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**DOI**

[10.1111/idh.12344](https://doi.org/10.1111/idh.12344)

**Publication date**

2018

**Document Version**

Final published version

**Published in**

International Journal of Dental Hygiene

**License**

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**Citation for published version (APA):**

Van Dijk, L. J., Lie, M. A., Van den Heuvel, E. R., & van der Weijden, G. A. (2018). Adult periodontitis treated with a new device for subgingival lavage: a randomized controlled clinical trial using a split-mouth design. *International Journal of Dental Hygiene*, 16(4), 559-568. <https://doi.org/10.1111/idh.12344>

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# Adult periodontitis treated with a new device for subgingival lavage—a randomized controlled clinical trial using a split-mouth design

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## Funding information

The study was self-funded by the Clinic for Periodontology Groningen, The Netherlands.

## Abstract

**Objectives:** To evaluate in patients with untreated adult periodontitis, the effect of treatment with a novel pocket irrigator/evacuator device (IED) compared to conventional subgingival debridement (CPT), both provided during the initial phase of active periodontal therapy.

**Methods:** This study was an examiner-blind, randomized controlled clinical trial using a split-mouth design. Systemically healthy patients with adult periodontitis were selected. Full-mouth probing pocket depth (PPD), gingival bleeding on pocket probing scores (BOPP), gingival recession (REC) and dental plaque (PI) were assessed at baseline. All participants received oral hygiene instructions and supragingival prophylaxis including polishing. In 2 randomly assigned contra-lateral quadrants, approximal sites were irrigated with the IED, whereas in the other quadrants, CPT was provided. The CPT consisted of subgingival debridement using ultrasonic devices followed by the use of hand instruments. At 3 months post-treatment, the clinical parameters were re-assessed.

**Results:** Twenty-five patients met the inclusion criteria and were willing to participate. At 3 months post-treatment, the PPD and BOPP had significantly improved for both treatment modalities. Pockets of  $\geq 5$  mm reduced by 0.64 mm in the IED group ( $P < .001$ ), compared to a reduction of 0.82 mm for the CPT group ( $P < .001$ ). With respect to the primary outcome parameter (PPD) and BI, the results with the IED were less pronounced. Between the test and control groups, no significant differences were observed for REC and PI.

**Conclusions:** Oral hygiene instructions, supragingival prophylaxis and subgingival lavage with the IED resulted in a significant reduction in PPD and BOPP. However, the effect does not reach the results of CPT which included the subgingival use of ultrasonic and hand instruments.

## KEYWORDS

bleeding on probing, irrigator, lavage, periodontitis, plaque, probing pocket depth, recession

## 1 | INTRODUCTION

Periodontitis is one of the most common chronic inflammatory diseases in humans, characterized by gingival inflammation and periodontal tissue breakdown. Loss of alveolar bone support ultimately results in loss of teeth.<sup>1</sup> The most important risk factor for periodontitis is the accumulation of a plaque biofilm at and below the gingival margin within which dysbiosis develops and which is associated with an inappropriate and destructive host inflammatory immune response.<sup>2</sup> Periodontitis is a ubiquitous disease affecting over 50% of the world's adult population, the occurrence of which increases with age.<sup>3</sup> Severe periodontitis is the sixth most prevalent human disease, with a standardized prevalence of 11.2%<sup>4</sup> according to the 2010 global burden of diseases study, and a major cause of tooth loss. It has a negative impact on oral health, quality of life, speech, nutrition, confidence and overall well-being and is independently associated with several systemic chronic inflammatory diseases. Periodontitis, therefore, represents a significant public health concern.<sup>2</sup>

The goals of periodontal therapy are to preserve, improve and maintain the natural dentition. The majority of patients can retain their dentition over their lifetime with appropriate treatment, self-performed dental plaque control and continue maintenance care.<sup>5</sup> Periodontal therapy consists of the elimination of the biofilm by supra- and subgingival cleaning, and if necessary the reduction in the residual deep periodontal pockets by surgical treatment. Subgingival instrumentation of the teeth is performed with curettes or with an ultrasonic device. Ultrasonic scalers are operated with a water flow that serves several purposes, including the reduction in frictional heating of the scaler tip. A documented benefit of the flowing water is the generation of biophysical forces—namely cavitation and microstreaming.<sup>6</sup> Meticulous subgingival debridement is an inherently time-consuming and difficult procedure, and it requires a great deal of stamina on the part of the operator as well as the patient. Success is highly dependent on the skill of the clinician and the attention to detail in instrumentation.<sup>7</sup>

Numerous studies from the past decade address the impact of subgingival irrigation on clinical and microbiologic parameters.<sup>8</sup> Investigations using subgingival irrigation as a monotherapy and in combination with root planing provided a perspective on the benefits and limitations of this treatment method.<sup>9</sup> The biological rationale for subgingival irrigation is a non-specific action of flushing the pocket contents and thereby effectively altering the quality and quantity of unattached subgingival plaque.<sup>10</sup> The pocket penetration by powered oral irrigation devices was found to be 71% for shallow sites, 44% for moderately deep sites and 68% for deep sites, with a maximum pocket penetration of 4–5 mm. Using specially designed subgingival irrigation tips placed 1 mm below the gingival margin, irrigants can access 90% of the depth of 6 mm pockets and 64% of the depth of pockets exceeding 7 mm.<sup>11</sup> The American Academy of Periodontology (AAP)<sup>12</sup> concludes that there is insufficient evidence to support one-time, professionally provided subgingival irrigation even as a supplemental procedure to augment the effects of scaling and root planing.

A novel irrigator/evacuator device (IED) has been developed to improve the flushing of the subgingival area. A nozzle placed on the interdental papillae, covering the entrance of the interdental pockets is connected with a vacuum pump which causes a negative pressure in the pockets. This is alternated by the application of a rinsing fluid (demineralized water) through a small hose in the centre of the nozzle. A frequent change in evacuation and irrigation causes a hydrokinetics turbulence intended to flush out the subgingival biofilm.

The aim of this study was to evaluate in patients with adult periodontitis, the effect of this novel pocket irrigator/evacuator device without subgingival instrumentation, compared to conventional periodontal treatment using a combination of subgingival ultrasonic and hand instrumentation, both provided during the initial phase of active periodontal therapy.

## 2 | MATERIAL AND METHODS

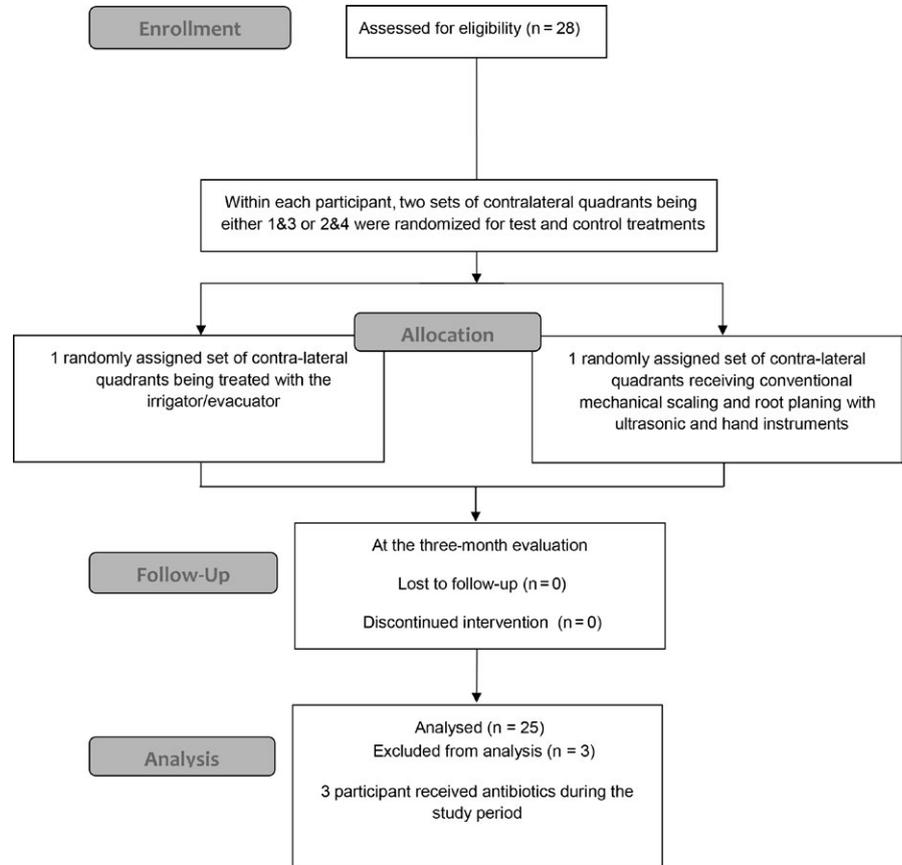
The recommendations for strengthening the reporting procedure were followed as suggested by the guideline Consolidated Standards of Reporting Trials (CONSORT) and the checklist Template for Intervention Description (TIDieR), as retrieved from the EQUATOR Network (available at: <https://www.equator-network.org/reporting-guidelines>).

### 2.1 | Design

The experiment used a split-mouth model in which contra-lateral quadrants were randomly assigned to the test treatment of irrigation or the conventional mechanical periodontal therapy as control.<sup>13</sup> All measurements were performed under identical conditions by one and the same clinical examiner (MAL) who was blinded to the assigned treatment. Randomization was performed using true random numbers, which were generated by sampling and processing a source of atmospheric noise (available at: <https://www.random.org>). The randomization code was kept in a sealed envelope in the investigator site file and was only accessible to the coordinator (LJvD), who was therefore responsible for allocation concealment. Records of earlier examinations were not available to the examiner at the time of re-examination. To further conceal the intervention from the examiner, the participants were instructed not to reveal their assignment in any way. Professional instructions and instrumentation took place in an area separate from that of the examiner (Figure 1).

### 2.2 | Participants

Consecutive patients with adult periodontitis who had been referred in the period of October 2010 up to June 2012 by general dentists to the Clinic for Periodontology Groningen (The Netherlands) were verbally invited to participate. Upon receiving a positive response, written detailed information about the outline, purpose and duration of the study was provided. Participants were asked to read this information carefully and if willing to participate they were requested



**FIGURE 1** CONSORT flow diagram

to sign the informed consent. Those who consented were scheduled for a baseline clinical assessment.

Eligible participants were defined by the following criteria:

1. Diagnosed with untreated adult periodontitis
2.  $\geq 10\%$  of sites with pockets of  $\geq 5$  mm
3. Pockets comparably divided over the 4 quadrants in the mouth
4. Systemically healthy as assessed by the medical questionnaire

Exclusion criteria were as follows:

1. antibiotic medication within 3 months preceding the start of the study;
2. use of other medication (such as anti-inflammatory medication) that might affect the outcome of the study;
3. partial dentures;
4. ongoing orthodontic treatment;
5. extensive dental restorations;
6. preventing adequate oral hygiene.

## 2.3 | Study products

### 2.3.1 | Supragingival scaling and polishing

Teeth were scaled and polished supragingivally with the purpose of making them free of plaque, stain and calculus. An piezoelectric-driven ultrasonic scaler (Piezo Master 400, EMS<sup>®</sup>, Nyon, Switzerland) with

metal EMS tips (P, PS, PL3) and hand instruments (Gracey, SG # 11/12, 13/14, Hu-Friedy Ins. Co., USA) followed by rotating polishing cups, points and brushes (Young #051101, and #090101; Young Dental<sup>®</sup>, USA) with polishing paste (Zircate Prophy Paste #677001, Dentsply<sup>®</sup>, USA) were used. Oral hygiene instructions included the use of an electric toothbrush (Philips Sonicare<sup>®</sup>, Amsterdam, The Netherlands), cylindrically shaped interdental brushes and woodsticks, the size of which was tailored to the individual patient's needs (Tepe<sup>®</sup>, Rijswijk, The Netherlands; Lactona<sup>®</sup>, Bergen op Zoom, The Netherlands).

### 2.3.2 | Conventional subgingival debridement (CPT)

The ultrasonic scaler (Piezo Master 400, EMS<sup>®</sup>) with metal EMS tips (P, PS, PL3) was used underwater irrigation according to the manufacturer's instructions. At the decision of the dental hygienist, this was followed by the use of an assortment of manual periodontal curettes (Gracey, SG # 11/12, 13/14, Hu-Friedy Ins. Co.). The curettes were sharpened as the operator deemed necessary. Conventional subgingival debridement was finished when the operator felt the surface to be smooth. Local anaesthesia was used according to the patients' needs (Septanest N 40 mg/ml, Septodont<sup>®</sup>, Saint-Maur-Des-Fossés, France).

### 2.3.3 | Novel pocket irrigator/evacuator device (IED)

Introducing an irrigation fluid into the periodontal pockets results in a positive pressure towards the base of the pocket, which likely prevents the fluid from reaching the entire subgingival area. With

this novel irrigation device, a light negative pressure of 0.35 mm Hg is applied with the nozzle at the entrance of a periodontal pocket thus removing subgingival fluid from the pocket (see Figure 2A). Alternatingly, irrigation fluid is applied by a thin hose which is located in the centre of the nozzle (see Figure 2B). In this study, demineralized water was used as the irrigation fluid. The negative pressure alternating with the application of fluid was repeated at a high frequency of 250 milliseconds per cycle.

## 2.4 | Study procedures

### 2.4.1 | Clinical measurements

The primary clinical outcome measured was a change in probing pocket depth. Bleeding upon probing and recession were considered as secondary outcomes. As the treatment effect is known to be dependent on the level of oral hygiene,<sup>14</sup> dental plaque was scored as a surrogate parameter providing an indication of the participants' compliance with instructions in daily oral self-care.

(A) nozzle in situ



(B) nozzle with fluid tube



**FIGURE 2** (A) Nozzle in situ. (B) Nozzle with fluid tube

The following clinical measurements were performed at baseline before the initial therapy and at the 3-month evaluation visit.

1. Probing pocket depth (PPD) as measured from the bottom of the pocket to the gingival margin.
2. Visible gingival recession (REC) as measured from the cemento-enamel junction to the gingival margin
3. Bleeding on pocket probing (BOPP) according to the criteria described by Lie et al.<sup>15</sup>
4. Plaque score (PI) according to the criteria of the modified Plaque Index of Silness & Loe<sup>16</sup>

Six sites around each tooth were scored (mesio-buccal, buccal, disto-buccal, mesio-palatal, palatal and disto-palatal). The PPD, BOPP and REC were measured using a periodontal probe with William's markings (PQW, Hu-Friedy Ins. Co.). Pocket probe readings were rounded off to the nearest millimetre. All measurements were performed by one examiner (MAL) who was blinded to the assigned treatment.

## 2.5 | Study outline

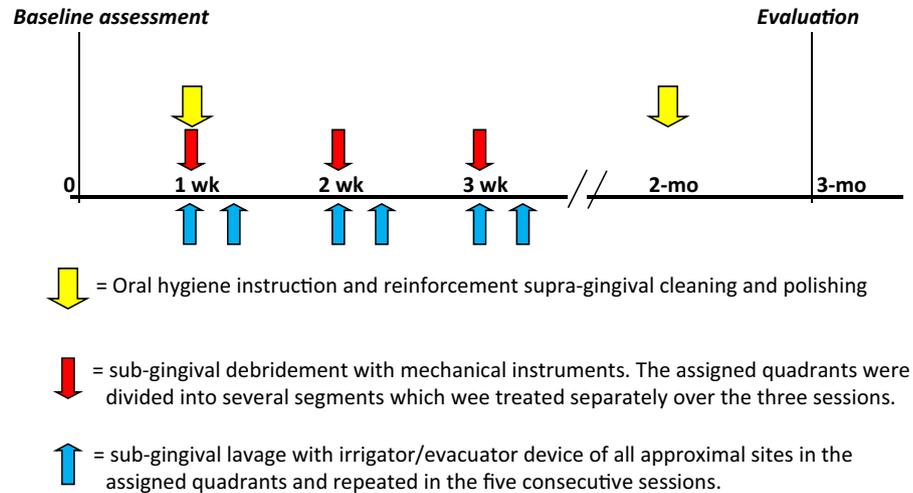
The flow of the treatment as provided is presented in Figure 3. At the baseline assessment, the clinical situation was assessed by the examiner (MAL), and appointments for active periodontal therapy were made. Treatment was provided by a dental hygienist with 3 appointments over the course of 3 consecutive weeks. These visits included repeated oral hygiene instructions as well as supragingival scaling and polishing. Two contra-lateral quadrants (one in the upper and one in the lower jaw; either 1st and 3rd or 2nd and 4th) were treated subgingivally in the conventional mechanical way using both ultrasonic and hand instruments and served as control sides (CPT).

In the opposing contra-lateral quadrants, the subgingival pocket areas were irrigated by the dental hygienist with the novel irrigation device (IED). The irrigation nozzle was applied for 10 seconds at each interproximal site and approached both from the buccal and palatal aspect. Treatment was provided twice a week for a period of 3 consecutive weeks.

During an intermediate appointment with the dental hygienist, 1 month prior to the final evaluation of the full-mouth dentition was scaled and polished supragingivally. Assessment of the periodontal condition was performed 3 months after the last treatment by the same examiner (MAL).

## 2.6 | Power calculation

Recent data indicate that the intra-individual standard deviation in mean PPD measurements is 0.48.<sup>17</sup> "A priori" power calculations revealed that a study with 23 pairs would be able to detect a difference of 0.28 ( $\alpha = .05$ ;  $\beta = .20$ ). For the purpose of this study, 28 subjects were enrolled to anticipate for potential dropouts.



**FIGURE 3** Flow of the clinical assessment during the 3-mo study period and the time points of the assigned interventions

## 2.7 | Statistical analysis

With the irrigation nozzle primarily applied at the interdental aspect, the data of 4 sites were used for the purpose of this study, namely the interproximal sites (mesio-buccal, disto-buccal, mesio-lingual and disto-lingual). Four repeated outcomes were calculated from the multiple repeated measures on all of the teeth, by taking either an average (for the numerical and ordinal outcomes) or a sum (for binary outcomes). They were calculated per treatment for each follow-up time (baseline and one follow-up). For numerical (PPD and REC) and ordinal values (plaque scores), a linear mixed effects model was applied, while for binary outcomes (bleeding score), a generalized linear mixed model was applied. Restricted maximum-likelihood estimation was used for the linear mixed effects model, and generalized estimating equations (GEE) were selected for the generalized linear mixed model. Each of the 4 results has a mean which may be differently affected by smoking (0 = participants who had not smoked for at least 1 year, 1 = smokers who smoke 1-10 cigarettes a day, 2 = smokers who smoke more than 10 cigarettes a day). To address correlation between the repeated values, an unstructured variance-covariance matrix was applied to follow-up time with an additional correlation coefficient for the treatments in case of numerical values. An exchangeable working correlation matrix with the empirical estimator was applied with GEE for the analysis of binary variables, using a binomial distribution with logit link function. Based on the

fitted model, appropriate contrast statements were created to determine the effect of treatment with respect to the baseline results as well as whether the effect size between the 2 treatments was different. Effect sizes with a *P*-value smaller than .05 were considered significant. Analysis was performed per protocol.

## 2.8 | Ethics approval

The study followed instructions based on the Helsinki principles (2008). The protocol was independently reviewed and approved by the Medical Ethics Committee of the University Medical Centre Groningen under the number NL31743.042.10.

## 3 | RESULTS

Of the 28 patients with adult periodontitis who were enrolled in the study, the data of 3 were excluded because they were prescribed antibiotics during the course of the study, thus leaving 25 patients for the study, consisting of 12 females and 13 males with a mean age of 46 years (range 34-67). Of these patients, 15 were non-smokers, 4 were light smokers and 6 were heavy smokers.

The plaque score data are presented in Table 1 and show that the level of oral hygiene at baseline for the control and test quadrants was comparable (*P* = .286). Self-performed oral hygiene improved

**TABLE 1** Mean plaque score and range [min-max] for control and test treatments for all patients. The results reported at the 2 time points are estimated means from the fitted model

Variable	Control treatment			Test treatment		
	Baseline	3 months	Difference	Baseline	3 months	Difference
Plaque score <sup>a</sup>						
Approximal	1.73 [1.58; 1.88]	0.52 [0.30; 0.75]	1.21 [0.96; 1.45]	1.76 [1.61; 1.91]	0.53 [0.31; 0.75]	1.24 [0.99; 1.48]
<i>P</i> -value <sup>b</sup>	<i>P</i> < .001			<i>P</i> < .001		

<sup>a</sup>0 = no plaque present, 1 = thin film of plaque visible by disclosing fluid or using a probe, 2 = moderate accumulation of plaque.

<sup>b</sup>Statistical analysis between baseline and end scores.

**TABLE 2** Mean probing pocket depth and range [min-max] in mm for control and test treatments for all patients. Results reported are estimated means from the fitted model. The number of sites represents the data per participant

Variable	Control treatment			Test treatment		
	Baseline	3 months	Difference	Baseline	3 months	Difference
Mean probing pocket depth						
Approximal <sup>a</sup>	4.37 [4.00; 4.75]	3.55 [2.30; 3.89]	0.82 [0.60; 1.05]	4.46 [4.08; 4.84]	3.82 [3.48; 4.17]	0.64 [0.41; 0.87]
P-value <sup>b</sup>	P < .001			P < .001		
Number of sites: median (range)	36 (16-48)			32 (12-48)		
Mean probing pocket depth 4-5 mm at baseline						
Approximal <sup>a</sup>	4.38 [4.28; 4.49]	3.34 [3.15; 3.53]	1.04 [0.82; 1.26]	4.43 [4.32; 4.53]	3.63 [3.44; 3.82]	0.80 [0.58; 1.02]
P-value <sup>b</sup>	P ≤ .001			P < .001		
Number of sites: median (range)	12 (2-26)			11 (2-28)		
Mean probing pocket depth ≥5 mm at baseline						
Approximal <sup>a</sup>	6.39 [6.13; 6.64]	4.68 [4.23; 5.13]	1.71 [1.33; 2.09]	6.58 [6.33; 6.84]	5.31 [4.86; 5.76]	1.27 [0.89; 1.65]
P-value <sup>b</sup>	p < .001			p < .001		
Number of sites: median (range)	6 (1-31)			6 (1-33)		

<sup>a</sup>Based on the 4 approximal sites per tooth.

<sup>b</sup>Statistical analysis between baseline and end scores.

**TABLE 3** Mean bleeding score and range [min-max] for control and test treatments for all patients (results reported are estimated proportions from the fitted model. The effect size for difference in proportions is reported as odds ratio)

Variable	Control treatment			Test treatment		
	Baseline	3 months	Difference	Baseline	3 months	Difference
Bleeding score <sup>a,b</sup>						
Approximal	72% [64; 79]	30% [22; 40]	5.99 [3.42; 10.5]	69% [60; 76]	35% [28; 43]	4.07 [2.83; 5.86]
P-value <sup>b</sup>	P < .001			P < .001		

<sup>a</sup>0 = no bleeding on probing, 1 = bleeding on probing.

<sup>b</sup>Statistical analysis between baseline and end scores.

significantly in both sets of contra-lateral quadrants ( $P < .001$ ). The incremental difference between treatments was  $-0.029$  and not significantly different ( $P = .571$ ).

The data for approximal sites only are presented in Table 2 with a subanalysis for pockets initially measuring 4-5 mm and  $\geq 5$  mm. At baseline, the mean approximal PPD was 4.37 and 4.46 mm for the control and test treatment sites, respectively, which was not significantly different ( $P = .425$ ). At 3 months, a significant reduction was observed in both sets of contra-lateral quadrants as a result of treatment ( $P < .001$ ). The incremental difference between both sets of contra-lateral quadrants of 0.19 mm was significantly different ( $P = .009$ ) in favour of the control treatment.

The bleeding upon probing data are presented in Table 3. At baseline, the mean BOBP was 72% and 69% for the control and test

treatment sites, respectively, which shows that the level of periodontal inflammation at baseline was not comparable ( $P = .033$ ) with a slightly higher number of bleeding sites in the control group. As a result of treatment, bleeding scores improved significantly in both sets of contra-lateral quadrants ( $P < .001$ ).

The data with respect to visible gingival recession are presented in Table 4 and show that the position of the gingival margin at baseline was comparable ( $P = .106$ ) for the control and test treatments. As a result of treatment, REC increased significantly in both sets of contra-lateral quadrants ( $P = .031$  and  $P = .006$  for the control and test treatments, respectively) but the incremental difference of 0.031 mm between treatments was not significant ( $P = .533$ ).

The subanalysis by smoking status revealed that the incremental difference between the control and test treatments for plaque scores

**TABLE 4** Mean visible recession and range [min-max] in mm for control and test treatments for all patients (results reported are estimated means from the fitted model)

Variable	Control treatment			Test treatment		
	Baseline	3 months	Difference	Baseline	3 months	Difference
Visible recession						
Approximal	0.063 [0.00; 0.12]	0.17 [0.04; 0.29]	0.10 [-0.20; -0.01]	0.12 [0.06; 0.18]	0.25 [0.12; 0.38]	0.13 [-0.23; -0.04]
P-value <sup>a</sup>	P = .031			P = .006		

<sup>a</sup>Statistical analysis between baseline and end scores.

**TABLE 5** Mean incremental differences and range [min-max] of change in outcome from baseline to 3 months between control and test treatments in outcomes in relation to smoking status (0 = participants who had not smoked for at least 1 year; 1 = smokers who smoke 1-10 cigarettes a day; 2 = smokers who smoke more than 10 cigarettes a day) and overall patients (overall)

Variable	Smoking status			
	0 N = 15	1 N = 4	2 N = 6	Overall N = 25
Difference average approximal probing pocket <sup>a</sup> depth on all observations	0.27 [0.10; 0.43] <b>P = .002</b>	0.15 [-0.14; 0.45] P = .305	0.14 [-0.09; 0.37] P = .234	0.19 [0.05; 0.23] <b>P = .009</b>
Difference average approximal probing pocket depth 4-5 mm at baseline <sup>a</sup>	0.17 [-0.08; 0.43] P = .172	0.29 [-0.16; 0.75] P = .194	0.26 [-0.10; 0.61] P = .154	0.24 [0.03; 0.45] P = .025
Difference average approximal probing pocket depth ≥5 mm at baseline <sup>a</sup>	0.80 [0.26; 1.33] <b>P = .005</b>	0.56 [-0.39; 1.51] P = .239	-0.05 [-0.73; 0.62] P = .873	0.43 [0.01; 0.86] <b>P = .047</b>
Difference Bleeding Score <sup>b</sup>	1.57 [0.90; 2.73] P = .112	1.48 [0.80; 2.74] P = .215	1.38 [0.78; 2.42] P = .267	1.47 [1.05; 2.06] <b>P = .024</b>
Difference Visible Recession <sup>a</sup>	0.025 [-0.098; 0.147] P = .680	0.030 [-0.189; 0.249] P = .779	0.039 [-0.135; 0.212] P = .650	0.031 [-0.070; 0.133] P = .533
Difference Plaque Score <sup>a</sup>	-0.129 [-0.255; -0.003] <b>P = .045</b>	0.035 [-0.190; 0.261] P = .751	0.006 [-0.172; 0.185] P = .942	-0.029 [-0.134; 0.075] P = .571

<sup>a</sup>A positive effect size indicates that the control treatment has a bigger effect with respect to baseline than the new treatment.

<sup>b</sup>Effect size is reported in an odds ratio. An OR larger than 1 indicates that the control treatment has a better effect with respect to baseline than the treatment.

p values in bold are considered statistically significant.

was significant in non-smokers (diff = -0.129,  $P = .045$ , see Table 5). The observed difference between treatment modalities for PPD was particularly present in the non-smokers (0.27 mm,  $P = .002$ ). The subanalysis by initial PPD showed that pockets initially measuring ≥5 mm were the main contributors to this observed incremental difference (0.43 mm,  $P = .047$ ) which was also mainly present in non-smokers (0.80 mm,  $P = .005$ ). The incremental change from baseline with respect to BOPP as expressed in the odds ratio was significant in favour of the control treatment ( $P = .024$ , see Table 5). Smoking status did not appear to have an effect on this outcome. Neither did smoking status appear to have an effect on REC as an outcome.

At the 3-month evaluation, participants were asked, using a 5-point Likert scale, about the additional burden of the extra bi-weekly

visits for the subgingival lavage; 1 participant agreed, 5 disagreed and 10 fully disagreed while 9 indicated having no opinion. These results indicate that most participants did not experience the additional visits as a problem. No adverse events were reported by the participants.

## 4 | DISCUSSION

The aim of the present study was to evaluate the effect of a newly developed pocket irrigator/evacuator in patients with untreated adult periodontitis and to compare the outcome with CPT, using ultrasonic and hand instruments. The outcome of this study shows that a significant improvement in PPD, and PI and BOPP scores were obtained.

The incremental difference between contra-lateral sides was, however, significant for the decrease in PPD and BOPP scores in favour of the CPT (Table 2). The absence of a difference in REC indicates that the reduction in PPD is probably the result of a gain in clinical attachment level. The results were likely not influenced by the level of self-care because incremental differences in plaque scores were comparable in both sets of contra-lateral quadrants. Optimal supragingival plaque control was secured through individual oral hygiene instruction as is evident from the plaque scores, which dropped in both the control and test quadrants with 70%. In addition, all participants in the present study were subjected to supragingival scaling.

The mean reduction in PPD for the control treatment, which represented conventional active periodontal therapy, in pockets of  $\geq 5$  mm was 1.71 mm. This compares favourably with the estimated mean outcome of subgingival debridement as estimated in a meta-analysis by Van der Weijden & Timmerman.<sup>18</sup> These authors calculated that in pockets  $\geq 5$  mm, a mean decrease of 1.18 mm in probing pocket depth may be expected. The mean results for the control treatment can also be considered comparable to those reported by Cobb.<sup>19</sup> Based on various clinical studies published over several decades, he calculated the mean reduction in PPD for pockets initially measuring 4–6 mm to be 1.29 and 2.16 mm for pockets of  $\geq 7$  mm. Also for the test treatment, the mean reduction of 1.27 mm in pockets of  $\geq 5$  mm is comparable to above-mentioned average outcomes.

Rinsing alone has been found to be an ineffective means of penetrating into periodontal pockets. Subgingival irrigation devices are suggested to improve access to pockets.<sup>20</sup> The intentional irrigation of a gingival crevice or pocket, with the point of delivery directed below the gingival margin, aims at disrupting bacterial colonization and growth. Lainson et al<sup>21</sup> suggest that improved gingival health after oral irrigation may be the result of altered microbial viability, while Hagiware et al<sup>22</sup> show that pocket irrigation by distilled water is potentially effective in eliminating subgingival plaque. The 2 approaches for the application of subgingival irrigation are either daily irrigation by the patient as part of a home-based oral hygiene programme and periodic, professionally administered application of irrigation.<sup>23</sup>

The present study evaluated subgingival irrigation/evacuation as a monotherapy in the treatment of periodontitis for which there is a paucity of data available. When aimed perpendicular to the tooth long axis, an irrigation device creates 2 zones of hydrokinetic activity which aid in the removal of plaque and debris. The first zone is due to the initial direct impact of spray against the tooth. A second zone is created by the deflection of spray from the tooth surface and results in a flushing action. The turbulence is further heightened as a portion of the stream impacting on the specimen bounces back into the emerging stream.<sup>24</sup> As irrigation does not routinely project fluid into deep pockets, devices usually provide a pulsating stream of water that incorporates a compression and interpulse decompression phase. The decompression phase is included to facilitate the displacement of debris and bacteria. A continuous flow of water would cause constant tissue compression and impede the escape of contaminants.<sup>25</sup> The novel IED in the present study goes beyond a decompression phase and utilizes a high-frequency change in

evacuation and irrigation to cause a hydrokinetics turbulence with the intention to flush out the subgingival biofilm.

Smoking is also implicated as a factor that reduces the effectiveness of treatment. It appears that smokers may respond to non-surgical periodontal therapy less favourably than non-smokers, especially in terms of probing depth and bone level. When the effect of the level of cigarette consumption is considered, it seems that the response to periodontal therapy is related to the amount of cigarettes smoked.<sup>26</sup> In agreement with this, the present study showed that the largest incremental difference in PPD was observed in non-smokers. At baseline, there was no significant difference between the BOPP scores of smokers and non-smokers. This observation is in agreement with Van der Weijden et al,<sup>27</sup> who also found no statistically significant differences between smokers and non-smokers regarding the mean percentage of sites that bled upon probing in untreated periodontitis patients. Recently, Ramseier et al<sup>28</sup> observed in patients enrolled in supportive periodontal therapy for at least 5 years that, concomitantly with an increased prevalence of residual pockets, smokers demonstrate a lower mean BOPP. In the present study, no significant incremental difference in treatment response between smokers and non-smokers was observed.

#### 4.1 | Limitation

- Penetration into deep pockets may have been easier than into moderate pockets because of the more advanced tissue inflammation in the former.<sup>29</sup> However, the results of this study did not show a predictable factor in enhanced penetration of the irrigation fluid to the bottom of the pocket. The major difference between the control and test treatments was found in pockets of  $\geq 5$  mm, which include deep pockets (Table 5).
- Application of the irrigator/evacuator was combined with supragingival scaling and polishing which may also have impacted the subgingival biofilm.<sup>30</sup>
- With conventional active periodontal therapy, the supragingival and subgingival biofilm and the calculus are mechanically removed by scaling and root planing.<sup>31</sup> Possibly, the lack of calculus removal negatively affected the outcome of irrigator/evacuator therapy. On the other hand, Listgarten & Ellegaard<sup>32</sup> show that epithelial adhesion in principle can take place on calculus. The root cementum of periodontitis involved teeth has been shown to contain cytotoxic products of bacterial origin, that is endotoxins, which have been suggested to prevent proper healing following periodontal therapy.<sup>33</sup> With the irrigator/evacuator, no diseased cementum was removed. However, endotoxin is lightly bound to the root surface and therefore may be easily removed by a turbulence streaming phenomenon.<sup>34</sup>

#### 4.2 | Future research considerations

Where the present study did not support the irrigator/evacuator as monotherapy over CPT, subgingival lavage may be of value when

root planing is less than ideal due to anatomy or other factors. The irrigator/evacuator may play a role in the treatment of gingivitis and maintenance of periodontal patients.<sup>12</sup> Research should assess whether multiple in-office irrigation appointments provide a substantial benefit beyond root planing in these patient categories. Lastly, the potential of producing soft tissue injury is critical to an evaluation of the risk/benefit ratio.

## 5 | CONCLUSION

Oral hygiene instructions, supragingival prophylaxis and subgingival lavage with the IED resulted in a significant reduction in PPD and BOPP. However, the effect does not reach the results of CPT which included the subgingival use of ultrasonic and hand instruments.

## 6 | CLINICAL RELEVANCE

### 6.1 | Scientific rationale for the study

Meticulous subgingival debridement with manual and ultrasonic instruments is a difficult and time-consuming procedure. The endpoint of periodontal therapy is to produce a root surface that is biologically acceptable for a healthy attachment.

### 6.2 | Principal findings

At the 3-month post-treatment visit, PPD significantly improved for both treatment modalities. However, the results for the monotherapy with the IED were less pronounced.

### 6.3 | Practical implications

The results are applicable for patients with adult periodontitis. The IED does not treat periodontal disease as effectively as CPT. A likely explanation is that the new device does not remove subgingival calculus. However, the observed treatment effect encourages further research.

## ACKNOWLEDGEMENTS

The authors acknowledge the support of the team of the Clinic for Periodontology Groningen for their efforts and support of this clinical study. Also, Nienke Hennequin-Hoenderdos and Dagmar Else Slot are acknowledged for their critical feedback on the draft of the manuscript.

## CONFLICT OF INTEREST

The pocket irrigator has been developed by L.J. Van Dijk. The other authors declare that they have no conflict of interests.

## In Memoriam

It is ironic that on the exact night the first version of this manuscript was finished and shortly before the corresponding author submitted it to this Journal, the first author passed away. Dr. Johan van Dijk developed during his career the product tested in this study with the intention to perform pain-free subgingival debridement with a device that is easy to use and comfortable for the patient.

Johan graduated as a dentist in 1970 and shortly thereafter went abroad for specialist training in periodontology in Portland Oregon, USA. Upon his return, Johan became a staff member at the Department of Periodontology of the University of Groningen and obtained his PhD in 1979. In 1983, together with a colleague, he was the first to open a referral practice dedicated to Periodontology in The Netherlands. Its organizational structure has become the blueprint for many of the periodontal practices that opened their doors in later years. Johan was also the initiator and first chairman of a society that now joins the periodontists who are accredited by the Dutch Association of Periodontology. We will miss Johan's optimism and drive for our profession.

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**How to cite this article:** Van Dijk LJ, Lie MA, Van den Heuvel ER, Van der Weijden GA. Adult periodontitis treated with a new device for subgingival lavage—a randomized controlled clinical trial using a split-mouth design. *Int J Dent Hygiene.* 2018;16:559–568. <https://doi.org/10.1111/idh.12344>