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Soft tissue augmentation applying a collagenated porcine dermal matrix during second stage surgery: A prospective multicenter case series

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Abstract

Background: The achievement and preservation of an adequate amount of soft tissue around implants is a critical factor for the prognosis of the treatment.

Purpose: To evaluate the effectiveness of a porcine dermal matrix applied during second stage implant surgery for horizontal soft tissue augmentation and preservation of dimensional stability.

Materials and Methods: Twenty patients (mean age 50.2 ± 11.9 [SD] years) candidate to implant therapy and requiring soft tissue augmentation were recruited in four centers. Augmentation was performed in 24 cases. A porcine dermal matrix was placed into a buccal split-thickness pouch during uncovering surgery. Silicone impressions were taken before surgery (T0), 2 weeks later at suture removal (T2), 6 months (T3), and 24 months (T4) post augmentation. Dimensional changes of soft tissue were evaluated using superimposition of digitalized study casts.

Results: Nineteen patients (23 implants) could be evaluated at 6 months and 13 patients (17 implants) at 24 months. After 6-month follow-up, there was a significant dimensional gain respect to baseline, averaging 0.83 ± 0.64 mm (P < .01). This did not change significantly at 24 months (0.77 ± 0.65 mm, P = .19). The gain was >0.5 mm in 65.2% and 64.7% of the cases, respectively. Soft tissue shrinkage averaged 34.2% ± 77.0% from T2 to T3 (P < .01) and did not change thereafter (P = .39). Shrinkage was more consistent in the posterior mandible than in the maxilla, but not significantly (P = .23 at 6-month and .36 at 24-month). No adverse events occurred.

Conclusion: Within the limitations of this prospective case series, the use of a porcine dermal matrix may provide consistent soft tissue augmentation that maintains up to 24-month follow-up, although graft shrinkage may occur in the first 6 months, depending on the location of surgery.

KEYWORDS

acellular dermal matrix, dental implant, gingival thickness, second stage surgery, soft tissue augmentation

Arndt Happe and Massimo Del Fabbro shared the senior position as last authors.

1 | INTRODUCTION

Dental implants show high survival and success rates on the implant level in fully and partially edentulous patients.[1-3] Osseointegration and peri-implant soft tissue stability are important factors to achieve predictable long-term outcomes. The amount of soft tissue volume may improve the esthetics and partially compensate for missing bone on the buccal aspect of dental implants.[4,5]

Soft tissue augmentation surgery can be performed at different stages of the implant therapy.[5-11] In general, the use of subepithelial connective tissue grafts (SCTG) harvested from the palate is considered the gold standard for soft tissue augmentation around dental implants.[12-14] However, the harvesting procedure with the second surgical site increases treatment time and patient morbidity. Therefore, current research focuses on alternative techniques and materials. A porcine acellular dermal collagen matrix (CM) has been introduced as an alternative to SCTGs in order to avoid surgical risks and to decrease patient morbidity.[15-19] These matrices proved their ability to increase soft tissue thickness in preclinical animal studies.[20-22] In a comparative dog study, a porcine CM has shown similar results as SCTG after a 10-month follow-up.[21] Preclinical studies suggested that acellular dermal matrices may represent a suitable scaffold for three-dimensional soft tissue thickening, showing good biocompatibility and appropriate biodegrading features.[23] Collagen-based dermal matrices have shown good clinical integration in plastic periodontal surgery[24,25] and implant surgery.[26,27] Linkevicius et al showed in a clinical study that mucosa thickness can be increased predictably with an acellular dermal matrix of allogenic origin in the molar region.[28]

Today, the use of collagen matrices as an alternative to SCTGs for the correction of localized ridge defects around dental implants cannot be recommended clinically, due to insufficient evidence regarding the effectiveness of the method in providing suitable three-dimensional tissue dimension and long-term stability.[5,12]

The aim of the present multicenter study was to test the effectiveness of a porcine acellular dermal matrix, applied at the time of second stage surgery, in providing adequate soft tissue augmentation at the buccal aspect, up to 24-month follow-up. The working hypothesis was that using a porcine acellular dermal matrix buccally positioned, soft tissue volume can be increased predictably, achieving and maintaining a horizontal gain of at least 0.5 mm.

2 | MATERIALS AND METHODS

2.1 | Study design

The Witten/Herdecke University's Ethical Committee of the Medical Faculty approved the consent form and study protocol (18/2015). Subjects were treated at four different clinical centers between May and November 2015. Three clinics were located in Germany (Witten/Herdecke University [K.F.], Private practice in München [H. W.], Private practice in Münster [A.H.]), and one in Italy (Private practice in Como [T.T.]). In total, four surgeons (one per each center) performed the interventions. All of them were highly skilled and equally trained, with more than 10 years of experience in implant dentistry and tissue augmentation procedures. Specific clinical procedures and instructions for handling of all materials used in this study were thoroughly reviewed in a preliminary meeting in the presence of the four surgeons. The study started only when all surgeons declared they were comfortable with the operative procedures of the surgical and prosthetic protocol.

Within this prospective case series, 20 patients (five patients per center) in need of minor soft tissue volume augmentation during second stage surgery were to be enrolled after thorough explanation of the study and after signing informed consent. The following inclusion and exclusion criteria were applied:

Inclusion criteria:

1. partially edentulous patients scheduled for fixed implant-supported rehabilitation;
2. implant treatment was performed with a two-piece implant system (bone-level implant);
3. implants underwent submerged healing;
4. minor localized buccal ridge contour deficiency (less than 1 mm defect, clinically estimated), with no exposure of the implant surface.

Exclusion criteria:

1. uncontrolled diabetes mellitus (HbA1c > 6.5%);
2. pregnant or lactating women;
3. infectious diseases (AIDS, Hepatitis B, C);
4. moderate or heavy smoking (>10 cigarettes per day);
5. untreated periodontitis;
6. implants planned for a removable denture;
7. immediate implants in fresh postextraction sockets.

2.2 | Surgical intervention (uncovering second stage)

Anesthesia was induced with 4% articaine chlorhydrate and epinephrine (1:100 000). After a crestal incision above the implant, a spilt-thickness flap was prepared to create a buccal pouch. A rehydrated, 2-mm thick acellular porcine dermal matrix (APDM; OsteoBiol Derma Standard, Tecnoss, Giaveno, Italy) was placed into the recipient site as reported in an earlier study.[29] Thereafter, a healing cap replaced the implant cover screw and the flap was readapted to fully cover the transplant using microsurgical sutures (6-0 Seralene, Serag Wiessner, Naila, Germany). In Figure 1, presurgical, as well as intrasurgical images of one case, to illustrate positioning of the matrix are shown.

Each patient was instructed not to brush in the surgical area for 14 days and to rinse with 0.2% chlorhexidine digluconate three times per day. Furthermore, each patient was prescribed 600 mg ibuprofen, to be taken as required.

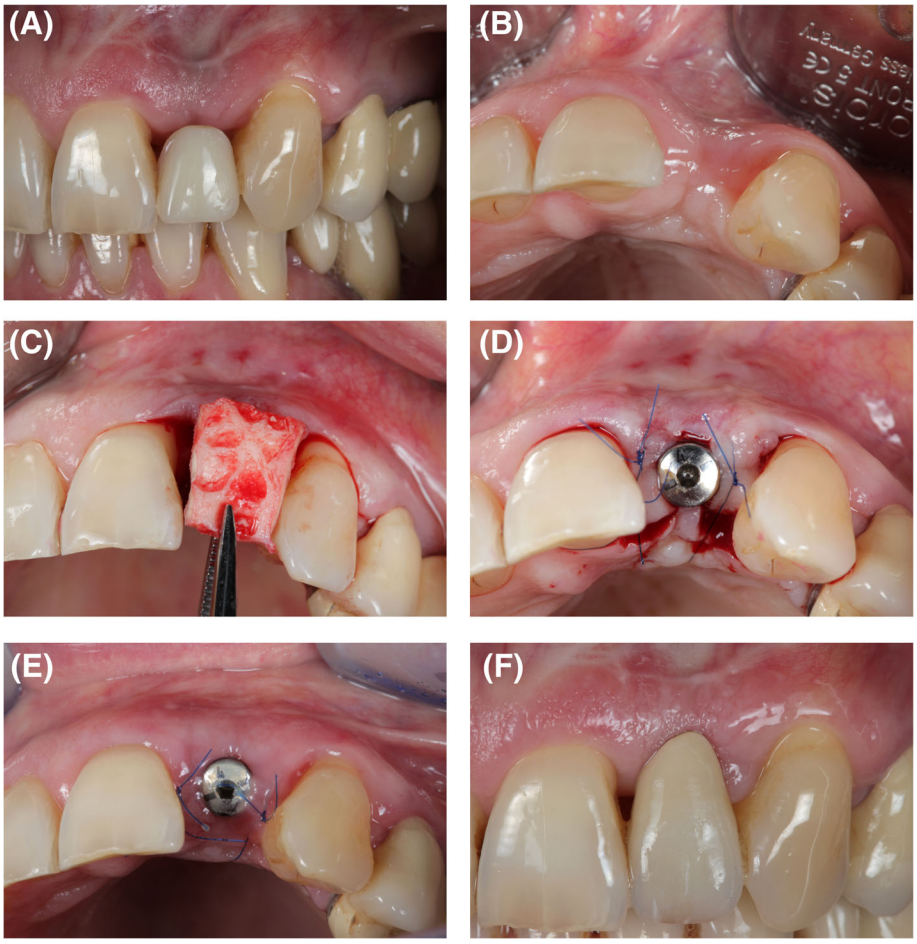

FIGURE 1 A, top left: Clinical case of a female patient of 55 years, rehabilitated with an implant placed in the upper left lateral incisor site. Initial situation at uncovering (T0), with the implant placed in region 22 and the adhesive bridge, splinted to adjacent teeth. B, top right: Horizontal defect soon before second stage surgery. The occlusal view shows insufficient contour profile, in need for augmentation. C, middle left: Augmentation of the soft tissue with dermal matrix. D, middle right: Occlusal view soon after suturing, at the end of surgery (T1). E, bottom left: Clinical situation 2 weeks postsurgery (T2). F, bottom right: Buccal view of the case 2 years after surgery (T4). In spite of a light tissue shrinking, the patient expressed full satisfaction

2.3 | Clinical measurements

Silicone impressions of the whole jaw (Impregum, 3M Espe, Neuss, Germany) were taken directly before surgery (T0), at suture removal (14 days postsurgery; T2), after 6 (T3) and 24 months (T4) of follow-up. At the end of surgery (T1) only clinical pictures were taken. The fixed prosthetic restoration was delivered 14 days after T2. There was no standardization regarding the prosthetic protocol: each center was free to choose the most appropriate fixed prosthetic restoration for each patient. In order to measure tissue contour changes, master casts were fabricated from dental stone casts (GC Fujirock type 4, GC Corp., Tokyo, Japan) using the presurgery and follow-up impressions. The casts were then optically scanned with a CEREC scan utility (inEosX5, Sirona Dental Systems, Bensheim, Germany) resulting in digital STL files (Standard Tessellation Language). All study centers sent their impressions to Witten/Herdecke University, where all the scans were performed. One single expert evaluator (S.M.), unaware of the type of surgery performed, undertook all measurements.

2.4 | Dimensional analysis

The obtained digital images of the casts reflecting the different treatment time points (presurgery, 14 days postsurgically, 6 and 24 months postsurgically) were then transferred into another digital imaging software (Swissmeda/SMOP, Zürich, Switzerland). This software allowed the superimposition and matching of the different digital models. The best-fit algorithm was used to superimpose the digital surface models based on unchanged tooth structures as reference.

The area of interest at the buccal aspect of the study-specific implant was defined according to the technique published in previous studies.[8,30,31] The mesial and distal papillary midline, the mucogingival line, and the crown margin served as anatomical reference structures. If necessary, the coronal area of interest was shifted 1-2 mm more apical to avoid nonreadable measurements because of invalid superimposition. Consequently, in each patient, the area of interest was of different size. To allow for a direct comparison between patients, the mean dimensional change per area was calculated, resulting in a linear buccal distance. Therefore, the study sites could be compared irrespective of their size and the size of the area of interest. Before the dimensional analysis, a calibration session was conducted to ensure reproducibility.

2.5 | Outcome measures

Primary outcomes: (a) Horizontal ridge augmentation. It was considered successful when augmentation was greater than 0.5 mm in the horizontal dimension, respect to baseline (T0). Such value was arbitrarily taken, based on previous similar studies, that showed a

considerable shrinking after initial augmentation.[20,31] In the present study, a net horizontal gain of 0.5 mm was considered clinically relevant. (b) Graft horizontal shrinkage after six (T3) and 24 months (T4) of healing, as compared to the 2-week dimension (T2)

Secondary outcomes: Incidence of adverse events following the surgical interventions defined as flap dehiscence, graft exfoliation, or allergic reactions.

2.6 | Statistical analysis

Descriptive statistics such as mean values, SDs, median, and percentiles were calculated using the software SPSS Statistics 22 (IBM, Ehningen, Germany). The normality of the distributions was assessed by means of the D'Agostino and Pearson omnibus normality test. The differences in horizontal soft tissue gain between T2, T3, and T4, as well as in shrinkage at T3 and T4, were assessed by means of Wilcoxon matched-pairs signed rank test. The difference in soft tissue shrinkage between regions (posterior maxilla vs posterior mandible) was assessed using the Mann-Whitney test. The single case was considered as the unit of analysis. A *P*-value <.05 was considered as statistically significant.

3 | RESULTS

3.1 | Participant flow

In total, 20 healthy patients were screened for eligibility, gave their informed consent for participation in this study, and were recruited. Each center contributed with five patients.

All patients were of Caucasian ethnicity (10 females and 10 males), with an age ranging from 33 to 66 years (average: 50.3 ± 11.9 [SD]). All participants were systemically and periodontally healthy and two were minor smokers (<10 cigarettes/day). Soft tissue augmentation was performed at 24 implants (11 in the mandible and 13 in the maxilla), but not all of them could be followed throughout the study.

3.2 | Suture removal (T2)

One patient (one implant) refused to continue the study and was considered dropout. In the remaining 19 patients, in four implants out of 23 (all in the posterior maxilla), the horizontal soft tissue gain at T2 could not be estimated due to inappropriate overlapping of the digital scan at T2 with the reference scan at T1. Hence, 19-paired observations were available for statistical comparisons between different time frames at T2 (2 weeks).

3.3 | Six-month follow-up (T3)

Nineteen subjects with a total of 23 implants were evaluated at the 6-month follow-up. The majority of implants (21/23) were located at premolar and molar level. Comparison with T1 was possible for all 23 cases.

3.4 | Twenty-four-month follow-up

Six more participants (six implants) were not available at T4 (24-month follow-up). They were considered lost-to follow-up and were excluded from the final data analysis. Hence, 13 patients (17 implants) were evaluated at 24 months. The majority of implants (15/17) were located at premolar and molar level. Horizontal gain respect to T1 could be correctly estimated at T4 in all 17 cases, but shrinkage could be calculated only for 14 cases matching with T2 measurements (five in the mandible and nine in the maxilla).

A clinical case is shown in Figure 2A-D. Occlusal pictures of T0, T1, T2, and T3 are shown. The digital analysis of the same case, followed up to 24 months, is shown in Figure 3.

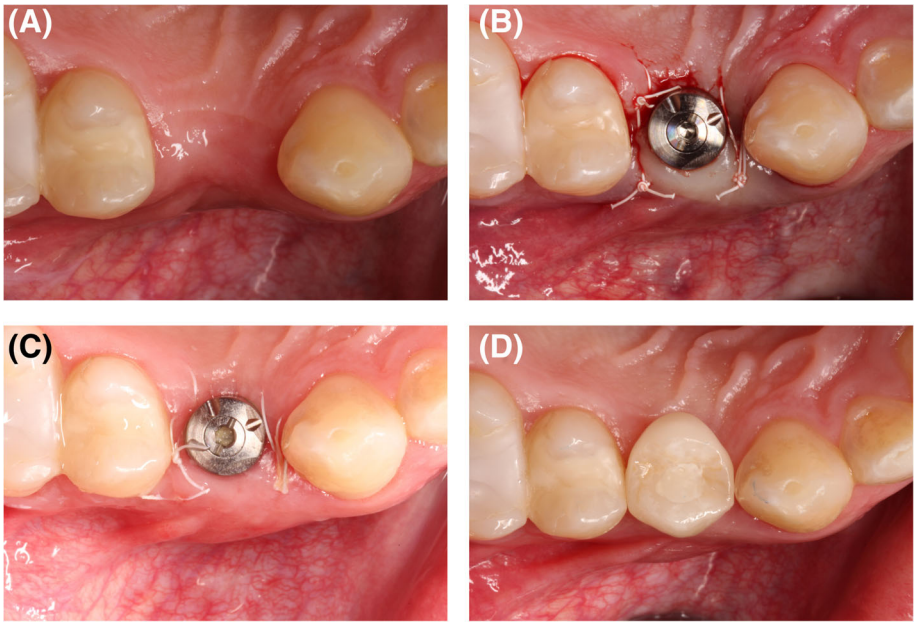

FIGURE 2 Clinical occlusal pictures of a male patient of 33 years, that was rehabilitated through a submerged implant placed in the upper right first premolar site. A, top panel, left: presurgical clinical view (T0), note the vestibular contour invagination before second stage surgery. B, top, right: Postsurgical view after flap closure (T1), care was taken to completely cover the APDM. C, bottom panel, left: Primary soft tissue healing: note the relevant gain in vestibular contour volume 14 days after surgery (T2). D, bottom, right: After 6 months follow-up, nearly complete maintenance of the augmented volume with healthy peri-implant tissues is observed (T3)

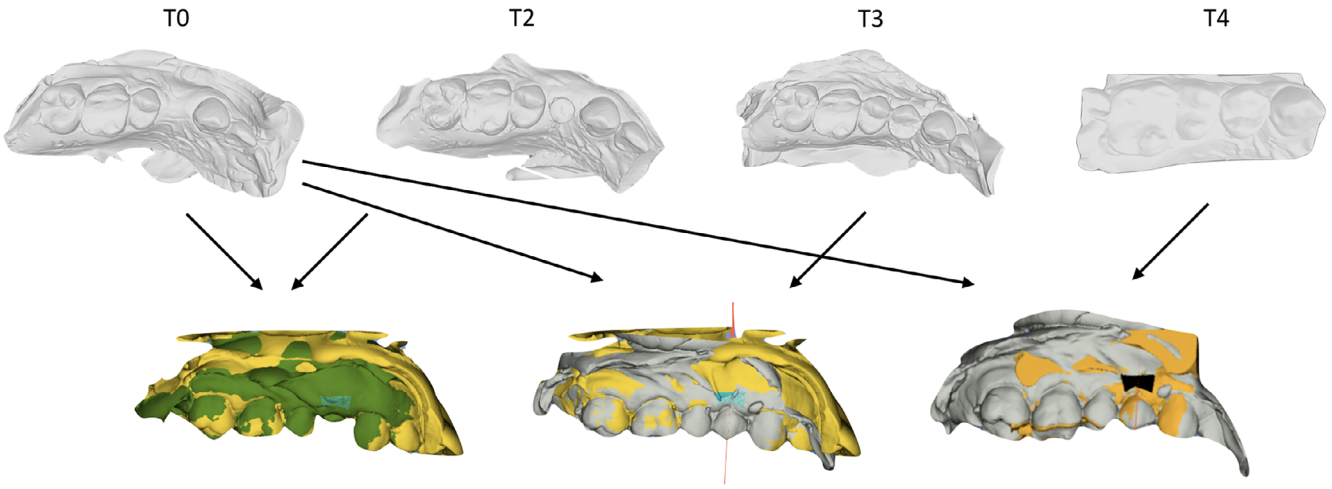

FIGURE 3 Top images: digital reconstruction of casts of the clinical case shown in Figure 1, taken at T0, T2, T3, T4. Bottom images: examples of analysis of the volume gain, obtained by overlapping two digital reconstructions. From left to right: T2-T0, T3-T0, T4-T0

3.5 | Primary outcomes

Soft tissue gain after 2 weeks was 1.57 ± 0.76 mm (median 1.53, 95% CI [confidence intervals]: 1.20, 1.93 mm), although a reduction was expected in the first months. Six months after soft tissue augmentation, the mean change in horizontal dimension respect to T1 was +0.83 ± 0.64 mm (median 0.62, 95% CI: 0.56, 1.11 mm) ($P < .01$). Fifteen out of 23 implants (65.2%) achieved a clinically relevant horizontal gain of >0.5 mm. In five cases (21.7%), the horizontal gain was >1 mm. The highest chance for success was observed in the upper posterior jaw (82%; 9 of 11), while in the other regions it was 50%. At 24-month follow-up, the horizontal gain averaged 0.77 ± 0.65 mm (median 0.61, 95% CI: 0.44, 1.11 mm), being not significantly different from T3 ($P = .19$). The gain was >0.5 mm in 64.7% of the cases (in five cases [29.4%], it was >1 mm). Figure 4 is a box-and-whiskers plot showing the horizontal gain at T2, T3, and T4. As the data did not follow a Gaussian distribution, nonparametric tests were used for comparisons.

The mean overall horizontal shrinkage of soft tissue observed at T3 and T4, compared to the data evaluated at T2, was 34.2% ± 77.0% (median 67%, 95% CI: −3.1, 71.5%; $P < .01$) and 19.9% ± 96.1% (median 65.3, 95% CI: −31.2, 71.1%), respectively. There was no significant difference in shrinkage between T3 and T4 ($P = .39$), suggesting a fair volume maintenance from 6 to 24 months. The SD is rather high, as in some cases, a further expansion instead of a shrinkage was observed. Figure 5 compares the shrinkage observed in the posterior maxilla versus posterior mandible. The difference in shrinkage between the two posterior regions was not statistically significant ($P = .23$ and $P = .36$ at 6 and 24 months, respectively). The two cases located in the anterior region of the maxilla (both were lateral incisors) were excluded from such comparison. Such cases showed a rather high shrinkage at T3, equal to 74% and 66.5%. Such values remained essentially unchanged at T4.

3.6 | Secondary outcomes

No adverse event such as dehiscence, postmeasurement infection, or bleeding was recorded at any time.

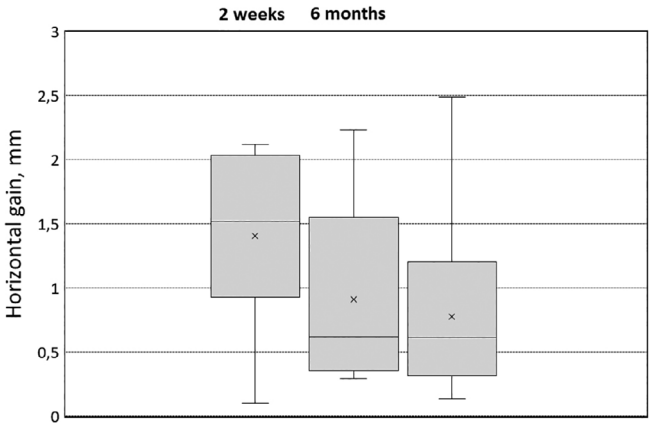

FIGURE 4 Whiskers box plots of the horizontal dimensional gain at 2 weeks (T2), 6 months (T3), and 24 months (T4) after soft tissue augmentation. Median values (horizontal black lines) and mean values (crosses) are shown, with the 25th and 75th percentiles outline by the box plot. Vertical lines with horizontal bars extend to the 95% confidence intervals (CIs). Values outside 95% CI are shown (hollow circles). The Wilcoxon matched-pairs signed rank test showed statistically significant difference at T3 respect to T2 ($P = .001$), while no significant difference was found between T2 and T3 ($P = .19$), indicating good maintenance

4 | DISCUSSION

In the present prospective multicenter case series, we aimed to assess (a) the possibility to augment the horizontal ridge dimension by using an APDM during second stage implant surgery and (b) how much graft shrinkage needs to be expected 6-month postsurgery.

The main limitation of this study could be considered the absence of a control group. The latter, with just repositioning of the flap, could certainly have added value to this study, and possibly confirm that the observed results were dependent on the application of APDM. Ideally, each test site should have a matched control, with similar anatomical and morphological features, which may not be as easy to find.

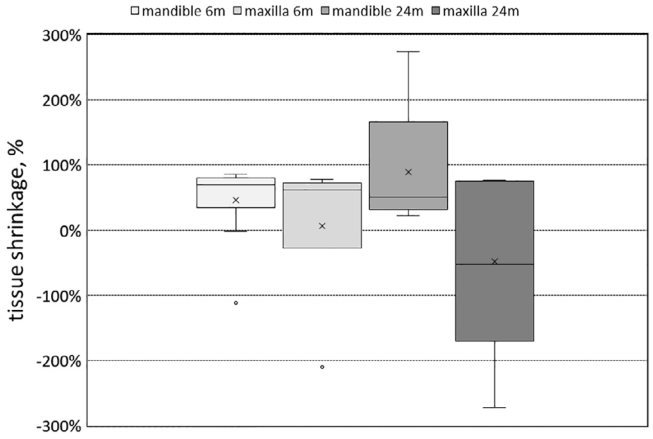

FIGURE 5 Whiskers box plots of the soft tissue shrinkage between T2 (2 weeks postaugmentation) and T3 (6-month follow-up), and between T2 and T4 (24-month follow-up) in cases located in the posterior mandible (n = 5) and in the posterior maxilla (n = 9). Negative values indicate expansion. Median values (horizontal black lines) and mean values (crosses) are shown, with the 25th and 75th percentiles outline by the box plot. Vertical lines with horizontal bars extend to the 95% confidence intervals (CIs). Values outside 95% CI are shown (hollow circles). The Mann-Whitney test showed nonsignificant difference in shrinkage between posterior arches (P = .22). Variability tended to increase with follow-up time

Furthermore, the sample size is limited, especially if comparisons between different jaw regions (requiring data split into subgroups) are to be made. Also, although a multicenter study design may allow to recruit a larger number of patients in a relatively short time, one has to consider possible differences in patient management and prosthetic protocols among different centers. Given the similar expertise of the surgeons, and their specific training on the procedures used in this study, it was assumed that there was no relevant interoperator difference. Finally, specific clinical parameters like plaque index, soft tissue bleeding, or inflammation, that might play a role in affecting tissue volume, were not systematically measured in the different centers. Within the limitations of this case series, it seems to be possible to predictably gain at least 0.5 mm of soft tissue in the horizontal dimension applying an APDM during second stage surgery, especially in the posterior maxilla, where in a few cases even more than 2 mm augmentation were observed at 6 months. Defects in the mandible, anterior sites, and free-end situations seem to be less favorable. We underline that the flap at second stage was not buccally repositioned but it was only closely adapted to the healing abutment, and the observed increase in thickness was likely only due to the porcine dermal matrix. When using this technique, "graft" shrinkage of around 30% to 40% may occur after 6 months, depending on the location of surgery. The quite variable shrinkage observed (Figure 4), and the fact that in some cases an expansion occurred between T2 and T3 deserves further studies with larger sample size to investigate the factors that may affect augmentation prognosis. Therefore, this may be considered a pilot study, whose results need to be confirmed by further prospective studies.

Mucosal thickness is an important factor regarding esthetics and long-term tissue stability. The difference in light reflection (translucency) of soft tissue covering titanium or zirconia abutments is no longer noticeable for the human eye when the mucosa thickness exceeds 2 mm.[8]

Multiple preclinical investigations regarding the effectiveness and safety of different soft tissue substitutes have been published, focusing on graft integration and dimensional changes.[8,20,27,30-32] One of the major concern of such studies was to determine to what extent xenograft collagen matrices would be resorbed by the host, namely the soft tissue gain stability along time. One animal study showed that the gain in volume is rather stable after a few months.[22] The authors concluded that in spite of the degradation of the xenograft, which leads to a significant amount of volume loss, part of the CM may remain, or being replaced by newly formed connective tissue.[22]

In a split-mouth study, Fickl et al compared SCTG and APDM for the treatment of buccal dehiscence defects at upper canines in five dogs.[24] After 4-month follow-up, they found no statistical significant difference neither in soft tissue height nor in thickness and, thereby, concluded that the applied APDM might be a valid alternative to autologous grafts. Schmitt et al used a similar preclinical model applying another type of APDM.[21] The mean horizontal gain was 0.65 mm for SCTG and 0.96 mm for APDM directly after surgery; however, after 10 months, only 0.13 mm for SCTG and 0.01 mm for residual APDM, showing a net tissue loss. In 2010, Thoma et al evaluated a porous CM for volumetric augmentation in chronic ridge defects in dogs.[22] While they used a 5 mm thick CM folded twice, they gained 1.4 mm in thickness after 84 days. They found similar results for SCTG folded twice—5 mm thick before removal of epithelium remnants, fatty and glandular tissue—and CM after 28 and 84 days. However, they did not report on the volumetric gain directly after surgery, which would have been interesting to evaluate graft shrinkage. More recently, the same group used a similar cross-linked, porous CM for soft tissue augmentation after bone grafting using guided-bone-regeneration.[20] While the achieved dimensional gain was stable for the first 2 months, a significant loss was observed in the following 4 months. Only a minimal gain of 0.55 mm for the SCTG and 0.23 mm for CM was noted in the most coronal aspect compared to 2.5 mm (SCTG) and 2.1 mm (CM) after 1 month, while around 50% of the tissue gain (SCTG: 0.64 mm, CM: 0.68 mm; P = .98) was maintained at the level of implant shoulder. The observed dimensional gain in our study population using a 2-mm thick and rather dense APDM might be comparable to the above reported results using a thicker, porous CM. It remains unclear whether a more porous—and maybe more prone to compression—or a denser structure of soft tissue substitutes is more favorable regarding long-term stability.

Clinically, Puisys and Linkevicius showed that mucosal thickness around dental implants can be successfully increased with an ADM of allogenic origin with concomitant reduction of bone loss compared to untreated cases with thin tissues.[33,34] Allogenic ADM was also used to correct horizontal ridge defects before prosthetic rehabilitation.[35] About 40% horizontal volume loss was observed, with the highest change occurring within the first 3 months. It was concluded that

allogenic ADM might be a suitable material for the treatment of soft tissue ridge deformities due to its biocompatibility, color matching, and horizontal gain. However, only in few cases was the desired tissue gain achieved.[35] De Bruyckere et al used SCTG to correct horizontal alveolar defects around single implants in the anterior maxilla.[36] Horizontal tissue thickness gain averaged 0.97 mm equivalent to 90.5% of the gain observed immediately after SCTG placement. This represents one of the lowest reported tissue loss after soft tissue augmentation. In that study, however, all implants had been restored with screw-retained provisional, as opposed to our cases and the majority of reports in literature.

As previously said, the major limitation of the present clinical study is the lack of a control group. SCTG is still seen as the gold standard and could have been served as a control; however, it is complicated to standardize graft thickness and composition (connective vs fatty/glandular tissue), especially in a multicenter study. In addition, as SCTG is an operator-sensitive technique, the variability introduced by the different operators involved should have been taken into account.

The present preliminary data confirmed that using APDM, a soft tissue augmentation greater than 0.5 mm can be achieved after 6 months of follow-up, and maintained up to 2 years, in two-thirds of cases. Future studies should aim at providing clear indication of possible achievements and limitations of substitutes used for soft tissue augmentation in the clinical practice. These studies should focus on the comparison of collagen matrices with different features (eg, xenogenic vs allogenic origin, or dense vs porous structure), in order to give recommendations for the proper indication and use of these materials as a feasible alternative to autologous grafts. Standardized research protocols should be established to allow comparison of different studies.

CONFLICT OF INTEREST

There was no financial support for this study. The materials for augmentation were kindly provided by Tecnoss Dental S.r.l., Torino, Italy. The authors declare they have no conflict of interest.

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