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A randomized multi-centre study on the effectiveness of non-surgical periodontal therapy in general practice

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Abstract

Aim: To evaluate the effectiveness of two non-surgical treatment protocols for periodontitis patients in general dental practice.

Materials and Methods: Ninety-five dental hygienists (59 dental clinics) were randomly assigned to one of two treatment protocols: (i) establishment of adequate self-performed oral hygiene prior to a single session of ultrasonic instrumentation (guided periodontal infection control [GPIC]) or (ii) conventional non-surgical therapy (CNST) including patient education and scaling and root planing integrated in multiple sessions. Residual pockets at 3 months were retreated in both groups. The primary outcome was pocket closure (probing pocket depth \leq 4 mm) at 6 months. Multilevel models were utilized.

Results: Based on data from 615 patients, no significant differences with regard to clinical outcomes were observed between treatment protocols. Treatment-related costs (i.e., chair time, number of sessions) were significantly lower for GPIC than CNST. Smoking and age significantly affected treatment outcomes.

Conclusions: No significant differences between the two approaches were observed in regard to clinical outcomes. GPIC was more time-effective. Patient education should include information on the detrimental effects of smoking. ClinicalTrials.gov (NCT02168621).

KEYWORDS

effectiveness, field study, infection control, non-surgical therapy, periodontitis

Clinical Relevance

Scientific rationale for study: Available evidence on non-surgical periodontal therapy is largely based on efficacy studies. It is needed to evaluate the effectiveness of treatment protocols for patients in general dental practice.

Principal findings: No significant differences in clinical outcomes were observed between the two non-surgical approaches at 6 months. The GPIC protocol, however, was more time efficient.

Practical implications: A strategic focus on patient education establishing a sufficient level of oral hygiene is beneficial. Treatment strategies should be based on individual patient needs.

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The need for mechanical debridement should be evaluated avoiding over-instrumentation. Smoking cessation should be addressed.

INTRODUCTION 1

According to the Clinical Practice Guidelines for the management of periodontitis produced by the European Federation of Periodontology (Sanz et al., 2020), treatment should be provided in a step-wise approach. Thus, following communication with the patient regarding diagnosis, aetiology and therapeutic options, the first step of therapy aims at establishing adequate patient-performed infection control (Carra et al., 2020) and control of risk factors, for example, smoking cessation (Ramseier et al., 2020). In the second step, teeth with pathological periodontal pocket formation require mechanical instrumentation to further reduce the bacterial load (Suvan et al., 2020). This strategy was evaluated, among others, by Wennström et al. (2005) who applied a guided approach to periodontal infection control (GPIC). This approach included an initial phase of patient education for the establishment of adequate self-performed infection control prior to the initiation of mechanical instrumentation, which was carried out in one session of ultrasonic debridement. At the 3-month evaluation, residual pathology guided the clinician in the allocation of additional mechanical subgingival instrumentation.

Pocket closure (probing pocket depth [PPD] \leq 4 mm) is recognized as a relevant clinical outcome of periodontal therapy (Loos & Needleman, 2020). There is evidence (Eberhard et al., 2015; Suvan et al., 2020) that a single session of ultrasonic instrumentation results in treatment outcomes of similar magnitude when compared with conventional section-wise scaling and root planing (SRP). Both treatment approaches are recognized by Swedish (Socialstyrelsen, 2011) and European guidelines (Sanz et al., 2020). As the evidence was largely generated in randomized control trial studies, the external validity of these findings remains to be evaluated (Suvan et al., 2020). Available evidence is essentially based on efficacy evaluations, that is, care provided under ideal conditions to selected populations, while studies evaluating effectiveness of therapy, that is, care provided to the general population under conditions found in practice, are lacking.

The overall objective of the current field study was to evaluate the effectiveness of clinical and patient-centred outcomes of the GPIC approach when compared with conventional non-surgical periodontal treatment (CNST). It was hypothesized that the treatment effect obtained by GPIC should not be inferior to CNST at 6 months.

MATERIALS AND METHODS 2

2.1 Study design

The study was designed as a multi-centre, quasi-randomized, twoarmed field study focusing on the effectiveness of non-surgical

treatment of patients with periodontitis. The study protocol was evaluated and approved by the Regional Ethical Review Board, Gothenburg, Sweden (Dnr: 288-13) and registered at ClinicalTrials.gov (NCT02168621). Written informed consent was obtained from all participants. A flow chart of the study is shown in Figure 1.

Therapists 2.2

All interventions were performed by registered dental hygienists (DHs) within the Public Dental Service, Region Västra Götaland, Sweden. Based on a pre-study questionnaire (Liss et al., 2018), DHs treating adult patients with periodontitis on a regular basis were identified. Of 120 DHs invited, 95 (employed at 59 clinics within general dental care) agreed to participate.

Each DH was randomized to one of two treatment protocols (GPIC or CNST). Prior to randomization. DHs were stratified with regard to geographical location and sociodemographic characteristics of the respective clinics. Randomization was performed by the use of a computer-generated random numbers table. All DHs attended a 1-day training session including (i) principles of Good Clinical Practice in research, (ii) a detailed review of the respective research protocols and (iii) calibration of all clinical assessments. In addition, DHs allocated to the GPIC group received detailed instructions to ensure standardized treatment procedures. A study monitor performed repeated site visits at all clinics throughout the study period.

2.3 **Patient enrolment**

Adult patients diagnosed with periodontitis were considered. The patient should have a minimum of 18 teeth with ≥5 teeth showing periodontal pockets at proximal sites (PPD ≥ 5 mm and bleeding on probing [BoP]). Further, to be eligible, the patient should have a general health allowing periodontal treatment in a general care setting and a sufficient understanding of the Swedish language. Subjects having received subgingival instrumentation within 6 months prior to enrolment were not considered. Recruitment was started in June 2014 and completed by December 2017.

The characteristics of the patient sample are presented in Table 1. Subjects presented with a mean of 10 and 12 periodontal pockets in GPIC and CNST, respectively. The mean percentage of sites with PPD ≥5 mm at baseline (experimental sites) was 15% and 17%, respectively. Based on assessments of PPD, 18% of patients in GPIC and 10% in CNST were categorized as periodontitis stage II (Papapanou et al., 2018), while the remaining patients were classified

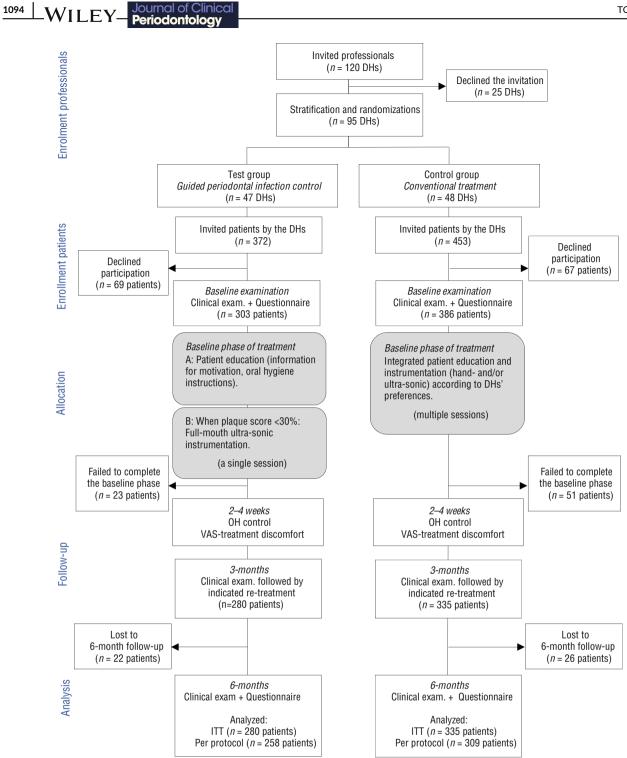


FIGURE 1 Flow chart of the clinical field study outline. DH, dental hygienist; ITT, Intention To Treat; OH, Oral Hygiene; VAS, Visual Analog Scale

as periodontitis stage III or IV. In all, 46% of subjects in GPIC and 59% in CNST presented with \geq 4 teeth with PPD \geq 6 mm.

2.3.1 | Power calculation

The study was designed as a non-inferiority study. The primary outcome variable was pocket closure (PPD \leq 4 mm). Based on data presented by Wennström et al. (2005), a total sample of 506 patients (253 patients per group) would provide a power of 80% at a significance level of

p < .05 to detect a difference of 5% between groups. Considering the risk of drop-out, we aimed to include 700 patients.

2.4 | Interventions

2.4.1 | Guided periodontal infection control

The protocol included dedicated visits focusing on patient education and motivation towards efficient self-performed infection control.

TABLE 1 Characteristics of the study sample at baseline

	GPIC $(n = 280 \text{ patients})$	CNST ($n = 335$ patients)
Age, mean ± SD (range)	53.3 ± 11.6 (26-78)	53.3 ± 12.6 (25-82)
Gender, %		
Female	45.7	43.6
Male	54.3	56.4
Education, %		
Elementary school	21.5	18.6
High school	46.2	47.4
University	32.3	33.9
Smoker, %		
Current	22.5	25.3
Years smoking	31.8 ± 14.4	33.8 ± 12.8
Cigarettes/day	9.8 ± 5.4	11.4 ± 6.0
Former	37.5	36.4
Years cessation	12.4 ± 11.0	13.8 ± 12.8
Years smoking	20.3 ± 12.3	20.6 ± 13.1
Cigarettes/day before quitting	14.5 ± 7.4	13.2 ± 7.0
Never	40.0	38.3
Body mass index, %		
Underweight (<18.5)	1.1	0.3
Normal (18.5–24.9)	28.6	34.6
Overweight (25-29.9)	51.4	43.0
Obesity (≥30)	18.8	22.1
Systemic health status, % (A	SA classification)	
Healthy	78.3	81.0
Minor disease	19.2	18.7
Major disease	2.5	0.3
No. of teeth	26.0 ± 2.3	26.5 ± 2.2
No. of teeth with PPD ≥ 5 mm	10.4 ± 4.5	11.5 ± 4.9
No. of teeth with PPD ≥ 6 mm	3.9 ± 3.5	5.2 ± 4.4
Periodontal disease severity	, %	
Stage II	18.2	10.4
Stage III–IV (≤3 teeth with PPD ≥ 6 mm)	36.1	31.0
Stage III−IV (≥4 teeth with PPD ≥ 6 mm)	45.7	58.6

Note: Data are represented as mean \pm SD and %. Total number of participants n = 615.

Abbreviations: CNST, conventional non-surgical therapy; GPIC, guided periodontal infection control; PPD, probing pocket depth.

Prior to subgingival debridement, the patient had to demonstrate sufficient oral hygiene (full-mouth plaque score < 30%). Then, full-mouth ultrasonic debridement was performed during a single session (EMS Piezon[®], P and PS tips, EMS Dental, Nyon, Switzerland).

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2.4.2 | Conventional non-surgical treatment

The conventional treatment approach comprised, in an integrated manner, patient education, motivation and SRP at consecutive appointments. No specific directives in regard to therapy were provided. The number of sessions required to complete CNST was judged by the DH, that is, "business as usual". Sessions were typically booked in an interval of 1–2 weeks.

Two to four weeks after the baseline phase of treatment, patients in both groups were scheduled for oral hygiene control. Subsequently, patients were recalled at 3 months for evaluation and reinstrumentation (SRP using hand and/or ultrasonic instruments) of sites with residual PPD \geq 5 mm and clinical signs of inflammation. An additional evaluation was performed at 6 months.

2.5 | Data collection

Patient characteristics (e.g., age, gender and systemic health status) were noted. PPD and BoP were assessed at four sites per tooth (mesial, buccal, distal and lingual) at baseline and at 3 and 6 months. PPD values ≥4 mm were recorded to the nearest millimetre. For clinical assessments, DHs used a standardized periodontal probe (52B XSI Perio Probe, LM Dental, Parainen, Finland; 2 mm markings and 0.5 mm tip diameter). Dental plaque was scored as present/absent at four sites/tooth in quadrants 1 and 3. Clinical data were entered and stored in electronic patient records.

In addition, the following information was recorded for each treatment session:

- Local anaesthesia (volume) used during treatment
- Time (minutes) used for patient education/motivation
- Time (minutes) used for mechanical instrumentation

Any adverse events were noted at 2-4 weeks.

2.6 | Patient-reported outcomes

Impact of the treatment on self-perceived oral health was assessed. At the 6-month evaluation, patients responded to the question: "*How do you judge your oral health after treatment compared to before treatment?*". Patient response was scored on a 5-point scale from "very much improved" to "worse".

2.7 | Data analysis

All patients who received and completed the baseline treatment phase were considered in the analysis by applying a modified intention-totreat strategy (Figure 1). For patients subsequently lost to follow-up, the recorded data from the latest available time point were brought forward. Third molars were excluded from the analysis, as were distal

TABLE 2 Treatment description

	GPIC ($n = 280$ patients)	CNST ($n = 335$ patients)	p-Valu
Total treatment time baseline phase (min)	96.1 ± 33.8	119.7 ± 50.3	<.001
Fime patient education baseline phase (min)	57.1 ± 30.6	39.3 ± 20.4	<.001
ime mechanical instr. baseline phase (min)	39.0 ± 14.0	80.4 ± 41.6	<.001
No. of visits for treatment, %			
1	3.6	3.9	
2	23.8	27.5	
3	39.7	35.9	
4	30.0	17.4	
5 or more	2.9	15.3	
lo. of instrumentation sessions, %			
1	100.0	29.0	
2	0.0	37.7	
3	0.0	17.7	
4 or more	0.0	15.6	
nstruments used initial, %			
Ultrasonic	100.0	13.4	
Hand instruments	0.0	14.0	
Ultrasonic and hand instruments	0.0	72.6	
naesthetic used initial, %			
None	70.0	59.9	<.001
Anaesthetic injection	4.5	23.6	
Anaesthetic gel	21.4	12.6	
Both	4.1	3.9	
naesthetic injected (carpules)	0.2 ± 0.7	1.2 ± 2.3	<.001
naesthetic gel (carpules)	0.3 ± 0.6	0.3 ± 0.7	.581
ime for check-up at 2–4 weeks (min)	18.6 ± 10.0	17.9 ± 10.3	.464
otal treatment time 3 months (min)	37.8 ± 15.4	40.2 ± 22.3	.136
ïme patient education 3 months (min)	12.8 ± 8.5	13.3 ± 10.6	.595
ime mechanical instrumentation 3 months (min)	24.9 ± 13.1	27.0 ± 18.8	.146
nstruments used 3 months, %			
Ultrasonic	65.7	75.0	.734
Hand instruments	9.8	12.5	
Ultrasonic and hand instruments	24.5	12.5	
naesthetic used 3 months, %			
None	81.9	79.2	.819
Anaesthetic injection	4.2	6.0	
Anaesthetic gel	12.2	13.0	
Both	1.7	1.8	
naesthetic injected (carpules)	0.1 ± 0.4	0.2 ± 0.7	.181
naesthetic gel (carpules)	0.1 ± 0.3	0.3 ± 2.0	.179
otal treatment time baseline $+ 3$ months (min)	134.0 ± 40.1	160.9 ± 61.3	<.001
iotal. mechanical instrumentation time baseline + 3 months (min)	64.7 ± 21.3	107.5 ± 49.2	<.001
lean instrument time per closed pocket (min)	9.5 ± 10.5	14.5 ± 20.8	.001

Note: Data are represented as mean \pm SD and %. Total number of participants n = 615.

Abbreviations: CNST, conventional non-surgical therapy; GPIC, guided periodontal infection control.

 ${}^{a}\chi^{2}$ -test and independent samples *t*-test.

sites of second molars in the presence of a third molar. The primary outcome was pocket closure (PPD \leq 4 mm). Data were described using mean values, standard deviations as well as proportions. Treatment time was expressed in minutes and the use of local anaesthesia was measured through number of carpules.

Comparisons between treatment groups were performed using independent t-test for continuous variables after verifying normal distributions and chi-square test for categorical parameters. Descriptive analysis was performed using SPSS (version 26, IBM, Armonk, NY). A logistic multilevel analysis (STATA 16.1, StataCorp, College Station, TX and MLwiN 3.05, Centre for Multilevel Modelling, Bristol, United Kingdom) with three levels (clinician, patient and tooth site) was performed to evaluate the probability of pocket closure. In a second linear multilevel analysis (two levels: clinician and patients), change in the proportion/number of teeth with periodontal pockets following treatment was estimated. Analyses were adjusted for patient- and treatment-related factors. The relationship between clinical and patient-reported outcomes was assessed using partial correlation adjusted for treatment allocation and baseline disease severity.

3 | RESULTS

DHs were randomly assigned to GPIC (n = 47) and CNST (n = 48). Of 825 invited patients, 689 agreed to participate in the study. While 74 patients did not complete the baseline phase of treatment, the modified intention-to-treat analysis comprised 615 patients (GPIC: 280; CNST: 335). A total of 48 patients were lost to follow-up prior to the 6-month evaluation. For details, see Figure 1.

Details pertaining to therapy are described in Table 2. Treatment time including patient education/motivation and mechanical instrumentation during the baseline phase was 96 ± 33 min for GPIC and 120 ± 50 min for CNST (p < .001). The time used for re-treatment at 3 months was similar in both groups. Overall, the average treatment time was 134 ± 40 min for GPIC and 161 ± 61 min for CNST (p < .001). More anaesthesia was used in CNST during the baseline treatment phase, while no differences were observed during re-treatment. No adverse events were reported.

3.1 | Treatment outcomes

Treatment resulted in a significant reduction of BoP at 6 months. About 69%–72% of all initial pockets were closed. No significant differences between treatment groups were observed, neither for initially shallow (5–6 mm) nor deep (\geq 7 mm) sites (Figure 2a,b). The proportion of closed pockets for initially shallow sites was 72% (GPIC) and 75% (CNST). The respective proportions for initially deep sites were 30% and 33%.

Treatment outcomes at patient level were associated with disease severity (staging). While about 75% of all pockets resolved in patients with stage II periodontitis, the respective proportions of pocket closure were about 66% and 50% in patients with localized and



(a)

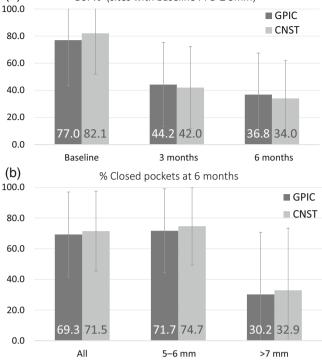


FIGURE 2 (a) Mean bleeding on probing (BoP) scores for experimental sites (baseline probing pocket depth [PPD] \geq 5 mm) and (b) proportion of pockets closed at the 6-month examination. Mean values and SD. CNST, conventional non-surgical therapy; GPIC, guided periodontal infection control

generalized stage III-IV periodontitis, respectively (Table 3). Among the most affected subjects, 6% were free of any periodontal pocket (PPD \ge 5 mm) after treatment, while about 62% presented with >4 teeth with residual pockets. No differences between groups were observed.

As shown in Table 3, more than 75% of all patients judged their oral health to be significantly improved ("much improved" and/or "very much improved") after treatment. A significant positive correlation (0.16; p < .001) was observed between patient-reported outcome and clinical results expressed as percentage of pocket closure at 6 months. Figure A2 in the appendix shows a scatterplot to illustrate the relation between self-perceived benefit from the treatment and clinical improvement as measured from number of teeth with residual PPD \geq 5 mm at baseline and 6 months.

3.2 | Multilevel models

The first model with pocket closure (yes/no) as the dependent outcome revealed that initial PPD was a significant predictor at site level. Thus, the probability of pocket closure was significantly lower for a deep when compared with a shallow site. Each mm of the initial PPD decreased the probability of closing the pocket by odds ratio (OR) 0.33 (95% confidence interval [CI] 0.31–0.36). Probability of

TABLE 3 Tr	reatment outcomes according to disease severity: Percentage of patients with teeth with probing pocket depth (PPD) ≤5 mm, number of teeth at given time points with different	
pocket depth, a	iverage percentage of closed pockets (PPD ≤ 4 mm) and patient-reported perception regarding oral health outcome "How would you compare your oral health after treatment with	
the way it was befo	before treatment?"	

	Stage II n = 51 GPIC	n = 35 CNST	p-Value	Stage III-IV (≤3 teeth PPD ≥ 6 mm) <i>n</i> = 101 GPIC	n = 104 CNST	<i>p</i> -Value	Stage III-IV (>3 teeth PPD ≥ 6 mm) n = 128 GPIC	n = 196 CNST	p-Value
Patients % at 6 months with									
No tooth with PPD ≥ 5 mm	35.3	48.6	.167	14.9	18.3	.623	6.3	6.1	.446
$1-4$ teeth with PPD ≥ 5 mm	41.2	42.9		48.5	51.0		30.5	32.7	
>4 teeth with PPD $\ge 5 \text{ mm}$	23.5	8.5		36.6	30.7		63.2	61.2	
No. of teeth at baseline	26.1 ± 2.3	27.1 ± 1.3	.023 ^a	26.3 ± 2.2	26.8 ± 2.0	.088 ^a	25.8 ± 2.4	26.2 ± 2.4	.112 ^a
No. of teeth with PPD $\ge 5 \text{ mm}$									
Baseline	8.7 ± 3.1	8.6 ± 2.3	.976 ^a	8.4 ± 3.0	9.2 ± 3.5	.087 ^a	12.7 ± 4.9	13.3 ± 5.0	.287ª
3 months	2.6 ± 2.8	1.8 ± 1.8	.119 ^a	4.4 ± 3.1	4.2 ± 3.2	.642 ^a	7.9 ± 4.6	7.9 ± 5.4	.899 <mark>ª</mark>
6 months	2.4 ± 2.7	1.5 ± 1.9	.108ª	3.7 ± 2.9	3.4 ± 3.2	.501 <mark>ª</mark>	7.0 ± 5.0	7.0 ± 5.1	.975 ^a
% closed pockets (PPD ≤ 4 mm)									
3 months	76.0 ± 31.7	83.3 ± 19.8	.233ª	64.0 ± 27.6	64.7 ± 26.2	.849 ^a	53.7 ± 29.9	57.9 ± 28.5	.210 ^a
6 months	81.9 ± 23.8	90.6 ± 13.4	.054 ^a	71.9 ± 26.0	75.4 ± 23.5	.321 ^a	61.6 ± 28.5	65.2 ± 27.1	.260 ^a
Initial PPD 5-6 mm									
3 months	76.0 ± 31.7	83.3 ± 19.8	.233ª	65.6 ± 27.6	66.5 ± 25.7	.810 ^a	58.5 ± 30.6	61.6 ± 28.8	.348ª
6 months	81.9 ± 23.8	90.6 ± 13.4	.054 ^a	73.4 ± 25.8	77.7 ± 23.0	.217ª	66.0 ± 28.6	69.5 ± 26.7	.259 ^a
Initial PPD ≥ 7 mm									
3 months	I	I	Ι	9.6 ± 28.4	22.8 ± 39.0	.153 ^a	28.1 ± 39.1	24.7 ± 36.9	.496 ^a
6 months	I	Ι	Ι	21.2 ± 40.4	28.8 ± 43.1	.487 ^a	31.6 ± 39.7	32.8 ± 38.9	.818 ^a
Patient-reported oral health outcome, %	ime, %								
Very much better	28.6	27.6	.754	28.4	20.9	.338	26.0	34.4	.396
Much better	54.3	62.1		44.3	56.0		52.0	41.6	
Slightly better	14.3	10.3		20.5	19.8		18.0	20.1	
No difference	0.0	0.0		6.8	3.3		4.0	3.9	
Worst	2.8	0.0		0.0	0.0		0.0	0.0	

TABLE 4Multilevel logisticregression model to predict probability ofpocket closure at 6 months

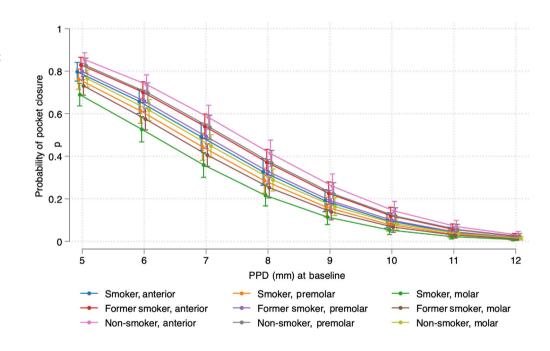
Variables	В	95% CI	p-Value
Constant	10.18	9.19 to 11.19	.000
Test/GPIC group (ref: Control/CNST group)	-0.35	-0.85 to 0.09	.117
PPD at baseline	-1.10	-1.19 to -1.02	.000
Smoking (ref: non-smoker)			
Current smoker	-0.65	-1.06 to -0.22	.003
Former smoker	-0.35	-0.71 to 0.02	.066
Age	-0.03	-0.05 to -0.02	.000
BMI (ref: Normal/underweight)			
BMI overweight	0.19	-0.17 to 0.55	.311
BMI obese	-0.12	-0.57 to 0.34	.607
Tooth type (ref: Anterior)			
Premolar	-0.33	-0.50 to -0.15	.000
Molar	-0.93	-1.09 to -0.77	.000
Random part			
Variance operator level	0.69	0.39 to 1.23	
Variance patient level	2.77	2.28 to 3.36	

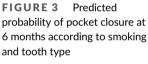
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Note: Adjusted for systemic health and gender. LL = -4581.88 Wald test 0.000 R² 0.27.

Abbreviations: BMI, body mass index; CI, confidence interval; CNST, conventional non-surgical therapy; GPIC, guided periodontal infection control; PPD, probing pocket depth.





pocket closure was affected by age (OR 0.97; 95% CI 0.96–0.98), smoker versus non-smoker (OR 0.56; 95% CI 0.37–0.85) and molar versus incisor/canine (OR 0.41; 95% CI 0.35–0.48). Treatment group and body mass index (BMI) had no significant impact. The model explained 27% of the variance as testified from the R^2 value. For details, see Table 4. Figure 3 illustrates the predicted probability of closing a pocket by initial PPD, smoking status and tooth category, and Table A5 report predicted probabilities with 95% CIs. The second model using proportion of teeth with residual pockets as a continuous outcome demonstrated that the proportion of teeth with pockets at baseline, age and smoking status were significant predictors (Table A1). Thus, as illustrated in Figure 4, current smokers showed less pocket reduction at 6 months when compared with nonsmokers and former smokers. Also, in this model, neither treatment group nor BMI had a significant impact. The results from the third model with number of teeth with residual pockets are presented in

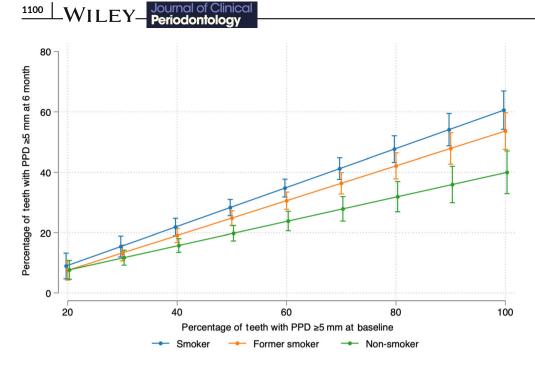


FIGURE 4 Predicted proportion of teeth with probing pocket depth (PPD) ≥5 mm at 6 months according to smoking habit

Table A2. Both models explained 40% of the variance. Figure A1 illustrates the influence of smoking status.

Time efficiency, expressed as minutes of instrumentation per closed pocket, was greater for GPIC (9.5 ± 10.5 min/closed pocket) than CNST (14.5 ± 20.8 min/closed pocket; p < .001; Table 2).

4 | DISCUSSION

The present multi-centre study evaluated the effectiveness of two treatment protocols of non-surgical periodontal therapy. While no significant differences in clinical outcomes were observed between the two protocols at 6 months, treatment time and number of sessions were significantly lower for the guided periodontal infection control procedure than conventional non-surgical therapy. In addition, multilevel regression analyses revealed that smoking habits and age among patients affected the probability of pocket closure.

There are several components of the present study that underpin the importance of the obtained results. Thus, the characteristics of effectiveness are illustrated by a representative study population and a treatment carried out in general practice. In addition, the achieved outcomes of 70% of pocket closure at 6 months after non-surgical therapy are in line with data from efficacy studies reported in a systematic review by Suvan et al. (2020). Our findings are also in agreement with observations made in a study on GPIC by Wennström et al. (2005), who reported that pocket closure was more frequent at initially shallow (86%) than at deep sites (50%). While a similar difference in outcomes between initially shallow and deep sites was observed in the present study, a slightly lower rate of treatment success for deep sites (30%) was noted. It should be kept in mind, however, that the present data exhibited an overall larger variation in treatment outcomes than typically shown in efficacy studies. This observation is not unexpected as our data originate from a heterogeneous patient

sample treated by a multitude of clinicians. In addition, DHs were recruited among professionals with a wide range of working experience (average: 13 years), as previously described by Liss et al. (2018) (Table A3).

The analysis of the data in the present study revealed that complete disease resolution at 6 months was rarely observed among patients with severe forms of the disease, that is, generalized periodontitis stage III and IV. While this observation is in agreement with results reported in the systematic review by Suvan et al. (2020), it should be noted that the distribution of subjects with severe forms of periodontitis was unbalanced between treatment groups. As the variation in disease severity may have influenced clinicians in their decision to enrol study participants, all analyses were adjusted for disease severity at baseline.

In accordance with findings reported in studies by Koshy et al. (2005) and Wennström et al. (2005), the present study demonstrated that GPIC was a more time-efficient protocol than CNST. Not only was the time of instrumentation significantly lower in GPIC than for CNST, clinicians also used smaller amounts of local anaesthesia. In this context, it noteworthy that the same study population did not report any significant differences between groups in terms of treatment discomfort or pain (Liss et al., 2021). Thus, given the clinical effectiveness and the apparent patient acceptance in combination with potential health economic benefits, it is reasonable to suggest that caregivers should consider implementing the principles of GPIC. A further note regarding the findings of the present study was that the total treatment time was unrelated to the severity of the disease at baseline (Table A4). This observation may reflect a commonly applied standardized approach to periodontal care in general practice rather than decisions on treatment based on individual needs.

The analysis of data in the present study identified factors that influenced treatment outcomes. Patients categorized as smokers showed a lower probability of pocket closure at 6 months. This observation is consistent with findings reported previously (D'Aiuto et al., 2005; Tomasi et al., 2007; Wan et al., 2009) and highlights the importance of smoking cessation as part of the management of periodontitis. Age was also found to have a significant impact, as indicated by a lower response to treatment in older patients. A similar observation was reported in a retrospective study by Trombelli et al. (2010), who demonstrated that elderly subjects showed a higher number of residual pockets after treatment. A third factor influencing treatment outcomes in the present analysis was tooth category, which is in line with data presented in efficacy studies (D'Aiuto et al., 2005; Tomasi et al., 2007; Wan et al., 2009).

In the interpretation of the findings, limitations and strengths of the present study need to be considered. First, the lack of comprehensive assessments of plaque scores and local anatomical features (e.g., angular bony defects and furcation defects) together with a potential selection bias of study participants may have impacted evaluations. The challenge of calibrating 95 clinicians in terms of treatment and examination procedures should also be acknowledged. The strengths of the study include the choice of clinically relevant outcomes (Hujoel, 2004; Tomasi & Wennström, 2017; Loos & Needleman, 2020) and the representative and large sample of patients and clinicians reflecting day-to-day clinical practice.

5 | CONCLUSIONS

This field study demonstrated that both GPIC and CNST were effective non-surgical treatment protocols for periodontitis. GPIC was more time-effective. Patient education should include information on the detrimental effects of smoking on periodontal health.

AUTHOR CONTRIBUTIONS

Cristiano Tomasi performed the data analysis and was involved in interpretation of data and drafting of the manuscript. Anna Liss contributed to data collection, data analysis, interpretation of data and drafting of the manuscript. Maria Welander contributed to interpretation of data and drafting of the manuscript. Anna Ydenius Alian contributed to data collection and preliminary analysis. Kajsa H. Abrahamsson and Jan L. Wennström designed, planned and coordinated the study. Both contributed to data analysis, interpretation of data and drafting of the manuscript.

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CONFLICT OF INTEREST

All 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.

ETHICS STATEMENT

The study protocol was approved by the Regional Ethical Review Board, Gothenburg, Sweden (Dnr: 288-13) and registered at Clinical-Trials.gov (NCT02168621). Written informed consent was obtained from all participants.

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APPENDIX A

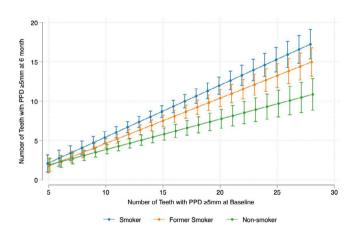


FIGURE A1 Predicted number of teeth with probing pocket depth (PPD) ≥5 mm at 6 months according to smoking habit

Clinical vs patient-perceived outcomes

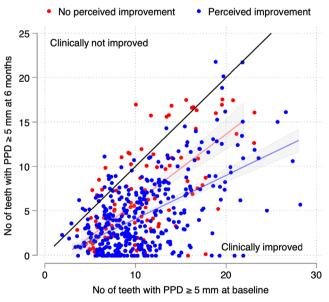


FIGURE A2 Scatter plot with clinical outcome expressed as number of teeth with probing pocket depth (PPD) ≥ 5 mm at baseline and at 6 months and colour depicting the perceived improvement from the patient. The black line represents the border between areas, and the two regression lines with 95% confidence interval represent the clinical outcome trend for the two perceived outcome categories, with a significant difference (p < .001).

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L	enodonioi	bgy	
Variables	В	95% CI	p-Value
Constant	-21.06	-28.70 to -13.41	.000
Test/GPIC group (ref: Control/CNST group)	3.96	-3.78 to 11.70	.316
Proportion of teeth \ge 5 mm baseline	0.40	0.29 to 0.51	.000
Smoking (ref: Non-smoker)			
Current smoker	-3.54	-10.82 to 3.73	.340
Former smoker	-3.62	-9.86 to 2.62	.256
Smoking \times Prop. teeth \ge 5 mm baseline (ref: Non-s	moker)		
Current smoker \times Prop. teeth \ge 5 mm baseline	0.24	0.09 to 0.39	.002
Former smoker \times Prop. teeth \ge 5 mm baseline	0.17	0.03 to 0.31	.016
Age	0.28	0.18 to 0.37	.000
BMI (ref: Normal/underweight)			
BMI overweight	-1.99	-4.41 to 0.44	.108
BMI obese	0.34	-2.66 to 3.34	.824
Instrumentation time \times Treatment (min)			
Instrumentation time \times Test treatment	0.05	-0.04 to 0.14	.274
Instrumentation time \times Control treatment	0.06	0.16 to 0.28	.002
Random part			
Variance operator level	50.78	31.55 to 81.73	
Variance patient level	140.36	123.08 to 160.05	
	VariablesConstantTest/GPIC group (ref: Control/CNST group)Proportion of teeth \geq 5 mm baselineSmoking (ref: Non-smoker)Current smokerFormer smokerSmoking \times Prop. teeth \geq 5 mm baseline (ref: Non-smoker)Current smoker \times Prop. teeth \geq 5 mm baselineFormer smoker \times Prop. teeth \geq 5 mm baselineAgeBMI (ref: Normal/underweight)BMI overweightBMI obeseInstrumentation time \times Treatment (min)Instrumentation time \times Control treatmentRandom partVariance operator level	VariablesBConstant-21.06Test/GPIC group (ref: Control/CNST group)3.96Proportion of teeth \geq 5 mm baseline0.40Smoking (ref: Non-smoker)	Constant -21.06 -28.70 to -13.41 Test/GPIC group (ref: Control/CNST group) 3.96 -3.78 to 11.70 Proportion of teeth \geq 5 mm baseline 0.40 0.29 to 0.51 Smoking (ref: Non-smoker) -3.54 -10.82 to 3.73 Current smoker -3.62 -9.86 to 2.62 Smoking \times Prop. teeth \geq 5 mm baseline (ref: Non-smoker) -3.62 -9.86 to 2.62 Smoking \times Prop. teeth \geq 5 mm baseline (ref: Non-smoker) 0.09 to 0.39 Current smoker \times Prop. teeth \geq 5 mm baseline 0.17 0.03 to 0.31 Age 0.28 0.18 to 0.37 BMI (ref: Normal/underweight) BMI overweight -1.99 -4.41 to 0.44 BMI obese 0.34 -2.66 to 3.34 Instrumentation time \times Treatment (min) -0.04 to 0.14 Instrumentation time \times Control treatment 0.06 0.16 to 0.28 Random part $Variance$ operator level 50.78 31.55 to 81.73

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Note: LL = -2158.38 Wald test 0.000 R^2 0.40.

Abbreviations: BMI, body mass index; CI, confidence interval; CNST, conventional non-surgical therapy; GPIC, guided periodontal infection control.

Variables	В	95% CI	p-value
Constant	-5.44	-7.43 to -3.46	.000
Test/GPIC group (ref: Control/CNST group)	1.07	-0.93 to 3.07	.294
Number of teeth \geq 5 mm at baseline	0.39	0.28 to 0.50	.000
Smoking (ref: Non-smoker)			
Current smoker	-1.22	-3.10 to 0.67	.205
Former smoker	-1.11	-2.76 to 0.53	.185
Smoking \times No. of teeth \ge 5 mm baseline (ref: Non-s	moker)		
Current smoker \times No. of teeth \ge 5 mm baseline	0.27	0.12 to 0.42	.000
Former smoker \times No. of teeth \ge 5 mm baseline	0.19	0.05 to 0.33	.010
Age	0.08	0.05 to 0.10	.000
BMI (ref: Normal/underweight)			
BMI overweight	-0.45	-1.01 to 0.18	.160
BMI obese	0.24	-0.54 to 1.02	.547
Instrumentation time \times Treatment (min)			
Instrumentation time \times Test treatment	0.01	-0.01 to 0.03	.367
Instrumentation time \times Control treatment	0.01	0.004 to 0.02	.004
Random part			
Variance operator level	3.31	2.05 to 5.35	
Variance patient level	9.44	8.28 to 10.77	

Note: LL = -1426.02 Wald test 0.000 R^2 0.40.

Abbreviations: BMI, body mass index; CI, confidence interval; CNST, conventional non-surgical therapy; GPIC, guided periodontal infection control.

TABLE A2 Multilevel linear regression model to predict number of teeth with probing pocket depth ≥5 mm at the 6-month examination

TABLE A1Multilevel linearregression model to predict proportion ofteeth with probing pocket depth ≥5 mmat the 6-month examination

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TABLE A3 Characteristics of the study sample at baseline according to disease severity

	Stage I–II		Stage III-IV (≤:	Stage III–IV (≤3 teeth)		3 teeth)
	n = 51 GPIC	n = 35 CNST	n = 101 GPIC	n = 104 CNST	n = 128 GPIC	n = 196 CNST
Age	51.7 ± 12.7	45.4 ± 10.6	53.5 ± 11.1	52.5 ± 12.8	53.7 ± 11.6	55.2 ± 12.2
Gender, %						
Male	41.2	42.9	48.5	51.0	30.5	32.7
Female	23.5	8.5	36.6	30.7	63.2	61.2
Education, %						
Elementary school	27.5	11.4	16.8	14.4	22.8	22.2
High school	45.0	48.6	46.5	47.1	46.5	47.4
University	27.5	40.0	36.6	38.5	30.7	30.4
Smoker, %						
Current	10.2	13.3	23.2	24.7	26.8	27.5
Years smoking	51.7 ± 12.7	45.4 ± 10.6	53.5 ± 11.1	52.5 ± 12.8	53.7 ± 11.6	55.2 ± 12.2
Cigarettes/day	51.7 ± 12.7	45.4 ± 10.6	53.5 ± 11.1	52.5 ± 12.8	53.7 ± 11.6	55.2 ± 12.2
Former	36.7	26.7	32.6	33.0	41.5	39.7
Years cessation	51.7 ± 12.7	45.4 ± 10.6	53.5 ± 11.1	52.5 ± 12.8	53.7 ± 11.6	55.2 ± 12.2
Years smoking	51.7 ± 12.7	45.4 ± 10.6	53.5 ± 11.1	52.5 ± 12.8	53.7 ± 11.6	55.2 ± 12.2
Cigarettes/day before quitting	51.7 ± 12.7	45.4 ± 10.6	53.5 ± 11.1	52.5 ± 12.8	53.7 ± 11.6	55.2 ± 12.2
Never	53.1	60.0	44.2	42.3	31.7	32.8
Body mass index, %						
Underweight (<18.5)	2.0	0.0	1.0	0.0	0.8	0.5
Normal (18.5–24.9)	34.0	34.4	26.7	37.8	28.0	33.0
Overweight (25-29.9)	42.0	50.0	55.5	43.9	52.0	41.4
Obesity (≥30)	22.0	15.6	16.8	18.3	19.2	25.1
Systemic health status, % (ASA classific	cation)					
Healthy	78.4	91.4	77.0	83.7	79.2	77.7
Minor disease	17.6	8.6	21.0	15.4	18.4	22.3
Major disease	3.9	0.0	2.0	1.0	2.4	0.0

Note: Data are represented as mean ± SD and %.

Abbreviations: CNST, conventional non-surgical therapy; GPIC, guided periodontal infection control.

TABLE A4 Treatment time in minutes at different phases according to disease severity

	Stage I–II		Stage III–IV (≤	Stage III–IV (≤3 teeth)		3 teeth)
	n = 51 GPIC	n = 35 CNST	n = 101 GPIC	n = 104 CNST	n = 128 GPIC	n = 196 CNST
Total treatment time initial phase (min)	98.7 ± 34.3	113.9 ± 46.1	92.1 ± 34.1	109.6 ± 44.3	98.2 ± 33.4	126.1 ± 53.1
Time patient education initial phase (min)	60.0 ± 31.8	41.1 ± 19.5	56.3 ± 29.2	37.7 ± 18.1	56.1 ± 31.3	39.8 ± 21.8
Time mechanical instr. initial phase (min)	37.8 ± 11.9	72.7 ± 41.6	35.9 ± 14.4	71.9 ± 35.3	41.9 ± 13.9	86.3 ± 43.8
Time for check-up at 2–4 weeks (min)	19.1 ± 9.0	20.3 ± 10.2	19.7 ± 10.8	17.9 ± 9.6	17.5 ± 9.9	17.6 ± 10.7
Total treatment time 3 months (min)	34.5 ± 15.6	34.7 ± 21.5	37.8 ± 16.3	39.7 ± 20.6	39.0 ± 14.5	41.5 ± 23.3
Time patient education 3 months (min)	13.5 ± 8.6	17.7 ± 13.5	13.8 ± 9.4	12.8 ± 8.4	11.9 ± 7.6	12.7 ± 11.0
Time mechanical instr. 3 months (min)	21.1 ± 14.0	17.0 ± 15.8	24.0 ± 13.5	26.9 ± 16.2	27.1 ± 12.2	28.8 ± 20.1
Total treatment time baseline $+$ 3 months (min)	133.3 ± 39.4	149.2 ± 55.4	130.9 ± 40.1	149.7 ± 55.7	136.5 ± 40.1	169.2 ± 64.2
Total. mechanical instrumentation time baseline $+$ 3 months (min)	59.3 ± 20.4	89.5 ± 44.5	60.8 ± 21.8	99.1 ± 42.6	69.7 ± 20.1	115.4 ± 52.0
Mean instrument. time per closed pocket (min)	8.8 ± 8.3	9.9 ± 6.2	10.3 ± 10.1	16.4 ± 22.4	9.2 ± 11.5	14.4 ± 21.5

Note: Data are represented as mean \pm SD.

Abbreviations: CNST, conventional non-surgical therapy; GPIC, guided periodontal infection control.

TABLE A5Predicted probability(95% confidence intervals) of pocketclosure for different baseline probingpocket depth (PPD), smoking habit andtooth types

		ì	lournal of Clin Periodontolog	ical y —WII	_EY <u>1105</u>
Baseline PPD	5 mm	6 mm	7 mm	8 mm	9 mm
Non-smoker					
Anterior	87% (84-90)	75% (71-80)	60% (55-66)	43% (37–49)	28% (22-33)
Premolar	84% (81-87)	71% (67–76)	55% (50–61)	38% (32-44)	24% (18-29)
Molar	78% (74-81)	63% (58–68)	46% (41-51)	30% (25-35)	17% (13-21)
Smoker					
Anterior	81% (77-85)	67% (62-72)	50% (44-57)	34% (28–40)	20% (15-25)
Premolar	77% (73-82)	62% (57-68)	45% (39-52)	29% (23–35)	17% (12-21)
Molar	69% (64–75)	53% (47-59)	36% (31-42)	22% (17–27)	12% (8-15)