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The effects of adjunctive use of a desiccant agent in the treatment of stage III periodontitis (Randomized controlled clinical trial)

Belal Khalil [a,*], **Ali Abou Sulaiman** [a], **Batoul Al Hajjar** [b]

[a] *Department of Periodontology, Faculty of Dentistry, Damascus University, Damascus, Syria*
[b] *Department of Cosmetic Dentistry, Faculty of Dentistry, Damascus University, Damascus, Syria*

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KEYWORDS

Periodontitis;
Scaling and root planning;
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HYBENX gel

Abstract *Introduction:* Several bacterial species inhabiting the dental plaque biofilms are associated with periodontitis.

Objective: The main objective of this study was to compare the efficacy of the desiccant agent HYBENX (HBX) as an adjunct to scaling and root planning (SRPX) versus scaling and root planning (SRP) alone in the treatment of periodontitis.

Materials and Methods: The study sample comprised 25 patients with periodontitis stage III (grades A and B). Each maxillary quadrant was randomly allocated to two groups: SRPX group, including 25 quadrants treated with SRP plus HYBENX, and SRP group, including 25 quadrants treated with SRP alone. The following clinical periodontal parameters were recorded at baseline (immediately after treatment, T0), and 1 month (T1), 3 months (T3), and 6 months (T6) after treatment: probing pocket depth (PPD), relative attachment level (RAL), plaque index (PLI), gingival index (GI), gingival height (GH), and bleeding on probing index (BOP).

Results: Comparisons within each study group showed that all clinical parameters significantly improved ($P < 0.001$) at all follow-up intervals. In contrast, a statistically significant difference ($P < 0.001$) was observed in RAL, PPD, BOP, and GI indices at all follow-up intervals between the SRPX and SRP groups. In contrast, no significant differences ($P > 0.05$) were found in GH and PLI between the study groups.

Conclusion: Both treatment groups showed improved periodontal parameters. However, applying desiccant gel as an adjunct to SRP was significantly effective in the treatment of stage III periodontitis.

* Corresponding author at: Department of Periodontology, Faculty of Dentistry, Damascus University, Damascus, Syria.
E-mail addresses: khlelbelal@gmail.com, bilal.khalil@damascusuniversity.edu.sy (B. Khalil).
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1. Introduction

Periodontitis is defined as an inflammatory disease of the supporting tissues of the teeth caused by specific microorganisms, causing gradual destruction of the periodontal ligament and alveolar bone with an increase in the depth of the periodontal pocket, gingival recession, or both (Flemmig, 1999).

The success of periodontal therapy depends on patient plaque control and removal of supra- and subgingival bacterial biofilms with the smear layer containing endotoxins, bacteria, and contaminated cementum (Socransky, 2002).

Scaling and root planning (SRP) remains the cornerstone of nonsurgical periodontal therapy. SRP was shown to be remarkably effective at reducing clinical inflammation, pocket probing depth, attachment loss, and bleeding on probing (Mombelli, 2018).

Nonetheless, complete elimination of subgingival bacteria is rarely achievable in cases of impaired access, such as deep periodontal pockets and furcation areas, thus leading to persistent inflammation and progressive loss of attachment after treatment (Quirynen et al., 2001).

However, several lines of evidence suggest that the adjunctive use of chemotherapeutic agents, such as antibiotics and antiseptics can significantly improve the effectiveness of conventional nonsurgical therapy. A plethora of locally delivered antimicrobials have been used in conjunction with SRP to inhibit dental plaque biofilms (Krayer et al., 2010).

Chemotherapeutic agents (antiseptics, antibiotics, and host modulatory therapy) administered systemically or locally have been shown to make nonsurgical therapies more predictable (Isola et al., 2021).

The oral microbial biosphere encompasses bacterial microorganisms in a water-rich cellular matrix comprising10%–30 % extracellular polymeric substances and 70 % water. This bacterial habitat prevents antimicrobial agents from reaching all bacterial targets in the subgingival area and hinders mechanical attempts to achieve complete biofilm removal following basic SRP therapy (Marsh, 2005).

Therefore, Lombardo et al. (2015 suggested that exposure of the biofilm to a desiccant can lead to its destruction and ease its removal from subgingival areas and reported enhancement of SRP effectiveness when using ultrasonic debridement plus a desiccant. HYBENX® is a novel desiccating agent that has been used as an adjunct to standard mechanical dental hygiene procedures to assist in the removal of biofilm-associated plaque (Lopez et al., 2016). Similarly, Isola et al. (2018) revealed that SRP plus a desiccant resulted in a greater reduction in clinical, microbial, and inflammatory mediators compared with SRP alone when treating chronic periodontitis.

Based on these previous findings, the purpose of the present study was to investigate the efficacy of using a desiccant agent as an adjunct to SRP compared with SRP alone in the treatment of stage III periodontitis.

2. Materials and methods

2.1. Study design:

This study was a randomized controlled clinical trial with a split-mouth design. The study protocol (#3675) was approved by the Research Ethics Committee of Damascus university. This clinical trial was conducted in accordance with CONSORT guidelines (Fig. 1).

2.2. Study sample:

Patients referred to the Department of Periodontology, Faculty of Dentistry, Damascus University were invited to participate in the study. All participants provided written consent after being informed of the nature and purpose of the project. The inclusion criteria were as follows: nonsmokers, healthy with no systemic disease that might affect the study outcome, diagnosis of periodontitis stage III in line with the new classification of periodontal diseases (Tonetti et al., 2018), and having at least five teeth per quadrant (not including wisdom teeth) with a minimum of five proximal nonadjacent sites with a probing depth $\geq$ 6 mm in each quadrant. Patients were excluded if they were pregnant or lactating, were allergic to sulfonated compounds, had furcation involvement, had class III tooth mobility, had undergone periodontal therapy during the last 6 months, used antibiotics during the last 6 months, used mouthwashes containing antimicrobials, or used medication with anti-inflammatory drugs over the past 3 months.

2.3. Clinical examination

A full-mouth periodontal chart was recorded for all patients. One masked periodontist (AAS), who was not involved in the treatment, used a standardized periodontal probe (UNC-15, Hu-Friedy, Chicago, IL, USA) to perform clinical measurements at six sites per tooth. The following periodontal parameters were examined: plaque index (PLI) (Löe,1967), gingival index (GI) (Löe,1967), bleeding on probing index (BOP) (Newbrun, 1996), probing pocket depth (PPD) (Listgarten, 1980), relative attachment level (RAL), and gingival height (GH). RAL is the distance from the customized resin stent margin to the bottom of the pocket. HG represents the distance from the customized resin stent margin to the top of the interproximal papilla. An individually customized resin stent with guiding grooves was fabricated using the Exocad dental program, and served as a reference point for clinical measurements. Intraexaminer reproducibility and repeatability were assessed over two separate calibration sessions. All clinical parameters were recorded at the following intervals: baseline (immediately after treatment, T0) and 1 month (T1) (Fig. 3), 3 months (T3), and 6 months (T6) after treatment.

2.4. Treatment protocol

A screening visit was scheduled one week before the treatment to perform radiographic evaluation and full-mouth periodontal charting. Simultaneously, the patients' awareness of appropriate oral hygiene was assessed, proper oral health motivation and instructions were provided, and the importance of oral care during the treatment period and beyond was asserted.

The designated method of therapy (control = SRP alone or test = SRP + desiccant) was randomly allocated to each patient's maxillary quadrants. A fellow clinician who was not directly involved in this study used a random-number generator software to establish a haphazard quadrant scheme.

Subsequently, during the first treatment session, a sulfonic/-sulfuric acid gel solution (HYBENX®, Oral Tissue Decontam-

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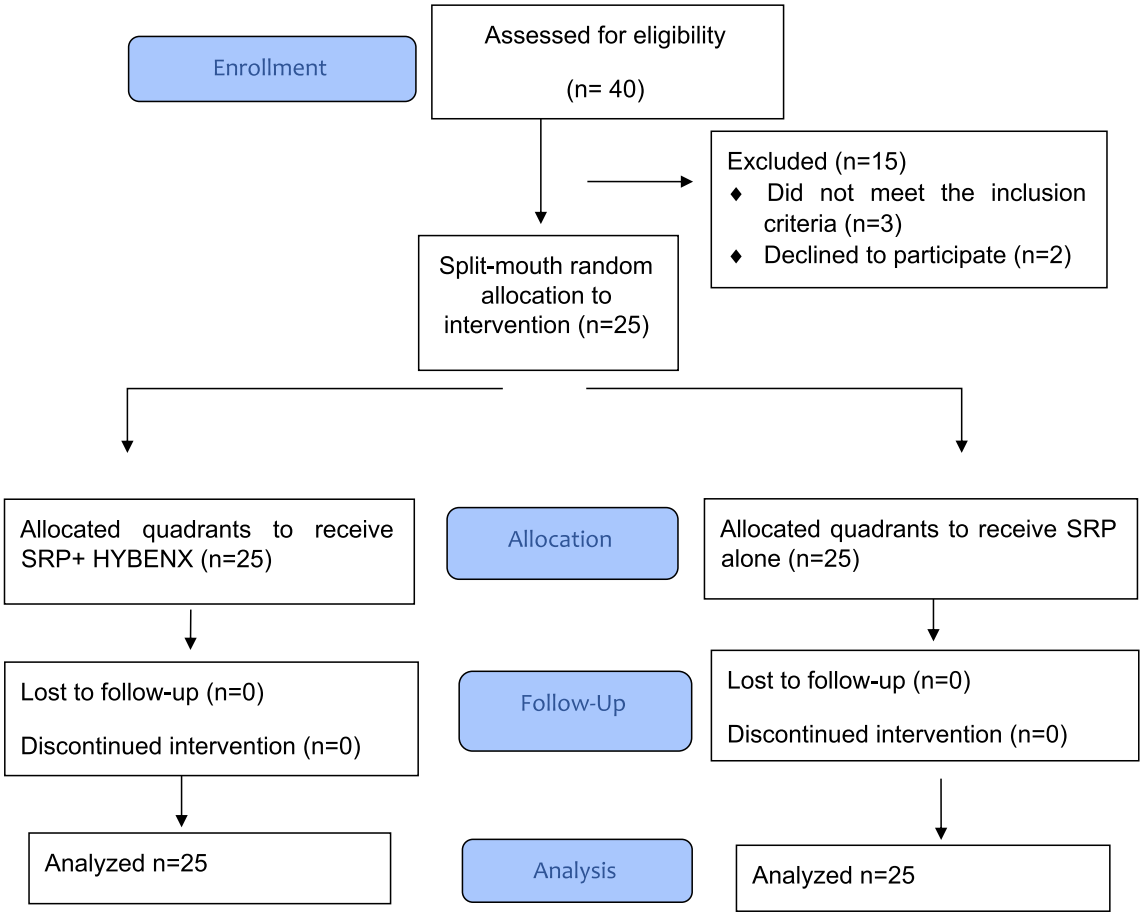

Fig. 1 CONSORT flow diagram.

inant™, EPIEN Medical, MN, USA) was delivered subgingivally to all periodontal pockets. The gel was left in place for 30 s and then rinsed thoroughly with abundant sterile saline solution (Fig. 2). A trained periodontist (BK) performed manual SRP by using hand-scaling instruments (CK6 and U-15; Zaffiro™, Germany) and Gracey curettes (Zaffiro™, Germany).

In contrast, the quadrants in the control group (SRP) were subjected to SRP alone. Finally, all participants were asked to stop brushing their teeth on the same day of treatment. In addition, they were advised not to use any antimicrobial mouthwashes or antibiotics during the follow-up period and were instructed to adopt only optimal tooth brushing as a means of plaque control.

2.5. Statistical analysis

The sample size was calculated based on the data from previous studies (Isola et al., 2018; and Lombardo et al., 2015). G* power software V.1.7.9 (Dusseldorf, Germany) was used to determine the required number of patients. It was calculated that a minimum of 25 quadrants were necessary to achieve a statistical power of 80 % with an effect size of 0.35 and $\alpha = 0.05$, which was considered as the primary outcome parameter.

Data analysis was performed using SPSS software version 23 (IBM, Chicago, USA). Normality of the distribution for all examined data was checked using the Kolmogorov–Smirnov test. The data showed a normal distribution; thus, a parametric approach was applied in the data analysis. A paired sample *t*-test was used for intragroup comparisons, whereas the independent samples *t*-test was applied for intergroup comparisons. A *P* value of 0.05 and a confidence interval of 95 % were considered significant in all tests.

Fig. 2 Application of HYBENX gel.

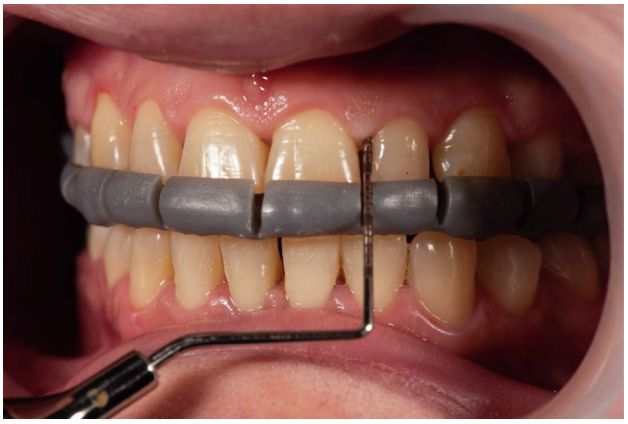

Fig. 3 Recording probing pocket depth at T1.

3. Results

A total of 25 patients (15 females, 10 males) aged 25–60 years were eligible to be enrolled in the study (Table 1).

The changes in the mean values ± standard deviations of PPD, RAL, PLI, GI, GH, and BOP indices are shown in Table 2. Both study groups presented significant differences at all follow-up intervals compared with the baseline *($P < 0.001$)*. The SRPX group demonstrated a highly significant reduction *($P < 0.001$)* in PPD, RAL, BOP, and GI compared with the SRP group.

4. Discussion

Mechanical nonsurgical periodontal therapy is considered the cornerstone of periodontitis treatment and its aim is to eliminate pathogenic bacteria in the biofilms; however, complete elimination remains elusive, especially in advanced severe cases and deep pockets (Goodson et al., 2012). To overcome these problems, adjunctive local and systemic antimicrobial agents have been employed to facilitate the elimination of pocket microflora (Jepsen and Jepsen, 2016).

Various adjunctive treatment modalities include systemic antimicrobial therapy, full-mouth disinfection, subgingival local drug delivery, topical antimicrobials, and intraoral irrigation with chlorhexidine and other chemotherapeutic agents (Smiley et al., 2015).

In the recent past, encouraging data emerged regarding the use of desiccant agents as an adjuvant to SRP, although the number of these studies is quite limited. Hence, this study was undertaken to assess the potential effectiveness of utilizing a new desiccant agent in combination with SRP for the management of patients with stage III periodontitis.

Table 1 Distribution of patients by age and sex.

Sex			
Age group	**Male (%)**	**Female (%)**	[a] ***p***
25–30	1(10 %)	0 (0 %)	0.562
31–36	2(20 %)	2 (14.4 %)	0.577
37–42	2(20 %)	3 (20 %)	0.533
43–48	1(10 %)	4 (26.6 %)	0.543
49–54	2(20 %)	3 (20 %)	0.522
55–60	2(20 %)	3 (20 %)	0.567
Total	10 (100 %)	15 (100 %)	

[a] chi–squared test.

The present study revealed highly significant improvements in PPD, RAL, GI, and BOP in the test group at all follow-up intervals than in the control group. These findings are consistent with the findings of Isola et al. (2018) who reported that the HYBENX gel provides a statistically significant improvement in these indices when treating patients with chronic periodontitis. Likewise, our findings are in agreement with those of Reddy et al. (2018) who reported an improvement in clinical indices when the HYBENX gel was used to treat a series of cases of acute periodontal abscess. Our data are also in line with the findings of Lombardo et al. (2015) regarding GI and BOP, but not regarding RAL and PPD. The reason for this conflict might be attributed to the differences in study design and treatment modality between the two studies.

The findings of the present study can be explained based on the evidence from the published literature. Although SRP is the most common nonsurgical treatment, it is known to be effective in reducing microorganisms in dental plaque. However, SRP alone has several limitations, such as difficulty in accessing deeper gingiva, narrower area, and removal of penetrated pathogenic microbes in the dentinal tubules, thus not causing a sufficient change in the subgingival bacterial structure (Sampaio et al., 2011). Furthermore, meticulous subgingival debridement is inherently time-consuming and a difficult procedure that relies heavily on the skill of the clinician for success (Laleman et al., 2017).

Another explanation for the results of this study is based on the properties of the desiccant agent being evaluated. Recent research has shifted from using antiseptics and antibiotics for eliminating germs to using substances that destroy biofilms. HYBENX belongs to a new generation of desiccant materials that dry and coagulate dental plaque by means of its acidic composition, leading to the elimination of germs and the death of germs in the biofilm (Isola et al., 2021). Dental biofilms have a high water content and porous structure; thus, they are expected to be particularly sensitive to the disruptive action of HYBENX solution. Additionally, the use of HYBENX gel as an adjunct to mechanical treatment results in enhanced debridement and cleansing of pathologic debris from tissue surfaces, which is far better than what can be achieved when using regular irrigation solutions (Zafar et al., 2021).

Moreover, Microbiological analysis from studies of Lombardo et al., (2015) and Isola et al., (2018) revealed a significant reduction in the proportion of bacteria from the red and orange complexes in the SRP + desiccant group compared with the SRP alone group. Moreover, this is further supported by the findings of Isola et al., (2018) who reported that the reduction in periodontal pathogens observed in the SRP + desiccant group might have influenced the reduction in proinflammatory cytokines in the gingival crevicular fluid, as indicated by the decrease in the interleukin (IL)-1β/IL-10 ratio and tumor necrosis factor (TNF)-α levels compared with that in the SRP alone group.

Data from this study demonstrated no significant differences in PLI between the test and control groups. This finding can be attributed to the compliance with oral hygiene instructions from all participants over the course of the study, leading to a similar decrease in the amount of plaque accumulation in

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Table 2 Changes in periodontal indices (PPD, RAL, GI, BOP, PLI, and GH) at different time points after treatment.

Parameter	T0	T1	T0 vS T1	T3	T0 vS T3	T6	T0 vS T6
	‡*P*		‡*P*		‡*P*		
PPD							
SRP	7.50 ± 0.51	6.83 ± 0.66	0.000	6.72 ± 0.71	0.000	6.67 ± 0.75	0.000
SRPX	7.47 ± 0.50	6.14 ± 0.73	0.000	6.02 ± 0.61	0.000	5.9 ± 0.59	0.000
Intergroup	**P* = 0.621	**P* < 0.001		**P* < 0.001		**P* < 0.001	
RAL							
SRP	8.95 ± 1.803	7.64 ± 1.876	0.000	7.48 ± 1.936	0.000	7,43 ± 1.901	0.000
SRPX	8.97 ± 1.705	7.20 ± 1.933	0.000	7.12 ± 1.946	0.000	7.02 ± 1.881	0.000
Intergroup	**P* = 0.532	**P* < 0.001		**P* < 0.001		**P* < 0.001	
GI							
SRP	1.04 ± 0.201	0.54 ± 0.501	0.000	0.55 ± 0.500	0.000	0.60 ± 0.607	0.000
SRPX	1.06 ± 0.243	0.27 ± 0.474	0.000	0.26 ± 0.447	0.000	0.25 ± 0.435	0.000
Intergroup	**P* = 0.567	**P* < 0.001		**P* < 0.001		**P* < 0.001	
BOP							
SRP	70.28 %	50.52 %	0.000	44.22 %	0.000	40.32 %	0.000
SRPX	71.02 %	31.01 %	0.000	22.03 %	0.000	23.01 %	0.000
Intergroup	**P* = 0.531	**P* < 0.001		**P* < 0.001		**P* < 0.001	
PLI							
SRP	1.35 ± 0.481	0. 58 ± 0.469	0.000	0.55 ± 0.500	0.000	0.55 ± 0.500	0.000
SRPX	1.36 ± 0.486	0.47 ± 0.502	0.000	0.36 ± 0.484	0.000	0.36 ± 0.484	0.000
Intergroup	**P* = 0.546	**P* = 0,543		* *P* = 0,544		**P* = 0,544	
GH							
SRP	6.74 ± 1.448	6.91 ± 1.447	0.000	6.91 ± 1.447	0.000	6.98 ± 1.442	0.000
SRPX	6.23 ± 1.123	6.70 ± 1.243	0.000	6.82 ± 1.225	0.000	6.90 ± 1.232	0.000
Intergroup	**P* = 0.542	**P* = 0.506		**P* = 0,612		**P* = 0,521	

RAL: Relative attachment level, PPD: Probing pocket depth, GI: Gingival index,
BOP: Bleeding on probing index, PLI: Plaque index, GH: Gingival height,
SRP: Scaling and root planning, SRPX: Scaling and root planning + HYBENX,
‡ Paired sample *t*-test for intragroup comparison.
* Independent samples *t*-test test for intergroup comparison.

both study groups. This finding is in accordance with the findings of Isola et al., (2018) but not with the data from the study by Lombardo et al., (2015) who reported no difference in plaque scores between the test and study groups. This disagreement may be because of the experimental conditions of their study (insufficient time for ultrasonic instrumentation and the inability to reach deep pockets because of the thick periodontal tips used for debridement).

A noteworthy finding of the present study was that there was no statistical difference in the GH index between the two study groups and no direct harm after application and during follow-up intervals was recorded. This finding is in line with the findings of the previous studies that reported that HYBENX gel is safe and harmless for use in periodontal tissues (Isola et al., 2018; Lombardo et al., 2015).

Finally, the lack of microbiological analysis and molecular biological testing because of limited funding and financial restraints could be considered the shortcomings of the present study. Nevertheless, in light of the promising clinical outcomes of this study, it can be suggested that a topically applied desiccant agent has good potential as an adjunct to SRP and can be a safer alternative to conventional treatment that can aid in decreasing plaque biofilm without causing bacterial resistance.

5. Conclusion

Within the limits of this study, it can be concluded that applying desiccant gel as an adjunct to SRP was significantly effective in the treatment of stage III periodontitis and improved the treatment outcome.

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