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RESEARCH ARTICLE

Evaluation of Pain Reduction and Clinical Efficacy of Feedback-Controlled Ultrasonic Scaler

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Background: Recently, a piezoelectric ultrasonic scaler based on a feedback control mechanism was introduced for pain relief. This study aimed to investigate the effects of a new ultrasonic scaler in reducing pain and discomfort in adults.
Methods: A newly introduced ultrasonic scaler (Master 700®) was used as the test device and a conventional ultrasonic scaler device (PIEZON®) was used as the control device. Forty-one healthy adults visited the dental clinic for dental scaling but did not undergo scaling or periodontal treatment within 6 months. Intraoral examinations were performed before scaling and 3 months later; before scaling, both devices were randomly assigned on the left or right side of each dentition (split-mouth model) and scaling was performed by a registered dental hygienist. The levels of pain and discomfort during scaling were evaluated subjectively and objectively using the visual analog scale (VAS) and physiological monitoring of the heart rate (HR), respectively. Time was measured for each device.
Results: All clinical indicators, except bleeding on probing, significantly improved with both devices. The treatment times were 7 minutes, 13 minutes (control) and 6 minutes, 59 minutes (test). VAS scores for pain were 4.89±2.12 (control) and 4.58±2.77 (test) points out of 10; for noise, these were 4.68±2.33 (control) and 4.55±2.55 (test), and for vibration, the values were 4.26±2.0 (control) and 4.18±2.48 (test). HR averages were 72.34±3.39 (control) and 75.97±9.78 (test) beats/min. No statistically significant differences were observed between the devices.
Conclusion: The pain, discomfort levels, and scaling time of the new piezoelectric ultrasonic scaler did not differ from those of the conventional device. Further research and development are necessary for more prominent pain-relief effects of scaling devices.

Key Words: Dental scaling, Feedback, Pain, Treatment outcome, Ultrasonic

Introduction

1. Background

Piezoelectric ultrasonic scalers are frequently used in clinical practice. A recent study reported that 30% of the patients who underwent scaling with an ultrasonic scaler experienced pain[1]. Depending on the intensity, the pain experienced by each patient varies[2]. The experience of pain is associated with dental phobia[3], which can lead to the refusal of dental treatment in the future[4].

To solve this problem, various scaling devices have been introduced to reduce pain and discomfort[5], including Vector® (Lunos, Bietigheim-Bissingen, Germany)[6] and Perioscan® (Sirona Dental Systems, Bensheim, Germany)[7]. However, these scales have several disadvantages. First, these devices require the user to learn new techniques because they differ from conventional piezoelectric ultrasonic scalers[8]. Second, some scalers can cause root damge[8]. Finally, the treatment time with these scalers is longer than that with conventional piezoelectric ultrasonic scalers[9].

Recently, Master 700® (EMS, Nyon, Switzerland) was introduced, which is equipped with feedback-controlling technology to solve these problems of pain reduction scalers. This ultrasonic scaler is assured by manufacturers as highly effective in terms of easy operation because skills for its use do not vary from those of conventional devices,

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thereby requiring no additional training[10]. In addition, the generated vibration can be adjusted with the feedback control system in response to the various states of tooth surfaces in the oral cavity[11]. The manufacturer claims that the new device minimizes gingival damage and provides greater pain relief than conventional scalers[12].

Despite the requirements for manufacturing, a previous study reported that pain persisted with Master 700 in 60% of hypersensitive teeth; therefore, the pain reduction effect was not significant[12]. However, the results could not be generalized to normal patients, as the degree of hypersensitivity varies among patient[5]. Moreover, the study used only the visual analog scale (VAS) to compare pain intensity[12] and more information on new devices for pain reduction using more reliable methods is necessary. According to Johnson and Rice[13], pain intensity can be assessed in two ways; a subjective assessment based on the patient's self-report, and an objective assessment based on the physiological changes in the autonomic nervous system. The VAS is the most widely used pain rating scale based on a patient's self-report[14]. The heart rate (HR) is an objective assessment of physiological changes caused by pain and discomfort[15].

2. Objectives

The present study aimed to compare and evaluate pain and discomfort between the new and conventional piezoelectric ultrasonic scalers in a general adult population using more reliable subjective and objective measurement methods.

Materials and Methods

1. Study design

1) Subjects and sample size

Healthy adults aged 20 years or older who visited the dental clinic for scaling voluntarily agreed to participate in this study but did not undergo scaling or periodontal treatment within 6 months. The following patients were excluded: patients who were undergoing periodontal treatments; patients who requested anesthesia during scaling; patients with cardiovascular, digestive, respiratory, endocrine, or abnormalities in the central nervous system or mental disorders, and pregnant women. The sample size was estimated using G-Power 3.1 (Heinrich Heine University Düsseldorf, Düsseldorf, Germany) at a level of significance α of 0.05 and testing power of 0.95. The minimum number of samples for this study was calculated at 36, and the final number of samples was set to 41, considering dropouts.

2) Material

Master 700® (EMS, Nyon, Switzerland), a feedback-controlled piezoelectric ultrasonic scaler for pain relief, was used as the test device, and PIEZON®(EMS, Nyon, Switzerland) was used as the control device. Perioslim tip (EMS, Nyon, Switzerland) with a small diameter was used as the scaling tip. To evaluate the pain and discomfort from scaling with each device, a pain-rating scale (VAS) and an external electrocardiograph cable (ER2000, Boryung Consumer, Korea) were used for subjective and objective assessments, respectively.

3) Method

To recruit subjects, the researchers visited dental clinics in Gyonggi-do and enrolled participants who understood the study's purpose and voluntarily participated. After obtaining written informed consent from the participants, the researcher started the experiment. The complete study protocol is presented in Fig. 1.

After enrollment and providing consent to participate, the participants completed a dental anxiety scale (DAS) questionnaire. Subsequently, an intraoral examination was performed to compare the periodontal status before and after scaling; the plaque index (PI) and calculus rate (CR) were measured to assess oral hygiene status; bleeding on probing (BOP) and periodontal disease index (PDI) were measured to evaluate periodontal conditions, and the presence or absence of gingival recession in each section of the oral cavity was examined.

For the test, the present study applied the split-mouth model reported by Jotikasthira[16], and a comparison between the two devices was performed, not among subjects but among areas in the oral cavity of each subject to minimize experimental errors[17]. Before scaling, both

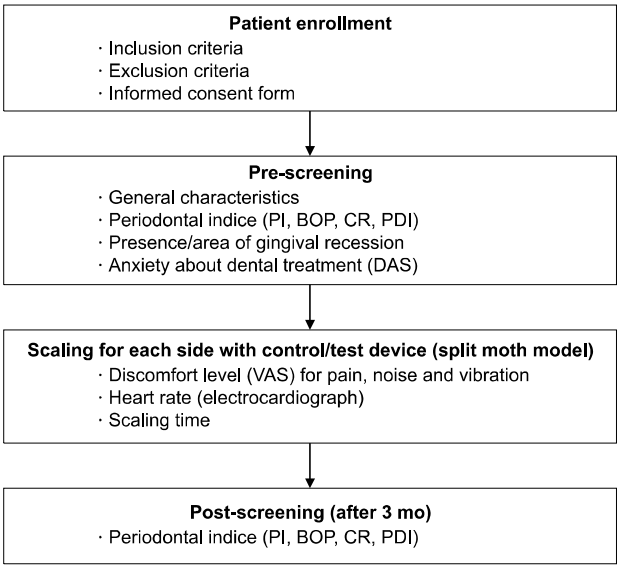

Fig. 1. The overall scheme of this study. PI: plaque index, BOP: bleeding on probing, CR: calculus rate, PDI: periodontal disease index, VAS: visual analog scale.

devices were randomly assigned to the left or right side of each dentition, and dental scaling was performed by a registered dental hygienist with more than five years of experience in a room isolated from the external environment. During scaling, the subjects wore an apron on their face to avoid figuring out the devices and attached an external electrocardiograph cable to their chest to monitor the HR during scaling; the time required for scaling was measured. After scaling, each subject's discomfort regarding pain, noise, and vibration was assessed using the VAS, and the subjects were asked to check the level of discomfort during scaling for each oral section. Three months later, another periodontal examination was performed on the subjects, similar to the first examination; PI, CR, BOP, and PDI were measured and compared with the previous conditions.

2. Statistical analysis

Data were analyzed using SPSS 25.0 (SPSS Inc., Chicago, IL, USA). Frequency analysis was conducted to describe the overall data, such as general characteristics, DAS, periodontal condition, gingival secession, VAS, and HR. Mann-Whitney U and Kruskal-Wallis tests were performed to examine differences in VAS and HR according to general characteristics, respectively. To compare the periodontal conditions before and after scaling and the discomfort reduction effect between the devices, the Mann-Whitney U test was used. For all statistical analyses, the significance level (p-value) was set at 0.05.

Results

1. Comparison of subjective and objective discomfort according to general characteristics

Table 1 shows the general characteristics of the participants, including age, gender, education, smoking status, alcohol consumption, periodontitis, gingival recession, and DAS. Most participants were 20～29 years old (34.1%), undergraduates (46.3%), nonsmokers (75.6%), and occasionally consumed alcohol (53.7%). Of the 41 patients, 23 (56.1%) had one or more areas of gingival recession. The mean DAS score was 10.29±2.61 out of 20, in which 11 (25.9%), 22 (25.9%), 6 (14.1%), and 2 (4.7%) showed normal, moderate, high, and severe dental anxiety, respectively.

However, the general characteristics of the subjects were not significantly related to the VAS (pain, noise, or vibration) or HR.

2. Comparison of the two devices

1) Treatment time

The average treatment time was 7 minutes 13 seconds±3 seconds for the control device and 6 minutes 59 seconds± 22 seconds for the test device, showing no statistically significant difference ($p < 0.05$).

2) Treatment effects after scaling

Periodontal examinations were performed before and 3 months after scaling. The PI, CR, and PDI scores, excluding the BOP score, significantly decreased before and after scaling for both devices ($p < 0.05$). The BOP score also improved after scaling with both devices; however, the difference was not statistically significant (Table 2).

3) Comparison of subjective pain and discomfort

Subjective pain, noise, and vibration evaluations were

Table 1. General Characteristics of Participants and the Level of Discomforts after Scaling

Variable	Division	N (%)	VAS (point)			Heart rate (beat/min)
			Pain	Noise	Vibration	
Age	20～29	14 (34.1)	4.5±2.1	4.2±1.9	3.6±1.5	67.6±21.2
	30～39	11 (26.8)	4.5±2.5	4.6±2.2	4.4±2.1	67.6±23.7
	40 more than	16 (39.0)	4.8±2.5	4.9±2.5	4.3±2.4	74.5±7.9
Gender	Man	13 (31.7)	4.0±2.6	4.3±2.5	3.3±1.8	75.5±5.1
	Woman	28 (68.3)	4.9±2.1	4.7±2.0	4.3±2.1	68.0±19.0
Education	High school	4 (9.8)	3.8±3.3	3.6±3.1	3.1±2.3	77.4±9.0
	University	19 (46.3)	4.6±2.3	4.4±2.0	4.1±2.0	69.5±16.7
	Graduate school	5 (12.2)	3.0±2.2	3.8±2.1	5.3±3.5	54.5±3.74
	Non-response	10 (24.4)	5.6±1.9	5.9±1.8	4.6±1.8	73.7±9.47
Smoking	Smoking	7 (17.1)	4.1±2.3	4.5±2.9	3.9±2.8	73.4±10.8
	Non-smoking	3 (7.3)	5.0±2.5	5.2±2.5	3.2±1.2	72.1±6.9
	Unexperienced	31 (75.6)	4.7±2.2	4.6±2.0	4.4±2.0	69.5±20.0
Alcohol consumption	Occasionally	22 (53.7)	4.4±2.1	4.5±2.1	3.7±1.8	71.5±16.9
	Frequently	4 (9.8)	4.5±3.5	4.5±3.3	4.6±3.4	70.1±14.3
	Unexperienced	15 (36.6)	4.9±2.3	4.8±2.1	4.8±2.0	68.7±20.9
Periodontitis	Unaffected	37 (90.2)	4.7±2.1	4.7±2.1	4.3±2.1	69.6±18.6
	Affected	4 (9.8)	3.9±2.8	4.0±2.9	3.3±1.8	75.8±5.1
Presence of gingival rcession	Unaffected	18 (43.9)	4.5±2.3	4.4±2.2	4.2±2.0	69.4±17.2
	Affected	23 (56.1)	4.7±2.3	4.8±2.1	4.2±2.2	71.6±19.2
DAS	Normal	11 (26.8)	3.7±2.2	3.5±2.0	3.1±1.6	73.6±8.4
	Moderate	22 (53.7)	5.0±2.5	4.9±2.4	4.6±2.4	72.8±9.5
	High	6 (14.6)	3.8±2.0	4.5±2.4	4.4±2.3	78.2±9.2
	Severe	2 (4.9)	7.8±1.7	6.3±1.5	5.3±1.5	77.3±11.8
Total/average		41 (100.0)	4.9±2.1	4.5±2.4	4.2±2.2	74.0±9.2

Values are presented as n (%) or mean±standard deviation, and statistical analysis was performed by Mann-Whitey or Kruskal-Wallis test.
VAS: visual analog scale, DAS: dental anxiety scale.

Table 2. Evaluation of Periodontal Status Pre-and Post-Scaling

	PI (%)		BOP (%)		CR (%)		PDI (point)	
	PIEZON	Master700	PIEZON	Master700	PIEZON	Master700	PIEZON	Master700
Initial	33.1±23.1	35.5±22.9	18.1±20.2	20.6±26.8	40.8±23.9	38.4±24.4	2.9±0.8	2.8±0.6
3M after	22.7±11.9	25.0±11.9	16.2±20.6	11.8±20.2	13.6±14.8	11.7±8.8	2.2±0.6	2.1±0.6
p-value	0.026*	0.007*	0.675	0.432	0.003*	0.000*	0.003*	0.005*

Values are presented as mean±standard deviation, p-value was calculated by Mann-Whitey test.
PI: plaque index, BOP: bleeding on probing, CR: calculus rate, PDI: periodontal disease index.
*There was a significant difference test between periodontitis affected and unaffected.

performed using the VAS on a 10-point scale. For pain, the mean score was 4.62±2.44; the control and test devices scored 4.89±2.12 and 4.58±2.77 points, respectively. For noise, the mean score was 4.53±.36; the control and test devices scored 4.68±2.33 and 4.55±2.55 points, respectively. For vibration, the mean score was 4.20±2.19; the control and test devices scored 4.26±2.0 and 4.18±2.48 points, respectively. All VAS scores for pain, noise, and vibration were slightly higher for the control device than the test device; however, no statistically significant difference was found (Fig. 2).

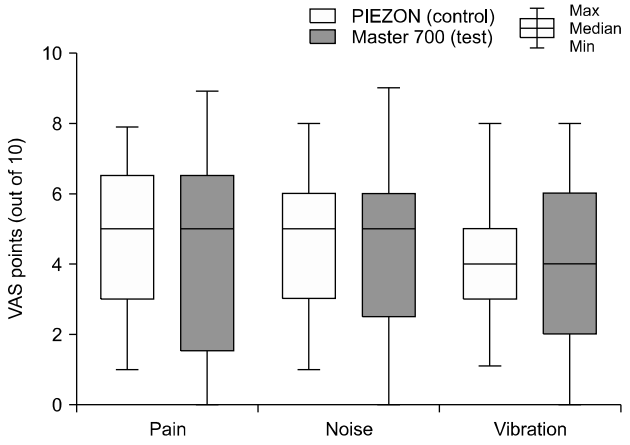

Fig. 2. Comparison for pain, noise and vibration scored by subjective method (VAS). VAS: visual analog scale.

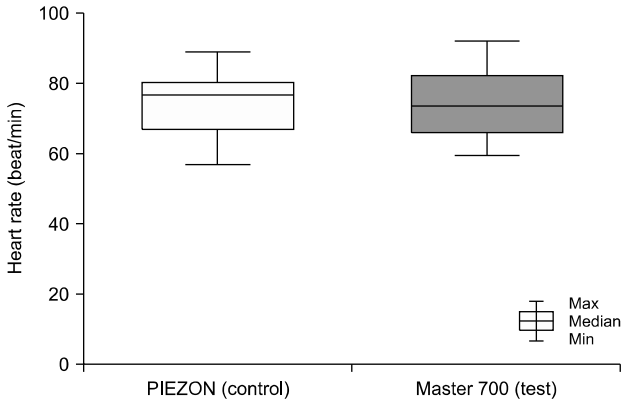

Fig. 3. Comparison of physical tension detected by objective method (Heart rate).

4) Comparison of physiological changes caused by pain and discomfort

The overall HR average during scaling of all subjects was 73.99±9.24 beats/min. Specifically, the mean HR was 72.34±3.39 and 75.97±9.78 beats/min for the control and test devices, respectively, indicating a slight increase from the normal range for both devices. However, no statistically significant differences were observed between devices (Fig. 3).

Discussion

1. Key results and comparison with previous studies

Dental scaling is important for improving periodontal health. However, it can cause physical and psychological pain in some patients[18]. Ju and Park[19] stated that the main cause of patients' avoidance of dental treatment was pain experienced during past treatment, and Park et al.[18] stated that a method is needed to reduce patients' pain during dental scaling. de Jongh and Stouthard[20] reported that patients experience a great deal of anxiety due to the noise and vibrations generated during dental scaling, and the anxiety can lead to pain during treatment[21].

The present study aimed to confirm whether Master 700, a feedback-controlled ultrasonic dental scaler, significantly improved pain, noise, and tooth vibration compared to the conventional ultrasonic scaler. Pain and discomfort, which are difficult to express verbally, were measured using objective and subjective methods. In the present study, unlike the manufacturer's advertisement, there was no significant difference between the experimental and control devices when the levels of pain and discomfort were compared and evaluated, along with the time taken for scaling.

With respect to the clinical results after scaling, most clinical indicators, except for BOP, improved significantly with both devices 3 months later, and there was no difference between the devices. No statistically significant values were obtained for BOP, which may be because the initial BOP values of the subjects in this study were low, and the differences among subjects were markedly large. BOP is related to PI, which indicates the amount of dental plaque, and PDI, which indicates the degree of periodontal disease. However, previous studies have reported that BOP may result in false-positive readings related to the force during probing[22], and non-bleeding on probing is not an appropriate criterion for evaluating gingival health, although bleeding on probing can be a criterion for gingival disease[23]. Therefore, the treatment outcomes were evaluated using various clinical indicators, and the clinical indicators improved substantially with both devices, confirming that the experimental device was as clinically effective as the existing control device.

Regarding the time required in this study, it took 7 minutes and 13 seconds for the control device and 6 minutes and 59 seconds for the experimental device to remove

calculus from the 1/2 jaw. A previous study reported that 10～20 minutes is the maximum time required for full jaw scaling[24], implying that scaling time in this study was 1.5 times less than in other cases. Furthermore, it took slightly less time for the experimental device than for the control device; however, there was no significant difference between the devices. This may be because the dental hygienist involved in this study was an experienced clinician with more than five years of experience, so she could quickly adapt to the experimental device despite it being new, and both devices were used smoothly.

The main result of this study was that the average VAS score for pain during scaling was 4.62 points. In previous studies, the average VAS scores were 4.2 points for dental scaling[25], 5.18 points for vaccination, and 5.38 points for orthodontic treatment[26], suggesting that the pain in our study was substantially low compared to that in previous studies. According to the manufacturer, the Master 700 feedback-control technology allows the tip of the device to inspect the tooth surface and control the vibration intensity through signal transmission between the feedback controller and tip according to the amount of calculus[10,11]. From the study's result, however, the pain VAS score was 4.58 points for the experimental device and 4.89 points for the control device. Although the experimental device showed slightly lower pain than the control device, no significant pain-reduction effect was observed, contrary to the manufacturer's claim. This is similar to the results of a previous study using Mater 700. The results of a study comparing pain intensity between the Master 700 and the existing ultrasonic scaler for patients with dentin hypersensitivity confirmed no statistically significant differences[12]. The reason there was no difference between the devices in this study may be due to the characteristics of our subjects and the ethical principles for clinical treatment. First, the subjects in our study voluntarily participated, so the amount of calculus in the subjects was unintentionally small; thus, the area that experienced a strong force was small. Second, if the patient complained about scaling for pain, the scaling was stopped, and the painful areas were not treated. In Korea, dental hygienists cannot administer local anesthetic injections; therefore, teeth that could have caused pain were excluded from the analysis. This could have led to a lack of significant differences between the devices.

However, the score of each VAS for noise was 4.68 points for the control device and 4.55 points for the experimental device. According to Okamoto[27], the noise score when cutting teeth using a high-speed handpiece is 4.1 points. This suggests that the noise level observed in this study was slightly higher than that experienced during the treatment of dental caries. However, the difference in noise scores between the devices was not significant, presumably because both devices used ultrasonic waves with a vibration frequency of 20 kHz or higher. Sound is a wave generated and transmitted by the vibrations of objects and media. Humans can distinguish frequencies up to 20 kHz as sound but all frequencies above are noise[28]. The wave frequency outputs from the devices used in this study were 24～32 kHz and 28～32 kHz for the test and control devices, respectively[11]. Therefore, the difference in noise score was not significant because the subjects of this study felt both the frequencies from the two devices as an unpleasant sound, i.e., 'noise'.

The VAS score for vibration was 4.26 points for the control device and 4.18 points for the experimental device, with no significant difference. According to a study by Okamoto[27], the VAS score for vibration felt during tooth cutting was 5.9 points. Teeth are harder than dental calculus; therefore, it is natural that the vibration VAS scores for calculus removal in this study were lower than those for tooth cutting in a previous study. The reason there was no significant difference in the vibration VAS between the devices in this study may be due to the vibrations generated by the two devices which could not be distinguished within the range of human tactile perception. Humans require a minimum time interval to recognize each stimulus as discrete, or the somesthetic temporal discrimination threshold (STDT). Lacruz[29] reported that the STDT for adults is 8 ms (0.008 s). In this study, the average time required for one unit vibration of the control device was 1/32 ms (0.00031 s), and that of the experimental device was 1/28 ms (0.00035 s)[11]. It is thought that the time interval between the waves was significantly shorter than that of the STDT; therefore, the subjects did not recognize the differences between the two ultrasound devices used in this study. Therefore, in future studies, it will be necessary

to evaluate the patient discomfort caused by vibrations using a more precise measuring device for calculus removal.

The mean HR during scaling was collected for a more objective assessment. The mean HR was 72.34 beats/min for the control device and 75.97 beats/min for the test device, showing no significant difference. In a study by Cho et al.[30] the HR of adults with no pathophysiological state was in the normal range (60～100 BPM) despite various physical changes. Since the subjects in this study were a general adult population without any pathophysiological state, it is presumed that all mean HRs were within the normal range, even in the presence of pain or discomfort during scaling, whereby there was no difference between the two devices. Malliani et al.[31] reported that patients' feelings of tension and discomfort can momentarily affect their HR. Thus, we attempted to further analyze the presence of tachycardia using both devices. However, it was difficult to determine tachycardia because the portable electrocardiograph we used was of a simplified and popular type and not suitable for experts. The scaling time was relatively short for the analysis and the measurement interval of the instrument was too long. Therefore, professional electrocardiographic equipment should be used for a more meaningful result analysis, and professional data collection for tachycardia determination is necessary.

The purpose of this study was to compare and analyze whether Master 700 significantly reduces pain and discomfort compared to existing piezoelectric ultrasonic scalers in real patients. It was expected that Master 700, which has a feedback control mechanism, would reduce pain by detecting the amount of calculus and adjusting the vibration frequency; however, the results of this study suggest otherwise. According to previous studies on dental pain, patients who experienced pain tended to avoid dental treatment compared to those who did not experience pain[32]. In order to avoid this, it is necessary to develop a calculus-removal device and a method with a more significant pain-reduction effect.

2. Limitations

This study has some limitations. First, various periodontal conditions were not targeted. As the experimental design was voluntary and calculus removal was performed without anesthesia, patients with the periodontal disease more than severe periodontitis could not be included. Therefore, the generalization of all periodontal conditions is limited. Therefore, in the future, it will be necessary to verify the pain-reducing effect of Master 700 in patients with more diverse periodontal conditions. Second, the past dental treatment experience of each participant was not considered. A previous report suggested that past dental experience can affect the pain level of the current treatment[33]. Thus, it is necessary to include the past dental treatment experiences of the subjects in future research. Third, the electrocardiograph was a simplified version of a professional electrocardiograph. It is recommended that future studies use a more specialized device to collect additional data on the number or percentage of tachycardia cases.

3. Significance of this study and suggestions for further studies

Despite the above limitations, this study attempted to measure the level of pain and discomfort more objectively, unlike previous studies, and confirmed that the degree of pain during calculus removal is still considerable, despite the use of a newly developed ultrasonic scaler. Therefore, the related technology still needs more supplementation for more meaningful research results. We suggest further studies supplemented with the following; 1) research subjects settings with various periodontal conditions, 2) comprehensive data collecting on subjects such as past dental experiences, and 3) use of more specialized measurement tools that can analyze tachycardia.

Notes

Conflict of interest

No potential conflict of interest relevant to this article was reported.

Ethical approval

This study was approved by the Institutional Review Board of Eulji University (IRB No. EU19-10).

Author contributions

Conceptualization: Min-ju Kim and Im-hee Jung. Data acquisition: Min-ju Kim. Formal analysis: Min-ju Kim and Im-hee Jung. Supervision: Im-hee Jung. Writing-original draft: Min-ju Kim and Im-hee Jung. Writing-review & editing: Hee-jung Lim, Myoung-hee Kim, and Young-sun Hwang.

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Data availability

The datasets of this study are available from the corresponding author upon reasonable request.

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