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RESEARCH ARTICLE

The Clinical Effect with the Use of Gel Anesthesia within Gingival Sulcus during Scaling

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Although scaling is the primary method for improving oral health, it is also associated with dental fear. The objective of this study was to empirically verify whether the use of gel anesthetic within the gingival sulcus during scaling relieves pain and improves other factors. A total of 128 patients scheduled to undergo scaling at a dental clinic of a general hospital located in the Gyeonggi Province, between July 2014 and July 2015, were enrolled in the study. The participants underwent scaling following the application of 20% benzocaine gel or placebo gel anesthetic within the gingival sulcus, and the data was collected using a questionnaire. There was a significant difference in the severity of pain, participant satisfaction, perceived sensitivity, overall discomfort, and fear of scaling between the two groups. The two groups were compared in terms of perceived need for gel anesthesia, willingness to pay for anesthesia costs, and willingness to receive scaling in the future. There were significant differences in all the three parameters depending on whether gel anesthesia was used or not. There were significant differences between the two groups in perceived sensitivity immediately after scaling and one day after scaling, with no difference seen one week after scaling. With regards to overall discomfort over time, there were significant differences between the two groups immediately after scaling. Based on these findings, we expect that application of gel anesthetic within the gingival sulcus during scaling will reduce pain, perceived sensitivity, overall discomfort, and fear of scaling with increased satisfaction.

Key Words: Anesthesia, Dental anxiety, Dental scaling, Hypersensitivity

Introduction

There has been a recent trend of increased interest in oral health among individuals with the improvements in quality of life due to societal growth and advancements in standard of living and medical sciences[1]. With respect to oral health awareness, the awareness of its importance increased with age from 19.8% in their 20s to 41.7% in their 40s and 64.7% in their 60s[2]. Those with better oral health conditions seemed to have better general health and quality of life, and these were closely related to oral health[3,4]. For the improvement in oral health of its citizens, the Korean government is enforcing many projects on preventative measures such as teeth sealants, fluoride mouth rinsing program, and prophylactic scaling[5,6] and has expanded the qualification criteria for calculus removal to patients older than 19 years, whose treatment can be completed without follow-up[7].

Periodic scaling is important for the improvement of periodontal health[8], and is the most basic method in prevention of gingivitis, periodontal diseases, and dental loss as well as maintaining or improving oral health[9]. However, some patients who underwent scaling reported sensitivity[10], which was also reported in 8% to 35% of patients undergoing periodontal treatment[11]. These symptoms have a negative impact on future visits to dental clinics and are an obstacle in availing dental services due to dental fear and anxiety[12]. De Jongh and Stouthard[13] reported that 85% of the recipients of dental hygiene treatment felt anxiety, while Kim[14] reported that patients

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felt more fear due to higher level and frequency of pain in previous dental treatments. Grant et al.[15] reported that fear and pain are felt when the dental instrument is inserted into the periodontal pocket without anesthesia during scaling, which is related to fear and anxiety, and that dental fear was greater when pain was directly experienced[16]. Hence, reducing this dental fear and pain during scaling can be assumed to be very important in the prevention of oral diseases.

To reduce the pain during scaling, extensive research is being conducted abroad to study the effectiveness of non-injection anesthesia in pain reduction and its safety. Steenberghe et al.[17] reported that patients prefer gel anesthesia (non-injection anesthesia) over injection anesthesia, and gel anesthetic used as a periodontal local anesthetic during scaling was effective in pain reduction[18,19]. Previous research in Korea reported that using happycaine gargle anesthesia during scaling was effective in reducing the psychological burden and pain in patients[20], but no Korean research has used gel anesthetic within gingival sulcus for scaling. Therefore, there is a need of a study that realistically investigates the effectiveness of non-injection anesthesia in pain reduction during scaling, and is suitable for the Korean population as well as identifies the clinical effects of related factors.

This study examines the effectiveness of local anesthetic gel in pain reduction during scaling and evaluates the clinical effects, such as reduction in discomfort like fear and perceived sensitivity, and patient satisfaction in scaling due to pain reduction that can contribute to the expansion of preventative treatments such as scaling.

Materials and Methods

1. Research subjects

A total of 128 patients scheduled to undergo scaling at a dental clinic of a general hospital located in the Gyeonggi Province, between July 2014 and July 2015, were enrolled in the study and equally and randomly divided into the experimental group (n=64) and the control group (n=64). The G*Power 3.1 program was used to calculate the number of study subjects as 128 with the two-tailed t-test to observe the difference between the two independent groups at alpha (α) level of 0.05, power 80%, and moderate effect size 0.05. This study was conducted after receiving approval from the Institutional Review Board (IRB) of Catholic University Bucheon Sungmo Hospital (HIRB-00178_1-010). Participants older than 20 years providing voluntary consent from self or a legal guardian were chosen as research subjects. Here, patients with hypersensitivity to procaine, butacaine, benzocaine, or other local anesthetics of the amino ester group, those with relevant medical history such as trauma or inflammation in the liver, kidney disease, and application area, and pregnant women were excluded from the study.

The participants underwent scaling following the application of 20% benzocaine gel and placebo gel anesthetic within the gingival sulcus, and the data was collected using a questionnaire.

2. Research methods

This study used a single center, double-blind, double placebo, and randomization design. For double-blindness, the experimental and placebo drugs were manufactured identically in shape, color, viscosity, taste, and fragrance. The experimental and placebo drugs were assigned and packaged according to randomization table, so that neither the medical provider nor the recipients were aware of the package contents.

1) Research design

Research subjects were limited to those who voluntarily gave written informed consent in their first visit. Subjects underwent sociodemographic and periodontal examinations and were randomly assigned to the experimental and control groups.

Scaling was performed 30 seconds after injecting the drug, using a 1.2 ml syringe with dull tip into the entire gingival sulcus, on randomly assigned subjects. After the scaling procedure, each subject measured their level of pain (100 mm pain visual analogue scale [VAS]) and completed a survey on the fear of scaling, perceived sensitivity, overall discomfort, patient satisfaction, and necessity of gel anesthesia. VAS 100 mm is the most commonly used method to measure the level of pain, with proven sensitivity and accuracy[21,22]. After the scaling

procedure, the levels of perceived sensitivity and general discomfort were evaluated at different timelines, such as immediately following the procedure, after one day, and after one week. For reliability of the experimental results, the scaling procedure and survey were conducted by the same researcher.

2) Experimental drug

Ultracare (Ultradent Products Inc., South Jordan, UT, USA), a local topical anesthetic containing benzocaine 20% and artificial sweetener and strawberry scent as additives, was used as the active gel. To match the color, viscosity, flavor, and fragrance of the active gel, a placebo gel was created that contained a mix of corn syrup (90%) and food coloring (10%) with a strawberry fragrance.

3) Assessment of the periodontal condition

An instrument measuring periodontal pockets was developed by the World Health Organization to measure the community periodontal index (CPI), which is a periodontal health condition evaluation index. Periodontal tissue of the main tooth was measured using the CPI probe and evaluated along scores 0～4 (0: health periodontal conditions, 1: gingival bleeding, 2: calculus and bleeding, 3: shallow periodontal pockets, and 4: deep periodontal pockets).

Pain level was evaluated using 100 mm pain VAS, with responses ranging from minimum 0 mm of 'no pain' to the maximum 100 mm of 'worst pain imaginable.' VAS is the most commonly used method in estimating the level of pain[22] due to its sensitivity and accuracy[23]. The assessment of satisfaction, level of perceived sensitivity, and discomfort were given on a 5-point Likert scale, with higher scores defined as higher satisfaction, higher level of perceived sensitivity, and more discomfort. Evaluation of the fear of scaling used 19 questions from the Korean Scaling Fear (KSF 1.0) which has a reliability of Cronbach's α=0.915.

3. Analysis methods

Collected data were analyzed using PASW Statistics 17.0 (IBM Co., Armonk, NY, USA) with statistical significance set to $p<0.05$. The distribution of the two groups was examined, and independent sample t-test and analysis of variance (ANOVA) were conducted to explore the level of pain, satisfaction, degree of perceived sensitivity, difference in discomfort, and appropriate costs. The Scheffe test was used for post-hoc analysis. The

Table 1. The General Characteristics of Study Subjects

Characteristic	Active gel (n)	Placebo gel (n)	n (%)
Total	64	64	128 (100)
Gender			
Male	27	43	70 (54.7)
Female	37	21	58 (45.3)
Age (y)			
20～29	6	4	10 (7.8)
30～39	5	10	15 (11.7)
40～49	11	13	24 (18.8)
50～59	25	32	57 (44.5)
≥60	17	5	22 (17.2)
Occupation			
Office job	10	34	44 (34.4)
Technical post	10	9	19 (14.8)
Profession	14	9	23 (18.0)
Service sector	3	0	3 (2.3)
Be unemployed	12	11	23 (18.0)
Etcetera	15	1	16 (12.5)
Education			
High school and less than	33	12	45 (35.2)
Collage	3	10	13 (10.2)
University	25	41	66 (51.6)
Graduate	3	1	4 (3.1)
Monthly allowance (10,000 won)			
＜100	26	12	38 (29.7)
100～200	2	2	4 (3.1)
201～300	29	33	62 (48.4)
＞300	7	17	24 (18.8)
Smoking			
Yes	9	20	29 (22.7)
No	55	44	99 (77.3)
Drinking			
Yes	26	39	65 (50.8)
No	38	25	63 (49.2)
Scaling experience			
Yes	56	60	116 (90.6)
No	8	4	12 (9.4)
Community periodontal index			
0	2	4	6 (4.7)
1	14	14	28 (21.9)
2	20	33	53 (41.4)
3	18	7	25 (19.5)
4	10	6	16 (12.5)

chi-square test was used to identify among the two groups the perceived need of gel anesthesia, willingness to pay for anesthesia costs, and willingness to receive scaling in the future.

Results

1. General characteristics

A total of 128 subjects (70 males and 58 females) were enrolled in the study, with 64 subjects each in the experimental and the control groups. The distribution of the age groups was as follows, 7.8% between 20 and 29 years, 11.7% between 30 and 39 years, 18.8% between 40 and 49 years, 44.5% between 50 and 59 years (highest), and 17.2% at 60 years or older. The most common form of employment was the office job (34.4%), most common level of education was college graduate (51.6%), and most common monthly income was between 2,010,000 and 3,000,000 million Korean won (48.4%). With respect to the smoking status, 22.7% of the subjects were smokers and 77.3% were non-smokers. About 90.6% had previous scaling experience, while 9.4% had none. The assessment of periodontal condition revealed a common score of 2 (calculus and bleeding, 41.4%; Table 1).

2. Difference in level of pain, satisfaction, perceived sensitivity, discomfort, and scaling fear between two groups

Using the VAS 100 mm gradation table to measure the level of pain, the two groups showed a significant difference with the active gel group at 19.7 mm and placebo gel group at 30.8 mm ($p<0.001$).

Patient satisfaction scores, immediately following scaling, showed significant difference with an average of 4.28 for the active gel group and 3.80 for the placebo gel group; perceived sensitivity symptom scores were 1.78 and 2.22 for the active gel and placebo gel groups, respectively; level of discomfort scores were significantly different with 1.41 and 2.06 for the active gel and placebo gel groups, respectively ($p<0.001$); and scaling fear was also significantly different between the groups with 1.57 for the active gel group and 2.44 for the placebo gel group ($p<0.001$; Table 2).

3. Differences in level of pain depending on general characteristics

When investigating the difference in level of pain depending on general characteristics within each group, drinkers felt more pain than non-drinkers with a significant difference in the active gel group ($p<0.001$). Those who had previous experience of scaling felt more pain than those who did not, with a significant difference ($p<0.05$). Men felt more pain than women with a significant difference in the placebo gel group ($p<0.01$). With regards to age, the level of pain felt was the highest at 43.0±8.2 mm in patients between 30 and 39 years ($p<0.001$). Smokers experienced more pain than non-smokers ($p<0.05$), and drinkers felt more pain than non-drinkers ($p<0.01$; Table 3).

Table 2. The Comparison of Visual Analogue Scale (VAS), Participant Satisfaction, Hypersensitive, Inconvenience, Scaling Fear of Two Groups

Variable	Active gel (n=64)	Placebo gel (n=64)	p-value
VAS (mm)	19.7±1.40	30.8±1.14	<0.001
Participant satisfaction	4.28±0.60	3.80±0.67	<0.001
Hypersensitive	1.78±0.72	2.22±0.80	0.002
Inconvenience	1.41±0.63	2.06±0.75	<0.001
Scaling fear	1.57±0.33	2.44±0.51	<0.001

Values are presented as mean±standard deviation.
VAS is minimum point 0 mm to maximum point 100 mm. Participant satisfaction, hypersensitive, inconvenience, scaling fear used 5-point Likert scale.
p-value was determined from t-test.

Table 3. The Visual Analogue Scale (VAS) Comparison according to the General Characteristic

Characteristic	Active gel (n=64)			Placebo gel (n=64)		
	n	Mean±SD	p-value	n	Mean±SD	p-value
Gender			0.241			0.003
Male	27	17.4±10.5		43	33.7±10.9	
Female	37	21.4±16.0		21	24.8±10.3	
Age (y)			0.059			<0.001
20～29	6	28.3±14.7		4	40.0±8.1[b]	
30～39	5	14.0±5.4		10	43.0±8.2[b]	
40～49	11	20.0±21.4		13	23.8±10.4[a]	
50～59	25	14.8±10.4		32	28.4±8.8[ab]	
Over 60	17	25.3±11.7		5	32.0±16.4[ab]	
Monthly allowance (10,000 won)			0.621			0.200
<100	26	18.5±16.1		12	28.3±16.4	
100～200	2	15.0±7.0		2	30.0±0.0	
201～300	29	22.1±13.7		33	29.1±9.4	
>300	7	15.7±5.3		17	35.9±11.4	
Smoking			0.276			0.046
Yes	9	24.4±8.8		20	35.0±11.0	
No	55	18.9±14.6		44	28.9±11.2	
Drinking			0.003			<0.001
Yes	26	25.8±13.3		39	34.6±11.2	
No	38	15.5±13.0		25	24.8±9.1	
Scaling experience			0.036			0.608
Yes	56	21.1±13.8		60	30.3±10.2	
No	8	10.0±11.9		4	37.5±25.0	
Community periodontal index			0.210			<0.001
0	2	10.0±0.00		4	42.5± 9.5[b]	
1	14	15.0±12.2		14	28.6±8.6[ab]	
2	20	27.5±15.8		33	33.6±9.6[b]	
3	18	19.4±13.9		7	27.1±17.0[ab]	
4	10	13.4±4.8		6	16.7±5.1[a]	

VAS is minimum point 0 mm to maximum point 100 mm.
p-value was determined from t-test or ANOVA.
[a,b]Post-hoc test was conducted from Scheffe test.

4. Perceived need of gel anesthesia, willingness to pay for anesthesia costs, and willingness to receive scaling in the future in the two groups

For the perceived need of gel anesthesia, the proportion of patients who responded positively was higher in the active gel group (56.1%) while the proportion of patients who responded negatively was higher in the placebo gel group (70.0%), which showed a statistically significant difference ($p<0.05$). For the willingness to pay for gel anesthesia costs, the proportion of patients who responded positively was significantly higher in the active gel group (56.8%), while the proportion of negative responses was significantly higher in the placebo gel group (69.7%) ($p<0.01$). The proportion of patients willing to receive scaling in the future was higher in the active gel group (53.8%), while those not willing was higher in the placebo gel group (46.2%), with a statistically significant difference ($p<0.05$; Table 4).

5. Difference between the two groups in the perceived sensitivity and discomfort with the passage of time

Comparing the perceived sensitivity between the two groups with the passage of time showed that perceived sensitive was higher in the placebo gel group immediately following scaling and after one day, with a significant

Table 4. The Comparison of Gel Anesthesia Need, Anesthesia Cost Payment or Not, Scaling Re-Treatment of Two Groups

Variable	Total	Active gel	Placebo gel	p-value
Gel anesthesia need				
Necessary	98 (76.6)	55 (56.1)	43 (43.9)	0.012
Unnecessary	30 (23.4)	9 (30.0)	21 (70.0)	
Anesthesia cost				
Payment	95 (74.2)	54 (56.8)	41 (43.2)	0.009
Not	33 (25.8)	10 (30.3)	23 (69.7)	
Scaling re-treatment				
Yes	119 (93.0)	64 (53.8)	55 (46.2)	0.002
No	9 (7.0)	0 (0)	9 (100)	

Values are presented as n (%).
p-value was determined from chi-square test.

Table 5. The Comparison of the Hypersensitive, Inconvenience according to the Time-Out

Variable	Active gel	Placebo gel	p-value
Hypersensitive			
Immediately after	1.78±0.72	2.22±0.80	0.002
1 day after	1.31±0.46	1.54±0.53	0.017
1 week after	1.03±0.18	1.13±0.34	0.055
Inconvenience			
Immediately after	1.41±0.63	2.06±0.75	<0.001
1 day after	1.15±0.36	1.49±0.53	<0.001
1 week after	1.00±0.00	1.03±0.18	0.015

Values are presented as mean±standard deviation.
Hypersensitive and inconvenience used 5-point Likert scale.
p-value was determined from t-test.

difference between the groups ($p<0.01$). However, after one week, neither groups showed a significant difference. The difference in discomfort between the two groups with the passage of time demonstrated higher discomfort in the placebo gel group immediately following scaling, after one day, and after one week, with a significant difference between the groups ($p<0.01$; Table 5).

6. The cost of gel anesthesia during scaling procedure

After explaining that the injection anesthesia used during tooth extraction was about 3,000 Korean won, subjects were asked their opinion on the appropriate cost for the gel anesthesia used in scaling procedure. Active gel group responded that about 2,000 Korean Won was appropriate, while placebo gel group thought 1,100 Korean won was appropriate, showing a significant difference between the groups ($p<0.001$; Table 6).

Table 6. The Cost for Gel Anesthesia Which Is Proper in the Scaling Procedure

Variable	Active gel	Placebo gel	p-value
Anesthesia cost (won)	2,000±1,227	1,100±864	<0.001

Values are presented as mean±standard deviation.
p-value was determined from t-test.

Discussion

With the increase in the average lifespan of individuals, more attention is being paid to improving quality of life and oral health[1]. Dental plaque, calculus, and food remnants must be removed to maintain and improve oral health, and scaling is considered as the most basic method to effectively prevent periodontal diseases[9]. However, scaling fear is greatly related to pain, and anesthetic injection was reported as the most anxiety-inducing stimulus in the dental environment[23]. Related previous studies have shown that patients prefer gel anesthesia over injection anesthesia during scaling and that they are willing to pay for the costs associated with gel anesthesia[17,24].

Therefore, this study used an experimental-control group research and survey to evaluate the clinical effect, such as scaling fear, reduction in perceived sensitivity and discomfort, and increase in patient satisfaction, using gel anesthesia in pain control during scaling.

Using VAS 100 mm to compare the pain level between the two groups showed that placebo gel group (control group) showed an approximately 11 mm higher result than

the active gel group (experimental group). This is in line with the study by Jeffcoat et al.[18] which reported that gel anesthetic products have the clinical effect of reducing periodontal pain and that VAS scores were significantly different between both groups. Thus, the pain reduction effect of clinical active gel in our study is sufficiently meaningful, and it is thought that pain control is possible using anesthetic gel during scaling.

Comparing the satisfaction level with gel anesthesia among the subjects of our study showed that active gel group showed higher satisfaction than the placebo gel group, which is in line with the results by Chang et al.[25] who reported that patients' satisfaction increases with decrease in the level of pain. Additionally, comparing the two groups showed that placebo gel group showed higher perceived sensitivity, discomfort, and scaling fear than the active gel group, which is similar to results by Kang et al.[20] that reported lower perceived sensitivity and fear in the group that used happycaine gargle anesthesia. These results indicate that increased pain is associated with higher perceived sensitivity, discomfort, and scaling fear. Pain control using gel anesthesia, as in our study, is thought to reduce discomfort, perceived sensitivity, and scaling fear and increase satisfaction.

Symptoms of perceived hypersensitivity or hyperesophoria after scaling were different between the two groups immediately after the scaling procedure and after one day, but were not different after one week. This can be an important basis to caution that the teeth may be sensitive after scaling, but the sensitivity commonly dissipates after a week.

Comparing the perceived need of gel anesthesia, willingness to pay for anesthesia costs, and willingness to receive scaling in the future revealed that active gel group was more positive than the placebo gel group. This can be viewed to be in the same vein with the results from Kang et al.[20] that willingness to receive scaling in the future was higher in the group that used gargle anesthesia. Moreover, the results are similar to the results by Steenberghe et al.[17] that showed that most patients indicated willingness to undergo gel anesthesia in their next treatment, and 60% indicated willingness to pay the costs associated with gel anesthesia. Patients recognized anesthetic injection as the most anxiety-inducing stimulus in dental treatments[23]. It is thought that patients prefer gel anesthesia that can reduce this anxiety-inducing stimulus and control pain even if they need to pay extra.

Limitation of our study was that because sample selection was limited to a single center in Gyeonggi Province, it was difficult to generalize the study results to all scaling patients in Korea. However, our study is significant because it investigated the clinical effect of gel anesthesia within gingival sulcus during scaling, which has not yet been studied in Korea. Even more significant fact was that it confirmed the clinical effect of decreasing pain in increasing satisfaction and reducing perceived sensitivity, discomfort, and scaling fear during scaling, which is the main job role of a dental hygienist. We also suggest, through the results of our study, the need for health insurance coverage of gel anesthesia to allow optional selection of pain control using gel anesthesia during scaling procedures.

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