ORIGINAL ARTICLE

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투고일 : 2016. 9. 19 심사일 : 2016. 4. 22 / 2016. 10. 25 게재확정일 : 2016. 11. 1

# Evaluation of Effectiveness of Vacuum Oral Cleaner Developed for Patients with Limited Mobility

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## ABSTRACT

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Purpose : The purpose of this study was to compare the plaque removal effects of vacuum oral cleaner developed for the patients with limited mobility with those of manual toothbrushes and high pressure injection oral cleaner (dental water jet).

Meterials and methods : Thirty human subjects were measured with Patient Hygiene Performance index (PHP index) and O'Leary index before and after the use of toothbrush, high pressure injection oral cleaner and vacuum oral cleaner. These three different oral hygiene methods were conducted with seven-day intermittence. Then the statistical analysis was carried out to define plaque removal rate of three different oral hygiene methods ( $\alpha = 0.05$).

Results : According to the efficacy analysis of plaque removal before and after the oral cleaning using each of three methods, significant reduction in plaque after the treatment compared to the previous state when using toothbrush, high pressure injection oral cleaner, and vacuum oral cleaner was observed ($P < 0.001$). PHP index of tooth brushing was higher than that of the high pressure injection oral cleaner, while PHP index of vacuum oral cleaner did not show significant difference from either of the other two methods. There was no significance difference in O'Leary index among the three methods.

Conclusion : Effect of plaque removal using the vacuum oral cleaner is comparable to that of manual tooth brush or high pressure injection oral cleaner, so it will be helpful for self-oral hygiene care of the patients with limited mobility.

Key words : Oral Hygiene, Nursing homes, Disabled persons, Dental plaque

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The vacuum oral cleaning devices (Dr.Pik, Dr.Pik Inc., Incheon, Korea) used in this study were generously supplied by their manufacturers.

# Ⅰ. INTRODUCTION

Many patients live with the aid of caregivers in nursing facilities or in-home due to physical or mental disabilities caused by aging or congenital disease[1]. Compared to healthy, independent individuals, disabled patients have a higher risk of plaque accumulation, dental caries, gingivitis, periodontal disease, and loss of teeth[2~7]. There are numerous studies reporting positive correlation between the physical disability and the number of the missing teeth in the patients under care in shelters or homes[8~10]. It is also reported that oral hygiene of the physically or mentally disabled patients with limited mobility is most effectively carried out by trained caregivers[11~14]. In addition, more effective oral hygiene education is carried out with giving official guides, which should include lectures or practices, rather than having a discussion on oral health only[16].

Another study described that daily plaque control with a manual toothbrush is an effective method of preventing plaque deposition around the teeth[17]. However, this applies only to the patients who can normally handle the toothbrush. Besides use of the toothbrush or dental floss, a high pressure dental injection oral cleaner (dental water jet) is one of the most routinely used oral cleaning devices[18]. When using the high pressure oral cleaner as an adjunct to manual or electric toothbrushes, plaque and gingivitis were decreased just as effectively as using the hand toothbrush and the dental floss[19].

Many other studies reported that the high pressure oral cleaner can be an appropriate substitute for the dental floss[20]. However, it is hard to use for physically disabled patients who are bed-ridden since large amounts of water may overflow when injected into the oral cavity. Furthermore, it is reported that using water to clean the oral cavity of patients with decreased gag reflex can cause intraoral pathogens to enter into the bronchial tubes and lead to the possible risk of iatrogenic aspiration pneumonia or ventilator associated pneumonia (VAP)[21].

A vacuum oral cleaner was newly developed to facilitate the oral cavity cleaning of the disabled patients (Fig. 1a). A tray, made of silicone material in the form of a mouthpiece, is connected to a portable aspirator, which is commonly used in the dental clinic. When the tray is positioned in the mouth, a marginal seal is formed where water is suctioned into an inhaler by negative pressure (Fig. 1b).

The purpose of this paper was to assess the effect of plaque removal by use of the vacuum-cleaning device, which was developed for oral cleaning of patients with limited mobility. Then the study compared its efficacy to the plaque removal ability with the manual toothbrush and high pressure injection oral cleaner.

# Ⅱ. MATERIALS AND METHODS

## 1. Study subject

Subjects for this study involved Seoul National

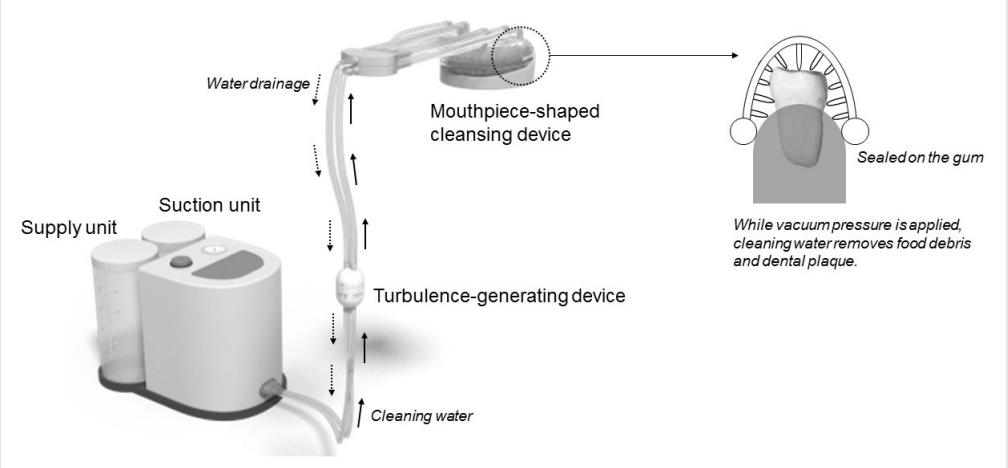


Fig. 1a. The mechanism of the vacuum oral cleaner.

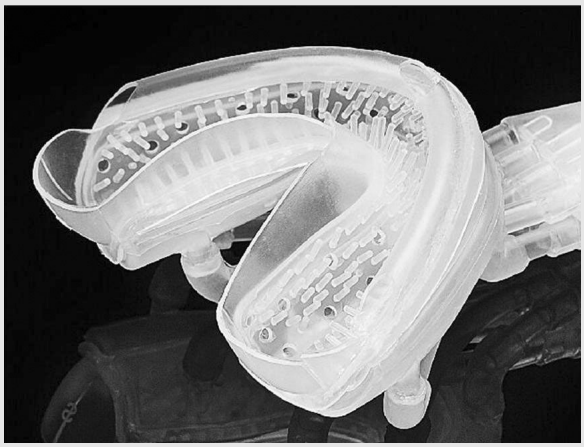

Fig. 1b. The vacuum oral cleaner has brushes made from biocompatible, bisphenol S free silicone materials.

University School of Dentistry students who were required to have all of their natural teeth, no loss of teeth, and no prosthesis in their mouth. Eligible subjects did not include those with fixed or removable orthodontic appliances, severe loss of tooth structure or periodontal tissue, calculus, discoloration, oral mucosal lesions, or medication due to systemic illness. Subjects were also excluded from the test if they already possessed medical-profession licenses or qualifications, due to chance that their expertise may affect the results. Thirty study subjects were selected within the mean age of 27.9 ( ± 1.94). They involved all male students since no female participants applied for the study.

## 2. Method

After receiving Seoul National University Dental Hospital Research Ethics Committee

approval (IRB No. CRI16008), signed consents from the all of the recruited study participants were obtained before initiating the clinical trials.

Three oral cleaning methods were utilized within intervals of one week periods; manual tooth brushing (Perio care original, LG Household & Healthcare LTC, Seoul, Korea), high pressure injection oral cleaner (Waterpik® Water Flosser Model WP-450K, Waterpik Inc., Fork Collins, CO, USA), and newly developed vacuum oral cleaning device (Dr. Pik, Dr.Pik Inc., Incheon, Korea). These were administered to all subjects and the results were measured.

Subjects were asked to abstain from any oral hygiene procedure 24 hours prior to starting each cleaning methods. Between each method, a 7-day "wash-out" period was implemented.

On the day of the study, disclosing agents (RED-COTE®, Butler Co., IL, USA) were applied on the teeth in order to evaluate discolored plaque present on the tooth surface before the oral cleaning.

After rinsing the oral cavity for 15 seconds, Patient Hygiene Performance index (PHP index) and O'Leary plaque index were recorded. For the PHP index, labial surface of maxillary right central incisor, buccal surface of maxillary bilateral first molars, labial surface of mandibular left central incisor, and lingual surface of mandibular bilateral first molars were examined. Tooth surfaces were divided into mesial, distal, central, cervical, and incisal, which allowed for the calculation of dental plaque level.

The O'Leary index evaluated all of the teeth inside the oral cavity. The teeth were divided into the mesial, distal, buccal and lingual, and then the percentile ratio of identified colored surfaces to the sum of all tooth surfaces was calculated. One individual observer carried out all measurements in this portion of the study. The difference between the PHP index and O'Leary plaque index, before and after each oral cleaning procedure, was divided by the value before usage in order to calculate the plaque removal rate.

During the first visit for the clinical trial, the toothbrushing oral hygiene procedure was conducted. In order to simulate the act of caregivers enforcing the toothbrush for patients with limited mobility, paired subjects brushed each other's teeth. A commonly used brushing method called Fone's Method was performed for 3 minutes. Toothpaste was not used since its use may give additional effects. After brushing, PHP index and O'Leary index were measured, then calculating the plaque removal rate before and after use of toothbrush.

The subjects' second visit was appointed after 7 days. Twenty-four hours prior to the second visit, any other kinds of oral cleaning procedures were prohibited. During the second visit, the high pressure oral cleaner was used to remove plaque, which was then measured via the PHP index and O'Leary index. The previous model of the high pressure injection oral cleaner was set as the control group to compare the cleaning ability of the newly developed vacuum cleaning device, despite its difficulty of use for bed-ridden patients with limited mobility due to the risk of

water overflow in the mouth. The subjects were told to clean their own teeth for three minutes with the water pressure switch on high mode attached to the classic jet tip. Plaque removal rate, before and after the cleaning, was then measured following the process.

The third visit was then appointed after another 7 days. All subjects were asked to refrain from other oral hygiene aid for 24 hours prior to the third visit. This time, using the vacuum oral cleaning device, the PHP index and O'Leary indexes were calculated. Paired subjects were instructed to insert the tray and guide each other in slightly biting down on the tray or make left-right jaw movement without any additional help for a span of three minutes (maxilla 1 minute 30 seconds, mandible 1 minute 30 seconds). Plaque removal amount was then measured using the disclosing agent to compare the before and after results of cleaning.

### 3. Statistical Analysis:

Statistical analysis software programs (IBM SPSS Statistics v23.0, SPSS Inc., Chicago, IL, USA) were used. After Shapiro-Wilk normality test was used to perform normality test, PHP index and O'Leary index before and after the use of each oral cleaning method were compared with T test. In order to compare the three different methods, one-way ANOVA and Turkey's HSD post verification was performed ($\alpha = 0.05$).

## Ⅲ. RESULTS

### 1. Analysis of plaque removal effect before and after the three oral hygiene methods

The procedures of tooth brushing, high pressure injection oral cleaner, and vacuum oral cleaner were compared in terms to their before and after plaque removal results using two types of index then analyzed with the T test. All three cleaning methods resulted significant reduction of the dental plaque after the treatment compared to the before treatment ($P < 0.001$) (Table 1).

### 2. Comparison of plaque removal rate of the three oral hygiene methods

Plaque removal rate, measured via the Shapiro-Wilk, showed that normality was met ($P > 0.05$). The average PHP index value and standard deviation of plaque removal rate were 59.41 ± 18.30% for the tooth brush, 43.41 ± 25.46% for the high pressure oral cleaner, and 48.77 ± 22.16% for the vacuum oral cleaner. A significant difference was present among the three groups when comparing their differences through the one-way ANOVA. The results of Turkey's HDS post-test showed that plaque removal rate of tooth brushing was significantly higher than that of the removal rate of high pressure injection oral cleaner. As for the vacuum oral cleaner, there was no significant difference in plaque removal rate when compared with either of other two groups (Table 1, Fig. 2a).

Table 1. Means and standard deviations in parenthesis of PHP index and O'Leary plaque index values before and after each oral cleaning method and plaque reduction ratio (%) values of each testing

| | | Before | After | Plaque reduction ratio (%) |
|---|---|---|---|---|
| PHP index | Toothbrush | 2.79 (0.81) | 1.14 (0.65) | 59.41 (18.30)[a] |
| | High pressure injection oral cleaner | 2.64 (0.90) | 1.57 (0.99) | 43.41 (25.46)[b] |
| | Vacuum oral cleaner | 3.03 (0.71) | 1.63 (0.78) | 48.77 (22.16)[a,b] |
| O'Leary plaque index | Toothbrush | 69.16 (17.84) | 29.95 (13.21) | 56.52 (15.57)[c] |
| | High pressure injection oral cleaner | 63.74 (18.19) | 35.85 (21.61) | 45.59 (25.94)[c] |
| | Vacuum oral cleaner | 72.7 (15.86) | 36.79 (18.32) | 50.74 (20.55)[c] |

Means with the same superscript letter in each column are not significantly different from each other based on Turkey's HSD test ($P > 0.05$).

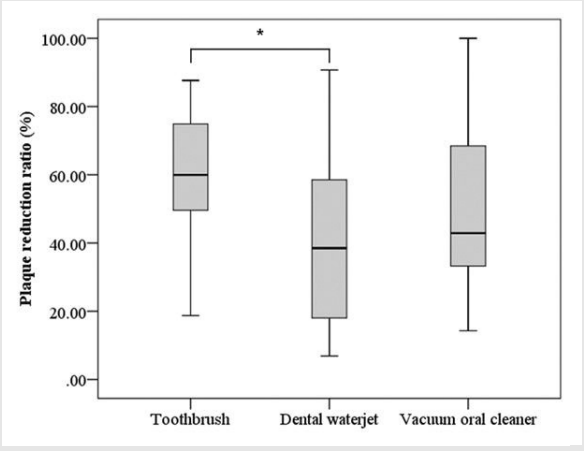


Fig. 2a. The plaque reduction ratio (%) was calculated with PHP index. *Significant difference at $P < 0.05$ level.

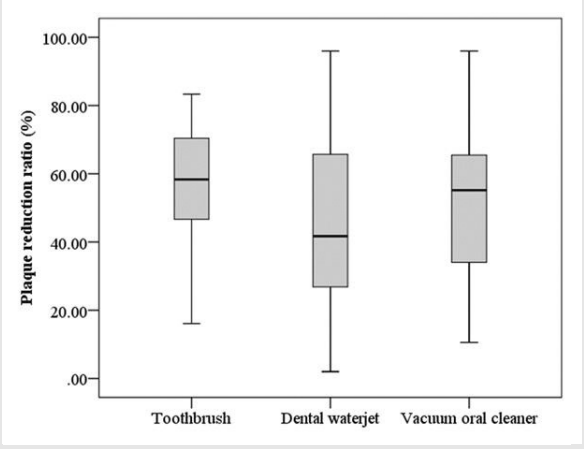


Fig. 2b. The plaque reduction ratio (%) was calculated with O'Leary plaque index.

The average plaque removal rate and standard deviation calculated using O'Leary plaque index were 56.52 ± 15.57% for the tooth brush, 45.59 ± 25.94% for the high pressure injection oral cleaner, and 50.74 ± 20.55% for the vacuum oral cleaner. There was no statistically significant difference between groups using the one-way ANOVA ($P > 0.05$) (Table 1, Fig. 2b).

## Ⅳ. DISCUSSION

This study compared the effects of the newly developed vacuum oral cleaner to the manual tooth brush and high pressure injection oral cleaner. To assess the plaque removal rate, PHP index and O'Leary index values were evaluated. In both values, the vacuum oral cleaner did not show any significant difference to the other two methods of oral cleaning. However, when comparing PHP index, manual brushing showed significantly higher plaque removal rate than high pressure injection oral cleaner. Overall, all three methods used in this clinical trial were able to remove oral plaque at a significant level.

The use of the manual tooth brush did show slightly higher plaque removal compared to the vacuum oral cleaner, although not significantly different. Most people manually brush their teeth in order to remove the plaque, and its effectiveness increases when applied to caregivers with training[23, 24]. However, there is a report saying that the motivation and hand dexterity during brushing can produce varied results[25]. In fact, it can be difficult to clean the lingual surfaces of teeth when using a single-headed tooth brush, while the use of a triple-headed brush can prove to be more effective in removing plaque on the lingual surface[15].

The high pressure injection oral cleaner, the most well-known representative for oral cleaning devices, was used as the control group. Each subject was instructed to perform self-oral cleaning according to the manufacturer's instruction in order to compare the performance of the vacuum oral cleaner. For bed-ridden patients with limited mobility, the high pressure oral cleaner can be uncomfortable due to possible overflow of water out of the mouth. A higher plaque removal rate value was observed in the vacuum oral cleaner compared to the high pressure injection oral cleaner, however there was no significant difference.

The hospital care centers for disabled patients increased from 19 in 2000 to 1103 in 2012[26]. As the number of centers increased, caregivers began holding responsibility for the oral hygiene of patients with limited mobility. Reports have shown that the degree of attention to the elder's oral health directly correlated with the level of oral healthcare training experience from caregivers[27]. When caregivers were given training from the oral healthcare management education program, they showed improved performance on brushing teeth and cleaning dentures for the patients. Hence, reports have proven that knowledge of oral health care for caregivers is vital[28].

The brush material inside the vacuum oral cleaning device is composed of silicone which is

much softer than the typical brush in regular toothbrushes, so there is less possibility of causative damage to the periodontal soft tissue. Water in the vacuum oral cleaning device can only be sucked from the water supply when there is a complete marginal seal formed by the inhaler. Removing the tray from the patient's mouth or breaking the marginal sealing prevents water overflow since sealed pressure cannot be formed. Therefore, a situation where water flows out of the tray does not happen, and it is possible to use the tray on the bed without experiencing water leakage. Moreover, reports have shown that water should be avoided in oral hygiene care of the patients with poor gag reflex, since it can increase the risk of aspiration pneumonia[21, 29]. The vacuum oral cleaning device also has an automation system, allowing for less personnel labor and labor intensity. With these advantages, vacuum oral cleaning devices are beneficial to patients with limited mobility, given that no significant difference of plaque removal rate is present among the three procedures used in this study.

One can also consider using Chlorohexidine solution as a substitute for water with the vacuum oral cleaner, a product used widely in oral health care for patients with systemic illness[30, 31]. However, the disadvantages of the chlorohexi dine such as allergic response, and tooth discoloration should be considered[32].

To conduct this study, subjects were recruited within the Dental School. Although the students have not acquired health-profession license yet, they possess the upper-hand due to their knowledge and background in oral conditions compared to the typical caregiver. In addition, the dental school students received the manual toothbrush to play the role of patients with limited mobility. Consequently, this could result in better cooperation and compliance with brushing. Therefore, it is possible that plaque removal was measured at a higher rate compared to caregivers that perform the same task.

Patients with mental or physical disability have difficulty keeping their mouth open while receiving oral cleaning, and it is harder to provide oral examination with tensed lip muscles[11]. According to previous research, patients with developmental disability tend to have stronger lower lip force[12]. As a result, cooperation for the oral cleaning can be a challenge with disabled patients. More significant results could be obtained if the actual patients and caregivers were recruited.

Another factor was the participation of only males, making us unable to determine female trends. More reliable results could be obtained if supragingival calculus removal procedure were recorded for all subjects prior to performing the test.

Plaque removal rate was measured in the order of manual tooth brushing, vacuum oral cleaning, and high pressure injection oral cleaning. In most cases, no significant differences were observed among the three methods. However, if the total number of subjects were to increase, the difference could be more statistically significant. Therefore, to apply the result of this study to clinical practice, a long-term prospective clinical

research would be required with increased number of subjects. Additional studies on effectively educating caregivers on handling the vacuum oral cleaning device should also be conducted.

## Ⅴ. CONCLUSION

Based on the result of this study, the effect of the vacuum oral cleaner compared to tooth brush or high pressure oral cleaner is comparable. Considering the advantages such as automation, procedure standardization, and reduced risk when rinsing with water, the vacuum oral cleaner will be helpful for oral health management of disabled patients.

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