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ORIGINAL ARTICLE

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Non-surgical retreatment versus papillary preservation flap surgery for residual pockets: A randomized controlled trial with clinical and patient-reported outcomes

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Abstract

Aim: To compare the efficacy of non-surgical re-instrumentation (NSR) and papillary preservation flap (PPF) surgery at single-rooted teeth with residual pockets.

Materials and Methods: Patients with at least a residual pocket depth (PD ≥ 5 mm) after Steps I and II were enrolled and randomly assigned to receive NSR or PPF surgery. The primary outcome was PD reduction, and secondary outcomes were clinical attachment level (CAL) change and patient-reported outcome measures (PROMs). Outcome variables were measured at baseline, 3 and 6 months. The examiner was blinded. Statistical analysis, one site for each patient, included descriptive statistics and analysis of covariance.

Results: Forty-six participants were enrolled, and one patient dropped out in the PPF group. After 6 months, both treatments resulted in significant PD reduction (1.3 ± 1.2 mm, $p = .009$ NSR; 2.0 ± 0.7 mm, $p < .001$ PPF) and CAL gain (1.0 ± 2.4 mm, $p = .031$ NSR; 1.4 ± 0.8 mm, $p < .001$ PPF). PD reduction between groups was not statistically significant (diff: 0.6 mm; 95% confidence interval [CI] [−0.3 to 1.5]; $p = .167$). Pocket closure was 61% NSR versus 86% PPF ($p = .091$). Smoking was associated with less PD reduction of almost 1 mm in both treatments. Treatment time was longer for PPF surgery, but PROMs and post-operative pain were similar between groups.

Conclusions: Both NSR and PPF reduced PD without significant difference between treatments at 6 months. PPF surgery may offer faster PD reduction, but smoking habits reduce treatment efficacy.

KEYWORDS

non-surgical re-instrumentation, papillary preservation flap, patient-reported outcomes, RCT, residual periodontal pockets, Step III

Clinical Relevance

Scientific rationale for study: Few data provided information on the potential benefits of non-surgical re-instrumentation (NSR) at residual periodontal pockets compared with papillary preservation flap (PPF).

Principal findings: NSR and PPF surgery are equally effective in terms of pocket depth (PD) reduction 6 months after treatment. Smoking habits reduced the magnitude of the expected outcomes.

Practical implications: Both procedures are effective to reduce residual pockets. The clinical decision-making in applying NSR or PPF is influenced by several factors as general patient needs, number of residual pockets and contiguity with deeper pockets.

1 | INTRODUCTION

1.1 | Background

The ideal goal of comprehensive periodontitis treatment is to achieve periodontal disease stability with minimal bleeding on probing (BoP), shallow pocket depth (PD) and stable clinical attachment level (CAL) (Lang & Bartold, 2018). Steps I and II of periodontal treatments are associated with a PD reduction and a CAL gain (Eberhard et al., 2008; Lang et al., 2008; Suvan et al., 2020), and the extent of clinical improvement is influenced by patient-related factors (smoking habits, plaque control) and tooth-related factors (multi-rooted anatomy) (Tomasi et al., 2007). Minimal PD after Steps 1 and 2 therapy (PD ≤ 4 mm) without BoP (Chapple et al., 2018; Schätzle et al., 2004) is associated with higher periodontal stability, while PD ≥ 6 mm and BoP scores ≥30% are risk factors for future tooth loss (Claffey & Egelberg, 1995; Loos & Needleman, 2020; Matuliene et al., 2008).

Residual bleeding pockets following cause-related therapy are considered an indication for further periodontal treatment (Sanz et al., 2020). For deep pockets associated with intra-bony defects ≥3 mm, periodontal regeneration is highly recommended (Nibali et al., 2020). However, in cases of moderate residual pockets with minimal intra-bony components, non-surgical re-instrumentation (NSR) is suggested, while for deep residual pockets, flap surgery is suggested (Sanz et al., 2020).

The effectiveness of NSR following initial scaling and root planing (Badersten et al., 1984) is a matter of debate, even if it may potentially reduce the need for surgical intervention. Classical periodontal trials comparing scaling and root planing with surgery have shown that flap elevation is more effective in terms of CAL gain and PD reduction for moderate and deep pockets, despite an increased incidence of gingival recession (Rec) at sites with pocket probing depths (PPDs) < 6 mm (Heitz-Mayfield et al., 2002; Sanz-Sánchez et al., 2020). Moreover, modern papillary preservation flap (PPF) surgery appears to enhance the clinical outcome of traditional access flap (AF) procedures by promoting wound healing stability and improving final clinical results (Barbato et al., 2020; Graziani et al., 2012). More recently, a minimally invasive non-surgical technique (MINST) has been described to minimize the removal of soft tissue during root debridement, aiming to promote more effective healing compared with classical scaling and root planing (Kučič & Gâsperčič, 2023; Ribeiro et al., 2011). To our knowledge, no previous randomized trial has compared the clinical efficacy of NSR and PPF surgery in treating residual periodontal pockets.

1.2 | Aims

The primary aim of this randomized controlled trial (RCT) was to compare NSR versus PPF surgery in terms of PD reduction. Secondary outcomes were CAL gain, gingival recession and pocket closure. Moreover, patient-reported outcome measures (PROMs) were evaluated.

2 | MATERIALS AND METHODS

2.1 | Trial design and participants

The present protocol was registered in Clinicatrial.gov (NCT05460988). The CONSORT statement checklist (http://www.consort-statement.org) was used for reporting the results. This study was a parallel, single-centre, examiner-blinded, randomized clinical trial. Experimental procedures were conducted according to the principles of the Declaration of Helsinki on study involving human subjects, as revised in 2004. This study was authorized by the Ethical board CEAVC (Comitato Etico Area Vasta Centro, Toscana, Italia. n° 18876_spe). The participants had to sign the informed consent.

2.1.1 | Inclusion criteria

- Age ≥18 years old.
- Patients affected by periodontitis and re-evaluated 12–14 weeks after Steps I and II of periodontal therapy.
- At least one inter-dental site with PD ≥ 5 mm/BoP+ or PD ≥ 6 mm and an intra-bony component of the defect ≤3 mm at x-ray examination.
- Patient smoking less than 10 cigarettes/day.
- No systemic antibiotic therapy in the last 3 months.
- Full-mouth plaque score (FMPS) < 15% at the baseline of the study (clinical re-evaluation).
- No previous periodontal surgery at the experimental tooth.

2.1.2 | Exclusion criteria

- Molar tooth.
- Chronic diseases affecting connective tissue.

- Diabetes.
- Pregnancy or lactating.
- Furcation involvement.
- Crowned tooth.
- Severe tooth mobility, defined according to the Miller class III index (Miller, 1950).
- Radiographical horizontal bone resorption exceeding 50% of the root.

2.1.3 | Randomization and allocation concealment

The patients were randomly assigned to one of the two treatment groups. A computer-generated blocked randomization list was used. Sealed opaque envelopes, sequentially numbered, were prepared. A different person, instructed by the statistician, assigned a sealed envelope containing the treatment for each patient. After the administration of local anaesthesia, a person not involved in diagnostic or therapeutic procedures communicated the assigned group to the operator.

2.1.4 | Blinding

A single-blinded examiner (W.C.) was trained for clinical and radiographic measurements and attended a calibration session, reporting an intra-class correlation coefficient of 0.88 (95% confidence interval [CI] 0.83; 0.92). However, it was not possible to maintain blindness for the operator or patient.

2.2 | Treatment procedure

All the experimental treatments were performed at the Unit of Periodontology and Periodontal Medicine at the University of Florence (Italy) by an expert operator (LB) with more than 10 years of experience in periodontal non-surgical and surgical treatments. Experimental treatments were performed between November 2022 and May 2023.

2.2.1 | Re-evaluation (baseline of the study)

Steps I and II of periodontal treatment (MINST, Ribeiro et al., 2011) were provided by periodontology residents under the close supervision of tutors from the EFP Master Program at the University of Florence. Patients were visited monthly for reinforcement of oral hygiene practices up to re-evaluation. Patients who, 12–14 weeks after completing non-surgical periodontal therapy (NSPT), were diagnosed with at least one interdental site with PD ≥ 5 mm and an intra-bony component of the defect ≤3 mm on x-ray were considered for possible enrolment. An experimental site was selected for each patient based on the inclusion criteria. In the case of more than one site meeting the inclusion criteria, the deepest affected was considered the experimental one. While in the case of similar sites, the decision was made by tossing a coin.

2.2.2 | NSR (control group)

The subgingival debridement was performed after the administration of local oral anaesthesia (articaine 4% with epinephrine 1:100,000, 1.8 mL). Following the principles of MINST (Ribeiro et al., 2011), under 3.4× magnification, a periodontal tip on an ultrasonic instrument (EMS) and mini Gracey's curettes were used, depending on the tooth surface to be treated to obtain a smooth root surface. No adjunctive treatment was planned (Figure 1).

2.2.3 | PPF surgery (test group)

After the administration of local anaesthesia (articaine 4% with epinephrine 1:100,000, 1.8 mL), a flap was raised according to the principles of minimally invasive periodontal surgery with PPF (Cortellini & Tonetti, 2007). The decision to raise the flap only buccal/palatal or on both sides depended on the possibility of properly accessing the root and the defect (Cortellini & Tonetti, 2009; Schincaglia et al., 2015; Trombelli et al., 2009). Roots were carefully debrided; ostectomy/osteoplasty was never performed. Absorbable polyglactin 6-0 sutures were used (Figure 1).

2.2.4 | Post-treatment instructions

Test group patients were instructed to apply an ice bag during the first 4 hours. Sutures were removed after 1 week. Patients were instructed to resume tooth brushing after 2 weeks, using a soft toothbrush during the third and fourth weeks after the surgery. Inter-dental brushing was resumed after 4 weeks.

Patients in the re-instrumentation group were instructed to routinely continue tooth brushing and inter-dental brushing after treatment. Chlorhexidine mouth rinses (0.12%) were prescribed twice a day for 2 weeks, and ibuprofen 600 mg if needed (maximum 3 tablets/day) after both re-instrumentation and PPF surgery. Supragingival plaque control and home oral hygiene reinforcement were conducted at 1, 3 and 6 months post-treatment.

2.3 | Outcomes

A case report form was used to collect all the data. The following characteristics were recorded at baseline evaluation: age, gender,

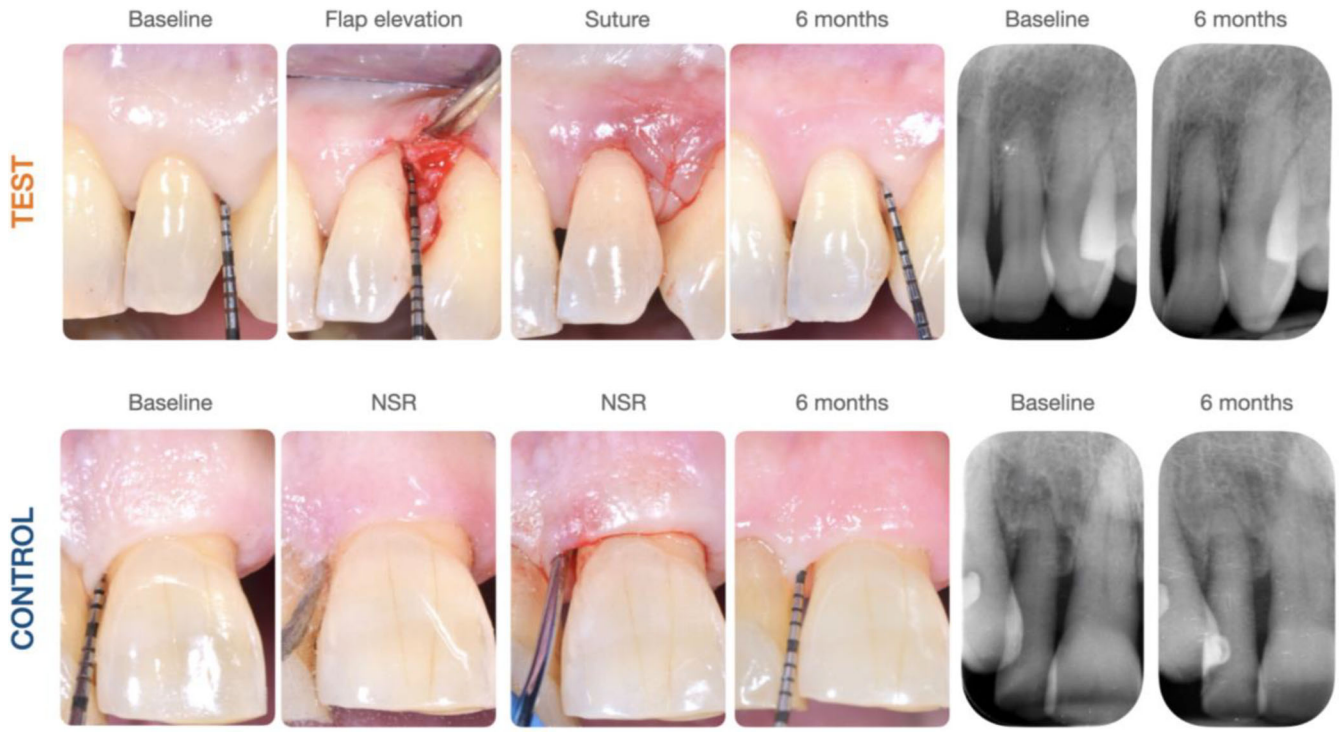

FIGURE 1 Clinical cases in control (non-surgical re-instrumentation [NSR]) and test (papillary preservation flap [PPF] surgery) groups.

smoking habits (Y/N, number of cigarettes/day) and medications/drugs.

2.3.1 | Clinical measurements

The following clinical measures were registered at baseline, 3 and 6 months after therapy with a standardized periodontal probe (UNC 15 probe, HuFriedy Group, Chicago, IL, USA):

- PD (pocket depth): distance in mm between the gingival margin (GM) and the base of the pocket.
- Rec (Gingival recession): distance in mm between the cemento-enamel junction (CEJ) and the GM.
- BoP: yes/no until 10 s after probing.
- PI (Plaque Index): yes/no.
- KT (Keratinized tissue): distance in mm between the GM and the muco-gingival junction (MJG).
- MJG measured at the middle buccal point.
- Tooth mobility: class 0, 1, 2, 3 (Miller, 1950).
- CAL: estimated as the sum of PD and REC.
- FMPS and FMBS (full-mouth bleeding score).
- CP–TP: the distance in mm from the tip of the papilla and the contact point of mesial and distal to the experimental tooth.

PD, Rec, BoP, PI and the estimation of CAL were measured at six sites per tooth: mesio-buccal, mid-buccal, ditto-buccal, mesio-lingual, mid-lingual and disto-lingual.

2.3.2 | Pocket closure

Pocket closure (Wennström et al., 2005) was calculated at 6 months at the experimental site as PD ≤ 4 mm and absence of BoP.

2.3.3 | Intra-operative measurements

Chair time in minutes from the delivery of local anaesthesia to the end of the procedure was recorded.

2.3.4 | Clinical measurements to monitor early healing

Oedema (yes/no), spontaneous bleeding (yes/no) and any other complications were recorded at 1, 2 and 4 weeks after therapy.

2.3.5 | Radiographic examinations

Periapical x-rays were taken at baseline and after 6 months. The following measurements were performed:

- CEJ–BC: distance between CEJ and bone crest (BC) measured at the experimental site in mm.

- CEJ–RA: distance between CEJ and root apex (RA). This measurement was used to standardize possible misalignments between pre- and post-treatment x-rays.
- BC–DB: distance between BC and bottom of the defect in mm.

2.3.6 | Questionnaires, PROMs and total cost

Immediately after the treatment, the following data were recorded:

- Hardship perception of the procedure using a visual analogue scale (VAS) (0–100).
- Pain perceived during the procedure using a VAS (0–100).

One, 2 and 4 weeks after the treatment, the following data were recorded:

- Number of analgesic/anti-inflammatory tablets (number).
- Post-surgical discomfort (number of days).
- Post-surgical pain using a VAS (0–100).
- Tooth hypersensitivity (Yes/No). In case of positivity, it was quantified using the VAS (0–100).

After 6 months, data on aesthetic satisfaction, overall satisfaction and tooth hypersensitivity (VAS 0–100) were collected.

The total cost of the treatment per patient was calculated as the sum of the fee for each visit/treatment in both test and control groups. Possible complications and the related management costs were also considered.

2.4 | Sample size

A possible difference between treatments of 0.5 mm for PD reduction was considered after 6 months, using a standard deviation of 0.55 mm (Tomasi et al., 2008). A two-sided 5% significance level and a power of 80% was considered, leading to a total sample size of 46 patients (23 patients per arm), given an anticipated dropout rate of 10%.

2.5 | Statistical method

Descriptive statistics using mean and standard deviation for quantitative variables and frequencies and percentages for qualitative variables were employed. The statistical unit was the experimental site.

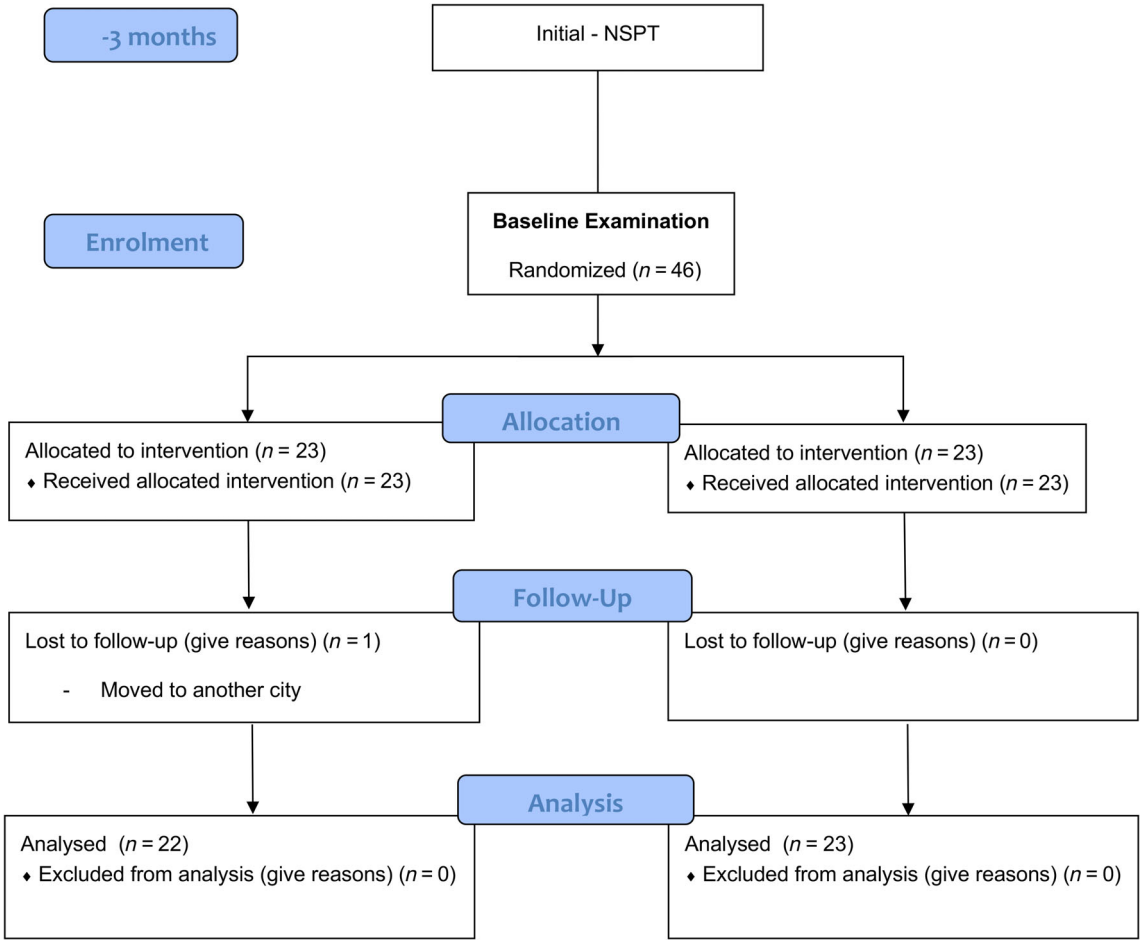

FIGURE 2 CONSORT flow diagram of the study.

The primary outcome was PD reduction at 6-month follow-up, and secondary outcomes included CAL gain, pocket closure, chair time, PROMs, overall satisfaction and aesthetic satisfaction.

Analysis of covariance was conducted for PD reduction, CAL gain, recession reduction, KT change, CEJ–BC reduction and BC–BD reduction between baseline and 6 months, using the baseline value as a covariate. For pocket closure and dichotomous variables, Fisher exact test was performed. Student's *t*-tests were used for variables such as chair time, perception of hardship during the procedure, pain experienced during the procedure, number of anti-inflammatory tablets taken, overall satisfaction, aesthetic satisfaction and dental hypersensitivity. Multiple testing correction was not applied because the focus was on a single primary confirmatory variable (PD gain at 6-month follow-up) while the other variables were considered exploratory.

3 | RESULTS

3.1 | Patients and defect characteristics at baseline

A total of 46 patients participated in the study, 23 in each group (Figure 2). (For details on demographics and patients' characteristics see Tables 1 and 2). In the PPF group, FMPS was 12.3% ± 3.7 and FMBS was 16.3 ± 6.1. In the NSR group, FMPS was 12.5% ± 4.8 and FMBS was 16.2 ± 3.7. At the experimental site, baseline PD was 5.7 ± 0.6 in the PPF group and 5.6 ± 0.7 in the NSR group, while CAL was 6.4 ± 1.3 and 6.6 ± 1.6, respectively. BoP was detected at 74% of sites in the PPF group and 78% in the NSR group. Smokers accounted for 43% in PPF and 39% in NSR. No significant difference was detected between groups at baseline.

TABLE 1 Demographics, patients' characteristics and experimental teeth at baseline.

	Re-instrumentation (23 patients)	Flap (23 patients)
Age (yy)	55 ± 9.4 (35; 69)	55.7 ± 8.7 (37;73)
Gender F (*n*/%)	15 (65%)	16 (70%)
Systemic diseases no (*n*/%)	19 (83%)	16 (70%)
Medication/drugs yes (*n*/%)	7 (30%)	9 (39%)
Smoker (*n*/%)	9 (39%)	10 (43%)
Cigarettes/die	8 ± 4	9 ± 4.7
Before NSPT		
N teeth	26.6 ± 4.3	24.5 ± 3.8
1–3 mm PD	92 ± 33.3	79.2 ± 32.3
4–5 mm PD	36 ± 19.6	40.7 ± 13.5
≥6 mm PD	19.2 ± 14.3	27.2 ± 23.5
FMPS	63.2 ± 22.5	61.7 ± 25.3
FMBS	60.3 ± 17.9	60.6 ± 24.6
After NSPT (baseline)		
N teeth	24.3 ± 4.3	24.1 ± 3.9
1–3 mm PD	112.2 ± 31.5	101 ± 24.3
4–5 mm PD	26.2 ± 14.4	30.8 ± 15.2
≥6 mm PD	7.3 ± 7.7	13 ± 14
FMPS	12.5 ± 4.8	12.3 ± 3.7
FMBS	16.2 ± 3.7	16.3 ± 6.1
Experimental tooth		
Maxillary incisor	7	11
Maxillary canine	1	4
Maxillary premolar	4	3
Mandibular incisors	1	2
Mandibular canine	4	-
Mandibular premolar	6	3
Experimental site (Initial) (before NSPT)		
PD	6.3 ± 0.9	6.6 ± 0.8
CAL	7 ± 1.5	7 ± 1.1
Rec	0.6 ± 1.1	0.4 ± 1

Abbreviations: CAL, clinical attachment level; FMBS, full-mouth bleeding score; FMPS, full-mouth plaque score; NSPT, non-surgical periodontal therapy; PD, pocket depth; Rec, recession.

3.1.1 | Surgical and post-surgical period

The mean treatment duration was 20.5 ± 7.1 minutes for the PPF group and 6.9 ± 1.5 min for the NSR group (difference: 13.6; 95% CI [10.5; 16.7]; $p < .001$). In two cases in the PPF group, the operator decided to elevate the papilla from the vestibular to the palatal side, to improve visibility and the ability to instrument the root surface. Both procedures were well tolerated (VAS 0–100: 7.0 ± 16.5 for test vs. 3.5 ± 8.3 for control) and associated with low post-operative pain (VAS 0–100: 4.6 ± 9.8 for test vs. 2.5 ± 4.9 for control) and discomfort (VAS 0–100: 0.9 ± 1.3 for test vs. 0.8 ± 1.6 for control) in the first post-operative week (Table 4). No adverse event was reported. PPF patients took a mean of 0.5 ± 0.8 painkillers in the first week, while NSR patients did not take any painkillers (difference: 0.5; 95% CI [0.1–0.8]; $p = .006$).

3.1.2 | Clinical outcomes

One patient in the PPF group dropped out after 2 weeks, and one patient in the NSR group developed a periodontal abscess at 6 months. PD reduction was 2.2 ± 0.7 mm in the PPF group versus 1.3 ± 1.5 mm in the NSR group at 3 months, with a mean difference favouring PPF (difference: 0.8 mm; 95% CI [0.1–1.4]; $p = .024$). CAL gain was 1.8 ± 0.9 mm in the PPF group versus 1.0 ± 1.8 mm for the NSR group; KT change was −0.4 ± 0.8 mm versus 0.1 ± 0.5 mm, respectively. More NSR-treated sites were BoP+ (61% vs. 27%; $p = .036$). Recession increased by 0.4 mm in both groups, and the difference was not significant (difference: 0.0 mm; 95% CI [−0.4 to 0.4]; $p = .950$) (Table 2; Figure 3).

PD reduction was 2.0 ± 0.7 mm (95% CI [1.7–2.3]; $p < .001$) in the PPF group and 1.3 ± 1.0 mm (95% CI [0.3–2.2]; $p = .009$) in

TABLE 2 Clinical and radiographic measurements at baseline, 3 and 6 months.

	Baseline		3 months		6 months	
	NSR $N = 23$	PPF $N = 23$	NSR $N = 23$	PPF $N = 22$	NSR $N = 23$	PPF $N = 22$
PD (mm)	5.6 ± 0.7	5.7 ± 0.6	4.2 ± 1.3	3.5 ± 0.7	4.3 ± 2.0	3.7 ± 0.6
CAL (mm)	6.6 ± 1.6	6.4 ± 1.3	5.7 ± 2.1	4.6 ± 1.5	5.6 ± 2.5	5 0 ± 1.3
Rec (mm)	1.0 ± 1.1	0.7 ± 1.1	1.4 ± 1.2	1.1 ± 1.3	1.3 ± 1.2	1.3 ± 1.2
BoP+	18 (78%)	17 (74%)	14 (61%)	6 (27%)	7 (30%)	3 (14%)
Plaque+	3 (13%)	6 (26%)	7 (30%)	12 (55%)	3 (13%)	3 (14%)
KT buccal (mm)	3.6 ± 1.6	4.1 ± 1.1	3.7 ± 1.4	3.7 ± 1.3	3.5 ± 1.5	3.8 ± 1.4
Mobility (yes)	3 (13%)	5 (22%)	3 (13%)	5 (23%)	5 (22%)	8 (36%)
CP–TP (mm)	2.8 ± 1.7	3.4 ± 2.5	-	-	3.0 ± 1.8	3.8 ± 2.7
BS (mm)	6.7 ± 1.0	6.6 ± 0.7	-	-	-	-
CEJ–BC (mm)	4.5 ± 1.9	4.1 ± 1.6	-	-	4.1 ± 1.4	4.0 ± 1.6
BC–BD (mm)	1.4 ± 1.0	± 0.9	-	-	1.3 ± 1.3	0.9 ± 0.7
FMPS (%)	12.5 ± 4.8	12.3 ± 3.7	-	-	12.4 ± 4.5	10.9 ± 3.9
FMBS (%)	16.2 ± 3.7	16.3 ± 6.1	-	-	14.2 ± 4.9	12.3 ± 5.6

Abbreviations: BC–BD, the distance between the bony crest and the bottom of the defect measured on x-ray; BOP, bleeding on probing; BS, bone sounding; CAL, clinical attachment level; CEJ–BC, distance between the cemento-enamel junction and the bony crest measured on x-ray; CP–TP, the distance between the contact point and the tip of the papilla; FMBS, full-mouth bleeding score; FMPS, full-mouth plaque score; KT, keratinized tissue; PD, pocket depth; Rec, recession.

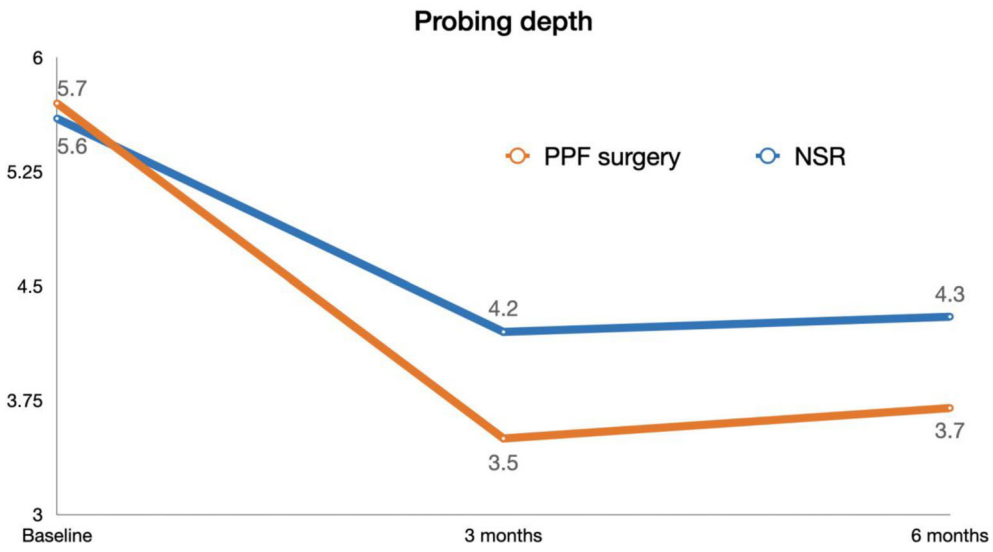

FIGURE 3 Pocket depth (PD) mean at different points in time in the test group and control group. NSR, non-surgical re-instrumentation; PPF, papillary preservation flap.

the NSR group at the 6-month follow-up. The difference favoured the PPF group, although it was not statistically significant (difference: 0.6 mm; 95% CI [−0.3 to 1.5]; $p = .167$). CAL gain at 6 months was 1.4 ± 0.8 mm (95% CI [1.0–1.7]; $p < .001$) in the PPF group and 1.0 ± 2.4 mm (95% CI [−0.1 to 1.0]; $p = .071$) in the NSR group (difference: 0.5 mm; 95% CI [−0.6 to 1.6]; $p = .368$). Recession at 6 months increased by 0.3 ± 0.6 mm (95% CI [0.0–0.6]; $p = .031$) in the NSR group and by 0.6 ± 0.5 mm (95% CI [0.4–0.9]; $p < .001$) in the PPF group. The difference favoured the NSR group, although not reaching a statistical significance (difference: 0.3 mm; 95% CI [0.7–0.7]; $p = .073$). The differences in terms of KT change (difference: −0.2 mm; 95% CI [−0.7 to 0.3]; $p = .504$) and CP–TP (difference: −0.3; 95% CI [−0.6 to 0.1]; $p = .135$) were not significant. Pocket closure at 6 months was higher in the PPF group (86%) than in the NSR group (61%), but it almost reached statistical significance ($p = .091$). A secondary analysis found that smoking was associated with less PD reduction (difference: −1.0 mm; 95% CI [−1.8 to −0.1]; $p = .036$) and CAL gain (difference: −1.1 mm; 95% CI [−2.1 to 0.0]; $p = .053$) at 6 months in both groups.

At 6 months, aesthetic satisfaction was 93.0 ± 12.6 in the NSR group and 89.5 ± 15.3 in the PPF group (difference: −3.5; 95% CI

TABLE 3 Statistical analysis.

	NSR	PPF	Difference	95% CI	*p*-Value
PD red 3 m	1.3 ± 1.5	2.2 ± 0.7	0.8	0.1; 1.4	**.024**
PD red 6 m	1.3 ± 2.1	2.0 ± 0.7	0.6	−0.3; 1.5	.167
CAL gain 3 m	1.0 ± 1.8	1.8 ± 0.9	0.9	0.0; 1.7	.051
CAL gain 6 m	1.0 ± 2.4	1.4 ± 0.8	0.5	−0.6; 1.6	.368
Rec reduction 3 m	−0.4 ± 0.6	−0.4 ± 0.7	0.0	−0.4; 0.4	.950
Rec reduction 6 m	−0.3 ± 0.6	−0.6 ± 0.5	−0.3	−0.7 ± 0.0	.073
KT change 3 m	0.1 ± 0.5	−0.4 ± 0.8	−0.4	−0.8; 0.0	.051
KT change 6 m	0.0 ± 0.7	−0.3 ± 1.0	−0.2	−0.7; 0.3	.504
Pocket closure	14 (61%)	19 (86%)	-	-	.091
CEJ–BC gain 6 m	0.3 ± 1.0	−0.1 ± 1.0	−0.3	−0.8; 0.2	.253
BC–BD gain 6 m	0.1 ± 0.9	0.3 ± 0.5	0.3	−0.2; 0.7	.254
CP–TP gain 6 m	−0.2 ± 0.4	−0.5 ± 0.7	−0.3	−0.6; 0.1	.135
BoP + 3 m	14 (61%)	6 (27%)	-	-	**.036**
BoP + 6 m	7 (30%)	3 (14%)	-	-	.283
Est paz 6 m (VAS)	93.0 ± 12.6	89.5 ± 15.3	−3.5	−11.9; 4.9	.405
Satisf paz 6 m (VAS)	96.1 ± 11.2	95.5 ± 7.4	−0.6	−6.4; 5.1	.825
Sens 6 m (VAS)	7.2 ± 14.8	5.9 ± 15.0	−1.3	−10.2; 7.7	.777
Duration (min)	6.9 ± 1.5	20.5 ± 7.1	13.6	10.5; 16.7	**<.001**
Hard Per (VAS)	3.5 ± 8.3	7.0 ± 16.5	3.5	−4.3; 11.3	.372
Pain procedure (VAS)	2.3 ± 6.7	2.2 ± 6.7	−0.1	−4.1; 3.9	.948

Note: Statistically significant *p*-Value are given in bold.
Abbreviations: BC–BD diff 6 m, the difference between the distance from the bony crest to the bottom of the defect from baseline to 6 months measured on x-ray; BOP + 6 m, sites bleeding on probing at 6 months; CAL gain 3 m, Clinical attachment level gain at 3 months; CAL gain 6 m, Clinical attachment level gain at 6 months; CEJ–BC diff 6 m, the difference between the distance from cemento-enamel junction to bony crest from baseline to 6 months measured on x-ray; CP–TP diff 6 m, the difference among the distance from the contact point to the bottom of the defect from baseline to 6 months; BOP + 3 m, sites bleeding on probing at 3 months; Duration, duration of the treatment; Est paz 6 m, Aestethic satisfaction rated by the patient at 6 months; Hard Per, How hard the patients perceived the procedure; KT change 3 m, keratinized tissue change at 3 months; KT change 6 m, keratinized tissue change at 6 months; PD red 3 m, pocket depth reduction at 3 months; PD red 6 m, pocket depth reduction at 6 months; Rec change 3 m, buccal recession change at 3 months; Rec change 6 m, buccal recession change at 6 months; Satisf Paz 6 m, Overall satisfaction by the patient at 6 months.

[−11.9 to 4.9]; $p = .405$), while overall treatment satisfaction was 96.1 ± 11.2 in the NSR group and 95.5 ± 7.4 in the PPF group (difference: −0.6; 95% CI [−6.4 to 5.1]; $p = .824$). Conversely, sensitivity was 7.2 ± 14.8 in the NSR group and 5.9 ± 15.6 in the PPF group (difference: −1.3; 95% CI [−10.2 to 7.7]; $p = .777$) (Table 3).

The total cost of the treatment was 187€ in the NSR group and 245€ in the PPF group. The patient in the NSR who developed an abscess at 6 months underwent a surgery with an additional cost of 100€.

3.1.3 | X-ray measurements

At baseline, the radiographic intra-bony component of the defect (BC–BD) was 1.3 ± 0.9 mm in the PPF group and 1.4 ± 1 mm in the NSR group. At 6 months, the BC–BD was reduced by 0.3 ± 0.5 mm in the PPF group and 0.1 ± 0.9 mm in the NSR group (difference: 0.3 mm; 95% CI [−0.2 to 0.7]; $p = .254$).

4 | DISCUSSION

Modern periodontal treatment is based on a series of subsequent steps aimed at controlling inflammation associated with the disease. Non-surgical therapy (Steps I and II) has been shown to be highly effective in reducing the initial number of pockets (Citterio et al., 2022; Suvan et al., 2020). Surgical treatment (Step III) is highly recommended for the treatment of deep residual pockets in order to minimize the risk of periodontal reinfection and disease progression at tooth level (Sanz et al., 2020). Strong evidence supports the use of periodontal regeneration in residual pockets with deep (≥3 mm) intra-bony defects (Nibali et al., 2020). In cases of residual pockets, both subgingival re-instrumentation and AF may be suggested (Sanz et al., 2020).

The present RCT was aimed to assess the clinical efficacy of re-instrumentation and PPF surgery in the treatment of residual pockets after Step 2. Both procedures achieved significant benefits 6 months after therapy delivery, with a non-significant difference in terms of PD reduction (primary outcome).

TABLE 4 Statistical analysis.

	NSR	PPF	Difference	95% CI	*p*-Value
1 week					
Oedema (y/n)	1 (4%)	1 (4%)	-	-	1.0
Bleeding (y/n)	1 (4%)	0 (0%)	-	-	1.0
Pain post-op (VAS)	2.5 ± 4.9	4.6 ± 9.8	2.1	−2.5; 6.7	.365
N° painkillers (*n*)	0	0.5 ± 0.8	0.5	0.1; 0.8	**.006**
Discomfort (VAS)	0.8 ± 1.6	0.9 ± 1.3	0.1	−0.8; 0.9	.840
Sens post-op (VAS)	12.5 ± 25	5.7 ± 12	−6.9	−18.5; 4.8	.242
2 weeks					
Oedema (y/n)	0	0	-	-	-
Bleeding (y/n)	0	1 (4%)	-	-	1.0
Pain post-op (VAS)	0.7 ± 2.3	0.3 ± 1.1	−0.3	−1.4; 0.8	.541
N° painkillers (*n*)	0.2 ± 1.0	0.0 ± 0.0	−0.2	−0.7; 0.2	.334
Discomfort (VAS)	0.2 ± 0.8	0.2 ± 1.1	0.1	−0.5; 0.6	.852
Sens post-op (VAS)	11.8 ± 18.8	3.0 ± 6.3	−8.9	−17.4; 0.4	**.041**
4 weeks					
Oedema (y/n)	0	0	-	-	-
Bleeding (y/n)	0	0	-	-	-
Pain post-op (VAS)	0.4 ± 1.4	0.2 ± 1.1	−0.2	−1.0; 0.6	.587
N° painkillers (*n*)	0.0 ± 0.0	0.0 ± 0.0	-	-	1.0
Discomfort (VAS)	0.1 ± 0.6	0.0 ± 0.0	−0.1	−0.4; 0.1	.334
Sens post-op (VAS)	8.5 ± 16.1	6.0 ± 12.2	−2.5	−11.1; 6.1	.564

Note: Statistically significant *p*-Values are given in bold.
Abbreviations: Discomfort, level of discomfort rated by the patients using a VAS 0–100; Pain post-op, pain reported by the patients using a VAS 0–100; Sens post-op; experimental tooth sensitivity rated by the patient using a VAS 0–100.

The re-instrumentation group (NSR group) demonstrated a PD reduction of 1.3 mm and a CAL gain of 1.0 mm at the 6-month follow-up. The magnitude of the reported benefit is comparable to that observed in other trials investigating a secondary debridement procedure, reporting additional PD reduction ranging from 0.7 to 1.3 mm (Aimetti et al., 2004; Jentsch et al., 2021; Kinane & Radvar, 1999; Tomasi et al., 2008). In contrast, an earlier study by Badersten and colleagues reported smaller additional benefits 3 months after re-instrumentation (Badersten et al., 1984). This difference between the present and other recent studies and the classical Badersten's study may be due to differences in subgingival treatment procedures, such as careful root debridement versus heavy scaling/root planning. It is important to note that in Badersten's study, the statistical analysis relied on mean data for pocket distribution, whereas the present study applied a site-specific analysis, allowing detection of minimal clinical variations.

In the PPF surgery group (Test), PD reduction was 2.2 mm at 3 months and 2.0 mm at 6 months, while CAL gain was 1.8 mm and 1.4 mm, respectively. The present outcomes are similar to those reported in a systematic review on the effect of flap surgery (Graziani et al., 2014) and in the control group of a RCT testing periodontal regeneration versus flap surgery at a shallow (≤3 mm) intra-bony defect (Cortellini et al., 1998).

There is evidence that blood clot stability is a critical factor for periodontal healing (Wikesjö et al., 1991), and higher clinical attachment gain for AF performed by means of PPF raised on one side was reported (Barbato et al., 2020; Graziani et al., 2012). Almost all the flaps in this study were raised on one side (i.e., buccal or lingual). Modern RCTs testing minimally invasive periodontal surgery concepts raising the flap on one side reported higher PD reduction and CAL gain compared with this study (Cortellini et al., 2022; Cortellini & Tonetti, 2011; Trombelli et al., 2012). These differences may probably be explained by the defect anatomy and the depth of the intra-bony component.

Altogether, these data suggest that PPF surgery may be associated with a PD reduction of up to 2 mm in this specific clinical scenario.

In the present study, surgery was associated with a significantly higher PD reduction compared with subgingival re-instrumentation of 0.8 mm at 3 months ($p = .024$) and a non-significant difference of 0.6 mm at 6 months ($p = .167$), favouring PPF. It could be speculated that conservative surgery at moderate residual pockets may induce a faster PD reduction compared with NSR, even if no significant difference was reported at the 6-month follow-up. The present outcomes are similar to those reported in an RCT comparing repeated subgingival scaling versus flap surgery (König et al., 2008), although there are significant differences in terms of treated residual pockets, surgical and non-surgical treatments, and statistical analysis. Interestingly, both treatments in the present RCT led to very limited increase of buccal gingival recession (0.3 mm NSR vs. 0.6 mm PPF) and CAL gain (1.0 NSR vs. 1.4 mm PPF), thus supporting the concept that

modern periodontal treatment may lead to effective clinical outcomes limiting side effects. In fact, it should be kept in mind that an increase in gingival recession is an important aesthetic limitation of therapy and a frequent reason for further treatment (Cairo et al., 2020). Furthermore, this study confirmed that smoking habits impair the healing process after treatment (Scabbia et al., 2001; Tomasi et al., 2007), leading to approximately 1 mm less PD reduction at both PPF- and NSR-treated sites with no significant difference among groups.

In the present study, a trend for higher pocket closure (PD ≤ 4 mm and absence of BoP) at the 6-month follow-up was observed at PPF surgery sites compared with NSR sites (86% vs. 61%), although this difference did not reach a statistically significant threshold ($p = .091$). It could be speculated that raising a flap determines a direct access to the root surface, thus allowing for more effective root debridement (Caffesse et al., 1986). Conversely, a clinical trial testing one or two subgingival instrumentations detected minimal improvements in terms of pocket closure. However, these procedures positively influenced the reduction of further surgical needs (Ferrarotti et al., 2023). Furthermore, data from the present study seem to suggest a lower predictability in pocket closure for the NSR group. In fact, PD did not improve at 5 NSR sites, and one patient experienced a periodontal abscess during experimental procedures and needed additional flap surgery. However, the clinical decision to perform surgery or NSR in residual moderate pockets is influenced by several potential factors. From a clinical perspective, the general needs of the patient (e.g., restorative and/or implant therapy), the number of residual pockets at the involved teeth and the contiguity with deep and/or shallower pockets may affect the decision-making process.

Regarding PROMs, PPF treatment duration was significantly longer at 13.6 minutes, but there was no difference in terms of perception of the procedures. Both treatments were highly tolerated by the patients. The mean number of painkillers for the flap group was 0.5 during the first week, while no patient in the re-instrumentation group reported the need for anti-inflammatory drugs. Nevertheless, postoperative pain and discomfort were rated very low in both groups by the patients. These findings confirm that both surgical and nonsurgical treatments at residual pockets are very well tolerated by patients (Tonetti et al., 2004).

The limitations of the study may be associated with very restrictive entry criteria. In fact, only residual pockets at single-rooted teeth and associated with shallow infrabony defects were considered. In addition, the a priori estimate of standard deviation was lower than that obtained in the study for PD reduction. Moreover, a difference of 0.5 mm between treatments was settled as statistically significant but could be questioned from a clinical standpoint. Furthermore, larger, multi-centre studies are also suggested to assess the generalizability of the present outcomes.

In conclusion, the present trial suggests:

- Both PPF and NSR are effective in treating residual pockets, and no significant difference in clinical outcomes was observed between groups at 6 months.
- PPF may promote faster pocket reduction compared with NSR.
- Smoking habits reduce the magnitude of benefits of both procedures.

AUTHOR CONTRIBUTIONS

Conceptualization: L.B. and F.C. *Data curation*: D.N. and W.C. *Methodology*: L.B., F.C. and M.D.M. *Formal analysis*: C.R., F.S., L.B. and M.N. *Investigation*: D.N., W.C., C.R., F.S. and L.B. *Writing—original draft preparation*: L.B. and F.C. *Writing—review and editing*: F.C., D.N., L.B., W.C. and M.D.M. *Supervision*: F.C. *Project administration*: L.B. and D.N. All authors have read and agreed to the published version of the manuscript.

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CONFLICT OF INTEREST STATEMENT

The authors declare no conflicts of interest.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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