

Efficacy of soft tissue augmentation around dental implants and in partially edentulous areas: a systematic review

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Thoma DS, Buranawat B, Hämmerle CHF, Held U, Jung RE. Efficacy of soft tissue augmentation around dental implants and in partially edentulous areas: A systematic review. *J Clin Periodontol* 2014; 41 (Suppl. 15): S77–S91. doi: 10.1111/jcpe.12220.

Abstract

Aim: To review the dental literature in terms of efficacy of soft tissue augmentation procedures around dental implants and in partially edentulous sites.

Methods: A Medline search was performed for human studies augmenting keratinized mucosa (KM) and soft tissue volume around implants and in partially edentulous areas. Due to heterogeneity in between the studies, no meta-analyses could be performed.

Results: Nine (KM) and eleven (volume) studies met the inclusion criteria. An apically positioned flap/ vestibuloplasty (APF/V) plus a graft material [free gingival graft (FGG)/subepithelial connective tissue graft (SCTG)/collagen matrix (CM)] resulted in an increase of keratinized tissue (1.4–3.3 mm). Statistically significantly better outcomes were obtained for APF/V plus FGG/SCTG compared with controls (APF/V alone; no treatment) ($p < 0.05$). For surgery time and patient morbidity, statistically significantly more favourable outcomes were reported for CM compared to SCTGs ($p < 0.05$) in two randomized controlled clinical trials (RCTs), even though rendering less keratinized tissue. SCTGs were the best-documented method for gain of soft tissue volume at implant sites and partially edentulous sites. Aesthetically at immediate implant sites, better papilla fill and higher marginal mucosal levels were obtained using SCTGs compared to non-grafted sites.

Conclusions: An APF/V plus FGG/SCTG was the best-documented and most successful method to increase the width of KM. APF/V plus CM demonstrated less gain in KM, but also less patient morbidity and surgery time compared to APF/V plus SCTG based on two RCTs. Autogenous grafts (SCTG) rendered an increase in soft tissue thickness and better aesthetics compared to non-grafted sites.

Key words: allogenic dermal matrix graft; collagen matrix; dental implant; free gingival graft; keratinized tissue; soft tissue augmentation; soft tissue volume; subepithelial connective tissue graft; vestibuloplasty

Accepted for publication 24 November 2013

Conflict of interest and source of funding statement

This review was funded by the Clinic of Fixed and Removable Prosthodontics and Dental Material Science, University of Zurich. Dres. Hämmerle, Jung and Thoma have received lecture fees from Geistlich Pharma AG, Wolhusen, Switzerland and are member (Jung, Thoma) of the Osteology Foundation Expert Council or president (Hämmerle) of the Osteology Foundation. Other than mentioned, the authors do not report any conflict of interest for this study.

Plastic periodontal procedures to augment keratinized tissue and to increase soft tissue volume are well described (Cairo et al. 2008, Thoma et al. 2009). These procedures are indicated to establish functional and biological stability around teeth and implants, mainly in conjunction with reconstructive therapy. The question whether there is a need for keratinized tissue to maintain periodontal health around teeth and peri-implant health around dental implants has been controversially discussed in the literature citing a number of parameters to be considered: (i) establishment and maintenance of biological health; (ii) prevention of recession; (iii) aesthetics; and (iv) cleansability of the reconstruction (Hoelscher & Simons 1994, Marquez 2004, Mehta & Lim 2010, Wennstrom & Derks 2012). For dental implants, clinical evidence suggests that a lack of keratinized mucosa (KM) may not be crucial in maintaining the health of peri-implant soft tissues (Wennstrom et al. 1994), may not be associated with more bone loss (Chung et al. 2006) or that despite the presence of KM, peri-implantitis may occur (Roos-Jansaker et al. 2006). In contrast, more recent clinical studies concluded that a wider zone of KM may better preserve soft and hard tissue stability (Bouri et al. 2008), may be more favourable for the long-term maintenance of dental implants (Kim et al. 2009) and that a lack of KM may result in poorer oral hygiene and greater soft tissue recession (Schrott et al. 2009). This resulted in a clinical recommendation of 2 mm for the width of KM (Bengazi et al. 1996, Adibrad et al. 2009), a dimension similar to the zone of keratinized gingiva recommended to be adequate around teeth (Lang & Loe 1972). Treatment-wise, plastic procedures to augment keratinized tissue include an apically positioned flap or a vestibuloplasty procedure (Palacci & Nowzari 2008, Thoma et al. 2009). This can be performed prior to implant placement, simultaneously with second stage surgery or post insertion of the final reconstruction. Moreover, to compensate for hard and soft tissue deficits in localized defects, soft tissue volume augmentation is mainly indicated for aesthetic reasons and to facilitate oral hygiene in pontic areas

(Seibert 1983a, Pini-Prato et al. 2004). In these sites, the classic procedures include the use of free gingival grafts (FGG), subepithelial connective grafts (SCTG) and various types of roll and pedicle flaps (Seibert 1983b, Cho 1998, Studer et al. 2000, Batista et al. 2001, Breault et al. 2004). In conjunction with dental implants, plastic augmentative procedures were recommended to enhance the thickness of the soft tissues simultaneously with implant placement or during the healing phase of the implants (Grunder 2000, Speroni et al. 2010, Schneider et al. 2011). Clinical studies demonstrated various techniques to be successful, resulting in greater flexibility for the choice of the reconstruction material, better aesthetic outcomes with respect to the colour of the peri-implant tissues, maintenance or even improvement of the marginal mucosal height and higher papillae scores (Cornelini et al. 2008, Jung et al. 2008, Kan et al. 2009, Speroni et al. 2010). From a functional point of view, however, there is still a lack of scientific evidence whether thicker peri-implant soft tissues result in better long-term success and survival rates of dental implants.

Since controversy still exists with respect to the efficacy of soft tissue augmentation and new materials were evaluated more recently, there is a strong need to critically assess the dental literature for optimized procedures and graft materials in terms of soft tissue augmentation.

Therefore, the aim of the present systematic review was to assess dental literature focusing on the efficacy of soft tissue augmentation procedures to increase the width of the KM around dental implants and to increase the soft tissue volume around implants and in partially edentulous areas.

Materials and Methods

Protocol development and eligibility criteria

A detailed protocol was developed and followed according to the PRISMA (Preferred Reporting Items for Systematic Review and Meta-Analyses) statement (Liberati et al. 2009, Moher et al. 2009).

Focused question

What is the efficacy of different soft tissue augmentation methods in terms of (i) increasing the width of KM and (ii) gain in soft tissue volume around implants and in partially edentulous areas?

Search strategy

A Medline (PubMed) search was performed for human studies, including articles published from 1 January 1966 up to 15 May 2013 in the dental literature. The search was limited to the English and German language. The search was complemented by manual searches of the reference list of all selected full-text articles. In addition, full text articles of reviews published in the same time period were obtained. An additional hand search was performed searching for relevant studies by screening these reviews.

Search terms

The following search terms were selected: "acellular dermal matrix" OR "dermal matrix allograft" OR "allograft" OR "keratinized gingiva" OR "keratinized tissue" OR "soft tissue graft" OR "subepithelial connective tissue graft" OR "connective tissue" OR "FGG" OR "human fibroblast-derived dermal substitute" OR "dermagraft" OR "apligraf" OR "collagen matrix" OR "extracellular membrane" OR "gingival autograft" OR "attached gingiva" OR "attached mucosa" OR "KM" OR "soft tissue augmentation" OR "soft tissue transplantation" OR "vestibuloplasty" OR "ridge augmentation" OR "soft tissue correction" OR "apically positioned flap" AND "dental implants" OR "Jaw, Edentulous, Partially" OR "pontic" (all MeSH terms).

The search was limited to language (English, German), "human trial" (MeSH term, clinical studies), and "Dental Journals". In addition, the MeSH terms: "case reports", "clinical trial", "comparative study", "controlled clinical trial (CCT)", "randomized controlled clinical trial (RCT)", "meta-analysis", "review" and "systematic reviews" were used.

Inclusion criteria

The applied inclusion criteria for studies dealing with gain of KM or

gain of soft tissue volume were as follows:

Increase in width of keratinized mucosa

Any case series, cohort study, CCT and RCT with at least five patients was included. A follow-up period of at least 3 months was required for the primary outcome "gain in KM". The reported treatment outcomes had to include either clinical and/or histological measures of the width of KM. The primary outcome of the studies had to be localized gain in width of KM.

Augmentation of soft tissue volume around dental implant and in partially edentulous areas

For studies focusing on soft tissue volume gain, any prospective case series, cohort study, CCT and RCT with at least five patients was included. The minimal follow-up time was 3 months for the primary outcome "gain in soft tissue volume". The reported treatment outcomes had to include either clinical and/or histological measures of the soft tissue volume.

The minimal follow-up time (3 months) for the primary outcome variables chosen in this systematic review is based on a lack of a scientific data with long-term results and in line with a previously published systematic review (Thoma et al. 2009).

Exclusion criteria

Studies not meeting all inclusion criteria were excluded from the review. Publications dealing with the following topics were also excluded: *in vitro* studies, pre-clinical (animal) studies, studies dealing with the treatment of recession defects, studies augmenting keratinized tissue around teeth only, studies augmenting soft tissue in fully edentulous patients, studies where the effect of soft tissue augmentation surgery could not be extracted from the data (e.g. combination of guided bone regeneration and soft tissue augmentation).

Selection of studies

Titles derived from this broad search were independently screened by two authors (DT, BB) based on the inclu-

sion criteria. Disagreements were resolved by discussion. Cohen's Kappa-coefficient was used as a measure of agreement between the two readers. Following this, abstracts of all titles agreed on by both authors were obtained, and screened for meeting the inclusion criteria. If no abstract was available in the database, the abstract of the printed article was used. The selected articles were then obtained in full text. If title and abstract did not provide sufficient information regarding the inclusion criteria, the full report was obtained as well. Again, disagreements were resolved by discussion.

Finally, the selection based on inclusion/exclusion criteria was made for the full text articles. For this purpose, Material and Methods and Results of these studies were screened. This step was again carried out independently by two readers. Disagreements were resolved by discussion.

Data extraction

Two reviewers independently extracted the data using data extraction tables. Any disagreements were resolved by discussion aiming for consensus.

Quality assessment

A quality assessment of the included RCTs and controlled clinical studies was performed independently by two reviewers (BB, DTH) according to the Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0 (updated March 2011) (Higgins & Green 2011). Three main quality criteria were assessed: allocation concealment, blinding treatment outcomes to outcome examiners and completeness of follow-up. The studies were then rated to have a low risk of bias (all three criteria met) or a high risk of bias (one or more criteria not met).

Statistical analysis

Means and standard deviations were calculated for a number of outcome parameters. No meta-analyses could be performed due to heterogeneity in between the studies (different indications, study designs, control groups, observation periods).

Results

Study characteristics

The electronic search identified a total of 2396 titles (for details, refer to Fig. 1). From assessing the titles, 2283 were excluded (inter-reader agreement $k = 0.98 \pm 0.48$). The resulting number of abstracts obtained was 113, of which 83 were excluded (inter-reader agreement $k = 0.98 \pm 0.25$). Thirty full-text articles were obtained, seven articles were further excluded after reading the full text. Finally, including studies found through hand searching, nine studies of keratinized tissue and 11 studies of soft tissue volume articles met the inclusion criteria.

Exclusion of studies

The reasons for excluding studies (7) after full text was obtained were no reported or insufficient clinical details ($n = 3$), an insufficient number of patients ($n = 1$), only hard tissue augmentation ($n = 2$) and soft tissue augmentation in combination with implant placement and guided bone regeneration ($n = 1$). Details are provided in Table 1.

Included studies

The 20 studies that met the inclusion criteria are presented in Tables 2–5. Tables 2 and 4 represent data for "gain of keratinized tissue" (nine studies) and Tables 3 and 5 refer to clinical studies regarding "soft tissue volume" (11 studies).

Increase in width of keratinized mucosa

Patient-based treatment outcomes for the width of keratinized tissue retrieved from nine studies are presented in Tables 2 and 4. Three studies were designed as RCT, two as CCT and the rest of four studies were case series reports. 283 patients and 375 sites were treated for gain of keratinized tissue around the implants. The methods and techniques used for gain of keratinized tissue included no treatment, vestibuloplasty, apically positioned flap/vestibuloplasty (APF/V) in combination with autogenous tissues FGG, SCTG and APF/V in combination with allogenic grafts (ADMG) or collagen matrices (CM). The mean follow-up period was

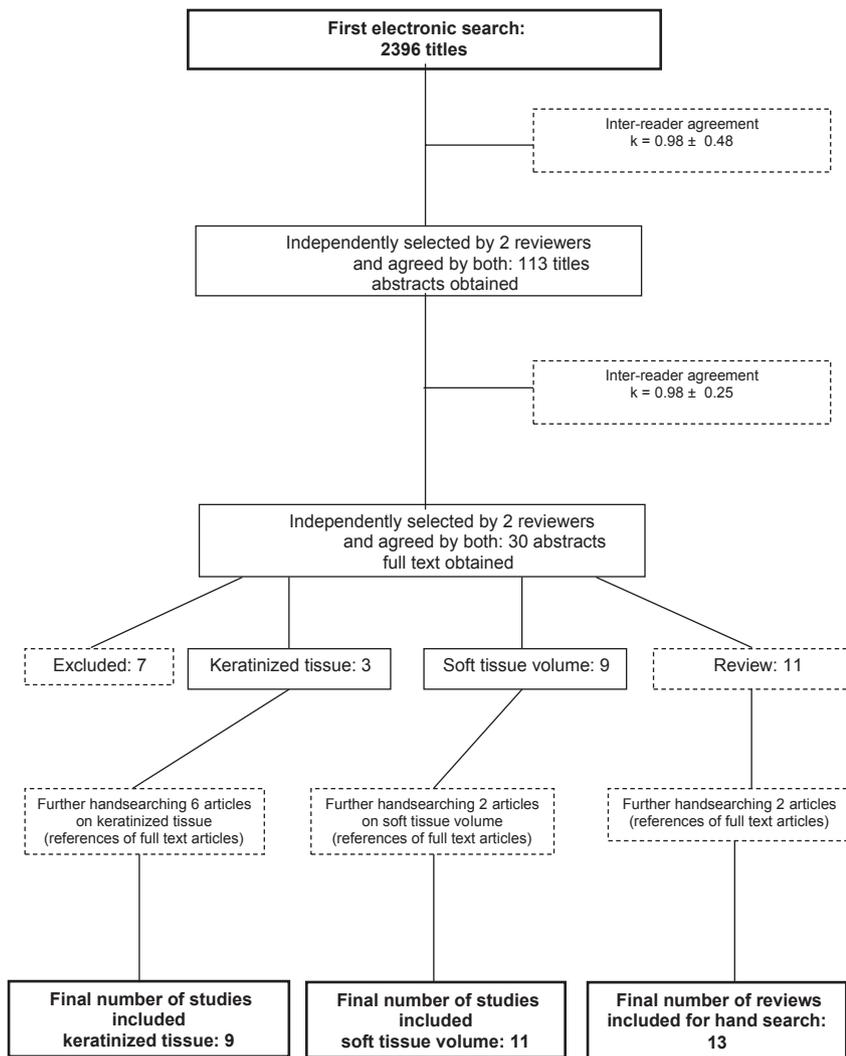


Fig. 1. Search strategy.

Table 1. Excluded studies with reason for exclusion

Author	Reason for exclusion
Alpert (1994)	Only descriptive, no data
Becker (2001)	Hard tissue only
Bidra & Rungruanunt (2011)	Two cases only
Collins & Nunn (1994)	Hard tissue augmentation only
Fagan et al. (2008)	No data, immediate implant placement and soft tissue augmentation at the same time
Kwakman et al. (1998)	No detailed information about procedures
Liu & Weisgold (2002)	No data, only classifications

16.2 months (6–48). The main reason for treating the patients encompassed a lack of or an inadequate width of attached gingival/keratinized tissue. In summary, three studies were eligible for comparison using meta-analyses. The hypothesis of the heterogeneity test could not be rejected ($p = 0.43$);

therefore, a fixed effects model was chosen.

Quality assessment

The quality assessment of the included studies revealed a high risk of bias for all included studies except for the three RCTs (Sanz et al. 2009,

Basegmez et al. 2012, Lorenzo et al. 2012).

Treatment outcomes

Width of keratinized tissue. A total of seven studies (three RCTs, two CCTs, two case series) reported on the width of augmented keratinized tissue. The increase in keratinized tissue ranged between 1.4 and 3.3 mm depending on the technique used. Four studies investigated the efficacy of collagen matrices (Mucograft[®], Geistlich, Wolhusen, Switzerland and Collatape[®], Zimmer Dental, Carlsbad, CA, USA) (gain between 1.8 and 2.3 mm) or an acellular dermal matrix graft (SureDerm[™], Hans Biomed Corp, Seoul, Korea) (gain of 1.4 mm) compared to autogenous grafts (FGG, SCTG) for augmenting the band of keratinized tissue. In two RCTs, the application of a CM (gain of 1.8–2.3 mm) demonstrated a gain of keratinized tissue as effective and predictable as the gold standard, an autogenous SCTG (gain of 2.3 mm; Sanz et al. 2009, Lorenzo et al. 2012). One study evaluated the changes in width of keratinized tissue following APF/V, APF/V plus CM and APF/V plus FGG. After 3–4 weeks, the FGG cases showed a greater increase in keratinized tissue (2.5 mm), while the APF/V plus CM (1.8 mm) demonstrated a more physiological and a more favourable morphology than the APF/V only cases (1.6 mm) (Lee et al. 2010). In addition, one study reported on the effects of different time-points for performing FGGs (Stimmelmayer et al. 2011). In this study, no statistical significance ($p = 0.562$) was found in width of keratinized tissue between FGGs performed at the time of implant placement or at the time of uncovering the implants (Stimmelmayer et al. 2011). The mean gain of keratinized tissue for APF/V plus FGG ranged between 2.2 and 3.3 mm.

Percent shrinkage or contraction of keratinized tissue. Two RCTs (Sanz et al. 2009, Basegmez et al. 2012) and one case series (Park 2006) reported post-operative shrinkage or contraction of augmented tissue. All studies found shrinkage of the augmented grafts (SCTG, CM, ADMG, FGG). Only one study reported on

Table 2. Included studies: augmentation of keratinized mucosa

Author	Year of publication	Study design	Indication for treatment	Test treatment	Control 1 treatment	Control 2 treatment	Follow-up period (months)
ten Bruggenkate et al. (1991)	1991	Case series	Inadequate width of keratinized mucosa ≤ 2 mm on both sides of the implant	APF/V plus FGG	NA	NA	6–32
Lauer et al. (1996)	1996	Case series	Inadequate width of attached gingiva	APF/V in combination with implant placement	No treatment	NA	18
Park (2006)	2006	Case series	Inadequate width of attached gingival ≤ 2 mm	APF/V plus ADMG	NA	NA	6
Sanz et al. (2009)	2009	RCT	Inadequate width of keratinized mucosa ≤ 1 mm	APF/V plus CM (Mucograft)	APF/V plus SCTG	NA	6
Lee et al. (2010)	2010	CCT	If keratinized mucosa > 3 mm; APF/V $2-3$ mm; APF/V plus CM (minimal); APF/V plus FGG	APF/V plus CM (Collatape)	APF/V	APF/V plus FGG	6
Lorenzo et al. (2012)	2012	RCT	Inadequate width of keratinized mucosa ≤ 1 mm	APF/V plus CM (Mucograft)	APF/V plus CTG	NA	6
Stimmelmayr et al. (2011)	2011	CCT	Inadequate width of keratinized tissue (≤ 3.5 mm)	Single stage implant placement and ridge augmentation with later FGG	Two stage ridge augmentation and later implant placement and FGG	NA	12
Basegmez et al. (2012)	2012	RCT	Inadequate width of attached mucosa < 1.5 mm or signs of peri-implant mucositis	APF/V plus FGG	Vestibuloplasty according to Edlan & Mejchar)	NA	12
Bruschi et al. (2012)	2012	Case series	Inadequate width of keratinized tissue	APF/V in combination with implant placement	NA	NA	48

ADMG, acellular dermal matrix graft; APF/V, apically positioned flap/vestibuloplasty procedure; CCT, controlled clinical trial; CM, collagen matrix; FGG, free gingival graft; RCT, randomized controlled clinical trial; SCTG, subepithelial connective tissue graft.

% mean graft contraction, revealing more favourable results for the autogenous control group (SCTG; 59.7%) compared to a CM group (67.2%) at 30 days (Sanz et al. 2009).

Width of attached mucosa. One RCT study (Basegmez et al. 2012) reported on the efficacy of two techniques (APF/V + FGG or APF/V alone) for increasing the amount of keratinized tissue around the implants. Sixty-four patients with 64 implants with a minimal keratinized tissue (< 1.5 mm) and signs of peri-implant mucositis were randomly assigned and treated. The results demonstrated that the width of the attached mucosa and the final gains in the FGG group were significantly greater than in the APF/V group (Basegmez et al. 2012).

Immobilized mucosa. In order to extend the immobilized mucosa, a case series (Lauer et al. 1996) reported on an APF/V procedure in combination with implant placement using transalveolar sutures to increase the stability of the lingual peri-implant soft tissue. More immobilized mucosa was obtained lingually compared with a control group of six patients with no APF/V (Lauer et al. 1996).

Surgery time. Two RCT studies reported on total surgery time spent to increase the width of keratinized tissue (Sanz et al. 2009, Lorenzo et al. 2012). Surgery time spent in both studies was less in the CM group compared to the SCTG group with a difference of roughly 15 min. These differences were statistically significantly different in both studies in favour of the test groups (CM) compared to the control groups (autogenous tissue).

Patient-reported outcomes. Two RCT studies assessed the postoperative pain (Sanz et al. 2009, Lorenzo et al. 2012). In both studies, patient morbidity was evaluated using a visual analogue scale (VAS, with a grading of 0–10) through a questionnaire while the perception of pain was measured based on the utilization of the intake of a postoperative analgesic. Comparable results with less morbidity in the CM groups were observed in both studies. At 10 days,

Table 3. Included studies: augmentation of soft tissue volume

Author	Year of publication	Study design	Indication for treatment	Test treatment	Control 1 treatment	Control 2 treatment	Follow-up period (months)
Allen et al. (1985)	1985	Case series	Localized alveolar ridge defect	SCTG	Hydroxylapatite	NA	36 for SCTG and 18 for HA
Studer et al. (2000)	2000	RCT	Localized alveolar ridge defect	SCTG	FGG	No treatment	3.5
Batista et al. (2001)	2001	Case series	Localized alveolar ridge defect	ADMG	NA	NA	6
(Bianchi & Sanfilippo (2004)	2004	CCT	Immediate implant placement	Immediate implant +SCTG	Immediate implant	NA	12-108
Cornelini et al. (2008)	2008	CCT	Extraction socket and immediate implant placement	Immediate implant +SCTG	Immediate implant	NA	12
Kan et al. (2009)	2009	Case series	Immediate implant placement	Immediate implant +SCTG	NA	NA	25.8
Wiesner et al. (2010)	2010	RCT	At implant placement	SCTG at implant placement	No SCTG	NA	12
Speroni et al. (2010)	2010	Retrospective case series	At second stage surgery	SCTG at 2nd stage surgery	NA	NA	36
Schneider et al. (2011)	2011	Case series	During healing period of implant placement	SCTG at healing period of implant	NA	NA	4
Simion et al. (2012)	2012	Case series	Localized ridge augmentation at implant placement or after implant placement	CM+PDGF-BB	NA	NA	4
Akcali et al. (2013)	2013	RCT	Localized alveolar defect	Interpositional connective tissue graft (VIPCG)	SCTG	NA	6

ADMG, acellular dermal matrix graft; CCT, controlled clinical trial; CM, Collagen matrix; FGG, free gingival graft; PDGF, platelet-derived growth factor; RCT, randomized controlled clinical trial; SCTG, subepithelial connective tissue graft; VIPCG, Interpositional connective tissue graft.

patients in the SCTG group had higher mean pain scores compared to the CM group. These differences were statistically significant. In addition, the amount of anti-inflammatory medication (ibuprofen) needed by patients during postoperative was statistically significantly higher in the SCTG group compared to CM group (Sanz et al. 2009).

Augmentation of soft tissue volume

Eleven studies met the inclusion criteria as they report on soft tissue volume (Tables 3 and 5). Two studies were designed as RCT, three as CCT and the remaining six studies were case series reports. In total, 295 patients with 320 sites were treated to enhance the soft tissue volume around implants and in partially edentulous areas. The mean follow-up period was 14.5 months (range 1–108 months). In four of the studies grafting procedures were performed to augment localized alveolar ridge defects (Allen et al. 1985, Studer et al. 2000, Batista et al. 2001, Akcali et al. 2013), while in the remaining studies, soft tissue was grafted at the day of implant placement (Bianchi & Sanfilippo 2004, Cornelini et al. 2008, Kan et al. 2009, Wiesner et al. 2010, Simion et al. 2012) and/or during the healing period of the implant (Speroni et al. 2010, Schneider et al. 2011, Simion et al. 2012). The methods and surgical techniques used for increasing soft tissue volume included: immediate implant placement with SCTG, hydroxylapatite graft, a collagen matrix in combination with a growth factor (platelet-derived growth factor-BB = PDGF-BB), allogeneic dermal matrix graft (ADMG), a SCTG (alone) and a palatal vascularized interpositional periosteal-connective tissue graft (VIPCG). No meta-analysis could be performed due to heterogeneity in the study design and treatment modalities.

Quality assessment

The quality assessment of the included studies revealed a high risk of bias for all included studies except for one RCT (Wiesner et al. 2010).

Treatment outcomes

Volume increase measured by two-dimensional methods. Four studies

Table 4. Characteristics of included studies: width of keratinized mucosa

Author (year)	Study design	Total number of patients	Total number of sites	Number of patients test	Number of sites test	Number of patients control 1	Number of sites control 1	Number of patients control 2	Number of sites control 2	Follow-up period (months)
ten Bruggenkate et al. (1991)	Case series	30			30		30			6-32
Lauer et al. (1996)	Case series	12	12	6	6	6	6			18
Park (2006)	Case series	10	10	10	10					6
Sanz et al. (2009)	RCT	20	20	10	10	10	10			6
Lee et al. (2010)	CCT	9	14	3	3	3	3	8	8	6
Lorenzo et al. (2012)	RCT	24	24	12	12	12	12			6
Stimmelmayr et al. (2011)	CCT	29	70	19	46	10	24			12
Basegmez et al. (2012)	RCT	64	64	32	32	32	32			12
Bruschii et al. (2012)	CCT	85	131	85	131					48
Author (year)	Test treatment	Control 1 treatment	Control 2 treatment	Outcome measure (mm)	Baseline test	SD	Post-surgery test	SD		
ten Bruggenkate et al. (1991)	APF/V plus FGG			Width of keratinized tissue	NR	NR	5 (3-8)	NR		
Lauer et al. (1996)	APF/V in combination with implant placement	No treatment		Immobile mucosa Attached gingiva	NR	NR	B2.2, L4.2 B0.7, L2.9	NR		
Park (2006)	APF/V plus ADMG			Width of keratinized tissue	1.62	0.09	6.24	0.19		
Sanz et al. (2009)	APF/V plus CM (Mucograft)	APF/V plus SCTG		Width of keratinized tissue	2.13	1.2	6.3	1.67		
Lee et al. (2010)	APF/V plus CM (Collatape)	APF/V	APF/V plus FGG	Width of keratinized tissue	1.3	0.5	3.1	1		
Lorenzo et al. (2012)	APF/V plus CM (Mucograft)	APF/V plus CTG		Width of keratinized tissue	0.5	0.52	2.8	0.42		
Stimmelmayr et al. (2011)	Single stage implant placement and ridge augmentation with later FGG	Two stage ridge augmentation and later implant placement and FGG		Keratinized tissue	3	NR	B3.7, L2.6	NR		
Basegmez et al. (2012)	APF/V plus FGG	Vestibuloplasty according to Edlan & Mejchar		Width of attached mucosa	0.75	0.36	3.11	0.58		
Bruschii et al. (2012)	APF/V in combination with implant placement			keratinized tissue	2.3	0.25	7.37	2.12		
Author	Change test	Baseline SD	Post-surgery control 1	Change control 1	Baseline control 2	SD control 2	Change control 2	SD control 2	Effect of test versus control 1	Effect of test versus control 2
ten Bruggenkate et al. (1991)	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
Lauer et al. (1996)	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
Park (2006)	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
Sanz et al. (2009)	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
Lee et al. (2010)	1.8	0.75	3	0	4.6	0	0.75	3	0	4.8

Table 4. (continued)

Author	Change test	Change test SD	Baseline control 1	SD control 1	Post-surgery control 1	SD control 1	Change control 1	SD control 1	Change control 2	SD control 2	Baseline control 2	SD control 2	Post-surgery control 2	SD control 2	Change control 2	SD control 2	Effect of test versus control 1	Effect of test versus control 2
Lorenzo et al. (2012)	NR	NR	0.42	0.51	2.75	1.55	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
Stimmelmayr et al. (2011)	B3.3, L-0.05	NR	2.75	NR	B3.3, L2.65	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
Basegmez et al. (2012)	2.36	0.49	0.67	0.32	1.83	0.72	1.15	0.81	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
Bruschii et al. (2012)	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR

reported horizontal and/or vertical changes in soft tissue volume following soft tissue grafting procedures using stents and periodontal probes or endodontic instruments to measure the changes over time. In a case series, localized alveolar defects in eight patients with 18 sites were treated with ADMG. A gain in vertical ridge width of 0.61 mm (SD = 0.77) and in horizontal ridge width of 1.72 mm (SD = 0.59) was reported during the course of 6 months (Batista et al. 2001). A newly developed collagen matrix was evaluated in a prospective case series, using the matrix in combination with a growth factor (PDGF-BB) at the day of implant placement or at second-stage surgery (Simion et al. 2012). The obtained gains in ridge width ranged between 0.35 and 2.14 mm with standard deviations of up to 3.27 mm at 4 months depending on the level where the measurements were taken using a stent and an endodontic instrument. Since no other treatment modalities were tested, neither the effect of the collagen matrix alone nor the effect of the growth factor can be estimated (Simion et al. 2012). Three years after grafting with SCTGs at the day of implant uncovering, 14 sites in 14 patients demonstrated a mean gain of 1.4 mm in mucosal thickness in a subsequent case series (Speroni et al. 2010). The only RCT reporting on soft tissue volume increase following grafting at implant placement, tested the effect of SCTGs versus no treatment in 10 patients in a split-mouth design (Wiesner et al. 2010). Statistically significant more favourable outcomes were obtained using SCTGs (mean thickness of 3.2 ± 0.42 mm) compared to sites not receiving soft tissue grafting (1.9 ± 0.32 mm).

Volume increase measured by three-dimensional methods. Only three studies reported truly three-dimensional changes of the soft tissue volume following grafting. In the first one, the Moiré method was used to calculate the volume changes following grafting with two types of autogenous tissue grafts in localized alveolar defects (Studer et al. 2000). The study demonstrated a volume gain between 159 mm^3 (SCTG; SD = 80) and 104 mm^3 (FGG; SD = 31). The differences between

the two treatment modalities were statistically significant in favour of the SCTG group, while untreated defects showed a slight increase in volume of 6 mm^3 (SD = 5.4), which was statistically significantly different compared to the two test groups using autogenous tissue (Studer et al. 2000). In a more recent RCT, SCTGs were compared to VIPCGs for augmentation of localized alveolar defects (Akcali et al. 2013). A more advanced technique was used to calculate the volume changes and revealed statistically significant more volume for VIPCG-treated sites (1.18 mm; range 0.16–1.75 mm) compared to free SCTGs (0.63 mm; 0.28–1.22 mm). In a case series, SCTGs were used during the healing phase of implants in 16 sites and patients (Schneider et al. 2011). The mean increase due to grafting was 0.55 mm with a standard deviation of 0.53 mm after 4 weeks of healing (Schneider et al. 2011).

Shrinkage. In a case series, 21 patients with 26 localized alveolar defects were treated either with a SCTG or hydroxylapatite implants. All sites with SCTG demonstrated some shrinkage within the first 4–6 weeks, but the augmented sites remained stable for 3 years. In all but two sites (out of 12) treated with hydroxylapatite implants, no shrinkage was observed (Allen et al. 1985). The shrinkage of the horizontal ridge width amounted to 41.4% over 6 months when localized alveolar defects were augmented with ADMGs in a case series (Batista et al. 2001). This is in line with results from a RCT comparing SCTGs (shrinkage 47% after 6 months) with similar defects to VIPCGs (shrinkage of 6.4% only) (Akcali et al. 2013).

Aesthetic outcomes. The Jemt score (Jemt 1997) was used to evaluate the aesthetic outcomes in two studies (Cornellini et al. 2008, Kan et al. 2009). Both studies demonstrated favourable results for soft tissue grafting with higher papilla scores during the course of the study (2.15 years; Kan et al. 2009) and significantly better outcomes (higher papilla scores) compared to sites without grafting for immediate implants combined with SCTGs

Table 5. Characteristics of included studies: augmentation of soft tissue volume

Author (year)	Study design	Total number of patients	Total number of sites	Number of patients test	Number of sites test	Number of patients control 1	Number of sites control 1	Number of patients control 2	Number of sites control 2	Follow-up period (month)	Test treatment	Control 1 treatment	Control 2 treatment
Allen et al. (1985)	Case series	21	26	NA	14	NA	12	NA	NA	1.5	SCTG	Hydroxyl-apatite	NA
Studer et al. (2000)	RCT	30	30	12	12	12	12	6	6	3.5	SCTG	FGG	Untreated defect
Batista et al. (2001)	Case series	8	18	8	18	NA	NA	NA	NA	6	ADMG	NA	NA
Bianchi & Sanfilippo (2004)	CCT	116	116	96	96	20	20	NA	NA	48	Immediate implants + SCTG	Immediate implants NA	NA
Cornelini et al. (2008)	CCT	34	34	17	17	17	17	NA	NA	12	Immediate implants + SCTG	Immediate implants NA	NA
Kan et al. (2009)	Case series	20	20	20	20	NA	NA	NA	NA	26	Immediate implants + SCTG	NA	NA
Wiesner et al. (2010)	RCT	10	20	10	10	10	10	NA	NA	12	SCTG	No SCTG	NA
Speroni et al. (2010)	Retrospective case series	14	14	14	14	NA	NA	NA	NA	36	SCTG	NA	NA
Schneider et al. (2011)	Case series	16	16	15	15	NA	NA	NA	NA	4	SCTG	NA	NA
Simion et al. (2012)	Case series	6	6	6	6	NA	NA	NA	NA	4	Collagen matrix + rhPDGF-BB	NA	NA
Akeali et al. (2013)	RCT	20	20	10	10	NA	NA	NA	NA	6	VIPEG	SCTG	NA
Author	Outcome measure	Outcome test	SD	Outcome control 1	SD control 1	Outcome control 2	SD control 2	Effect of test versus control 1	Effect of test versus control 2				
Allen et al. (1985)	Shrinkage (descriptive)	14 of 14 sites: shrinkage within first 4-6 weeks, then stable for 3 years	NR	10 of 12 sites: no shrinkage									
Studer et al. (2000)	Soft tissue volume	159 mm ³	80 mm ³	104 mm ³	31 mm ³	6 mm ³	5.4 mm ³	Significant	Significant				
Batista et al. (2001)	Gain in horizontal ridge width (mm)	1.72	0.59										
Bianchi & Sanfilippo (2004)	Keratized mucosa	NR	NR	NR	NR	NA	NA	Higher values for test group	NA				
Cornelini et al. (2008)	Papilla index (Jemt)	19 papillae (score 2); 15 papillae (score 3)	NR	22 papillae (score 2); 12 papillae (score 3)	NA	NA	NA	In favor of test group	NA				

Table 5. (continued)

Author	Outcome measure	Outcome test	SD	Outcome control 1	SD control 1	Outcome control 2	SD control 2	Effect of test versus control 1	Effect of test versus control 2
Kan et al. (2009)	Biotype	Thick biotype at latest follow-up in all sites	NR						
Wiesner et al. (2010)	Pink esthetic score	11.32	1.63	8.45	1.46	NA	NA	Statistically significant in favor of test group	NA
Speroni et al. (2010)	mucosal thickness (stent)	1.4 mm	NR						
Schneider et al. (2011)	3D volume measurements based on casts	0.55 mm	0.53 mm						
Simion et al. (2012)	2D volume measurements using stents	0.87 mm (apical); 2.14 mm (central); 0.35 mm (occlusal)	2.13 mm (apical); 3.27 mm (central); 3.20 mm (occlusal)						
Akcali et al. (2013)	3D volume measurements based on casts	1.18 mm	0.16–1.75 mm	0.63 mm	0.28–1.22 mm	NA	NA	Statistically significant in favor of test group	NA

ADMG, acellular dermal matrix graft; CCT, controlled clinical trial; FGG, free gingival graft; RCT, randomized controlled clinical trial; SCTG, subepithelial connective tissue graft; SD, standard deviation; VIPCG, palatal vascularized interpositional periosteal-connective tissue graft.

(Cornelini et al. 2008). The same two studies also evaluated the position of the mucosal margin compared to neighbouring teeth. Similar to the Jemt scores, a more favourable outcome with a higher mean facial line was observed after 2.15 years (Kan et al. 2009), while grafted sites revealed significantly higher mucosal margin levels for grafted sites after 12 months (Cornelini et al. 2008).

Additional outcome parameters. Additional outcome measures included the amount of KM, the stability of the emergence profile, the patient satisfaction (all in Bianchi & Sanfilippo 2004) and the tissue biotype changes (Kan et al. 2009).

Discussion

The present systematic review focused on the efficacy of soft tissue grafting procedures around implants and in partially edentulous areas. For gain of keratinized tissue, nine studies were included. For augmentation of soft tissue volume, a final number of 11 studies met the inclusion criteria. Due to heterogeneity between the studies, no meta-analysis could be performed neither for gain of keratinized tissue nor for soft tissue volume.

Increase in width of keratinized tissue

Gain of keratinized tissue

Seven studies specifically reported on various techniques and materials to augment keratinized tissue around dental implants. In all studies, the width of keratinized tissue could be successfully augmented. Due to a large heterogeneity between the studies, with some studies missing control groups and different time-points applying the soft tissue grafting (simultaneous with implant placement, during the healing phase of the implants and after the insertion of the final reconstruction), it is difficult to recommend a specific technique. The selection of the included studies also demonstrates advances and trends in clinical research. In older studies, either an APF/V alone or in combination with autogenous tissue harvested from the patient's palate was the treatment of choice

(ten Bruggenkate et al. 1991, Lauer et al. 1996). The main disadvantage of using autogenous tissue results from the morbidity associated with the harvesting procedure and the subsequent healing. Research has therefore focused on alternative materials and techniques. In one of the studies, a human-derived ADMG was applied (Park 2006). This material has been documented extensively in dentistry in various fields, such as for gain of keratinized tissue around teeth, for recession coverage, for gain of KM around dental implants and for volume increase (Wei et al. 2000, Aichelmann-Reidy et al. 2001, Batista et al. 2001, Carney et al. 2012). The advantage of using alternative materials is documented with less patient morbidity compared to autogenous tissue for gain of keratinized gingiva (Griffin et al. 2006). Around dental implants, the combination of an APF/V and ADMG was successful to augment keratinized tissue (Park 2006). However, due to the lack of a control group, any comparison to the gold standard (autogenous tissue) is missing. No further included studies were using this material. In contrast, a number of human studies used ADMG for gain of keratinized tissue. High shrinkage rates were reported during healing around teeth (Wei et al. 2000) and the tissue, histologically resembled scar tissue (Wei et al. 2002). More recently, collagen matrices were developed and extensively evaluated in preclinical and clinical studies (Jung et al. 2011, 2013, Vignoletti et al. 2011, Rocchietta et al. 2012, Thoma et al. 2012a, Jepsen et al. 2013). Three of the included studies reported on the use of two types of collagen matrices (Sanz et al. 2009, Lee et al. 2010, Lorenzo et al. 2012). In all three studies, autogenous tissue served as a control group. The increase in width of keratinized tissue with a range of 1.8–2.3 mm indicates a successful use of both CM types, even though demonstrating that the gain of keratinized tissue was slightly less compared to sites augmented with autogenous tissue (mean gain between 2.2 and 2.5 mm). This may even more serve as part of the discussion, since alternative devices (e.g. CM) can significantly reduce patient morbidity, reduce the overall treatment

time and slightly improve aesthetics compared with control groups (Griffin et al. 2006, Sanz et al. 2009, Lorenzo et al. 2012, Thoma et al. 2012a). In one study, the width of KM was reported as gain in width of attached mucosa (Basegmez et al. 2012). While at teeth, the keratinized tissue (i.e. the gingiva) consist of two parts, the attached gingiva and the free gingiva, at implant sites, no such terms exist. The dimension of the keratinized tissue appears to be similar at teeth and implant sites, but a clear soft tissue attachment to implants has yet to be reported (Berglundh & Lindhe 1996). It may therefore be speculated that the reported attached mucosa represents the KM found in other studies.

Per cent shrinkage and contraction of keratinized tissue

The changes in width over time following the initial augmentation procedure is of great importance and serves as a reliable mean to estimate the predictability of the applied technique. Therefore, the overall contraction or shrinkage over time needs to be evaluated. Three studies reported on these outcomes and revealed that independently of the applied surgical technique or material used to augment, a certain loss of the initially augmented width has to be accepted. This ranged quite extensively in the present systematic review, with one study reporting only 2% of shrinkage over 12 months (Basegmez et al. 2012), while the remaining two studies reported shrinkage rates higher than 50% at 1 or 6 months (Park 2006, Sanz et al. 2009). The variability may be due to the use of different techniques (vestibuloplasty according to Edlan & Mejchar, APF/V), different observation time-points (1, 6 and 12 months), differences in graft materials (CM, FGG, SCTG) and different indications (inadequate width of KM, inadequate width of attached mucosa, peri-implant mucositis). Other influences such as the thickness of the graft, which appears to be important when augmenting keratinized tissue around teeth (Mormann et al. 1981) and the lack of a pre-vascularization (for CM compared to autogenous tissue) could not be evaluated due to a low

number of include studies reporting on these outcomes.

Surgery time

As reported above, the gain in width of KM is not the only outcome parameter that may favour one over the other technique. In two RCTs, the overall treatment time was calculated and clearly demonstrated that by avoiding the use of autogenous tissue and the associated harvesting procedure, the surgery time can be significantly reduced (Sanz et al. 2009, Lorenzo et al. 2012). A mean difference of roughly 15 min. in favour of the CM groups was reported in both studies. This has to be considered as a major advantage for the use of alternative devices and may be directly correlated with the postoperative healing and the patient morbidity.

Patient-reported outcomes

The post-operative complications of soft tissue grafting procedure include bleeding and swelling as major contributors (Dordick et al. 1976a,b, Farnoush 1978, Del Pizzo et al. 2002, Griffin et al. 2006, Wessel & Tatakis 2008). Several studies evaluated the patient morbidity following gingival augmentation. The data are not conclusive, but predominantly demonstrate less morbidity associated with soft tissue substitutes compared to autogenous tissue (McGuire & Nunn 2005, Griffin et al. 2006, McGuire et al. 2008). Only two included studies provided data of postoperative pain in the present review. The information derived from the two RCTs clearly demonstrates superiority with less morbidity for soft tissue substitutes compared to autogenous tissue (Sanz et al. 2009, Lorenzo et al. 2012). Data were provided by questionnaires and the intake of pain killer medication in the follow-up. Since both studies were not designed as split-mouth studies, the data are conclusive and more relevant than data obtained in previous studies. In older studies, split-mouth designs appeared to confuse patients, making it difficult to differentiate between two sites (McGuire & Nunn 2005, McGuire et al. 2008). Therefore, in a previous systematic review on soft tissue grafting procedures, no benefit was shown for soft tissue

substitutes (Thoma et al. 2009). The outcomes on patient morbidity are of major relevance and might help to thrive the choice for a grafting material towards soft tissue substitutes in the future.

Augmentation of soft tissue volume

Compared to a previous systematic review (Thoma et al. 2009), the number of included studies increased with 11 studies finally meeting the inclusion criteria. The difference is due to broader inclusion criteria (implant sites, partially edentulous sites), a number of very recent studies applying new materials and techniques (growth factors, soft tissue substitutes) and the development of new techniques to assess soft tissue volume changes (non-invasive three-dimensional analyses). Still, due to heterogeneity between the studies, no meta-analysis could be performed.

Volume increase measured by two-dimensional methods

Four studies reported two-dimensional changes of soft tissue volume applying autogenous tissue (SCTG) and soft tissue substitutes (CM, ADMG) (Batista et al. 2001, Speroni et al. 2010, Wiesner et al. 2010, Simion et al. 2012). The measurements were performed using endodontic instruments or periodontal probes, mostly with the aid of a standardized stent. The outcomes provided variability with respect to the increase in soft tissue thickness over time with a range of 0.35–3.2 mm depending on the location (buccal at different levels, occlusal) and the follow-up time-point (4 months to 3 years). In all studies, a volume increase was obtained independent of the technique and material, but it was also demonstrated that some shrinkage might occur over time. Similar to studies for gain of keratinized tissue, autogenous tissue appears to be the gold standard as it was used most often, but new soft tissue substitutes are being evaluated. Research has strongly focused on the development and testing of alternative devices with collagen matrices being the most promising ones (Thoma et al. 2013). Unlike for gain of keratinized tissue where pre-clinical and clinical data are published (Sanz et al. 2009, Jung et al.

2011, Lorenzo et al. 2012), collagen matrices for gain of soft tissue volume are scarce and mostly documented in vitro and in preclinical studies (Mathes et al. 2010, Thoma et al. 2010, 2011, 2012b). Only one clinical study used a collagen matrix (Simion et al. 2012), which was originally designed to serve as a matrix for gain of keratinized tissue and showed only a minimal increase in thickness based on pre-clinical data (Jung et al. 2011). Therefore, this matrix was combined with a growth factor to enhance the vascularization and the connective tissue formation (Simion et al. 2012). The outcomes of the study demonstrated a short-term increase in soft tissue volume at all levels. Some more data at just one buccal level over 3.5 years, however, revealed that the obtained soft tissue thickness decreased by more than 50% to roughly 0.9 mm (Simion et al. 2012). This demonstrates that a soft tissue substitute for soft tissue volume increase may have additional requirements for long-term stability and a successful outcome. In order to overcome these issues and to meet the demands and requirements for soft tissue substitutes, a new modified collagen matrix with cross-linking has been tested over the course of the past years. In vitro and preclinical data are favourable and a direct comparison with the gold standard, the autogenous graft, demonstrated non-inferiority in a canine model (Mathes et al. 2010, Thoma et al. 2010, 2011, 2012b). Clinical data however are still lacking.

Volume increase measured by three-dimensional methods

Recent development not only focused on new devices but also on the evaluation of non-invasive methods to assess volumetric changes (Windisch et al. 2007, Fickl et al. 2009, Strelbel et al. 2009). Three studies used casts to evaluate the soft tissue volume over time. In all three studies, autogenous tissue was used for volume increase, in two studies for partially edentulous sites (Studer et al. 2000, Akcali et al. 2013), in one for volume increase at implant sites (Schneider et al. 2011). Again, due to heterogeneity, the outcomes could not be compared, but data provide clinically more relevant

data since the measurements capture the entire augmented area. The mean augmented thickness ranged between 0.55 and 1.18 mm, while the remaining study reported an increase of 104–159 mm³ (Studer et al. 2000). The outcomes at partially edentulous sites are difficult to put into context unless aesthetic, functional and/or long-term data are provided. At implant sites, a soft tissue thickness of 2 mm appears to be the threshold thickness at the buccal aspect for more aesthetic outcomes (Jung et al. 2007, 2008, van Brakel et al. 2011). Unfortunately, the entire soft tissue thickness and suitable aesthetic outcome parameters were not provided by the included study (Schneider et al. 2011). Conclusions on whether the treatment was successful are difficult to draw.

Shrinkage

Similar to keratinized tissue, the overall shrinkage rate provides data on the reliability of the applied technique and material. Autogenous tissue was reported to shrink by more than 40% in two studies, while a pedicle flap (VIPCG) appears to be more reliable resulting in less shrinkage over time (6.4% at 6 months) (Akcali et al. 2013). Data on soft tissue substitutes were not reported in the included studies.

Aesthetic outcomes

There is a huge variety of aesthetic factors reported in the literature (Benic et al. 2012). For maximal aesthetics, the soft tissue thickness at the buccal aspect of the implant sites and the height of the papillae appears to be the key factors (Thoma et al. 2013). The Jemt score (Jemt 1997) is considered an easily applicable method to assess the aesthetic outcome in the papilla area and provides relevant clinical information on the aesthetic outcome at implant sites. Two included studies demonstrated that the use of autogenous tissue combined with immediate placement results in favourable clinical aesthetics at one and 2.15 years (Cornellini et al. 2008, Kan et al. 2009). Since one of the studies was designed as a CCT, data on non-grafted sites are included. The outcomes clearly demonstrate that necessity and the superiority of grafted sites resulting in better aes-

thetics over the course of one year (Cornelini et al. 2008).

Conclusion

The present systematic review revealed that for gain of KM at implant sites, various methods and various materials could be used successfully. All applied techniques were based on an APF/V in combination with autogenous tissue (SCTG/FGG) or a soft tissue substitute (ADMG/CM) and rendered a gain in keratinized tissue for an observation period of up to 48 months. In contrast to gingival augmentation, only one study reported on APF/V alone, which might indicate that most studies were commercially funded. However, some shrinkage may occur with all applied grafting materials and may result in a decrease in width of keratinized tissue of more than 50% within a couple of months. For soft tissue volume augmentation, autogenous tissue (SCTG) has to be considered treatment of choice resulting in an increase in soft tissue thickness at implant sites and in partially edentulous sites. Soft tissue substitutes lack clinical data and can currently not be recommended. Again, some shrinkage of the augmented sites has to be considered. From an aesthetic point of view, soft tissue volume grafting concomitant with immediate implant placement may result in superior outcomes with respect to papilla height and the level of the marginal mucosa compared to natural teeth and control groups.

Future direction of research

The present systematic identified a relatively low number of studies to be included for gain of keratinized tissue around dental implants and for gain of soft tissue volume around dental implants and in partially edentulous sites. Moreover, there was a lack of RCTs, specifically for gain of soft tissue volume. For gain of keratinized tissue, some RCTs were available, but appeared to be fully sponsored by companies, thereby including a greater risk of bias. In order to provide the clinicians with data on optimal techniques and materials, more self-funded studies or studies funded by

independent organizations and foundations are needed. Such RCTs would have a great impact for the benefit of patients and clinicians.

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Clinical Relevance

Scientific rationale for the study: the aim of this systematic review was to assess the efficacy of soft tissue augmentation procedures to gain keratinized mucosa around dental implants and to increase the soft tissue volume around implants and in partially edentulous areas

Principal findings: An apically positioned flap/ vestibuloplasty (APF/V) plus a graft material was considered a successful treatment concept resulting for gain of keratinized mucosa. The amount of keratinized mucosa could statistically signifi-

cantly be increased combining an APF/V with autogenous tissue FGG/SCTG when compared to control groups (no treatment, APF/V alone). The use of collagen matrices (CM) reduced surgery time and patient morbidity, but rendered less gain of keratinized mucosa compared to the use of autogenous tissue (SCTG/FGG). Autogenous grafts (SCTG/FGG) rendered a two- and three-dimensional gain of soft tissue thickness at implant sites and partially edentulous sites.

Practical implications: Larger evidence is available for APF/V plus

autogenous tissue (FGG/SCTG) and supports these procedures for gain of keratinized mucosa. If surgery time and patient morbidity are considered, APF/V plus CM might serve as an alternative treatment modality, even though rendering less gain in keratinized mucosa and being less documented. For soft tissue volume increase, the use of autogenous grafts (SCTG/FGG) has to be considered as gold standard. No soft tissue substitute materials can be recommended for this procedure.