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## Consensus Report of Working Group 2

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# Soft tissue management at implants: Summary and consensus statements of group 2. The 6th EAO Consensus Conference 2021

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## Abstract

**Objectives:** The task of working Group 2 at the 6th Consensus Meeting of the European Association for Osseointegration was to comprehensively assess the effects of soft tissue augmentation procedures at dental implant sites on clinical, radiographic and patient-reported outcome measures (PROMs) including an overview on available outcome measures and methods of assessment.

**Materials and methods:** Three systematic reviews and one critical review were performed in advance on (i) the effects of soft tissue augmentation procedures on clinical,

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radiographic and aesthetic outcomes, (ii) reliability and validity of outcome measures and methods of assessment and (iii) PROMs applied in clinical studies for soft tissue augmentation procedures at dental implant sites. Major findings, consensus statements, clinical recommendations and implications for future research were discussed in the group and approved during the plenary sessions.

**Results:** The four reviews predominantly revealed:

- Soft tissue augmentation procedures in conjunction with immediate and delayed implant placement result in superior aesthetic outcomes compared to no soft tissue augmentation in the zone of aesthetic priority.
- Soft tissue augmentation procedures have a limited effect on marginal bone level changes compared to implant sites without soft tissue augmentation. Clinically relevant parameters (gingival index, mucosal recession) and plaque control improve at implant sites when the width of keratinised mucosa is increased.
- A variety of aesthetic indices have been described with good reliability. Pink Esthetic Score and Complex Esthetic Index are the most validated aesthetic indices for single implants, though. Superimposed digital surface scans are most accurate to assess profilometric tissue changes.
- PROMs following soft tissue augmentation procedures have been assessed using various forms of questionnaires. Soft tissue augmentation had a limited effect on PROMs.

**Conclusions:** Soft tissue augmentation procedures are widely applied in conjunction with implant therapy. Depending on the indication of these interventions, clinical, radiographic and aesthetic outcomes may improve, whereas the effect on PROMs is limited.

**KEYWORDS**

dental implant, patient-reported outcome measures, soft tissue augmentation

## 1 | INTRODUCTION

Soft tissue augmentation procedures are frequently performed in partially and fully edentulous patients prior to, simultaneously with, and post-implant placement (Cairo et al., 2019; Thoma et al., 2014). These interventions are proposed to optimise aesthetic, functional and biological outcomes of implant therapy on the short- and long run.

The clinician is confronted with various time-points to perform soft tissue augmentation procedures (pre-, in conjunction with or post-implant placement, and post-insertion of the final restoration) as well as with the decision on the optimal time-point of implant placement. The effect of soft tissue augmentation procedures depending on the timing of implant placement and the chosen implant timing protocol has not been thoroughly analysed.

Positive effects of soft tissue augmentation procedures on clinical, aesthetic, radiographic and biological outcomes have frequently been described in the scientific literature (Jung et al., 2008; Puisys & Linkevicius, 2015; Rocuzzo et al., 2016; Zuiderveld et al., 2018). More recent evidence even suggested that these procedures might

replace or reduce the need for hard tissue augmentation around dental implants (De Bruyckere et al., 2020). Whether or not soft tissue augmentation procedures are more beneficial than hard tissue regeneration or have an additional positive effect on the short- and long-term outcomes of implant therapy remains unknown.

From a scientific point of view, a plethora of outcome measures and methods of assessment have been introduced evaluating the effects of interventions at the level of the peri-implant soft tissues (Cosyn et al., 2017). The reliability and validity of these aesthetic indices and soft tissue metric assessment methods have not been systematically reviewed.

From a patient's perspective, the decision for a specific soft tissue augmentation procedure relies not only on the expected outcomes, but with increasing evidence on the morbidity associated with the chosen intervention and/or material. Patient-reported outcome measures (PROMs) have, therefore, been applied more frequently in recent clinical studies (Sanz et al., 2009; Tavelli et al., 2020; Thoma et al., 2020).

The task of Working Group 2 of the EAO Consensus Meeting was to comprehensively assess: (i) the optimal timing to perform

a soft tissue augmentation procedure during implant therapy and the effect of soft tissue augmentation procedures being applied with various implant placement protocols; (ii) the efficacy of soft tissue augmentation versus the absence of such an intervention or versus hard tissue augmentation alone on radiographic and clinical outcomes; (iii) the reliability and validity of aesthetic indices and soft tissue metric assessment methods used in conjunction with soft tissue augmentation procedures and (iv) PROMs applied in clinical studies on soft tissue augmentation procedures at dental implants.

## 2 | WORKSHOP DISCUSSION AND CONSENSUS

The present Consensus Report of Working Group 2 was based on the following reviews

- Linear and profilometric changes of the mucosa following soft tissue augmentation in the zone of aesthetic priority—a systematic review and meta-analysis (Raghoobar et al., 2021)
- The influence of soft tissue augmentation procedures around dental implants on marginal bone level changes—a systematic review (Fickl et al., 2021)
- Soft tissue metric parameters, methods and aesthetic indices in implant dentistry: a critical review (Cosyn et al., 2021)
- Patient-reported outcome measures following soft tissue grafting at implant sites: a systematic review (Stefanini et al., 2021)

### 2.1 | Linear and profilometric changes of the mucosa following soft tissue augmentation in the zone of aesthetic priority—a systematic review and meta-analysis

Raghoobar et al., 2021

#### 2.1.1 | Focused question

What are the outcomes of soft tissue augmentation procedures, in terms of change in mid-buccal mucosa level and thickness at implants sites in areas of aesthetic priority?

#### 2.1.2 | Major findings

- Soft tissue augmentation in the aesthetic zone results in less recession of the mid-buccal mucosa [0.34 mm; 95% confidence interval (CI): 0.13, 0.56;  $p = .002$ ] and a thicker mid-buccal mucosa (0.66 mm; 95% CI: 0.35, 0.97;  $p < .001$ ) in immediate implant placement compared to no augmentation [4 randomised

controlled clinical trials (RCTs) and 2 controlled clinical trials (CCTs) including 215 patients and 215 implants].

- Soft tissue augmentation in the aesthetic zone results in less recession of the mid-buccal mucosa (0.17 mm; 95% CI: 0.01, 0.34;  $p = .042$ ) in delayed implant placement compared to no augmentation (1 RCT and 5 CCTs including 199 patients and 199 implants).
- No sufficient evidence is available to identify a preferable time-point for soft tissue augmentation at implant sites.
- At a medium-term follow-up, there is limited clinical evidence indicating that soft tissue augmentation using connective tissue grafts results in stable peri-implant soft tissues (2 RCTs, 3 CCTs and 1 case series including 102 patients and 102 implants).
- No data for soft tissue substitutes with medium-term follow-up are available.

#### 2.1.3 | Consensus statements

*What are the effects of additional soft tissue augmentation regarding change in the soft tissue level and thickness of mid-buccal mucosa of immediate implant placement in the area of aesthetic priority?*

The addition of soft tissue augmentation results in less recession of the mid-buccal mucosa (4 RCTs and 2 CCTs) and a thicker mid-buccal mucosa (2 RCTs) in immediate implant placement compared to no augmentation.

*What are the effects of additional soft tissue augmentation regarding change in soft tissue level and thickness of mid-buccal mucosa of delayed implant placement in the area of aesthetic priority?*

Soft tissue augmentation in conjunction with delayed implant placement results in less recession of the mid-buccal mucosa (1 RCT and 5 CCTs) and no significant increase in thickness of the mid-buccal mucosa (1 RCT and 3 CCTs) compared to no augmentation.

*Is there a difference in recession of the mucosal margin and/or in mucosal thickness following soft tissue augmentation with autologous tissue grafts compared to soft tissue substitutes at implant sites in areas of aesthetic priority?*

Based on the available studies, there is no significant difference between autologous grafts and soft tissue substitutes. However, a consistent tendency of less recession (2 RCTs) and thicker mid-buccal mucosa (4 RCTs) was shown for autologous grafts in areas of aesthetic priority. The included studies were possibly under-powered and characterised by inhomogeneity (time-point of implant placement, type of soft tissue graft).

*Is there a preferable time-point to perform soft tissue augmentation in the area of aesthetic priority?*

There is insufficient evidence for a preferable time-point for soft tissue augmentation.

### 2.1.4 | Clinical recommendations

- In cases of high aesthetic priority, soft tissue augmentation may be recommended simultaneously with immediate implant placement to reduce soft tissue recession and increase mucosa thickness.
- In cases of high aesthetic priority, soft tissue augmentation may be recommended with delayed implant placement to reduce soft tissue recession.
- No clinical recommendation can be given on the use of soft tissue substitutes.
- No clinical recommendation can be given on the preferable time-point for soft tissue augmentation.

### 2.1.5 | Implications for future research

#### *Future research should be directed towards*

- The comparison between autologous grafts and soft tissue substitutes in terms of two- and three-dimensional changes of the soft tissues as well as PROMs.
- Long-term follow-up of studies.
- Studies focusing on soft tissue augmentation procedures performed at different time-points during implant therapy.

#### *Investigators are advised to*

- Apply validated and reliable outcome measures to assess two- and three-dimensional changes of the soft tissues as well as PROMs.

## 2.2 | The influence of soft tissue augmentation procedures around dental implants on marginal bone level changes—A systematic review

Fickl et al., 2021

### 2.2.1 | Focused question

In systemically healthy patients with at least one dental implant [P], how does soft tissue augmentation with or without hard tissue augmentation [I] compared to only soft or hard tissue augmentation or the absence of any augmentation [C] affect marginal bone level changes [O] at least one year after implant placement [T]?

### 2.2.2 | Major findings

#### *Soft tissue augmentation versus no augmentation*

- Soft tissue augmentation (to increase keratinised mucosa or to augment tissue volume) showed a limited effect on marginal bone level changes (range:  $-2.13$ – $0$  mm) when compared to the absence of soft tissue augmentation (range:  $-2.10$  to  $-0.17$  mm) (2 RCTs, 4 prospective and 1 retrospective cohort studies including 543 patients and 643 implants).

- Clinically relevant parameters (gingival index, mucosal recession) and plaque control were improved by augmentation of keratinised mucosa (1 RCT, 1 prospective and 1 retrospective cohort study including 187 patients and 287 implants).
- Procedures to augment soft tissue volume using connective tissue grafts had a beneficial effect on aesthetic parameters (Pink Esthetic Score, marginal soft tissue level) (1 RCT and 3 prospective cohort studies including 356 patients and 356 implants).

#### *Soft and hard tissue augmentation versus hard tissue augmentation alone*

- Sites treated with a combination of hard and soft tissue augmentation demonstrated no statistically significant differences in terms of marginal bone level changes when compared to hard tissue augmentation alone [weighted mean difference: 0.28; 95% CI:  $-0.30$ , 0.86;  $p = .34$ ] (4 RCTs and 2 prospective cohort studies including 220 patients and 220 implants).
- Concomitant soft and hard tissue augmentation resulted in less marginal soft tissue recession when compared to hard tissue augmentation alone (weighted mean difference: 0.48; 95% CI: 0.17, 0.80;  $p = .003$ ) (4 RCTs including 200 patients and 200 implants).

#### *Aesthetic contour augmentation with either soft tissue augmentation alone or hard tissue augmentation alone*

- Based on one RCT, including 42 patients and 42 implants, both, soft and hard tissue augmentation procedures resulted in comparable marginal bone level changes [ $-0.78$  (0.88) vs.  $-0.42$  (0.36) mm].

### 2.2.3 | Consensus statements

#### *Do soft tissue augmentation procedures around dental implants improve marginal bone level changes?*

The scientific evidence does not consistently demonstrate a benefit of soft tissue augmentation procedures in terms of marginal bone level changes compared to no soft tissue augmentation (2 RCTs, 4 prospective and 1 retrospective cohort study).

#### *Do soft tissue augmentation procedures around dental implants improve clinical and/or aesthetic outcomes as assessed by professionals?*

Procedures to increase the zone of keratinised mucosa may improve clinical parameters (gingival index, mucosal recession) and plaque control compared to no soft tissue augmentation (1 RCT, 1 prospective and 1 retrospective cohort study).

Interventions to augment soft tissue volume may improve aesthetic outcomes compared to no soft tissue augmentation (1 RCT and 3 prospective cohort studies).

#### *Does the combination of soft and hard tissue augmentation around dental implants improve marginal bone levels?*

Concomitant soft and hard tissue augmentation procedures do not significantly improve marginal bone level changes compared

to hard tissue augmentation alone (4 RCTs and 2 prospective cohort studies).

*Does the combination of soft and hard tissue augmentation around dental implants improve clinical and/or aesthetic outcomes as assessed by professionals?*

Concomitant soft and hard tissue augmentation procedures significantly reduce marginal soft tissue recession compared to hard tissue augmentation alone (4 RCTs).

*What is more beneficial for aesthetic contour augmentation (i.e. to facilitate a convex ridge contour) in terms of marginal bone level changes—soft or hard tissue augmentation around dental implants?*  
Based on one RCT, soft or hard tissue aesthetic contour augmentation procedures do not differ in terms of marginal bone level changes.

*What is more beneficial for aesthetic contour augmentation in terms of clinical and/or aesthetic outcomes as assessed by professionals—soft or hard tissue augmentation around dental implants?*

Based on one RCT, soft or hard tissue contour augmentation procedures do not differ in terms of clinical and aesthetic outcomes except for increased scarring in case of hard tissue augmentation.

*Are soft tissue volume augmentation procedures applying soft tissue substitutes beneficial in terms of marginal bone level changes?*

Based on 1 RCT and 2 prospective cohort studies using different materials and different indications, there is inconclusive evidence on the possible benefits and disadvantages of soft tissue substitutes applied for soft tissue volume augmentation on marginal bone level changes.

## 2.2.4 | Clinical recommendations

- Interventions to augment keratinised mucosa in the posterior area may be recommended to improve peri-implant clinical outcomes (gingival index, mucosal recession) and plaque control.
- Interventions to augment soft tissue volume may be recommended to improve aesthetic outcomes as assessed by professionals.
- Interventions to augment the vertical peri-implant soft tissue thickness in the posterior area may also be performed to minimise marginal bone level changes in clinical situations with a thin phenotype.
- The addition of soft tissue augmentation to hard tissue augmentation cannot be recommended to improve marginal bone level changes at implant sites. However, if performed it may better prevent the development of mucosal recessions.

## 2.2.5 | Recommendations for future research

*Future research should be directed towards*

- Evaluate marginal bone level changes in the corresponding area of soft and hard tissue augmentation sites assessed by non-invasive diagnostic tools.

- Evaluate the long-term effect (>5 years) of autologous soft tissue augmentation on dimensional stability, tissue overgrowth and keloid formation.

*Investigators are advised to*

- Evaluate marginal bone level changes with an adequate follow-up (>1 year) when soft tissue augmentation procedures are investigated.
- Report baseline soft tissue measurements, in particular in terms of vertical soft tissue thickness.
- Use a uniform terminology to address peri-implant soft tissue changes both in a linear and a volumetric way to allow studies to be more homogenous and comparable.

## 2.3 | Soft tissue metric parameters, methods and aesthetic indices in implant dentistry: a critical review

Cosyn et al., 2021

### 2.3.1 | Focused question

What is the reliability and validity of aesthetic indices and what soft tissue metric assessment methods have been applied in implant dentistry?

### 2.3.2 | Major findings

- Good inter-rater reliability (correlation coefficients  $\geq 0.6$ ) was found for 6 aesthetic indices (Papilla Index, Pink Esthetic Score, Implant Aesthetic Score, Californian Dental Association Index, Implant Restoration Esthetic Index, Mucosal Scarring Index).
- A limited number of correlations between aesthetic indices was found. For Pink Esthetic Score and Complex Esthetic Index, 8 correlations were identified and 6 of them were rated as good (correlation coefficients  $\geq 0.6$ ).
- With respect to metric assessment methods, clinical measurements with a periodontal probe, endodontic reamer or injection needle were least accurate, whereas volumetric tissue changes on the basis of superimposed digital surface scans were most accurate.

### 2.3.3 | Consensus statements

*What are the most reliable aesthetic indices for single implants?*

Papilla Index, Pink Esthetic Score, Implant Aesthetic Score, Californian Dental Association Index, Implant Restoration Esthetic Index, Mucosal Scarring Index are the most reliable aesthetic indices for single implants.

*What are the most validated aesthetic indices for single implants?*

Pink Esthetic Score and Complex Esthetic Index are the most validated aesthetic indices for single implants.

*Which aesthetic index should be preferred for single implants?*

The most reliable and validated aesthetic index is the Pink Esthetic Score.

*What is the aesthetic index to be used for multiple implants?*

None of the aesthetic indices fulfilled the quality criteria for clinical research on multiple implants.

*How should linear measurements be performed to assess vertical and horizontal changes of peri-implant soft tissues?*

Linear methods that enable measuring peri-implant soft tissue changes from a fixed reference point qualify. Digital evaluation demonstrated higher accuracy than periodontal probe, endodontic reamer or injection needle.

*How should three-dimensional measurements be performed to assess changes of peri-implant soft tissues?*

Three-dimensional soft tissue changes should be measured by means of either a conventional impression for cast models to be scanned, or directly by using an intra-oral scanner. Fixed reference points, whether or not gain of soft tissue, and the region of interest should always be defined.

### 2.3.4 | Implications for future research

*Future research should focus on*

- Further validation of aesthetic indices for single implants.
- Development and validation of aesthetic indices for multiple implants.
- Non-invasive digital technologies to assess aesthetics and peri-implant soft tissue changes.

*Clinical investigators are advised*

- To use a reliable and validated aesthetic index.
- To measure linear and three-dimensional peri-implant soft tissue changes.

## 2.4 | Patient-reported outcome measures following soft tissue grafting at implant sites: a systematic review

Stefanini et al., 2021

### 2.4.1 | Focused question

What is the impact of soft tissue augmentation procedures around dental implants relative to PROMs?

### 2.4.2 | Major findings

- PROMs are not commonly included in the evaluation of soft tissue augmentation procedures at implant sites.
- The majority of the studies did not find significant differences in terms of patient morbidity following augmentation with autologous grafts or soft tissue substitutes. Nevertheless, a trend towards less postoperative discomfort was observed for soft tissue substitutes compared to autologous grafts (6 RCTs including 165 patients and 165 implants).
- High scores for patient satisfaction [mean visual analogue scale (VAS) ranged from 90 to 98] and aesthetic evaluation (mean VAS ranged from 87 to 95) were observed in all interventions (grafted and non-grafted sites) (8 RCTs, 1 non-RCT and 4 case series including 425 patients and 430 implants).

### 2.4.3 | Consensus statements

*What are the most often investigated patient-reported outcomes when soft tissue augmentation is performed at implant sites?*

Patient-reported outcomes have been evaluated using questionnaires including dichotomous or open questions, a VAS or oral health impact profile-14 (13 RCTs, 2 non-RCTs and 4 case series). These included evaluation of:

- Patient-reported morbidity
- Patient's overall satisfaction
- Patient's perception of aesthetics
- Patient's oral health-related quality of life

*Does an additional soft tissue augmentation procedure around dental implants influence patient-reported morbidity?*

Soft tissue augmentation with a xenogeneic collagen matrix concomitant with implant placement did not influence patient-reported morbidity (pain perception based on a VAS score) when compared to implant placement alone (1 RCT). There is no evidence of the possible impact of autologous soft tissue harvesting on pain perception for this indication.

*Does an additional soft tissue augmentation procedure around dental implants influence the patient's satisfaction with the overall treatment?*

The addition of a soft tissue graft (acellular dermal matrix, connective tissue graft, xenogeneic collagen matrix) did not seem to influence patient's satisfaction with the overall treatment (2 RCTs). In both RCTs, patient's satisfaction was high (>90 on a VAS) in test and control interventions.

*Does an additional soft tissue augmentation procedure around dental implants influence patient's perception of aesthetics?*

An additional soft tissue augmentation procedure did not consistently influence patient's perception of aesthetics (3 RCTs).

Does the use of autologous grafts versus soft tissue substitutes influence the patient's reported morbidity, satisfaction, aesthetics and quality of life?

- A consistent tendency towards less patient morbidity for soft tissue substitutes was found compared to autologous grafts (6 RCTs).
- The type of graft material had an inconsistent influence on patient's satisfaction (3 RCTs).
- The type of graft material did not significantly influence patient's perception of aesthetics (2 RCTs).
- The type of graft material had an inconsistent influence on patient's perception of quality of life (3 RCTs).

#### 2.4.4 | Implications for future research

Future research should be directed towards

- Developing reliable and validated outcome measures to assess PROMs for soft tissue augmentation procedures.
- Defining adequate time-points to assess PROMs.

Investigators are advised to consider

- Using PROMs as (primary) outcome measures.
- Describing the method of assessment in detail.
- Reporting the assessed outcomes in detail.
- Applying adequate pre- and post-treatment time-points to assess PROMs.

#### CONFLICT OF INTERESTS

The authors and members of the working groups declare that they have no conflict of interests related to this consensus report.

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