recessions treatment with the use of modified coronally advanced tunnel technique with either collagen matrix or subepithelial connective tissue graft: A randomized clinical study. *Journal of Clinical Periodontology*, *46*(1), 86–95. https://doi.org/10.1111/jcpe.13031

Poskevicius, L., Sidlauskas, A., Galindo-Moreno, P., & Juodzbalys, G. (2017). Dimensional soft tissue changes following soft tissue grafting in conjunction with implant placement or around present dental implants: a systematic review. *Clinical Oral Implants Research*, *28*(1), 1–8. https://doi.org/10.1111/clr.12606

Roccuzzo, M., Dalmasso, P., Pittoni, D., & Roccuzzo, A. (2018). Treatment of buccal soft tissue dehiscence around single implant: 5-year results from a prospective study. *Clinical Oral Investigations*, *23*(4), 1977–1983. https://doi.org/10.1007/s00784-018-2634-4

Roccuzzo, M., Dalmasso, P., Pittoni, D., & Roccuzzo, A. (2019). Treatment of buccal soft tissue dehiscence around single implant: 5-year results from a prospective study. *Clinical Oral Investigations*, *23*(4), 1977–1983. https://doi.org/10.1007/s00784-018-2634-4

Roccuzzo, M., Gaudioso, L., Bunino, M., & Dalmasso, P. (2014). Surgical treatment of buccal soft tissue recessions around single implants: 1-year results from a prospective pilot study. *Clinical Oral Implants Research*, *25*(6), 641–646. https://doi.org/10.1111/clr.12149

Roccuzzo, M., Grasso, G., & Dalmasso, P. (2016). Keratinized mucosa around implants in partially edentulous posterior mandible: 10-year results of a prospective comparative study. *Clinical Oral Implants Research*, *27*(4), 491–496. https://doi.org/10.1111/clr.12563

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

Santos, F. (2018). KappaGUI: An R-Shiny Application for Calculating Cohen's and Fleiss' Kappa. R package version 2.0.2. https://CRAN.R-project.org/package=KappaGUI

Schallhorn, R. A., McClain, P. K., Charles, A., Clem, D., & Newman, M. G. (2015). Evaluation of a porcine collagen matrix used to augment keratinized tissue and increase soft tissue thickness around existing dental implants. *International Journal of Periodontics and Restorative Dentistry*, *35*(1), 99–103. https://doi.org/10.11607/prd.1888

Slade, G. D. (1997). Derivation and validation of a short-form oral health impact profile. *Community Dentistry and Oral Epidemiology*, *25*(4), 284–290. https://doi.org/10.1111/j.1600-0528.1997.tb00941.x

Stefanini, M., Felice, P., Mazzotti, C., Mounssif, I., Marzadori, M., & Zucchelli, G. (2018). Esthetic evaluation and patient-centered outcomes in single-tooth implant rehabilitation in the esthetic area. *Periodontology 2000*, *77*(1), 150–164. https://doi.org/10.1111/prd.12215

Stefanini, M., Marzadori, M., Tavelli, L., Bellone, P., & Zucchelli, G. (2020). Peri-implant Papillae reconstruction at an esthetically failing implant. *International Journal of Periodontics & Restorative Dentistry*, *40*(2), 213–222. https://doi.org/10.11607/prd.4296

Sterne, J. A. C., Hernán, M. A., Reeves, B. C., Savović, J., Berkman, N. D., Viswanathan, M., Henry, D., Altman, D. G., Ansari, M. T., Boutron, I., Carpenter, J. R., Chan, A.-W., Churchill, R., Deeks, J. J., Hróbjartsson, A., Kirkham, J., Jüni, P., Loke, Y. K., Pigott, T. D., … Higgins, J. P. T. (2016). ROBINS-I: a tool for assessing risk of bias in non-randomised studies of interventions. *BMJ*, *355*, https://doi.org/10.1136/bmj.i4919

Stillwell, S. B., Fineout-Overholt, E., Melnyk, B. M., & Williamson, K. M. (2010). Evidence-based practice, step by step: asking the clinical question: a key step in evidence-based practice. *American Journal of Nursing*, *110*(3), 58–61. https://doi.org/10.1097/01.NAJ.0006868959.11129.79

Suarez-Lopez Del Amo, F., Lin, G. H., Monje, A., Galindo-Moreno, P., & Wang, H. L. (2016). Influence of soft tissue thickness on peri-implant marginal bone loss: a systematic review and meta-analysis. *Journal of Periodontology*, *87*(6), 690–699. https://doi.org/10.1902/jop.2016.150571

Tavelli, L., Asa'ad, F., Acunzo, R., Pagni, G., Consonni, D., & Rasperini, G. (2018). Minimizing patient morbidity following palatal gingival harvesting: a randomized controlled clinical study. *International Journal of Periodontics & Restorative Dentistry*, *38*(6), e127–e134. https://doi.org/10.11607/prd.3581

Tavelli, L., Barootchi, S., Avila-Ortiz, G., Urban, I. A., Giannobile, W. V., & Wang, H. L. (2020). 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

Tavelli, L., Barootchi, S., Di Gianfilippo, R., Kneifati, A., Majzoub, J., Stefanini, M., Zucchelli, G., & Wang, H.-L. (2020). Patient experience of autogenous soft tissue grafting has an implication for future treatment: A 10 to 15-year cross-sectional study. *Journal of Periodontology*, *92*(5), 637–647. https://doi.org/10.1002/JPER.20-0350

Tavelli, L., Barootchi, S., Di Gianfilippo, R., Modarressi, M., Cairo, F., Rasperini, G., & Wang, H. L. (2019). Acellular dermal matrix and coronally advanced flap or tunnel technique in the treatment of multiple adjacent gingival recessions. A 12-year follow-up from a randomized clinical trial. *Journal of Clinical Periodontology*, *46*(9), 937–948. https://doi.org/10.1111/jcpe.13163

Tavelli, L., Barootchi, S., Majzoub, J., Chan, H. L., Giannobile, W. V., Wang, H. L., & Kripfgans, O. D. (2021). Ultrasonographic tissue perfusion analysis at implant and palatal donor sites following soft tissue augmentation: A clinical pilot study. *Journal of Clinical Periodontology*, *48*(4), 602–614. https://doi.org/10.1111/jcpe.13424

Tavelli, L., McGuire, M. K., Zucchelli, G., Rasperini, G., Feinberg, S. E., Wang, H. L., & Giannobile, W. V. (2020). Extracellular matrix-based scaffolding technologies for periodontal and peri-implant soft tissue regeneration. *Journal of Periodontology*, *91*(1), 17–25. https://doi.org/10.1002/JPER.19-0351

Tavelli, L., Ravida, A., Saleh, M. H. A., Maska, B., Del Amo, F. S., Rasperini, G., & Wang, H. L. (2019). Pain perception following epithelialized gingival graft harvesting: A randomized clinical trial. *Clinical Oral Investigations*, *23*(1), 459–468. https://doi.org/10.1007/s00784-018-2455-5

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., Gasser, T. J. W., Jung, R. E., & Hammerle, C. H. F. (2020). Randomized controlled clinical trial comparing implant sites augmented with a volume-stable collagen matrix or an autogenous connective tissue graft: 3-year data after insertion of reconstructions. *Journal of Clinical Periodontology*, *47*(5), 630–639. https://doi.org/10.1111/jcpe.13271

Thoma, D. S., Mühlemann, S., & Jung, R. E. (2014). Critical soft-tissue dimensions with dental implants and treatment concepts. *Periodontology 2000*, *66*(1), 106–118. https://doi.org/10.1111/prd.12045

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., Zeltner, M., Hilbe, M., Hammerle, C. H., Husler, J., & Jung, R. E. (2016). Randomized controlled clinical study evaluating effectiveness and safety of a volume-stable collagen matrix compared to autogenous connective tissue grafts for soft tissue augmentation at implant sites. *Journal of Clinical Periodontology*, *43*(10), 874–885. https://doi.org/10.1111/jcpe.12588

Tonetti, M. S., Cortellini, P., Pellegrini, G., Nieri, M., Bonaccini, D., Allegri, M., Bouchard, P., Cairo, F., Conforti, G., Fourmousis, I., Graziani, F., Guerrero, A., Halben, J., Malet, J., Rasperini, G., Topoll, H., Wachtel, H., Wallkamm, B., Zabalegui, I., & Zuhr, O. (2018). Xenogenic collagen matrix or autologous connective tissue graft as adjunct to coronally advanced flaps for coverage of multiple adjacent gingival recession: Randomized trial assessing non-inferiority in root coverage and superiority in oral health-related quality of life. *Journal of Clinical Periodontology*, *45*(1), 78–88. https://doi.org/10.1111/jcpe.12834

Vellis, J., Kutkut, A., & Al-Sabbagh, M. (2019). Comparison of xenogeneic collagen matrix vs. free gingival grafts to increase the zone of keratinized mucosa around functioning implants. *Implant Dentistry*, *28*(1), 20–27. https://doi.org/10.1097/ID.0000000000000842

Wennstrom, J. L., & Derks, J. (2012). Is there a need for keratinized mucosa around implants to maintain health and tissue stability? *Clinical Oral Implants Research*, *23*(Suppl 6), 136–146. https://doi.org/10.1111/j.1600-0501.2012.02540.x

Wiesner, G., Esposito, M., Worthington, H., & Schlee, M. (2010). Connective tissue grafts for thickening peri-implant tissues at implant placement. One-year results from an explanatory split-mouth randomised controlled clinical trial. *European Journal of Oral Implantology*, *3*(1), 27–35.

Zucchelli, G., Felice, P., Mazzotti, C., Marzadori, M., Mounssif, I., Monaco, C., & Stefanini, M. (2018). 5-year outcomes after coverage of soft tissue dehiscence around single implants: A prospective cohort study. *European Journal of Oral Implantology*, *11*(2), 215–224.

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., Mele, M., Stefanini, M., Mazzotti, C., Marzadori, M., Montebugnoli, L., & de Sanctis, M. (2010). Patient morbidity and root coverage outcome after subepithelial connective tissue and de-epithelialized grafts: a comparative randomized-controlled clinical trial. *Journal of Clinical Periodontology*, *37*(8), 728–738. https://doi.org/10.1111/j.1600-051X.2010.01550.x

Zucchelli, G., Tavelli, L., McGuire, M. K., Rasperini, G., Feinberg, S. E., Wang, H. L., & Giannobile, W. V. (2020). Autogenous soft tissue grafting for periodontal and peri-implant plastic surgical reconstruction. *Journal of Periodontology*, *91*(1), 9–16. https://doi.org/10.1002/JPER.19-0350

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

SUPPORTING INFORMATION

Additional supporting information may be found in the online version of the article at the publisher's website.

How to cite this article: Stefanini M, Tavelli L, Barootchi S, Sangiorgi M, Zucchelli G. Patient-reported outcome measures following soft-tissue grafting at implant sites: A systematic review. *Clin Oral Impl Res*. 2021;32(Suppl. 21): 157–173. https://doi.org/10.1111/clr.13767