การรับรสชาติในผู้ป่วยใส่เครื่องมือจัดฟันชนิดถอดได้บนที่มีแผ่นระนาบกัดด้านหลัง

นางสาวสราวรรณ สิริพันธนะ

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TASTE PERCEPTION IN PATIENTS WEARING UPPER REMOVABLE ORTHODONTIC APPLIANCES WITH POSTERIOR BITE PLANES

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A Thesis Submitted in Partial Fulfillment of the Requirements
for the Degree of Master of Science Program in Orthodontics
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สราวรรณ สิริพันธนะ : การรับรสชาติในผู้ป่วยใส่เครื่องมือจัดฟันชนิดถอดได้บนที่มีแผ่นระนาบกัดด้านหลัง (TASTE PERCEPTION IN PATIENTS WEARING UPPER REMOVABLE ORTHODONTIC APPLIANCES WITH POSTERIOR BITE PLANES) อ.ที่ปรึกษาวิทยานิพนธ์หลัก: อ. ทพ. ดร. ชิษณุ แจ้งศิริพันธ์, อ.ที่ปรึกษาวิทยานิพนธ์ร่วม: อ. ดร. ณัฐธิดา โชติช่วง, 44 หน้า.

วัตถุประสงค์ เพื่อเปรียบเทียบความเข้มข้นที่ต่ำที่สุดที่ผู้ป่วยสามารถรับรู้รสชาติได้ใน 4 รส ก่อนและหลังการใส่เครื่องมือจัดฟันชนิดถอดได้ชิ้นบนที่มีแผ่นระนาบกัดด้านหลัง

วิธีการ ผู้ป่วย 18 คน (ชาย 12 คน, หญิง 6 คน อายุเฉลี่ย 10.89 ± 1.57 ปี) ที่ในแผนการรักษาจำเป็นต้องใช้เครื่องมือจัดฟันชนิดถอดได้ชิ้นบนที่มีแผ่นระนาบกัดด้านหลังเข้าร่วมการศึกษานี้ ค่าความเข้มข้นที่ต่ำที่สุดที่ผู้ป่วยสามารถรับรู้รสชาติได้ ใน 4 รส คือ รสหวาน รสเค็ม รสเปรี้ยว และรสขม ถูกทดสอบด้วยวิธีโมดิฟายแฮริสคาลมัส การทดสอบกระทำที่ระยะเวลาต่างๆ 3 ครั้ง ดังนี้ ก่อนใส่เครื่องมือ 1 เดือน (T0) หลังจากใส่เครื่องมือทันที (T1) และหลังจากใส่เครื่องมือ 1 เดือน (T2) วิเคราะห์ข้อมูลโดยใช้สถิติทดสอบฟรีดแมน เปรียบเทียบความแตกต่างของความเข้มข้นที่ต่ำที่สุดที่ผู้ป่วยสามารถรับรู้รสชาติได้ ก่อนและหลังใส่เครื่องมือในแต่ละช่วงเวลา และเปรียบเทียบการเปลี่ยนแปลงของความเข้มข้นที่ต่ำที่สุดที่ผู้ป่วยสามารถรับรู้รสชาติได้ในแต่ละรส ที่ระดับความเชื่อมั่นร้อยละ 95

ผลการศึกษา ความเข้มข้นที่ต่ำที่สุดที่ผู้ป่วยสามารถรับรู้รสชาติได้ มีค่าเพิ่มขึ้นในวันแรกหลังจากผู้ป่วยใส่เครื่องมือ (T1) ยกเว้นรสหวาน และมีค่าลดลงที่ระยะเวลา 1 เดือนหลังจากใส่เครื่องมือ (T2) เมื่อเปรียบเทียบกับวันแรกที่ใส่เครื่องมือ (T1) ทั้งนี้ ไม่พบว่ามีความแตกต่างอย่างมีนัยสำคัญทางสถิติ และเมื่อเปรียบเทียบการเปลี่ยนแปลงค่าความเข้มข้นที่ต่ำที่สุดที่ผู้ป่วยสามารถรับรู้รสชาติได้ของทั้ง 4 รส พบว่าไม่แตกต่างอย่างมีนัยสำคัญ

สรุปผลการศึกษา การใส่เครื่องมือจัดฟันชนิดถอดได้ชิ้นบนที่มีแผ่นระนาบกัดด้านหลังในช่วงระยะเวลาสั้นๆ ไม่มีผลต่อความเข้มข้นที่ต่ำที่สุดที่ผู้ป่วยสามารถรับรสชาติได้ ใน 4 รส

ภาควิชา ทันตกรรมจัดฟัน	ลายมือชื่อนิสิต .....
สาขาวิชา ทันตกรรมจัดฟัน	ลายมือชื่อ อ.ที่ปรึกษาหลัก .....
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5675820632 : MAJOR ORTHODONTICS
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SARAWAN SIRIPANTHANA: TASTE PERCEPTION IN PATIENTS WEARING UPPER REMOVABLE ORTHODONTIC APPLIANCES WITH POSTERIOR BITE PLANES. ADVISOR: CHIDSANU CHANGSIRIPUN, Ph.D., CO-ADVISOR: NATTIDA CHOTECHUANG, Ph.D., 44 pp.

Objective: To compare the recognition threshold of four taste sensations in patients wearing upper removable orthodontic appliances with posterior bite planes before and after insertion.

Methods: Eighteen orthodontic patients (12 males and 6 females aged 10.89 ± 1.57 years old) who treatment planned to receive upper removable orthodontic appliances with posterior bite planes were recruited for the study. The recognition threshold for tasting salty, sweet, bitter and sour was measured using a Modified Harris–Kalmus test. The tests were conducted on three different occasions: T0 – one month before appliance insertion, T1 – on the day of appliance insertion, T2 – one month after appliance insertion. The Friedman test was used to statistically compare the recognition thresholds between different testing times and tastes. A 95% confidence level was applied for all statistical analyses.

Results: The patients' taste recognition threshold increased immediately after insertion of the appliances (T1) for all the tastes except for sweet and decreased at T2 compared to T1, however the differences were not statistically significant. When investigating the threshold changes among different tastes at specific times, the results showed no significant differences.

Conclusion: Short-term treatment with upper removable orthodontic appliances with posterior bite planes does not affect the taste recognition threshold in four taste sensations.

Department:	Orthodontics	Student's Signature	.....
Field of Study:	Orthodontics	Advisor's Signature	.....
Academic Year:	2014	Co-Advisor's Signature	.....

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Chapter I
INTRODUCTION

Background and Rationale

Removable orthodontic appliances with posterior or anterior bite planes have to be worn constantly, even during meals, to correct the malocclusion. Many patients often complain about a change in their taste sensation while wearing these appliances. Taste receptors within taste buds is known to locate not only on the tongue but also on the palate, pharynx, epiglottis and at the beginning of esophagus (1).

Removable orthodontic appliances consist of an acrylic portion that covers a considerable area of the palate and oral mucosa. This change in the oral environment may affect a patient's gustatory sensitivity. Alteration in taste perception can contribute to the loss of appetite and finally may lead to malnutrition. In addition, the patients may refuse to wear the appliances as they feel the appliances interfere with their taste sensations. Not wearing the appliance can result in an unfavorable treatment outcome.

Previous studies (2, 3) found no significant effect of removable orthodontic appliances on taste or flavor perception. However, in these studies, the evaluations were based on subjective verbal descriptions and semi-quantitative rating of the hedonics and intensity of the stimuli. To the best of our knowledge, no studies have evaluated the effect of upper removable orthodontic appliances with posterior bite planes on quantitative outcomes such as taste threshold. On top of those, their studies only focused on the 3 tastes: salty, sweet and sour; but bitter taste had never been tested. Moreover, due to the recruitment of patient wearing removable orthodontic appliances without posterior bite planes as subjects, we found that their experimental setting might not link to the real situation because the patients are commonly not instructed to wear removable orthodontic appliances without posterior bite planes during meals.

Therefore, the aim of the present study was to evaluate the effect of wearing upper removable orthodontic appliances with posterior bite planes on the taste recognition thresholds of the four basic tastes.

Research Questions

1. Does the patients' taste recognition threshold change after insertion of upper removable orthodontic appliances with posterior bite planes?
2. Is the threshold change of each taste (salty, sweet, sour and bitter) different?

Objectives

1. To compare the taste recognition threshold before and after insertion of upper removable orthodontic appliances with posterior bite planes at different periods of time.
2. To compare the threshold change among four tastes (salty, sweet, sour and bitter).

Research Hypotheses

1. The taste recognition threshold before and after insertion of upper removable orthodontic appliances with posterior bite planes in each taste is different.
2. The taste threshold change of each taste is different.

Limitations

1. We are not able to include the umami taste in this study because Thai children are not familiar with umami taste and may get confuse with other taste like salty or sweet. The test itself is time-consuming, thus adding the umami in the test procedure may induce subject fatigue.
2. We are not able to extend the study further than 1 month after insertion due to the time limit of the project.

Expected Benefits and Applications

This study will provide beneficial information about the effect of upper removable orthodontic appliances with posterior bite planes on taste perception. The dentist can use this information to explain and motivate the patients to wear

the appliances all the time including during meals which will be helpful in the treatment outcome. The results from this study can be applied for further study.

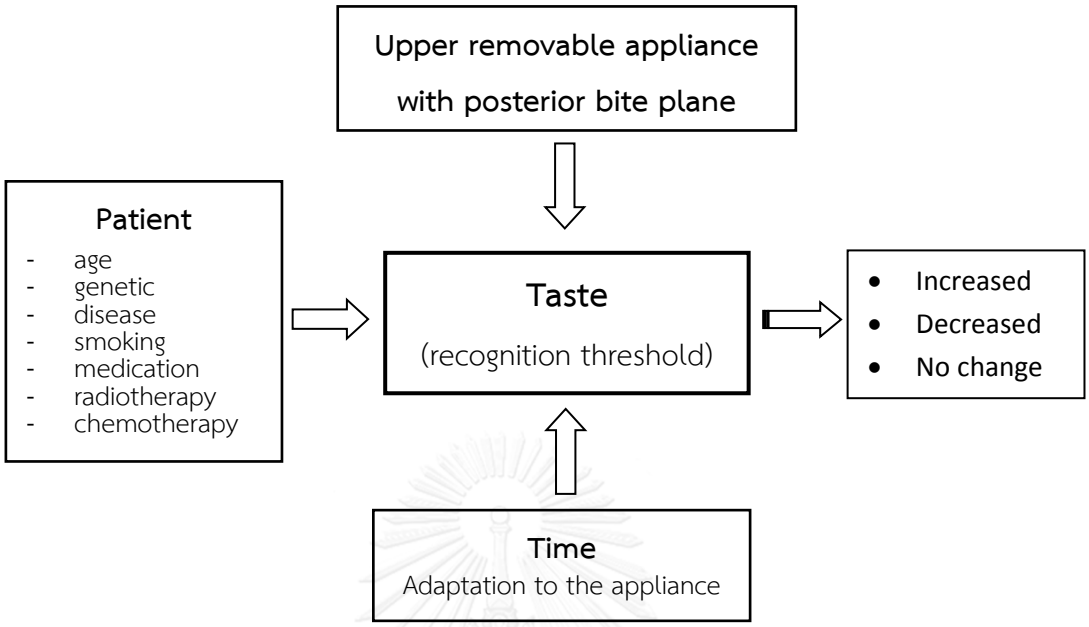
Research Design

A longitudinal quasi-experimental study in vivo.

Obstacles and strategies

1. The patients are unfamiliar with the tastes and uncooperative.
   - At the screening test, the researcher will introduce taste qualities and evaluate the cooperative of the patients.
2. The patients do not wear the appliances.
   - Advice the patients and their parents that the success of the treatment depends on their compliance to wear the appliance all the time.
3. Subject fatigue.
   - To prevent subject fatigue, the procedure will have 10 minutes rest in the middle of the test session.

Conceptual Framework



Chapter II

LITERATURE REVIEW

Removable orthodontic appliances

Removable appliances are widely used in orthodontic treatment for growth modification and for correcting minor malocclusions, such as an anterior and posterior dental crossbite or a deep overbite**.** Therefore, there are lots of children and young adolescents receiving removable appliances as their part of the treatment process.

Orthodontic appliances represent foreign objects inserted in a physically and psychologically sensitive area. Hence, susceptible individuals possibly feel uncomfortable and have negative impact on their compliance during the time of treatment, and finally compromised the quality of the treatment result (4).

The sense of taste

Taste is one of the two main chemical senses of humans and is responsible for the pleasure and enjoyment of a meal. The sense of taste is based on the detection of chemicals by specialized taste cells in the mouth. The actual taste organ consists of approximately 10,000 taste buds, which are situated predominantly on the tongue and soft palate, each with 50 to 150 receptor cells (5).

Taste buds and taste receptors

Human taste buds are formed through epithelial-mesenchymal tissue interactions within the developing tongue, soft palate, pharynx, larynx and epiglottis. These cells are modified epithelial cells (skin-like cells) rather than neurons (nerve cells). The taste cells have a lifespan of about a week, thus they are constantly developing and being replaced (6).

Taste receptors in taste buds are found in four discrete fields within the human oral cavity. One field encompasses the dorsal and lateral surfaces of the anterior two thirds of the tongue. In this anterior lingual field, taste receptors are most concentrated at the tip of the tongue, and their numbers progressively fall off

posteriorly and dorsally. The second oral taste field, the palatal field, lies in the stratified squamous and columnar epithelia covering the soft palate. Apparently, palatal taste buds are not associated with papillae of any form. Taste receptors in the third and fourth oral fields are found below the tongue's surface within trenches of foliate and circumvallate papillae, respectively. Thousands of taste buds occur on the walls of these papillae, which are surrounded by circular trenches. In addition to the oral fields, numerous taste buds are also found on the laryngeal side of the epiglottis (7).

The full development of taste bud is completed in early childhood, and no numerical or histological changes have been observed between the ages of 4 to 25 years (8).

The taste bud cells form a small opening called the taste pore. The pore is exposed to the intraoral microenvironment. The taste molecules that induce the chemosensory perception diffuse into the taste pore and physically bind to the cell surface transmembrane receptor molecules or to the various ion channels within cell membrane of the taste buds cell receptors. The taste signal is then generated (sensory transduction) and send the information on to the higher processing centers of the brain (6, 9).

According to current knowledge, the former theory of specified receptor cells that respond to only one of the basic tastes has been abandoned. There is now evidence that a receptor cell may respond to a particular taste, but the same cell may also respond to other tastes (10).

Nerve innervation for taste sensation

The taste sensation is mediated by three cranial nerves. The anterior two thirds of tongue and the palate are innervated by chorda tympani branch and greater superficial petrosal branch of the facial nerve (cranial nerve VII), respectively. The glossopharyngeal nerve (cranial nerve IX) innervates the posterior one-third of the tongue and the pharynx. And the vagus nerve (cranial nerve X) innervates and the base of tongue and epiglottis in the larynx (6).

The trigeminal nerve (cranial nerve V) provides general sensory innervation to a region that overlaps the areas served by these other cranial nerves.

The classical basic tastes

The four classical primary taste qualities are generally recognized as sweet, sour, salty, and bitter. Recently, *umami* (the taste of glutamate) was added as a fifth quality.

The fifth taste "Umami"

Umami is an oral sensation stimulated by salts of glutamic or aspartic acids. The umami sensation, roughly translated from Japanese as "delicious taste," is attributed to the taste of monosodium glutamate (MSG) and ribosides such as salts of 5' inosine monophosphate (IMP) and 5' guanine monophosphate (GMP). The sensation is sometimes rendered in English by the term "brothy" due to its resemblance to the sensations from bouillon or soup stocks. The taste properties of glutamate and aspartate salts form the building blocks of flavor principles in some ethnic (notably Asian) cuisines (9).

The four classical taste qualities may not sufficient to describe all taste sensations. However, they describe many taste experiences and have common reference materials, making them quite useful for practical sensory evaluation (9). Umami, on the other hand, is considered difficult for the Western since no description such "Umami" exists in their culture (11).

Factors affecting taste sensation

Pathophysiological factors

Various pathophysiological conditions are known to have effect on the gustatory function such as medications/drugs, radiation or chemotherapy, autoimmune and salivary gland disorders, cigarette smoking, chronic sinusitis and rhinitis, some toxic environmental exposures and peripheral nerve damage due to invasive procedures including dental interventions (12).

Physiological factors

Age

With advancing age, a progressive atrophy of taste buds take place and this may well be the reason for the lowered level of sensitivity of taste in adults (8). Besides, elderly patients are more likely to take medications, and suffer from systemic diseases, which, together or alone, makes the aging population much more likely to experience taste disorders (13).

Gender

Many studies investigated the influences of gender in taste thresholds. Conflicting sets of data have been reported for the existence of gender differences in adults. Some studies (14-16) reported that women exhibit higher gustatory sensitivity than men. The reasons for the sex-related differences in taste perception are not clear. The idea is related to the differences in the endocrine system between males and females that could indirectly influence the gustatory system (14, 15). Whereas James et al. (17) reported no significant differences in adult and concluded that, if a difference exists between the taste thresholds of women and men, it is very small and favors women. The effects of gender on taste sensitivity of 8–9-year-old children were also reported by James et al. (17), whose results showed that female children are more sensitive to tastants than males. But the differences appeared to be transitory, because no significant differences were found between female and male adults.

Saliva

Saliva is the principal fluid component of the external environment of the taste receptor cells and, as such, could play a role in taste sensitivity (18). Saliva could affects taste sensitivity in various ways such as through diffusion of taste substances, chemical interaction with taste substances, stimulation of taste receptors, and protection of taste receptors. But there is considerable individual variation e.g. the composition of saliva, changes in the flow rate and circadian rhythm. In response to these variations in saliva, taste sensitivity may also fluctuate

widely (18). Whether saliva is actually necessary for taste response is a matter of historical controversy (9). At least in short time spans it does not seem to be required, as extensive rinsing of the tongue with deionized water through a flow system does not inhibit the taste response, but can actually sharpen it (19).

Genetic

Part of the ability to detect bitter tastes is genetically determined. The best known examples of variation in sensitivity to bitterness are how different individuals perceive phenylthiocarbamide (PTC) and 6-npropylthiouracil (PROP). Approximately 75% of humans perceive these compounds as bitter, while others perceive them as relatively tasteless (non-tasters) (20). Although the ability to taste PROP does not predict a person's ability to taste all bitters, good correlations have been found to other bitter compounds (21). However, correlations with PROP non-tasters cannot be extended to other taste qualities (22).

Hunger and satiety

Relationship between taste thresholds and hunger is contradictory. Pangborn (23) concluded that no significant variation occurs after measuring taste identification thresholds for sucrose, sodium chloride, citric acid and caffeine in fasted and in satiated conditions. Agreeable result was found in Pasquet et al study (24) of taste recognition thresholds. On the contrary, Zverev (25) demonstrated that recognition thresholds for sucrose and sodium chloride were significantly lower during fasting state than after a meal while taste sensitivity to bitter substances (quinine sulphate) was not affected.

Removable denture and taste sensation

Previous studies have been done to evaluate the effect of removable denture upon taste perception. The findings were inconsistent. Henkin & Christiansen (26), Murphy (27) and Hermel et al (8) reported increased threshold in patients wearing removable denture. Other investigators (28, 29) found no effect on taste sensation whereas Bartoshuk et al (30) reported lower threshold in elderly participants with dentures.

Murphy (27) suggested that the increased threshold may result from stimulated saliva which diluted the test solution, therefore the apparent elevation of threshold may not be directly caused by the dentures but indirectly by the dilution of the stimulus. Also he suggested another explanation that denture might affect the oral perception by altering touch, temperature and pain receptors in the oral mucosa.

While many others showed varied explanations on how removable denture affect smell and taste;

- Schiffman (31) indicated no taste buds can be found in the area covered by the upper removable appliances, while Nilsson (32) claimed that some gustatory ability can be found between soft and hard palate.
- The entrapment of the sample between the plate and the palate could have either inhibitory (33, 34) or enhanced (35) effect on relevant senses.
- Palatal coverage can modulate taste information by sensations of pain, pressure or touch, thus changing the perceived taste (31).
- Late release of the self-curing acrylic monomer (36).
- Changes in thermal conductivity in the palate of the patients wearing dentures (37).
- Increased salivation (4).

Residual monomer

Self-curing acrylic resins used commonly in removable orthodontic appliances have greater amounts of free residual monomer compared to heat-cured poly methyl methacrylate (PMMA) denture-base resins (36). The residual monomer has the potential to create irritation, mucosal inflammation, and an allergic reaction. Also, the monomer released into saliva in the early phases could be tasted by the subjects (36).

Acrylic resins applied in orthodontics are generally manipulated by one of two different techniques: the dough (mass technique) and spray-on technique (additional technique). Ica et al. (38) investigated the effects of manipulation method and found that the residual monomer rate was higher in the specimens created by the dough method than the spray-on technique with the polymer:monomer ratio 2.5:1 and 3:1, respectively.

The amount of residual monomer released from orthodontic acrylic resins is high in the first 24 hours and began to decline after the first day. Therefore, researchers recommended that removable appliances should be placed in a water bath after polymerization for at least 24 hours before application in the patient (38, 39).

Removable orthodontic appliances and taste sensation

So far, there is limited data on how the removable orthodontic appliances affect the taste sensation. Har-Zion et al. (2) made suggestions based on their clinical experiences that upper removable appliances (URA) might affect taste and smell by preventing regular contact between the palatal receptor sites and the taste samples and also by disturbing the natural airflow between the oral and nasal cavities.

Therefore, their study was carried out using subjective psychophysical method to evaluate the possible influences of wearing URA on the sensations of the three tastes (sweet, salty and sour) and three flavors (mint, banana and orange) in young orthodontic patients age 9-16 years. The method was based on verbal description and semi-quantitative rating of the hedonics and intensity of the stimuli by the visual analogue scale (VAS). For each of the taste stimuli, the above threshold concentration value was used. The testing procedures were done in three different sessions for the orthodontic patient group: 10 days before insertion of URA; immediately after insertion of URA; 1 month after insertion of URA. The control group of untreated children were tested twice, at least 2 weeks apart.

Their results showed no significant differences among the various sessions or between the orthodontic patient group and the control group, indicated that a URA

does not influence the patient's ability to detect and identify taste and flavor sensations (2).

Another study was done by Hedge and Dwivedi in children age 8-13 years using the same design as Har-Zion et al., they concluded that minimal alteration perceived by the children with removable orthodontic appliance regarding change in taste and flavor seems to be transient in nature and at times was observed even in control group. Hence, the dentist should make the children and their parents understand this problem and motivate the children to wear the appliance including during meals, without fear of affecting taste and flavor sensations (3).

Psychophysics of taste

Measurement of human gustatory function

Psychophysics is the study of relationships between physical stimuli and sensory experience. Psychophysical tests used for the assessment of changes in gustatory sensitivity can be divided into two general approaches: regional testing and whole-mouth testing.

Regional testing is used for evaluating taste function in specific areas of the tongue. This technique allows the detailed examination of innervations fields of the tongue by the cranial nerves (14).

Whole-mouth testing is needed to assess "everyday" taste experiences that are not reflected by regional tests. Taste stimuli are not restricted spatially and may reach all taste bud fields, as in most real-life experiences (40).

Whole-mouth testing

In whole-mouth gustatory testing, chemical stimuli are sampled and moved throughout the mouth, stimulating all oral taste bud fields simultaneously. Laboratory tests of oral sensation involve the presentation of chemical sample at multiple concentrations spanning the functional range of perception.

A number of tests that allow assessment of whole-mouth gustatory function have been described such as the three-drop method, tasting tablet method (14), thin edible wavers (41), and the most frequently used Sip-and-spit technique.

Sip-and-spit technique

The classic sip-and-spit technique involves the participant's sampling 5–20 ml of a liquid taste stimulus, swirling the solution around in the mouth, and expectorating the contents (42-44). This technique stimulates the whole mouth, which closely represents the way humans consume food (44).

Threshold procedures (45)

Thresholds have been used for sensory evaluation almost 150 years ago. Although thresholds present technical challenges, they are conceptually straightforward.

The American Society for Testing and Materials (ASTM) provides the definition of the threshold concept for the chemical senses: "A concentration range exists below which the odor or taste of a substance will not be detectable under any practical circumstances, and above which individuals with a normal sense of smell or taste would readily detect the presence of the substance."

The *absolute or detection threshold* is the lowest concentration at which its presence can be detected as something, whether or not it is qualitatively discernible.

The *recognition threshold* is the lowest concentration at which the quality of a stimulus (e.g. sweet, bitter) can be identified. Recognition thresholds are often a bit higher than detection thresholds. For example, dilute NaCl is not always salty, but at low concentrations just above the detection threshold is perceived as sweet (46).

Lawless and Hayman suggested method for taste detection thresholds using ascending forced-choice method of limits. Ascending forced-choice procedure is widely used technique for threshold measurement in the experiment. It is a reasonably useful compromise between the need to precisely define a threshold level and the problems encountered in sensory adaptation and observer fatigue when extensive measurements are made (47).

Because thresholds are sensitive to sensory adaptation, subject fatigue, and criterion shift and yet the procedure itself is very time-consuming, so Harris & Kalmus (21) had developed an abbreviated method that provided reliable threshold

estimates with fewer trials and minimal bias. Even so, the procedure takes approximately 20 minute to administer.

Harris-Kalmus test (21)

In 1949, Harris and Kalmus developed a method for determining sensitivity to the bitter compound phenylthiourea or PTC. The test started with the lowest concentration and so on in ascending order until the subject could identify the taste quality. Then subjects had to complete the sorting task by sorting the four target samples out of the four blanks (often tap water) at each concentration step. The first concentration that subjects can correctly sorts following the quality recognition will serve as the recognition threshold. The chance probability of sorting correctly is only 0.014, so this is a fairly difficult test (47).

Modified Harris-Kalmus (m-HK) test

Wise et al. had modified the Harris-Kalmus test by reducing the number of samples used in the sorting task from 4 taste samples plus 4 blanks to 3 taste samples plus 3 blanks (48).

Comparing the m-HK for recognition threshold to the staircase method (SC) for detection threshold, Galindo-Cuspinera et al. (49) demonstrated that the SC method show less variability among subjects as compared to the m-HK but no significant differences were found on repeatability between threshold methods.

The m-HK, although less reliable, is a quick threshold method as it requires about 15 minutes per test as opposed to approximately 30 to 45 minutes needed for SC determinations. Furthermore, m-HK method can be applied simultaneously to a group of people as compared to SC, which requires a one-to-one session (49).

Gustatory test in children (50)

Measurements of gustatory function in children are rarely investigated by clinicians, and no suitable tests or normative data are available for this population group. Recently, Laing et al have developed chemosensory tests for school-age children that could be used by clinicians to detect olfactory and gustatory loss. The tests require children to identify odors or tastes, each requires no special training, and are well within the cognitive and attentive abilities of 5-year-old children. Using

sip-and-spit method of a 10 mL solution for the whole-mouth testing, they suggested using this test as *a screening test* which is a rapid and simple procedure providing the general status of taste function in a child.

The testing procedure

If possible, it is wise to give the subject a preliminary sample at a detectable level, in order to show them the target item that they will be trying to sense in the test (47).

During the test, each stimulus was separated by at least 30 seconds to minimize adaptation (51, 52). Another thing to be considered is rinsing the mouth before and between each application of taste solution. There is a possibility that if the mouth is not rinsed with water, the gustatory receptors may adapt to the test solution and the taste threshold will be elevated (53).

Mojet et al. recommended the concentration differences of the stimuli that subjects can perceive the differences is at least 0.2 log concentration step (54).

Chapter III

RESEARCH METHODOLOGY

Subject

Orthodontic patients between 8-14 years of age who need upper removable appliances with posterior bite planes during their orthodontic treatments in the Department of Orthodontics, Faculty of Dentistry, Chulalongkorn University.

Exclusion criteria

- have systemic disease or using any kind of drugs.
- have previous orthodontic treatment.
- suffer from any acute problems or diseases in their upper respiratory tract at the time of examination.

Sample size

Sample size estimation to compare the taste threshold between before and after insertion was demonstrated as following:

Sample size estimation formula for testing mean of two dependent populations.

$$n = \frac{(Z_\alpha + Z_\beta)^2 {\sigma_d}^2}{{\mu_d}^2}$$

Using the data based on previous study (27) (σ_d = 0.00924, μ_d = 0.00534) at a 95% confidence level (α = 0.05) and statistical power of 0.80 (β = 0.20), the calculated sample size was 23.

Removable appliance

The removable orthodontic appliances were constructed at the Department of Orthodontics, Faculty of Dentistry, Chulalongkorn University, using self-curing acrylic resin (Orthocryl, Dentaurum, Germany) and stainless steel wires. The polymer:monomer ratio in the preparation of the appliances was 3:1 using the spray-

on method. All appliances were prepared approximately 1 week before delivery and soaked in water for 24 hours before insertion.

Figure 1 Self-curing acrylic resin (Orthocryl, Dentaurum, Germany)

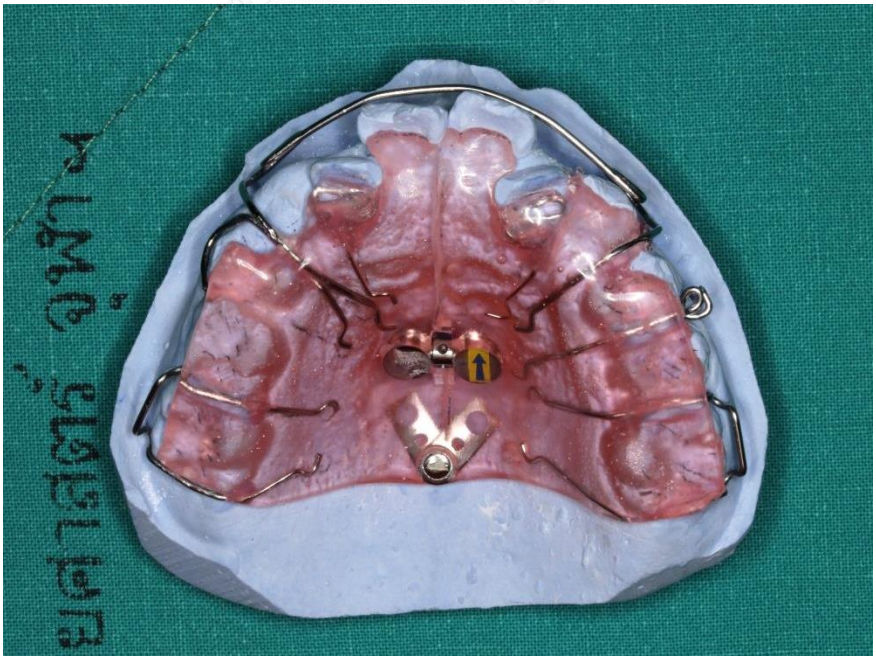


Figure 2 Upper removable orthodontic appliances with posterior bite planes

Stimuli

- The stimuli representing the four classical basic tastes were
  - Sodium chloride (NaCl) for salty
  - Sucrose for sweet
  - Citric acid for sour
  - Caffeine for bitter
- For each taste, 5 concentrations were prepared by successive 0.2 log dilutions with deionized water to avoid differences in salt levels. The range of concentrations was chosen on the basis of threshold values reported in previous studies (30, 55-58): sodium chloride 120–19.02 mM, sucrose 103–20.60 mM, citric acid 3–0.48 mM, and caffeine 4–0.63 mM.
- The solutions were prepared less than 1 week before use, stored under refrigeration at 4°C and brought to room temperature one hour before use.
- Filtered deionized water was used as rinsing solution.

Screening test

The screening test was done on the first session using the suprathreshold sample to ensure that the patients had a functioning sense of taste and were able to follow the directions. Before the test start, the tastes were explained to the patient.

Testing Procedure

The patients were asked to refrain from chewing gum, brushing their teeth, or consuming anything except water at least an hour before beginning the tests.

Modified Harris–Kalmus procedure

- The patients sat down on the dental unit with a headrest. The procedure was briefly explained
- The patients first rinsed their mouth with deionized water
- A 10-mL sample in a 30-mL cup was presented to the patient in ascending order started with the lowest concentration.

- The patients were instructed to hold and rinse the sample in their mouth for at least 5 seconds and then expectorate (whole-mouth, sip-and-spit procedure).
- Between each of the samples, the patients rinsed their mouths with deionized water.
- The patients had to identify the taste of the samples using 5 forced-choice labeled cards: sweet, sour, salty, bitter or water.
- If the patients identified the taste of the sample incorrectly, they proceed with the next higher concentration in the series.
- After the patients identified the taste correctly, they continued with a sorting task.
    - A sorting task composed of 6 cups, 3 cups containing deionized water and 3 cups containing the sample solution previously identified as having the taste. The patients' task was to sort the cups into taste and water.
    - If the patients could correctly sort the samples, the threshold run end.
    - If the patients fail to sort correctly, the sorting task will be repeated at the next higher concentration.
- The concentration that first allowed successive, correct sorts following taste recognition would serve as the taste recognition threshold.
- There was a break of 5 minutes between each taste quality series.

An example of the testing procedure is shown in Figure 3.

The testing procedures were conducted at 3 different sessions:

T0 – 1 month before appliance insertion

T1 – immediately after appliance insertion

T2 – 1 month after appliance insertion

To evaluate within-subject reliability, a retest was performed prior to appliance insertion on insertion day and focused on salty taste.

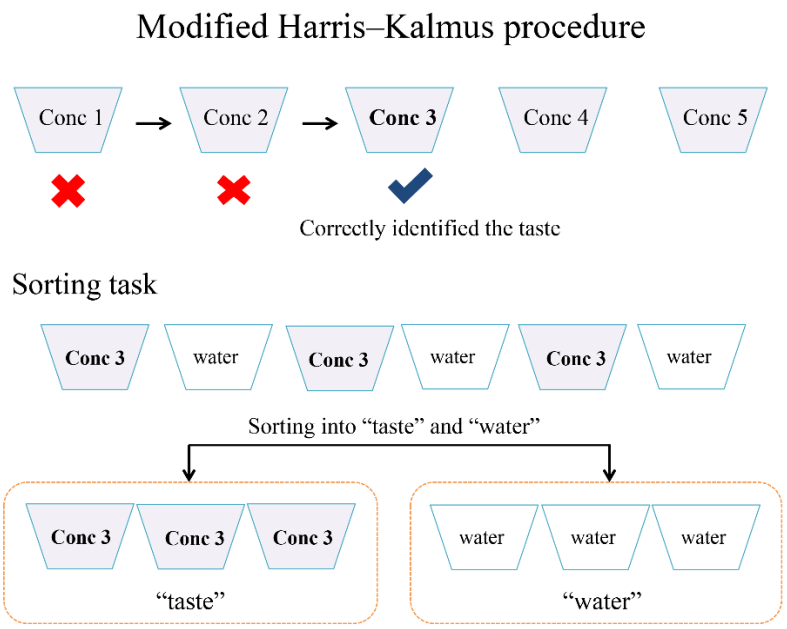


Figure 3 Example of a Modified Harris–Kalmus test. The patient received the sample solutions in ascending order, begining with the lowest concentration and attempted to identify the taste. In the example here, the patient identified the correct taste quality at solution Conc 3. The patient then proceeded with the sorting task composed of six cups, three containing water and three containing the solution previously identified as having the taste (Conc 3). The patient's task was to group the solutions in two sets and identify those that contained the taste. If the patient succeeded in sorting the solutions, Conc 3 was labeled as the taste recognition threshold.

Figure 4 The testing procedure

Data analysis

1. The recognition threshold in each taste (before and after insertion) are tested separately with Kolmogorov-Smirnov test for normality assumption, whether or not a parametric statistics is appropriate.
2. The patients' recognition threshold before and after insertion of each taste will be analyzed with repeated measures ANOVA (parametric statistics) or Friedman test (non-parametric statistics).
3. The threshold changes of four tastes are tested separately with Kolmogorov-Smirnov test for normality assumption, whether or not a parametric statistics is appropriate.
4. The threshold changed of four tastes will be analyzed with repeated measures ANOVA (parametric statistics) or Friedman test (non-parametric statistics).
5. Test-retest reliability is assessed using intraclass correlation coefficient.

Note : All statistics are tested at 95% confidence intervals.

Ethical consideration

The research protocol was approved by the Human Reasearch Ethic Committee of Faculty of Dentistry, Chulalongkorn University. The patients and their parents were informed about the research information and written informed consent was obtained prior to any testing.

Chapter IV
RESULTS

Twenty-five patients were recruited in the study, all were treatment planned to receive upper removable appliances with posterior bite planes. During the research experimental period, seven were excluded. Three patients did not pass the screening test, one patient had developed a cold during treatment, two patients missed the scheduled sessions and the other one discontinued the appliance. Thus, there were 18 patients included in the study (12 males, 6 females), whose ages ranged from 8 - 14 years old (mean ± SD, 10.89 ± 1.57).

Threshold values

Before analysis, the threshold values were log transformed to reduce skew. Analyses were conducted using SPSS software version 17. P-values less than 0.05 were considered significant for all statistical analyses. Geometric mean recognition threshold for each taste was calculated (Table 1).

Subject Reliability

The within-subject reliability was established based on the salty taste. The intraclass correlation coefficient (ICC) was 0.690. Using the classifications of ICC value by Fleiss (59), where ICC between 0.4 - 0.75 was considered fair to good, the subject reliability proved to be reasonably reliable.

Recognition threshold at different sessions

From the descriptive data of recognition threshold shown in Table 1, the mean recognition threshold increased immediately after insertion of the appliances (T1) for all the taste stimuli except sweet and decreased at T2 compared to T1. To compare the recognition thresholds among T0, T1 and T2 in each taste, a non-parametric Friedman test was used since some of the data were not normally distributed. For all the tastes, the results showed no statistically significant differences.

Table 1 Recognition threshold for each taste and comparison of the recognition threshold at different testing sessions

Taste	Session	Recognition threshold		p-value
		Geometric mean in mM unit	Mean ± SD in log mM unit	
Sweet (sucrose)	T0	52.61	1.72 ± 0.19	0.219
	T1	47.50	1.68 ± 0.22	
	T2	55.37	1.74 ± 0.18	
Salty (NaCl)	T0	41.05	1.61 ± 0.23	0.607
	T1	50.37	1.70 ± 0.27	
	T2	43.21	1.64 ± 0.25	
Sour (citric acid)	T0	0.74	-0.13 ± 0.24	0.052
	T1	1.01	0.00 ± 0.28	
	T2	0.86	-0.06 ± 0.26	
Bitter (caffeine)	T0	1.47	0.17 ± 0.30	0.052
	T1	1.90	0.28 ± 0.25	
	T2	1.67	0.22 ± 0.36	

T0 - 1 month before appliance insertion; T1- on the day of appliance insertion; T2 – 1 month after appliance insertion. P-value < 0.05 was considered statistically significant (Friedman test).

Threshold changes

Data of the threshold changes of each taste were analyzed with Komolgorov-Smirnov test. Most of the data were not normally distributed, so Friedman test was used to compare the threshold change among different tastes at specific period of time (T0-T1, T1-T2, T0-T2). The change in threshold was highest in sour taste at T0-T1 and T0-T2 period but no significant difference was found at 95% confidence level, as presented in Table 2.

Table 2 Threshold changes at different times and comparison of the threshold changes between the tastes.

Time period	Recognition threshold changes in log mM unit (Mean ± SD)				p-value
	Sucrose	NaCl	Citric acid	Caffeine	
T0-T1	-0.04 ± 0.23	0.09 ± 0.30	0.13 ± 0.17	0.11 ± 0.17	0.170
T0-T2	0.02 ± 0.22	0.02 ± 0.23	0.07 ± 0.18	0.06 ± 0.28	0.716
T1-T2	0.07 ± 0.14	-0.07 ± 0.26	-0.07 ± 0.26	-0.06 ± 0.28	0.284

Positive values indicate an increased threshold. Negative values indicate a decreasing threshold. P-value < 0.05 was considered statistically significant (Friedman test).

Chapter V
DISCUSSION AND CONCLUSION

Discussion

Orthodontic treatment with a removable appliance relies on the patient's cooperation and motivation. According to Schott & Göz (60), a majority of young patients prefer wearing their removable appliances overnight only. Inadequate wearing time makes the desired treatment result more difficult to achieve. Removable orthodontic appliances occasionally cause discomfort to the patient, including feelings of tension, pain, increased saliva, and disturbed swallowing and tongue mobility (61). Some patients additionally complain about alterations in taste. Basically, taste sensations induce the feelings of satiety and are primary reinforcers of eating (62) which in turn affect the patient's quality of life. To date, the effect of orthodontic removable appliances on gustatory sensitivity has not been extensively investigated.

A review of the literature revealed only two studies on the effect of orthodontic removable appliances on taste (2, 3). These studies focused on suprathreshold intensity and palatability using a visual analogue scale. They concluded that upper removable appliances do not affect the taste and flavor sensation. The participants were able to differentiate between the low and the high concentrations of the tastes used in these studies. However, the use of only low and high concentrations in their evaluations may not detect a slight amount of change in taste sensitivity. The use of the taste threshold can provide a more physiologic measure and is free from the subjective units of rating scales (47). Therefore, we chose to use the threshold measure in our study. Moreover, we focused only on patients with upper removable orthodontic appliances with posterior bite planes, which require the patients to eat with the appliances in their mouths. Although the previous studies used different methods than that of our study, their results (2, 3) showed that an appliance made a transient alteration in taste perception that was not statistically significant, which agrees to our findings.

A study had demonstrated that the late release of self-curing acrylic monomer could affect taste sensation (36). Researchers found that the amount of monomer released from orthodontic acrylic resins is high in the first 24 hours and began to decline after the first day (38, 39). Thus, in our protocol, the appliance fabrication was done 1 week in advance and we immersed the appliance in a water bath for at least 24 hours before delivery to avoid monomer release after appliance delivery.

An important factor affecting taste function that needs to be considered is saliva. Saliva has been linked to taste sensitivity, because it is the principal component in the external environment of the taste receptor cells (12). Patients reported increased salivary flow immediately after appliance insertion, which tended to decline overtime (4). This increased saliva may be partly responsible for the increase in the taste threshold at T1 and its decline at T2 that we found in our study.

The idea that increased saliva affected taste sensation was supported by Murphy (27) whose study was done on patients with complete dentures and found that dentures interfered with taste perception. His explanation was that dentures stimulated saliva, which diluted the solution, and this effect persisted up to 3 weeks until the patients adapted to the dentures. He also suggested another explanation that dentures might alter touch, temperature and pain receptors in the oral mucosa and thus change the perceived taste.

A number of studies have been performed on the effect of complete dentures on taste sensation. Henkin and Christiansen (26), Hermel et al. (8), and Murphy (27) reported an increased threshold in denture patients. In contrast, Bartoshuk et al. (30) reported a lower threshold in elderly participants with dentures. Wayler et al. (29) and Ghaffari et al. (28) found no significant effect on taste sensation, which is consistent with our study and others on removable orthodontic appliances (2, 3). Considering the inconsistent findings of the effect of removable dentures on taste, Wayler et al. (29) suggested that the reason might be the use of non-standardized testing techniques, including differences in the procedures used for the delivery of the stimuli, the amount of the stimuli given, solution temperature and the influence of water rinses. Differences in these parameters can produce

measurement variations. However, it is difficult to compare the present results with the complete denture studies mentioned earlier, due to the age of the patients, the more extensive coverage of the denture, and the different testing technique and stimuli.

Conclusions

The results from the present study indicated that short-term treatment using upper removable orthodontic appliances with posterior bite planes does not affect the taste recognition threshold of the four basic taste qualities. Therefore, orthodontists should use this information to explain and motivate their patients to wear their appliances all the time including during meals, which will be helpful for a successful treatment outcome.

Suggestion

Currently, the numbers of studies regarding the relationship between removable orthodontic appliances and taste sensation is very limited. Here, we focused on the threshold aspect of four taste qualities (sweet, sour, salty, and bitter) and follow-up period lasted only for 1 month after appliance insertion due to the limitations of our clinical study. Recently, umami has been introduced as the fifth taste that is believed to play an important role in the taste palatability and acceptability of the foods (63). Hence, further investigation is required for more information of all the five taste qualities in a longer period of time, and the effect of removable orthodontic appliances on taste threshold as well as taste palatability.

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APPENDICES

SPSS statistic tables

1. Subject reliability

Intraclass correlation for test-retest reliability on salty taste (NaCl)

taste		Intraclass Correlation[b]	95% Confidence Interval		F Test with True Value 0			
			Lower Bound	Upper Bound	Value	df1	df2	Sig
NaCl	Single Measures	.690[a]	.343	.872	5.461	17	17	.001
	Average Measures	.817[c]	.510	.932	5.461	17	17	.001

Two-way mixed effects model where people effects are random and measures effects are fixed.

a. The estimator is the same, whether the interaction effect is present or not.

b. Type C intraclass correlation coefficients using a consistency definition-the between-measure variance is excluded from the denominator variance.

c. This estimate is computed assuming the interaction effect is absent, because it is not estimable otherwise.

2. Recognition threshold at different sessions

Test of Normality

taste		Kolmogorov-Smirnov[a]		
		Statistic	df	Sig.
before	Sucrose	.203	18	.048
	NaCl	.171	18	.176
	Citric acid	.282	18	.001
	Caffeine	.210	18	.035
Day1	Sucrose	.220	18	.021
	NaCl	.181	18	.124
	Citric acid	.222	18	.019
	Caffeine	.234	18	.010
Month1	Sucrose	.294	18	.000
	NaCl	.175	18	.148
	Citric acid	.250	18	.004
	Caffeine	.160	18	.200*

*. This is a lower bound of the true significance.

a. Lilliefors Significance Correction

3. Comparison of recognition threshold at different testing sessions

Friedman Test

Ranks

taste		Mean Rank
Sucrose	before	1.97
	Day1	1.78
	Month1	2.25
NaCl	before	1.83
	Day1	2.11
	Month1	2.06
Citric	before	1.67
	Day1	2.31
	Month1	2.03
Caffeine	before	1.81
	Day1	2.36
	Month1	1.83

Test Statistics[a]

Sucrose	N	18
	Chi-Square	3.042
	df	2
	Asymp. Sig.	.219
NaCl	N	18
	Chi-Square	1.000
	df	2
	Asymp. Sig.	.607
Citric	N	18
	Chi-Square	5.911
	df	2
	Asymp. Sig.	.052
Caffeine	N	18
	Chi-Square	5.907
	df	2
	Asymp. Sig.	.052

a. Friedman Test

4. Threshold change among different taste qualities

Test of Normality

taste		Kolmogorov-Smirnov[a]		
		Statistic	df	Sig.
Day1_Before	Sucrose	.187	18	.097
	NaCl	.165	18	.200*
	Citric	.342	18	.000
	Caffeine	.297	18	.000
Month1_Before	Sucrose	.237	18	.009
	NaCl	.218	18	.023
	Citric	.254	18	.003
	Caffeine	.356	18	.000
Month1_Day1	Sucrose	.279	18	.001
	NaCl	.269	18	.001
	Citric	.158	18	.200*
	Caffeine	.253	18	.004

*. This is a lower bound of the true significance.

a. Lilliefors Significance Correction

5. Comparison of the threshold change among different taste qualities

Friedman Test

Ranks

Time period		Mean Rank
Day1-Before	Sucrose	1.97
	NaCl	2.61
	Citric	2.78
	Caffeine	2.64
Month1-Before	Sucrose	2.53
	NaCl	2.53
	Citric	2.69
	Caffeine	2.25
Month1-Day1	Sucrose	2.94
	NaCl	2.47
	Citric	2.31
	Caffeine	2.28

Test Statistics[a]

D1-Before	N	18
	Chi-Square	5.020
	df	3
	Asymp. Sig.	.170
Month1-Before	N	18
	Chi-Square	1.356
	df	3
	Asymp. Sig.	.716
Month1-Day1	N	18
	Chi-Square	3.801
	df	3
	Asymp. Sig.	.284

a. Friedman Test

เอกสารข้อมูลคำอธิบายสำหรับอาสาสมัครที่เข้าร่วมในการวิจัย
(Patient/Participant Information Sheet)

1. โครงการเรื่อง การรับรสชาติในผู้ป่วยใส่เครื่องมือจัดฟันชนิดถอดได้บนที่มีแผ่นระนาบกัดด้านหลัง
2. ชื่อผู้วิจัยหลัก น.ส.สราวรรณ สิริพันธนะ
   สถาบันที่สังกัด ภาควิชาทันตกรรมจัดฟัน คณะทันตแพทยศาสตร์ จุฬาลงกรณ์มหาวิทยาลัย
   แหล่งทุนวิจัย คาดว่าจะมาจากบัณฑิตวิทยาลัย จุฬาลงกรณ์มหาวิทยาลัย
3. วัตถุประสงค์ของโครงการ เพื่อเปรียบเทียบการรับรสชาติในผู้ป่วย ก่อนและหลังจากใส่เครื่องมือจัดฟันชนิดถอดได้บนที่มีแผ่นระนาบกัดด้านหลัง
4. สถานที่ดำเนินการวิจัย คณะทันตแพทยศาสตร์ จุฬาลงกรณ์มหาวิทยาลัย
5. วิธีการที่เกี่ยวข้องกับการวิจัย

   การวิจัยนี้เป็นการทดลองทางคลินิก โดยให้อาสาสมัครที่เข้าร่วมการวิจัย กลั้วปากด้วยสารละลายที่มีรสชาติต่างๆ (เค็ม หวาน เปรี้ยว ขม) เป็นระยะเวลาสั้นๆแล้วบ้วนทิ้ง แล้วให้อาสาสมัครตอบว่าสารละลายนั้นมีรสชาติอะไร โดยจะมีการทดสอบทั้งหมด 4 ครั้ง คือ 2 ครั้งก่อนใส่เครื่องมือ วันที่ใส่เครื่องมือ และหนึ่งเดือนหลังจากใส่เครื่องมือ

   อนึ่ง สารละลายที่ใช้ในการทดลองนั้น เตรียมจากสารปรุงแต่งรสที่เป็นเกรดอาหาร เช่น เกลือ น้ำตาล กรดมะนาวอ่อนและคาเฟอีน จึงไม่เป็นอันตรายต่อร่างกาย
6. เหตุผลที่เชิญเข้าร่วมเป็นอาสาสมัครในโครงการ

   เนื่องจากท่านได้รับการรักษาโดยใช้เครื่องมือจัดฟันชนิดถอดได้บนที่มีแผ่นระนาบกัดด้านหลัง และมีอายุอยู่ในช่วง 8-15 ปี มีสุขภาพแข็งแรงดี ไม่มีโรคประจำตัว ผู้วิจัยจึงเชิญอาสาสมัครเข้าร่วมโครงการ
7. ความรับผิดชอบของอาสาสมัคร และระยะเวลาที่อาสาสมัครจะอยู่ในโครงการ

   ผู้วิจัยได้แจ้งให้ท่านรับทราบข้อมูลและรายละเอียดเกี่ยวกับการวิจัยและขอให้ท่านปฏิบัติตามที่ผู้วิจัยแนะนำ ตลอดระยะเวลาที่เข้าร่วมโครงการ 2 เดือน ดังนี้
   - ขอให้ท่านมารับการตรวจตามวันและเวลาที่กำหนด ครั้งละ 20 – 30 นาที รวมทั้งหมด 4 ครั้ง
   - ขอให้ท่านงดเว้นการแปรงสีฟัน เคี้ยวหมากฝรั่งหรือรับประทานอาหารอย่างน้อย 1 ชั่วโมงก่อนทำการทดสอบในแต่ละครั้ง
   - หากเครื่องมือจัดฟันแบบถอดได้มีปัญหาหรือเนื้อเยื่อในช่องปากเกิดการระคายเคือง กรุณาติดต่อผู้วิจัยทันที ตามเบอร์โทรศัพท์ 086-5534987
8. ประโยชน์ของการวิจัยที่อาสาสมัครและ/หรือผู้อื่นที่อาจได้รับ

   ท่านจะไม่ได้รับประโยชน์โดยตรงในการร่วมการวิจัยครั้งนี้ แต่ผลการวิจัยที่ได้จะนำไปใช้เป็นแนวทางในการแนะนำและให้คำอธิบายแก่ผู้ป่วย ถึงผลของการใส่เครื่องมือจัดฟันแบบถอดได้ที่จำเป็นต้องใส่ในขณะรับประทานอาหารที่มีต่อการรับรสชาติ 9. ความเสี่ยงหรือความไม่สะดวกที่อาจจะเกิดขึ้นแก่อาสาสมัคร และในบางกรณีแก่ทารกในครรภ์ หรือทารกที่ดื่มนมมารดา

   การวิจัยนี้จำเป็นต้องรบกวนเวลาของอาสาสมัครประมาณ 20-30 นาทีต่อการทดสอบ 1 ครั้ง เป็นจำนวน 4 ครั้ง
10. ค่าใช้จ่ายที่อาสาสมัครจะต้องจ่าย หรืออาจจะต้องจ่าย

อาสาสมัครต้องออกค่าใช้จ่ายในการรักษาจัดฟันตามปกติ ส่วนการเข้าร่วมในงานวิจัยนี้ท่านไม่ต้องเสียค่าใช้จ่ายใดๆ

11. การชดเชยใดๆ และการรักษาที่จะจัดให้แก่อาสาสมัครในกรณีที่ได้รับอันตรายซึ่งเกี่ยวข้องกับการวิจัย

หากท่านได้รับอันตรายจากการทำวิจัย ผู้วิจัยจะดำเนินการให้ท่านได้รับการรักษาโดยผู้วิจัยจะเป็นผู้รับผิดชอบค่าใช้จ่ายของการรักษา

12. การจ่ายค่าเดินทาง ค่าเสียเวลา (ถ้ามี ซึ่งต้องกำหนดไว้เป็นรายครั้ง) แก่อาสาสมัครที่เข้าร่วมในการวิจัย (ทั้งนี้ต้องไม่มีข้อแม้หรือเงื่อนไขใดๆ ทั้งสิ้นในการจ่ายเงิน)

ไม่มีการจ่ายค่าเดินทางหรือค่าเสียเวลา

13. เหตุการณ์ที่อาจจะเกิดขึ้น หรือเหตุผลซึ่งผู้วิจัยจะต้องยกเลิกการเข้าร่วมในโครงการวิจัยของอาสาสมัคร

ถ้าท่านไม่มาเข้ารับการตรวจตามวันและเวลาที่กำหนด หรือไม่ปฏิบัติตามที่ผู้วิจัยแนะนำ หรือป่วยเป็นโรคของระบบทางเดินหายใจส่วนบน เช่น หวัด ในวันที่นัดทำการทดสอบ ผู้วิจัยมีความจำเป็นที่จะขอยกเลิกการเข้าร่วมในโครงการวิจัยของอาสาสมัคร

14. มีการเก็บชิ้นตัวอย่างที่ได้มาจากอาสาสมัครเอาไว้ใช้ในโครงการวิจัยในอนาคตหรือไม่ เก็บจำนวนเท่าไหร่ อย่างไร และที่ไหน

ไม่มีการเก็บชิ้นตัวอย่างใดๆ เอาไว้ใช้ในงานวิจัยในอนาคต

15. การกำกับดูแลและควบคุมการดำเนินโครงการ

ผู้กำกับดูแลการวิจัย ผู้ตรวจสอบ คณะกรรมการพิจารณาจริยธรรม และคณะกรรมการที่เกี่ยวข้อง สามารถเข้าไปตรวจสอบการดำเนินโครงการ รวมทั้ง ตรวจสอบบันทึกข้อมูลของอาสาสมัคร เพื่อเป็นการยืนยันถึงขั้นตอนในการวิจัยทางคลินิกและข้อมูลอื่นๆ โดยไม่ล่วงละเมิดเอกสิทธิ์ในการปิดบังข้อมูลของอาสาสมัคร ตามกรอบที่กฎหมายและกฎระเบียบได้อนุญาตไว้ นอกจากนี้ โดยการลงนามให้ความยินยอม อาสาสมัครหรือ ผู้แทนตามกฎหมายจะมีสิทธิตรวจสอบและมีสิทธิที่จะได้รับข้อมูลด้วยเช่นกัน

16. จริยธรรมการวิจัย

การดำเนินการโครงการวิจัยนี้ ผู้วิจัยคำนึงถึงหลักจริยธรรมการวิจัย ดังนี้

1. หลักความเคารพในบุคคล (Respect for person) โดยการให้ข้อมูลจนอาสาสมัครเข้าใจเป็นอย่างดีและตัดสินใจอย่างอิสระในการให้ความยินยอมเข้าร่วมในการวิจัย รวมทั้งการเก็บรักษาความลับของอาสาสมัคร
2. หลักการให้ประโยชน์ไม่ก่อให้เกิดอันตราย (Beneficence/Non-Maleficence) ซึ่งได้ระบุในข้อ 8 และ 9 ว่าจะมีประโยชน์หรือความเสี่ยงกับอาสาสมัครหรือไม่
3. หลักความยุติธรรม (Justice) คือมีเกณฑ์คัดเข้าและคัดออกชัดเจน มีการกระจายความเสี่ยงและผลประโยชน์อย่างเท่าเทียมกัน โดยวิธีสุ่มเข้ากลุ่มศึกษา

17. ข้อมูลที่อาจนำไปสู่การเปิดเผยตัวของอาสาสมัครจะได้รับการปกปิด ยกเว้นว่าได้รับคำยินยอมไว้โดยกฎระเบียบและกฎหมายที่เกี่ยวข้องเท่านั้น จึงจะเปิดเผยข้อมูลแก่สาธารณชนได้ ในกรณีที่ผลการวิจัยได้รับการตีพิมพ์ ชื่อและที่อยู่ของอาสาสมัครจะต้องได้รับการปกปิดอยู่เสมอ และ

อาสาสมัครหรือผู้แทนตามกฎหมายจะได้รับแจ้งโดยทันท่วงที ในกรณีที่มีข้อมูลใหม่ซึ่งอาจใช้ประกอบการตัดสินใจของอาสาสมัครว่าจะยังคงเข้าร่วมในโครงการวิจัยต่อไปได้หรือไม่

18. หากท่านมีข้อสงสัยต้องการสอบถามเกี่ยวกับสิทธิของท่านหรือผู้วิจัยไม่ปฏิบัติตามที่เขียนไว้ในเอกสารข้อมูลคำอธิบายสำหรับผู้เข้าร่วมในการวิจัย ท่านสามารถติดต่อหรือร้องเรียนได้ที่ ฝ่ายวิจัย คณะทันตแพทยศาสตร์ จุฬาลงกรณ์มหาวิทยาลัย ตึกสมเด็จย่า 93 ชั้น 10 หรือที่หมายเลขโทรศัพท์ 02-218-8866 ในเวลาทำการ
19. หากท่านต้องการยกเลิกการเข้าร่วมเป็นอาสาสมัครในโครงการนี้ ให้ท่านกรอกและส่งเอกสารขอยกเลิกมาที่
    ผู้วิจัยหลัก ทันตแพทย์หญิง สราวรรณ สิริพันธนะ
    ที่อยู่ ภาควิชาทันตกรรมจัดฟัน คณะทันตแพทยศาสตร์ จุฬาลงกรณ์มหาวิทยาลัย ถนนอังรีดูนังต์ ปทุมวัน กรุงเทพมหานคร 10330
20. อาสาสมัครสามารถติดต่อผู้วิจัยได้**<u>ตลอด 24 ชั่วโมง</u>** ที่:
    ผู้วิจัยหลัก ทันตแพทย์หญิง สราวรรณ สิริพันธนะ เบอร์โทรศัพท์ 086-5534987
    ที่อยู่ ภาควิชาทันตกรรมจัดฟัน คณะทันตแพทยศาสตร์ จุฬาลงกรณ์มหาวิทยาลัย ถนนอังรีดูนังต์ ปทุมวัน กรุงเทพมหานคร 10330

.....

(ทันตแพทย์หญิง สราวรรณ สิริพันธนะ)

ผู้วิจัยหลัก

วันที่...../...../.....

เอกสารยินยอมเข้าร่วมการวิจัย (Consent Form)

การวิจัยเรื่อง การรับรสชาติในผู้ป่วยใส่เครื่องมือจัดฟันชนิดถอดได้บนที่มีแผ่นระนาบกัดด้านหลัง

ข้าพเจ้า (นาย/ นาง/ นางสาว/ เด็กชาย/เด็กหญิง) .....

อยู่บ้านเลขที่.....ถนน.....ตำบล/แขวง..... .....

อำเภอ/เขต.....จังหวัด.....รหัสไปรษณีย์..... .....

ก่อนที่จะลงนามในใบยินยอมให้ทำการวิจัยนี้

1. ข้าพเจ้าได้รับทราบรายละเอียดข้อมูลคำอธิบายสำหรับอาสาสมัครที่เข้าร่วมในการวิจัย รวมทั้งได้รับการอธิบายจากผู้วิจัยถึงวัตถุประสงค์ของการวิจัย วิธีการทำวิจัย อันตรายหรืออาการที่อาจเกิดขึ้นจากการทำวิจัยหรือจากยาที่ใช้รวมทั้งประโยชน์ที่จะเกิดขึ้นจากการวิจัยอย่างละเอียดและมีความเข้าใจดีแล้ว

2. ผู้วิจัยรับรองว่าจะตอบคำถามต่างๆ ที่ข้าพเจ้าสงสัยด้วยความเต็มใจไม่ปิดบังซ่อนเร้นจนข้าพเจ้าพอใจ

3. ผู้วิจัยรับรองว่าจะเก็บข้อมูลเฉพาะเกี่ยวกับตัวข้าพเจ้าเป็นความลับและจะเปิดเผยได้เฉพาะในรูปที่เป็นสรุปผลการวิจัย การเปิดเผยข้อมูลเกี่ยวกับตัวข้าพเจ้าต่อหน่วยงานต่างๆ ที่เกี่ยวข้องกระทำได้เฉพาะกรณีจำเป็นด้วยเหตุผลทางวิชาการเท่านั้น และผู้วิจัยรับรองว่าหากเกิดอันตรายใดๆ จากการวิจัยดังกล่าว ข้าพเจ้าจะได้รับการรักษาพยาบาลโดยไม่คิดมูลค่า

4. ข้าพเจ้ามีสิทธิที่จะบอกเลิกการเข้าร่วมในโครงการวิจัยนี้เมื่อใดก็ได้และการบอกเลิกการเข้าร่วมการวิจัยนี้จะไม่มีผลต่อการรักษาโรคที่ข้าพเจ้าจะพึงได้รับต่อไป

ข้าพเจ้าจึงสมัครใจเข้าร่วมโครงการวิจัยนี้ตามที่ระบุในเอกสารข้อมูลคำอธิบายสำหรับอาสาสมัครและได้ลง นามในใบยินยอมนี้ด้วยความเต็มใจ และได้รับสำเนาเอกสารใบยินยอมที่ข้าพเจ้าลงนามและลงวันที่ และเอกสารยกเลิกการเข้าร่วมวิจัย อย่างละ 1 ฉบับ เป็นที่เรียบร้อยแล้ว ในกรณีที่อาสาสมัครยังไม่บรรลุนิติภาวะจะต้องได้รับการยินยอมจากผู้ปกครองด้วย

ลงนาม.....(อาสาสมัคร) (.....) วันที่...../...../.....	ลงนาม.....(ผู้ปกครอง) (.....) วันที่...../...../.....
ลงนาม.....(ผู้วิจัยหลัก) (ทันตแพทย์หญิงสราวรรณ สิริพันธนะ) วันที่...../...../.....	ลงนาม.....(พยาน) (.....) วันที่...../...../.....

ข้าพเจ้าไม่สามารถอ่านหนังสือได้ แต่ผู้วิจัยได้อ่านข้อความในใบยินยอมนี้ให้แก่ข้าพเจ้าฟังจนเข้าใจดีแล้ว ข้าพเจ้าจึงลงนาม หรือประทับลายนิ้วหัวแม่มือขวาของข้าพเจ้าในใบยินยอมนี้ด้วยความเต็มใจ

ลงนาม.....(อาสาสมัคร) (.....) วันที่...../...../.....	ลงนาม.....(ผู้ปกครอง) (.....) วันที่...../...../.....
ลงนาม.....(ผู้วิจัยหลัก) (ทันตแพทย์หญิงสราวรรณ สิริพันธนะ) วันที่...../...../.....	ลงนาม.....(พยาน) (.....) วันที่...../...../.....

VITA

Miss Sarawan Siripanthana was born on 6th February 1985. She graduated with Doctor of Dental Surgery from Chulalongkorn University in 2008. After graduation, she worked at Prasat hospital as a general practitioner for 4 year. In 2013, she started her Master degree at Chulalongkorn University in Orthodontic department and continued ever since.