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A new ultrasonic device in maintenance therapy: perception of pain and clinical efficacy

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Abstract

Background: A recently introduced piezo-driven ultrasonic device (Vector®) generates longitudinal oscillations. As a result, the instrument tip moves parallel to the tooth surface. By avoiding vertical oscillations, maintenance treatment with the Vector® device should be less painful than treatment with conventional systems. We investigated whether patients perceive treatment with the Vector® device as less painful than with a conventional ultrasonic device, and whether the clinical efficacy of the Vector® device is comparable with that of the conventional ultrasonic device in maintenance patients.

Material and methods: Thirty-eight maintenance patients with moderate to advanced periodontal disease took part in this prospective, randomized controlled clinical study. Each patients had to have at least two teeth with probing depths of >4 mm. They were treated either with Dentsply® ($n = 22$) at a reduced power setting or with the Vector® device ($n = 16$). The observation period was 6 months. Probing pocket depth, attachment level, and bleeding upon probing were assessed at six sites on each treated tooth by a blinded investigator Patient were asked to report perceived pain during instrumentation with a visual analog scale immediately after treatment, in the evening of the treatment day, and in the evenings 1 and 2 days after treatment.

Results: Bleeding on probing, probing depth, and attachment level improved in both instrumentation groups from baseline to month 6; however, there was no difference between the two instrumentation modalities. The patients perceived treatment with neither instrument as unpleasant, and their perception of pain intensity both during instrumentation and on the following days did not differ.

Conclusion: In maintenance therapy, clinical efficacy of the vector® device is comparable with that of conventional ultrasonic device. It makes no difference whether the ultrasonic device at a reduced power setting or the Vector® device is used, since patients perceive both instruments as causing very little pain.

Key words: instrumentation; maintenance; pain; ultrasonic scaler; vas; vector

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If residual subgingival pockets remain after cause-related periodontal therapy, they frequently become recolonized with periopathogenic bacteria within a few weeks. It is known that deeper pockets have a higher risk of losing attachment in the future. In supportive periodontal therapy, frequently perfomed subgingival mechanical plaque removal in pockets >4 mm has been shown to be necessary for the maintenance of periodontal health (Joss et al. 1994, Kaldahl et al. 1996). Since subgingival instrumentation is performed repeatedly during maintenance, it is crucial to prevent even minimal root damage. As a result of the cumulative effect, even minor substance removal by scaling may result in severe root damage over time (Flemmig et al. 1998, Kocher et al. 2001a, Zappa et al. 1991).

Recent studies have shown that endotoxins are located on the periodontally diseased root surface and not within it (Hughes & Smales 1986, Nakib et al. 1982). These studies have led to the suggestion that the root surface should be treated less aggressively during periodontal therapy and that simple procedures such as washing and brushing a periodontally diseased root render the surface virtually endotoxin free (Blomlöf et al. 1987, Moore et al. 1986). Kocher showed in a clinical trial on maintenance patients that subgingival plaque removal with a plastic curette reduces the frequency of bleeding pockets to the same extent as conventional sharp curettes. Based on this knowledge, different power-driven

devices have been developed, which are intended to be non-aggressive in terms of substance removal (Dragoo 1992). A new piezo-driven ultrasonic device (Vector®, Dürr Dental, Bietigheim, Germany) was recently introduced onto the market. The Vector® system generates ultrasonic oscillations at a frequency of 25 kHz; the oscillations are converted by a resonating ring, so that a horizontal oscillation pattern is deflected vertically. As a result, the instrument tip moves parallel to the tooth surface. By avoiding oscillations applied vertically on the root surface, treatment with the Vector® system should be less aggressive than treatment with conventional systems.

Besides these clinical aspects of deposit removal, the subjective perception of the clinical treatment session is an important aspect in the patient–dentist relationship. A less painful treatment might increase patient compliance and may give a better prognosis for periodontal therapy. In a clinical study, Braun et al. (2003) showed that subjects treated with this newly developed instrument perceive less discomfort and pain than subjects who are treated either with hand instruments or a conventional ultrasonic scaler.

In this prospective, randomized controlled clinical study on maintenance patients we investigated

(I) whether patients perceive the application of the Vector® device as less painful than the use of a conventional ultrasonic device with Slimline inserts,
(II) whether the clinical efficacy of the Vector® device is comparable with that of conventional ultrasonic device.

Materials and methods

Patient sample

Forty-six patients (age >35, mean age 48 ± 8 years) with moderate to advanced periodontal disease were selected from the maintenance subject pool of the Unit of Periodontology, School of Dentistry, Greifswald, Germany and invited to participate in the study. In order to qualify, the patients had to have at least two teeth with probing depths of >4 mm and at least 15 remaining teeth. Initial periodontal treatment had to have been completed at least one year previously, and patients had to receive supportive periodontal treatment at regular 3-months intervals to maintain periodontal health. Patients with any of the following conditions were excluded from the study: systemic disease, use of systemic antibiotics in the previous 6 months, pregnancy, lactation.

A computer-generated randomization list assigned 23 patients to each instrument groups. One patient in the conventional ultrasonic scaler group and five patients in the Vector® group did not show up after the initial treatment. Two patients in the Vector® group were excluded because they took antibiotics for non-periodontal reasons during the treatment period. Thus we report on 22 subjects in control group (seven men, three smokers) and 16 subjects in Vector® group (eight men, two smokers).

Clinical examination was performed by a blinded investigator, patients did not receive detailed explanation which instrument was actually used. The observation period continued for two maintenance intervals of an average of 3 months per interval. The patients had from two to five teeth requiring treatment. The randomized controlled trial was designed with reference to the Consort guidelines. Treatment and clinical examination were performed at baseline and in an identical manner at weeks 12 and 24. The study was approved by the local ethics comittee.

Clinical protocol

Twenty-two control patients were treated with Slimline® instruments by Cavitron (Cavitron® SPS Ultrasonic, power setting 1/4 (end of Blue zone), tips FSI-SLI and FSI-10 (Dentsply, Konstanz, Germany), tips chosen based on operator's assessment) and 16 with the Vector® device (carbon fiber instruments, straight recall probe, recall curette, Vector® fluid polish as irrigation medium (Dürr Dental). The patients were re-motivated at each appointment. Before subgingival instrumentation, the supragingival plaque was stained with a disclosing agent and then removed by polishing. Reinstrumentation was performed in sites >4 mm irrespective of bleeding on probing in each session.

Clinical parameters

Plaque index

Plaque deposits were stained with a disclosing solution and assessed as present or absent on all teeth in the mouth and on six sites/tooth.

Probing pocket depth

The probing depth was measured with a Florida Probe® (Florida Probe Corporation, Gainesville, FL, USA) from the free gingival margin to the base of the pocket. This and all following clinical parameters were studied at six locations (mesio-, mid- and distobuccal, mesio-, mid- and distolingual).

Relative attachment level

Relative attachment level (RAL) was measured with the Florida Disc Probe® (Florida Probe Corporation) from the occlusal surface or incisal edge to the base of the pocket.

Bleeding upon probing

Bleeding upon probing was assessed after assessing the probing depth. The percentage of sites which bled upon probing was calculated.

Assessment of pain intensity

To assess the subjective perception of treatment, pain was assessed on an interval scale (visual analogue scale, VAS) ranging from 0, representing no pain or discomfort, to 10, representing maximum pain and discomfort. Patients were asked to protocol their perception of the rendered instrumentation immediately after treatment (timepoint A), in the evening of the treatment day (timepoint B), and in the evenings one day (timepoint C) and 2 days after the treatment (timepoint D). To minimize bias the subjects received an envelope for each day to mail the VAS assessment sheet to the Dental School the following morning.

Treatment time

The time required to perfom the subgingival treatment was assessed with a stop-watch; time for insert change was included in the complete instrumentation time.

Statistical analysis

As the main variable, we selected patient comfort; explorative variables were oral hygiene, bleeding on probing, probing depth, attachment level, and treatment time. For all clinical variables we report patient both means of the included teeth and means restricted to

sites >4 mm with probing depth at baseline on the selected teeth. The patient served as statistical unit. The analysis between the treatment modalities was performed with the Mann–Whitney *U*–Test. A significance level of $p<0.05$ was assumed for all analyses (SPSS, Version 11; SPSS Inc., Chicago, IL, USA).

Results

Plaque index

Besides intensive motivation and instruction during the study period, the Plaque Index changed very little – from 39% to 35% – in the Cavitron® group, while it decreased from 37% to 28% in the Vector® group. A similar observation could made if only sites >4 mm were included. At no timepoint was the difference between the treatment groups statistically significant (Table 1 and 2).

Bleeding on probing

In the Cavitron® group, bleeding prevalence dropped slightly from 16% to 13%, while the average bleeding prevalence in the Vector® group remained virtually constant at ca. 18% (Table 1). Considering only sites with an initial probing depth >4 mm, bleeding decreased from 41% to 19% in the Cavitron® group and increased from 25% to 28% in the Vector® group (Table 2).

Probing depth

The mean initial probing depth was 3.0 mm in both treatment groups, and was reduced to 2.6 mm independent of treatment type. No further change in probing depth occurred between the second and third examinations. The proportion of pockets with a probing depth >4 mm was initially 24% in the Cavitron® group and 22% in the Vector® group. In both groups, these proportions dropped to ca 17%, regardless of treatment type (Table 1).

Restricting the analysis to sites initially >4 mm they were reduced from 5.3 to 3.5 mm in the Dentsply and in the Vector® group from 5.2 to 3.3 mm. In both groups the proportion decreased to about 30% (Table 2).

Relative attachment level

At baseline, relative clinical attachment level was about 11 mm in the Cavitron® and 10.5 mm in the Vector® group. Treatment did virtually not alter attachment level in both groups (Table 1 and 2).

Table 1. Prevalence of plaque experience, bleeding upon probing (BOP), mean probing depth, percent of surfaces with a probing depth >4 mm, mean attachment loss, treatment time (mean and SD) at baseline, 3 and 6 months after the start of treatment

		Baseline	3 months	6 months
Plaque index in %	Cavitron®	39.2 ± 20.3	39.0 ± 18.8	35.3 ± 17.0
	Vector	36.7 ± 22.7	34.5 ± 23.4	28.0 ± 15.1
BOP in %	Cavitron®	15.9 ± 11.7	14.1 ± 11.6	13.1.4 ± 17.8
	Vector	17.9 ± 13.4	16.5 ± 15.3	17 ± 13.9
Mean probing depth (mm)	Cavitron®	3.0 ± 0.6	2.7 ± 0.6	2.7 ± 0.8
	Vector	3.0 ± 0.4	2.6 ± 0.4	2.6 ± 0.5
% probing depth >4 mm	Cavitron®	24.8 ± 13.0	17.7 ± 13.7	17.6 ± 15.5
	Vector	21.7 ± 10.6	13.3 ± 10.1	15.8 ± 10.8
Mean attachment (mm)	Cavitron®	11.0 ± 1.7	10.8 ± 1.5	10.7 ± 1.5
	Vector	10.5 ± 1.1	10.4 ± 1.3	10.2 ± 1.0
Treatment time/tooth (min.)	Cavitron®	4.1 ± 1.2*	3.9 ± 1.2	3.0 ± 1.0
	Vector	5.7 ± 2.2	4.4 ± 1.5	3.5 ± 1.0

*Statistically significant between treatment groups.

Table 2. Prevalence of plaque experience, bleeding upon probing (BOP), mean probing depth, percent of surfaces with a probing depth >4 mm, mean attachment loss, (mean and SD) at baseline, 3 months (3 mo) and 6 months (6 mo) after the start of treatment restricted to sites with an initial probing depth >4 mm

		Baseline	3 mo	6 mo
Plaque index %	Cavitron®	42.6 ± 28.7	46.1 ± 31.3	40.0 ± 32.1
	Vector	46.0 ± 34.9	42.5 ± 35.0	39.5 ± 34.5
BOP %	Cavitron®	40.5 ± 32.1	22.9 ± 21.8	18.8 ± 24.0
	Vector	25.2 ± 23.2	30.1 ± 28.5	28.1 ± 26.7
Mean probing depth (mm)	Cavitron®	5.3 ± 0.6	3.6 ± 1.3	3.5 ± 1.4
	Vector	5.2 ± 0.6	3.4 ± 0.8	3.3 ± 1.0
% probing depth >4 mm	Cavitron®	(100)	39.6 ± 30.5	31.3 ± 30.0
	Vector	(100)	31.7 ± 26.3	29.3 ± 24.5
Mean attachment (mm)	Cavitron®	11.7 ± 1.8	11.5 ± 2.0	11.3 ± 2.2
	Vector	10.5 ± 1.2	10.4 ± 1.7	10.5 ± 1.3

Assessment of pain intensity

At almost all times, the median pain score was 0. Patients did not find instrumentation itself to be unpleasant. The two treatment groups did not differ in terms of pain intensity either during instrumentation (timepoint A) or during the following days (timepoints B, C, D). Furthermore, the pain score within a treatment group did not differ significantly between any of the timepoints (Fig. 1).

Treatment time

At baseline, treatment time with the Vector® was significantly longer (5.7 min. $p<0.025$) than with the Cavitron® (4.1 min.) Over the course of the three sessions, treatment time decreased in both groups; however, operators needed about 30 s more with the Vector® than with the Cavitron®. The decrease was more pronounced in the Vector® than in the Cavitron® group.

Discussion

The patients included in this study had chronic periodontitis, had been in maintenance therapy for at least 1 year, and regularly attended their maintenance appointments. Given their average plaque index of 40%, their oral-health-related cooperation can only be described as moderate. It is not clear why, despite intensive professional attention, the plaque index improved only marginally. An average bleeding index of ca. 15% for patients in maintenance therapy corresponds to the usual values for a well-treated group (Badersten et al. 1985). The trial situation presumably led to the operator taking considerably greater pains with the patients than would be the case in a routine session. A clear indication of this is the great amount of debridement time spent per tooth. This more intensive care is

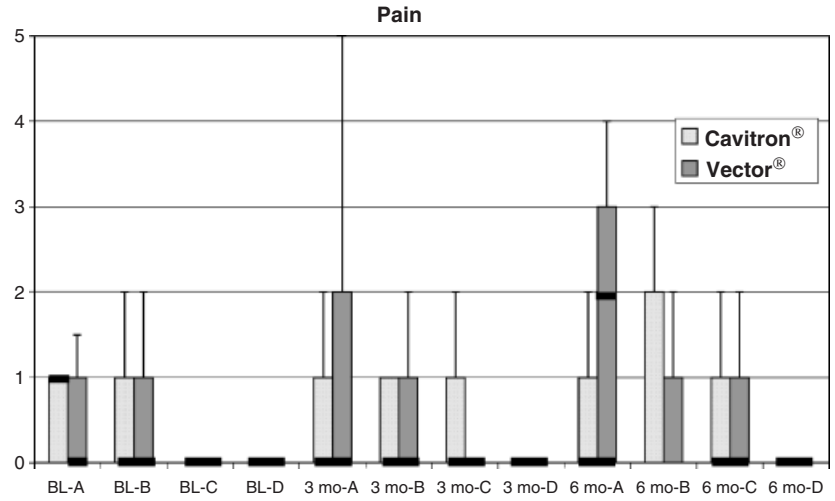

Fig. 1. Pain intensity (median, 25%, 75% and 90% percentile). The median is represented by the thick bars in the columns. Pain was recorded at baseline (BL) and at reinstrumentation at 3 months (3 mo)) and 6 months (6 mo) after the start of treatment. A, pain during treatment; B, pain in the evening of treatment day; C and D, evening of 1 and 2 days after treatment, respectively.

reflected in the decrease in bleeding index, and the reduction in probing depth and attachment loss in both groups. Although the mean clinical changes seem rather slight, they are very similar to those of Petersilka et al. (2003). They compared two different treatment strategies for the maintenance phase (scaling with curettes and a newly developed non-abrasive air-polishing powder) in pockets with a probing depth of >3 mm. Over time, they also observed a slight decrease in average probing depth from 3.0 to 2.7 mm and a reduction in the proportion of pockets >4 mm, independent of the instrument used. Considering only sites with an initial probing depth >4 mm both instrumentation modalities resulted in a pronounced probing depth reduction of about 2 mm, which however was not accompanied by gain of attachment. In the present study, the improved gingival conditions are attributed to the subgingival removal of the biofilm and to supragingival, professional tooth-cleaning, and not to improved cooperation on the part of the patient. The Cavitron® device was applied at the lowest setting, and the Vector® device in polishing mode. These settings are sufficient to remove subgingival biofilm (Schwarz et al. 2003), but not to remove calculus (Moore et al. 1986). Rühling et al. (2004) demonstrated that using slimline inserts at low settings, as little cementum was removed as when polishing with cup and polishing paste. According to information from the manufacturer, no loss of dental hard tissue is expected from the use of carbon–fiber reinforced instruments combined with polishing paste (our own pilot studies confirm this statement). In patients who regularly attend maintenance therapy, the removal of mineralized biofilm components (i.e., calculus) plays a subordinate role, because only slight amounts of subgingival calculus can re-accumulate when patients keep to the 3-month intervals. It is known that the exclusive removal of the biofilm with non-destructive instruments leads to wound healing which is comparable with that observed where conventional debriding instruments are used (Bardet et al. 1999, Kocher et al. 2001b, Nyman et al. 1988).

Although the operator had used the Vector® device for some time before the actual study began, he needed considerably more time for treatment with the Vector® than with the Cavitron® device. The time difference can confidently be ascribed to the operator's unfamiliarity with the device than to the device itself. At the second and third appointments, no further differences were noted. The total time the operator required to treat these teeth was very long. However, it must be taken into account that the total time also included the changing of inserts. Thus, these times are only comparable with those of other studies to a very limited extent. Badersten et al. (1985) reported that they needed an average of 1 min. treatment time per tooth in maintenance therapy. Presumably, the operator was so biased by the test situation that he took much more time than usual for instrumentation.

In contrast, the Vector® device produces oscillations parallel to the long-axis of the instrument, while all other ultrasonic devices create transverse or rotating oscillations. According to manufacturer information, this oscillation direction causes particularly little pain, because the instrument's tip does not hit the tooth's surface but instead moves parallel to the tooth's long axis. While using this instrument during the first treatment, it was observed that the patients complained less of pain than when conventional ultrasonic devices or curettes were used (Braun et al. 2003). These contradictory observations are presumably because of the fact that during the maintenance phase, we used the Cavitron® device at the lowest setting, while Braun et al. (2003) conducted initial treatment with a higher-power device and a thicker tip, which is actually more suitable for removing supragingival than subgingival calculus. Because of this low power setting – which is also accompanied by a lower amplitude (Lea et al. 2003) – patients apparently experienced almost no pain. Recall treatment does not seem to impose great stress on most patients (Chung et al. 2003, Karadottir et al. 2002).

We performed post hoc power analyses for the clinical variables. To detect a statistically significant difference of 0.2 mm difference in probing depth between the two instrumentation modalities 567 subjects had to be included in each arm. Although the power of the study was much too small for sound statistical reasoning, we interprete our results that there exists no clinical superiority of one instrument over the other.

Conclusion

In maintenance therapy, it does not matter whether a conventional ultrasonic instrument at a low setting for exclusive removal of biofilms or a Vector® device is used. Patients perceive both devices as causing little pain. Biofilm can be removed with the Vector® device as well as with conventional ultrasonic instruments at low power settings.

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