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ORIGINAL ARTICLE

Prognostic value of a composite outcome measure for periodontal stability following periodontal regenerative treatment: A retrospective analysis at 4 years

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Abstract

Background: Recently, a composite outcome measure (COM) was proposed to describe the short-term results of periodontal regenerative treatment. The present retrospective study aimed at evaluating the prognostic value of COM on clinical attachment level (CAL) change over a 4-year period of supportive periodontal care (SPC).

Methods: Seventy-four intraosseous defects in 59 patients were evaluated at 6 months and 4 years following regenerative treatment. Based on 6-month CAL change and probing depth (PD), defects were classified as: COM1 (CAL gain ≥3 mm, PD ≤4 mm); COM2 (CAL gain <3 mm, PD ≤4 mm); COM3 (CAL gain ≥3 mm, PD >4 mm); or COM4 (CAL gain <3 mm, PD >4 mm). COM groups were compared for "stability" (i.e., CAL gain, no change in CAL or CAL loss <1 mm) at 4 years. Also, groups were compared for mean change in PD and CAL, need for surgical retreatment, and tooth survival.

Results: At 4 years, the proportion of stable defects in COM1, COM2, COM3, and COM4 group was 69.2%, 75%, 50%, and 28.6%, respectively, with a substantially higher probability for a defect to show stability for COM1, COM2, and COM3 compared with COM4 (odds ratio 4.6, 9.1, and 2.4, respectively). Although higher prevalence of surgical reinterventions and lower tooth survival were observed in COM4, no significant differences were detected among COM groups.

Conclusions: COM may be of value in predicting CAL change at sites undergoing SPC following periodontal regenerative surgery. Studies on larger cohorts, however, are needed to substantiate the present findings.

KEYWORDS

periodontal attachment loss, periodontal diseases, periodontitis, prognosis, reconstructive surgical procedures, regeneration, supportive periodontal therapy, treatment outcome

1 | INTRODUCTION

Periodontal regeneration of intraosseous defects is an effective treatment option to substantially improve probing parameters and tooth prognosis.[1–5] In the last decades, several surgical techniques and regenerative technologies have been proposed and investigated to enhance the clinical results of the procedure[4,6–8] and successfully expand its application to challenging defects extending to the root apex.[9] Several trials demonstrated that the outcomes of periodontal regeneration, as observed within 1 year after surgical treatment, can be maintained over time for periods longer than 10 years.[10–16] In this respect, high levels of periodontal stability and tooth retention rates have been reported after guided tissue regeneration (GTR)[11,12,15,16] as well as the application of enamel matrix derivative (EMD) either alone[13–15] or in association with a bone substitute.[10,13] According to the same trials, however, recurrences of periodontal breakdowns may occur, thus calling for retreatment, adjunctive treatments, or tooth extractions. Despite some tools for the evaluation of tooth prognosis have been developed and partly validated,[17] none of the above is specifically designed to estimate periodontal stability and tooth prognosis following periodontal regenerative treatment.

Recently, a composite outcome measure (COM) has been proposed to describe the short-term outcomes of periodontal regenerative treatment. According to COM, treatment should be considered "successful" when a clinically relevant result (i.e., clinical attachment level, CAL, gain ≥3 mm) is associated with the absence of a residual pocket (i.e., probing depth [PD] ≤4 mm), while should be considered a "failure" when a residual pocket (i.e., PD > 4 mm) persists at a site where surgical treatment resulted in a limited (<3 mm) CAL gain.[18] COM was recently applied to describe the 6-month treatment results in a patient cohort undergoing a periodontal regenerative procedure according to the Single Flap Approach (SFA).[19,20] However, the prognostic relevance of COM for the long-term periodontal stability following regenerative treatment remains unknown.

The aim of the present study was to evaluate the prognostic value of COM on periodontal stability, as assessed on CAL change, in a cohort of deep intraosseous defects followed for 4 years after surgical treatment with or without regenerative devices. The need for surgical retreatment and tooth survival were also evaluated.

2 | MATERIALS AND METHODS

2.1 | Experimental design and ethical aspects

Patients were selected among those seeking care at the Research Centre for the Study of Periodontal and Peri-implant Diseases, University of Ferrara, Italy and one private dental office in Ferrara, Italy. The study protocol was approved by the Ethical Committee of Area Vasta Emilia Centro, Regione Emilia-Romagna (CE-AVEC) (protocol number: 481/2020/Oss/UniFe, date of approval: May 21, 2020). All the clinical procedures were performed in full accordance with the Declaration of Helsinki and the Good Clinical Practice Guidelines. Each patient provided a written informed consent to nonsurgical and surgical treatments.

2.2 | Study population

Deidentified data were derived from the record charts of patients receiving periodontal treatment between May 2013 and May 2016. All surgeries were performed by experienced periodontal surgeons (L.T., R.F., L.M.) who had been involved in previous studies on SFA.[19–28]

Patients were included only if they had been enrolled in a supportive periodontal care (SPC) program based on a suggested interval between consecutive SPC visits ranging between 3 and 6 months, as determined according to the patient PerioRisk level[29,30] at the re-evaluation visit following active therapy.[31]

Defects were included in the present analysis if: (i) treated with buccal/oral SFA alone or in association with regenerative devices (i.e., graft materials, membrane devices, bioactive agents, either alone or in combination); (ii) clinical data (see the paragraph "*Study parameters*" for details) related to the presurgery visit (baseline), 6-month and 4-year follow-up visits were available. Defects were excluded from the analysis whenever (i) a furcation involvement coexisted with the treated intraosseous lesion and (ii) the related tooth had been extracted due to reasons not directly attributable to periodontal deteriorations (e.g., tooth fracture) during the follow-up period.

2.3 | Clinical procedures

2.3.1 | Surgical procedures

Within 4 to 6 weeks from the completion of active non-surgical therapy, each defect was accessed with a buccal or lingual SFA.[19,20] Briefly, a sulcular incision was performed, keeping the mesiodistal flap extension limited while ensuring access for defect debridement. An oblique or horizontal butt-joint incision was performed at the level of the interdental papilla overlying the intraosseous defect. The greater the distance from the tip of the papilla to the underlying bone crest, the more apical (i.e., closer to the base of the papilla) the incision in the interdental area. A buccal/oral mucoperiosteal envelope flap was elevated using a microsurgical periosteal elevator, leaving the residual portion of the interdental supracrestal soft tissues undetached. Root and defect were debrided using both ultrasonic and manual (i.e., area-specific curets and Hirschfeld file scalers) instruments. At operator's discretion, defects were treated with one of the following modalities: (1) open flap debridement alone; (2) EMD alone or in combination with deproteinized bovine bone mineral (DBBM) and/or connective tissue graft (CTG); (3) DBBM alone; or (4) GTR with a resorbable collagen membrane in combination with DBBM. The suturing technique was performed according to the original description of the SFA[19,20,32] or according to its modification when additional CTG was used concomitantly.[26] Primary flap closure was always obtained at suturing. Sutures were removed at 2 weeks after surgery.

2.4 | Study parameters

2.4.1 | Patient-related parameters

The following patient-related parameters related to the time of the surgical procedure were extracted from the record charts: age (in years), sex, smoking status (non-smoker/current smoker). Also, the mean interval between SPC sessions, derived as the length of the observation period (expressed in months)/total number of attended SPC sessions and the SPC frequency, derived as the total number of attended SPC sessions/ observation period (in years), were calculated.

2.4.2 | Defect-related parameters

At baseline as well as at the 6-month and 4-year follow-up visits, the following parameters were assessed at the interproximal aspect of the defect showing the most severe baseline CAL using a manual probe (i.e., UNC15, Hu-Friedy, Chicago, IL, USA): (i) PD, measured in millimeters from the gingival margin to the bottom of the pocket; (ii) CAL, measured in millimeters from the cemento-enamel junction (CEJ) or the apical margin of a restoration to the bottom of the pocket.

Immediately after the completion of root and defect debridement, the following defect-related characteristics were assessed (in millimeters) using a UNC15 periodontal probe: (i) depth of the intrabony component (IBD), measured as the distance between the most coronal point of the alveolar crest and the base of the defect; (ii) distance between the CEJ and the base of the defect (CEJ–BD); and (iii) distance between the CEJ and the most coronal extension of the interproximal bone crest (iCEJ-BC). Whenever the CEJ could not be detected, the apical margin of the restoration replaced the CEJ when performing CEJ-BD and iCEJ-BD measurements.

The morphology of the intraosseous defect (i.e., number of residual bony walls) was also recorded as follows: (1) mainly 1-wall; (2) combined 1- to 2-wall; (3) mainly 2-wall; (4) combined 2- to 3-wall; and (5) mainly 3-wall.

When the defect site showed a progressively increasing attachment loss and PD, an additional surgical procedure was considered according to the individual needs. For those teeth receiving a second surgery due to disease recurrence between 6-month and 4-year visits, PD and CAL values as recorded immediately before the second surgical procedure were used to describe the 4-year site conditions. The number of defects undergoing a second surgical procedure as well as the number of teeth extracted due to worsening periodontal condition were recorded. For each patient, the same operator performing the surgical procedure took care of the assessment of all clinical parameters and performed surgical reinterventions and/or tooth extractions whenever needed.

2.4.3 | Composite outcome measure (COM)

At the 6-month visit, the outcomes of periodontal regenerative treatment were evaluated according to COM.[18] COM is based on the assessment of the following two parameters (to be recorded in millimeters at the defect site with the highest baseline CAL) and their combination in a 2 × 2 table:

- CAL gain (to assess the clinical relevance of the regenerative procedure): the effect of the regenerative procedure was considered as clinically relevant if ≥3 mm of CAL gain was obtained;

- Residual PD (to assess pocket closure following the regenerative procedure): a pocket was considered as "closed" if a residual PD ≤4 mm was recorded.

Accordingly, defects were classified as: COM1: relevant CAL gain and pocket closure (treatment success); COM2: nonrelevant CAL gain and pocket closure; COM3: relevant CAL gain and residual pocket; COM4: nonrelevant CAL gain and residual pocket (treatment failure).

2.5 | Statistical analysis

Data were entered in a database file. For each defect, changes in CAL and PD were calculated by subtracting the 6-month follow-up value from 4-year follow-up value. Therefore, a positive value indicated an increase in PD or a CAL loss. Based on CAL change, defects were classified as "stable" (i.e., showing a CAL gain, no change in CAL or a CAL loss <1 mm) or "unstable" (i.e., showing a CAL loss ≥1 mm). Stability at the 4-year examination was considered as the primary outcome, whereas mean CAL change, mean PD change, tooth survival, and number of defects undergoing surgical retreatment were regarded as secondary outcomes. According to the last observation carried forward method, PD and CAL values as recorded immediately before the second surgical procedure, were used to describe the 4-year site conditions for those teeth receiving a second surgery due to disease recurrence.

Within each COM group, continuous data were expressed as mean ± standard deviation (SD), while frequency was calculated for categorical data. COM groups were compared for primary and secondary outcome variables. Since some patients contributed with more than one intraosseous defect, mixed models analysis was used when comparing groups to compensate for potential lack of data independency using the defect as the statistical unit. One-way ANOVA was used for continuous outcomes with correction for multiple comparison and Chi-square analysis for categorical variables. Longitudinal changes were tested by the use of paired *t-test* and between groups with a generalized linear mixed model. Descriptive analysis and statistical modeling were performed with a statistical software (STATA v17, TStat, Italy). The level of statistical significance was set at 5%.

3 | RESULTS

3.1 | Study population

Seventy-four defects in 59 patients were included for analysis. Baseline patient and defect characteristics as well as defect distribution according to treatment modality are reported in Appendix 1. Over the 4-year follow-up, no variations in smoking and diabetes status were self-reported by the patients.

Among the 75 sites evaluated 6 months after regenerative treatment and followed during a 4-year follow-up, 74 defects in 59 patients (46 contributing with one defect, 11 contributing with two defects, two contributing with three defects) were included for analysis. One site was excluded from the evaluation since the associated tooth was extracted due to reasons not attributable to periodontal deterioration (i.e., crown and root fracture) 3 years after treatment.

Thirty-nine defects (52.7%), 16 defects (21.6%), 12 defects (16.2%), and 7 defects (9.5%) were classified as COM1, COM2, COM3, COM4, respectively. Patient and defect characteristics within each COM group are reported in Table 1. The parameter CEJ-BD showed significant variation among groups as detected by ANOVA ($p = 0.030$), with COM3 group being characterized by greater mean severity (12.6 mm) compared with COM2 group (8.8 mm) ($p = 0.025$) (Table 1).

SPC regimen was conducted with a frequency ranging from 3.1 ± 1.2 to 3.9 ± 1.3 sessions/year in COM1 and COM4, respectively, and with a mean interval between two consecutive SPC sessions ranging from 3.6 ± 1.8 and 4.9 ± 3.5 months in COM4 and COM1, respectively, the differences not reaching statistical significance ($p = 0.682$, Table 1).

3.2 | Clinical outcomes

Table 2 shows the proportion of stable and unstable defects within each COM group. The proportion of defects that were stable at the 4-year follow-up was 69.2%, 75%, 50%, and 28.6% in COM1, COM2, COM3, and COM4, respectively. The odds ratio (OR) for stability at 4 years was 4.6, 9.1, and 2.4 for COM1, COM2, and COM3, respectively, the difference with the reference group (i.e., COM4) being not statistically significant for all comparisons. The model was adjusted for defect configuration, treatment procedure and CEJ-BD, none of which resulted significantly associated with the odds for stability.

Probing parameters in COM1, COM2, COM3, COM4 defects are reported in Table 3.

Between the 6-month and 4-year visit, mean CAL change ranged from a gain of 0.3 mm (COM2) to a loss of 0.6 mm (COM4). Compared with defects in COM4 group, no significant intergroup differences in CAL change were observed for each of the other COM groups.

In the same period, mean PD increased in all groups, the difference between the 6-month and the 4-year value

TABLE 1 Patient and defect characteristics in COM groups.

		COM1 (n = 39)	COM2 (n = 16)	COM3 (n = 12)	COM4 (n = 7)	Intergroup comparison
Patient-related characteristics	**Age (years) (mean ± SD)**	51.0 ± 8.7	55.9 ± 5.9	55.1 ± 8.0	52.6 ± 10.8	0.183[a]
	Sex					
	Males (n)	18	10	9	5	0.236[b]
	Females (n)	21	6	3	2	
	Smoking status					
	Nonsmokers (n)	28	12	10	6	0.780 [b]
	Current smokers (n)	11	4	2	1	
	Mean interval between two consecutive SPC sessions (months)	4.9 ± 3.5	4.2 ± 2.0	4.3 ± 2.7	3.6 ± 1.8	0.682[a]
Site-specific characteristics	**Dental arch**					
	Maxillary (n)	27	8	5	5	0.249[b]
	Mandibular (n)	12	8	7	2	
	Tooth type					
	Incisors (n)	13	3	4	1	0.121[b]
	Canines (n)	13	7	3	1	
	Premolars (n)	9	5	2	5	
	Molars (n)	4	1	3	0	
	IBD (mm) (mean ± SD; range min-max)	5.9 ± 2.8	4.0 ± 1.9	6.3 ± 2.4	5.1 ± 1.7	0.052[a]
	CEJ-BD (mm) (mean ± SD; range min-max)	10.6 ± 3.7	8.8 ± 2.2	12.6 ± 3.8	9.4 ± 3.5	0.030[a,*]
	iCEJ-BC (mm) (mean ± SD; range min-max)	4.7 ± 1.7	4.8 ± 1.5	5.6 ± 2.1	4.1 ± 2.0	0.344[a]
	Defect configuration					
	Mainly 1 wall (n)	3	3	0	2	0.185[b]
	Combined 1-2 walls (n)	9	1	4	1	
	Mainly 2 wall (n)	8	1	0	1	
	Combined 2-3 walls (n)	9	7	6	1	
	Mainly 3 wall (n)	10	4	2	2	
Treatment modality	SFA alone (n)	5	8	3	2	0.455[b]
	SFA + EMD[†] (n)	2	2	2	1	
	SFA + DBBM[‡] (n)	2	0	1	0	
	SFA + autologous bone (n)	0	1	0	0	
	SFA + autologous bone + EMD[†] (n)	0	0	0	1	
	SFA + EMD[†] + DBBM[‡] (n)	21	1	4	2	
	SFA + EMD[†] + DBBM[‡]+CTG (n)	5	3	1	1	
	SFA + HA[§] + resorbable membrane[‖] (n)	4	1	1	0	

Abbreviations: CEJ-BD, cemento-enamel junction and the base of the defect; CTG, connective tissue graft; DBBM, deproteinized bovine bone mineral; EMD, enamel matrix derivative; PD, probing depth; SFA, Single Flap Approach.

[a]One-way ANOVA.

[b]Chi-square test.

*$p = 0.025$ (multiple comparison, COM2 vs. COM3).

[†]Emdogain gel, Institute Straumann, Basel, Switzerland.

[‡]Bio-Oss spongiosa granules, 0.25–1.0 mm, Geistlich Pharma, Wolhusen, Switzerland.

[§]BIOSTITE, GABA Vebas, Rome, Italy.

[‖]PAROGUIDE, GABA Vebas, Rome, Italy.

TABLE 2 Stable and unstable defect distribution according to COM (as evaluated at 6-month follow-up).

	6-month CAL gain ≥3 mm AND 6-month PD ≤4 mm COM1 (*SUCCESSFUL TREATMENT*) *n* = 39	6-month CAL gain <3 mm AND 6-month PD ≤4 mm COM2 (*SUCCESSFUL TREATMENT*) *n* = 16	6-month CAL gain ≥3 mm AND 6-month PD >4 mm COM3 (*SUCCESSFUL TREATMENT*) *n* = 12	6-month CAL gain <3 mm AND 6-month PD >4 mm COM4 (*TREATMENT FAILURE)* *n* = 7
Stable defects	27 (69.2%)	12 (75%)	6 (50%)	2 (28.6%)
Unstable defects	12 (30.8%)	4 (25%)	6 (50%)	5 (71.4%)
OR (Ref. COM4)[a]	4.6	9.1	2.4	Reference
p value	0.395	0.323	0.692	

Abbreviations: CEJ-BD, distance between the cemento-enamel junction and the base of the defect; CTG, connective tissue graft; EMD, enamel matrix derivative; IBD, depth of the intrabony component; DBBM, deproteinized bovine bone mineral; HA, hydroxyapatite; iCEJ-BD, distance between the cemento-enamel junction and the most coronal extension of the interproximal bone crest; PD, probing depth; SFA, Single Flap Approach.

[a]Multilevel logistic model (model adjusted for defect configuration, treatment procedure, and cemento-enamel junction and the base of the defect distance; none of the factors was significant for the outcome "stable defect").

TABLE 3 Probing parameters at baseline, 6-month and 4-year follow-up in COM groups.

		Presurgery (baseline)	6 months	*p* value[a] (intragroup comparison baseline vs. 6 m)	4 years	4 years–6 months change	*p* value[a] (intragroup comparison 4y vs. 6 m)
COM 1 (*n* = 39, 52.7%)	PD (mm) (mean ± SD; range min-max)*	8.5 ± 1.9	3.4 ± 0.6	<0.001	3.9 ± 1.1	0.5 ± 1.2	0.025
	CAL (mm) (mean ± SD; range min-max)	10.2 ± 2.6	5.9 ± 2.1	<0.001	5.8 ± 2.1	-0.1 ± 1.4	0.737
COM 2 (*n* = 16, 21.6%)	PD (mm) (mean ± SD; range min-max)*	6.8 ± 1.1	3.7 ± 0.5	<0.001	3.9 ± 0.9	0.2 ± 0.9	0.261
	CAL (mm) (mean ± SD; range min-max)	8.1 ± 1.5	6.5 ± 1.4	<0.001	6.2 ± 1.8	-0.3 ± 1.1	0.321
COM 3 (*n* = 12, 16.2%)	PD (mm) (mean ± SD; range min-max)*	10.2 ± 2.2	5.0 ± 0.4	<0.001	5.3 ± 1.1	0.3 ± 1.1	0.429
	CAL (mm) (mean ± SD; range min-max)	11.9 ± 2.4	7.4 ± 1.1	<0.001	7.7 ± 2.1	0.3 ± 1.4	0.555
COM 4 (*n* = 7, 9.5%)	PD (mm) (mean ± SD; range min-max)*	8.1 ± 1.2	5.4 ± 0.8	<0.001	5.9 ± 2.1	0.4 ± 1.9	0.573
	CAL (mm) (mean ± SD; range min-max)	8.7 ± 1.7	7.3 ± 2.0	<0.001	7.9 ± 2.2	0.6 ± 2.4	0.558
	Intergroup comparisons for PD[b]					Ref. COM4 COM1 *p* = 0.962 COM2 *p* = 0.798 COM3 *p* = 0.806	
	Intergroup comparisons for CAL[b]					Ref. COM4 COM1 *p* = 0.463 COM2 *p* = 0.340 COM3 *p* = 0.732	

Abbreviations: CAL, clinical attachment level; PD, probing depth.

[a]*t*-test one sample.

[b]Generalized linear model.

TABLE 4 Tooth survival and number of surgically retreated defects in COM groups at the 4-year follow-up.

	COM1 ($n = 39$)	COM2 ($n = 16$)	COM3 ($n = 12$)	COM4 ($n = 7$)	Intergroup comparison
Tooth survival, n (%)	39 (100%)	16 (100%)	12 (100%)	6 (85.7%)	0.21
No. of surgically retreated defects, n (%)	0 (0%)	1 (6.25%)	2 (16.6%)	2 (28.6%)	0.019

Abbreviations: COM, composite outcome measure; COM1, clinical attachment level [CAL] gain ≥3 mm, probing depth [PD] ≤4 mm; COM2, CAL gain <3 mm, PD ≤4 mm; COM3, CAL gain ≥3 mm, PD >4 mm; COM4, CAL gain <3 mm, PD >4 mm.

reaching statistical significance only in COM1 group (PD change: 0.5 ± 1.2 mm; $p = 0.025$). Compared with defects in COM4 group, no significant intergroup differences in PD change were observed for each of the other COM groups.

In COM4 group, at 1 year after surgery one defect experienced recurrent periodontal abscesses that severely compromised the residual periodontal support of the tooth and was incompatible with patient comfort. The recurrence of a deep pocket motivated surgical retreatment in five defects (one defect at 9 months and one defect at 12 months in COM4 group; one defect at 12 months and one defect at 24 months in COM3 group; and one defect at 4 years in COM2 group) (Table 4). All surgical reinterventions consisted of surgical debridement of the defect-associated root surface and application of a regenerative device, when indicated. All defect sites undergoing retreatment showed a residual PD ≤4 mm at 6 months following retreatment administration.

4 | DISCUSSION

Recently, COM has been proposed to evaluate the effectiveness of regenerative treatment of intraosseous defects.[18] According to COM, treatment outcomes are classified into four different scenarios, including "successful treatment" when a clinically relevant result (i.e., a CAL gain ≥3 mm) is associated with the absence of a residual pocket (i.e., PD ≤4 mm) (COM1), "treatment failure" when limited CAL gain (<3 mm) is associated with a residual pocket (i.e., PD >4 mm) (COM4), and intermediate conditions characterized by limited CAL gain in association with pocket closure (COM2) or relevant CAL gain in association with a residual pocket (COM3). Since its description in 2020, COM has been used by other authors to describe the effect of periodontal regenerative treatments at both short-term[33–36] and long-term observation intervals.[14] In the present study, the association between COM and the 4-year clinical outcomes of periodontal regenerative treatment (as assessed in terms of periodontal stability, need for surgical retreatment due to disease recurrence, and tooth survival) was evaluated. Seventy-four intraosseous defects in 59 patients treated with SFA with or without regenerative technologies were retrospectively selected, the 6-month clinical outcomes were expressed using COM, and the 4-year outcomes were compared among groups with different COM.

In the present cohort, patient-related characteristics with an established negative impact on periodontal prognosis were similarly distributed among COM groups. The presence of smokers was limited to light smokers (i.e., patients smoking <10 cigarettes/day), who were similarly represented among groups (COM1: 39%; COM2: 33%; COM3: 20%; COM4: 17%), and no subjects with diabetes were present in the entire study population. Additionally, patients were selected only if enrolled in a similarly intense SPC program, with a mean interval between consecutive sessions between 3.6 to 4.9 months in different COM groups. It is therefore reasonable to hypothesize that the interference of the confounders listed above on the evaluation of the prognostic value of COM has been limited.

The use of different treatment strategies may have determined a wide heterogeneity either in terms of clinical[5] and histological[37–39] outcomes, as evaluated at the completion of tissue maturation phase after treatment. However, long-term data stemming from well-designed RCTs on different regenerative modalities seem to suggest that the stability of periodontal condition can be maintained irrespectively of the regenerative device used, provided the patients are enrolled in a stringent SPC regimen.[12,13,15]

High prevalence of periodontal stability between 6 months to 4 years and 100% tooth survival were observed among defects in COM1 group. All cases in this group did not need surgical retreatment during the observation period. Similarly, high stability and survival rates were obtained for defects in COM2 group, one of which needed surgical re-entry due to the worsening of periodontal conditions. A completely different scenario was observed in COM4 group, where >70% of defects lost at least 1 mm of CAL during the observation period, periodontal instability motivated an additional corrective surgery in almost 30% of cases, and two cases of tooth extraction due to periodontitis recurrence were recorded. Overall, the occurrence of periodontitis-related tooth loss only in COM4 group, a trend towards more frequent need for surgical retreatment in groups with higher COM, as well as a higher (although not significantly) odds for periodontal stability in groups with lower COM seem to support the predictive value of COM on the medium-term outcomes of periodontal regenerative treatment.

Relying on the results of the present analysis, we may assume that both 6-month residual PD and 6-month CAL change may substantially influence the long-term stability of the regenerative outcomes. In this respect, the presence/absence of a residual pocket represented the main difference between COM1/COM2 and COM4, further corroborating the current evidence on the predictive value of residual PD for disease progression/recurrence following active periodontal therapy, in general,[40–42] and regenerative procedures, in particular.[11,13,43] Moreover, defects categorized in COM3 showed an intermediate behavior between COM1/2 and COM4 in terms of proportion of stable defects at 4 years and need for surgical reintervention, thus suggesting the importance of a relevant CAL gain in mitigating the detrimental effect of the residual pocket on the long-term stability of the regenerative outcome. The magnitude of the contribution of either residual PD or relevant CAL gain to the predictive value of COM, however, remains currently undetermined and deserves future investigation.

Some practical implications may derive from the present study findings. First, for the patient undergoing regenerative treatment of an intraosseous defect, a combined assessment of periodontal risk level and COM is encouraged at re-evaluation following active therapy to evaluate if patient and local conditions are compatible with limited to no CAL loss and low incidence of tooth loss during SPC.[44] Whenever the defect falls within COM4, the lower odds for periodontal stability and the consequent risk for tooth loss due to periodontitis recommend the reinforcement of active periodontal therapy (including reinstrumentation with/without adjunctive therapies and/or surgical retreatment) before enrolling the patient in an SPC program. Also, the relatively high (50%) proportion of unstable cases in COM3 group seems to encourage additional efforts aimed at reducing residual PD before entering the patient in an SPC program. If the defect falls within COM1 or COM2, a personalized SPC based on supra- and subgingival professional mechanical plaque removal tailored on periodontal risk level[45,46] as for the frequency of recall sessions may be compatible with periodontal stability at 4 years.[31]

The results of the present study should be considered in the light of some limitations. Events related to disease recurrence such as tooth loss due to periodontitis and need for additional surgery, occurred with a very low frequency during SPC in all COM groups. Moreover, patient distribution among COM groups was unbalanced towards COM1 and COM2 groups, with a few patients falling into COM4 group. Although, on one hand, these aspects can be considered as a further confirmation of the high predictability of SFA when performed either as a stand-alone protocol or in association with regenerative devices, on the other hand it has probably limited the possibility to detect significant inter-group differences for these outcomes. Because of its retrospective nature, the present study lacks examiner calibration. Although this aspect represents a limitation, its potential impact on the robustness of our findings should be mitigated by the fact that assessments were performed by expert clinicians who had been involved in calibration sessions within previous trials on SFA.[19–28] Lastly, the low prevalence of multirooted teeth (which was partly due to the exclusion of intraosseous defects extending to the furcation areas) in the present cohort may limit the generalizability of the results. Further investigation should therefore be performed to confirm the predictive value of COM on medium- and long-term clinical outcomes of periodontal regenerative procedures.

5 | CONCLUSIONS

Within their limits, the results of the present study seem to indicate that COM, as used at 6 months following regenerative treatment of intraosseous defects, may be of value in predicting CAL change over an SPC period of 4 years. Studies on larger cohorts, however, are needed to substantiate the present findings.

AUTHOR CONTRIBUTIONS

Anna Simonelli, Roberto Farina, and Leonardo Trombelli designed the study and finalized the manuscript for submission. Cristiano Tomasi performed data analysis. Leonardo Trombelli, Roberto Farina, and Luigi Minenna performed all surgical treatments.

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CONFLICT OF INTEREST

All authors declare no conflicts of interest.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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