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Primary clinical effectiveness of full-mouth scaling combined with S-PRG particle for non-surgical treatment of stage III and IV periodontitis: randomized controlled clinical pilot study with a 3-month follow-up

Eficácia clínica primária da raspagem completa das arcadas dentárias combinada com partículas S-PRG no tratamento não cirúrgico da periodontite estágios III e IV: estudo clínico piloto randomizado e controlado com acompanhamento de 3 meses

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ABSTRACT

Objective: This pilot study aims to evaluate the primary clinical effectiveness of S-PRG nanoparticle dispersion as an adjunct to non-surgical periodontal treatment in patients with stage III/IV periodontitis. **Material and Methods:** The methodology followed the CONSORT guidelines. Twelve patients with stage III and IV periodontitis received full-mouth scaling (FMS) treatment with ultrasound within 24 hours, instrumentation for 1 minute for each site with a pocket ≥ 4mm. They were divided into two groups: FMS with filtered water (n=6); FMS + S-PRG adjuvant (n=6). Clinical periodontal parameters were evaluated: plaque index (PI), bleeding on probing (BoP), probing depth (PD), and clinical attachment level (CAL), at baseline and 3-month follow-up. The Oral Health Impact Profile questionnaire (OHIP-14) was used to assess the impact of oral health on quality of life. The FMS+S-PRG group showed a greater reduction in BoP at 3 months. **Results:** Regardless of the treatment modality, both groups showed a reduction in the plaque index after 3 months and also a reduction in PD. There was a statistically significant difference in CAL when comparing FMS+S-PRG baseline (3.23±0.50) vs. FMS+S-PRG 3 months (2.40±0.65) (p=0.0313). Only the FMS+S-PRG group showed improved understanding of quality of life in the OHIP-14 questionnaire, FMS+S-PRG baseline vs. 3 months (p=0.0156). **Conclusion:** Promising results regarding the use of the S-PRG nanoparticles as an adjuvant in the treatment of stage III and IV periodontitis, for reducing the plaque index and bleeding on probing, as well as the improvement in quality of life observed in the S-PRG group.

KEYWORDS

Biocompatible materials; Clinical trial; Nonsurgical periodontal debridement; Periodontal disease; Ultrasonics.

RESUMO

Objetivo: Este estudo piloto tem como objetivo avaliar a efetividade primária da dispersão de nanopartículas de S-PRG como adjuvante ao tratamento periodontal não cirúrgico em pacientes com periodontite em estágio III/IV. **Material e Métodos:** A metodologia seguiu as diretrizes CONSORT. Doze pacientes com periodontite nos estágios III e IV foram submetidos à raspagem *full mouth* (FMS), com ultrassom, dentro de 24 horas, com instrumentação de 1 minuto por sítio com bolsa ≥ 4 mm. Foram divididos em dois grupos: FMS com água filtrada (n=6); FMS + adjuvante S-PRG (n=6). Os parâmetros clínicos periodontais avaliados foram: índice de placa (IP), sangramento à sondagem (SS), profundidade

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de sondagem (PS) e nível clínico de inserção (NIC), no baseline e no acompanhamento de 3 meses. O questionário *Oral Health Impact Profile* (OHIP-14) foi utilizado para avaliar o impacto da saúde bucal na qualidade de vida. **Resultados:** O grupo FMS+S-PRG apresentou maior redução no SS após 3 meses. Independentemente da modalidade de tratamento, ambos os grupos apresentaram redução do IP e do PS após 3 meses. Houve diferença estatisticamente significativa no NIC ao comparar FMS+S-PRG no baseline (3,23±0,50) vs. 3 meses (2,40±0,65) (p=0,0313). Apenas o grupo FMS+S-PRG demonstrou melhora na percepção da qualidade de vida no questionário OHIP-14, baseline vs. 3 meses (p=0,0156). **Conclusão:** Resultados promissores em relação ao uso da nanopartícula de S-PRG como adjuvante no tratamento da periodontite nos estágios III e IV, com redução do índice de placa e do sangramento à sondagem, além da melhora observada na qualidade de vida no grupo tratado com S-PRG.

PALAVRAS-CHAVE

Materiais biocompatíveis; Ensaio clínico; Desbridamento periodontal não cirúrgico; Doença periodontal; Terapia ultrassônica.

INTRODUCTION

Periodontitis is a multifactorial chronic inflammatory disease associated with a dysbiotic biofilm that leads to periodontal attachment breakdown [1]. Epidemiological studies indicate a high prevalence in the adult population, representing one of the main causes of tooth loss [2]

Non-surgical periodontal therapy aims to remove plaque and calculus deposits from the oral cavity to control periodontal inflammation and stop disease progression [3,4]. Subgingival instrumentation in non-surgical periodontal therapy can be performed using hand instruments, ultrasonic devices, or a combination of both. In addition, different approaches have been proposed, such as periodontal scaling by quadrant (PSQ) or by sextant (PSS), full-mouth scaling (FMS), and full-mouth disinfection (FMD) [5,6].

When comparing their effectiveness, systematic reviews show that the three treatment methods (PSQ, FMS, FMD) are equally competent in removing subgingival deposits and treating periodontal disease [7-9]. From a practical point of view, less time is needed for complete full-mouth treatment in a single session [10]. The decision to select the treatment method should be based on anatomical factors, medical history, patient profile and degree of impairment, convenience of the treatment regimen, patient preference and cost-effectiveness [8,11].

Despite the aforementioned treatment modalities being effective in controlling periodontal disease in most cases, a subset of the population and/or specific periodontal sites do not respond well to therapy, particularly in advanced cases. Moreover, approximately 30% of deep periodontal sites fail to achieve the periodontal endpoint (PD <5 mm without bleeding on probing), leading to an increased risk of further attachment loss and tooth loss [12,13]. Therefore, various adjuncts in the form of irrigants, such as chlorhexidine, povidone-iodine, and essential oils, have been suggested [14-16]. However, two systematic review of Van der Sluijs et al. (2016) and Silveira et al. (2026) [17,18] demonstrated no efficacy of these agents when used as irrigants in periodontal pockets, highlighting the need for additional chemical adjuvant options.

New technologies have been developed to help advance and improve periodontal therapy. Bioactive liquid materials composed of nanoparticles that have the ability to attach to the root surface, thus preventing periodontal bacteria from adhering, have been studied [19]. The S-PRG Filler particles (surface pre-reacted glass) are described as a biofunctional ion-releasing glass material to improve dental materials' physical and bioactive properties, already used in composite resins and endodontic cements [19]. In previous studies, the particles released fluoride and borate ions, which are antimicrobial, over 90 days [20,21].

A bioactive ion-releasing material (S-PRG) with nanometric particles was developed to attach to the tooth surface. The surface pre-reacted glass (S-PRG) is capable of releasing six ions: fluorine (F), strontium (Sr), sodium (Na), boron (B), aluminum (Al), and silica (Si) [22]. Miyaji et al 2022 [23], used the S-PRG nanoparticle dispersion in the non-surgical treatment of dogs with periodontitis. The dispersion was injected into the periodontal pockets of the animals, and the following parameters were assessed weekly for 4 weeks: plaque index, bleeding on

probing, probing depth, and attachment loss. The dispersion containing S-PRG nanoparticles led to a statistically significant reduction in the parameters evaluated, showing that it is capable of improving the clinical parameters of periodontal inflammation in dogs.

In conjunction with ultrasonic instrumentation, the S-PRG nanoparticle dispersion demonstrated antimicrobial characteristics, mainly on red complex periodontal bacteria (*Porphyromonas gingivalis* and *Treponema denticola*), leading to a reduction in the inflammatory clinical parameters of periodontitis in dogs. The particles attach to the cementum, leading to changes in the subgingival microflora within 12 weeks [23].

In addition to antibacterial activity, the S-PRG nanoparticle containing fluoride, borate, and strontium ions also exhibits anti-inflammatory effects. Strontium has been shown to reduce levels of IL6 and TNF-α, as well as generate reactive oxygen species [24]. Tooth surfaces coated with S-PRG nanoparticles can provide long-term antibacterial, anti-inflammatory, and bone-forming effects, helping to reduce periodontal disease and promote oral health [6]. Iwamatsu-Kobayashi et al. (2017) [22], confirmed the distribution of these metal ions on the tooth surface of rats, with strontium and fluoride detected in the alveolar bone and dentin, and boron, aluminum, and silica found in the periodontal ligament. The bactericidal activity of materials coated with these metal ions and metalloids suggests their potential use as new antibacterial therapeutic agents for reducing periodontal bacteria.

Thus, this pilot study aims to evaluate the primary clinical effectiveness of S-PRG nanoparticle dispersion as an adjunct to non-surgical periodontal treatment in patients with stage III/IV periodontitis.

MATERIALS AND METHODS

This is a 3-month follow-up pilot study. The methodology followed the CONSORT guidelines 2025 [25]. This study was submitted to and approved by the Ethics Committee for Research Involving Human Beings under protocol number 5.892.739 and has already been published in the Brazilian Registry of Clinical Trials (ReBEC) under number RBR-7k87ynr in October 2023. This research has a data management system that stores data on a drive available to the research team and is administered by the research coordinator.

Study population

Patients with stage III and IV periodontitis [1], referred to the São Paulo State University (UNESP). The participants were recruited through a screening at the university and were also referred from the Basic Health Units in the municipality of São José dos Campos, São Paulo, Brazil.

For this pilot study 12 participants were included, which is equivalent to 25% -30% of the total sample of the full clinical trial [26].

The study participants were informed about the nature, risks, and benefits of the proposed treatment and signed an informed consent form. The following inclusion criteria were adopted:

- Stage III and IV periodontitis, attachment loss of 5 mm or more [1].
- Radiographic bone loss extending from the middle to the apical third of the roots.
- Minimum number of teeth (≥ 18 teeth).
- Minimum age 30 years.
- Agree to take part in the study by signing the consent form.

Criteria for non-inclusion were:

- Smokers.
- Diabetics
- Pregnant or breastfeeding women.
- Patients who have received periodontal treatment in the last 6 months.
- Chronic use of drugs that affect the response of the periodontium (antibiotics, anti-inflammatories, anticonvulsants, immunosuppressants and sodium channel blockers) within 6 months.
- Systemic diseases (chronic kidney disease, cancer, obesity, rheumatoid arthritis, metabolic syndromes, respiratory diseases) or the need for antibiotic prophylaxis.
- Patients with orthodontic braces.

Randomization, blinding and allocation concealment

Randomization was carried out as follows: each selected participant was assigned a code.

A computer-generated random sequence was used by an individual not part of the study team to allocate the therapeutic modalities: (FMS) full-mouth scaling with full-mouth ultrasound debridement, and (FMS + S-PRG) full-mouth scaling with the adjuvant S-PRG - Shofu®. This sequence was placed in opaque, sealed envelopes. The envelopes containing the assigned therapeutic modality for each participant were given to an assistant responsible for organizing and setting up the ultrasonic device. The reservoir of the device was covered with opaque adhesive to prevent the patient from knowing which type of solution they were receiving. This study was double-blind, as the participants were unaware of the dispersion being applied, and the evaluators conducting the clinical examinations at baseline and at 3 months were not involved in the treatments. The randomization and blinding procedures were conducted in accordance with the CONSORT statement 2025 [25].

Periodontal therapy

All participants (n=12) received periodontitis treatment after being diagnosed [1]. The patients received oral hygiene instruction, which was reinforced over a period of 3 months. After randomization, patients were allocated to one of two treatment groups:

- (FMS) full-mouth scaling: full-mouth ultrasonic debridement within 24 hours - dispersion used in the reservoir - distilled water (n=6).
- (FMS + S-PRG) full-mouth scaling with S-PRG adjuvant: ultrasound debridement with the adjuvant. Solution used in the reservoir - Dispersion with S-PRG nanoparticles - Shofu ® (n=6).

The S-PRG nanoparticle dispersion is not a product manufactured for sale by SHOFU. It is an experimental material, whose presentation is in the form of dispersion, and it is supplied for research by SHOFU. For homogenization, the S-PRG dispersion was shaken before being poured into the reservoir. The amount of dispersion and duration of full mouth scaling depend on the number of pockets ≥ 4 mm to be instrumented.

A trained operator was responsible for instrumentation. After anesthesia, all treatment groups received ultrasonic subgingival instrumentation with a subgingival tip (P2 – Helse Ultrasonic®) using an ultrasonic device (Dabi Profi Neo®) for 1 minute at each site with a pocket ≥ 4mm in both groups. The power used was between 5 and 7 with maximum irrigation. In both groups, the professional moved the ultrasound tip slowly, vertically from the gingival margin to the apical extent of the pocket, and laterally in a sweeping motion. Manual instrumentation with curettes was not carried out, as the intention is for the S-PRG nanoparticle dispersion to adsorb to the root surface.

Clinical periodontal parameters

The clinical parameters assessed included plaque index (PI) by O'Leary et al. (1972) [27], bleeding on probing (BoP), probing depth (PD - the distance from the gingival margin to the bottom of the periodontal pocket), and clinical attachment level (CAL - the distance from the cementoenamel junction (CEJ) to the bottom of the periodontal pocket). Six sites per tooth were assessed with a standardized North Carolina millimeter periodontal probe (Hu-Friedy®) for PD and CAL. PI and BoP were recorded on the faces that showed bleeding or plaque. All clinical parameters were assessed at baseline and at the 3-month follow-up by two properly calibrated assessors (EACS and LCT). Calibration was carried out by examining 5 patients, 2 quadrants per patient, repeated 2 times, 1 week apart. The correlation coefficients between the duplicate measurements were then calculated (ICC 0.72). The subgingival debridement procedure was carried out by another calibrated professional (CCMM).

Standardized effect sizes were calculated using Hedges' g. Effect sizes and their 95% confidence intervals (CI) were calculated for the change (baseline to 3 months) in mean PD, mean CAL, PI, and BOP, using the effectsize package in R, run in RStudio (RStudio 2026.06.0+242 "Blue Plumbago" Release, 2026-06-18, for Windows). Effect sizes were interpreted using conventional thresholds (small: ~0.2, medium: ~0.5, large: ~0.8).

Outcomes

The primary outcome was the improvement of the clinical parameters evaluated (plaque index, bleeding index, probing depth, clinical attachment level, and periodontal pocket closure)

comparing the test group and the control group in 3 months of follow-up.

The secondary outcome was that the patient's quality of life is expected to improve, and will be assessed using the OHIP-14 questionnaire at baseline and at 3 months for this pilot study.

Patient-centered parameters

To measure the impact of oral health on the participants' quality of life, the Brazilian version of the OHIP-14 questionnaire was given before and after treatment (3-month follow-up) [28-30]. Participants received instructions on how to fill in the self-administered questionnaire.

The answers were on a Likert scale, and each was assigned a value (never = 0; rarely = 1; sometimes = 2; constantly = 3; and always = 4). The OHIP-14 score range is from 0 to 56; higher scores denote a greater frequency of negative impacts [28,30,31].

Adverse effects

Seven days after the scaling treatment, all patients answered a questionnaire about possible adverse effects. Symptoms such as a change in taste, product taste, pain after application, a feeling of dryness, and a change in color (teeth, tongue, and mucosa) were assessed by score. Each symptom was quantified as: absent =0, reasonable =1, moderate =2 and severe = 3 [32,33].

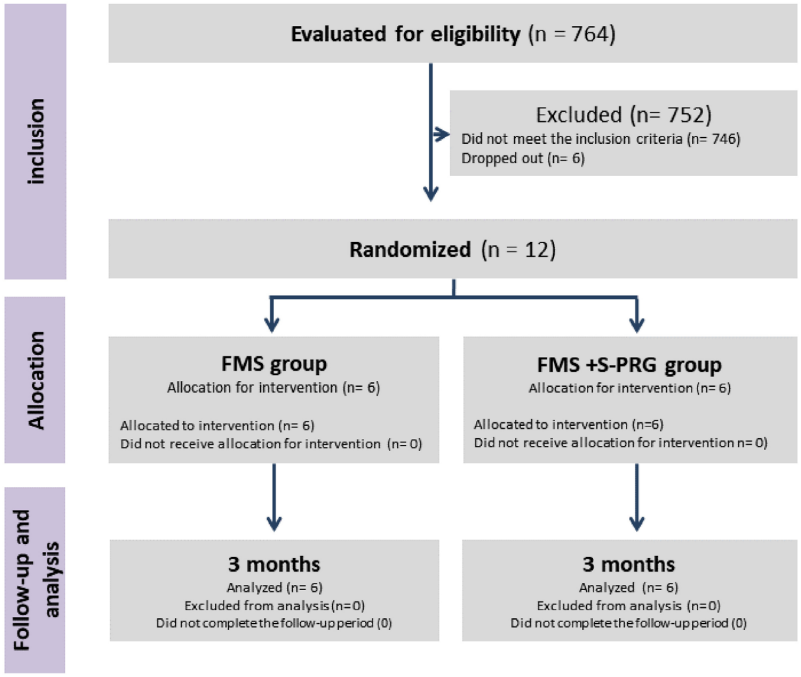
Statistical analysis

The primary outcome was analyzed according to pocket stratification criteria: shallow pocket (PS ≤ 4 mm), moderate pocket (PS = 5-6 mm), and deep pocket (PS ≥ 7 mm) (Retamal-Valdes et al.,2021) in the evaluation periods described, baseline and 3 months.

The GraphPad Prism 9 statistical program was used for this analysis. The baseline and 3-month data from 12 patients were checked for normality, using the T-test if they were normally distributed and the Mann-Whitney and Wilcoxon tests if they were not normally distributed. A significance level of 5% was adopted.

RESULTS

The participants (n=12) were selected from May 2023 to May 2024 at the São Paulo State University (UNESP), São José dos Campos Institute of Science and Technology (ICT UNESP) (Figure 1).



Legenda: Participant randomization flowchart.

Figure 1 - Randomization flowchart for research participants.

Demographic data

The control group (FMS) had the highest number of male participants. The age of the participants ranged from 50 to 55 years, and the number of teeth was between 23 and 24 (Table I). There were no statistical differences regarding sex, age, or number of teeth between the groups.

A reduction in the clinical parameters of bleeding on probing (BoP), plaque index (PI), probing depth (PD), and clinical attachment level (CAL) was found in the FMS + S-PRG group when comparing the baseline and 3-month periods ($p<0.05$). Meanwhile, the control group showed a reduction in PD and PI parameters ($p<0.05$). There was a significant difference between the control and FMS + S-PRG groups in BoP at the 3-month follow-up period (Table II).

After calculating the effect size, the results showed a moderate effect size with an attachment gain favoring the FMS + S-PRG group (0.71), as shown in Table III.

Table IV shows the PD and CAL data for sites up to 4 mm, pockets larger than 5 mm, and deep pockets (> 7 mm). No statistically significant difference was found.

The results obtained after applying the adverse effects questionnaire showed that both groups mostly reported no signs or symptoms after scaling (Figures 2 and 3). When asked about the presence of any other adverse effects than those listed in the questionnaire, only 3 patients reported sensitivity after scaling, but this can be attributed to the non-surgical periodontal therapy itself.

Table I - Demographic data

Variable	FMS (n=6)	FMS + S-PRG (n=6)	*p Value*
Gender (M/F)	3/3	2/4	0.9999
Age	55.50 ± 15	50.33 ± 7.6	0.4692
Number of teeth	23.50 ± 3.5	24.17 ± 1.16	0.6681

Demographic data of the FMS and FMS + SPRG groups. T-test. M: male / F: female. FMS: full mouth scaling. FMS +S-PRG: full mouth scaling with S-PRG dispersion.

Table II - Clinical data baseline and 3 months

Variable	Time Point	FMS n=6	FMS+S-PRG n=6
PD (mm)	*Baseline*	3.09 ± 0.45*	2.97 ± 0.26*
	3 months	2.74 ± 0.23*	2.43± 0.28*
CAL (mm)	*Baseline*	3.10 ± 0.69	3.23 ± 0.50*
	3 months	3.01 ± 0.99	2.40 ± 0.65*
PI (%)	*Baseline*	63.02 ± 10.53*	65.66 ± 12.74*
	3 months	41.63 ± 18.33*	43.30 ± 18.10*
BoP (%)	*Baseline*	31.90 ± 17.89*	26.31 ± 16.71*
	3 months	18.59 ± 10.31*#	9.58 ± 3.12*#

*Indicates significant intra-group difference. #Indicates significant inter-group difference. Test t ($p<0.05$). Probing depth (PD), Clinical attachment level (CAL), Plaque index (PI), Bleeding on probing (BoP).

Table III - Effect size

Outcome	Mean difference (FMS – FMS + SPRG), 95% CI	Hedges' g (95% CI)	p value
Δ Mean PD	-0.18 (-0.61 to 0.24)	-0.51 (-1.57 to 0.57)	0.357
Δ Mean CAL	-0.74 (-1.46 to -0.01)	-1.20 (-2.35 to -0.01)	0.049
Δ %PI	-0.97 (-18.50 to 16.56)	-0.07 (-1.11 to 0.98)	0.904
Δ %BOP	-3.42 (-22.90 to 16.07)	-0.21 (-1.25 to 0.84)	0.701

The effect size was calculated using Hedge's test.

Table IV - PD data at baseline and 3 months

Variable	Time Point	FMS n=6	FMS+S-PRG n=6
N sites up to 4 mm PD	*Baseline*	87.48 ± 7.03	84.83 ± 7.74
	3 months	91.27 ± 3.02	91.09 ± 5.80
Mean of Pockets ≥ 5 mm PD	*Baseline*	5.40 ± 0.17	5.47 ± 0.24
	3 months	5.40 ± 0.24	5.26 ± 0.09
Mean of deep pockets (> 7 mm) PD	*Baseline*	7.76 ± 1.11	7.93 ± 0.54
	3 months	6.43 ± 3.36	5.68 ± 3.22

Legenda: No group showed a significant difference. t-test ($p < 0.05$). (PD) Probing depth.

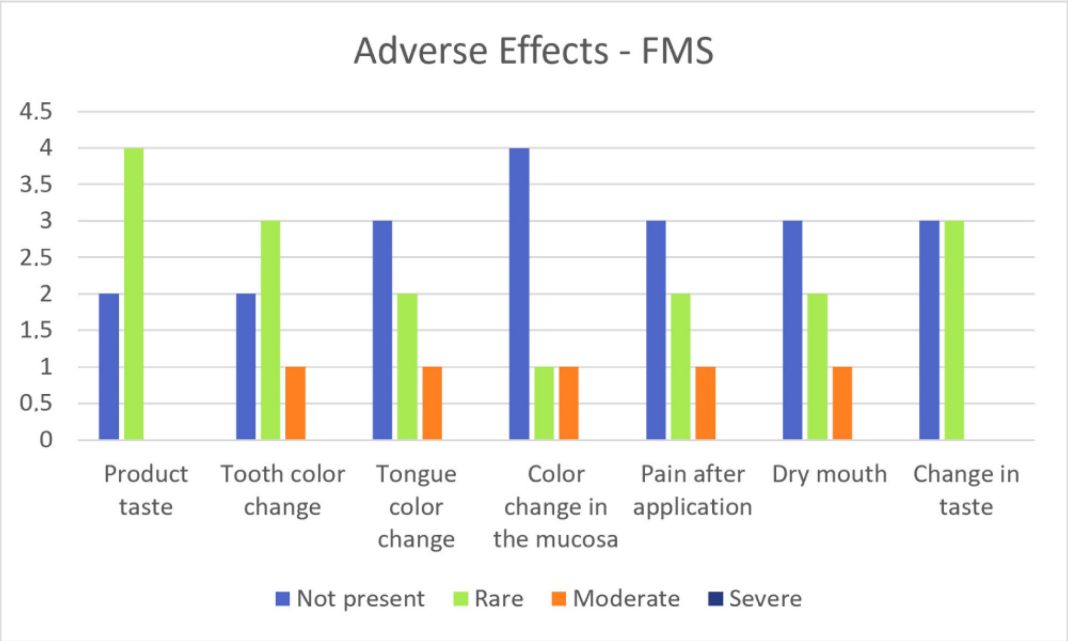


Figure 2 - Adverse effects – FMS group. Adverse effects after 7 days of treatment in the FMS group.

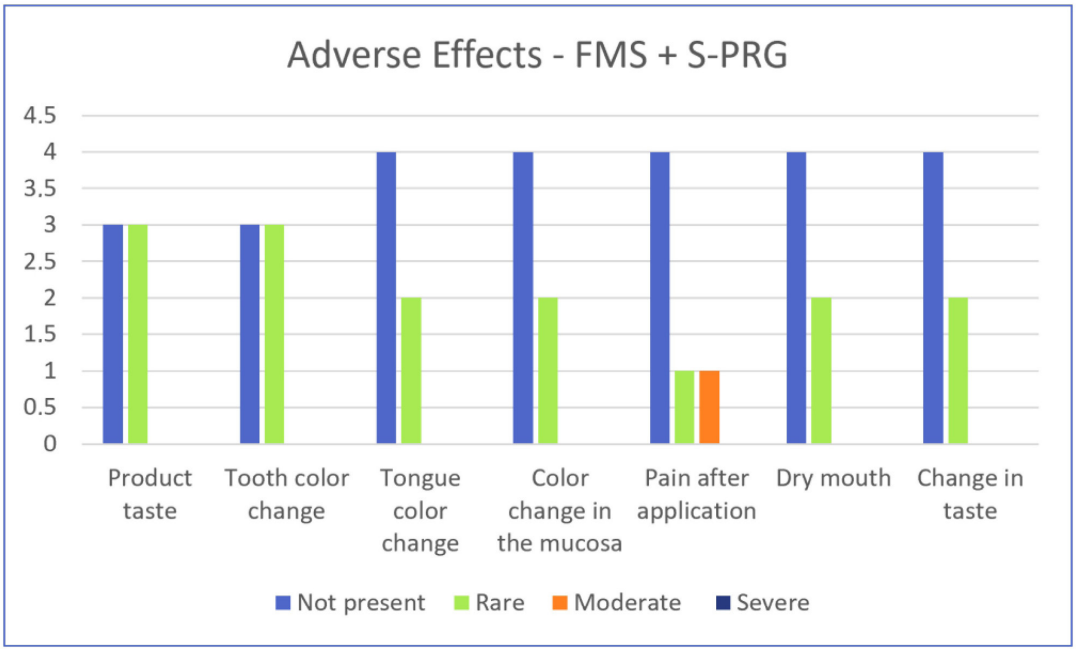


Figure 3 - Adverse effects – FMS + S-PRG group. Adverse effects after 7 days of treatment in the FMS + S-PRG group.

The OHIP 14 questionnaire made it possible to measure the impact of oral health on individuals' lives. In the subdivision domains, most of the reports were about physical pain and psychological discomfort in both groups. Only the FMS+S-PRG group showed an improvement in quality of life in the OHIP-14 questionnaire, FMS+S-PRG baseline vs. 3 months (p=0.0156) (Figure 4 and 5).

DISCUSSION

The aim of this pilot study was to evaluate the primary effectiveness of S-PRG nanoparticle - Shofu ® as an adjunct to non-surgical periodontal treatment in patients with stage III/IV periodontitis.

Studies in several areas have verified the properties of the S-PRG nanoparticle. Amaechi et al. (2018) [34],found that toothpaste containing the S-PRG nanoparticle inhibited tooth demineralization and has the potential to prevent caries. Suzuki et al. (2014) [35], found that S-PRG inhibited biofilm formation and maturation. Han et al. (2011) [21], showed that fluoride, borate, and silicate ions were incorporated into root canal dentin 90 days after application. The present study is a pioneer in the use of the S-PRG nanoparticle in the treatment of periodontal disease in humans.

The clinical parameter of bleeding on probing at 3 months was the only one that showed a statistically significant reduction. The other

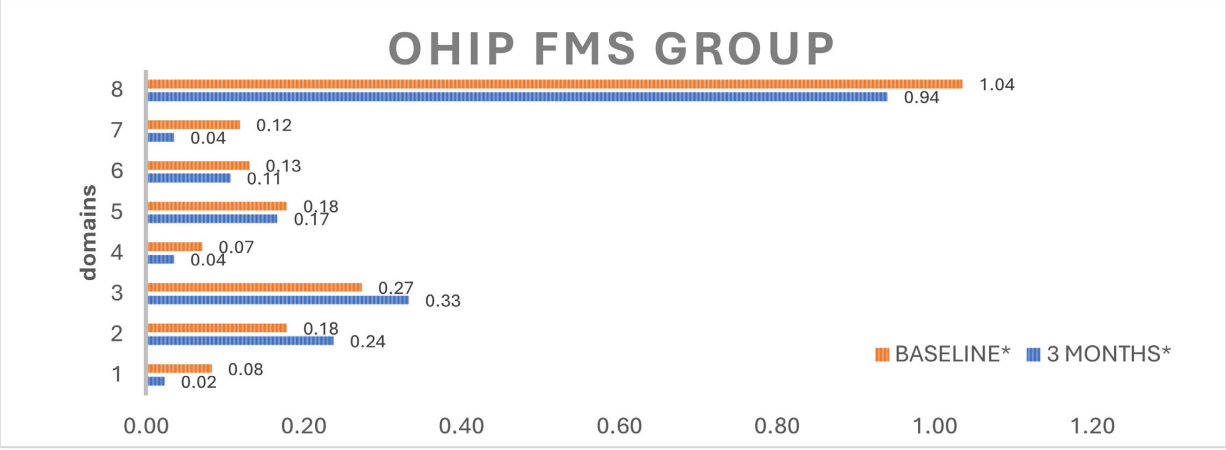


Figure 4 - OHIP-14 of FMS group. Total mean of the OHIP-14 questionnaire by domain. Number 8 represents the overall mean of the control group at baseline and 3 months.

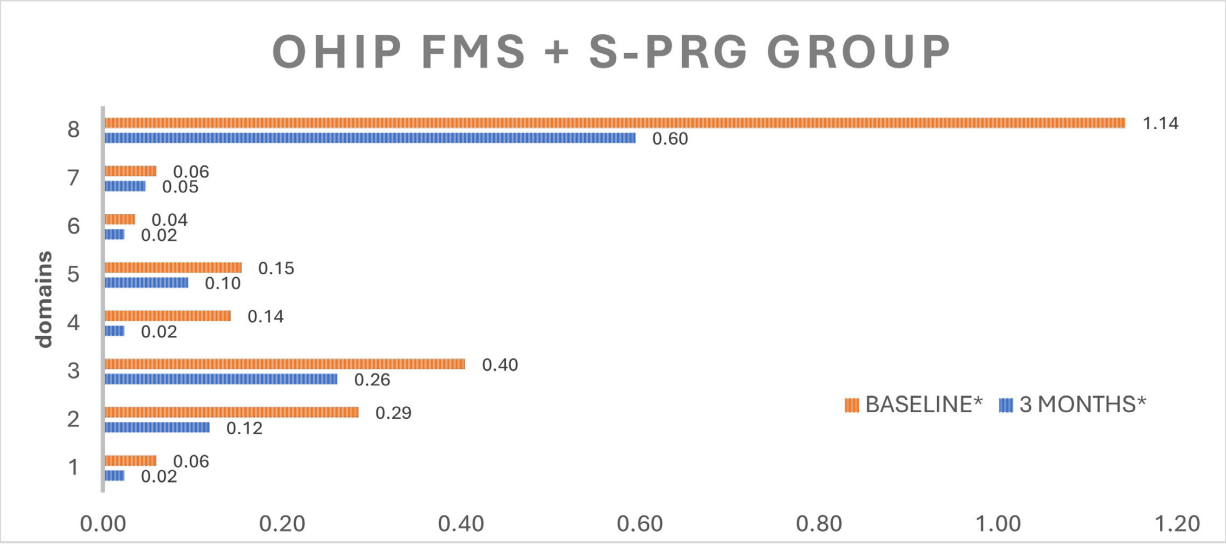


Figure 5 - OHIP-14 of FMS + S-PRG group. Total mean of the OHIP-14 questionnaire by domain. Number 8 represents the overall mean of the control group at baseline and 3 months.

parameters at 3 months showed no differences between the groups, a fact that could possibly be related to the low number of participants, as this was a pilot study. In this study, it was possible to observe an improvement in periodontal parameters such as plaque index (PI) and bleeding on probing (BoP) in the FMS + S-PRG group after 3 months of treatment, corroborating with the findings of the pre-clinical study of Mayumi et al. (2021) [20], in which a significant reduction in bleeding on probing was observed after 4 weeks of irrigation with the S-PRG nanoparticle in beagle dogs. In the same study, the *in vitro* test showed that the roots treated with the S-PRG nanoparticle inhibited biofilm formation and reduced periodontal inflammation, with a consequent reduction in bleeding on probing. The antibacterial action of fluoride and borate ions and the anti-inflammatory effect of strontium demonstrated a reduction in the expression of interleukin-6 [20].

In the present study, both the PI and PD showed a reduction within both groups (FMS and FMS + S-PRG) at 3 months, which aligns with the expected outcomes following non-surgical periodontal therapy [36]. Shimazu et al. (2016) [37] observed the inhibitory effect on the formation of oral streptococcus biofilm with the use of S-PRG nanoparticles. It is possible that the ions released by the S-PRG filler contribute to inhibiting bacterial cell growth and subsequent biofilm formation [37].

Patient perception of quality of life was measured using the OHIP-14 questionnaire, and the group treated with the FMS + S-PRG nanoparticle was the only one to show a statistically significant difference between the evaluation periods. Bleeding on probing is the parameter most complained about and perceived by patients, so it is easier to observe this change in daily life; this preliminary result could suggest the potential benefits in these patients' perception of quality of life. The group treated with the FMS + S-PRG adjuvant showed the greatest reduction in bleeding on probing at 3 months, and this clinical symptom is easily recognized by patients in their daily lives, in addition to the change in gingival color and edema reduction; this, in a way, has a direct impact on the individual's perception of the improvement in their oral and general health. This result corroborates the study by Mayumi et al. (2021) [20], which mentions that the S-PRG nanoparticle has an anti-inflammatory effect.

In terms of adverse effects, the participants in the FMS + S-PRG group did not report any changes in taste, product taste, or changes in the color of teeth and mucous membranes. This shows that the S-PRG nanoparticle was safe for clinical application and did not cause any adverse effects in the participants. In addition, no participant reported a dry or burning sensation in the mouth. So far, based on 12 patients in this pilot study, the results suggest that the S-PRG nanoparticle is safe as an adjuvant for FMS. But a few more studies are needed to confirm that potential. Thinking about the adjuvants that are already commercialized, we have essential oils (EO) and chlorhexidine (CLX). In the systematic review by Van der Slujis et al. (2016) and da Silveira et al. (2026) [17,18], it was found that neither showed beneficial effects when associated with full-mouth scaling.

The results of this pilot study using S-PRG nanoparticles proved to be positive in terms of resolving the clinical parameters assessed in periodontitis. Even with a small sample size (n=12), promising results from this therapeutic adjuvant can be observed. In any case, more clinical studies involving the use of S-PRG nanoparticles in periodontics are needed so that its indications can be better understood.

Considering that this is still a pilot study with a smaller number of participants, a limitation of this study is the research design. Initially, the proposal was to carry out a triple-blind clinical trial, but due to the coloring of the S-PRG nanoparticle, it was not possible for the operator to not know which dispersion was being applied at the time of treatment. Returning for follow-ups was not considered a limitation or difficulty of this pilot study, as no patient or follow-up was missed. In the future, the aim is to complete the full study with the full sample of 40 patients (number determined by a sample calculation), in the 3- and 6-month evaluation periods, in addition to the immunological and microbiological analyses, and evaluate the results obtained. Likewise, more studies are needed with S-PRG nanoparticles to better understand their role in achieving and maintaining periodontal health.

CONCLUSION

This pilot study demonstrates promising potential for favorable results in the use of

S-PRG nanoparticle dispersion as an adjuvant in the treatment of stage III and IV periodontitis. The study showed a reduction in the plaque index and bleeding on probing, as well as a potential positive impact on the quality of life for the S-PRG group when comparing baseline and the 3-month follow-up.

These results will be incorporated into the final study, which is still ongoing but already showing primary potential for favorable outcomes for the use of S-PRG nanoparticle dispersion in periodontitis treatment. This could potentially make the dispersion an available adjuvant option for clinicians.

Data availability

The authors declare that they have a conflict of interest.

Author's Contributions

CCMM, BAS, AOM: Data Curation. CCMM, BAS, AOM, LCT, EACS: Methodology. CCMM, BAS, AOM: Resources. ACDM, ESR, MANJ: Project Administration. ACDM, ESR, MANJ: Supervision. CCMM, BAS, AOM: Writing – Original Draft Preparation. CCMM, ACDM, ESR, TN: Writing – Review & Editing.

Conflict of Interest

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Regulatory Statement

The methodology followed the CONSORT guidelines [24]. This study was submitted to and approved by the Ethics Committee for Research Involving Human Beings under protocol number CAAE: 66809123.3.0000.0077 and has already been published in the Brazilian Registry of Clinical Trials (ReBEC) under number RBR-7k87ynr.

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