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HUMAN RANDOMIZED CONTROL TRIAL

Effect of interproximal home oral hygiene on clinical parameters and inflammatory biomarkers in patients receiving periodontal maintenance

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Abstract

Background: The purpose of this 6-week, single-blinded, randomized clinical trial was to determine if the use of an interproximal brush, with or without a tracking device, is more effective than an oral irrigator in improving interproximal probing depth (PD), clinical attachment level (CAL), plaque index (PI), gingival index (GI), bleeding on probing (BOP), and inflammatory markers.

Methods: Seventy-six patients with Stages III–IV, Grade B periodontitis and a 5–7 mm posterior interproximal PD with BOP were randomized: (1) interproximal brush alone (IB; $n = 26$), (2) interproximal brush with tracking device (TD; $n = 23$), (3) oral irrigator (OI; $n = 27$). Participants used devices once daily for 6 weeks. Clinical measurements (PD, CAL, PI, BOP, GI) and gingival crevicular fluid (GCF) samples were collected at baseline and 6 weeks.

Results: All groups showed a significant reduction in PD and CAL (≥1.1 mm, $p < 0.0001$) and improvement in BOP (≥56%, $p < 0.0001$) and GI (≥82%, $p < 0.001$) at the experimental site with no differences among groups. The IB and IB+TD groups showed a significant reduction in PI (≥0.9, $p \leq 0.01$). Interleukin (IL)-1β was reduced in all groups ($p = 0.006$), but IB+TB more than OI ($p \leq 0.05$). IL-10 was reduced among all groups ($p = 0.01$), while interferon-gamma significantly increased ($p = 0.01$) in all groups.

Conclusions: IB and OI improved clinical parameters of PD and CAL and reduced inflammatory markers (BOP, GI, GCF IL-1β). IB had better interproximal plaque reduction. Tracking did not significantly improve clinical parameters compared with the IB and OI groups, suggesting future modifications are needed.

KEYWORDS
biomarkers, inflammation, periodontitis

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1 | INTRODUCTION

Periodontal maintenance therapy (PMT) is the key to managing periodontitis over the long-term. This is particularly true in posterior interproximal areas where disease is more prevalent and oral hygiene is more difficult.[1] Treatment is typically provided by a hygienist, whether in a specialty periodontal practice or general practice, and is focused on oral hygiene instruction with or without adjuvants and clinical interventions.[2,3] Studies have shown that adjuvants can be instrumental in maintaining home care stability[3,4] and can perform better than toothbrushing alone. However, with multiple adjuvants on the market, it can be difficult to ascertain which modality is the most effective for these patients.

The clinical measurements used to determine the periodontal stability during maintenance are probing depth (PD) and bleeding on probing (BOP) as well as clinical attachment level (CAL). Deepening pockets and persistent BOP usually alert the hygienist that home care methods need improvement and/or additional therapy is warranted. Adjuncts to home oral hygiene programs have not been studied extensively in patients on PMT. A well-executed prospective PMT cohort study[4] using full-mouth measurements found that both interdental brushes and oral irrigators reduced recurrent periodontitis over a 6-year period. Additional information exploring individual vulnerable sites would be valuable in dissecting how site-specific interventions might work. The hypothesis of the current study was that interproximal brushes are more effective than oral irrigators at reducing clinical measurements and biochemical markers of inflammation in posterior interproximal pockets in patients receiving periodontal maintenance. Additionally, we hypothesized that the use of a compliance tracking device would further reduce these parameters compared with an interproximal brush alone.

2 | MATERIALS AND METHODS

2.1 | Survey

To identify hygienist preferences, a survey was conducted using various clinical scenarios that may present during PMT. Anonymous responses were solicited from periodontal practices around the country and in general practices in matching states. Hygienists in periodontal practice (DHPP, $n = 62$) consistently recommended interproximal brushes while hygienists in general practice (DHGP, $n = 74$) favored oral irrigators, showing statistical significance between the recommendations (Figure 1). As a result of this survey, a randomized clinical trial was developed to test home oral hygiene outcomes between interproximal brushes (DHPP) and oral irrigation (DHGP) for inflamed moderate pockets.

2.2 | Study participants

Approval for this randomized clinical trial was obtained from the University of Nebraska Medical Center (UNMC) Institutional Review Board (NCT #04546295) and was in accordance with the Declaration of Helsinki of 1975, as revised in 2013. Patients with generalized periodontitis Stage III or IV, Grade B[5] from the UNMC College of Dentistry were screened for this study.

Patients receiving periodontal maintenance with a 5–7 mm interproximal PD and a history of BOP and enough space for interproximal brushes were eligible for this study. All study participants had been previously diagnosed with Stage III, Grade B periodontitis before initial therapy. Following initial therapy, all participants had been enrolled in a periodontal maintenance program at UNMC and had been receiving PMT. The most recent periodontal maintenance visit was within a month of the experimental baseline visit, thus minimal calculus was noted in the test teeth at the initiation of the study and patients did not elect more active therapy. Exclusion criteria included the following: (i) porcelain crown at the test site; (ii) surgical therapy at the test site within the last year; (iii) medications that significantly affect inflammation (i.e., rheumatoid arthritis drugs, daily use of nonsteroidal anti-inflammatory drugs); and (iv) a mobile phone not supportive of the compliance tracking device application. Those who qualified (Figure 2) were presented with a study protocol and consented. Seventy-six participants were enrolled (between July and December 2021) in the 6-week study and provided baseline plaque index (PI),[6] PDs, recession, BOP, gingival index (GI),[7] and gingival crevicular fluid (GCF) samples from a single posterior interproximal test site.

2.3 | Data collection and treatment protocol

Sociodemographic data were collected which included age, sex, and smoking status. Baseline data collection was completed by a calibrated and blinded examiner (R.R. or A.K.) in the following order: GCF samples at the facial and lingual interproximal areas, PD, BOP within 30 s, recession (REC) from cemento-enamel junction, CAL (PD + REC), GI, and PI. Examiners (R.R., A.K.) were calibrated by sequential analysis of 20 posterior interproximal sites, resulting in 94% accuracy within 1 mm for PD and REC, respectively, 95% accuracy within one unit for GI and PI, and 85% for presence or absence of BOP. Examiners were

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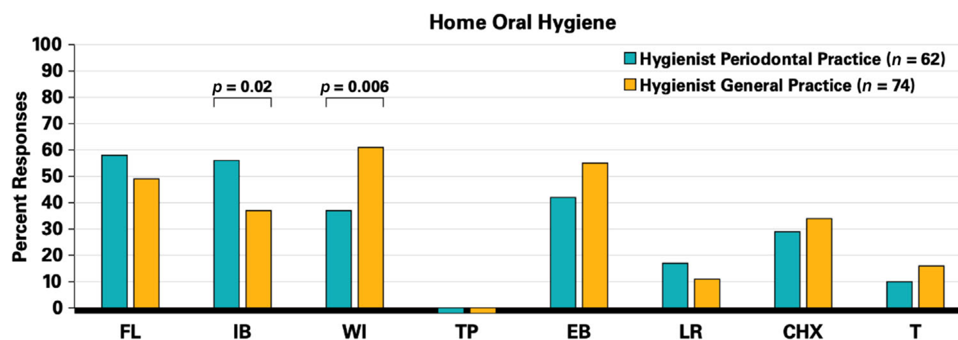

FIGURE 1 Survey results of home hygiene preferences of general office hygienists and periodontal office hygienists. IB, interproximal brush only; WI, water (oral) irrigator. TP, toothpick; FL, floss; EB, electric toothbrush; LR, Listerine rinse; CHX, chlorhexidine rinse; T, tracking daily performance

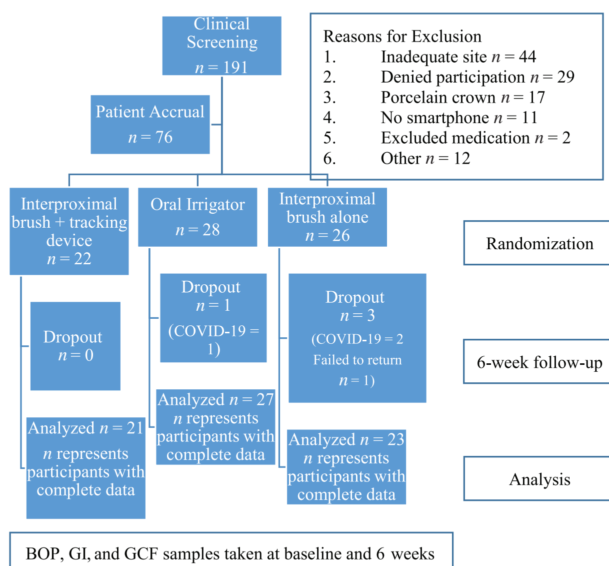

FIGURE 2 Study flow including group allocation. BOP, bleeding on probing; GCF, gingival crevicular fluid; GI, gingival index.

calibrated for GCF sampling by observing each other in paper strip application.

For GCF sampling, the test tooth was isolated using a cotton roll and gently air dried. Samples were then collected by inserting gingival fluid collection strips[*] into the sulcus toward the midinterproximal until slight resistance was felt, for 30 s. This was completed at both the facial and lingual aspects of the test site. The two GCF samples were placed into a single microcentrifuge tube and frozen at –80°C immediately following collection.[8] Clinical measurements, BOP, and GI were measured at both the facial and lingual of the test site. PI was measured using the Quigley-Hein PI with the Turesky modification with a score from 0 to 5 being assigned to each site. Following baseline data collection, sites were scaled supragingivally with no subgingival instrumentation by one of two clinicians (K.S. or G.M.) not involved with clinical data collection.

Participants were then randomized by arch, sex, and smoking status (current smoker or nonsmoker) into one of three treatment groups: interproximal brush alone (IB), interproximal brush with tracking device (IB+TD), or oral irrigator (OI). Randomization was completed via a randomization table. Participants were given standardized verbal and written instructions for their allocated treatment group by nonblinded clinicians (K.S. or G.M.). Instructions are specified as follows: In the IB group, an interproximal brush handle and six interproximal brush refills[†] were dispensed. Brush head sizes, including either tight, moderate, or wide, were selected based on the ability to provide mild resistance when inserted into the space without causing tissue trauma or patient discomfort. Demonstration at the test site was provided, participants handled the device, and then were given written instructions for interproximal use; application of brushes horizontally through the interproximal space or irrigator angled through the space for 5 s from each side once daily. A diagram of the interproximal test site was given with directions labeled. It was recommended to change brush heads weekly.

In the IB+TD group, in addition to the above instructions, participants in this group received a Bluetooth-linked tracking device with smartphone application[‡] which was manually attached to the proxabrush handle via a rubber strap provided by the manufacturer. The application was downloaded to the participant's device and set-up was completed by the resident. Participants were familiarized with the application and shown how to ensure record of use. Participants demonstrated understanding of the

[*] PerioPaper; Oraflow, Smithtown, NY

[†] GUM, Sunstar Americas, Inc, Schaumburg, IL
[‡] Brushlink, Menlo Park, CA

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protocol and how to use the device. The device tracks day and duration of use; however, it does not indicate the exact interproximal location at time of use.

In the OI group, an oral irrigating device[§] was distributed to participants. Demonstration of irrigator set-up and use was provided via product brochure and verbal instruction. Recommendation for use of the universal tip at an intensity level of 5 was made. Instructions were given to clean the test site interproximally for 5 s via both facial and lingual entry, once daily. Written instructions with a diagram of the interproximal site of interest were dispensed.

Participants returned after 6 weeks and the same protocol was performed as described for the baseline GCF sample and data collection. All samples were collected by a calibrated examiner (R.R. or A.K.). Data from the tracking device application were retrieved to determine the number of days the patient did or did not use the interproximal brush during the 6-week period.

2.4 | Analysis of GCF samples

At the time of analysis, each pooled GCF sample was eluted into 45 μL of 1× PBS by gently agitating the samples on a rocker plate for 1 h at 4°C. Cytokine concentrations were measured using a customized human cytokine magnetic bead panel[‖] with a MAGPIX instrument and software[¶] per the manufacturers' recommendations. Three proinflammatory cytokines (interleukin (IL)-1β, IL-6, and tumor necrosis factor alpha [TNF-α]), and two anti-inflammatory cytokines (IL-10, and interferon gamma [IFN-γ]) were reported. The cytokine quantities were reported in picograms per milliliter.

2.5 | Statistical analyses

A power analysis was completed showing that a sample size of 22 per group was needed to achieve at least 80% power to detect a difference of 1.0 mm in CAL between groups with a common estimated group standard deviation of 1.1 mm with a significance level of 0.05 using a two-sided independent samples t-test. This was determined based on mean data from a previous study.[9]

For PD, CAL, BOP, and GI measurements, the deepest pocket was identified (i.e., interproximal facial or palatal/lingual) at baseline (i.e., worst side) for each patient, and analysis was run on only measurements from the worst side. If both sides had equally deep pockets at baseline, then both measurements were averaged for each measure of interest. PD and CAL were reported as mean mm ± standard error (SE).

BOP was reported as present or not at baseline and 6-week follow-up. For change in BOP from baseline to 6 weeks, if a participant improved or maintained having no BOP, they were classified as "Improved/Maintained," otherwise they were classified as "Worsened/No Improvement." The GI variable was similarly dichotomized due to limited variability in the measurement data. If a participant had improved GI, or a GI score of one or less at both the baseline and final measurements, they were considered "Improved/Maintained." If their GI score increased (and the final GI score was greater than 1.0) or started above 1 and did not improve, they were considered to be "Worsened/No Improvement."

Associations between categorical variables were assessed using Chi-Square tests and Kruskal–Wallis tests were used to examine differences in distributions among the three treatment conditions (e.g., OI, IB, IB+TD). Significant Kruskal–Wallis tests were followed up with Wilcoxon Rank Sum tests for each pairwise comparison, and p values were Bonferroni adjusted to account for multiple comparisons. Means and SEs were calculated for age and differences in baseline values among groups were assessed using linear models with a main effect for group. Significant main effects were followed with Bonferroni-adjusted pairwise comparisons. Linear models were used to assess the association between the outcome change in measurement (final − baseline) and group, while adjusting for the initial measurement, arch, and side of worst pocket. For BOP and GI, logistic regression models were used to assess the association between the change outcome of "Improved/Maintained" versus "Worsened/No Improvement" and group, while adjusting for arch and worst side. In addition, a paired comparison of presence of BOP at baseline and 6 weeks was made for all groups combined using a McNemar test to assess if overall BOP levels changed over the study period.

For cytokines, given the distribution of the data, descriptive statistics for continuous data are given as medians and interquartile ranges (IQRs) and only nonparametric statistics were used. Kruskal–Wallis tests were used to examine differences in distributions of variables of interest among the three experimental groups. Significant Kruskal–Wallis tests ($p < 0.05$) were followed by post-hoc pairwise comparisons using Wilcoxon Rank Sum tests, for which p values were Bonferroni adjusted. To assess overall change, difference scores (final − baseline) from each group were compared with a value of zero (i.e., no change) using

[§] Waterpik, Philips Oral Healthcare, Snoqualmie, WA
[‖] Milliplex MAP kit; Millipore, Billerica, MA
[¶] Luminex Corp, Austin, TX

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TABLE 1 Demographics of participants finishing study.

		OI ($n = 27$)	IB ($n = 23$)	IB+TD ($n = 21$)	p value
Age (mean years ± SE)		68.9 ± 1.5	66.8 ± 2.3	61.0 ± 2.6	0.03*
Sex, n (%)	Women	14 (51.9)	9 (39.1)	12 (54.6)	0.53**
	Men	13 (48.2)	14 (60.9)	10 (45.5)	
Smoking status, n (%)	Nonsmoker	23 (85.2)	19 (82.6)	19 (86.4)	1.00***
	Smoker	4 (14.8)	4 (17.4)	3 (13.6)	
Arch, n (%)	Mandible	14 (51.9)	12 (52.2)	12 (54.6)	0.98**
	Maxilla	13 (48.2)	11 (47.8)	10 (45.5)	

Abbreviations: IB, interproximal brush alone; OI, oral irrigator; TD, tracking device.
*p value from linear model. The mean age for the OI group is significantly greater than the IB+TD group (adjusted $p = 0.03$).
**p values from Chi-square tests.
***p value from Fisher exact test.

signed-rank tests. All analyses were performed using SAS software version 9.4.[#]

3 | RESULTS

3.1 | Patient characteristics

Following screening of 191 patients (Figure 2), 76 eligible patients were enrolled and consented to the study. Intervention was initiated on all 76 subjects and 72 completed the 6-week follow-up (5% dropout rate). The reasons for dropout were not believed to be related to the intervention assigned in any of the four patients.

Characteristics of the participants who completed this clinical trial are represented in Table 1. There were no significant differences among groups at baseline for sex ($p = 0.53$), smoking status ($p = 1.00$), or arch ($p = 0.98$). However, the mean age for the OI group was significantly greater than the IB+TD group ($p = 0.03$).

3.2 | Clinical outcomes

The mean baseline and mean change results for respective clinical outcomes among the three groups are displayed in Table 2. There were no significant differences among groups at baseline. All three groups showed a statistically significant reduction in model adjusted mean PD at the experimental site (OI: –1.1, IB: –1.5, IB+TD: –1.1) after 6 weeks of device use ($p < 0.001$). Similarly, all three groups also showed a statistically significant reduction in model adjusted mean change in CAL at the experimental site (OI: –1.1, IB: –1.6, IB+TD: –1.3), ($p < 0.001$). However, there were no significant differences in the change observed among groups for PD ($p = 0.19$) or CAL ($p = 0.37$) at the experimental site. From baseline to 6 weeks, the IB and IB+TD groups showed a significant reduction in PI at the experimental site (model adjusted mean change for IB: –1.6, $p < 0.001$; IB+TD: –0.9, $p = 0.01$), while the OI group did not show a significant reduction (OI: -0.6, p = 0.11). Despite having a significant reduction in the IB and IB+TD groups that was not observed in the OI group, there was no significant difference between groups for change in PI at the experimental site ($p = 0.14$).

BOP was recorded for the buccal and lingual sides of test interproximal surfaces. There were no significant differences among the groups regarding the number of sites with BOP at baseline and 6 weeks. When looking at all groups combined, fewer participants had BOP at follow-up than at baseline ($p < 0.0001$); however, there was no difference in the change in BOP observed between the groups, $p = 0.81$.

Similarly, for GI, there was no significant difference between groups in baseline ($p = 0.25$), 6-week ($p = 0.53$), or improvement GI scores ($p = 0.85$). When looking at all groups together, GI scores were significantly decreased over the study period ($p < 0.0001$).

3.3 | Inflammatory biomarker outcomes

GCF samples from 72 patients were analyzed, and results are shown in Table 3. For proinflammatory cytokines, there were no significant differences among groups for IL-1β at baseline ($p = 0.36$). While the IB+TD group was the only group to show a significant decline in IL-1β between baseline and 6 weeks ($p < 0.001$), there was no significant difference in change in IL-1β between the treatment groups ($p = 0.11$). Similarly, there also were no significant differences between groups for IL-6 at baseline. The IB+TD group was the only group that showed a significant reduction in IL-6 during the study period ($p = 0.004$), and while

[#] SAS Institute, Cary, NC

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TABLE 2 Clinical measurements among groups

Measurement		OI ($n = 27$)	IB ($n = 23$)	IB+TD ($n = 21$)	p value for differences between groups
PD** (mean mm ± SE)	Baseline	5.3 ± 0.2	5.5 ± 0.3	5.7 ± 0.2	0.42
	6-week change***	–1.1 ± 0.2	–1.5 ± 0.2	–1.1 ± 0.2	0.19
	p value for change over time within group	<0.0001	<0.0001	<0.0001	
CAL** (mean mm ± SE)	Baseline	5.9 ± 0.3	5.9 ± 0.3	6.3 ± 0.3	0.48
	6-week change***	–1.1 ± 0.2	–1.6 ± 0.3	–1.3 ± 0.3	0.37
	p value for change over time within group	<0.0001	<0.0001	<0.0001	
PI (mean ± SE)	Baseline	3.7 ± 0.3	4.0 ± 0.2	4.0 ± 0.3	0.74
	6-week change***	–0.6 ± 0.4	–1.6 ± 0.4	–0.9 ± 0.4	0.14
	p value for change over time within group	0.11	<0.0001	0.01	
BOP,** n (%)	Baseline BOP	24 (88.9)	18 (78.3)	21 (95.5)	0.24*
	6-week BOP	7 (25.9)	5 (21.7)	8 (36.4)	0.53
	% Improved from baseline or maintained no BOP****	22 (81.5)	19 (82.6)	17 (77.3)	0.81
GI,** n (%)	Baseline GI > 1	23 (85.2)	18 (78.3)	21 (95.5)	0.25*
	6-week GI > 1	7 (25.9)	4 (17.4)	7 (31.8)	0.53
	% Improved from baseline or maintained GI ≤ 1****	22 (81.5)	20 (87.0)	18 (81.8)	0.85

p values obtained from linear models for continuous variables or from Chi-Square tests for categorical variables, unless otherwise noted.

Abbreviations: BOP, bleeding on probing; CAL, clinical attachment level; GI, gingival index; IB, interproximal brush alone; OI, oral irrigator; PD, probing depth; PI, plaque index; TD, tracking device.

*p value from Fisher exact test.

**Measured on the side with the deepest pocket at baseline.

***p values and means (which are model adjusted means) were derived from models with 6-week change (final – initial) as the outcome, which adjusted for initial value, arch, and worst side (i.e., lingual, facial, or both).

****Descriptive statistics reported, but p values were derived from logistic regression models with improvement/maintenance (yes vs. no) as the outcome which adjusted for arch and worst side (i.e., lingual, facial, or both).

there was a significant main effect of group for change in IL-6 ($p = 0.03$), there were no Bonferroni-adjusted differences between groups that were significant at the 0.05 alpha level (e.g., IB vs. IB+TD, $p = 0.05$). For TNF-α levels, no significant differences among groups were found at baseline or in change observed from baseline to the 6-week follow-up. Additionally, no significant change was seen in TNF-α levels within groups from baseline to follow-up.

Anti-inflammatory IL-10 levels showed no significant differences among the groups at baseline. There was a significant reduction in IL-10 levels for the OI ($p = 0.04$) and IB + TD ($p = 0.01$) groups; however, there were no significant differences in the change observed between groups ($p = 0.49$). For IFN-γ, there was a significant main effect of group for baseline measures ($p = 0.049$), however there were no Bonferroni-adjusted differences between groups that were significant at the 0.05 alpha level (e.g., OI vs. IB+TD, $p = 0.06$). Unlike the other cytokines, a significant increase in IFN-γ was observed, but only in the OI group ($p = 0.04$), however the observed change in IFN-γ was not significantly different between groups ($p = 0.68$).

From the 6-week follow up appointment to at least 3 months after, there were far fewer patients in the IB + TD group (0%) who continued to use this interproximal cleaning protocol compared with the IB (68.2%) or OI (96.2%) groups ($p < 0.001$).

4 | DISCUSSION

The current study exhibited no significant differences in sex, smoking status, or arch among groups at baseline. However, mean age for the OI group was greater than the

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TABLE 3 Cytokine measurements by group

Measurement	OI		IB		IB + TD		p value for differences between groups
	Median (pg/mL)	IQR	Median (pg/mL)	IQR	Median (pg/mL)	IQR	
IL-Iβs							
Baseline	172.66	(60.48 to 682.15)	391.29	(29.30 to 1365.18)	638.77	(97.22 to, 1711.07)	0.36
6-week change[a]	−53.54	(−421.16 to 223.05)	−1.39	(−1131.74 to 132.32)	−154.69	(−1377.85 to −66.73)	0.11
p value for change over time within group		0.36		0.48		< 0.001	
IL-6							
Baseline	20.19	(8.97 to 49.22)	11.92	(6.55 to 39.40)	30.51	(17.36 to 55.20)	0.08
6-week change[a]	−3.40	(−12.02 to 12.60)	4.76	(−11.07 to 26.33)	−12.90	(−26.44 to −0.93)	0.03[b]
p value for change over time within group		0.56		0.39		0.004	
TNF-α							
Baseline	9.49	(0.00 to 14.50)	8.83	(6.52 to 13.83)	13.75	(9.09 to 18.07)	0.15
6-week change[a]	0.00	(−6.86 to 6.99)	0.00	(−12.16 to 19.41)	−7.36	(−11.24 to 0.53)	0.14
p value for change over time within group		0.89		0.40		0.07	
IL-10							
Baseline	15.92	(5.70 to 47.43)	17.04	(7.24 to 39.20)	29.97	(17.79 to 61.19)	0.32
6-week change[a]	−7.32	(−26.80 to 0.99)	−2.34	(−24.73 to 13.18)	−9.34	(−33.38 to 0.00)	0.49
p value for change over time within group		0.04		0.37		0.01	
IFN-γ							
Baseline	5.24	(3.06 to 8.09)	6.61	(4.44 to 9.79)	8.43	(5.28 to 9.92)	0.049[c]
6-week change[a]	1.55	(−2.19 to 8.09)	1.22	(−2.15 to 7.87)	0.78	(−3.80 to 6.23)	0.68
p value for change over time within group		0.04		0.12		0.53	

p values for between group comparisons were derived from Kruskal–Wallis tests, and p values assessing change over time were assessed using signed-rank tests for the median change values, separately for each group.
Abbreviations: IB, interproximal brush alone; IFN-γ, interferon-gamma; IL, interleukin; IQR, interquartile range; OI, oral irrigator; TD, tracking device; TNF-α, tumor necrosis factor-α.
[a]Change was calculated by subtracting baseline measurements from 6-week measurements.
[b]After Bonferroni adjustment, the lowest p value for all post-hoc pairwise comparisons was 0.05, for the IB versus IB+TD comparison.
[c]After Bonferroni adjustment, the lowest p value for all post-hoc pairwise comparisons was 0.06, for the OI versus IB+TD comparison.

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IB+TD group. This difference may have been a result of an enrollment error where three patients were excluded following randomization into the IB+TD group after discovery that they did not own a smartphone device to support the tracking application. Older patients may be less likely to own a smartphone, resulting in a collectively younger group making up the IB+TD group. Aging has been associated with delayed cell proliferation and wound healing, and increased systemic diseases, medications and oral hygiene performance.[10] Further, xerostomia, altered bone physiology, and microbiome could impact the course of PMT stability.[11] However, the mean age in all groups was >60 years considered elderly[10] and the 6–8 year difference in the IB+TD group may be statistically, but not clinically relevant.

It must be understood that a periodontium minimally affected by periodontitis versus a reduced periodontium present differing anatomic topography[12] that require individualized interproximal cleaning recommendations to be effective. While research has been conducted on interproximal cleaning aids, previous studies[13–15] on interproximal oral hygiene often included non-periodontitis sites or did not report the periodontal status of the patient, making direct comparisons with the current population of patients receiving periodontal maintenance difficult. Additionally, studies[16,17] were either supported by the manufacturer of a certain device, introducing possible bias, or did not include direct comparisons between aids.

An independent study[4] of full-mouth effects of IP and OI indicate that both contribute to more stable CAL, PD, BOP, and GI over 6 years, consistent with the efficacy in the current study. The current study demonstrated small but statistically significant treatment improvements in CAL, PD, PI, BOP, and GI at the experimental sites for all three treatment modalities (except for PI for the OI group where there was no significant change). To our knowledge, no other study has compared interproximal clinical measures among an interproximal brush, a tracking device mobile application in conjunction with an interproximal brush, and an oral irrigator in patients receiving periodontal maintenance.

The reduction in PD for OI (1.1 ± 0.2 mm) in the current study was greater than a study which showed a significant reduction in PD of 0.4 mm in just 2 weeks of using an oral irrigator.[15] The greater PD reduction in this study may relate to a longer time for anti-inflammatory tissue remodeling and focusing on the worst site in the area. The IB group also showed a significant reduction of 1.5 ± 0.2 mm at the experimental site, and the IB+TD group showed a significant reduction of 1.1 ± 0.2 mm. These results are in agreement with previous studies which have shown that interproximal brushes are effective in improving PD if used correctly in embrasure spaces that support interdental brushes.[18–20] The improvements seen were not found to be significantly different between groups.

CAL from baseline to 6 weeks showed statistically significant improvement at the experimental site with a reduction of 1.1 ± 0.2 mm for the OI group, 1.6 ± 0.3 mm for the IB group, and 1.3 ± 0.3 mm for the IB+TD group. This result is to be expected given the significant reduction in PD among the three groups. There were no significant differences in observed change in CAL between groups at the conclusion of the study. Current systematic reviews show no other studies that have reported on CAL comparing IB, IB+TD, and OI groups. While the improvements in PD and CAL are statistically significant, the clinical relevance may be questioned. However, improvements >1.0 mm are notable for a home oral hygiene intervention.[21]

For PI, from baseline to 6 weeks the IB and IB+TD groups showed a statistically significant reduction in PI at the experimental site of 1.6 ± 0.4 and 0.9 ± 0.4, respectively. For the OI group, there was a reduction in PI of 0.6 ± 0.4 at the experimental site which was not statistically significant. The lack of a significant difference in change in PI between groups is in agreement with a 2-week study which showed no statistically significant reduction in PI comparing OI to an interdental brush in patients with 4–6 mm pockets.[22] This study disagreed with a similar study that showed single use of an OI removed significantly more plaque than an interdental brush; however, this study focused on whole mouth plaque removal.[23] Two systematic reviews have shown significant improvements in plaque and bleeding scores along with PD with the use of interdental brushes compared with brushing alone.[20,24] A review by Sälzer et aler[25] found interdental brushes to be the most effective aid for interproximal plaque removal. The majority of evidence would suggest the function of the OI is to flush away nonadherent plaque, remove bacteria, and interfere with plaque maturation, rather than provide any mechanical plaque debridement.[26] Another influence on the decrease in PI could be explained by the Hawthorne effect, which describes a modification of behavior when individuals are aware that they are being observed.[27]

With all groups combined, there was a significant decrease in BOP, but there were no significant differences in change of BOP between groups. Existing literature, along with the present study, supports BOP reduction via oral irrigators and interproximal brushes over short time periods.[3,4,28] In a meta-analysis of different oral hygiene aids, oral irrigators, and interproximal brushes were found to be the most effective at reducing gingival bleeding.[29] However, these values included facial and lingual surfaces and were not limited to interproximal sites as in the present study.

Although the present study found significantly improved GI over the course of the study for all groups,

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there were no significant differences in the improvement of GI between groups. However, a meta-analysis of 10 different interproximal oral hygiene aids found interproximal brushes achieved the highest reduction in GI, followed by oral irrigators.[29]

There are no existing studies investigating a compliance tracking method, neither analog nor digital, in combination with an interproximal cleaning aid. However, studies exploring the effectiveness of a smartphone device to track daily compliance of manual toothbrushing showed dramatic improvements in oral hygiene including significant reductions in plaque levels at 4 weeks.[30] This study did not use a diary to ensure compliance across the OI or IB groups, however, the IB+TD group was able to show daily compliance via the application at the 6-week appointment, which was a variable in this study.

Analysis of GCF changes in response to interproximal cleaning is limited. Literature potentially biased by manufacturer funding[21] reported a reduction in proinflammatory IL-1β and an increase in anti-inflammatory IL-10 with the use of an oral irrigator in conjunction with routine oral hygiene over a period of 14 days. In our study, the OI group had a significant reduction in IL-10 and a significant increase in IFN-γ over the course of the study. However, the IB+TD group had significant decreases in IL-1β, IL-6, and IL-10. The significant reduction observed in anti-inflammatory IL-10 in the OI and IB+TD groups in the present study could potentially be due to a decrease in overall GCF volume in periodontally healthy sites.[31] In contrast, an increase in IFN-γ was observed for only the OI group at 6 weeks. While excessive release of IFN-γ has been associated with the pathogenesis of chronic inflammatory diseases such as periodontitis, the concept of a dual role of IFN-γ in inflammation has support. Mühl and Pfeilschifter[32] described the anti-inflammatory aspects of IFN-γ to include induction of anti-inflammatory molecules such as interleukin-1 receptor agonist (IL-1Ra), activation of apoptosis and modulation of proinflammatory cytokine production. The IB+TD group showed short-term anti-inflammatory GCF profiles; longer studies are needed to show the tracking device's true potential with inflammation control.

There were several limitations in this study. The COVID-19 pandemic forced some participants to reschedule their 6-week follow up appointment, which could have affected the results. Smoking was not assessed beyond the determination of "smoker" or "nonsmoker" and amount of smoking could have affected the results in terms of BOP or GI. Software design of the TD application was a further limitation of this study. Participants reported that TD software gave negative feedback when used for a limited time at a singular location. Software updates to allow for local monitoring would likely improve patient acceptance and clinical outcomes.

5 | CONCLUSIONS

Focused interproximal cleaning with an interdental brush or oral irrigator in inflamed, posterior periodontal pockets during periodontal maintenance results in improved clinical parameters of PD, and CALs, as well as signs of inflammation in this 6-week study.

AUTHOR CONTRIBUTIONS

All authors have made substantial contributions to conception and design of the study. Grace C. Moore, Kevin T. Smith, Amy C. Killeen, Richard A. Reinhardt, Mary M. Christiansen, and Laura Anderson have been involved in data collection. Lisa J. Moravec and David K. Okano have been involved in survey preparation. Kaeli K. Samson, Amanda Ramer-Tate, and Kristin Beede have been involved in data analysis. Grace C. Moore, Kevin T. Smith, Amy C. Killeen, Richard A. Reinhardt, and Kaeli K. Samson were responsible for drafting the manuscript and revising it critically and have given final approval of the version to be published.

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CONFLICT OF INTEREST

The authors declare no conflicts of interest related to this study.

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