One Month Follow up Study to Seek Patient's Environmental Factors Affecting Silicone-Based Resilient Denture Liners Embedded in Maxillary Complete Dentures

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Abstract

Objective: This study aimed to seek patient's environmental factors affecting silicone-based resilient denture liners. **Methods:** Thirty individuals with maxillary complete dentures were recruited for the study. One investigator measured the Shore D hardness of commercially available SRDLs Evatouch Super (EVA), Mucopren soft (MCP), and GC RELINE (GCR) embedded in maxillary complete dentures using a Vesmeter®. Participants' environments smoking, drinking, denture wearing during sleeping, and denture cleanser usage were asked as environmental factors potentially affecting on Silicone Based Resilient Denture Liners (SRDLs). A two-way repeated measure Analysis of Variance (ANOVA), with the material type (EVA, MCP, and GCR) and time (baseline and 1 month after application) as factors, was used to assess changes in the hardness of the three SRDLs over time. The effects of categorical variables, such as sex, smoking, drinking, denture wearing during sleeping, and denture cleanser usage, on the hardness of the ARDLs were analyzed using a two-way ANOVA without a post hoc test; we were not interested in comparing each ARDL but rather in analyzing the effects of categorical variables on the ARDLs. A p-value of <0.05 was considered statistically significant. **Results:** The changes in hardness for the GCR were less than the changes for EVA and MCP. The type of denture material and participants with complete maxillary complete dentures had harder SRDLs than did those with complete maxillary and mandibular complete dentures. The resting salivary flow rate, pH of the resting and stimulated saliva, and occlusal force showed associations with the hardness of EVA, MCP, and MCP respectively. **Conclusions:** The results suggest that the hardness of SRDLs changes over time and patients' environments could not influence on the hardness changes of SRDLs.

Key Words: Complete denture, Resilient denture liner, Hardness, In vivo study

Introduction

From 2016, Japanese health insurance has started to cover treatment for relining to an existing mandibular complete denture with Silicone Based Resilient Denture Liners (SRDLs). It is very helpful for edentulous patients suffering from wearing conventional hard acrylic complete dentures with pain during mastication due to atrophied alveolar ridge. The number of edentulous patients with atrophied alveolar ridge by a thin mucosa and progressive alveolar bone resorption who cannot wear conventional hard acrylic dentures because of occlusal force-induced pain is increasing in today's rapidly aging society. The application of Resilient Denture Liners (RDLs) on the base of mandibular dentures reportedly improves masticatory function and generates greater maximum biting force without influencing muscle activity[1,2], thus improving patients' satisfaction with their dentures[3,4]. The evidence derived from researches and reality of rapidly aging population structure change might move Japanese government to change health insurance for dentures.

Although RDLs are useful materials for denture wearers due to their softness, they deteriorate with time. There are several types of deteriorations in RDLs. One of the most fatal deteriorations of RDLs is hardening, since clinical effects of RDLs are contributed by their softness. However, RDLs cannot keep their softness when used in clinical setting. Although no change of the original properties of RDLs in the oral cavity is highly desirable, deterioration over time is inevitable [5]. An increase in hardness results in altered distribution of the masticatory load and decreased absorption of elastic energy, which make denture wearing difficult for individuals who cannot tolerate conventional hard denture base resin [6].

Several researchers have been studying the hardness changes of RDLs over time by using different study designs. Some studies focused on the long-term use of dentures in the clinical setting by assessing specimens after storage in water at 37°C for 1 year [7,8]. Other studies simulated the intraoral temperature changes induced by food or beverages by subjecting specimens to 2000 complete cycles between 5–55°C in water [9-11]. The influence of the composition of storage media used for specimen immersion was also evaluated in one study [12]. Furthermore, changes in hardness caused by disinfection methods [13,14], immersion in different beverages [15], and pressure from the denture base have been investigated [16]. In all of these studies, the researchers made considerable efforts to simulate the oral environment in laboratory studies.

However, the results of laboratory studies are not entirely conclusive, even though the researchers tried to simulate the oral environment as best as possible; consequently, clinical trial on the deterioration of RLDs that are applied to denture bases is academically necessary. Additionally, considering that SRDLs listed to Japanese health insurance will increase to be applied to mandibular complete denture in clinical setting, the clinical trial is clinically important for dentists working based on evidences from researches. The aim of this clinical trial was to seek patients' environmental factors affecting SRDLs embedded in maxillary complete dentures worn by

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patients for 1 month. We hypothesized that the hardness 1 month after SRDL application would be affected by the patients' environmental factors such as smoking, drinking, wearing dentures while sleeping, use of denture cleanser.

Materials and Methods

Participants

This study was approved by the Human Ethics Committee of Nihon University School of Dentistry, Matsudo, Japan (EC 13-006). Thirty maxillary complete denture wearers (12 men, mean age: 71.8 ± 9.2 years; 18 women, mean age: 70.2 ± 10.7 years) who visited the Department of Removable Prosthodontics at our institute were recruited for this study. There were 15 wearers of complete single maxillary dentures and 15 wearers of complete maxillary and mandibular dentures in this study. The volunteers were enrolled only after they provided written informed consent. Maxillary complete denture wearers who used tissue conditioner, RDLs, and denture adhesive were excluded. All participants were instructed to wear their dentures per their normal routine.

Relining with SRDLs

Three 4-mm-diameter and 2-mm-deep cylindrical holes were drilled into the inner surface of the maxillary denture base. The reason why maxillary denture base was selected for relining with SRDLs was that inner surface of the maxillary denture base have flat plane to be appropriate for measurement. The 3 holes were set at regions of second premolar, first molar, and second molar on inner surface of the denture base at middle part between denture border and denture median line (*Figure 1*).

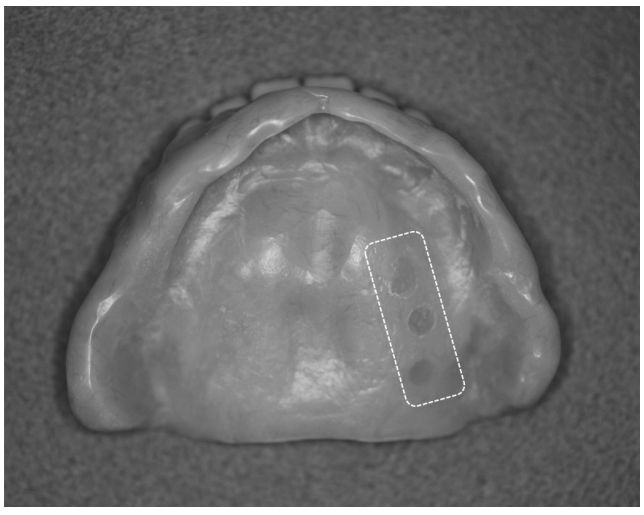

Figure 1. *SRDLs-embedded complete maxillary denture. Cylindrical RDLs with a 4-mm diameter and 2-mm depth were embedded in the complete maxillary denture.*

The 3 holes were packed by 3 different SRDL materials after treatment with each adhesive according to manufacturer's instruction; thereafter, the denture was set in a proper position on the maxillary alveolar ridge under occlusal pressure. After polymerization, the flash of the SRDL was removed. The cylindrical specimens in the denture were in contact with the oral mucosa. *Table 1* lists the details of the three commercial SRDLs used in this study: Evatouch Super (EVA; Neo Dental Chemical products, WA, USA), GC RELINE (GCR; GC Dental Products Corp, Tokyo, Japan), and Mucopren soft (MCP; Kettenbach GmbH & Co KG, CA, USA).

Table 1. *Commercial resilient denture liner used.*

Code	Brand name	Polymerization type	Lot No.	Manufacturer
EVA	Evatouche Super	Auto Polymerization	A3G1	NEO Dental chemical products, WA, USA
MCP	Mucopren Soft	Auto Polymerization	130841	Kettenbach GmbH & Co KG, CA, USA
GCR	GC Reline Ultrasoft	Auto Polymerization	1302141	GC Dental Products Corp, Tokyo, Japan

Measurements

Hardness: Hardness was measured using a Vesmeter® (WaveCyber Corp, Saitama, Japan). When the probe, which included a built-in position sensor connected to a personal computer, was placed perpendicular to the SRDL located inner surface of denture, the indenter of the probe was depressed onto the SRDL at a constant speed through electromagnetic power. Simultaneously, the path of the indenter was constantly traced by the position sensor. The computer processed electrical signals from the measuring device and calculated the Shore D hardness, which was the primary outcome in the present study. The same investigator measured the hardness at each subsequent appointment. The baseline hardness and the hardness at 1 month after oral exposure were used in the analysis. Each specimen was evaluated five times, and the highest and lowest values were eliminated from the calculation of the mean representative value for each specimen. The specimens embedded in the dentures were measured on a hot plate to maintain the temperature at 37°C or as close to the oral temperature as possible. The change in the hardness after 1 month of oral exposure was calculated using the following formula: (1-month hardness − initial hardness)/initial hardness × 100 (%).

Statistical analyses

Before other statistical analyses were performed, the normality of the data was tested using the Kolmogorov–Smirnov test; then, parametric statistical methods were applied.

A two-way repeated measure Analysis of Variance (ANOVA), with the material type (EVA, MCP, and GCR) and time (baseline and 1 month after application) as factors, was used to assess changes in the hardness of the three SRDLs over time. The Tukey–Kramer test was used as a post hoc test after the two-way repeated-measures ANOVA.

The effects of categorical variables, such as sex, smoking, drinking, denture wearing during sleeping, and denture cleanser usage, on the hardness of the ARDLs were analyzed using a two-way ANOVA without a post hoc test; we were not

interested in comparing each ARDL but rather in analyzing the effects of categorical variables on the ARDLs. All statistical analyses were performed using IBM® SPSS® Statistics 21 (IBM, Armonk, NY, USA). A p-value of <0.05 was considered statistically significant.

Results

Changes of hardness

The mean initial hardness values for the EVA, MCP, and GCR SRDLs were 4.1 ± 1.2, 2.7 ± 0.7, and 1.2 ± 0.3, respectively, while those at 1 month after oral exposure were 4.5 ± 0.5, 4.8 ± 0.6, and 1.6 ± 0.4, respectively.

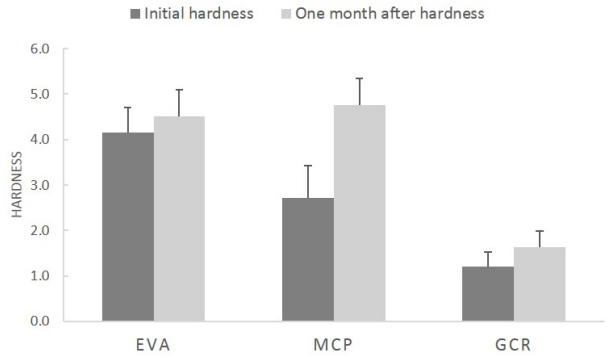

Figure 2. *Changes in hardness. A two-way repeated measures analysis of variance revealed a significant change in the hardness over time (p < 0.0001), with each SRDL exhibiting significant changes (p < 0.0001). An interaction between the material type and time course was not observed (p > 0.05). A Tukey–Kramer test showed that the hardness of the GCR SRDL was less than that of the EVA and MCP SRDL (p < 0.0001). Abbreviations: EVA, Evatouch Super; MCP, Mucopren soft; GCR, GC RELINE; SRDL, silicone-based resilient denture liners.*

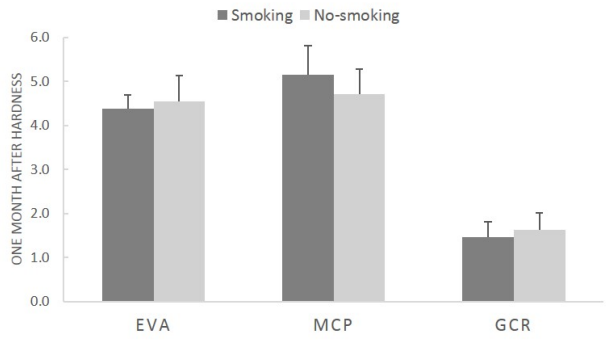

Figure 3. *Smoking and hardness. A two-way analysis of variance showed that the hardness at 1 month after application was not affected by smoking (p = 0.86). The EVA, MCP, and GCR are following abbreviated word: Evatouch Super, Mucopren soft, and GC RELINE respectively.*

The changes in hardness observed for the EVA, MCP, and GCR SRDLs were 9.7%, 77.8% and 33%, respectively. A two-way repeated measures ANOVA revealed a significant change in hardness over time (p < 0.0001), with each SDRL exhibiting a significantly unique change (p < 0.0001). An interaction between the material type and time course was also observed (p < 0.0001). The Tukey–Kramer test showed that the hardness value of the GCR SRDL was less than the hardness values of the EVA and MCP SRDLs (p < 0.0001) *(Figure 2)*.

Patients characteristics and hardness

Smoking: In this study, three of the subjects (9 specimens) were smokers, and 27 (81 specimens) were non-smokers. A two-way ANOVA showed that the hardness at 1 month after application was not affected by smoking (p = 0.86) *(Figure 3)*.

Drinking: Among the subjects in this study, 12 (36 specimens) were drinkers, and 18 (54 specimens) were non-drinkers. A two-way ANOVA showed that the hardness at 1 month after application was not affected by drinking (p = 0.43) *(Figure 4)*.

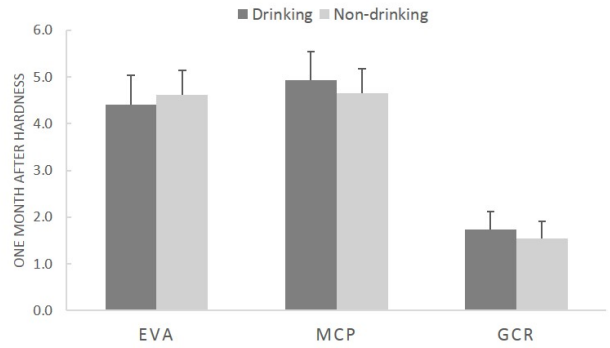

Figure 4. *Drinking and hardness. A two-way analysis of variance showed that the hardness at 1 month after application was not affected by drinking (p = 0.43). The EVA, MCP, and GCR are following abbreviated word: Evatouch Super, Mucopren soft, and GC RELINE respectively.*

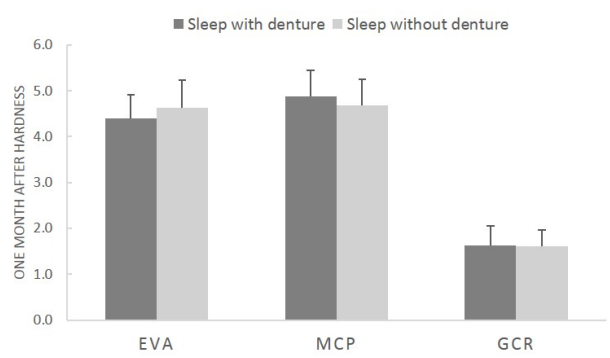

Figure 5. *Denture wearing while sleeping and hardness. A two-way analysis of variance showed that at 1 month after application, the hardness was not affected by wearing dentures while sleeping (p = 0.90). The EVA, MCP, and GCR are following abbreviated word: Evatouch Super, Mucopren soft, and GC RELINE respectively.*

Denture wearing while sleeping: Thirteen participants (39 specimens) wore their dentures while sleeping and 17 participants (51 specimens) did not. A two-way ANOVA

showed that the hardness at 1 month after application was not affected by wearing dentures while sleeping (p = 0.90) *(Figure 5)*.

Denture cleanser usage: Twenty-four participants (72 specimens) used denture cleanser and six (18 specimens) did not. A two-way ANOVA showed that the hardness at 1 month after application was not affected by the usage of denture cleanser (p = 0.64; *Figure 6*).

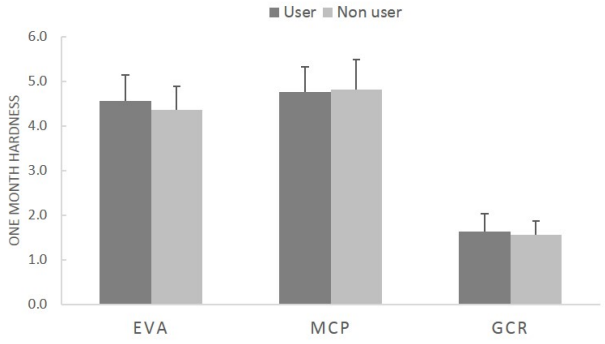

Figure 6. *Denture cleanser usage and hardness. A two-way analysis of variance showed that at 1 month after application, the hardness was not affected by the use of denture cleanser (p = 0. 64). The EVA, MCP, and GCR are following abbreviated word: Evatouch Super, Mucopren soft, and GC RELINE respectively.*

Discussion

This follow up study investigated one month after hardness of SRDLs partially embedded in maxillary complete dentures and exposed to the oral environment and found that the effect of denture type and pH value of the resting saliva on the hardness were statistically significant but not clinically great. This one month follow up study implied that SRDLs are stable even if they were exposed to patients' environments such as smoking, drinking, denture cleansers use, nocturnal wearing, and gender. To our knowledge, this study is the first clinical study to investigate effects of environmental factors derived from patients' intra-oral conditions and daily life style on SRDL hardness.

The hardness at 1 month after SRDL application/exposure to the intraoral conditions differed between the EVA, MCP, and GCR SRDLs. This result might be due to the different components of the SRDLs. The application of properly surface-treated silica fillers results in the formation of bonds between the filler and the silicone polymer and increases the hardness. Furthermore, the hardness of SDLs is modulated by the degree of their cross-linking or by the addition of fillers [6]. Hence, the hardness differences that were observed between the EVA, MCP, and GCR SRDLs might be attributed to the different concentrations of silica fillers that were present in each SRDL. Unfortunately, information related to the material composition, chemical properties, and polymerization procedure is proprietary knowledge and cannot be accessed.

The percent changes in hardness that were observed in the EVA, MCP, and GCR SRDLs were 9.7%, 77.8% and 33%, respectively. Many reports have shown that the hardness changes in SRDLs range from 5% to 63% in distilled water, even though SRDLs are known to be more stable compared to acrylic-based RDLs [7,8,17-20]. The hardness changes observed in our study were similar to the changes observed in previous reports although different materials were used among the studies. Parr et al. [8] showed that the hardness of the auto-polymerized SRDLs was lower than that of laboratory-processed material since the auto-polymerized SRDLs cannot complete polymerization in the first 24h, resulting in continuously changing hardness of SRDLs. Additionally, there are reports show that the hardness of SRDLs increases and reaches its maximum value after 1 month [7,8]. These reports might explain our study results that the hardness changes of SRDLs even though SRDLs are known as physically stable.

This study could not find influence of patients' environment characteristics such as smoking, drinking, nocturnal denture wearing, and denture cleanser usage. Before stating the study, we believed some of the characteristics would influence on the hardness change of SRDLs. These results implied that the SRDLs were stable to patients' environments and could be applied to any patients.

Conclusion

Within the limitations of this study, we conclude that the hardness of SRDLs changes over time and that the hardness may not influenced by patients' environments

Acknowledgement

This study was conducted in accordance with the Declaration of Helsinki, and each subject received oral and written information about the study and provided informed consent. The study protocol was reviewed and approved by the Human Ethics Committee of Nihon University School of Dentistry at Matsudo (EC 13-006) This research was performed with a grant from the Japan Society for the Promotion of Science, scientific study subsidies (Grant-in-aid for Scientific Research (C) (2) assignment number 17K11767). There are no conflicts of interests to declare.

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