CONSENSUS REPORT

Group 1 ITI Consensus Report: The role of bone dimensions and soft tissue augmentation procedures on the stability of clinical, radiographic, and patient-reported outcomes of implant treatment

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Objectives: The aims of Working Group 1 were to address the role (i) of the buccolingual bone dimensions after implant placement in healed alveolar ridge sites on the occurrence of biologic and aesthetic complications, and (ii) of soft tissue augmentation (STA) on the stability of clinical, radiographic, and patient-related outcomes of implant treatments.

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Int for

International Team for Implantology **Materials and Methods:** Two systematic reviews were prepared in advance of the Consensus Conference and were discussed among the participants of Group 1. Consensus statements, clinical recommendations, recommendations for future research, and reflections on patient perspectives were based on structured group discussions until consensus was reached among the entire group of experts. The statements were then presented and accepted following further discussion and modifications as required by the plenary.

Results: Dimensional changes of the alveolar ridge occurred after implant placement in healed sites, and a reduction in buccal bone wall thickness (BBW) of 0.3 to 1.8 mm was observed. In healed sites with a BBW of <1.5 mm after implant placement, increased vertical bone loss, and less favorable clinical and radiographic outcomes were demonstrated. Implants with buccal dehiscence defects undergoing simultaneous guided bone regeneration, showed less vertical bone loss, and more favorable clinical and radiographic outcomes, compared to non-augmented dehiscence defects during initial healing.

At healthy single implant sites, probing depths, bleeding and plaque scores, and interproximal bone levels evaluated at 1 year, remained stable for up to 5 years, with or without STA. When single implant sites were augmented with connective tissue grafts, either for soft tissue phenotype modification or buccal soft tissue dehiscence, stable levels of the soft tissue margin, and stable or even increased soft tissue thickness and/or width of keratinized mucosa could be observed from 1 to 5 years. In contrast, non-augmented sites were more prone to show apical migration of the soft tissue margin in the long-term. Favorable aesthetic and patient-reported outcomes after STA were documented to be stable from 1 to 5 years.

Conclusions: It is concluded that dimensional changes of the alveolar ridge occur after implant placement in healed sites and that sites with a thin BBW after implant placement are prone to exhibit less favorable clinical and radiographic outcomes. In addition, it is concluded that STA can provide stable clinical, radiographic, aesthetic, and patient-reported outcomes in the medium and long-term.

KEYWORDS

aesthetics, bone augmentation, dental implant, evidence-based dentistry, patient-reported outcome measures, soft tissue augmentation, surgical techniques, systematic review

1 | INTRODUCTION

The objectives of Group 1 of the 7th ITI Consensus Conference were to provide statements and recommendations for clinicians and researchers related to the effect of buccal bone wall thickness (BBW) and soft tissue augmentation (STA) procedures on the development of peri-implant disease, incidence of complications, stability of clinical, volumetric and radiographic parameters, and patient-reported outcome measures (PROMs) after implant therapy.

For Working Group 1, two systematic reviews were prepared and reviewed before the Consensus Conference. Based on the data of the systematic reviews and on thorough discussions among the participants of Group 1 and among the entire plenum, the Consensus Statements and Clinical Recommendations were carefully formulated. In addition, Recommendations for Future Research were also prepared by the working group. Finally, patient perspectives were formulated supported by the Consensus Statements from the systematic reviews and the Clinical Recommendations.

The two systematic reviews are listed below:

- Influence of buccal bone wall thickness on the peri-implant hard and soft tissue dimensional changes: A systematic review. Alberto Monje, Andrea Roccuzzo, Daniel Buser, Hom-Lay Wang.
- Do soft tissue augmentation techniques provide stable and favorable peri-implant conditions in the medium and long-term? A systematic review.

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2.1

Influence of buccal bone wall thickness on the peri-implant hard and soft tissue dimensional changes: A systematic review. 2.3.2 It is well established that the presence of alveolar bone is a prerequisite for osseointegration of dental implants. However, the exact amount of alveolar bone that is required to ensure the long-term 2.3.3 stability of the peri-implant bone and to support the soft tissue has not yet been systematically evaluated. Lack of buccal bone has been documented to be a risk factor for the development of biologic and aesthetic complications. On the other hand, the potential preventive effect of bone augmentation of thin BBWs or dehiscence defects simultaneously with implant placement in healed sites on biologic and aesthetic complications has not been systematically evaluated. The aim of the present systematic review was to evaluate the influence of BBW and the overall dimensions of alveolar bone upon soft 2.3.4 and hard tissue stability and to assess the effectiveness of simultaneous bone augmentation procedures to prevent biological and aesthetic complications when implants were placed in healed sites.

The main goal was to correlate the BBW of implants placed in healed sites to the primary outcome parameter: vertical bone loss. Secondary outcome parameters included changes in buccal bone thickness, buccolingual ridge dimensions, peri-implant clinical parameters, crestal bone loss, and patient-reported outcome measures. In addition, the same primary and secondary outcome parameters were analyzed to evaluate the effect of bone augmentation of thin buccal bone walls and dehiscence defects simultaneous with implant placement in healed sites to prevent biological and aesthetic complications.

SYSTEMATIC REVIEW PAPER 1

Manuscript title

Preamble

Out of 1700 identified records, 16 studies (12 clinical and 4 preclinical studies) could be included for the qualitative analysis. Preclinical studies were included in the analysis to potentially provide histologic data explaining the biologic background for clinically and radiographically observed peri-implant changes.

For the present consensus report, a BBW of <1.5 mm was considered a "thin" buccal bone wall. "Initial healing" after implant placement in healed sites was defined as ≤6 months. The available data did not allow to distinguish between open-flap and flapless approaches during implant placement. However, most of the implants documented in the included studies were placed with open-flap procedures.

2.3 **Consensus statements**

2.3.1 | Consensus statement 1

The alveolar ridge is subjected to buccolingual dimensional reduction during initial healing after implant placement in healed sites. This statement was supported by two prospective clinical studies and one preclinical study. Reduction of BBW is observed after implant placement in healed sites (0.3 to 1.8 mm; up to 72 months). This statement was supported by 11 prospective clinical studies.

Consensus statement 2

After implant placement in healed sites with a thin BBW, vertical bone loss occurs during initial healing. This statement was supported by five prospective, two retrospective clinical studies, and 1 preclinical study.

Consensus statement 3

Implants with buccal dehiscence defects undergoing simultaneous guided bone regeneration, show less vertical bone loss, and more favorable clinical and radiographic outcomes, compared to nonaugmented dehiscence defects during initial healing. This statement was supported by one RCT (22 patients, 28 implants).

Consensus statement 4

Implants placed in healed sites exhibiting thin BBWs, not undergoing simultaneous bone augmentation, are prone to less favorable clinical (i.e., increased peri-implant probing pocket depth, bleeding on probing, suppuration or mucosal recession), and radiographic outcomes. This statement was supported by six prospective clinical studies and one preclinical study.

Clinical recommendations 2.4

2.4.1 Clinical recommendation 1

Do we need an intact buccal bone wall for long-term peri-implant health?

An intact buccal bone wall is necessary to avoid exposure to the implant surface designed to be inside the bone, such as a microrough surface. Therefore, simultaneous bone augmentation is recommended in cases of buccal dehiscence defects or a thin buccal bone wall to maintain long-term peri-implant health.

However, when soft tissue conditions are favorable, peri-implant health can be maintained in the presence of minor buccal bone deficiencies.

2.4.2 Clinical recommendation 2

How thick should the buccal bone wall be after implant placement in healed sites?

A buccal bone wall thickness of >1.5 mm is recommended at the time of implant placement to promote long-term peri-implant health. 46 WII F.Y- CLINICAL ORAL IMPLANTS RESEARCH

Aside from bone augmentation, this may, in selected cases, be achieved by reducing implant diameter, placing the implant deeper in the alveolar crest, or flattening the alveolar ridge (in the posterior region).

2.4.3 | Clinical recommendation 3

Is bone augmentation per se enough to achieve a satisfying aesthetic result?

In the majority of cases, simultaneous bone augmentation can achieve satisfactory aesthetic results. However, in cases with high aesthetic demands exhibiting a thin soft tissue phenotype or a soft tissue deficiency, an additional STA procedure is recommended.

2.5 Patent perspectives

2.5.1 Patient perspective 1

Question: Do I have enough bone for an implant to be placed? Answer: To answer this, we first need to examine your mouth, take radiographs and plan the best position for the implant. At this point, we can determine if there will be enough bone around it. The bone needs to be 1.5 mm thick on the cheek/ lip side of the implant and 1mm thick on the palate/tongue side. So if the implant is 4 mm in diameter the bone needs to be 6.5-7 mm wide.

2.5.2 Patient perspective 2

Question: Can I have a bone graft at the same time as the implant is placed?

Answer: Yes, it can be done at the same time, but it depends on how much grafting is required and how stable the implant is when it is placed. If we can place an implant in the correct position with good stability but still lack some bone thickness in places (see Section 2.5.1), then a bone graft can be performed at the same time.

2.5.3 Patient perspective 3

Question: Will the bone graft come from my mouth or from elsewhere?

Answer: In most cases, we can collect bone from the same site where the implant is being placed. When a greater amount of bone is needed, we may need to go to a second surgical site inside your mouth. Often, however, the use of a bone substitute material, alone or in combination with your own bone, will avoid the need to use bone from other surgical sites.

2.5.4 | Patient perspective 4

Question: When do I get my crown after implant placement and bone grafting?

Answer: In a routine case, you will need to wait 2-3 months after implant placement and bone grafting for a fixed temporary crown. With a more complex situation, it may take up to 6 months. In addition, some aesthetic changes may take place during healing, so it may take 6-9 months for the final crown to be delivered.

2.5.5 Patient perspective 5

Question: Will I need antibiotics after the implant surgery? Answer: This is a controversial topic. If bone grafting is required, we would recommend antibiotics. These can either be given before surgery, after surgery, or both. For implant placement, it will depend on vour medical risk factors.

Recommendations for future research 2.6

Recommendation 1 for future research 2.6.1

The influence of anatomical and procedural factors on the dynamics of buccal bone resorption during initial healing after implant placement in areas exhibiting different thicknesses of the buccal bone wall, such as mandible vs. maxilla, zone of keratinized mucosa, open flap vs. flapless procedure, submerged vs. transmucosal healing.

2.6.2 Recommendation 2 for future research

Long-term clinical performance of different implant designs and implant surface characteristics in sites with thin buccal bone walls or dehiscence defects.

Recommendation 3 for future research 2.6.3

The long-term effect of bone augmentation of thin buccal bone walls on clinical, aesthetic, and radiographic parameters.

SYSTEMATIC REVIEW PAPER 2 3

3.1 Manuscript title

Do soft tissue augmentation techniques provide stable and favorable peri-implant conditions in the medium and long-term? A systematic review.

3.2 | Preamble

STA is often performed around implants to treat aesthetic complications, improve mucosal thickness, increase keratinized mucosa width, and reconstruct papillae. Keratinized mucosa width has been associated with improved peri-implant health, as well as less marginal bone loss and reduced patient discomfort during brushing. However, the medium and long-term effects of STA around dental implants remain unclear in the literature. Although some studies report improvement in clinical parameters and PROMs in the short-term, questions remain regarding the stability of marginal soft tissue and bone levels.

The aim of this study was to systematically review prospective clinical reporting on medium and long-term stability of clinical, volumetric, and radiographic parameters, as well as the incidence of periimplant disease, complications, and PROMs.

The main goal and primary outcome of the systematic review was to evaluate the stability of peri-implant health after STA at medium and long-term follow-up (\geq 36 months).

Secondary outcomes were as follows:

- Implant survival
- Incidence of complications
- Changes in the position of the peri-implant soft tissue margin
- Changes in peri-implant clinical parameters (plaque index/score, bleeding on probing/bleeding index, pocket depths)
- Radiographic marginal bone levels
- PROMs

The present systematic review is based on 15 clinical studies, including 4 randomized controlled trials (RCTs), 5 non-randomized clinical trials, and 6 case series. The study population included 447 patients with 461 implants, with a follow-up period ranging from 3 to 10 years (mean 8 years).

Sufficient data was not available to perform a meta-analysis of the primary outcome (stability of peri-implant health after STA at medium and long-term follow-up; ≥36 months). Only descriptive analyses were possible for the primary and secondary outcome measures, including the incidence of peri-implant disease, stability of marginal soft tissue, stability of crestal bone levels, and PROMs.

When interpreting the results, it is important to understand that medium-term follow-up is defined as 3–5 years, and long-term refers to >5 years. STA procedures were performed for different indications (soft tissue phenotype modification and treatment of soft tissue dehiscences), and due to the limited available evidence, it was difficult to draw significant conclusions about soft tissue substitutes.

3.3 | Consensus statements

3.3.1 | Consensus statement 1

Single implant sites may display stable peri-implant interproximal bone levels in the medium and long-term, whether or not soft tissue

augmentation is performed. This statement is supported by 12 studies (3 RCTs and 9 prospective clinical studies).

3.3.2 | Consensus statement 2

At healthy single implant sites, probing depths, bleeding, and plaque scores evaluated at 1 year, remain stable for up to 5 years, with or without soft tissue augmentation. This statement is supported by 11 studies (2 RCTs and 9 prospective clinical studies).

3.3.3 | Consensus statement 3

Single implant sites augmented with connective tissue grafts, either for soft tissue phenotype modification or buccal soft tissue dehiscence, display a stable level of the soft tissue margin up to 5 years. This statement is supported by 10 studies (2 RCTs and 8 prospective clinical studies). Non-augmented sites may show apical migration of the soft tissue margin in the long-term. This statement is supported by five studies (1 RCT and 4 prospective clinical studies).

3.3.4 | Consensus statement 4

Single implant sites receiving connective tissue grafts, display stable, or even increased soft tissue thickness and/or width of keratinized mucosa, from 1 to 5 years. This statement is supported by five studies (1 RCT and 4 prospective clinical studies) for soft tissue thickness and three studies (1 RCT and 2 prospective clinical studies) for the width of keratinized mucosa.

3.3.5 | Consensus statement 5

Single implant sites after augmentation with connective tissue grafts or substitutes with favorable aesthetic outcomes (i.e., pink aesthetic score, visual analog scale) are maintained or even improved, from 1 to 5 years. This statement is supported by four studies (1 RCT and 3 prospective clinical studies) for connective tissue grafts and 1 RCT for substitutes (15 patients in total, 8 vs. 7 implants). Single implant sites without soft tissue augmentation may display a higher discoloration (ie. mucosal discoloration score) compared to sites with connective tissue grafts. This statement is supported by 1 prospective clinical study (17 patients in total, 28 implants, 20 vs. 8).

3.3.6 | Consensus statement 6

Single implant sites receiving soft tissue augmentation maintain stable patient-reported aesthetic outcomes, from 1 to 5 years. This statement is based on three studies (1 RCT and 2 prospective clinical 48

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studies). Patient-reported brushing discomfort is reduced at implant sites where keratinized mucosa width was augmented with a free gingival graft. This statement is based on 1 prospective clinical study, including 98 patients and 98 implants followed up to 10 years.

3.4 | Clinical recommendations

3.4.1 | Clinical recommendation 1

Are soft tissue augmentation procedures recommended in the presence of inadequate keratinized mucosa at healthy implant sites?

In patients with difficulty in plaque control and/or reporting brushing discomfort, a free gingival graft is recommended in nonaesthetic implant sites, whereas a connective tissue graft is recommended in aesthetic implant sites.

3.4.2 | Clinical recommendation 2

Are soft tissue augmentation procedures recommended in the presence of a thin soft tissue phenotype at healthy implant sites?

Soft tissue augmentation procedures are recommended only when there is a patient aesthetic request. A connective tissue graft should be used when there is no keratinized mucosa, while soft tissue substitutes may also be selected as an alternative in the presence of keratinized mucosa.

3.4.3 | Clinical recommendation 3

Are soft tissue augmentation procedures recommended in the presence of a mid-facial soft tissue dehiscence at a restored implant with healthy peri-implant conditions?

In case of acceptable 3-dimensional implant position: Soft tissue augmentation with a connective tissue graft is recommended to improve aesthetic outcomes and promote long-term stability of the soft tissue margin.

In case of facial implant malposition: In the presence of patient aesthetic complaints and based on the severity of implant malposition, two treatment options should be considered: connective tissue graft with a new implant crown/abutment, or removal of the implant.

3.4.4 | Clinical recommendation 4

In the presence of a concave soft tissue profile and thin buccal bone, can soft tissue augmentation be performed alone?

In the presence of patient aesthetic complaint or difficulty in plaque control due to a concave soft tissue profile, a connective tissue graft is recommended.

3.5 | Patient perspectives

3.5.1 | Patient perspective 1

Question: How long will I have to be without a tooth?

Answer: Ideally, we will try to avoid leaving you without a tooth. We can offer both fixed and removable solutions and design them so there is no pressure on the surgical site. If you already have a tooth replacement, we can adjust it (usually by cutting it back by 2 mm) to avoid any pressure.

3.5.2 | Patient perspective 2

Question: Will I need to have a soft tissue graft? Answer: It depends on the shape and volume of your jaw bone and gum where the implant is to be placed.

3.5.3 | Patient perspective 3

Question: Will you use part of my palate to increase the thickness of gum around the implant?

Answer: Most likely we will need to use soft tissue from your palate, either from behind the teeth or from the back of the upper jaw. In some specific cases, we may be able to use a soft tissue substitute.

3.5.4 | Patient perspective 4

Question: How long after implant placement and soft tissue grafting will I get the crown?

Answer: In some favorable cases it is possible to have a screwretained temporary crown fitted immediately. If this is not possible, 3 months is usually the longest you will have to wait.

3.5.5 | Patient perspective 5

Question: Can bone and soft tissue grafting be performed in the same surgical procedure?

Answer: Yes, this can be done if the conditions are favorable and feasible.

3.6 | Recommendations for future research

3.6.1 | Recommendation 1 for future research

Long-term efficacy of soft tissue substitute materials to increase peri-implant soft tissue phenotype and to treat soft tissue dehiscences.

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3.6.2 | Recommendation 2 for future research

Long-term stability of the level of the mucosal margin around dental implants with thin or missing buccal bone wall undergoing soft tissue augmentation.

AUTHOR CONTRIBUTIONS

All co-authors contributed to the wording of the consensus statements, clinical recommendations, patient perspectives, and recommendations for future research. Simon Storgård Jensen, Tara Aghaloo and Ronald E. Jung drafted the manuscript. All authors gave their final approval and agreed to be accountable for all aspects of the consensus report.

CONFLICT OF INTEREST STATEMENT

All co-authors reported no conflicts of interest with regards to the present consensus report.

DATA AVAILABILITY STATEMENT None.

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