







ORIGINAL ARTICLE

Interdental plaque reduction after the use of different devices in patients with periodontitis and interdental recession: A randomized clinical trial

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Abstract

Objectives: To determine the efficacy of four different oral hygiene protocols involving adjunctive interdental devices in terms of plaque and bleeding scores in periodontitis-affected patients.

Material and methods: This was a randomized clinical trial with a 5-week follow-up, including previously treated periodontitis patients not undergoing any supportive care. Patients were randomly allocated to 4 groups: manual toothbrush (group TB); toothbrush plus dental floss (group TB/F); toothbrush plus interdental brushes (group TB/IDB) and toothbrush plus rubber interdental picks (group TB/RIDB). Oral hygiene instructions (OHI) were provided at baseline (T-7) and at T0 (1-week) then bi-weekly (T14/T28). At T0, supragingival professional cleaning was delivered. Plaque and bleeding indexes were taken at all timepoints by a single calibrated examiner, blind to group allocation.

Results: At T-7, patients were comparable for age, body mass index (BMI) and all clinical parameters, exceptions for the Interdental Angulated Bleeding Index. At T28, significant reductions of plaque and gingival inflammation were noted in all groups ($p < 0.001$) and within the expected ranges. Intergroup comparisons identified that group TB/IDB and group TB/RIDB achieved lower levels of plaque and inflammation than group TB ($p < 0.05$). Group TB/IDB and group TB/RIDB showed lower levels of plaque and lower inflammation as measured by angulated bleeding index than group TB/RIDB ($p < 0.05$).

Conclusion: Interdental brushes and rubber interdental picks were more efficient than toothbrushing alone and toothbrushing and floss in reducing plaque and gingival inflammation measured in a periodontitis-affected population.

KEY WORDS

floss, interdental brushes, interdental picks, periodontitis, toothbrushing

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1 | INTRODUCTION

Periodontitis is a destructive inflammatory disease of the supporting tissues of the tooth and is the leading cause of tooth loss.¹ As demonstrated by epidemiological studies, about 30% of the adult population over the age of 50 is affected by this pathology,² with the prevalence of 11.2% for severe form of periodontitis.³ It is a chronic mixed infection of gram-negative bacteria with plaque being the primary etiological factor in its development.⁴ Plaque accumulation is predominantly observed in the interproximal areas of the dentition, making those areas more prone to develop gingival and periodontal lesions, as well as carious ones.⁵

The primary method of plaque control is achieved via mechanical cleaning with toothbrush, which is the most commonly used device.⁶ The efficacy of toothbrushing in terms of interdental cleaning is selectively influenced by the bristles shape and stiffness.⁷ Undoubtedly, the adjunct of self-performed interdental cleaning in addition to toothbrushing suggest further plaque and/or gingivitis reduction, higher than the ones achieved by toothbrushing alone.⁸ For that purpose, different interdental cleaning devices have been introduced, with varying efficacy among them.⁹⁻¹³ The superiority of interdental brushes and picks, over toothbrushing alone, in removing the interdental plaque deposits and thus preventing inflammation in healthy population has already been demonstrated.^{14,15}

Likewise, the interdental brushes demonstrated superiority over the dental floss not only in plaque removal in patients suffering from periodontitis but also in patients' preferences.⁹ Accordingly, the interdental cleaning has been recognized as important factor not only in the prevention but also in the maintenance of the re-established health status in population affected by periodontitis.¹⁶ However, the data regarding the efficacy of interdental devices in population affected by periodontitis are conflictual.^{8,16-19}

Therefore, the aim of this study was to assess the efficacy of toothbrushing accompanied with the use of dental floss, interdental brushes or interdental picks vs. toothbrushing alone in terms of plaque and gingival inflammatory scores in a population are affected and previously treated for periodontitis with no supportive care.

2 | MATERIAL AND METHODS

2.1 | Patient selection

This study was a single-centre, randomized, parallel design, clinical trial with a 5-week follow-up. The study was approved by the local ethics committee (#3140, protocol numb.74721), registered in a clinical trial database (NCT04527913), and it was conducted according to the principles outlined in the Declaration of Helsinki on experimentation involving human subjects.

Patients attending the Sub-Unit of Periodontology, Halitosis and Periodontal Medicine, University Hospital of Pisa, were asked to participate in the study. In order to be eligible to the study, participants had to be systemically healthy with at least 20 natural teeth with residual

periodontal pockets with probing pocket depth (PPD) \geq 4 mm, and in need of specific oral hygiene regimen. Third molars were excluded.

Exclusion criteria were (i) subjects younger than 18 years and older than 70 years, (ii) pregnant or lactating females, (iii) indication to antibiotic therapy prior to treatment, (iv) chronic infections and (v) not willing to give a consent.

This study was conducted between September 2011 and June 2019.

2.2 | Study design

The study design has already been described as this study is a companion research of a previously published manuscript evaluating interdental devices on subjects with intact papilla.¹⁴ The population in this study comprised patients diagnosed with periodontitis who had been preliminary treated in our unit and not enrolled in any supportive periodontal care. Patients were contacted through our database and invited to participate in the study. After signing an informed consent form, patients were randomly assigned to one of four treatment groups. Randomization was performed by a computer-generated table and concealed to the clinical examiner and statistician with sequentially numbered sealed opaque envelopes that were opened on the day of allocation by a clinical staff member. The patients were allocated in one of the four distinct study groups with respect to different oral hygiene regimens:

Group TB: use of manual toothbrush alone (TePe Select™; TePe Munhygienprodukt AB);

Group TB/F: manual toothbrush plus waxed dental floss (TePe Select™ and TePe Dental Tape);

Group TB/IDB: manual toothbrush plus interdental brushes (TePe Select™ and TePe interdental brush);

Group TB/RIDB: manual toothbrush plus rubber interdental picks (TePe Select™ and GUM® Soft-Picks®, Sunstar).

Study flowchart is depicted in the [Figure 1](#). Patients were followed for 5 weeks. The first week started at T-7 when the patients were randomized, given the tools according to group allocation with oral hygiene instructions (OHI). This week, from T-7 to T0 represented the 'unclean phase', in which patients tried to use the various tools brushing on unscaled teeth. At T0, tailored OHI were given focusing on the oral hygiene device of the allocated group for each patient. In groups TB/IDB and TB/RIDB, particular care in choosing the adequate dimension to fit the papillary embrasures was taken, as the size of the interdental device was chosen on the base of the resistance felt during the demonstration. A session of professional supra-gingival scaling and polishing was performed by a trained dentist with great care in performing exclusively coronal manoeuvres. No further formal OHI were given during the study, unless specifically asked by the patient. This period of the trial, from T0 to T28 represented the 'clean phase', in which patients were seen and reassessed two more times, bi-weekly (T14 & T28). No professional cleaning was performed at these timepoints, but OHI were reinforced at each timepoints. Reinforcements consisted of repeating oral hygiene instructions with particular care given to the areas that the patient

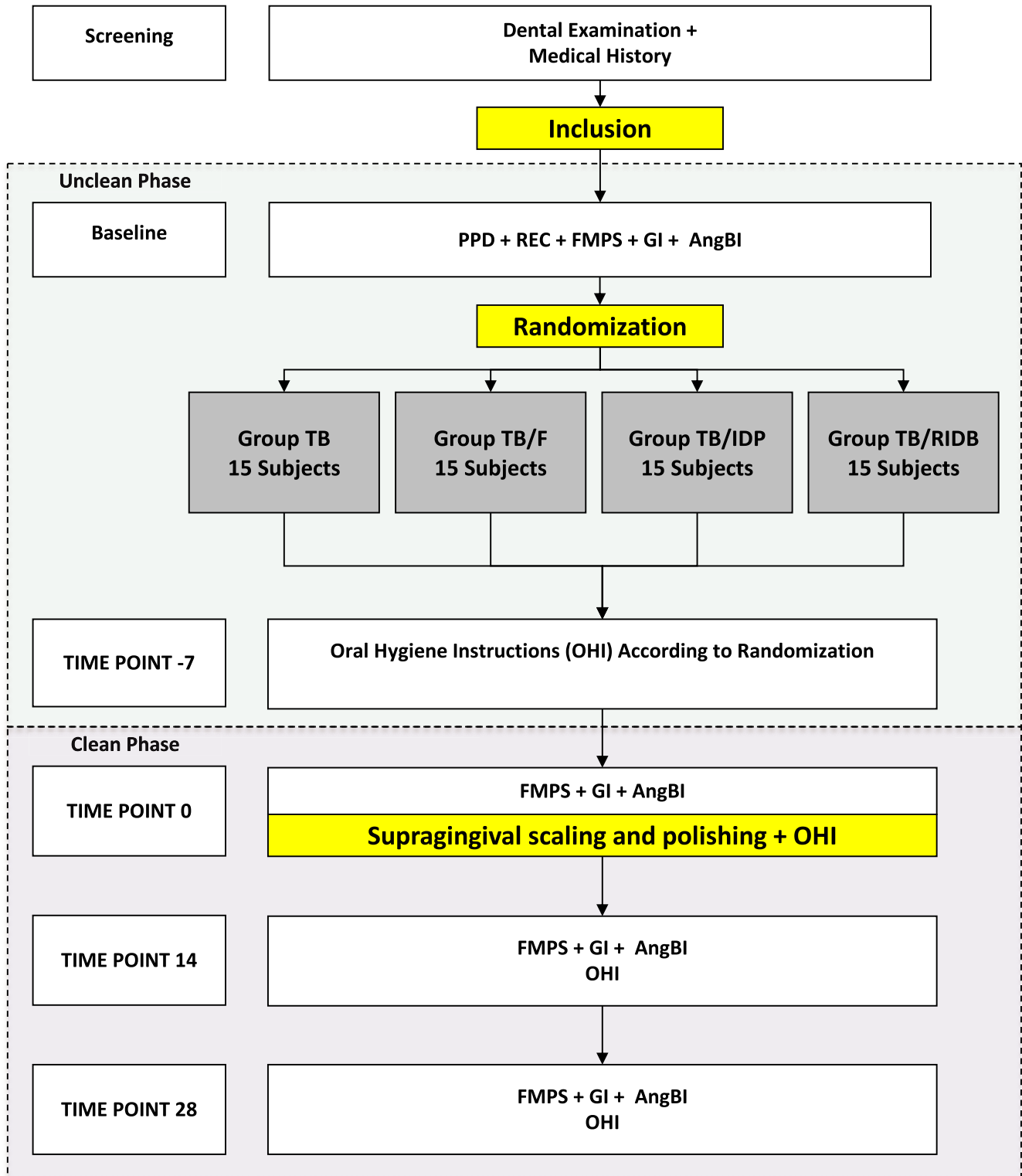


FIGURE 1 Study design

was not able to clean properly. The investigators performed intra-oral OHI demonstrations using mirrors.

Assessments of plaque and bleeding indexes were made at each timepoint (T-7, T0, T14 and T28) whereas periodontal parameters, such as PPD and recession (REC) were measured at the beginning of the study (T-7).

2.3 | Clinical parameters

At the baseline visit, standard periodontal clinical parameters were assessed using a UNC 15-mm periodontal probe by a masked calibrated examiner on all teeth excluded third molars. Calibration upon intra-examiner repeatability for clinical attachment level (CAL)

measurement was judged adequate when reaching a percentage of agreement within ± 2 mm between repeated measurements of at least 98%.²⁰

Full-mouth PPD and REC were recorded with measurements rounded to the nearest millimetre at six sites per tooth. Clinical attachment level (CAL) was calculated as the sum of PPD and REC. The full-mouth plaque score (FMPS) was measured as the percentage of the total surfaces showing plaque assessed dichotomously on six surfaces per tooth.²¹

Gingival index (GI) was determined taking into account gingival appearance, bleeding and inflammation, as quantified in the following scale²²:

0—normal appearance of gingiva, no bleeding, no inflammation; 1—slight change and moderate oedema with slight change in texture, no bleeding, mild inflammation; 2—redness, hypertrophy or oedema and glazing, bleeding on probing, moderate inflammation; 3—marked redness, hypertrophy or oedema, ulceration, spontaneous bleeding, severe inflammation.

Angulated bleeding index (AngBI) was calculated with the probe running along the marginal gingiva and held at an angle of approximately 60° to the longitudinal axis of the tooth.²³ The following scale was adopted as follows: 0: no bleeding; 1: bleeding upon probe stimulation; 2: spontaneous bleeding. However, point 1 and 2 were grouped together to form a dichotomous outcome.

Both, GI and AngBI were measured at four sites per tooth, including buccal, lingual and interproximal surfaces (mesial and distal) of each tooth. Consequently, interdental full-mouth plaque score (IntFMPS), interdental gingival index (IGI) and interdental angulated bleeding score (IntAngBI) were calculated by excluding the measurement of the buccal and lingual recordings.

Probing pocket depth and REC were measured at baseline and end of the trial, whereas FMPS, GI and AngBI were measured at all timepoints, as depicted in the study flowchart.

Smoking history was registered dichotomously by self-reporting as current or never/former smoker.

2.4 | Data management and statistical analysis

The sample size calculation was done as previously described.¹⁴ To sum up, 12 subjects per treatment arm were necessary to detect a difference of 15% between groups using FMPS as the primary outcome variable, with a power set at 95% and the standard deviation of 10%. Therefore, a total sample of 60 subjects was recruited as to compensate for possible dropouts during trial. An intention-to-treat, last observation carried forward analysis was performed.²⁴ Data were manually transferred from the clinical register to the Excel database, created specifically for this study (S.G.) and proofed for entry errors. All data are presented as mean and standard deviation, unless otherwise specified. The unit of analysis was the patient. Variables were analysed with ANOVA test for repeated measures to compare differences over time for each parameter within group and among groups at a given timepoint. Data

were adjusted for age, BMI, smokers, number of teeth and baseline percentage of pockets ≥ 6 mm using a multivariate analysis of covariance (MANCOVA).

Categorical variables were analysed with the Chi-squared and McNemar test. The Shapiro-Wilk test was used to check the normality of the data distribution. Bonferroni post-hoc corrections were adopted.

All analyses were performed with SPSS version 25 (SPSS Inc.). The *p*-value was set to the level of significance of 0.05.

3 | RESULTS

3.1 | Study flow and baseline characteristics

The flow of the patients throughout the study is depicted in [Figure 2](#). A total of 9 participants were eligible but never attended randomization. Therefore, patients were re-enrolled to reach a final number of 60 participants included, randomized and analysed. Forty-five participants were enrolled and treated within 2011 and 2013, whereas the remaining 15 were treated in 2019. Participants were comparable for all measured periodontal parameters at baseline, exceptions for the IntAngBI. Among included participants, 25.4% of them were smokers and 58.3% females.

Baseline characteristics are presented in the [Table 1](#). No significant differences among groups were noted.

3.2 | Periodontal parameters

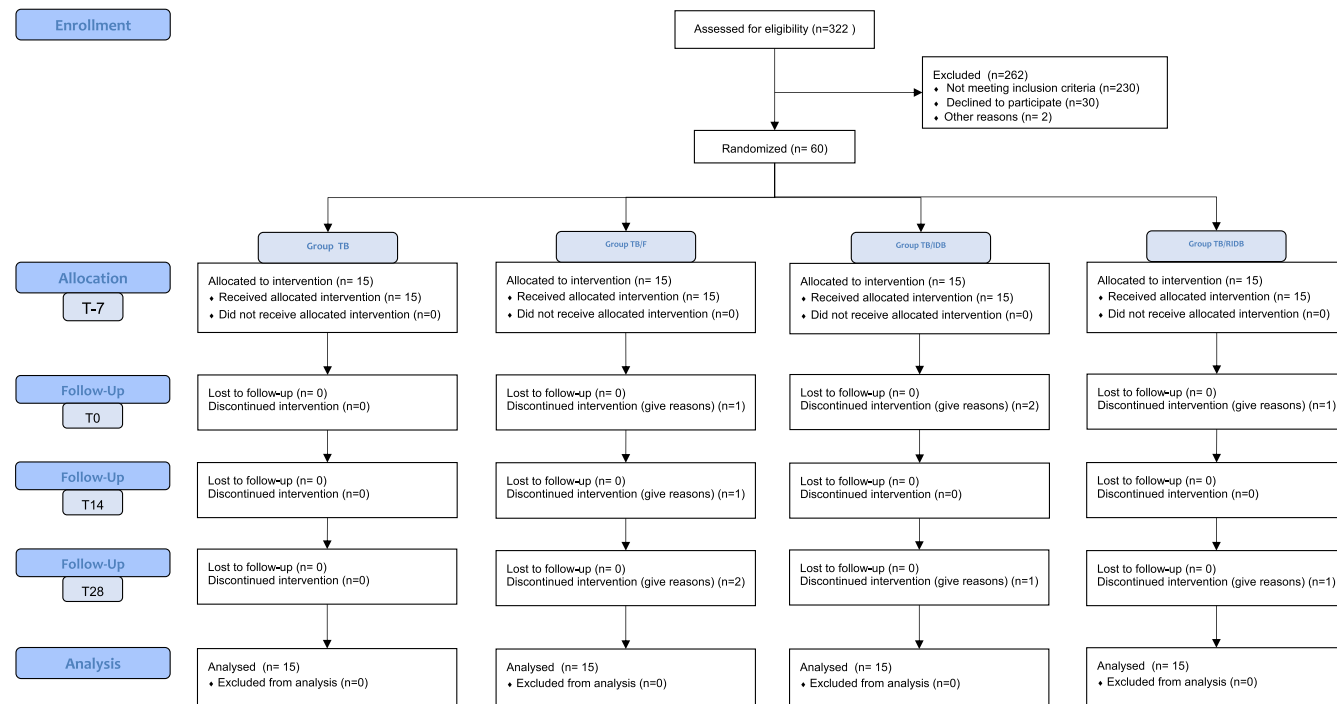
3.2.1 | Intra-group differences

Clinical periodontal parameters at different timepoints are presented in the [Table 2](#) and [Figure 3](#).

Full-mouth plaque score and IntFMPS decreased significantly in the unclean phase only in group TB/IDB ($p < 0.05$) and group TB/RIDB ($p < 0.01$). In all groups values decreased significantly at T14 and T28. Significant differences were noted between T-7 and T28 and between T0 and T28. Overall FMPS reductions from T-7 ranged from 38% (SD: 31%) in Group TB to 54% (SD: 18%) in group TB/RIDB whereas IntFMPS reductions ranged from 36% (SD: 38%) in group TB to 53% (SD: 34%) in group TB/IDB ([Table 3](#)).

Gingival index and int-GI decreased in all groups at T14 and T28 with significant differences in the periods T-7/T28 and T0/T28 ([Table 2](#)). Overall GI reductions from T-7 varied from 0.63 (SD 0.39) in group TB to 0.73 (SD 0.53) in group TB/RIDB whereas int-GI reductions ranged from 0.66 (SD 0.40) in group TB to 0.74 (SD 0.54) in group TB/RIDB ([Table 3](#)).

Angulated bleeding index decreased significantly in group TB, 3 and 4 and IntAngBI decreased in group TB/IDB and group TB/RIDB. Reductions of AngBI varied from -1% (SD: 22%) in group 'manual toothbrush + waxed dental floss' to 22% (SD: 30%) in group TB/RIDB whereas IntAngBI ranged from -1% (SD: 26%) in group 'manual



Variable	Group TB (N = 15)	Group TB/F (N = 15)	Group TB/IDB (N = 15)	Group TB/RIDB (N = 15)
Age, years	49.33 (12.82)	47.47 (12.25)	51.20 (13.89)	49.73 (11.31)
Females, N (%)	9 (60)	8 (53.3)	9 (60)	9 (60)
BMI	24.41 (3.63)	25.7 (5.10)	27.22 (10.70)	24.82 (6.60)
Smokers, N (%)	3 (21.4)	4 (28.6)	3 (21.4)	4 (28.6)
Teeth (N)	26.53 (3.23)	26.47 (3.76)	25.27 (5.20)	26.53 (2.45)
Mean REC	0.18 (0.30)	0.38 (0.68)	0.55 (0.96)	0.38 (0.92)
Mean CAL	3.25 (0.46)	3.22 (1.26)	3.37 (1.20)	3.48 (0.95)
% PPD < 4	75.51 (14.33)	69.56 (23.64)	74.03 (16.22)	75.68 (14.37)
% PPD ≥ 4	24.25 (14.23)	26.03 (13.97)	24.87 (15.92)	25.24 (13.81)
% PPD ≥ 5	6.02 (6.74)	5.15 (5.94)	4.75 (4.89)	6.46 (7.71)
% PPD ≥ 6	0.18 (0.30)	0.38 (0.68)	0.56 (0.10)	0.38 (0.92)

TABLE 1 Baseline characteristics

Abbreviations: BMI, body mass index; CAL, clinical attachment level; PPD, probing pocket depth; REC, recession; TB, toothbrush; TB/F, toothbrush plus dental floss; TB/IDB, toothbrush plus interdental brushes; TB/RIDB, toothbrush plus rubber interdental picks.

FIGURE 2 Flow of the patients during the study

toothbrush + waxed dental floss' to 20% (SD: 31%) in group TB/RIDB (Table 3).

Patients did not report deviations from the protocol at each timepoints.

3.3 | Intergroup differences

Comparison among groups identified some important differences. In terms of FMPS and IntFMPS at T0 lower level of plaque were noted

for group TB/IDB and group TB/RIDB versus group TB. This trend was maintained t T14 and T28. At T28 groups 3 and 4 showed lower values of FMPS versus group TB/F ($p < 0.05$) whereas in terms of IntFMPS significant differences were noted among groups TB/IDB and group TB/F ($p < 0.05$).

Gingival index and IntGI showed differences among group TB and group TB/RIDB at T14 and T28 (Table 2).

AngBI and IntAngBI showed differences at T0 among group TB and group TB/RIDB ($p < 0.05$). At T28 differences were noted also among group TB/IDB and group TB/RIDB versus group

TABLE 2 Clinical periodontal parameters among groups at different timepoints

Variable	T-7 (baseline)	T0	T14	T28
FMPS				
Group TB	74.25 (20.30)	62.03 (17.55)	45.38 (22.71)**; ****	36.21 (27.52)***; *****
Group TB/F	74.48 (22.25)	57.31 (33.04)	35.92 (18.95)***; ****	39.74 (15.81)***; ****
Group TB/IDB	71.51 (22.84)	52.78 (25.84)*	31.22 (18.15)***; ****	27.72 (21.04)***; *****
Group TB/RIDB	81.28 (11.95)	54.54 (30.40)**	31.41 (21.22)***; *****	27.31 (17.89)***; *****
-	-	$p(1 \text{ vs. } 3) < 0.05; p(1 \text{ vs. } 4) < 0.05;$	$p(1 \text{ vs. } 3) < 0.05; p(1 \text{ vs. } 4) < 0.05;$	$p(1 \text{ vs. } 3) < 0.05; p(1 \text{ vs. } 4) < 0.05; p(2 \text{ vs. } 3) < 0.05; p(2 \text{ vs. } 4) < 0.05;$
IntFMPS				
Group TB	85.81 (19.38)	74.70 (21.29)	58.56 (31.83)*;	49.35 (38.60)**; ****
Group TB/F	84.34 (19.04)	73.76 (24.37)	73.76 (44.09)***; *****	47.61 (18.89)***; *****
Group TB/IDB	85.94 (24.51)	71.07 (23.48)	40.61 (19.93)***; *****	35.79 (28.31)***; *****
Group TB/RIDB	95.23 (11.21)	70.33 (32.70)*	41.38 (28.20)***; *****	44.09 (32.21)***; ****
-	-	-	$p(1 \text{ vs. } 2) < 0.05; p(1 \text{ vs. } 3) < 0.05;$ $p(1 \text{ vs. } 4) < 0.05; p(2 \text{ vs. } 3) < 0.05; p(2 \text{ vs. } 4) < 0.05$	$p(1 \text{ vs. } 3) < 0.05; p(1 \text{ vs. } 4) < 0.05; p(2 \text{ vs. } 3) < 0.05;$
GI				
Group TB	1.27 (0.40)	1.05 (0.35)	0.76 (0.36)**; ****	0.64 (0.42)***; *****
Group TB/F	1.21 (0.38)	0.84 (0.42)**	0.69 (0.36)***	0.58 (0.26)***
Group TB/IDB	1.25 (0.34)	0.98 (0.42)*	0.72 (0.22)***; ****	0.57 (0.39)***; *****
Group TB/RIDB	1.31 (0.38)	1.03 (0.36)	0.66 (0.35)***; *****	0.58 (0.39)***; *****
-	-	-	$p(1 \text{ vs. } 4) < 0.05$	$p(1 \text{ vs. } 3) < 0.05; p(1 \text{ vs. } 4) < 0.05$
IntGI				
Group TB	1.33 (0.40)	1.12 (0.37)	0.81 (0.39)**; ****	0.67 (0.43)***; *****
Group TB/F	1.29 (0.44)	0.88 (0.48)*	0.73 (0.40)**	0.63 (0.31)***
Group TB/IDB	1.29 (0.39)	1.07 (0.45)	0.76 (0.24)***; ****	0.61 (0.39)***; *****
Group TB/RIDB	1.34 (0.43)	1.07 (0.39)	0.69 (0.38)	0.60 (0.34)***; *****
-	-	-	$p(1 \text{ vs. } 4) < 0.05$	$p(1 \text{ vs. } 4) < 0.05$
AngBI (%)				
Group TB	36.85 (23.02)	29.58 (18.31)	18.80 (19.20)*	17.84 (17.60)*
Group TB/F	23.04 (19.43)	23.72 (17.41)	24.20 (11.05)	25.90 (12.72)
Group TB/IDB	34.09 (29.85)	26.85 (33.08)	14.86 (12.82)*	14.17 (14.43)*
Group TB/RIDB	33.25 (26.85)	20.89 (16.59)	12.23 (10.88)**	11.44 (10.23)**
-	-	$p(1 \text{ vs. } 4) < 0.05;$	$p(1 \text{ vs. } 3) < 0.05; p(1 \text{ vs. } 4) < 0.05$	$p(1 \text{ vs. } 2) < 0.05; p(1 \text{ vs. } 3) < 0.05; p(1 \text{ vs. } 4) < 0.05; p(2 \text{ vs. } 3) < 0.01; p(2 \text{ vs. } 4) < 0.01$
IntAngBI (%)				
Group TB	41.68 (27.56)	37.63 (24.45)	23.88 (24.62)	23.48 (25.98)
Group TB/F	30.30 (23.06)	29.97 (21.83)	21.80 (10.72)	33.75 (17.59)
Group TB/IDB	39.41 (32.63)	31.16 (34.81)	16.78 (16.00)*	17.65 (20.52)*
Group TB/RIDB	37.10 (30.57)	26.10 (24.60)	14.91 (14.58)*	15.42 (14.95)*
-	-	$p(1 \text{ vs. } 4) < 0.05$	$p(1 \text{ vs. } 3) < 0.05; p(1 \text{ vs. } 4) < 0.05;$ $(2 \text{ vs. } 3) < 0.05; p(2 \text{ vs. } 4) < 0.05$	$P(1 \text{ vs. } 2) < 0.05; P(1 \text{ vs. } 3) < 0.05; P(1 \text{ vs. } 4) < 0.05; P(2 \text{ vs. } 3) < 0.05; P(2 \text{ vs. } 4) < 0.01$

Abbreviations: AngBI, angulated bleeding score; FMPS, full-mouth plaque score; IntFMPS, interdental full-mouth plaque score; GI, gingival index; IntGI, interdental gingival index; IntAngBI, interdental angulated bleeding score; TB, toothbrush; TB/F, toothbrush plus dental floss; TB/IDB, toothbrush plus interdental brushes; TB/RIDB, toothbrush plus rubber interdental picks.

* $p < 0.05$ vs. T-7.

** $p < 0.01$ vs. T-7.

*** $p < 0.001$ vs. T-7.

**** $p < 0.05$ vs. T0.

***** $p < 0.01$ vs. T0.

***** $p < 0.001$ vs. T0.

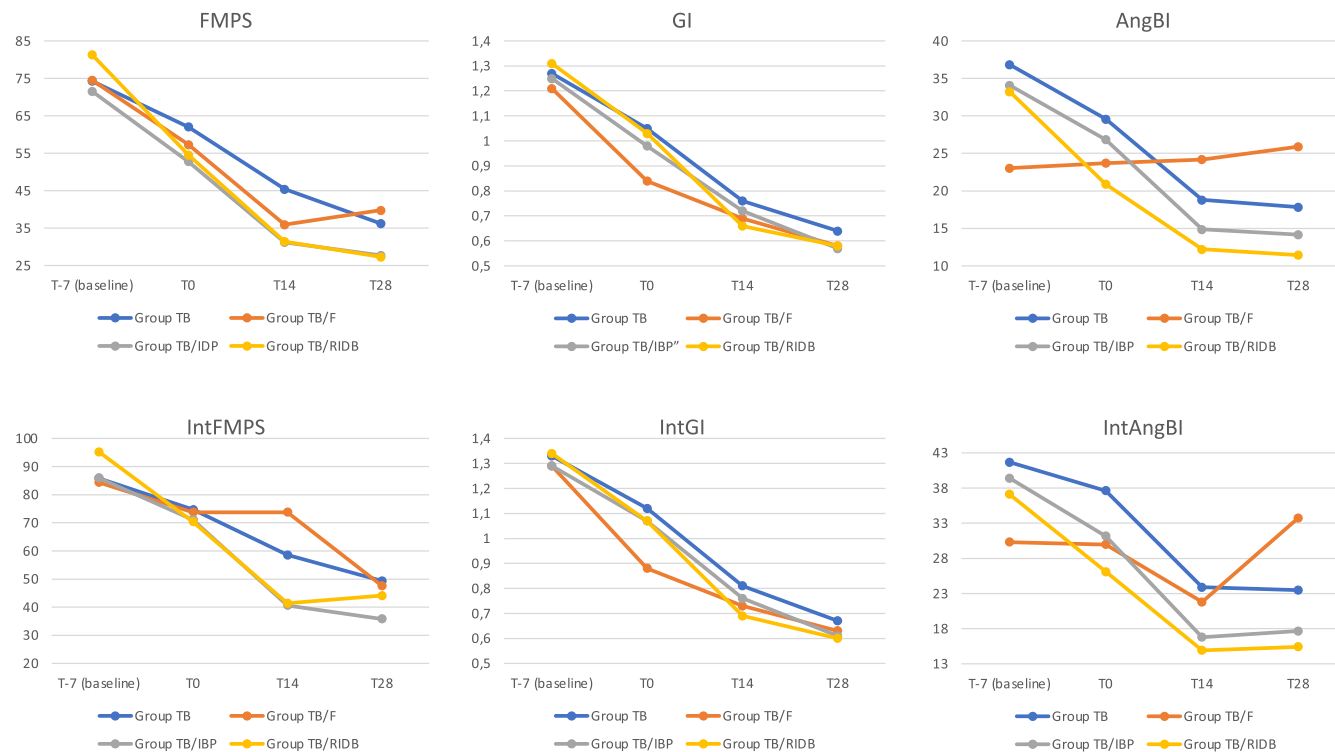


FIGURE 3 Clinical periodontal parameters among groups at different timepoints. AngBI, angulated bleeding index; GI, gingival index; FMPS, full-mouth plaque score; IBP, interdental brushes; PPD, periodontal pocket depth; REC, recession.

'manual toothbrush + waxed dental floss' ($p < 0.05$ and $p < 0.01$, respectively).

4 | DISCUSSION

Our findings indicate that the usage of toothbrush, alone or with the additional use of interdental devices, is successful in reducing plaque levels and consequently gingival inflammation in a population with interdental attachment loss due to periodontitis. Additional benefits in terms of plaque and gingival inflammation, as measured with angulated bleeding index, were noted when interdental brushes and rubber picks were used as compared to the usage of toothbrushing alone or dental floss.

Toothbrushing determined a significant reduction of plaque and inflammation. Our data were corroborating this concept and they showed a reduction of overall plaque level, which is within the expected range noticed in subjects without periodontitis after one single-brushing exercise.^{6,14}

The importance of interdental devices in terms of preservation of oral and dento-gingival health is one of the fundamentals of oral hygiene as higher reduction of plaque and inflammation is noted.²⁵ In our study, dental floss did not add any benefit in terms of plaque and gingival inflammation when compared to toothbrushing alone. This should not be surprising considering the available evidence on flossing indicating a lack of additional benefits.²⁶ This might be due to the manual dexterity and the lack of compliance of the patients in regard to flossing.²⁷ Moreover, in patients with periodontitis the

interdental attachment loss may also expose part of the root structure which is often presenting with concavities and grooves, which may diminish the efficiency of flossing.

Our data are confirming that plaque and inflammation are further reduced when interdental brushes are used. In this group the higher reductions were noted. The fact that interdental brushes have shown a higher plaque reduction than toothbrushing alone or flossing is not a novel finding and our data are confirmatory of the previous evidence.^{8,28} Nevertheless, a specific focus on periodontitis patients has not been frequent in previous trials. Interdental brushes showed to reduce plaque and gingival inflammation even during the unclean phase, indicating efficiency in removing mature plaque and consequently gingival inflammation. Accordingly, our findings are corroborating the current recommendations on periodontitis-affected patients indicating interdental brushes as the instrument of first choice to be used in such specific population unless trauma for brushing is foreseen.^{29,30}

Interestingly, no information is available on rubber dental picks in a population diagnosed with periodontitis. In our previous study we have indicated that in young subject with intact papilla a higher plaque and inflammation reduction was noted over toothbrushing alone and toothbrushing with flossing.¹⁴ These findings were further confirmed in periodontitis-affected patients in which no differences among interdental brushes were noted throughout the study.

The authors are aware of the strength and limitations of the current study. As in the companion paper two distinct phases were tested. The first one, the unclean phase, allows to resemble a 'real

TABLE 3 Reduction of clinical periodontal parameters at different timepoints

Variable	Baseline-T28	T0-T28
FMPS		
Group TB	38.04 (30.69)	25.82 (23.84)
Group TB/F	37.38 (25.47)	20.22 (30.27)
Group TB/IDB	45.63 (25.61)	26.91 (32.25)
Group TB/RIDB	53.97 (17.88)	27.23 (23.81)
	-	-
IntFMPS		
Group TB	36.46 (38.29)	25.35 (27.82)
Group TB/F	39.91 (26.57)	19.50 (33.15)
Group TB/IDB	52.54 (33.61)	32.93 (39.18)
Group TB/RIDB	51.15 (31.41)	21.55 (49.73)
	p (1 vs. 3) < 0.05; p (1 vs. 4) < 0.05; p (2 vs. 3) < 0.05; p (2 vs. 4) < 0.05;	p (1 vs. 2) < 0.05; p (1 vs. 3) < 0.05; p (2 vs. 3) < 0.05
GI		
Group TB	0.63 (0.39)	0.41 (0.34)
Group TB/F	0.68 (0.42)	0.19 (0.70)
Group TB/IDB	0.72 (0.48)	0.38 (0.59)
Group TB/RIDB	0.73 (0.53)	0.38 (0.47)
	-	-
IntGI		
Group TB	0.66 (0.40)	0.44 (0.37)
Group TB/F	0.70 (0.53)	0.18 (0.81)
Group TB/IDB	0.72 (0.50)	0.42 (0.62)
Group TB/RIDB	0.74 (0.54)	0.47 (0.51)
	-	-
AngBI (%)		
Group TB	19.01 (23.15)	11.73 (13.07)
Group TB/F	-1.12 (22.10)	-3.61 (23.36)
Group TB/IDB	20.86 (22.89)	11.83 (25.83)
Group TB/RIDB	21.80 (29.53)	8.05 (14.63)
	p (1 vs. 2) < 0.05; p (2 vs. 3) < 0.05; p (2 vs. 4) < 0.05	p (1 vs. 2) < 0.05; p (2 vs. 3) < 0.05; p (2 vs. 4) < 0.05
IntAngBI (%)		
Group TB	18.19 (28.67)	14.14 (17.69)
Group TB/F	-1.19 (26.46)	-5.52 (31.73)
Group TB/IDB	22.93 (22.20)	12.61 (24.65)
Group TB/RIDB	20.12 (31.32)	8.93 (20.74)
	p (1 vs. 2) < 0.05; p (2 vs. 3) < 0.05; p (2 vs. 4) < 0.05	p (1 vs. 2) < 0.05; p (2 vs. 3) < 0.05; p (2 vs. 4) < 0.05

Abbreviations: AngBI, angulated bleeding score; FMPS, full-mouth plaque score; IntFMPS, interdental full-mouth plaque score; GI, gingival index; IntGI, interdental gingival index; IntAngBI, interdental angulated bleeding score; TB, toothbrush; TB/F, toothbrush plus dental floss; TB/IDB, toothbrush plus interdental brushes; TB/RIDB, toothbrush plus rubber interdental picks.

life' situation whereas the clean phase it is a 4-week plaque and gingival inflammation study that follows the suggestions of Council on Scientific Affairs of the ADA of unsupervised usage of devices.³⁰ Moreover, the study subjects with periodontitis allows to gather important information on the type of patients, which may need oral hygiene improvements the most. In the study, smokers were also included; however, their presence was evenly distributed among groups and considered in the statistical analysis by duly adjusting the data for smoking status. The trial started in 2011, but it was put on halt because of other priorities in our research group. Nevertheless, the randomization sequence was established prior to the beginning of the study and maintained throughout the study. The examiner was calibrated regularly each year during the whole duration of the study. The authors are also aware that calibration was done on the parameter of CAL instead of FMPS, which was defined as the primary outcome of the study. However, the calibration on CAL constitutes the normal routine in the trials of our research group. Finally, the study did not formally assess compliance, as that no daily questionnaires on the usage of the devices were given to the patients, and adherence to the trial was investigated only verbally. However, the results obtained, as stressed previously, are indicating that the changes are in line with the expected ranges. It is important to underline that the latest evidence on efficacy of mechanical oral hygiene devices in patients under periodontal maintenance programme was not able to recommend any specific oral hygiene device due to the lack of high-quality studies on the subject.³¹

In conclusion, toothbrushing or toothbrushing with the additional use of interdental devices demonstrated efficacy in reducing the plaque levels and consequently gingival inflammation in periodontitis population over the period of 5 weeks. Within the limitations of the study, interdental brushes and interdental picks have shown higher plaque removal and gingival inflammation reduction than tooth brushing alone and toothbrushing and flossing. Further studies with larger samples are needed in order to elucidate the clinical meaningfulness of such differences.

5 | CLINICAL RELEVANCE

5.1 | Scientific rationale for study

The oral hygiene protocols involving interdental cleaning have been recognized as important in a periodontally compromised population. Therefore, this study was designed to determine the efficacy of four different cleaning modalities in terms of plaque and inflammatory scores reduction.

5.2 | Principal findings

Plaque and gingival inflammatory scores were reduced in all groups. The use of interdental brushes and rubber interdental picks showed to be equally efficient. Both devices were more efficient than

manual toothbrush alone, or manual toothbrush with the adjunction of interdental floss.

5.3 | Practical implications

The everyday use of interdental brushes or rubber interdental picks enables patients with periodontitis to achieve a high standard of interdental cleaning. The clinical recommendations should respect the manual ability and personal preferences of every single patient.

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CONFLICT OF INTERESTS

No conflict of interest has to be declared.

AUTHOR CONTRIBUTIONS

G.F. and G.S. conceived the ideas; N.M., P. Ma., M.U., I.R., M.T. and P.M. collected the data; G.S. analysed the data; and P. Ma. and M.U. led the writing.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the author, [G.S.], upon reasonable request.

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