Randomized Controlled Clinical Trial on Satisfaction with Resilient Denture Liners Among Edentulous Patients

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Purpose: The purpose of this study was to measure patients' satisfaction and their preference between mandibular dentures with permanent silicone–based resilient denture liner (SR) and conventional heat-activated acrylic resin (AR), both opposed by acrylic resin–based maxillary complete dentures. ***Materials and Methods:*** Twenty-eight edentulous patients who had fulfilled selection criteria and provided informed consent were enrolled in this trial. Subjects were allocated randomly to either arm of cross-over groups (AR-SR/SR-AR), stratified by gender, using a random permuted block within the strata method. The AR-SR group received AR denture treatment followed by SR denture treatment. The SR-AR group received treatment in the reverse sequence. The primary outcome was patient satisfaction measured on 100-mm VAS, analyzed by two-way ANOVA and the Bonferroni multiple comparison as a post hoc test. The secondary outcome was patients' preference, evaluated by chi-square goodness-of-fit test. An intention-to-treat analysis was performed. ***Results:*** Twenty-five subjects were enrolled in the analysis. There were no significant differences between AR and SR dentures 1, 2, and 3 months after the completion of control. Eighteen of 25 patients preferred SR dentures. ***Conclusion:*** Although there were no significant differences in patient satisfaction ratings between the two types of dentures, a significant majority of patients preferred those with a resilient denture liner. *Int J Prosthodont 2004;17:236–240.*

Despite the advancement of implant therapy for edentulous individuals, many patients are unable to receive implant treatment because of medical, psychologic, or financial constraints. Thus, conventional complete dentures will remain an important therapy for edentulous patients. Furthermore, the aging population will lead to a rising number of edentulous patients with atrophic mandibles. Therefore, in the future, the application of resilient denture liners may become clinically more frequent compared to conventional acrylic resin–based dentures.

Resilient denture materials have been used for decades and actively studied in the dental materials[1,2] and bacteriologic fields.[3,4] However, few valid reports on their clinical efficacy have been published. There is substantial need among general clinicians for evidence of the efficacy of resilient denture materials with complete dentures. The purpose of the present study was to determine whether there is any difference in patient satisfaction and preference between conventional heat-activated acrylic resin–based (AR) and permanent silicone-based resilient denture liner (SR) in mandibular dentures, with both types opposed by maxillary dentures with conventional heat-activated acrylic resin.

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Materials and Methods

Study Population

Edentulous male and female patients (aged 50 to 80 years) at Nihon University School of Dentistry at Matsudo Affiliated Hospital, Chiba, Japan, who were

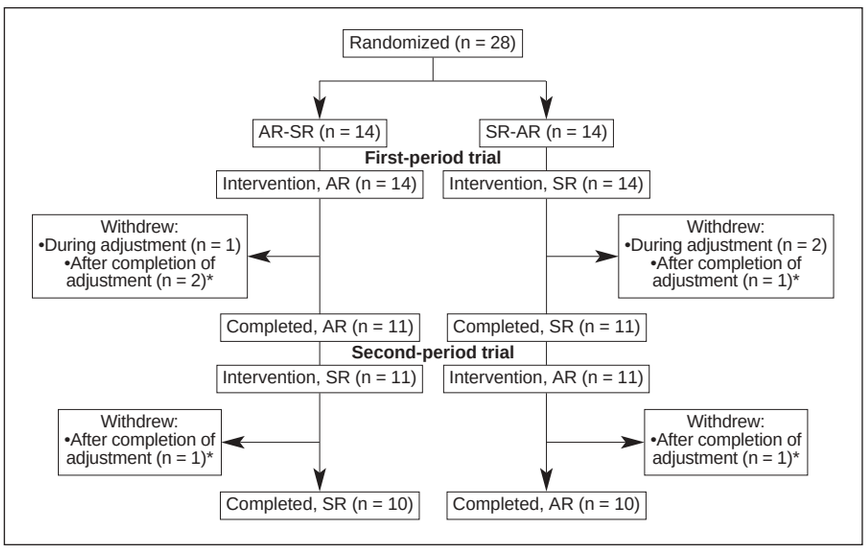

Fig 1 Participant flow diagram. *AR* = acrylic resin–based denture liner; *SR* = permanent silicone–based resilient denture liner; * = included in intention-to-treat analysis.

willing to undergo new complete denture treatment, were selected to participate in the study. Subjects participated in this study after informed consent was obtained. Exclusion criteria were: *(1)* systemic or neurologic disease; *(2)* lack of understanding of written or spoken Japanese; and *(3)* fewer than 2 years elapsed since the final tooth extraction(s). The protocol of the study was reviewed and approved by the Human Ethics Committee at Nihon University School of Dentistry at Matsudo (issue No. EC01-001).

Study Design

A randomized controlled clinical trial with two-period cross-over was carried out from February 2000 to August 2002. To allocate equal gender proportion in both arms, a random permuted block within the strata method[5] was used. Subjects were randomly allocated, using a computer-generated random-number table, into either arm of the cross-over groups (AR-SR/SR-AR). Both groups received two sets of complete maxillary and mandibular dentures: The AR-SR group received the AR denture first, followed by the SR denture, and the SR-AR group received the dentures in the reverse sequence (Fig 1). Seeking 20-mm differences with a standard deviation of 32 mm in general satisfaction[6] between groups on a 100-mm visual analogue scale (VAS), a total of 23 subjects were required to have 80% power with a two-sided alpha level of 5%. Considering potential dropout, 28 subjects were enrolled in the study.

Primary outcome was patients' ratings of general satisfaction with prostheses on 100-mm VAS. As a subscale, stability, retention, comfort, esthetics, ease of cleaning, and speaking ability were measured. The data were collected at baseline and 1, 2, and 3 months after completing adjustments of each sequence. Secondary outcome was patients' preference for AR or SR dentures 1 month after completion of the cross-over trial.

Treatment Protocol

Two sets of dentures were fabricated simultaneously, following a similar study design as Clough et al.[7] A preliminary impression was taken using stock trays (COE Impression Trays, GC) and irreversible hydrocolloid impression material (Algiace Z, Sankin). Border molding was done with individual trays and stick modeling compound (Peri Compound, GC), followed by a wash impression with zinc-oxide-eugenol impression material (Multi Form Impression Paste, Surgident). Master and duplicate casts were fabricated and mounted with the same facebow transfer and centric relation record on the same articulator (Hanau H2, Teledyne Waterpik).

After the processing of dentures, one set was inserted for the first-period trial according to the assigned order. Remounting and occlusal correction were completed at the insertion appointment. Postinsertion appointments for adjustments were scheduled until the patients were comfortable and free of tissue irritation. One month after completion of denture adjustments, subjects returned to the clinic three times, at 1-month intervals, for assessment of their level of satisfaction. The alternative prostheses were then inserted for the second-period trial and adjustments. One month after the end of the second-period trial, subjects were asked to return

Table 1 Mean (Standard Deviation) Baseline Characteristics of the 28 Subjects Enrolled in the Trial

Characteristic	AR-SR group (n = 14)	SR-AR group (n = 14)
Age (y)	71.7 (7.0)	69.4 (6.6)
Gender (male/female)	7/7	6/8
Edentulous period (y)	11.3 (8.0)	13.5 (8.0)
Age of existing dentures (y)	7.9 (6.7)	6.0 (7.6)
No. of previous dentures	3.0 (3.4)	2.6 (1.2)

AR = acrylic resin–based denture liner; SR = permanent silicone–based resilient denture liner.

Table 2 Mean (Standard Deviation) of 25 Patients' Satisfaction Ratings of Complete Dentures on 100-mm VAS

Parameter	Baseline (existing denture)	1-mo exam		2-mo exam		3-mo exam		Final exam	
		AR	SR	AR	SR	AR	SR	AR	SR
General satisfaction	44 (30)	88 (11)	88 (10)	89 (10)	89 (13)	89 (11)	89 (13)	89 (11)	91 (8)
Chewing	49 (31)	88 (13)	87 (14)	91 (11)	91 (12)	90 (12)	93 (10)	90 (11)	91 (10)
Speaking	56 (31)	88 (16)	89 (16)	88 (17)	89 (18)	89 (12)	89 (14)	90 (11)	89 (15)
Cleaning	66 (30)	88 (22)	85 (22)	92 (13)	91 (17)	90 (15)	90 (14)	92 (13)	92 (10)
Stability	43 (35)	88 (15)	89 (16)	91 (14)	90 (17)	91 (13)	91 (13)	91 (12)	91 (13)
Retention	45 (35)	87 (19)	87 (19)	88 (19)	88 (20)	86 (20)	80 (19)	88 (20)	89 (21)
Comfort	48 (34)	88 (13)	89 (12)	88 (15)	90 (18)	89 (13)	87 (17)	87 (15)	90 (14)
Esthetics	67 (28)	92 (12)	93 (12)	93 (11)	94 (11)	93 (8)	92 (13)	92 (7)	91 (13)

VAS = visual analogue scale; AR = acrylic resin–based denture liner; SR = permanent silicone–based resilient denture liner.

to the clinic to give their final preference for the prostheses. All treatment was performed by one prosthodontist. Blinding was not feasible, since it was clear for both patients and clinicians which materials were used.

Laboratory Protocol

The prostheses were replicated as closely as possible to ensure identical angulations, tooth position, occlusal vertical dimension, and occlusion. The denture teeth (Endura, Shofu) were arranged in bilateral balanced occlusion. The SR dentures were processed according to the manufacturer's instructions: Conventional dough-stage heat-activated acrylic resin denture base material (Urban, Shofu) was packed against the master cast, which was covered with a 2-mm wax spacer. After removing the wax spacer, resilient lining material (Sofreliner MS, Tokuyama) was inserted to replace it, and the flask was packed and processed. The AR dentures were processed with conventional heat-activated acrylic resin denture base material only. The curing cycle for both types of prostheses was 90 minutes at 70°C, followed by 30 minutes at 100°C. All laboratory work was done by one prosthodontist.

Statistical Analysis

The comparison of baseline characteristics for participants between AR-SR and SR-AR denture groups was performed by *t* test. Analyses of the satisfaction ratings of AR and SR dentures were performed by two-way analysis of variance (ANOVA) and Bonferroni multiple comparison post hoc testing. Carry-over effect and period effect[8] for satisfaction were analyzed by *t* test. Analysis of denture preference was performed by the chi-square goodness-of-fit test. *P* values below .05 were considered statistically significant.

To maintain the randomized condition, analyses were based on the intention-to-treat principle[9,10] (ie, data from dropout subjects who received at least one of the new dentures were included in the analysis). The last available data before dropout were used for missing data of satisfaction ratings. For preference, the denture in place at the time of dropout was determined as the preferred denture. The computer statistical package Dr SPSS II for Windows (SPSS) was used for this analysis.

Results

There were no significant differences between AR-SR and SR-AR baseline characteristics ($P > .05$; Table 1). Of 28 subjects, 20 completed the trial. Three subjects dropped out before completion of denture adjustment in the first period, and five dropped out because of loss of their determination to continue in the trial after receiving at least one denture. Since three dropout subjects did not receive even one denture and failed to make an assessment, they were excluded from analysis. Five dropout

subjects had at least one new denture delivered; thus, their data were included in the intention-to-treat analysis (Fig 1). The satisfaction ratings for SR dentures were not significantly different from those for AR dentures ($P > .05$; Table 2). Carry-over effect and period effect were not observed ($P > .05$). Of 25 subjects, 18 and 7 preferred SR and AR dentures, respectively ($P < .05$).

Discussion

This cross-over trial found no differences between patients' subjective ratings of AR and SR dentures measured with 100-mm VAS evaluating general satisfaction, stability, retention, comfort, esthetics, ease of cleaning, speaking ability, and chewing ability. This differed from earlier results reporting that application of resilient denture liner to mandibular complete dentures improves patient satisfaction ratings on VAS significantly in comparison to conventional acrylic resin–based dentures.[11] However, those subjects were limited to excessive atrophic ridge and prevalence of consecutive pain in the mandible. In our study, the subjects were recruited from a wide spectrum and were thus considered to be a more generalized sample. This difference would reasonably explain the disparity in patient ratings between the two studies, and it is considered that using a wide spectrum of subjects will result in equivalence between resilient and acrylic resin materials by measuring with VAS. It is speculated that VAS is less sensitive in making distinctions between extremely similar appliances, whereas VAS does indeed perform sufficiently well in detecting the differences in ratings between various implants and conventional complete dentures in comparative studies.[12] Patient preference in the present study, however, was significantly positive with SR dentures (72%), corresponding with the results that subjects show the same preference for resilient compared to acrylic resin materials.[13]

The disparity of results between VAS and patient preference indicates the limitation of VAS not only in detecting small differences between appliances, but also in measuring patient perception involving private satisfaction. Similar results were reported by others,[14] who concluded that disparity exists between patient satisfaction and preference with two different types of attachment of mandibular implant overdentures, magnet and O ring; also, Awad et al[15] discuss that patients' perception of prostheses cannot be measured based merely on satisfaction with prostheses. Some authors[16] suggest that oral health–related quality of life measured by the Oral Health Impact Profile is appropriate for use in edentulous patients. From a psychologic point of view, it is known that preference is based on both reason and emotion. Although the preference is straightforward ("desire to use SR dentures" was explicitly expressed by the respondents), decision making may be influenced by cognitive and affective components. Triandis[17] theorizes that intention is composed of perceived consequence, social factors, and affect. Thus, methods of future research to find "intention of wearing/choosing SR denture" should make a shift toward a qualitative approach, ie, the factors for measuring patients' perception of prostheses should include not only ratings based on function and esthetics of dentures, but also issues collected through in-depth open-ended questions and analyzed in a scientific manner.

The wide spectrum of edentulous subjects, cross-over design, and randomization to control bias in the present trial led to a result considered to be applicable in a clinical setting. In spite of the disparity between VAS and preference, the result gives clinically significant implications for clinicians to predict the prognosis of the mandibular complete denture using two different denture base materials, ie, applying permanent silicone–based resilient denture liner to a mandibular complete denture is an effective treatment from the viewpoint of patient preference. A further follow-up of these subjects is scheduled to track the influence of long-term effects.

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References

1. McCabe JF, Carrick TE, Kamohara H. Adhesive bond strength and compliance for denture soft lining materials. Biomaterials 2002;23: 1347–1352.
2. Parr GR, Rueggeberg FA. In vitro hardness, water sorption, and resin solubility of laboratory-processed and autopolymerized long-term resilient denture liners over one year of water storage. J Prosthet Dent 2002;88:139–144.
3. Olan Rodriguez L, Minah GE, Driscoll CF. *Candida albicans* colonization of surface-sealed interim soft liners. J Prosthodont 2000;9: 184–188.
4. Price C, Waters MG, Williams DW, Lewis MA, Stickler D. Surface modification of an experimental silicone rubber aimed at reducing initial candidal adhesion. J Biomed Mater Res 2002;63:122–128.
5. Fleiss JL. The Design and Analysis of Clinical Experiments. New York: John Wiley, 1986:46–47.
6. Awad MA, Feine JS. Measuring patient satisfaction with mandibular prostheses. Community Dent Oral Epidemiol 1998;26:400–405.
7. Clough HE, Knodle JM, Leeper SH, Pudwill ML, Taylor DT. A comparison of lingualized occlusion and monoplane occlusion in complete dentures. J Prosthet Dent 1983;50:176–179.

8. Hills M, Armitage P. The two-period cross-over clinical trial. Br J Clin Pharmacol 1979;8:7–20.
9. Hollis S, Campbell F. What is meant by intention to treat analysis? Survey of published randomised controlled trials. Br Med J 1999;319: 670–674.
10. Little R, Yau L. Intent-to-treat analysis for longitudinal studies with drop-outs. Biometrics 1996;52:1324–1333.
11. Murata H, Taguchi N, Hamada T, Kawamura M, McCabe JF. Dynamic viscoelasticity of soft liners and masticatory function. J Dent Res 2002;81:123–128.
12. Feine JS, de Grandmont P, Boudrias P, et al. Within-subject comparisons of implant-supported mandibular prostheses: Choice of prosthesis. J Dent Res 1994;73:1105–1111.
13. Wright PS. A three year longitudinal study of denture soft lining materials in clinical use. Clin Mater 1986;1:281–289.
14. Burns DR, Unger JW, Elswick RK Jr, Giglio JA. Prospective clinical evaluation of mandibular implant overdentures: Part II—Patient satisfaction and preference. J Prosthet Dent 1995;73:364–369.
15. Awad MA, Locker D, Korner Bitensky N, Feine JS. Measuring the effect of intra-oral implant rehabilitation on health-related quality of life in a randomized controlled clinical trial. J Dent Res 2000;79: 1659–1663.
16. Allen F, Locker D. A modified short version of the oral health impact profile for assessing health-related quality of life in edentulous adults. Int J Prosthodont 2002;15:446–450.
17. Triandis HC. Values, attitudes, and interpersonal behavior. Nebr Symp Motiv 1980;27:195–259.

Literature Abstract

Factors influencing the removal of posts.

This in vitro study investigated whether cement selection, metal type, and ultrasonic vibration affect the tensile force required to remove prefabricated parallel-sided posts from root canals. Ninety extracted canines were sectioned 1 mm coronal to the cementoenamel junction and embedded in acrylic resin. Post spaces were created with a No. 5 ParaPost drill to 10 mm. The teeth were randomly divided into three groups (n = 30) according to cement type, ie, zinc phosphate (Zinc Cement Improved), glass-ionomer (Fuji I), or resin composite (Panavia F). For each cement group, three subgroups were formed randomly according to metal type and ultrasonic vibration. ParaPost XP No. 5 stainless steel posts were placed in 20 canals, and Parapost XP No. 5 titanium posts were inserted in 10 canals. Half of the cemented stainless steel posts in each cement group were subjected to ultrasonic vibration for 16 minutes before testing. A scaler tip was applied to the post 2 mm above the coronal surface of the root. The tip was moved 360 degrees around the post to induce resonance. All specimens were stored in saline at 37°C for 2 weeks before testing. A tensile force at a cross-head speed of 5 mm/min was applied to remove the cemented post, and the dislodging force was recorded. The highest force recorded was 224.69 N (SD 99.26), which was required to remove the stainless steel post cemented with zinc phosphate and no ultrasonic vibration. Univariate ANOVA revealed no statistically significant differences between the nine subgroups at the .05 level. The three variables studied did not affect the force required to remove posts.

Hauman CHJ, Chandler NP, Purton DG. *Int Endod J* 2003;36:687–690. **References:** 16. **Reprints:** Dr C. H. J. Hauman, Department of Oral Rehabilitation, University of Otago School of Dentistry, PO Box 647, Dunedin, New Zealand. e-mail: tina.hauman@stonebow.otago.ac.nz—*Frederick C. S. Chu, Hong Kong*