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Pocket-depths-related effectiveness of an intrapocket anaesthesia gel in periodontal maintenance patients

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Abstract: *Aim:* The aim of this study was to determine the impact of the pocket depth on the effectiveness of an intrapocket anaesthesia gel during SRP in periodontal maintenance patients. Effectiveness was measured by pain levels during SRP via visual analogue scale (VAS) and verbal rating scale (VRS). Secondary endpoint was the evaluation of patients' preferred choice of anaesthesia for SRP. *Methods:* A total of 638 patients undergoing the periodontal maintenance programme and with the need for SRP participated in this observational study. After SRP, patients filled in questionnaires to record pain levels experienced and anaesthesia preference for future use. Mann–Whitney *U*-test was used to analyse intergroup difference in pain perception and anaesthesia choice. *Results:* Overall, increasing pocket depths were accompanied by higher pain levels, irrespective of maximum or commonest pocket depths ($P < 0.05$). For SRP procedures, patients definitely prefer the anaesthesia gel (72.4%). *Conclusions:* In this study, an effectiveness of local anaesthesia gel (lidocaine/prilocaine) related to pocket depths was found in periodontal maintenance patients during SRP. Increasing pocket depths were accompanied by increasing procedural pain levels. Nevertheless, the anaesthesia gel is well accepted and in the majority of cases was found to be the preferred option for future SRP treatments.

Key words: anaesthetics; periodontal maintenance; periodontal recall; periodontitis; scaling and root planing

Introduction

Scaling and root planing (SRP) in periodontal primary care and supportive therapy causes discomfort or pain and comes along with the need for local anaesthesia (1). The current most used form of pain control for SRP is local anaesthesia injections. However, many patients object to the use of 'the needle' (1), as injection given for SRP is in itself painful (2). In fact, some patients may delay or avoid dental procedures because of an aversion to dental needles or procedural pain during local anaesthesia injections (2, 3).

From the patients' points of view, subgingival application of an anaesthesia gel for SRP offers substantial advantages over injected anaesthesia (4). Efficacy and safety of the intrapocket anaesthesia gel containing lidocaine and prilocaine (25 mg g^{-1} each) are well documented (5–8). Independently, Friskopp *et al.* and Herdevall *et al.* (9, 10) proved a large safety margin with respect to systemic effects following the application of the anaesthesia gel in periodontal pockets. However, a minority of

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patients undergoing SRP with anaesthesia gel need an injected anaesthesia to achieve proper pain control (4).

Up to now, limited data are available for clinical parameters influencing the effectiveness of the intrapocket anaesthesia gel. A correlation between increasing probing pocket depths and higher pain levels is documented for periodontal probing as well as for scaling and root planing (11). Therefore, our hypothesis was that pain control ability of the intrapocket anaesthesia gel decreases in deep periodontal pockets. As the efficacy had been documented in detail, our study was planned to delineate and differentiate benefit estimation in terms of a phase four post-approval study.

The purpose of this study was to determine the impact of the pocket depth on the effectiveness of an intrapocket anaesthesia gel during SRP in periodontal maintenance patients. Effectiveness was measured by pain levels during SRP in medium and deep pockets via visual analogue scale (VAS) and verbal rating scale (VRS). Secondary endpoint was the evaluation of patients' preferred choice of anaesthesia for SRP.

Study population and methodology

Study design and anaesthesia gel

To reach the proposed objective, a multicentre, natural, non-disguised, human, direct and structured observational study was designed. This implies that no changes were made to a routine periodontal recall session (except for the additional questionnaire) unless patients were aware of being observed. The intrapocket anaesthesia gel (Oraqix®; Dentsply International, York, PA, USA) was applied prior to SRP in periodontal maintenance patients with clinical signs of periodontal progression.

Oraqix® contains lidocaine and prilocaine (25 mg g^{-1} each) in a thermosetting agent. The anaesthesia gel is fluid at room temperature and increases its viscosity after application in the periodontal pocket. The anaesthetic effect exists for some 20 min.

Study population and selection of participants

The patients were recruited from the periodontal departments of 14 University dental hospitals. A total of 638 patients (286 men and 318 women, 34 failed to mark the gender; 19–81 years of age) participated in this observational study. Inclusion criteria were (1) undergoing a periodontal maintenance programme after successfully completing periodontal therapy and (2) need for SRP because of clinical signs of localized periodontal progression. Medical history was performed to include patients with good general health and to exclude patients with contraindications to the product according to product guidelines.

Prior to SRP, all patients received detailed information about the observational study and gave their informed consent. The study was approved by the local ethics review board of the University of Cologne and was conducted in accordance with the Helsinki Declarations.

Clinical measurements and documentation

Data were collected during routine periodontal maintenance appointment. The number of sites to be treated was evaluated. Sites with the need for SRP were defined by probing depths equal to or exceeding four millimetres and bleeding on probing. After a full mouth and tooth cleaning (PMTC), SRP was performed using the intrapocket anaesthesia gel. Subsequently, patients filled in questionnaires to record pain levels experienced using a 0–100 (VAS) and a 4-step (VRS, no pain – mild pain – moderate pain – severe pain). In daily practice, almost all patients show various pocket depths with the need of reinstrumentation (SRP). We analysed whether the maximum pocket depth or the modest pocket depth influences the perception of procedural pain during SRP. For analysing the influence of the maximum pocket depth, the highest category of pocket depth was used, irrespective of the amount of treated sites. For analysing the influence of the modest pocket depth, the category of pocket depth with the highest amount of treated sites was used. Preference of anaesthesia used for SRP procedures was also the subject of enquiry.

Additionally, demographic data, periodontal diagnosis and pocket depths (maximum and mode) were extracted from patients' charts and documented on the case report forms by examiners.

Statistical analysis

Statistical unit was determined per patient. Mann–Whitney *U*-test was used to analyse intergroup differences in pain perception and anaesthesia choice between various pocket depths. All analysis was carried out with SPSS 15.0 software (SPSS Inc., Chicago, IL, USA). Differences between groups were considered as statistically significant, if $P \leq 0.05$.

Results

A total of 638 questionnaires were returned to the study centre (Cologne). 526 of them (82.2%) were filled in appropriately for pain measurements and used for data analysis. Age, gender and distribution of maximum pocket depths are shown in Table 1. Group size decreased with increasing pocket depth due to the natural appearance of periodontal diseases.

Table 1. **Baseline characteristics of patients by probing pocket depth and gender**

	Age (SD) (min–max)	Maximum probing pocket depths per patient			Total number (*n*)
		4–5 mm	6–8 mm	>8 mm	
Overall	52.1 (14.1) (19–89)	246	217	63	526
Female	52.3 (14.0) (21–89)	126	127	25	278
Male	51.8 (14.2) (19–81)	120	90	38	248

Table 2. **Visual analogue scale (VAS) scores (in mm) and verbal rating scale (VRS) scores (4-step) by maximum pocket depth**

Maximum pocket depth	VAS (SD) (min–max)	*P*-value* compared to	VRS (SD) (min–max)	*P*-value* compared to
4–5 mm (n = 246)	23.4 (22.2) (0–80)	0.275 6–8 mm	1.64 (0.68) (1–4)	0.001 6–8 mm
6–8 mm (n = 217)	25.9 (23.8) (0–96)	0.011 >8 mm	1.86 (0.76) (1–4)	0.252 >8 mm
>8 mm (n = 63)	33.4 (25.5) (0–98)	0.001 4–5 mm	1.98 (0.77) (1–4)	0.001 4–5 mm

*Mann–Whitney *U*-test.

Pain in relation to maximum pocket depth

VAS scores during SRP are shown in Table 2. Overall, increasing pocket depths were accompanied by higher pain levels. Compared with deep pockets (8 mm), lower pain levels were found in shallow (4–5 mm, $P = 0.001$) and medium (6–8 mm, $P = 0.011$) pockets. While female patients reported homogeneous pain levels irrespective of the maximum pocket depths ($P > 0.05$), male patients showed lower pain levels in shallow (4–5 mm, $P = 0.002$) and medium (6–8 mm, $P = 0.021$) pockets compared with the deep ones (>8 mm).

VRS scores during SRP are shown in Table 2. Just as in VAS score, increasing pocket depths were accompanied by higher pain levels. Compared with shallow pockets (4–5 mm), higher pain levels were found in medium (6–8 mm, $P = 0.001$) and deep (>8 mm, $P = 0.001$) pockets, whereas no differences could be identified between medium and deep pockets ($P > 0.05$). The same gender-specific differences were found: Female patients reported homogeneous pain levels irrespective of the maximum pocket depth ($P > 0.05$).

Pain in relation to commonest pocket depth

VAS and VRS scores are shown in Table 3. Dividing patients by commonest pocket depths, the group with shallow pockets (4–5 mm) showed less procedural pain (VAS 22.1, SD 21.4; VRS 1.73, SD 0.73) than the medium pocket group (VAS 35.8, SD 25.7; $P = 0.000$; VRS 1.95 SD 0.80, $P = 0.019$). Gender-related analysis showed the same findings, except for female VRS score, where no differences in pain levels could be found ($P > 0.05$).

Table 3. **(VAS) scores (in mm) and (VRS) scores (4-step) by modest pocket depth**

Modest pocket depth (n = 445)†	VAS (SD) (min–max)	VRS (SD) (min–max)
4–5 mm (n = 362)	22.1 (21.4) (0–93)	1.73 (0.73) (1–4)
6–8 mm (n = 83)	34.8 (25.7) (0–96)	1.95 (0.80) (1–4)
P-value*	0.000	0.019

*Mann–Whitney *U*-test.
†Patients with equal distribution of modest pocket depth excluded.

Anaesthesia preference

638 patients answered the question about the preferred type of anaesthesia for SRP. 462 patients (72.4%) preferred the intrapocket anaesthesia gel, 135 (21.2%) favoured the injected anaesthesia and 41 (6.4%) were indecisive.

Discussion

Beyond doubt, only RCTs including control groups could detect the efficacy of an intrapocket anaesthesia gel. These data are evident from several former studies (5–7, 12). A site-specific randomized group assignment to a gel and a control group (e.g. injected anaesthesia) within a single patient and a subdivision of pockets into medium and deep ones are practically infeasible. It can be assumed that patients are almost blinded with respect to the actual treatment site. Therefore, in our clinical trial, we are only able to draw conclusions from a possible influence of different periodontal probing depths on the effectiveness of the intrapocket anaesthesia gel. Observational studies offer useful methods to examine various questions, particularly those relating to drug effects in real clinical practice (13, 14). The existing RCTs demonstrate the efficacy in general. However, these studies do not distinguish between different pocket depths (5–7, 12).

Increasing pocket depths were accompanied by higher procedural pain during SRP in periodontal maintenance patients, irrespective of whether maximum or commonest pocket depths were regarded. These findings are in contrast to the results of a multicentre, placebo-controlled study with 122 patients undergoing SRP. Jeffcoat *et al.* (6) suggested that the anaesthesia gel has a more pronounced effect in advanced cases of periodontal diseases with deeper probing depths. The conflicting outcomes may be explained by the fact that the control group received no anaesthesia (placebo gel). So the difference in pain perception between anaesthesia gel and placebo gel increased with higher pocket depths, and this may have led to the suggestion made by Jeffcoat *et al.* (6).

Regarding maximum pocket depths and VAS scores, higher pain levels were found in deep pockets (> 8 mm, $P < 0.05$). In VRS scores, pocket depths ≥6 mm showed more procedural pain than shallow pockets (4–5 mm, $P < 0.05$). Canakci *et al.* (11) demonstrated a correlation between increasing pocket depths and higher procedural pain during periodontal probing and SRP. Correspondingly, higher pain levels could be

expected in deeper pockets. Additionally, Jeffcoat *et al.* (6) found higher pain levels during SRP in their placebo group when probing depth was deeper and bleeding on probing or exudates was present. Overall, the non-injected intrapocket anaesthesia gel showed to be effective in reducing pain levels during SRP, but did not lead to a total numbness (4–7). According to these findings, the higher pain levels during SRP in deeper periodontal pockets could be explained by more inflammation at these sites leading to a larger wound area and therefore higher pain levels. The same reasons apply to the higher pain level in increasing commonest probing depths.

Even though in most cases, total numbness was not reached by the anaesthesia gel, patients definitely preferred this type of anaesthesia for future SRP ($n = 462$, 72.4%). Comparable results were found by van Steenberghe *et al.* (4) in a multicentre, crossover, randomized study comparing anaesthesia gel (lidocaine/prilocaine) with injected anaesthesia (lidocaine, 2% adrenaline) in 170 patients undergoing SRP. 70% preferred the less profound anaesthesia with the gel which was reasoned by the low incidence of post-procedure problems.

Conclusion

In this study, an effectiveness of local anaesthesia gel (lidocaine/prilocaine) related to pocket depths was found in periodontal maintenance patients during SRP. Moderate pockets showed less procedural pain than deep pockets. Even when increasing pocket depths were accompanied by increasing procedural pain levels, the anaesthesia gel was well accepted by patients. In the majority of cases, it was identified as the preferred anaesthesia option for future SRP treatments.

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Conflict of interest

The authors declare that they have no conflict of interests.

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