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ORIGINAL ARTICLE

A randomized controlled trial of home-applied dual-light photodynamic therapy during supportive periodontal care (HOPE-CP study)

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Abstract

Background: Periodontitis is a common, chronic inflammatory disease that relies heavily on effective daily oral hygiene for long-term control. Light-based therapies have demonstrated strong antibacterial potential; however, their effectiveness in regular home use remains unexplored.

Methods: Two hundred stage I–III periodontitis maintenance patients were randomized for supportive periodontal care (SPC) or SPC combined with adjunct home-applied dual-light therapy. Bleeding on probing (BOP), visible plaque index (VPI), and the number of sites with ≥4 mm periodontal probing depth (PPD) were measured at the baseline, at 3 and 6 months.

Results: Of the 200 randomized patients, 184 completed all visits. At baseline, the groups were similar for BOP, VPI, and pocket depth. At 3 and 6 months, adjunctive dual-light therapy achieved lower BOP (12.6 ± 0.7% and 12.0 ± 0.8%) than SPC alone (17.8 ± 0.8% and 17.3 ± 1.0%); $p < 0.0001$ and $p = 0.0002$ and lower VPI (8.5 ± 0.7% and 9.7 ± 0.8%) vs. (13.3 ± 0.8% and 14.2 ± 1.0%); $p < 0.0005$ and 0.0142. The dual-light group also had fewer sites with PPD ≥ 4 mm (5.6 ± 0.7 and 5.3 ± 0.6) vs. (7.6 ± 1.2 and 7.8 ± 0.9); $p = 0.02$ and $p = 0.02$.

Conclusion: Regularly home-applied dual-light therapy may represent a promising addition to existing home-care strategies and a potential advance in adjunctive periodontal maintenance.

KEYWORDS

antibacterial photodynamic therapy (aPDT), dental devices, home care, dual-light photodynamic therapy, supportive periodontal care (SPC), periodontitis, photobiomodulation therapy (PBMT)

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Plain language summary

Periodontitis is a common disease that damages the tissues supporting the teeth. Daily brushing and cleaning between the teeth are essential, but even with good routines, people can still develop plaque and gum inflammation. Light-based treatments are known to eliminate plaque bacteria effectively, but until now, they have mostly been used in dental offices, and their potential for home use has not been tested. In the HOPE-CP study, we enrolled 200 adults with periodontitis to receive routine supportive periodontal care. Half of them were randomized to use a light-based antibacterial device to support their daily oral hygiene at home. After 3 and 6 months, those using the device had less gum bleeding, less visible plaque, and fewer sites with deeper periodontal pockets than those who used routine care alone. These results show that using a daily antibacterial light treatment at home may help people better control inflammation and maintain healthier gums between dental visits.

1 | INTRODUCTION

Effective periodontal disease management relies on the consistent control of the microbial biofilm burden.[1,2] In professional oral healthcare so far, mechanical debridement remains the cornerstone of treatment, but daily plaque control in between the visits is a key determinant of periodontal stability.[3,4] However, appropriate biofilm removal at home is challenging as toothbrushes can leave a significant amount of residual plaque behind, ranging from 35% to 50%.[5,6] Even when accompanied by appropriate interdental cleaning, areas with limited accessibility, such as deep periodontal pockets, interproximal spaces, or crowded teeth, are especially prone to this problem when relying solely on manual techniques.[7] These challenges highlight the need for adjunctive antimicrobial strategies that can be applied regularly in a home setting. Innovative technologies enhancing daily oral hygiene routines may offer a substantial benefit to dental health and prevent disease progression.[8,9]

Antibacterial photodynamic therapy (aPDT) and antibacterial blue light (aBL) have emerged as promising non-antibiotic approaches for controlling biofilm-associated infections.[10–12] While aPDT has demonstrated bactericidal effects in vitro and in clinical studies, its role in periodontitis treatment has remained controversial, with inconsistent clinical outcomes.[13–15] The powerful antibacterial effect of aPDT is indisputable, but the therapy has been applied in the dental office setting, typically as single treatments, which is possibly insufficient to achieve lasting therapeutic benefits.[14,15] Favorable clinical outcomes have been reported in protocols utilizing repeated or continuous aPDT applications, suggesting that treatment frequency may be a critical determinant of efficacy.[14,16,17]

Recent technological advancements have led to the development of LED-based aPDT devices for home use. One such device, now available on the market, integrates both aPDT and aBL into a single treatment modality known as dual-light aPDT.[12,18] The device provides standardized treatment regarding both light wavelengths and the location of the light source in the mouth.[19,20] This dual-light approach enhances antibacterial efficacy against dysbiotic biofilms and has been demonstrated to reduce dental plaque accumulation in both experimental and clinical studies.[21,22] Beyond its antimicrobial effects, dual-light aPDT may also exert photobiomodulation (PBMT) benefits through its near-infrared light component, which can promote tissue healing and modulate local inflammation and oral proteolytic burden.[23,24]

This randomized clinical trial evaluated the adjunctive effect and safety of repeated, home-applied dual-light aPDT on periodontal treatment outcomes. We hypothesized that during maintenance care, supportive periodontal care (SPC) combined with regular dual-light aPDT might reduce the load of supragingival biofilm and affect inflammation, thereby improving periodontal clinical parameters. The study's primary endpoint was a change in bleeding on probing (BOP).

Registered 2022-02-07, https://clinicaltrials.gov/study/NCT05278416.

2 | MATERIALS AND METHODS

2.1 | Study design

This single-center randomized controlled clinical trial was conducted at the Metropolia University of Applied

Sciences dental clinic (Helsinki, Finland). The protocol was approved by the Ethics Committee of the Hospital District of Helsinki and Uusimaa (HUS/3089/2021) and followed the Declaration of Helsinki and ISO 14155 guidelines. Written informed consent was obtained from all participants.

Participants with stage I–III periodontitis[25] attending scheduled SPC visits were recruited. All received a standardized anti-infective session at study initiation, including supra- and subgingival debridement when indicated. Follow-up visits occurred at 3 and 6 months. The first visit occurred on February 15, 2022, and the last visit on April 14, 2025.

Participants were randomized (1:1) to either SPC alone or SPC with adjunctive daily dual-light antimicrobial photodynamic therapy (SPC + dual-light aPDT). Both groups received standardized oral hygiene instruction and an electric toothbrush (Jordan TB200B).

No patient or public involvement in the design, conduct, and reporting of the trial was used.

2.2 | Sample size

Of 511 patients screened, 200 were randomized. Two withdrew before randomization, and 184 completed the trial. The CONSORT diagram is presented in Figure 1. No protocol amendments were made after trial initiation. Study visits included screening/baseline, study initiation, and follow-up at 3 and 6 months.

The sample size was based on prior aPDT periodontal studies and an a priori calculation ($\alpha = 0.05$, 80% power), indicating that 200 participants with an estimated 10% dropout rate would be sufficient to detect differences in BOP.

2.3 | Eligibility criteria

Inclusion criteria:

- Stage I–III periodontitis (AAP classification)
- Age 18–85 years
- ≥20 natural teeth
- Written informed consent

Exclusion criteria:

- Poorly controlled diabetes (HbA1c ≥ 7%; ≥ 8% for insulin users)
- Systemic diseases or medications affecting periodontal status
- Periodontal therapy within the prior 3 months*
- Allergy to the photosensitizer
- Physical or cognitive limitations affecting oral hygiene
- Major removable prostheses or orthodontic appliances
- Current tobacco use
- Pregnancy or lactation
- Teeth requiring urgent extraction or endodontic therapy

*Scheduled SPC visits within the study were not exclusionary.

2.4 | Randomization and blinding

Randomization occurred after baseline examinations using sequentially numbered sealed envelopes prepared by an independent study monitor. Baseline measurements were examiner-blinded. After allocation, the examiner and participants were unblinded, but follow-up assessments were performed using a standardized protocol to minimize measurement bias. Data analysis and statistical analysis were performed blinded to group allocation (I.R.). Although blinding of participants and the examiner after randomization was not feasible due to the visible light emission and mild warmth produced by the device, baseline examinations and all statistical analyses were performed blinded to group allocation. A single calibrated examiner using a standardized probing force was employed to minimize measurement variability.

2.5 | Examiner calibration

All clinical measurements were performed by a single calibrated examiner (S.P.). Calibration on a phantom model (24 sites) required ≥85% agreement within 1 mm. Calibration was repeated approximately every 3 months (10 sessions total; agreement 87.5%–100%).

2.6 | Outcome measures

Primary outcome:

- Change in full-mouth BOP at 3 and 6 months.

Secondary outcomes:

- Change in visible plaque index (VPI)
- Change in probing pocket depth (PPD)
- Change in clinical attachment level (CAL)
- Change in aMMP-8 levels

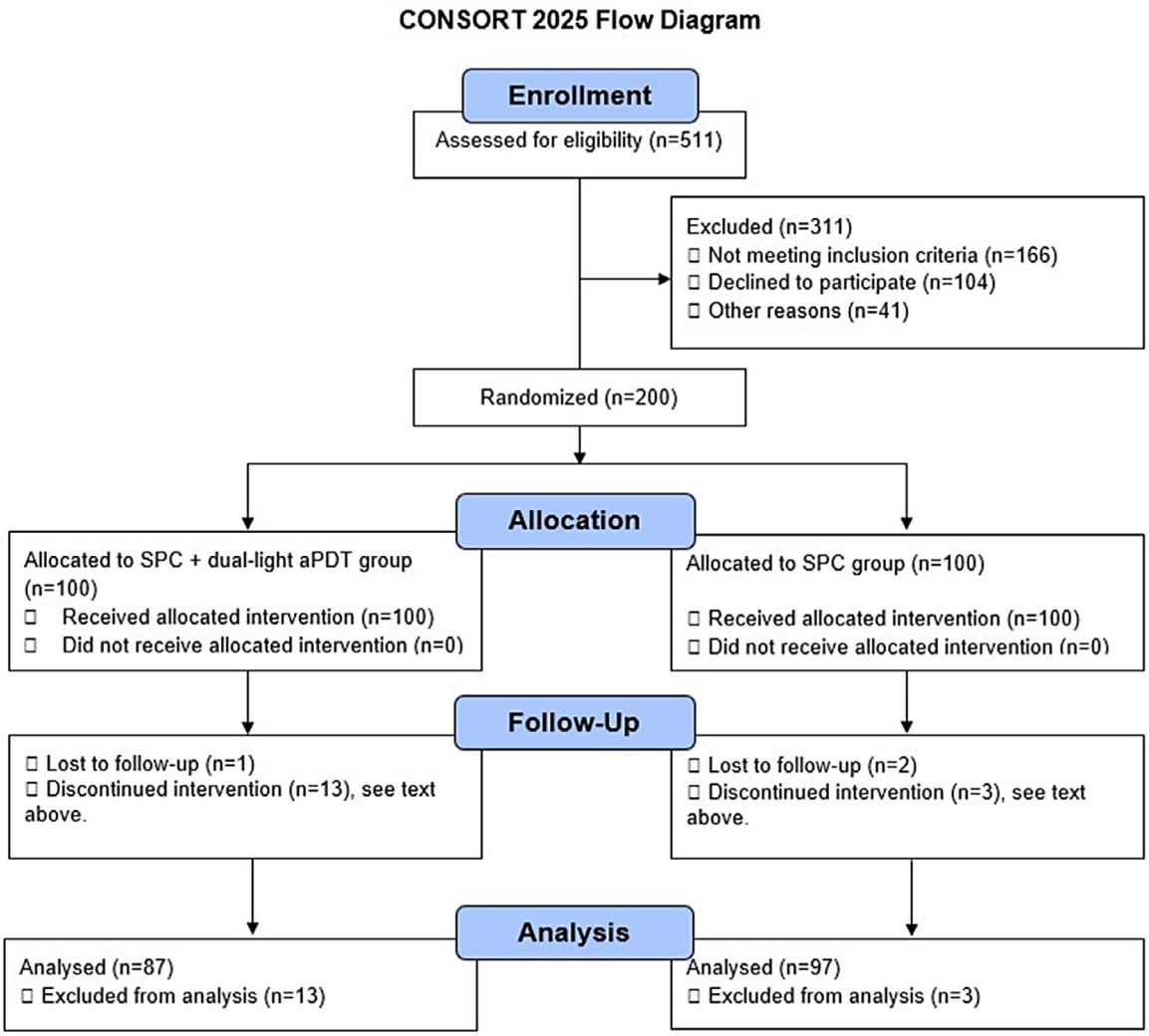

FIGURE 1 Flow diagram according to the CONSORT protocol.

2.7 | Clinical procedures

Full-mouth examinations were performed at baseline, 3 months, and 6 months. BOP, VPI, PPD, and CAL were recorded at six sites per tooth using a manual periodontal probe (North Carolina 54B, Hu-Friedy) with 0.25 N force.

- BOP: bleeding presence/absence within 15 seconds.
- VPI: dichotomous scoring at six sites per tooth.
- PPD: distance from the gingival margin to the pocket base.
- CAL: CEJ (cemento-enamel junction)-to-pocket base, adjusted for recession.
- aMMP-8: measured from mouthrinse samples using Periosafe according to manufacturer instructions.

Self-reported oral hygiene practices were assessed using the Oral Self-Care Assessment (OSCA) questionnaire at each study time point.

2.8 | Anti-infective treatment

All participants received Step 1–2 periodontal therapy according to EFP S3 guidelines, including scaling and root planing (SRP) of pockets ≥4 mm using ultrasonic and manual instruments. Powder cleaning was used unless contraindicated. This represented routine SPC debridement, not comprehensive active periodontal therapy. Oral hygiene instructions were reinforced at baseline and at 3 months.

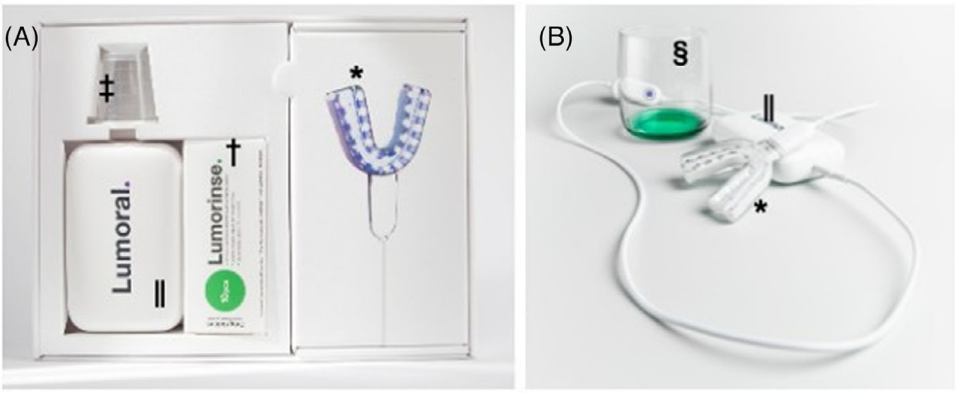

FIGURE 2 (A and B) The dual-light antimicrobial photodynamic therapy (aPDT) starter pack includes a light applicator mouthpiece (*) designed to deliver simultaneous light irradiation to both the maxillary and mandibular dental arches. Each LED emits light at two wavelengths: 405 and 810 nm. The mouthrinse (†) is provided as an effervescent tablet, which is dissolved in 30 mL of water using the supplied measuring cup (‡) to yield a solution containing 250 mg/mL of indocyanine green (ICG). When dissolved, the rinse appears green (§). The light applicator mouthpiece is powered via an external power supply (‖).

2.9 | Intervention: Dual-light aPDT

Participants in the SPC + dual-light aPDT group used the Lumoral device (Koite Health, Finland) once daily. The mouthrinse (ICG 250 μg/mL) was activated by a dual-wavelength LED mouthpiece (405 and 810 nm; 30 J/cm^2 over 10 min). Treatment was performed before toothbrushing and interdental cleaning (Figure 2).

2.10 | Adverse events and safety monitoring

Safety was assessed in accordance with ISO 14155 Good Clinical Practice for medical device investigations. The safety endpoints were: (i) treatment-emergent adverse events (TEAEs), seriousness, severity, and relatedness; (ii) exposure-adjusted TEAE incidence rates (EAIR) per 1000 treatment sessions; (iii) discontinuations due to adverse events or intolerance; (iv) device malfunction events; and (v) hard-tissue safety indicators (participants with ≥1 chipped restoration and ≥1 chipped tooth recorded between visits). Adverse events were solicited at each visit and via interim contacts; electronic patient records were reviewed between visits for dental findings, aligned with CONSORT-Harms 2022. In addition, possible adverse events data were collected for the manufacturer in line with the regulatory aspects set forth by the European Medical Device Regulation (MDR 2017/745).

The investigational LED mouthpiece emits visible blue (≈405 nm) and near-infrared (≈810 nm) light (no ultraviolet radiation is emitted). Before entering the market, as a home-use light device, the safety has been assessed against IEC/EN 62471 photobiological safety (blue-light retinal and tissue exposure risk groups) and IEC 60601-2-57 essential performance for non-laser light source equipment, and the home environment collateral standard IEC 60601-1-11.

2.11 | Compliance

Participants in the aPDT group maintained a treatment diary and returned unused tablets. Compliance was calculated as the proportion of tablets used relative to scheduled treatment days.

2.12 | Statistical analysis

Analyses were performed using GraphPad Prism version 10.4.2 (GraphPad Software, CA, USA). Repeated measurements analysis using mixed-effects analysis, including multiple comparisons test. Fisher's exact test was applied to categorical variables. Exact Poisson 95% confidence intervals (CIs) for EAIRs were calculated using the chi-square distribution. Risk differences were calculated using the Newcombe–Wilson method without continuity correction. Whitney U tests were used for nonparametric data comparisons between the groups, as appropriate. Statistical significance was set at $p < 0.05$.

Pseudonymized data cannot be openly shared due to GDPR restrictions. Data or the full protocol may be made available upon reasonable request to the

TABLE 1 Baseline demographics and clinical characteristics of participants in the SPC + dual-light aPDT group and the SPC group. Baseline demography data are presented as frequency and percentage, or as median with range where applicable. No statistically significant differences were observed between the groups in terms of sex distribution, age, or prevalence of systemic conditions.

	SPC + dual-light PDT/ PTT group ($n = 99$)	SPC group ($n = 101$)	Statistical difference
Sex, F/M	82%/18%	71%/29%	p = ns.
Age, median (range)	67 years (33–84)	66 years (22–84)	p = ns.
Chronic illness diagnosed, Y/N	84/15 (85%)	81/20 (80%)	p = ns.
Regular medication, Y/N	58/41 (59%)	65/36 (64%)	p = ns.
High blood pressure, Y/N	43/56 (43%)	42/59 (42%)	p = ns.
High cholesterol, Y/N	15/84 (15%)	22/79 (22%)	p = ns.
Asthma, Y/N	11/88 (11%)	12/89 (12%)	p = ns.
Diabetes, Y/N	11/88 (11%)	8/93 (8%)	p = ns.
Hyper- or hypothyroidism, Y/N	11/88 (11%)	7/94 (7%)	p = ns.

Abbreviations: aPDT, antimicrobial photodynamic therapy; F/M, female/male; Y/N, yes/no; ns., non-significant; SPC, supportive periodontal care; Fisher's exact test, Mann–Whitney *U*-test.

corresponding author, subject to ethical approval and required de-identification procedures.

3 | RESULTS

3.1 | Demographic characteristics of the patient population

Out of 511 patients assessed for eligibility, 200 were randomized. The primary reasons for exclusion were not meeting the inclusion criteria ($n = 166$) and unwillingness to participate ($n = 104$). Additional reasons ($n = 41$) included language barriers and prior use of the investigational device. Among the randomized participants, 16 discontinued the study—13 from the SPC + dual-light aPDT group and three from the SPC group. Eight participants discontinued before the 3-month follow-up visit, and another eight before the final visit. Reasons for discontinuation included discomfort with device use ($n = 7$), loss to follow-up ($n = 3$), other health-related issues ($n = 2$), personal reasons ($n = 1$), and scheduling difficulties ($n = 1$). Two participants did not provide a specific reason for withdrawal. Data from 184 participants were included in the final analysis. The CONSORT protocol and patient demographics are presented in Table 1.

3.2 | Periodontal stage at baseline

In the SPC + dual-light aPDT group, 44 participants (44%) had stage I periodontal disease, 40 (40%) had stage II, and 15 (15%) had stage III. In the SPC group, 45 participants (45%) had stage I, 36 (36%) had stage II, and 20 (20%) had stage III. There was no statistically significant difference between the groups.

3.3 | Periodontal clinical outcomes

All clinical outcome measures at baseline, 3 months, and 6 months are presented in Table 2. Changes in BOP, visual plaque index (VPI), PPD, and clinical attachment loss (CAL) across visits are shown in Figures 3 and 4.

3.4 | Active matrix metalloproteinase-8 (aMMP-8)

At the baseline visit, pathological aMMP-8 levels in mouthrinse samples (≥20 ng/mL) were detected in 17% of patients in the SPC + dual-light aPDT group and 22% in the SPC group, with no statistically significant difference between the groups. At the 3-month visit, the proportion of patients with pathological aMMP-8 levels was 7% in the SPC + dual-light aPDT group and 7% in the SPC group; at 6 months, the corresponding figures were 8% and 7%, respectively. No statistically significant differences were observed at either time point.

3.5 | Oral self-care habits of study participants

No significant difference was observed in toothbrushing or interdental cleaning between the groups. See the table in the Supplementary material in the online *Journal of Periodontology* for more details.

JOURNAL OF Periodontology

TABLE 2 Numerical results of the clinical periodontal outcomes (mean ± SEM or %).

Periodontal outcomes (mean ± SEM or %) over time				
Parameter	**Timepoint**	**SPC + dual-light aPDT group**	**SPC group**	***p*-value**
BOP (%)	Baseline	24.2 ± 1.2	26.1 ± 1.1	0.3884
	3 months	12.6 ± 0.7	17.8 ± 0.8	<0.0001
	6 months	12.0 ± 0.8	17.3 ± 1.0	0.0002
BOP < 10% (%)	Baseline	9%	4%	ns.
	3 months	43%	16%	0.0001
	6 months	51%	23%	<0.0001
BOP < 20% (%)	Baseline	37%	37%	ns.
	3 months	86%	68%	0.0027
	6 months	86%	73%	0.046
VPI (%)	Baseline	21.0 ± 1.4	22.1 ± 1.5	0.986
	3 months	8.5 ± 0.7	13.3 ± 0.8	0.0005
	6 months	9.7 ± 0.8	14.2 ± 1.0	0.0142
VPI < 10% (%)	Baseline	21%	26%	ns.
	3 months	65%	43%	0.0025
	6 months	63%	38%	0.0011
PPD ≥ 4 mm (n sites)	Baseline	8.6 ± 0.9	10.6 ± 1.2	0.14
	3 months	5.6 ± 0.7	7.6 ± 1.2	0.0228
	6 months	5.3 ± 0.6	7.8 ± 0.9	0.0269
CAL ≥ 4 mm (n sites)	Baseline	9.5 ± 1.0	11.5 ± 1.2	ns.
	3 months	6.5 ± 0.8	8.5 ± 0.9	0.048
	6 months	6.4 ± 0.7	8.8 ± 1.1	0.066

Abbreviations: BOP, bleeding on probing; CAL, clinical attachment loss; ns., non-significant; PPD, probing pocket depth; SEM, standard error of the mean; SPC, supportive periodontal care; VPI, visual plaque index.

3.6 | Compliance and safety

The compliance regarding the dual-light aPDT device use, expressed as mean ± SEM, was 86.3 ± 2.1%, measured at the 3-month visit, and 85.3 ± 2.0% at the 6-month visit.

No device or protocol-related serious adverse events occurred. Thirteen device-related TEAEs were recorded: oral sensitivity or numbness ($n = 7$), sensations of warmth in the mouth or tongue ($n = 2$), and pharyngeal reflex ($n = 2$). Seven participants discontinued device use because of discomfort (two withdrawals directly attributed to adverse effects). Hard-tissue safety indicators were comparable between groups: chipped restorations in 22% of device-arm participants (26 events in 22 individuals) versus 19% in controls (23 events in 19 individuals) and chipped teeth in 11% versus 9%, respectively; no statistically significant between-group differences were observed (Table 3).

4 | DISCUSSION

This randomized controlled trial investigated the adjunctive effect of home-applied dual-light antimicrobial photodynamic therapy (aPDT) in patients receiving maintenance care for stage I–III periodontitis. The results demonstrate that the addition of daily dual-light aPDT to SPC improves clinical outcomes over 6 months when compared with SPC alone. Participants in the SPC + dual-light aPDT group exhibited significantly lower levels of bleeding on probing (BOP) at both 3 and 6 months. Furthermore, a significantly greater proportion of patients in this group reached the clinical target of BOP < 10%, suggesting enhanced resolution of gingival inflammation beyond that achieved with conventional therapy alone.

The adjunctive use of dual-light aPDT was also associated with improved plaque control, as evidenced by a consistently lower VPI throughout the follow-up period. This finding supports the hypothesis that dual-light aPDT may contribute to supragingival biofilm control through its local antimicrobial effects.[18,20] These outcomes are consistent with, and expand upon, earlier studies reporting clinical benefits from adjunctive photodynamic therapy in periodontal management.[19,21]

With respect to PPD, both groups showed meaningful reductions, yet the SPC + dual-light aPDT group presented fewer sites with PPD ≥4 mm at both follow-up

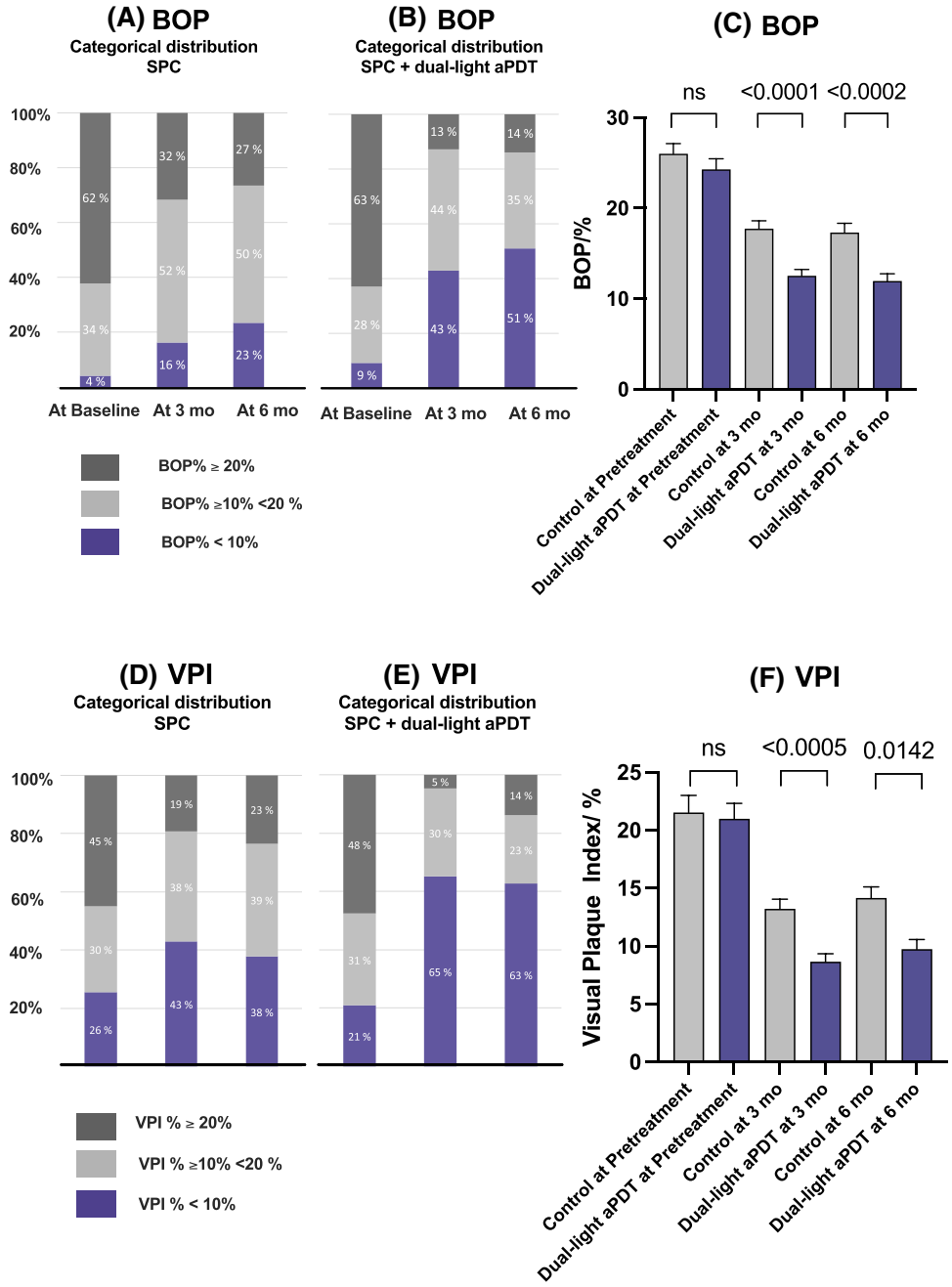

FIGURE 3 Bleeding on probing (BOP, panels A-C) and visual plaque index (VPI, panels D-F) percentages per visit per group, with *p*-values. aPDT, antimicrobial photodynamic therapy; BOP, bleeding on probing; ns., non-significant; SPC, supportive periodontal care; VPI, visual plaque index, Mixed-effects analysis with multiple comparisons test.

visits. This indicates a potential role for dual-light aPDT in enhancing pocket reduction, a key clinical parameter linked to long-term periodontal stability. These improvements may reflect not only local periodontal healing but also the potential to reduce systemic inflammatory load associated with periodontitis. The results are in accordance with the interim safety and outcomes analysis reported previously.[26]

Importantly, both treatment groups demonstrated low levels of aMMP-8 throughout the study period, indicating minimal collagenolytic activity and supporting the characterization of the study population as being in the periodontal maintenance phase. aMMP-8 is a well-established biomarker of active periodontal tissue breakdown, and its persistently low concentrations suggest that the participants were largely periodontally stable already at baseline. In this controlled, low-activity disease state, conventional therapies often reach a ceiling effect. Despite this low-risk profile, significant improvements were observed in both inflammatory and clinical parameters in the SPC +

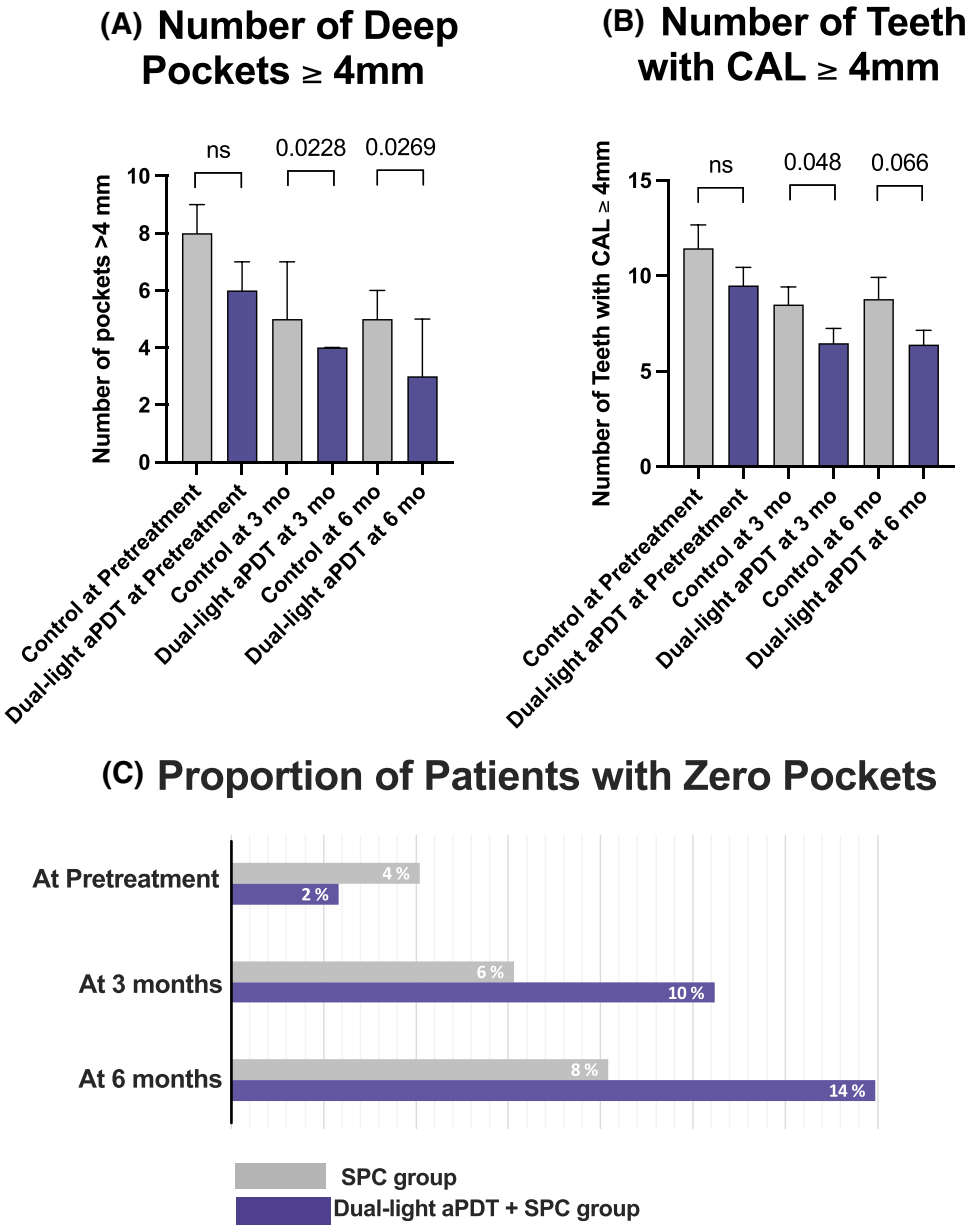

FIGURE 4 Mean number of sites with probing pocket depth (PPD) ≥ 4 mm (A), mean number of sites with clinical attachment loss (CAL) ≥ 4 mm (±SEM) (B), and proportion of patients with zero pockets (C). aPDT, antimicrobial photodynamic therapy; CAL, clinical attachment loss; ns., non-significant; PPD, probing pocket depth; SEM, standard error of the mean; SPC, supportive periodontal care, Mann–Whitney *U*-test.

dual-light aPDT group. These findings suggest that adjunctive dual-light aPDT may offer additional anti-inflammatory and antimicrobial effects beyond those achieved with SPC alone, even in patients with controlled disease. The ability of dual-light aPDT to further suppress subclinical inflammation and to enhance periodontal stability in a maintenance-phase population highlights its potential utility as a preventive adjunct in SPC.

The sustained anti-inflammatory and plaque-reducing effects observed in the HOPE-CP trial are in line with earlier evidence demonstrating that the dual-light aPDT approach reduces plaque formation, while the alpha-diversity of the plaque flora stays intact.[18] Our previous in vitro work showed that synchronized use of 405 nm aBL and 810 nm aPDT with indocyanine green (ICG) achieved a six-log reduction in *Streptococcus mutans* biofilm viability, outperforming light modality alone.[12] Unlike aBL or aPDT administered separately, the combined dual-light method prevented biofilm regrowth during repetitive exposures, a feature often referred to as substantivity in oral hygiene. This mechanistic phenomenon may explain the superior reductions in the key clinical parameters observed in the

TABLE 3 Safety outcomes, including treatment-emergent adverse events (TEAEs), discontinuations due to intolerance, exposure-adjusted incidence rates (EAIR), and hard-tissue findings (≥1 chipped restoration or ≥1 chipped tooth).

Safety endpoint	SPC + dual-light aPDT events	SPC + dual-light aPDT EAIR/1000 (95% CI)	SPC only events	SPC only EAIR /1000 (95% CI)	Statistics
TEAEs – overall	13	0.75 (0.40–1.29)	N/A	N/A	N/A
TEAEs – device-related	13	0.75 (0.40–1.29)	N/A	N/A	N/A
Discontinuation due to intolerance	7	0.40 (0.16–0.83)	N/A	N/A	N/A
Device malfunction	0	0.00 (0.00–0.21)	N/A	N/A	N/A
Chipped restorations	26	1.50 (0.98–2.20)	23	1.26 (0.80–1.89)	p = ns.
Chipped teeth	14	0.81 (0.44–1.36)	11	0.60 (0.30–1.08)	p = ns.

Abbreviations: aPDT, antibacterial photodynamic therapy; EAIR, exposure-adjusted incidence rate; ns., non-significant (Newcombe–Wilson method); SPC, supportive periodontal care; TEAE, treatment-emergent adverse event.

dual-light group, despite participants being mainly in a stable periodontal maintenance phase.

Compliance with the dual-light aPDT regimen was consistently high throughout the study period, with mean adherence rates of 86.3 ± 2.1% at 3 months and 85.3 ± 2.0% at 6 months. These rates indicate strong participant engagement with the home-based treatment protocol and support the feasibility of incorporating daily dual-light aPDT into long-term SPC.

No serious adverse events related to the investigational device or to study procedures were observed. A total of 13 device-related adverse events were reported, all of which were mild and self-limiting. These included sensations of oral sensitivity or numbness in seven cases, excessive warmth in the mouth or tongue in two cases, and a pharyngeal reflex in two cases. Seven participants discontinued device use due to discomfort, though only two withdrawals were directly attributed to adverse effects. These findings suggest good overall tolerability of the treatment. Beyond individual adverse events, we present structured safety indicators suitable for a home-use light device—EAIR, discontinuations for intolerance, device malfunctions, and hard-tissue findings—consistent with CONSORT-Harms 2022 guidance on harms reporting. These indicators complement the overall improvement in periodontal status and support that repeated intraoral illumination was well tolerated without evidence of device-related injury to teeth or restorations. From a standards perspective, home-use light devices are evaluated under the photobiological safety framework of IEC/EN 62471 (blue-light and thermal hazards) and the essential performance standard IEC 60601-2-57 for non-laser light source equipment; IEC 60601-1-11 addresses home-environment considerations. Chipped dental restorations and teeth were reported in both groups at similar frequencies, with no statistically significant differences, further supporting the safety of the intervention. The combination of high adherence and minimal, non-severe adverse effects underscores the acceptability, safety, and practicality of dual-light aPDT as an adjunctive treatment in a real-world maintenance population.

While the study presents compelling evidence for the efficacy of adjunctive dual-light aPDT, certain limitations should be acknowledged. The single-center design may limit the generalizability of the findings, and the study population's exclusion criteria, such as the omission of smokers and individuals with uncontrolled diabetes, may not reflect the broader patient population. The participants were enrolled during SPC visits and represented a relatively low-risk and compliant maintenance cohort with baseline aMMP-8 levels largely within non-pathological ranges, and most participants reported regular electric toothbrush use and twice-daily brushing. These characteristics likely contributed to the generally low inflammatory burden and may attenuate the absolute treatment effects compared with populations with higher disease activity or less optimal home care. Consequently, the generalizability of these findings to higher-risk or less adherent patients should be considered limited.

Another key methodological limitation was the inability to implement participant or investigator blinding. The physical properties of the investigational device—emitting visible light and mild heat—makes the creation of a credible sham impractical. Consequently, full blinding was not feasible. Additionally, due to staffing constraints, an independent blinded investigator could not be employed on-site. This may have introduced performance and measurement bias, particularly for examiner-dependent outcomes such as bleeding on probing and could lead to some overestimation of the treatment effect. Although the consistent pattern of benefit across clinical outcomes supports a genuine adjunctive effect, the magnitude of improvement should be interpreted with caution.

The study followed ISO 14155 Good Clinical Practice (GCP) guidelines and the European Medical Device

Regulation (EU MDR 2017/745). External study monitoring confirmed compliance regarding protocol adherence, adverse event management, and clinical data verification. The Finnish Medicines Agency (Fimea) oversaw MDR compliance and provided the approval reference FIMEA/2022/002648. Clinical measurements at baseline and data analyses were conducted in a blinded manner. Despite the blinding limitations discussed, methodological rigor and adherence to regulatory frameworks support the reliability of the trial results.

In conclusion, this trial highlights a possible added value of dual-light aPDT in maintenance-phase periodontal care. Given its tolerability and patient compliance, dual-light aPDT may serve as a promising adjunct in periodontitis management.

AUTHOR CONTRIBUTIONS

Saila Pakarinen: Conceptualization; Methodology; Visualization; Validation; Investigation; Resources; Data curation; Writing–original draft preparation; Writing–review and editing. **Riitta K. T. Saarela**: Conceptualization; Methodology; Writing–original draft preparation; Writing–review and editing. **Hannamari Välimaa**: Conceptualization; Methodology; Writing–original draft preparation; Writing–review and editing. **Anna M. Heikkinen**: Conceptualization; Methodology; Validation; Writing–original draft preparation; Writing–review and editing. **Dimitra Sakellari**: Conceptualization; Methodology; Writing-review and editing . **Marja Noponen**: Conceptualization; Methodology; Writing–original draft preparation; Writing–review and editing. **Heikki Alapulli**: Conceptualization; Methodology; Writing–original draft preparation; Writing–review and editing. **Taina Tervahartiala**: Conceptualization; Methodology; Resources; Writing–original draft preparation; Writing–review and editing. **Ismo T. Räisänen**: Conceptualization; Methodology; Formal analysis; Resources; Data curation; Writing–original draft preparation; Writing–review and editing; Visualization. **Timo Sorsa**: Conceptualization; Methodology; Resources; Writing–original draft preparation; Writing–review and editing; Supervision; Project administration; Funding acquisition. **Tommi I. Pätilä**: Conceptualization; Writing–review and editing; Funding acquisition.

All authors have read and agreed to the published version of the manuscript.

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CONFLICT OF INTEREST STATEMENT

Tommi Pätilä is a co-founder and owns stock in Koite, and Timo Sorsa owns stock in Koite and is the inventor of the aMMP-8 test. Other investigators declare no conflicts of interest related to this research.

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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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