Influence of silicone resilient relined complete denture on perception and pain sensation in edentulous mandibular mucosa

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Abstract

The number of elderly adults in Japan is increasing annually; this is recognized as a critical societal issue—a super-aging society. Survey of Dental Diseases by the Ministry of Health, Labor and Welfare in 2016 showed the number of denture wearers increase according to the aging, which indicates denture wearers remain. Denture wearers experience troubles, which include difficulty in food catching and, soreness or pain, and esthetic appearance. Of these, sore spots, painful gums, discomfort, and jaw soreness are the problems most frequently associated with new dentures. Furthermore, 63% of mandibular denture problems were related to pain.

One of Clinical effect of pain is resilient denture liners. The main interest of the resilient denture liner study was the pain induced by denture wearing. Our group studies sensation of the alveolar ridge mucosa under dentures by measuring current perception threshold (CPT) and pain threshold (PT) with a Neurometer®, a device that uses electrical stimulation to measure peripheral sensory nerve function quantitatively. However, edentulous patients wearing complete dentures with resilient denture liners has never been evaluated by objective measures such as quantitative sensory testing.

Thus, a randomized controlled trial was carried out to verify the effects of resilient denture liners applied mandibular complete dentures on sensory nerve using the CPT and PT. The initial study to achieve the objective was planned to measure and compare CPT and PT values of the mandible and maxilla using the Neurometer®. (Study I)

The successive study was to clarify the effects of resilient denture liners applied mandibular complete dentures on sensory nerve using the CPT and PT by randomized controlled trial. (Study II).

Materials and Methods

Study I

Twenty edentulous volunteers (10 men and 10 women; mean age, 77.9 ± 6.1 years) receiving treatment with new complete dentures at the Nihon University School of Dentistry at Matsudo were recruited for inclusion in the study and provided written informed consent before the enrollment. Measuring point for CPT and PT were incisor foramen, the left side of the greater palatine foramen region, and the left side of the mental foramen region by using the Neurometer® (Neurotron Inc., Baltimore, USA) delivering electrical stimulation at frequencies of 5, 250 and 2000 Hz at the respective measuring point. Differences in CPT and PT values among the three measurement regions were tested with an analysis of covariance (ANCOVA) with post hoc test: t-tests with the Bonferroni correction so as to adjust participant characteristics such as mucosal thickness, occlusal force, age, and sex as potential confounders.

Study II

Thirty-one individual (aged 60–90) were included as participants and were randomly allocated either into the mandibular denture with resilient denture liner (RD) group or mandibular conventional denture (CD) group. Measuring point for CPT and PT was left mental foramen region. CPT and PT measurements followed the methods to study 1. The outcomes were measured twice, at immediately after completion of denture adjustments (first measurement), and 3 months after the completion of denture adjustments (second measurement). All outcomes were analyzed using the Student's t-test. A p-value of less than 0.05 was considered statistically significant.

Result

Study I

There is no significant difference between CPT at mental foramen region, incisor papilla region, and, greater palatine region. The PT obtained from all current frequencies: 2000 Hz, 250 Hz, and 5 Hz were in the following order mental foramen region, incisor papilla region, and greater palatine region.

Study II

CPT was significantly higher with RD than CD only at second measurement with frequency level of 2000Hz and 5Hz. PT was significantly higher with RD than CD at first and second measurement with frequency level of 2000Hz, 250Hz, and 5Hz.

Conclusion

The mandibular alveolar ridge had inherent receptivity to external stimuli compared to maxillary alveolar ridge. However, the complete mandibular denture wearers with silicone-based resilient denture liners have a dull perception and decreased pain sensitivity compared to those of conventional denture wearers.

I. Introduction

The number of elderly adults in Japan is increasing annually; this is recognized as a critical societal issue—a super-aging society [1]. Consequently, the dental field sees an increasing number of patients with missing teeth; this condition is often treated with dentures [2]. Survey of Dental Diseases by the Ministry of Health, Labor and Welfare in 2016 showed the number of denture wearers were increasing due to the aging [3].

Denture wearers experience troubles, which include difficulty in food catching and soreness or pain and esthetic problems. Of these, sore spots, painful gums, discomfort, and jaw soreness are the problems most frequently associated with new dentures[4]. Furthermore, 63% of mandibular denture problems were related to pain [5].

One of the clinical solutions to relieve the pain is application of resilient denture liners. Several clinical researches found a clinically important effect of resilient denture liners, which increase satisfaction rating and chewing ability and reduce the sore spots of alveolar ridge mucosa as well [6-8]. The main interest of the resilient denture liner study was the pain induced by denture wearing. Resilient denture liners are used to reduce pain complaints in complete denture wearers, especially mandibular complete dentures. Recent report found that resilient denture liners were clinically effective in mandibular denture wearers with daily complaints of severe pain at the first appointment following denture delivery [9]. However, edentulous patients wearing complete dentures with resilient denture liners has never been evaluated by objective measures such as quantitative sensory testing [10-12].

The sensation of the oral mucosa has been evaluated by several methods [12-17] using two main types of stimulation: mechanical stimulation of peripheral nociceptors and electrical stimulation of peripheral sensory nerves. Our group studies sensation of the alveolar ridge mucosa under dentures by measuring current perception threshold (CPT) and pain threshold (PT) with a Neurometer, a device that uses electrical stimulation to measure peripheral sensory nerve function quantitatively. Ogura et al. [18] investigated alveolar ridge mucosal sensation in denture-wearing patients and demonstrated region-specific CPT values in the maxillary alveolar ridge mucosa. Kimoto et al. [19] also reported that individuals wearing complete dentures showed higher CPT for the maxillary alveolar ridge mucosa than individuals wearing partial dentures or those without the edentulous area.

Thus, a randomized controlled trial was conducted to verify the effects of resilient denture liners applied mandibular complete dentures on sensory nerve using the CPT and PT. The initial study to achieve the objective was planned to measure and compare CPT and PT values of the mandible and maxilla using the Neurometer®. (Study I)

The successive study was to clarify the effects of resilient denture liners applied mandibular

complete dentures on sensory nerve using the CPT and PT by randomized controlled trial. (Study II). The subjective outcomes: physical pain and psychological discomfort, were also measured by using the sub-domains of the OHIP-EDENT-J [21].

The large myelinated Aβ fibers, small myelinated Aδ fibers, and unmyelinated C fibers are evoked selectively by 2,000, 250, and 5 Hz frequencies, respectively [15].

II. Materials, Methods and Result

1. Receptivity of the mandible versus the maxilla to external stimuli in patients with complete dentures（Study I）

1) Participants

Twenty edentulous volunteers (10 men and 10 women; mean age, 77.9 ± 6.1 years) receiving treatment with new complete dentures at the Nihon University School of Dentistry at Matsudo were recruited for inclusion in the study and provided written informed consent before the enrollment. The exclusion criteria were as follows: (a) general health problems that could affect the measurement of nerve activity (e.g., trigeminal neuralgia or postherpetic neuralgia); (b) signs and symptoms of orofacial pain disorders; (c) use of a pacemaker; (d) obvious cognitive impairment; (e) inability to understand written or spoken Japanese; and (f) history of surgery on the mandible. This study was approved by the Human Ethics Committee of Nihon University School of Dentistry at Matsudo (EC16-020).

2) Measurement environment

Participants were seated comfortably on dental chairs in a quiet room. The targeted regions and order of measurement were the incisor foramen, the left side of the greater palatine foramen region, and the left side of the mental foramen region.

3) Measuring device

The Neurometer CPT®, a peripheral nerve testing device, was used to measure peripheral nerve responses to electrical stimulation. This device can produce frequencies of 2000 Hz, 250 Hz, and 5 Hz to selectively stimulate Aβ fibers, Aδ fibers, and C fibers, respectively.

To ensure contact between the mucosa and stimulation electrodes, a measurement apparatus with 1 mm diameter thermoforming discs (ERKODUR, ERKODENT®, Pfalzgrafenweiler, Germany) for maxillae (figure 1a) was fabricated. A detachable plate (18 × 6 × 3 mm^3) with stimulation electrodes (2 mm diameter) was used to stimulate the incisor foramen and greater palatine foramen regions. Measurement apparatus for mandibular was fabricated with a 3 mm diameter light-cured resin sheet (SPLINT-RESIN LC, GC Corp., Tokyo, Japan). A silicone based resilient denture liner (Sofreliner MS, Tokuyama Dental Corp., Tokyo, Japan) was attached to the apparatus at foramen region where stimulation is applied. A plate (18 × 6 × 3 mm^3) with stimulation electrodes (2 mm diameter) was mounted on the resilient denture liner of

the apparatus. The plate was mounted to measure the left mental foramen region (Figure 1). The resilient denture liner was used to stimulate without compressing mucosa of mental foramen region. The plate could be mounted to measure from the left greater palatine foramen region or the left mental foramen region. During the measurement, cotton rolls was applied to prevent saliva entry into the measurement region.

4) CPT and PT test

As per the manufacturer's instructions, the electrical current was slowly increased from 0.01mA until the subjects reported a sensation for each frequency. A rough perception threshold level was then determined. Second, a microprocessor-controlled forced-choice method was performed in a double blinded manner until the exact CPT were determined.[17]

The PT test was executed using the same methods as those for the CPT test except that the electrical current was slowly increased until subjects reported pain for each frequency. Participants initiated the stimulation by pushing a button on the device, and current stimulation increased automatically for as long as participants depressed the button[20, 21]. Participants were instructed to release the button when they perceived the stimulus painful, and the latency to button release was collected as PT value. PT were measured once for each frequency.

5) Measurement of mucosal thickness

Mucosal thickness over the mental foramen was measured by a single operator using an ultrasonic measuring device (Krupp SDM®; Austenal Medizintechnik, Cologne, Germany). The device probe was placed perpendicular to and in contact with each target point by applying slight pressure. Each measurement was performed three times, and the mean value was used for the analysis.

6) Measurement of occlusal force

An electronic recording device (Occlusal Force-Meter GM10s, Nagano Keiki, Tokyo, Japan) was used to determine occlusal force between the upper and lower first molars. The device was a digital force gauge with an 8.6 mm thick bite element. Participants were instructed to bite down as hard as possible on the force gauge, but to stop clenching at the first sensation of discomfort. The measurement was performed three times, and the mean value was used for the analysis.

7) Statistical analysis

All data distributions were tested for normality using the Kolmogorov-Smirnov test. Data with a normal distribution were subjected to parametric statistical analysis. Differences in mucosal thickness by region were tested using an analysis of variance (ANOVA) with post hoc t-tests and the Bonferroni correction. Differences in CPT and PT values among the three measurement regions were tested with an analysis of covariance (ANCOVA) with post hoc test: t-tests with the Bonferroni correction so as to adjust participant characteristics such as mucosal

thickness, occlusal force, age, and sex as potential confounders. Statistical analyses were performed using SPSS® Statistics version 21.0 (SPSS-IBM, MD, USA). The threshold for statistical significance was p-value of less than 0.05.

8) Result

8)-1. Participant characteristics

Participant characteristics are summarized in Table 1. The mucosal thickness of mental foramen region was significantly thinner than that of the incisor papilla and greater palatine foramen regions. All characteristics were used as covariates for ANCOVAs.

8)-2 CPT

The ANCOVA showed that there is no significant difference between CPT at mental foramen region, incisor papilla region, and, greater palatine region (Figure 2). The covariates: sex, mucosal thickness, occlusal force did not have significant effect on CPT at all frequencies.

8)-3 PT

The PT obtained from all current frequencies: 2000 Hz, 250 Hz, and 5 Hz were in the following order mental foramen region, incisor papilla region and greater palatine region. The ANCOVA showed that there was no significant difference of PT among three regions (Figure 3). The covariates: sex, mucosal thickness, occlusal force also did not have significant effect on CPT at all frequencies.

2. The effects of silicone-based resilient denture liners on pain

: A randomized controlled trial（Study II）

1) Trial registry and ethical issues

The trial was registered with the UMIN (University Hospital Medical Information Network) Registry (UMIN000027601) on 2nd June 2016. The study protocol was reviewed and approved by the human ethics committees of Nihon University School of Dentistry at Matsudo (EC17-001).

2) Inclusion and exclusion criteria

Inclusion criteria

To be included in the study, participants must be completely edentulous in both jaw and wished to fabricate new set of complete dentures.

Exclusion criteria

(1) General and local health problems that could affect measurement (e.g. Diabetes mellitus, trigeminal neuralgia or postherpetic neuralgia); (2) signs and symptoms of oro-facial pain disorders, as determined (3) presence of a pacemaker; (4) apparent cognitive impairment; (5) a lack of understanding of written or spoken Japanese; (6) history of mandibular surgery[21, 22].

3) Sample size calculation

A between-group difference of 28.5, 14.9, and 16.7 (0.01 mA) on CPT at 2000 Hz, 250 Hz, and 5 Hz respectively was considered as a clinically meaningful difference since the values were comparable to the difference of CPT between edentulous patients with dentures and dentulous patients [19]. Variances of 48.5, 28.2, and 23.4 (0.01 mA) at 2000 Hz, 250 Hz, and 5 Hz respectively in the mandibular denture with resilient denture liner (RD) group and 11.4, 5.9, and 5.6 (0.01 mA) at 2000 Hz, 250 Hz, and 5 Hz respectively in the mandibular conventional denture (CD) group were set based on previously reported data [19]. Then the sample size was calculated as 28, 32, and 19 subjects per group for 45.8, 28.2, and 23.4 (0.01 mA) at 2000 Hz, 250 Hz, and 5 Hz respectively (including an assumed dropout rate of 10%, which was required to achieve 80% power with an alpha level of 5%). A maximum value of 64 was set for total sample size. The sample size was not calculated based on PT since no data of PT with complete denture wearers are available.

4) Randomization, allocation concealment, and sequence generation

The design of this study was a randomized controlled parallel clinical trial. The included participants were informed of the study and provided informed consent, prior to the randomization. A random permuted block method (block size: 4) was used to ensure that a certain proportion of patients receive each treatment [23] [24]. The 6 possible permutations-were numbered as 1, 2, 3, 4, 5, and 6 respectively. Then, the allocation numbers were generated by the “RAND functions” in Excel (Microsoft Japan Co. Ltd, Tokyo, Japan) using 6 numbers, and were randomly assigned to either to the two groups: CD or RD. Blinding the participants was not feasible, since they were able to determine the type of denture.

5) Fabrication of dentures (Interventions)

Both maxilla and mandible complete dentures were fabricated by the conventional method; A stock tray (Mesh tray-Hayashi Dental Supply, Tokyo, Japan) and alginate (Algiace-Z, Dentsply-Sirona, Tokyo, Japan) were used for the preliminary impression. The final impression was registered using a custom tray, fabricated on the cast obtained from the preliminary impression and border-molded with impression compound (Peri Compound, GC Corp., Tokyo, Japan), followed by a wash impression with silicone impression material (EXADENTURE, GC Corp., Tokyo, Japan) After occlusal registration, the cast was mounted onto a semi-adjustable articulator (Hanau H2, Teledyne Water Pik, Fort Collins, USA) using a facebow record. This occlusal scheme was arranged as fully bilateral balanced articulation. Both groups used composite resin artificial teeth (Surpass, GC Corp, Tokyo, Japan). After the try-in session, occlusal adjustment was carried out in both groups for maximum intercuspation, lateral excursive and protrusive movements by selective and spot grinding. Dentures were additionally carried out to refine the occluding surfaces using silicon carbide abrasive materials (Lapping paste, GC Corp, Tokyo, Japan) The conventional dentures were fabricated with conventional heat-activated acrylic resin (Urban,

Shofu Dental Corp., Kyoto, Japan). The dentures with resilient denture liners were fabricated with same conventional heat-activated acrylic resin and a 2 mm thick permanent silicone-based denture liner (Sofreliner MS, Tokuyama Dental Corp., Tokyo, Japan). The curing cycle for both prostheses was 90 min at 70 °C, followed by 30 min at 100 °C.

6) Participant characteristics as covariates

6)-1 Mucosal thickness

The measurement method of study II was followed the methods as study I mentioned.

6)-2 Oral dryness

Oral dryness was measured using an oral moisture checking device (Mucus®, Life Co, Saitama, Japan) to assess its effect on the CPT and PT values. The oral moisture checking device measures oral mucosal moisture level through a sensor placed onto the oral mucosa for around 2 second until it is firmly attached (200 mg of pressure). The measurement area is the lingual mucosa, located 10 mm from the apex linguae [25].

7) Outcome measurement

7)-1 Measuring device

The Neurometer CPT® (Neurotron Inc., Baltimore, USA), a peripheral nerve testing device, was used to measure peripheral nerve responses to electrical stimulation. The reliability and validity of this device were confirmed in the previous manuscript [26, 27]. This device can produce frequencies of 2000 Hz, 250 Hz, and 5 Hz to selectively stimulate Aβ fibers, Aδ fibers, and C fibers, respectively.

A custom-made measurement apparatus was fabricated with a 3 mm diameter light-cured resin sheet (SPLINT-RESIN LC, GC Corp., Tokyo, Japan). A silicone based resilient denture liner (Sofreliner MS, Tokuyama Dental Corp., Tokyo, Japan) was attached to the apparatus at foramen region where stimulation is applied. A plate ($18 \times 6 \times 3$ mm^3) with stimulation electrodes (2 mm diameter) was mounted on the resilient denture liner of the apparatus. The plate was mounted to measure the left mental foramen region (Figure 1-b). The resilient denture liner was used to stimulate without compressing mucosa of mental foramen region.

7)-2 CPT and PT test

The measurement method of research 2 was followed the methods as research 1 mentioned.

7)-3 Physical pain and psychological discomfort questionnaire

The domains of physical pain and psychological discomfort from OHIP-EDENT-J were measured in order to analyze neurophysiological pain. The OHIP-EDENT-J is composed of 19 items distributed between the following 7 domains: functional limitations, pain, psychological discomfort, physical disability, psychological disability, social disability, and handicap [28]. Participants were asked to respond to the rating of frequency with which they believed they encountered during the last month on a 5-point Likert scale: never (score 0), hardly ever (score

1), occasionally (score 2), fairly often (score 3), and very often (score 4). In this study, this study was used two domains, physical pain composed of 4 items and psychological discomfort composed of 2 items. The sum of the ratings for physical pain and psychological discomfort ranged between 0 and 16 and 0 and 8 respectively.

8) Data analysis

The intention-to-treat principle (ITT) were used for any missing data post-randomization. The differences of proportion in categorical variables between the 2 groups were analyzed by using the chi-square test. To determine the testing method, the Kolmogorov–Smirnov test was applied to analyze normality of the variables of CPT and PT. The result indicted that the variables was normally distributed, thus, the parametric tests were used for following data analysis, i.e. the mean difference of participants' characteristics between the 2 groups were analyzed using the t-test, in addition with 95% confidence interval. Between group difference of the RD and CD at first measurement and second measurement were determined by using the t-test, in addition with 95% confidence interval. All statistical analyses were performed using the IBM SPSS Statistics Package v21 (IBM, Armonk, New York, USA). The statistical significance was $p < 0.05$.

9) Result

9)-1 Participant flow

Recruitment of participants commenced in May 2017. As shown in Figure 4, 122 patients (aged 36–96) were consecutively sampled for this trial. Of these, 91 patients were excluded based on the inclusion and exclusion criteria. The remaining 31 individuals (aged 60–90) were included as participants and were randomly allocated either into the RD or CD groups. Furthermore, 2 subjects in the RD group and 6 in CD group dropped out and were performed to the intention-to-treat analysis. No excess harm was observed in the participants through the trial, and the follow-up rate was 74%.

9)-2 Participant characteristics

There were no significant differences between the participants' characteristics (Table 1). Therefore, it was considered that the randomization has been successful.

9)-3 CPT measurement

CPT was significantly higher with RD than CD only at second measurement with frequency level of 2000Hz (RD:66.8 ± 19.9 CD: 48.7 ± 12.2 (95% CI 5.8 to 30.5) $p = 0.006$), and 5Hz (RD:53.32 ± 15.8 CD: 26.63 ± 10.9 (95% CI 16.6 to 36.8) $p < 0.001$). (Figure 5)

9)-4 PT measurement

PT was significantly higher with RD than CD at first and second measurement with frequency level of 2000Hz; (First; RD:182.0 ± 53.2 CD:134.6 ± 53.8 (95% CI 8.1 to 86.7) $p = 0.02$, second; RD:145.787 ± 27.9 CD: 104.5 ± 20.4 (95% CI 23.1 to 59.5) $p < 0.001$), 250Hz; (first RD:117.5 ± 53.8 CD:75.6 ± 21.5 (95% CI 1.4 to 82.4) $p = 0.04$, second; RD:82.787 ± 21.1 CD: 66.8 ± 11.6

(95% CI 3.1 to 28.8) p = 0.017) and with frequency level of 5Hz (first RD:157.3 ± 55.3 CD:90.3 ± 36.8 (95% CI 31.9 to 102.1) p = 0.001, second; RD:128.233 ± 38.1 CD: 75.988 ± 25.5 (95% CI 28.1 to 76.4) p < 0.001) (Figure 6)

9)-5 Physical pain

The physical pain was significantly lower for the RD than CD at only the first measurement; (first RD:1.5 ± 1.2 CD:4.0 ± 2.3 (95% CI -3.9 to -1.1) p = 0.001). (Figure 7)

9)-6 Psychological discomfort

The psychological discomfort was significantly lower for the RD than CD, both with first and second measurement. (first RD:1.0 ± 0.9 CD:2.2 ± 1.2 (95% CI - 2.0 to -0.4) p = 0.004, second; RD:0.7 ± 0.7 CD: 1.2 ± 0.9 (95% CI -1.2 to 0.0) p = 0.004) (Figure 8)

III. Discussion

Study I found that the PT of the mandibular alveolar ridge mucosa was significantly lower than that of the maxillary ridge mucosa, suggesting that the mandible ridge was more sensitive to pain than the maxilla ridge. This finding was consistent with a previous report that the mandibular pressure pain threshold (PPT) is lower than that of the maxilla [15]. The PPT obtained by mechanical stimulation to peripheral nociceptors with an algometer are different from PT obtained by electrical stimulation to peripheral sensory nerves in the alveolar ridge. The mechanical stimuli directly excite peripheral nociceptors, while the electrocutaneous stimuli bypass peripheral nociceptors and directly excite sensory fibers by depolarization [29]. In this study, although the target stimulated fiber is different, the mandible measuring point was sensitive than the than maxilla. McMillan [30] reported that the maxilla has higher PPT than the mandible at gingivae in dentate subjects who do not wear dentures. Ogawa et al. [13] reported region-specific PPT in the oral mucosa in dentulous individuals. Those two reports implies that similar to apparent differences in sensory sensitivity of the oral cavity, hand, and foot [20], the mandible would have inherently higher receptivity to external stimuli than the maxilla. These results potentially explain the reason why dentists more often encounter individuals with mandibular denture complaints than maxillary denture complaints.

In order to study the factors influencing differences in PT values between the mandible and maxilla, the present study measured mucosal thickness and occlusal force in addition to age and sex as possible confounders. Tanaka et al. [12] reported that strong bite force reduce PPT of edentulous mucosa of denture wearers. Furthermore, Ogawa et al. [15] stated that although the difference in mucosal thickness does not fully explain the inter-jaw PPT differences, disproportional changes of mucosal thickness between the maxilla and mandible after tooth extraction may induce inter-jaw PPT variation. Also, the present study did not identify significant effects of mucosal thickness or occlusal force on PT values. This may be explained by our selected method of stimulation; CPT and PT quantitative testing use a neuroselective

electrical stimulus to directly excite sensory nerve fibers in a manner not affected by skin thickness [31].

The present study showed that there were no significant differences in CPT between the maxilla and mandible. In previous work, Ito et al. found that: (a) individuals who wear dentures wearing have high CPT of the alveolar mucosa [32] and (b) the CPT of the alveolar mucosa increases in the following order The CPTs at all frequencies increased in the following order: wearing complete dentures greater than patients wearing partial dentures greater than patients retaining their natural teeth. [19]. These reports suggest that CPT increases as a potential result of compression caused by denture wearing on the denture-supporting area. Dentures produce higher compression of the mandible than of the maxilla since the denture-supporting area of the mandible is almost the half of the maxilla. Therefore, a reason for the absence of a significant difference in CPT between the maxilla and mandible in this study may have been that the higher compression on denture-supporting area in the mandible increased mandibular CPT and eventually decreased difference of CPT between maxilla and mandible. However, the study did not verify how denture wearing influence on mandibular CPT. Furthermore, the participants' denture factors, such as the number of previous dentures and duration of wearing denture, as well as occlusal force, and related factors. These were the limitations of the present study. Study II revealed that completely edentulous patients wearing mandibular complete denture with resilient denture liner had higher CPT at 2000Hz and 5Hz at second measurement as well as had higher PT and experienced less pain than those with conventional complete denture.

The most interesting finding was the pain sensation of edentulous patients with RD. There were no differences between the baseline PT values of the RD and CD groups at 2000 Hz, 250 Hz, and 5 Hz. However, the RD group showed significantly higher PT values than the CD group at all 3 frequencies at first measurement. The same pattern was also observed at second measurement. The Neurometer CPT®, a peripheral nerve testing device, was used to measure pain sensation in the peripheral nerves. This device uses different frequencies (2000 Hz, 250 Hz, and 5 Hz) to selectively stimulate different types of nerve fibers (Aβ fibers, Aδ fibers, and C fibers respectively). These 3 types of nerve fibers comprise the majority of the sensory nerve fibers. It was found that most sensory nerves in the denture liner bearing area of the mandible increased their pain thresholds when compared to conventional denture. Shaikh et al. reported that the affective attributes of tactile stimuli predicted their modulatory effects on pain, and that unpleasant stimuli evoked allodynia while pleasant stimuli evoked analgesia [33]. That is, emotional states can influence the pain threshold. The current study showed that the psychological discomfort score was lower in the RD group than the CD group. It was considered that, as a result of the small psychological discomfort derived from relining with resilient denture liner, PT was higher in RD group than in CD group. The previous report that

resilient denture liners decrease pain rating of complete mandibular denture wearers might be explained by the increased pain threshold evaluated using quantitative sensory testing [34]. This was similar to dentists' clinical findings that resilient denture liners decrease pain in complete mandibular denture wearers.

The resilient silicone denture liners used for relining mandibular complete dentures decreased patients' physical pain score (OHIP-DENT-J) more than conventionally used hard resin for mandibular complete dentures. Physical pain was calculated as the sum of the following 4 subdomains: painful aching in mouth, uncomfortable to eating, presence of sore spots, and dry in mouth. The explanation as to why physical pain was significantly lower in the RD group than in the CD group can be found in the following reports. Edentulous patients with mandibular complete dentures with silicone-based resilient denture liners feel less pain [8], have fewer sore spots in the support and border areas [8], and feel more comfortable [34] than patients with conventional hard resin dentures. Based on these reports, it was conceivable that participants with RD complained of less physical pain than those with CD. Beck reported that 63% of mandibular denture problems were related to pain [5]. Pain is, therefore, a critical issue for denture wearers. Therefore, application of resilient silicone denture liners to mandibular complete dentures is clinically beneficial for edentulous patients.

We could not reveal as clear findings in CPT as PT showed. There were no differences with CPT values of the RD and CD group with all 3 frequencies at in the first measurement, but significantly higher with the CD group at 2000Hz, 5Hz at the second measurement. Among the nerve fibers, Aβ and C fibers are the nerves responsible for the sense of tactile and touch [35] [36]. It could be considered as prolonged reaction of the nerve tactile and touch fibers, and could related to the extension of the early phase of the occlusion phase [6]. Outcomes were measured at immediately after the completion of denture adjustments and 3 months after the first outcome measurement. During this period, the deterioration of silicone liners [37] would not be relevant to pain sensation. Thus, the measurement was carried out in the same conditions. The homogeneity of participants' baseline characteristics between the two groups showed that the randomization was well performed. Well performed randomization meant that the obtained results have high internal validity. Thus, unknown interaction factors to modify the outcomes would be controlled.

IV. Conclusion

The mandibular alveolar ridge had inherent receptivity to external stimuli compared to maxillary alveolar ridge. However, the complete mandibular denture wears with silicone-based resilient denture liners have a dull perception and decreased pain sensation compared to those of conventional denture wearers.

V. References

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VI. Table and Figures

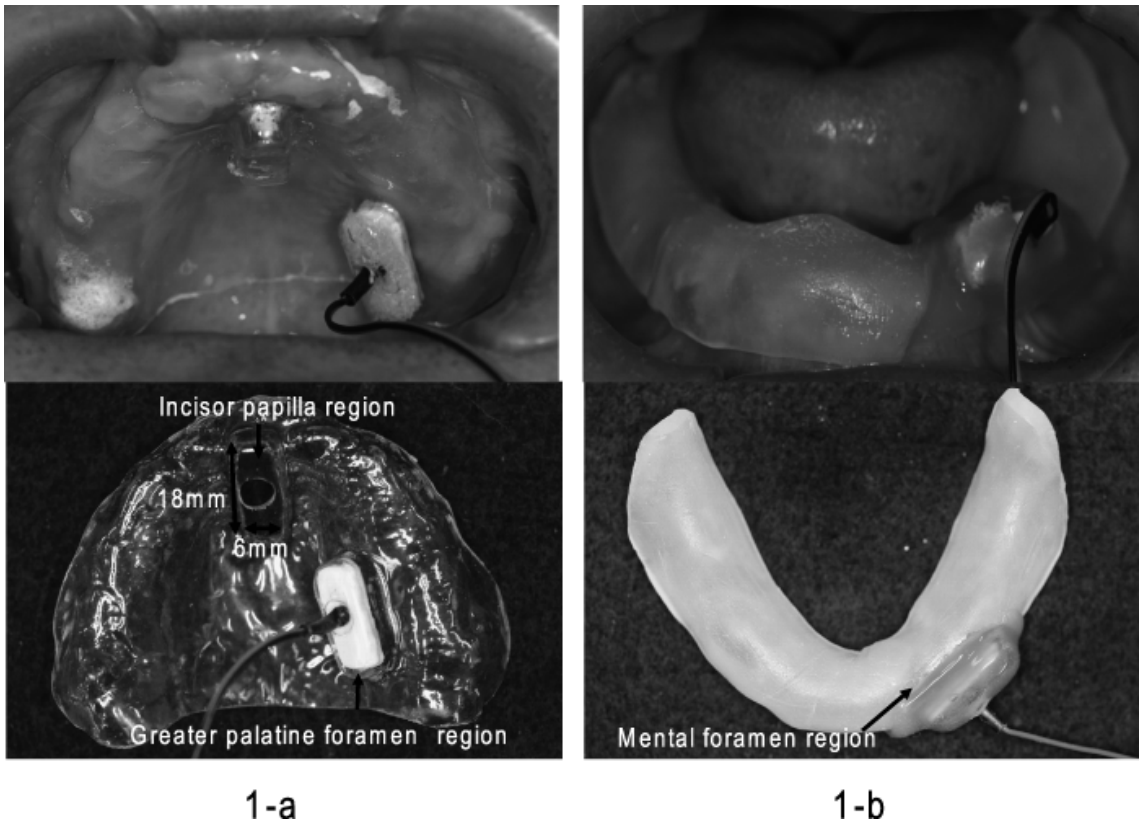

Figure 1: Intraoral removable device with stimulating electrodes. (a) Participants wore the measurement apparatus made with 1 mm diameter thermoforming discs for maxilla measurements. (b) Participants wore the measurement apparatus made with 3 mm diameter light-cured resin sheet with a resilient denture liner for mandible measurements. The apparatus had a detachable plate ($18 \times 6 \times 3$ mm^3) with stimulation electrodes (2 mm diameter).

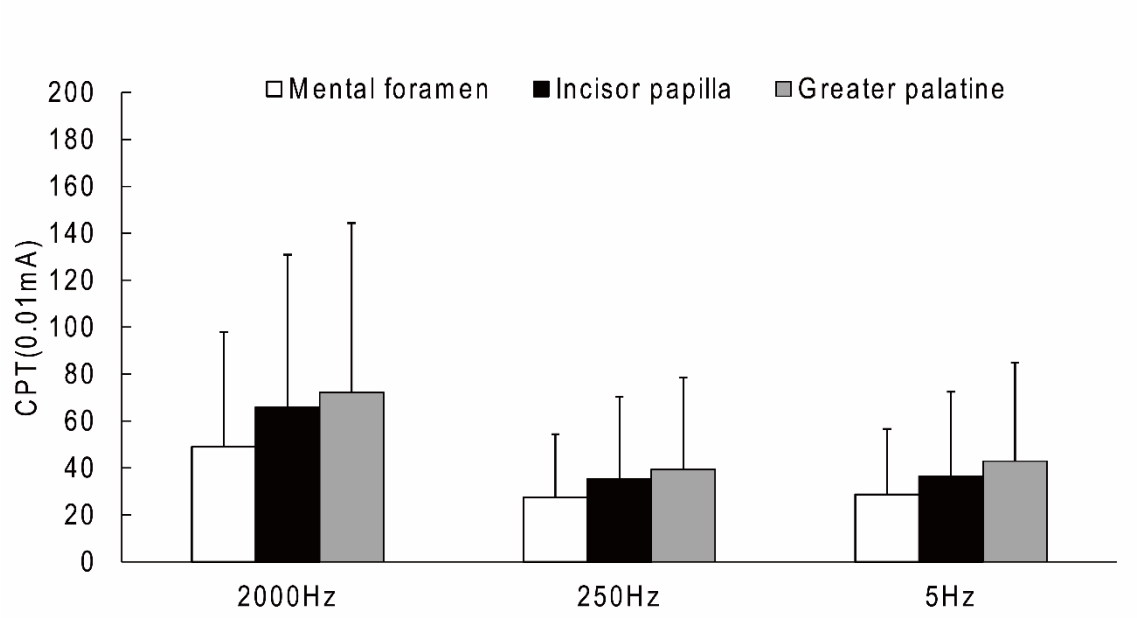

Figure 2: Differences in current perception thresholds (CPT) among the three measurement regions. There were no significant differences among the mental foramen, incisor papilla, and greater palatine regions.

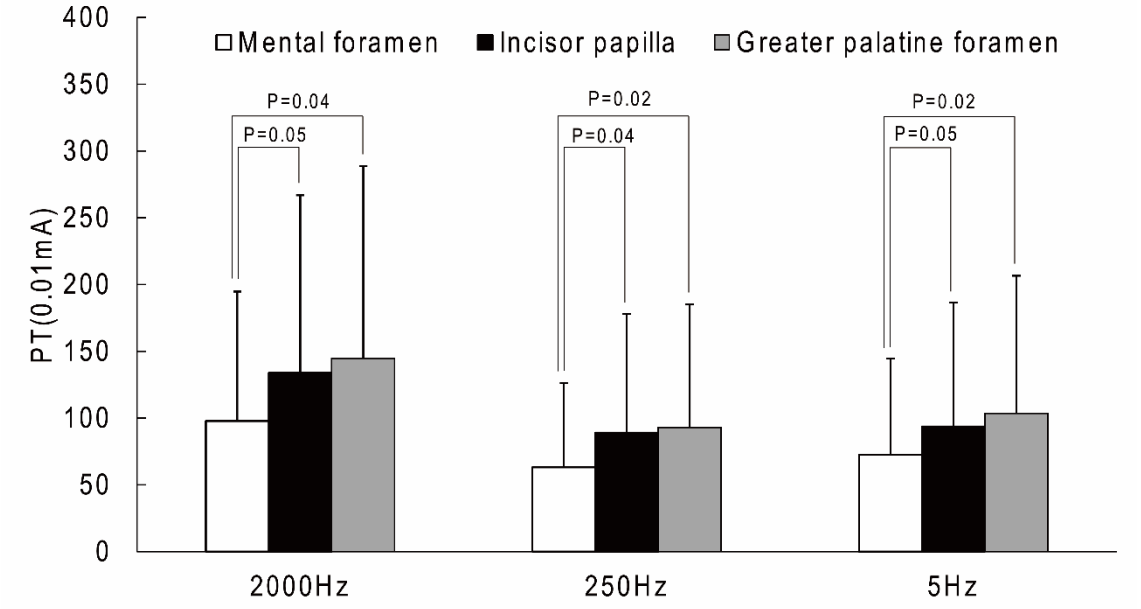

Figure 3: Differences in pain thresholds (PT) among the three measurement regions. PT at the mental foramen were significantly lower than those in incisor papilla and greater palatine regions.

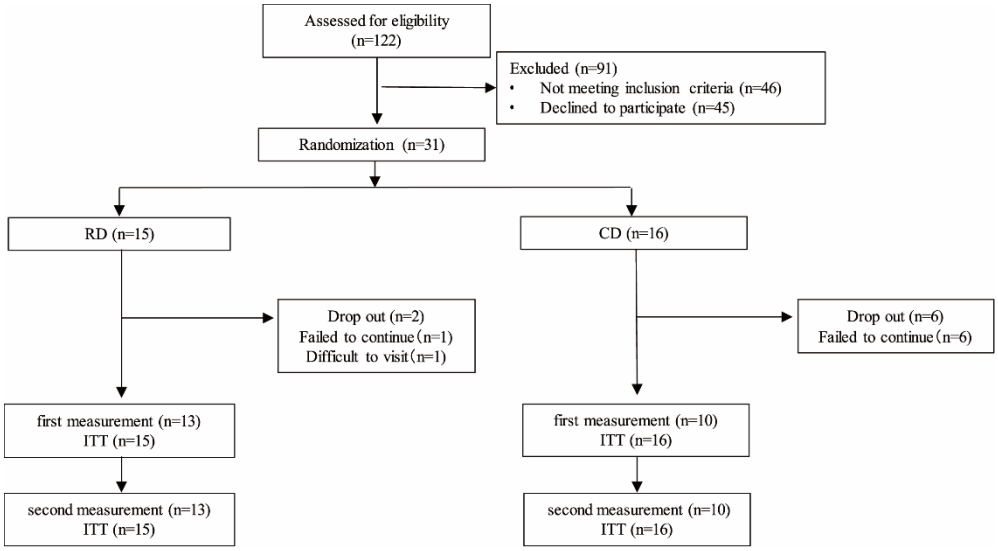

Figure 4: Trial flowchart

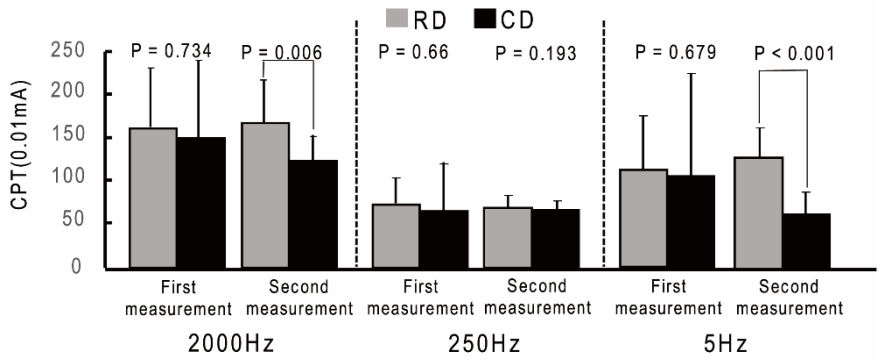

Figure 5: Current perception threshold at 2000 Hz, 250 Hz, and 5 Hz

CPT was significantly higher with RD than CD only at second measurement with frequency level of 2000Hz,5Hz.

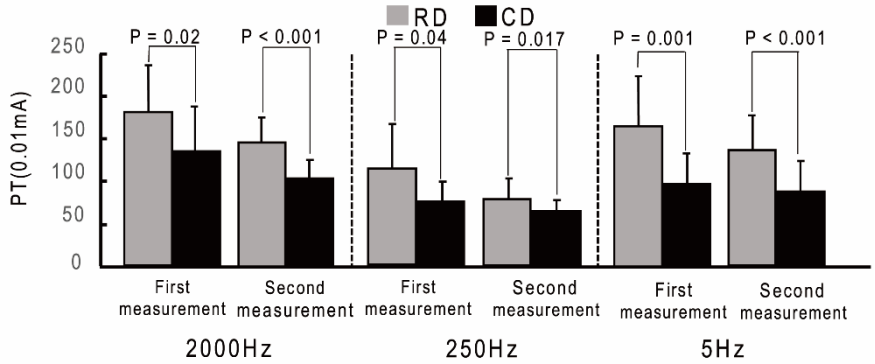

Figure 6: Pain threshold at 2000 Hz, 250 Hz, and 5 Hz.

There were significantly higher PT values for RD than CD groups at all frequencies at both

measurements.

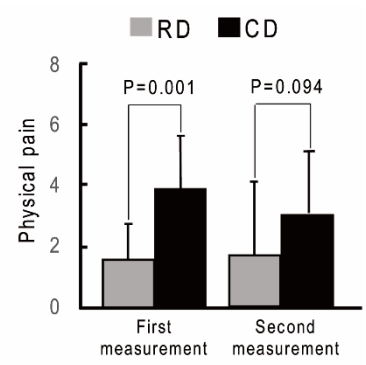

Figure 7 Physical pain

The physical pain was significantly lower for the RD group than for the CD group.

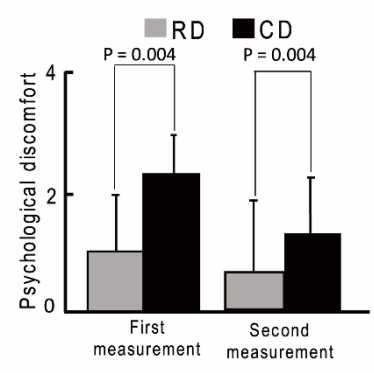

Figure 8 Psychological discomfort

The psychological discomfort was significantly lower for the RD group than for the CD group.

Table 1. Participants characteristics

Participants characteristics (31)	RD (n=15)	CD (n=16)	*P*-value
Age (years)	73.6 (7.7)	76.7 (7.0)	0.25 [a]
Sex (female/male)	9 / 6	9 / 7	0.83 [b]
Period wearing existing denture (months)	83.2 (93.1)	121.3 (85.8)	0.24 [a]
Classification of denture difficulty (I, II, III, IV)	(7,7,1,0)	(9,6,1,0)	0.56 [b]
Current perception threshold (0.01mA)			
2000Hz	61.6(7.1)	65.1(4.3)	0.68[a]
250Hz	33.9(4.2)	32.6(3.1)	0.81[a]
5Hz	38.8(5.1)	32.9(5.2)	0.43[a]
Pain threshold (0.01mA)			
2000Hz	122.6(9.9)	130.5(4.6)	0.48[a]
250Hz	78.2(9.0)	68.2(2.9)	0.30[a]
5Hz	83.3(10.1)	80.5(5.8)	0.81[a]
Mucosal thickness(mm)	2.2(0.8)	1.8(0.7)	0.35[a]
Occlusal force(10^{-2}N)	4.3(1.4)	5.9(2.7)	0.15[a]
Oral dryness (%)	25.5(3.5)	27.7(1.4)	0.11[a]

a: Analysis of variance; b: Chi-squared test

There is no significant difference of participants characteristics between RD and CD.