Clinical significance
In edentulous patients, the period between denture delivery and the first day of denture adjustment is the most painful days to adapt themselves to their new dentures. However, the use of mandibular complete dentures with an acrylic resilient denture liner can help these patients easily get through this uncomfortable period.

Abstract
Purpose: The purpose of this study was to investigate whether edentulous patients with a permanent acrylic resilient liner denture (RLD) in mandibles exhibit significant improvements in their satisfaction ratings at the first appointment following the delivery of RLD dentures when compared to those with conventional heat-activated acrylic resin dentures (ARD) in mandibles.

Methods: Seventy-four subjects were randomly allocated into RLD and ARD groups by a random permuted block within the strata method after written informed consent. A parallel-randomized controlled clinical trial at two centers was conducted from April 2004 to July 2006. The outcomes were satisfaction ratings with a 100 mm visual analog scale (VAS) involving general satisfaction as well as satisfaction related to chewing, speaking, cleaning, stability, retention, comfort, and esthetics. The pain rating was also measured by the VAS. The outcomes were analyzed by Student t-test and Pearson’s correlation coefficient.

Results: A significant difference between the RLD and ARD group in the maxillary denture was only obtained in the satisfaction rating of speaking. A significant difference between the RLD and ARD groups for the mandibular dentures was obtained in every satisfaction rating. The pain rating of the RLD group was significantly lower than that of the ARD group. The satisfaction ratings of mandibular denture functions significantly correlated with ratings of comfort and pain.

Conclusion: Despite the limitation of a short-term observation, the mandibular satisfaction ratings were dramatically higher in RLD wearers than in ARD wearers.

Key words: randomized controlled clinical trial, complete denture, resilient denture liner, satisfaction rating, visual analog scale

Introduction
It is predicted that the population of edentulous patients will increase during the next decade. There remain many edentulous patients who suffer while eating their daily meals with conventional complete dentures due to the overly atrophic and thin mucosa that bear the stress caused by occlusal force. This is in spite of patients’ desire for satisfactory dentures and the efforts of clinicians to make good dentures. These twin realities in the clinical scene motivated the authors, who specialize in complete denture prosthesis, to start research about resilient denture liners, since there is a possibility to solve the patients’ difficulty by using the inherent stress distribution effect.

The authors have carried out a crossover ran-
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domized clinical trial of resilient liners which revealed not only that patients preferred mandibular dentures with permanent silicone resilient denture liners, but also that the application of silicone-based permanent resilient denture liners on mandibular dentures resulted in edentulous patients having significant improvements in mastication. Nevertheless, there remain some interesting issues regarding resilient denture liners to be investigated. One clinically interesting subject is the effect of a resilient denture liner following complete denture delivery. Complete denture wearers with resilient denture liners appear to have fewer complaints than conventional complete denture wearers. Several authors have reported in in-vitro studies that the resilient denture liners have a stress distribution effect. This may be the reason why resilient denture liners have a clinical effect on patients. However, there is no evidence about the superiority of complete denture wearers with resilient denture liners at the first denture adjustment.

During the period from the day of denture delivery to the day of the first appointment, it is hard for patients to adjust to a dramatically changed environment. Having some irritations and pain in the oral mucosa, patients need to make an effort to adapt themselves to their new dentures. Additionally, clinicians may also need to make an effort to adjust patients’ dentures in order to solve patients’ complaints at the first appointment. Therefore, although the period from denture delivery to the first appointment is short, the authors believe that the clinical effect of resilient denture liner during this period is meaningful for patients and clinicians. Based on this background information, the authors conducted the present parallel, randomized, controlled trial. One of the purposes of this study was to determine the satisfaction ratings of complete denture wearers at the first appointment following denture delivery.

The null hypothesis was that the satisfaction and pain ratings between edentulous patients who wore mandibular complete dentures applied with a heat-activated acrylic resin and those who wore conventional mandibular complete dentures did not differ.

Materials and Methods

Study population

Edentulous patients at Nihon University School of Dentistry at Matsudo Affiliated Hospital in Chiba, Japan and Kanagawa Dental College Affiliated Hospital in Yokohama, Japan, who were willing to undergo new complete denture treatments, were selected to participate in the study. The exclusion criteria were: (1) systemic or neurologic disease and (2) lack of understanding of written or spoken Japanese. The patients participated in this study after written informed consent was secured. The protocol for this study was reviewed and approved by the Human Ethics Committee at Nihon University School of Dentistry at Matsudo (Issue # EC 02-036, 26th December 2002) and Kanagawa Dental College (Issue # 19, 26th December 2003).

Study design

A randomized controlled parallel clinical trial at two hospitals was conducted from April 2004 to July 2006. Subjects were consecutively sampled. The permuted block method of randomization with a block size of four consisting of, treatment with resilient liner denture (RLD) by a senior clinician (SC), treatment with RLD by a junior clinician (JC), treatment with acrylic resin denture (ARD) by a SC and treatment with ARD by a JC, in a combination of treatments and clinicians groups (treatments = ARD and RLD; clinicians = JC and SC) was used. Irrespective of the group (ARD or RLD), all maxillary complete dentures were fabricated only with acrylic resin, i.e. without resilient denture liner. The two types of clinicians, SC with over ten years of clinical experience of complete denture treatment and JC with a maximum of five years of clinical experience of complete denture treatment, performed all treatments at both hospitals. One block number utilizing the four combinations of treatment and clinician was selected out of twenty four permutation numbers, \((4 \times 3 \times 2 \times 1 = 24)\), as per the random block table. Blocking was used to ensure a nearly numeric balance for each type of treatment and clinician for any given time during the study. After block randomization, the number of participants for each type of treatment and clinician was equalized. One computer-generated random-block table was prepared for the Nihon University School of Dentistry at Matsudo Affiliated Hospital and one
table for Kanagawa Dental College Affiliated Hospital. The blinding of intervention was deemed not feasible since it was clear to both the patients and clinicians the types of materials that were being used.

**Treatment protocol**

Preliminary impressions were made using stock edentulous trays (DENTCRAFT StO-K TRAY, Yoshida, Tokyo, Japan) and irreversible hydrocolloid impression materials (Algiace Z, DENSPLY-Sankin Tokyo, Japan). Border molding using custom trays and stick modeling compound (Peri Compound, GC Tokyo, Japan) was then done. Next, wash impressions with polyether impression material (Impregum, 3M, Espe, Germany) were conducted. A jaw relation record was recorded by using occlusion rims and zinc-oxide bite registration paste (Superbite Paste, Harry J. Bosworth, IL, USA). In try-in of wax denture step, after verifying the vertical dimensions of the occlusion and centric relation records, the esthetics of the full contour wax trial denture tooth arrangement was done. Next, the patient’s feedback and acceptance of the complete dentures were obtained. After the processing of denture, dentures were delivered. Post-insertion appointments for adjustments were scheduled until the patients were comfortable and free of tissue irritation. Using paste-type (PIP; Mizzy, NJ, USA) and silicone-type (FiT CHECKER, GC, Tokyo, Japan) pressure-indicating materials, clinicians adjusted the dentures to relieve the area of irritation based on their diagnosis. Furthermore, if premature contacts were observed on a closure path, occlusal adjustments were performed using articulating paper (GC, Tokyo, Japan). When deemed necessary, the dentures were remounted with semi-adjustable articulators (Hanau H2, Teledyne Waterpik, Fort Collins, CO, USA) for occlusal equilibration during the adjustment period.

**Laboratory protocol**

ARDs were fabricated using only conventional heat-activated acrylic resin (Physio Resin, Nissin, Kyoto, Japan). Conversely, RLDs were fabricated with conventional heat-activated acrylic resin (Physio Resin, Nissin, Kyoto, Japan) and 2-mm thick permanent acrylic based denture liner (Physio Soft Rebase, Nissin, Kyoto, Japan). Maxillary complete dentures were fabricated with heat-activated acrylic denture resin (Physio Resin, Nissin, Kyoto, Japan). As per the manufacturer’s instructions, conventional dough-stage heat-activated acrylic denture base resin was packed against the master cast covered with a 2-mm spacer. After removing the spacer, resilient lining material in dough-stage was inserted to replace the spacer. The flask was then packed and processed. The curing cycle for the prostheses was 90 minutes at 70°C, followed by 30 minutes at 100°C.

**Sample size estimation**

To determine the appropriate sample size, the size estimation was calculated by using the general satisfaction rating as the primary outcome for this trial. A between-group difference of 10 mm in the 100-mm visual analog scale (VAS) ratings of general satisfaction during the initial adjustment session was sought using a variance of 15.0 mm for RLD and 10.0 mm for ARD, based on data obtained from a previous study. In order to fulfill the criteria of 80% power with a two-sided alpha level of 5%, as well as to factor in potential participant dropouts, a total of 74 subjects were enrolled in this study.

**Baseline measurements**

An assessor collected the baseline characteristics i.e. gender, age, body mass index (BMI), edentulous period, age of existing denture, number of previous dentures, and height of alveolar ridge (Table 1). The BMI was calculated using the following formula: Weight (Kg) / Height (m^2). Furthermore, satisfaction ratings for an existing denture were measured by the VAS.

**Outcome measurements**

Primary outcome (VAS): general satisfaction. Secondary outcomes (VAS): satisfaction ratings of chewing, speaking, cleaning, stability, retention, comfort, and esthetics as well as pain rating. The left side anchor on VAS of satisfaction rating was “Not at all satisfied”, and the right side anchor was “Extremely satisfied”. The left side anchor on VAS of pain rating was “Not at all”, and the right side anchor was “Extremely”. At the first appointment following the denture delivery, the same assessor measured the satisfaction and pain ratings. The first appointment was normally scheduled for three days after the delivery; however it depended on the subjects’ availability.
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Statistical analysis
The comparisons of the participant’s baseline characteristics between the RLD and ARD groups were tested by Student t-test. The proportions of baseline (gender and type of clinician) were tested by χ² test. The mean difference in satisfaction ratings between the ARD and RLD groups was tested by Student t-test. The Pearson’s correlation coefficient between satisfaction ratings regarding mandibular denture functions such as chewing, speaking, stability, retention, and esthetics and ratings of comfort and pain were analyzed. A p value below 0.05 was considered to indicate statistical significance. All analyses of satisfaction ratings were performed as per the intention-to-treat principle, in which the data from dropout subjects were substituted by the satisfaction ratings of the existing dentures. The pain rating was analyzed by the per-protocol analysis based only on those patients who completed the entire treatment protocol. All tests were two-tailed. All statistical analyses were performed on a personal computer with the statistical package Dr. SPSS II for Windows (SPSS, Chicago, IL, USA).

Results
Subjects
Seventy-four patients who had been consecutively sampled (aged 53 to 89 years) were randomized for this trial. The random permuted block within strata method assigned subjects to both groups – 37 to the ARD group and 37 to the RLD group, as well as 35 to junior clinicians and 39 to senior clinicians. Table 1 shows the baseline characteristics of the 74 subjects. No significant differences were observed in any of the characteristics of the baseline measurements between the SLD and ARD groups (p ≥ 0.05, t-test and χ² test). Figure 1 shows the participant flow. Of the 74 allocated subjects, 67 completed the trial and 7 dropped out of the trial.

Patients’ satisfaction ratings
Table 2 shows subjects’ satisfaction ratings related to the new dentures in the RLD and ARD groups. A significant difference between the RLD and ARD groups in the maxillary denture was only obtained in the satisfaction rating related to the speaking (p < 0.05 Student t-test). A significant difference between the RLD and ARD groups in the mandibular denture was obtained in every satisfaction rating (p < 0.05 Student t-test).

Patients’ pain ratings
The maxillary pain ratings for the RLD and ARD groups were 44.1 ± 40.8 and 56.3 ± 37.3. The mandibular pain ratings for the RLD and ARD groups were 48.7 ± 33.2 and 61.5 ± 33.0. Significant differences between the RLD and ARD groups in maxillary and mandibular pain ratings were observed (p < 0.05 Student t-test).

Pearson’s correlation coefficient
The satisfaction ratings regarding mandibular
denture functions such as chewing, speaking, stability, retention, and esthetics significantly correlated with ratings of comfort and pain (p < 0.01; Table 3).

**Discussion**

This randomized controlled clinical trial showed that the application of a permanent acrylic resilient denture liner to the mandible caused edentulous patients to have higher satisfaction ratings on the first appointment following the delivery of the new denture when compared to a conventional denture. In addition, analyses of secondary outcomes revealed that the satisfaction ratings regarding mandibular denture functions such as chewing, speaking, stability, retention, and esthetics significantly correlated with ratings of comfort and pain. It suggested that during the period from the day of denture delivery to the day of the first appointment, patients’ satisfaction rating about denture functions were greatly influenced by perceptions of comfort and pain.

Pain rating with VAS in the RLD group was less than that in the ARD group. The advantage of less pain in the RLD group may be derived from a stress distribution effect of the resilient denture liner, which has been shown in in-vitro studies. Pain comprises the majority of the patients’ complaints for complete denture wearers. This study suggests that the RLD is useful in solving one of the major problems for complete denture wearers. Furthermore, the significantly different pain rating for maxillary dentures between the ARD and RLD groups was interesting, since there is no particular difference in construction between the maxillary dentures of both groups. Considering that pain perception is influenced by the patients’ emotional condition, it is understandable. The comfort provided by mandibular dentures might be responsible for the difference in the pain ratings between the ARD and RLD groups.

The RLD group showed significantly higher satisfaction ratings related to chewing with mandibular dentures than the ARD group. The resilient denture liner permits a wider dispersion of forces and absorption of impact forces involved in the functional and parafunctional movements. These features might help to chew food without pain and to increase satisfaction rating related to chewing. This consideration is reinforced by the significantly negative correlation between pain rating and satisfaction rating of chewing, which means that denture wearers with lesser pain show higher satisfaction rating of chewing. Insofar as satisfaction ratings related to speaking are concerned, the RLD group showed a significantly higher satisfaction rating in both maxillary and mandibular dentures than the ARD

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**Table 2** Satisfaction ratings

<table>
<thead>
<tr>
<th></th>
<th>Maxillary denture</th>
<th>Mandibular denture</th>
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<tbody>
<tr>
<td></td>
<td>RLD</td>
<td>ARD</td>
</tr>
<tr>
<td>General satisfaction</td>
<td>72 (32)</td>
<td>63 (32)</td>
</tr>
<tr>
<td>Satisfaction of chewing</td>
<td>72 (30)</td>
<td>58 (34)</td>
</tr>
<tr>
<td>Satisfaction of speaking</td>
<td>77 (20)</td>
<td>57 (30)**</td>
</tr>
<tr>
<td>Satisfaction of cleaning</td>
<td>88 (20)</td>
<td>82 (31)</td>
</tr>
<tr>
<td>Satisfaction of stability</td>
<td>83 (23)</td>
<td>77 (27)</td>
</tr>
<tr>
<td>Satisfaction of retention</td>
<td>89 (18)</td>
<td>79 (27)</td>
</tr>
<tr>
<td>Satisfaction of comfort</td>
<td>75 (28)</td>
<td>65 (30)</td>
</tr>
<tr>
<td>Satisfaction of esthetics</td>
<td>91 (14)</td>
<td>81 (24)</td>
</tr>
</tbody>
</table>

All ratings are concerned only with mandibular denture. *p < 0.05 **p < 0.01

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**Table 3** Pearson’s correlation coefficient

<table>
<thead>
<tr>
<th></th>
<th>Satisfaction of comfort</th>
<th>Pain rating</th>
</tr>
</thead>
<tbody>
<tr>
<td>Satisfaction of chewing</td>
<td>0.689**</td>
<td>-0.321**</td>
</tr>
<tr>
<td>Satisfaction of speaking</td>
<td>0.576**</td>
<td>-0.285**</td>
</tr>
<tr>
<td>Satisfaction of stability</td>
<td>0.682**</td>
<td>-0.401**</td>
</tr>
<tr>
<td>Satisfaction of retention</td>
<td>0.501**</td>
<td>-0.360**</td>
</tr>
<tr>
<td>Satisfaction of esthetics</td>
<td>0.380**</td>
<td>-0.268**</td>
</tr>
</tbody>
</table>

All ratings are concerned only with mandibular denture. **p < 0.01
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group. Speaking is influenced by the coordination between dentures and oral organs such as cheeks, lips, and tongue. Obviously, annoyance to oral organs could affect fluent speaking. The satisfaction ratings of comfort in the RLD group were higher than those in the ARD group and the satisfaction ratings of comfort showed significantly positive correlation with satisfaction ratings of speaking. This might mean that patients wearing RLD could speak more fluently than those wearing ARD, because patients wearing RLD might feel more comfortable than those wearing ARD.

The RLD group showed a significantly higher satisfaction rating related to cleaning the mandibular denture than the ARD group. The permanent acrylic resilient denture liner material has a particular powder – a high methacrylate polymer and benzoyl peroxide as an initiator, as well as a specific liquid – a high methacrylate monomer, together with a plasticizer. These make the substance soften. It was assumed that subjects found the RLD easier to clean, since the soft substance was flexible, and the food particles trapped were easily removed. It is important to realize that the mechanical properties of the acrylic resilient denture liners continually degrade due to a plasticizer leaking out. As a result, the evaluation for cleaning may decrease with time.

The RLD group showed a significantly higher satisfaction rating related to retention in mandibular dentures than the ARD group. Mandibular complete dentures are controlled by the surrounding oral structures. When in pain, patients cannot control their dentures, which may result in loss of functions of dentures and harmony between dentures and surrounding oral structures. That might be why there was different satisfaction rating of retention between the RLD and ARD groups.

The RLD group showed a significantly higher satisfaction rating related to esthetics in mandibular dentures than the ARD group, although there was no difference in the fabricating method and a near-whiteout condition of mandibular teeth. The treatment satisfaction is influenced by whether subjects got their treatment of preference. Mersel et al reported that patients suffering from any systemic chronic diseases involving irritation or chronic pain were more dissatisfied with appearance. These reports suggest the satisfaction rating is influenced by emotional and physical factors. Considering that the pain rating in the ARD group was greater than that in the RLD group and pain rating showed significantly negative correlation with the satisfaction rating of esthetics, the emotion induced by physical pain on the mandibular ridge might reduce the satisfaction rating on maxillary dentures in the ARD group.

Readers should be aware that these short-term satisfaction data at the first appointment vary with time and differ from the satisfaction data after completion of denture adjustments. However, the first impression is important to encourage patients to get over the difficulties of wearing a new denture.

**Conclusion**

Despite the limitation of a short-term observation, the mandibular satisfaction ratings were dramatically higher in RLD wearers than in ARD wearers.

**Acknowledgements:** The authors would like to thank all subjects who participated in this trial, as well as the colleagues of the Departments of Gnatho-Oral Prosthetic Rehabilitation and Oral & Maxillofacial Rehabilitation, Kanagawa Dental College who assisted in this trial as volunteers. The authors also wish to thank Mr Munemitsu Hishimoto of Nissin Dental Products Inc. for their support in providing dental materials. This study was supported by the Japan Society for the Promotion of Science, scientific study subsidies (Grant-in-Aid for Scientific Research (C) (2) assignment number 15592071).

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