Soft tissue reconstructive techniques at implant sites: a clinical, volumetric and ultrasonographic analysis

University of Szeged

Faculty of Medicine

Doctoral School of Clinical Medicine

PhD Candidate

Lorenzo Tavelli, DDS, MS

PhD Mentors

Istvan Urban, DMD, MD, PhD

Hom-Lay Wang, DDS, MSD, PhD

Szeged

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I. INTRODUCTION

Implant therapy has been proved to be a reliable option for replacing missing dentition. Nevertheless, implant-related complications are often observed. Among them, peri-implant soft tissue dehiscences/ deficiencies (PSTDs) have become an emerging concern due to the recent increased patients' esthetic demand. The exposure of the abutment in the oral cavity or the presence of an implant-supported crown longer than the homologous tooth are often considered unacceptable for the patients, especially in the esthetic region. Peri-implant soft tissue dehiscences (PSTDs) are common findings among our patients. It has been speculated that these conditions are associated with several factors, including –but not limited to – implant malpositioning, limited mucosal thickness, absence of keratinized tissue, thin buccal bone, buccal bone dehiscence or fenestration, implant diameter, patient characteristics, etc. Neverthless, the prevalence of PSTDs, when definied as the apical shift of the peri-implant soft tissue margin compared to the cemento-enamel junction of the homologous contralateral tooth, has not been assessed in the literature at the present moment. In addition, limited information – mainly from case report or case series – are available when assessing surgical techniques for the correction of PSTDs and peri-implant soft tissue phenotype modification. It has been suggested that the treatment of PSTDs should aim at not only to coronally reposition the soft tissue margin at the ideal level but also to promote peri-implant soft tissue phenotype modification, which has been correlated to peri-implant health and esthetic satisfaction. As has been shown in natural dentition following root coverage procedures, it is reasonable to assume that the augmented soft tissue phenotype can affect the stability of the outcomes over time also at implant sites. In line with this assumption, clinical reports utilizing autogenous connective tissue graft (CTG) or substitutes have been described for the treatment of PSTDs. Burkhardt and coworkers assessed the 6-month outcomes of PSTDs treated with conventional trapezoidal CAF and sub-epithelial CTG, showing a substantial relapse of the soft tissue margin from 1 to 6 months, with none of the sites displaying complete soft tissue dehiscence coverage at the last follow-up. Another study confirmed the limited efficacy of conventional trapezoidal CAF for the treatment PSTDs, with a mean PSTD coverage of 40% and 28% for CAF + subepithelial CTG and CAF + acellular dermal matrix, respectively. Modifications of conventional CAF have been later suggested for improving its predictability around dental implants. These approaches included an envelope flap design and the choice of a CTG mainly composed of lamina propria, harvested either from the superficial palate or from the tuberosity. On the other hand, with its recent increase popularity among clinicians for root coverage purposes, tunnel-like approaches have been also attempted at implant sites and may be considered a valid option for the treatment of PSTDs due to the preservation of the integrity of the papillae, the enhanced graft nutrition and improved esthetic outcomes that have been advocated for these techniques. However, it should be mentioned that most of the evidence on PSTD treatment available in the literature is based on case series or case reports, with heterogeneous inclusion criteria and case definitions, and scarce information on soft tissue phenotype modification following the intervention.

II. AIMS OF THE STUDY

2.1 Aim of study 1

The aim of the study was to evaluate the prevalence of PSTD and some clinical and ultrasonographic risk indicators for this condition.

2.2 Aim of study 2

The aim of the clinical trial was to compare the clinical, volumetric, and ultrasonographic outcomes of PSTDs treated with CTG either with eCAF or TUN.

III. MATERIALS AND METHODS

A clinical and ultrasonographic study cross-sectional study assessing the prevalence and risk indicators for peri-implant soft tissue dehiscences (Study 1)

Study design and Ethical considerations

The study was approved by the University of Michigan Medical School Institutional Review Board (IRBMED) (HUM00176741), in accordance with the Helsinki Declaration of 1975, as revised in 2013. An informed consent was obtained from all individuals who had participated in the study. The study follows the STROBE statement.

Inclusion criteria

Subjects with one or more healthy dental implants in the esthetic area (from the right first premolar to the left first premolar) were identified and recruited from a population attending the Graduate Periodontics clinic at the Department of Periodontics and Oral Medicine, School of Dentistry, University of Michigan, Ann Arbor, USA between February 2020 and June 2021. The inclusion criteria were: 1) systemically and periodontally healthy subjects, 2) having at least one anterior dental implant with two adjacent natural teeth and/or dental implants, 3) dental implant(s) diagnosed as healthy ("absence of erythema, bleeding on probing, swelling and suppuration"), 4) dental implants rehabilitated with a single implant-supported crown, 5) loading time of at least 24 months, 6) presence of the homologous contralateral natural tooth, 7) available information regarding implant characteristics and 8) patients willing to provide an informed consent and attend the study.

Data Collection and Clinical measurements

At the time of the visit, patient demographics and implant characteristics were obtained, as well as the following parameters by a single examiner:

- Presence or absence of PSTD, defined as the apical shift of the mucosal margin compared to the gingival margin of the homologous contralateral natural tooth. In case of a PSTD, the class (I, II or III/IV) and subclass (a, b or c) were also identified. Since the implant-supported crown was not removed in the present study, implants with a PSTD characterized by a crown profile located outside (more facial to) an imaginary curve line connecting the profile of the adjacent teeth at the level of the mucosal margin were considered as class III/IV.

- Presence or absence of an implant-supported crown longer than the clinical crown of the homologous contralateral natural tooth
- Presence or absence of the exposure of the abutment and/or implant fixture to the oral cavity
- Presence of adjacent (mesial/distal) implants
- Probing pocket depth (PD) using a periodontal probe (PCP UNC 15, Hu-Friedy, Chicago, IL, USA)
- KMW, defined as the vertical distance between the mucogingival junction and the mucosal margin in the mid-facial region, and measured with a periodontal probe (PCP UNC 15, Hu-Friedy, Chicago, IL, USA).

Ultrasonographic image acquisition and measurements

A commercially available ultrasound imaging device (ZS3, Mindray, Mountain View, CA, USA) was coupled with a 24 MHz (64 μm axial image resolution) and miniature-sized (approximately 30 mm long, x 18 mm wide x 12 mm thick) probe prototype (L30-8) to generate ultrasound images (pixel size 0.05 mm). The following measurements were computed using a commercially available software package (Horos™, version 3.3.6, Horos Project):

- MT: horizontal thickness of the peri-implant soft tissue, calculated as the distance between the soft tissue margin and the abutment/implant fixture/buccal bone on a line parallel to the long axis of the implant body in the mid-facial scan. MT was measured at 1 and 3 mm (MT1 and MT3, respectively) from the soft tissue margin.
- Peri-implant buccal bone distance (BBD): Distance between the implant platform and the peri-implant bone crest evaluated on a line parallel to the long axis of the implant body in the mid-facial scan.
- Peri-implant buccal bone thickness (BBT): evaluated 0.5 mm apical to the bone crest as the distance between the peri-implant crestal bone and a line parallel to the long axis of the implant body in the mid-facial scan

A stepwise regression approach was utilized to univariately introduce the variables of interest for testing their predictive values and kept for multi-variate modeling if obtained a p of < 0.05. For significant predictors, the final coefficients from the multi-variate model were recorded, and exponentiated to produce odds ratios (OR). Confidence intervals (CI) were produced and a p value of 0.05 was set for statistical significance. The analyses were performed in software (Rstudio Version 1.1.383, Rstudio, Inc., Boston, MA, USA).

Methods Coronally Advanced flap vs Tunnel technique for the treatment of peri-implant soft tissue dehiscences: A randomized, controlled, clinical trial (Study 2)

Study design and trial registration

The present study was designed as a double-blind, parallel arm, randomized, controlled clinical trial on the treatment of PSTDs to compare two procedures in combination with CTG: the envelope Coronally Advanced Flap (eCAF) and the Tunnel technique (TUN). The trial was registered at ClinicalTrial.gov (NCT03498911) and follows the CONSORT statement (http://www.consort-statement.org/). The study protocol was approved by the Institutional

Review Board of the University of Michigan Medical School (HUM00140205) and is in accordance with the Declaration of Helsinki of 1975, revised in Fortaleza in 2013.

Inclusion criteria

Subjects presenting with PSTDs in non-molar sites were screened at the Department of Periodontics and Oral Medicine, University of Michigan School of Dentistry (Ann Arbor, USA) between July 2018 and September 2020. Patients satisfying the following inclusion criteria were recruited: i) Age ≥ 18 years, ii) Periodontally and systemically healthy, iii) Full-mouth plaque score and full-mouth bleeding score ≤ 20%, iv) Dental implants with isolated Class II PSTDs, subclass a or b, located in a non-molar site and with two adjacent natural teeth, v) Osseointegrated and functionally loaded dental implants and vi) No history of previous PSTD treatment at the implant site.

Interventions

An envelope coronally advanced flap with connective tissue graft (eCAF), as previously described by Zucchelli et al., was performed to treat the PSTDs allocated to the eCAF group. A modified tunnel technique with connective tissue graft (TUN), as previously described by Aroca et al. and Zuhr et al. was performed in implants with PSTD allocated to the TUN group.

Clinical measures

The following clinical measurements were collected at baseline, 3 months, and 6 months after surgery at each experiment site:

- Peri-implant soft tissue dehiscence (PSTD) depth: corono-apical distance between the peri-implant soft tissue margin and the ideal soft tissue margin, defined based on the level of the homologous contralateral unrestored tooth (3, 23);
- Pocket depth (PD): measured from the soft tissue margin to the bottom of the peri-implant sulcus;
- Clinical attachment level (CAL): obtained by adding PD to PSTD depth;
- Keratinized mucosa width (KMW): corono-apical width/height measured from the soft tissue margin to the mucogingival junction and identified using Lugol staining (23);
- Attached mucosa width (AMW): obtaining by calculating the difference between KMW and PD;
- Mucosal thickness (MT): measured 1.5 mm apical to the soft tissue margin using a short injection needle for anesthesia and a silicon disk stop, which was then fixed with a few drops of cyanoacrylate as described by Zucchelli and coworkers (24) (18). After needle removal, the distance between the tip of the needle and the disk stop was measured with a digital caliper with 0.01 mm accuracy.

PSTD depth, PD and KMW were measured with a periodontal probe (PCP UNC 15, Hu-Friedy, Chicago, USA) and rounded up to the nearest 0.5 millimeter.

Data acquisition and outcomes assessment

An intraoral optical scanner (Trios, 3Shape, Denmark) was utilized to generate digital models that were saved as STL files and imported in an image analysis software (GOM Inspect, GOM, Germany). A semi-automated alignment, based on the selection of reproducible points on the digital models and on a best-fit algorithm, was used to superimpose the STL files. Each time point (1, 3 and 6 months) was superimposed to baseline, which was used as the reference. The volumetric outcomes of interest were volume change in mm^3 (Vol) and the mean distance between the surface/ mean thickness of the reconstructed volume in mm (ΔD). The ultrasound (US) equipment setup and the scanning protocols have been described for the Study 1. The following outcomes of interest were assessed on the midfacial US scan at baseline, 1 month and 6 months: i) Mucosal thickness, evaluated 1, 3 and 5 mm apical to the soft tissue margin of the implant (UMT 1, UMT 3, and UMT 5, respectively); ii) Distance between the crown margin and the soft tissue margin (CM-STM); iii) Distance between the implant shoulder and the bone crest (ultrasonographic buccal bone dehiscence [UBD]); iv) Distance between the crown margin and the crestal bone (CM-CB); v) Supracrestal tissue height (STH), defined as the distance from the crestal bone to the soft tissue margin. In addition, the buccal bone dehiscence measured clinically in eCAF-treated sites (BD) was compared to the preoperative measurements of buccal bone dehiscence obtained from the ultrasound scans (UBD).

The preliminary pilot analysis of blood flow changes at grafted implant sites and palatal donor site was performed using ultrasonographic power doppler on a sample of 5 patients over a period of 12 months. The areas of interest at the implant site were: i) midfacial, ii) mesial (at the line angle between the crown and the mesial papilla), iii) distal (at the line angle between the crown and the distal papilla) and iv) transverse scan at 3 mm from the mucosal margin level. CV_m and CP_m were obtained as an average of CV/CP_w across at least 5 the cardiac cycles (6 second cine clips at minimum 20 Hz frame rate for cardiac averaging). The variation in percentages compared to baseline was computed and descriptive statistics were used to present the gathered data as means ± standard deviations (SD).

Sample size and statistical analysis

The study was powered to detect a minimum clinically significant difference in soft tissue dehiscence coverage of 0.5 mm using $\alpha = 0.05$, a power (1- β) of 80%, and a hypothesized within-group sigma of 0.446 mm (17). Considering possible dropouts, the number of patients were increased by 15% for each arm. On the basis of these data, the minimum number of patients needed to be enrolled in this study was in 28 totals, with 14 for the eCAF + CTG group, and 14 for the TUN + CTG group. Complete soft tissue dehiscence coverage was calculated as the percentage of sites that achieved a complete at 6 months and expressed as a binary outcome. T-test was utilized to compared baseline and the 6-month outcomes between the two interventions. Linear mixed-effects and logistic regression models were used to assess statistical changes in PSTD depth between different time points and differences between the eCAF and TUN groups. The randomization, as to which among the two groups (1 or 2) had served as the TUN sites was revealed at the end of the analysis by the study coordinator. All analyses were performed by an individual author with experience in biostatistical analyses (RStudio, Version 1.3.959).

IV. RESULTS

A clinical and ultrasonographic study cross-sectional study assessing the prevalence and risk indicators for peri-implant soft tissue dehiscences (Study 1)

One-hundred and fifty-three subjects (80 males and 73 females, with a mean age of 59.5 ± 15.6 years) with a total of 176 dental implants were included in the study. 54.2% patients had at least one implant with a PSTD. On an implant-level, 100 dental implants (56.8%) displayed a PSTD and 76 (43.2%) did not. Eighty-four percent (84%) of the implants with a PSTD showed a crown longer than the clinical crown of the homologous tooth, while the exposure of the abutment or implant fixture to the oral cavity was present in 74% of sites with a PSTD. Most of the implants with PSTD were diagnosed with class III/IV (58%), while 39% and 3% of cases were classified as PSTD class II and class I, respectively. The most frequent PSTD subclasses were subclass c and subclass b (52% and 40%, respectively). The mean time in function of the implants with PSTD was 9.3 ± 4.5 years, while for implants without PSTD was 4.9 ± 1.6 years. Implants with PSTD had an adjacent dental implant (without PSTD) in 54% of cases, while implants without PSTD had an adjacent implant (without PSTD) in 5.3% of cases. The mean PD was 2.6 ± 0.6 mm and 2.6 ± 0.8 mm in implants with and without PSTD, respectively, while the mean KM width was 2.2 ± 1.7 mm and 4.5 ± 1.7 mm in implants with and without PSTD, respectively.

The measurements of MT at the midfacial ultrasonographic scans tended to be higher at sites without PSTD compared to implants with PSTD (mean MT1 of 1.51 ± 0.58 mm vs 0.65 ± 0.36 mm and mean MT3 of 2.05 ± 0.79 mm vs 1.35 ± 0.56mm, respectively). The average BBD was also higher at implants with a PSTD (3.25 ± 2.07 mm for implants with a PSTD versus 1.73 ± 1.20 mm for implants without), while a mean BBT of 0.91 ± 0.43 mm, and 1.48 ± 0.66 mm was observed for implants with and without PSTD, respectively. The uni-variate analysis showed that the variables of presence of an adjacent implant (OR 14.4 (95% CI [3.22, 64.8]), p<0.001), implants' time in function (OR 1.73 (95% CI [1.47, 2.03]), p<0.001), KMW (OR 0.49 (95% CI [0.38, 0.63]), p<0.001), MT1 (OR 0.08 (95% CI [0.04, 0.17]), p<0.001), MT3 (OR 0.37 (95% CI [0.22, 0.63]), p<0.001), BBD (OR 1.86 (95% CI [1.35, 2.56]), p<0.001), and BBT (OR 0.09 (95% CI [0.02, 0.37]), p=0.001) were significantly related to higher odds of the presence of a PSTD.

Multi-variate analysis confirmed that the presence of an adjacent implant increases the odds of having a PSTD by a factor of approximately 11 (OR 10.9 (95% CI [2.98, 40.2]), p<0.001), as well as the time (in years) of the implants in function (OR 1.4 (95% CI [0.71, 2.73]), p=0.001). Additionally, the model showed an inverse correlation between MT both at 1 mm (OR 0.11 (95% CI [0.04, 0.24]), p<0.001), and 3 mm (OR 0.34 (95% CI [0.14, 0.82]), p=0.01) from the mucosal margin, and the amount of KMW (OR 0.73 (95% CI [0.55, 0.97]), p<0.001), with the presence of PSTD among the population cohort. Relative to the peri-implant buccal bone, BBD also was significantly associated with the presence of a PSTD (OR 1.41 (95% CI [1.02, 1.95]), p<0.001).

Advanced flap vs Tunnel technique for the treatment of peri-implant soft tissue dehiscences: A randomized, controlled, clinical trial (Study 2)

96 subjects were assessed for eligibility; among them, 63 did not meet the inclusion criteria and 2 declined participation. Therefore, twenty-eight subjects (mean age 47.0 ± 12.1 years, 14 females, 12 males), 14 per group, each contributing with one experimental site only, were randomized and received the allocated interventions. Seven PSTDs allocated to the eCAF group were classified as subclass a, while 6 PSTDs in the TUN group were judged as subclass a. All the implants that received PSTD treatment were bone level implants. The dimension of the CTG within the two groups were not statistically different. The average surgical time was 82 ± 8 min and 80 ± 5 min for the eCAF and TUN groups, respectively ($p>0.05$). The primary endpoint of the study was mean PSTD coverage at 6 months, that was significantly greater in the eCAF group compared to the TUN group (87.85% vs 64.40%, $p=0.04$). Sites treated with eCAF obtained also higher complete PSTD coverage (64.3% vs 42.9%, $p>0.05$), although this result was not statistically significant. A significantly greater KMW gain (1.64 mm vs 0.82 mm, on average, $p=0.03$) and AMW gain (1.14 mm vs 0.36 mm, $p=0.03$) were observed at implants allocated to eCAF compared to TUN, respectively. The mean MT gain, from baseline to the 6-month follow-up, was 1.44 mm and 0.99 mm, in the eCAF and TUN group, respectively ($p=0.02$).

Linear regression analysis demonstrated that treatment approach ($p=0.042$) and PSTD subclass ($p=0.045$) were significantly associated with mean PSTD coverage. Age, sex, arch, baseline KMW and baseline MT were not associated with final mean PSTD coverage ($p>0.05$). After 3 months, sites allocated to eCAF showed a statistically significant higher Vol and ΔD than sites allocated to TUN. At the last recall, the eCAF and TUN showed a mean Vol of 75.90 mm^3 and 37.25 mm^3 ($p<0.01$), and a mean ΔD of 1.01 mm and 0.53 mm ($p<0.01$), respectively. No difference between the two groups was present at baseline for the ultrasonographic outcomes of interest. At the sites allocated to eCAF, the distance between the crown margin and the bone crest measured with ultrasonography was 6.34 ± 2.42 mm, while with the intrasurgical correspondent measurement was 6.75 ± 2.37 mm.

A superior mean UMT gain at 3 mm was found for the eCAF over the TUN group (1.59 mm vs 1.10 mm, $p=0.01$) at the last follow-up, while no differences were noted for UMT gain at 1 mm, nor at 5 mm ($p>0.05$). The mean CM-CB change from baseline to 6 months was -0.72 mm and -0.21 mm for eCAF and TUN, respectively, indicating a higher buccal bone resorption following eCAF than TUN ($p<0.01$). A similar result was also observed when evaluating UBD changes at 6 months (-0.67 mm and -0.18 mm for eCAF and TUN, [$p<0.01$]). Both groups exhibited an increase in STH after 6 months, with eCAF-treated implants showing a greater mean STH change than sites allocated to TUN (2.44 mm vs 1.43 mm, $p<0.01$). In the midfacial scan, an increase in CV_m of 199% was observed compared to baseline at the 1-week follow-up. The CV_m increase in the mesial, distal and transverse scans were 102%, 95.6% and 163%, respectively, compared to baseline. The CV_m increase at 1 month was similar to the one observed at 1 week in all the scans. At the 6- and 12-month follow-up, CV_m was found to be lower than baseline. A similar trend was observed for CP_m change over time.

The professional esthetic evaluation using the Implant soft tissue Dehiscence coverage Esthetic Score (IDES) showed a mean final score of 7.00 vs 4.93 points for the eCAF and TUN groups, respectively (p=0.03). Regarding the individual component of the IDES, eCAF-treated sites obtained a statistically significant superior mean score for the level of the soft tissue margin (3.71 vs 2.14 points, p=0.03), while a significantly higher peri-implant mucosa appearance was observed in sites treated with TUN compared to eCAF (0.79 vs 0.36 points, p=0.02).

V. DISCUSSION

Prevalence and risk indicators for peri-implant soft tissue dehiscences

The result of the present cross-sectional study, with the aid of clinical and ultrasonographic measurements, identified the prevalence of dental implants with PSTD, as well as risk indicators for the presence of this condition. Most of the implants evaluated in our study displayed PSTD (56.8%), while on a patient-level, it was found that having at least one implant with PSTD was more common than having implants without this condition (54.2% vs 45.8%). It should be highlighted that our population cohort included patients which had implants placed both in a private practice and in a university setting, which would increase the generalizability of our findings. Given the fact that PSTD is an esthetic complication often associated with esthetic concerns/complaints from patients, it is reasonable to assume that the definition of PSTD should not solely include cases with exposure of the abutment/implant fixture but should also include conditions characterized by an implant-supported crown longer than the clinical crown of the homologous contralateral tooth. In this view, the present study represents the first report investigating the prevalence of PSTDs, together with their types, classes, and subclasses, according to the recent classification by Zucchelli et al.

We observed that most of the PSTDs are characterized by a crown longer than the homologous contralateral tooth (84%), with or without concomitant exposure of the abutment/implant fixture (58% and 26% of all the PSTD cases, respectively). This finding has implications on treatment of these defects, since the correction of PSTDs with inadequate crown length requires crown removal in combination with the prosthetic-surgical technique or the submerge approach. Clinicians are therefore advised that crown removal is necessary in most of the PSTD treatments. We also found that the exposure of the abutment/implant fixture was present in 74% of sites with PSTDs. Aside from patient esthetic concern, the exposure of the implant surface, especially if rough, may facilitate plaque accumulation on the implant fixture which is considered the main risk factor for peri-implantitis. It is important to further highlight that having a crown with an inadequate length and abutment/implant fixture exposed are common findings, with an overall prevalence (considering all the implants examined in our study) of 47.7% (PSTD with inadequate crown length) and 42% (PSTD with exposure of the abutment and or implant fixture). The multivariate analysis demonstrated that having an adjacent implant, the time in function of the implants, KMW, MT and BBD are risk indicators for PSTD. It is reasonable to assume that there are scenarios in which inadequate KMW can contribute to the development of this condition, and other cases in which KMW becomes narrow as a result of the PSTD.

The use of ultrasonography allowed us to evaluate BBD and BBT which otherwise could only be assessed with cone-beam computed tomography (CBCT). Ultrasonography may also be considered the technology of choice for assessing MT, given the limitations of transgingival horizontal probing (needing anesthesia, having patient discomfort and reduced accuracy),

optical scanners (needing at least two time points, unless the STL file were combined with the DICOM scan from the CBCT), and CBCT alone (radiation, and inaccuracy). Nevertheless, it has to be mentioned that a method's error of 0.015 mm and 0.08-0.2 mm was observed for MT and BBD, respectively, when obtained with US compared to direct measurements. Interestingly, US was found to be more accurate than CBCT in identifying crestal bone level and MT. We observed that BBD has an OR for PSTD of 1.41. In other words, each millimeter increase in the distance between the crestal bone and the implant platform, raises the odds of having a PSTD by a factor of approximately 41%. In our analysis, when other factors were taken into account, BBT was not found to be associated with PSTD. It may be reasonable to assume that buccal bone resorption in the vertical (BBD) – but not horizontal (BBT) – aspect can negatively affect the stability of the mucosal margin.

We also observed an inverse correlation between MT and PSTD, corroborating the notion that a thicker mucosa can improve the stability of the peri-implant mucosal margin and the esthetic outcomes. This concept has previously been proven in the natural dentition and seems to be valid also at implant sites. In addition, a recent network meta-analysis from our group further highlighted the importance of the dimension of the peri-implant soft tissues, demonstrating that MT augmentation has also beneficial effects on marginal bone level stability.

Treatment of Peri-implant soft tissue dehiscences

Limited evidence – mainly from case reports and case series – is available on the efficacy of different treatments on peri-implant soft tissue dehiscences. To the best of our knowledge, this is the first randomized clinical trial reporting the outcomes of PSTD treatment with two different approaches in combination with autogenous connective tissue graft. The rationale for this comparison is that coronally advanced flap and tunnel technique are considered the two most effective and performed root coverage techniques in natural dentition. Previous studies reported a mean PSTD coverage ranging from 28 to 89.6% when CAF was performed without removing the implant-supported crown. In order to facilitate generalizability of our outcomes and comparison with future trials, we utilized the recent classification of PSTDs. Also, to reduce possible confounding variables between eCAF and TUN, our protocol did not allow for crown removal.

Our results showed that eCAF + CTG obtained a statistically significant higher mean PSTD coverage and complete PSTD coverage than TUN + CTG after 6 months (87.9 vs 64.4% and 64.3 vs 42.9%, respectively). eCAF was also associated with significantly greater KMW gain, AM gain and MT gain compared to TUN. While these two techniques have been shown to provide overall similar root coverage outcomes in natural dentition, the reason for the different results in our study is open to speculation. A factor that may have contributed to the higher outcomes observed for eCAF, is the possibility of elevating the flap, preparing some areas split-thickness and other full-thickness. It has been advocated that the midfacial area of the PSTD should be raised split thickness in order to leave some connective tissue fibers over the exposed (and not contaminated) implant surface to facilitate the attachment of the CTG. The eCAF approach also allows for the stabilization of the graft to the de-epithelialized anatomical papillae and also to the adjacent or apical periosteum. This may have provided a greater stability of the CTG during the healing in the sites allocated to the eCAF compared to sites treated with TUN, where the graft was stabilized to the flap only.

Interestingly, the regression analysis found that the mean PSTD coverage is associated not only with the treatment approach, but also with the subclass. PSTDs subclass b, characterized by at least one papilla less than 3 mm in height (but not flat), negatively affected the amount of PSTD coverage. Although this finding is in line with the classification system of gingival recessions based on the interproximal clinical attachment level, this is the first time that the recent PSTD classification has been shown to also have a prognostic value.

The present study adopted three different methods for assessing mucosal thickness/profilometric changes. The superiority of eCAF compared to TUN in terms of volume/thickness gain was demonstrated through transmucosal piercing, intraoral optical scanning and ultrasonography. Although the importance of MT on peri-implant health and esthetics have been emphasized, there are not uniform guidelines for assessing volumetric changes at implant sites. One of the most utilized methods involve the piercing of the soft tissue with needles or endodontic files. However, this approach has several limitations, including patient discomfort and the need for customized stents, as well as a questionable accuracy in measuring tissue thickness due to possible bending of the needle. Optical scanning is a valuable and non-invasive approach for performing volumetric comparisons between different time points. However, this method can only provide volumetric changes and not the actual measurement at a specific time point. Ultrasonography is a non-invasive and reliable technology for assessing peri-implant structures. In our study, ultrasonography was also utilized for quantifying not only soft tissue thickness (MT and STH), but also buccal bone changes following the interventions. The reliability of ultrasonography in assessing buccal bone position has been previously demonstrated, with our intraoperative findings further corroborating this conclusion. Interestingly, PSTDs treated with eCAF exhibited an average buccal bone loss of 0.7 mm after 6 months, which was significantly higher compared to TUN-treated sites (0.2 mm on average). While classic studies already highlighted that a certain amount of bone resorption should be expected after raising split or full-thickness flaps in natural dentition, the fate of buccal bone following CAF and TUN at implant sites have never been investigated in a clinical trial so far. It can be speculated that the negligible bone loss observed for TUN is due to its more conservative approach that preserves the integrity of the papillae and the vascularization of the flap. On the other hand, the greater access provided by the eCAF and the incisions at the level of the interproximal soft tissue may have caused more damages to the peri-implant vasculature, resulting in a more extensive and prolonged inflammatory phase during the healing, with consequent higher bone resorption than TUN-treated sites. Future studies are needed to further explore this aspect.

Lastly, it has to be mentioned that both treatment approaches resulted in an increase in STH, with eCAF showing a significantly higher STH gain than TUN (2.44 mm vs 1.43 mm, respectively). The effect of STH on peri-implant health has been largely debated without reaching a definitive conclusion. While it has been shown that a reduced STH is associated with higher marginal bone loss after implant placement, a recent case-control study demonstrated that implants with excessive STH (≥ 3 mm) had delayed and incomplete resolution of peri-implant mucositis as compared to implants with shallow STH. Moreover, in subjects with history of periodontal disease, the risk for peri-implantitis was found to increase 1.5 mm times for 1 mm increase of STH. Nevertheless, readers should bear in mind that other implant and restorative factors could play a role on the manifestation and resolution of peri-implant diseases.

VI. NEW FINDINGS

1. PSTDs are commonly observed in the esthetic region. Factors associated with this esthetic complication include presence of an adjacent implant, increased time in function of the implant, higher buccal bone dehiscence, lower KMW and MT.

2. eCAF was found to be more effective than TUN for the treatment of class II PSTDs, when combined with CTG, in terms of mean and complete PSTD coverage.

3. eCAF resulted in a higher CAL gain, KMW gain, AM gain and MT gain than TUN at 6 months.

4. Superior 3D volumetric gain and ultrasonographic MT gain were observed for eCAF over TUN.

5. Ultrasonography showed to be a valuable tool for characterizing the peri-implant phenotype and assessing PSTD treatment outcomes, including tissue perfusion changes over time not only around implants but also at the palatal donor sites.

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