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Original article

Evaluation of dynamic impression lining material effects on masticatory function and the oral health-related quality of life of complete denture wearers: A six-month randomized controlled trial

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Abstract

Purpose: To determine the effect of a dynamic impression lining material (DIL) on the retention and stability of mandibular complete dentures (LCD), masticatory performance, and the oral health-related quality of life (OHRQoL) of the patients wearing complete denture (CD) compared with those wearing a denture with conventional hard denture liner (HL).

Methods: Twenty-five patients who wore CD with an ill-fitting LCD were randomly assigned to two groups: LCD relined with DIL (Dynamic impression lining material) or HL (Tokuyama® Rebase II (fast)). Three objective measures (denture retention, stability, and masticatory performance) were measured. The OHRQoL was also measured using the Thai version of oral impacts on daily performance. Outcomes were measured at six time points: baseline, 3 days, 1 week, 1 month, 3 months, and 6 months after relining. Outcome changes were analyzed using a generalized estimating equation, and all models were adjusted for age, mandibular ridge form, and CD age at a 5% significance level.

Results: After LCD relining, the frequency and severity of adverse oral impacts significantly decreased. In the DIL group, denture pain occurred on and off over six months, and an ill-fitting denture impacted at one month. In the HL group, denture pain continuously decreased over time. At 3 months, changes in the clinical properties of DIL were observed, including perceived odor. The material also peel-off from the denture base, and plaque accumulation was observed. In contrast, the HL properties remained stable for over 6 months.

Conclusion: Although DIL improves denture retention and stability, masticatory performance, and the OHRQoL of the patients who wear CD, oral adverse effects were not eliminated. The clinical properties of DILs changed at 3 months, while the HL remained relatively stable for up to 6 months.

(The clinical trial registration number: Thai Clinical Trials Registry (TCTR) number TCTR20210625005.)

Keywords: complete denture, dynamic impression liner, denture liner, oral impacts on daily performance, masticatory performance

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1. Introduction

The residual alveolar ridge of completely edentulous patients continuously resorbs after tooth extraction[1]. Alveolar ridge resorption in the patients who wear complete denture (CD) can result in ill-fitting dentures that negatively affect a wearer's masticatory function and oral health-related quality of life (OHRQoL)[2,3]. To improve denture fit, the fabrication of a new denture is always a treatment option. However, this option requires multiple clinical appointments, which may not be suitable for patients who have difficulty accessing dental care or economic limitations[4]. To overcome these obstacles, chair-side denture liners are used to improve denture fit.

Denture lining materials are categorized as hard or resilient (soft) denture liners. Hard denture liners are usually made of polymethylmethacrylate, whereas resilient denture liners are typically silicone elastomers or plasticized acrylic resins[5,6]. Resilient denture liners can also function as tissue conditioners, dynamic impression materials, and resilient denture lining material. Clinical studies have revealed that chair side resilient denture liners improve denture retention and stability[7,8], masticatory function[9–12], patient satisfaction[8], and oral health-related quality of life of the patients who wear CD[13,14]. However, other studies have reported that the masticatory function and satisfaction of the patients who wear CD with a resilient denture liner, conventional acrylic resin, or hard den-

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ture liner were not significantly different[10,15,16], or worse than a conventional acrylic-based denture[17]. Although silicone is the preferred resilient denture liner because of its longevity, it is more prone to debonding from an acrylic resin denture[18]. Plasticized acrylic denture liners can adhere better to dentures. However, this liner has a limited service life owing to material degradation over time, resulting from alcohol and plasticizer leaching[19]. Thus, plasticized acrylic dentures have shorter longevity than silicone dentures.

To overcome the limitations of resilient denture liners and combine the advantages of long-term denture liners, a 'dynamic impression lining material (DIL)' has been introduced. The manufacturer claims that DIL functions as both a resilient and long-term hard denture liner by being a tissue conditioner at the beginning while a functional impression surface forms during the first week after application. Over time, the material becomes a hard-lining material, with a service life of up to six months[20]. The manufacturer claims that the DIL possesses the advantages of both resilient and long-term denture liners. To our knowledge, no study has evaluated the efficacy of DIL in improving denture fit, masticatory function, and the OHRQoL compared with conventional hard denture liners.

The objective of this study was to determine the effect of DIL on the retention and stability of mandibular complete dentures (LCD), masticatory performance, and the OHRQoL of the patients who wore CD compared with those wearing LCD with a conventional hard denture liner (HL). The clinical properties of these materials were evaluated. Changes in the three outcomes were evaluated at 3 days, 7 days, 1 month, 3 months, and 6 months after denture relining. The null hypothesis was that the application of either DIL or HL would not result in a change in the OHRQoL score at baseline compared with after denture relining.

2. Materials and Methods

2.1. Study design, IRB approval, and trial registry

The present study was a two-armed parallel double-blind randomized controlled trial (RCT) design. The participants and outcome assessors were blinded to the type of denture liner used. The experimental protocol was approved by the Human Research Ethics Committee of the Faculty of Dentistry, Chulalongkorn University, Bangkok, Thailand (HREC-DCU 2019-068). The study was registered in the Thai Clinical Trials Registry (identification number TCTR20210625005). Informed consent was obtained from all study participants. All procedures were performed following the Declaration of Helsinki.

2.2. Participants, sample size, and randomization

The participants were patients wearing CD who received treatment from dental students at the Faculty of Dentistry, Chulalongkorn University, and were presented for follow-up from January 2020 to January 2021. To ensure that the patient had adapted to their dentures, each patient must have been wearing their dentures daily for at least one year to be eligible. The inclusion criteria were patients wearing CD who complained about having an ill-fitting LCD but were unwilling to have a new denture fabricated, mostly because of financial limitations. A prosthodontist with approximately twenty years of clinical experience (W.T.) evaluated and confirmed that the dentures had an acceptable vertical dimension at occlusion and during centric relation, and with appropriate denture border extension, and maxillary retention and stability. The exclusion criteria were patients who were allergic to any of the components in the denture lining materials, temporomandibular joint disorder, or psychological disorder.

The sample size was calculated using G*Power software with selected statistical analyses of F-test and ANOVA–repeated measures, within–between interactions[21]. The following parameters were used: input effect size, f = 0.15; α error = 0.05, power = 0.80, number of groups = 2, and number of measurements = 6. The total sample size was 50, resulting in an approximate sample size of 50/6 = 8.3 per group. Considering potential attrition, the number of participants in each group was slightly increased, with more participants in the experimental group (10 in the control group and 15 in the experimental group). Thus, a total sample size of 25 the patients who wore CD was necessary.

Randomization was performed using computer-generated numbers (Excel® 2010, Microsoft). The number was put in a sealed envelope, and the participants (n = 25) were randomly allocated into one of two groups, with an allocation ratio between the intervention and control (active comparison) group of 3:2. Participants numbered 1–10 were allocated to the control group. The rest were assigned to the experimental group. One of the investigators (W.T.), not involved in evaluating the treatment outcomes, generated the allocation sequence and assigned the participants to the control and experimental groups.

2.3. Baseline characteristics of the participants

At baseline (T0), data on confounding variables that could affect the treatment outcomes were collected. Information on demography and CD experience was obtained by interviewing the participants. CD age was obtained from the patients' hospital records. Each patient's maxillary and mandibular ridge forms were examined and classified as round or others (flat, knife-edge, or depressed) following Cawood and Howell's classification[22]. The occlusal anatomy of the artificial posterior teeth was visually inspected and categorized into anatomical or non-anatomical teeth based on the presence of an anatomic cusp on either the maxillary or mandibular denture teeth or not[3]. The occlusal scheme, such as bilateral balanced and lingualized articulation, was not determined because it could change over time due to occlusal wear of the artificial teeth.

2.4. Relining the mandibular denture (Intervention)

The descriptions of the two denture lining materials used in this study are listed in **Table 1**. The denture relining process was performed by a prosthodontist (T.P.). In the experimental group (DIL group), the LCD was relined with a denture lining material (Dynamic Impression lining material; Kamemizu Chemical Ind. Co. Ltd, Japan). In the control group (HL group), the LCD was relined using a conventional chairside acrylic-based hard denture lining material (Tokuyama® Rebase II (fast); Tokuyama Dental Corp. Inc., Japan). Descriptions of the two materials are listed in **Table 1**.

Dentures were removed from the oral cavity and cleaned by brushing with a toothbrush dipped in liquid soap. Before we applied the denture liner, 1.5–2 mm of the tissue surface of the LCD was removed using an acrylic carbide bur, while preserving the denture border. In the DIL group, a layer of a bonding agent (new top-coat) was applied to the entire tissue fitting and border surfaces. In contrast, the HL group, the surface was applied with a layer of HL adhesive to enhance the material adhesion to the acrylic denture base. In

Table 1. Materials used in the study

Material type	Brand	Manufacturer	Main composition
Conventional chair-side hard denture liner	Tokuyama® Rebase II (fast) (HL)	Tokuyama Dental Corporation Inc., Japan	Powder: - poly(ethyl methacrylate), - benzoyl peroxide Liquid: - 2-[(2-methyl-1-oxoallyl)oxy]ethyl acetoacetate - nonmethylendiol dimethacrylate - N,N-Diethyl-p-Toluidine Adhesive: Ethyl acetate, Acetone Tokuso Resin Hardener II: - sodium hydrogencarbonate - sodium sulphite
Experimental denture liner	Dynamic Impression Lining material (DIL)	Kamemizu Chemical Ind. Co., Ltd., Japan	Powder: poly(ethyl methacrylate) and others Liquid: polyfunctional methacrylate and others New top coat: ethyl acetate

both groups, the powder and liquid were mixed for 1 min, according to the manufacturer's instructions. The resin was spread onto the prepared tissue surface of the denture, and then, the LCD was inserted into the mouth with the maxillary denture already seated in place. The prosthodontist positioned the LCD, using the preserved denture border as a reference. The participants occluded the maxillary and mandibular dentures into a maximal intercuspal position without assistance, while the dentist performed muscle molding. After seating the LCD in the mouth for 4 min, the denture was removed from the mouth and any excess material on the denture base was removed using scissors and a #11 scalpel blade. In the DIL group, another layer of new top-coat was applied to the entire tissue surface of the denture, whereas in the HL group, the LCD was immersed in Resin Hardener II.

To ensure blinding, similar denture care instructions were provided to the DIL and HL groups based on the manufacturer's instructions[20], to control the participants' blindness. The participants were instructed to clean their LCD by running tap water over them during the first week. Subsequently, they were allowed to clean their LCD with an extra-soft toothbrush in liquid soup. To clean their UCD, an extra-soft toothbrush in liquid soup was used as usual. Use of a chemical denture cleanser was prohibited because it might affect the material's properties. The participants were told to take their CD out at bedtime and immerse it in water overnight[23]. The patients' compliance in cleaning the denture was done by placing a tick on a provided daily calendar when they finished cleaning their dentures.

2.5. Outcome assessments

The three outcome measures were 1) professional evaluation of denture retention and stability, 2) observation of a patient masticating a peanut, and 3) the self-reported OHRQoL. Denture retention, stability evaluation, and the OHRQoL interviews were performed by a prosthodontist (P.K.) who did not participate in the randomization and denture relining processes. Peanut particle size was evaluated in a laboratory by a blinded individual who was otherwise not involved in the study. The outcomes were collected at six time points: baseline (0 day), 3 days, 7 days, 1 month, 3 months, and 6 months after the denture liner was applied. These time points were chosen because the manufacturer claimed that the DIL would function as a resilient denture lining material for a week, and then become a hard denture lining material that can last up to 6 months[20]. At each visit, denture adjustment was performed if the participant complained of pain from the denture.

2.5.1. Primary outcome

Each participant's OHRQoL was assessed through face-to-face interviews using the Thai version of the oral impacts on daily performances (OIDP) index[24,25]. This index measures the ultimate impact of diseases that affect eight daily activities in three ways: 1) physical (eating, speaking, and cleaning oral mucosa/denture), 2) psychological (relaxing/sleeping, maintaining usual emotion, and smiling/laughing), and 3) social (working and contacting with people). The frequency and severity of each activity were rated on a five-point ordinal scale (score 0–5), and the score for each activity was used to generate a total score. A higher score indicated poorer OHRQoL. The OIDP score was further dichotomized into the absence (0) or presence (1) of an oral impact. Participants also provided information regarding their main oral impairments and the main symptoms caused by their denture.

2.5.2. Secondary outcomes

The multiple sieve method after peanut mastication has been used to evaluate the masticatory performance of the patients who wear CD[2,24]. The participants masticated 3 g of roasted peanuts for 20 strokes three times with a 15-min rest interval between each test. The comminuted peanut particles were dried and sieved through 12 standard test sieves (Retcsh Technology GmbH) on a vibrating sieve shaker. A simple linear regression was performed between the cumulative weight and diameter of each sieve test. The median peanut particle size (mm) was defined as the sieve diameter through which 50% of the comminuted peanut particles passed. A larger peanut particle size indicated a lower masticatory performance.

To evaluate LCD adaptation to the supporting tissue, the retention and stability of the LCD were assessed by a prosthodontist (P.K.) using the CU-modified Kapur criteria[26]. The retention score ranged from 3 (good), 2 (moderate), 1 (minimum), to 0 (no retention), while the stability score ranged from 2 (sufficient), 1 (some), and 0 (no stability), giving a total score ranging from 0 to 5.

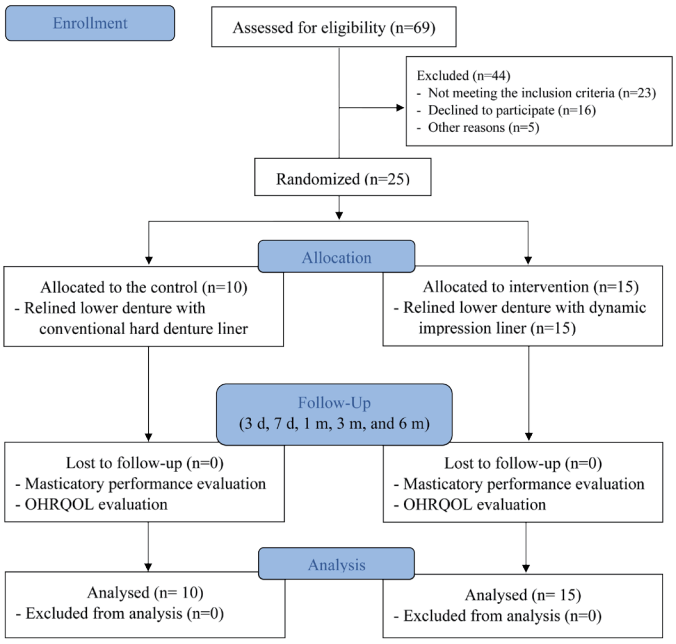

Fig. 1. Consort flow diagram of the study

2.6. Clinical properties of the materials

The clinical properties of the DIL and HL during follow-ups were recorded using the criteria for evaluating denture liner properties proposed by Wright (1984) and revised by Mutluay (2008)[27,28]. The criteria consisted of nine items: 1) physical integrity (material tearing/loss), 2) surface texture (texture loss, roughening), 3) adhesion to the denture base, 4) color stability, 5) odor, 6) plaque accumulation, 7) hygiene (food particle coverage), 8) resilience (compared with freshly mixed material), and 9) fungal colonization. The characteristics of each item were scored using a 4-point rating scale (4=excellent, 3=good, 2=fair, and 1=poor), except for resilience and fungal colonization, which were rated as present or absent.

2.7. Data analysis

The intention-to-treat principle was used for any missing data after randomization. Descriptive statistics were used to determine percentages, means (standard deviations, SD), and median (1st quartile (Q1) and 3rd quartile (Q3)). A generalized estimating equation (GEE) method was used for repeated observations (six time points) in a single patient. All models were adjusted for age, mandibular ridge form, and CD age. A GEE model with a Gaussian distribution and an identity link function, assuming an exchangeable working correlation structure, was used to assess the changes in peanut particle size between the six time points, and the adjusted beta coefficient was calculated. A GEE model with a negative binomial distribution and log link function, assuming an exchangeable working correlation structure, was used to assess the changes in OIDP scores between time points, and the adjusted incidence rate ratio (aIRR) was calculated. To determine the changes in the presence of an oral impact between time points, a GEE model with a binomial distribution and log link function, assuming an exchangeable working correlation structure, was used. Data were statistically analyzed using STATA version 13.0 (StataCorp LP, College Station, TX, USA) at a 5% significance level.

Table 2. Baseline characteristics of the participants

	Overall distribution (%)	DIL (n=15)	HL (n=10)
Age (years): mean (±s.d.)	71.0 (±8.7)	73.4 (±8.1)	69.3 (±5.6)
Sex: Male	70.0	70.0	70.0
Female	30.0	30.0	30.0
Education: None to primary	44.0	53.3	30.0
Secondary and above	56.0	46.7	70.0
Having CD experience: No	52.0	53.3	50.0
Yes	48.0	46.7	50.0
Mandibular ridge form: Flat, Knife edge	48.0	53.3	40.0
Round	52.0	46.7	60.0
Occlusal anatomy: Non-anatomic	20.0	20.0	20.0
Anatomic	80.0	80.0	80.0
CD age: mean (±s.d.)	3.1 (±1.0)	3.0 (±0.8)	3.2 (±1.2)

3. Results

3.1. Participant flow

The flow diagram of the study is presented in **Figure 1**. Initially, 69 patients who wore CD were eligible for the trial, however, 44 were excluded. The remaining 25 individuals were included as participants and were randomly allocated to either the DIL or HL groups. No harmful side effects were observed or reported by participants during the trial. The retention rate was 100%.

3.2. Participant characteristics

The participants had a mean age of 71.0 (±8.7) years (range 57–85 years). The baseline characteristics, sex, CD experience, occlusal anatomy, and CD age were comparable between the groups (**Table 2**). The prevalence of flat residual ridges in the DIL group was 10% higher than that in the HL group. The difference was not significant.

3.3. Changes in retention and stability, masticatory performance, and the OIDP score

The changes in the CU-modified Kapur score of the LCD, masticatory performance, and the OIDP score at the six time points are presented in **Table 3**. Immediately after denture relining, the median Kapur score of the DIL and HL groups increased from two points at baseline to four points. The median Kapur score in the DIL group decreased to 3 and 2 points at 3 days and 1 month, respectively. In contrast, the median Kapur score in the HL group remained stable at 4 points until 6 m with a slight reduction in retention score at 1 month. The GEE analysis results demonstrated that peanut particle size significantly decreased at 3 days and increased to the baseline level at 7 days and 1 month in the DIL group. Peanut particle size reduced again at 3 months, with peak reduction at 6 months. In the HL group, peanut particle size continuously decreased from baseline, with a significant reduction at 1 month and a peak reduction at 3 months. The OIDP scores of the participants in both groups significantly reduced from 3 days to 6 months, but with different patterns. In the DIL group, the OIDP score reduced until 7 days and increased at 1 and 3 months. In contrast, the OIDP score in the HL group continuously decreased from baseline to 6 months.

Table 3. Changes in the Kapur score of the mandibular dentures, peanut particle size (mm), and the OIDP score

Time	LCD Kapur score: median (Q1, Q3)						Peanut particle size (mm)				OIDP score			
	Total score		Retention score		Stability score		DIL		HL		DIL		HL	
	DIL	HL	DIL	HL	DIL	HL	mean (±s.d.)	adjusted β (95% CI)	mean (±s.d.)	Adjusted beta (95% CI)	median (Q1, Q3)	IRR (95% CI)	median (Q1, Q3)	aIRR (95% CI)
Baseline	2 (2,3)	2 (2,3)	1 (1,2)	1 (1,2)	1 (1,1)	1 (1,1)	3.56 (±1.32)	0 (ref)	3.11 (±1.04)	0 (ref)	15.0 (5.0, 25.0)	1 (ref)	10.7 (7.0, 15.0)	1 (ref)
Immediately after relining	4 (4,5)	4 (4,5)	2 (2,3)	2 (2,3)	2 (2,2)	2 (2,2)	NM	NM	NM	NM	NM	NM	NM	NM
3 days	3 (3,4)	4 (4,4)	2 (1,2)	2 (2,2)	2 (2,2)	2 (2,2)	2.98 (±0.83)	-0.64 (-1.11, -0.18)*	3.02 (±1.01)	-0.12 (-0.70, 0.46)	2.5 (1.0, 7.5)	0.29 (0.15, 0.54)**	1.7 (0.0, 5.0)	0.32 (0.18, 0.57)**
7 days	3 (2,3)	4 (4,4)	1 (1,2)	2 (2,2)	2 (1,2)	2 (2,2)	3.20 (±0.90)	-0.41 (-0.88, 0.06)	2.75 (±0.90)	-0.36 (-0.92, 0.21)	2.5 (1.5, 4.0)	0.20 (0.10, 0.38)**	0.5 (0.0, 5.0)	0.18 (0.10, 0.34)**
1 month	2 (2,3)	4 (3,4)	1 (1,2)	2 (1,2)	1 (1,2)	2 (2,2)	3.20 (±1.08)	-0.39 (-0.83, 0.06)	2.52 (±0.54)	-0.59 (-1.12, -0.06)*	2.5 (0.5, 9.5)	0.33 (0.17, 0.62)*	0.5 (0.0, 1.5)	0.10 (0.05, 0.20)**
3 months	2 (2,3)	4 (3,4)	1 (1,2)	2 (1,2)	1 (1,2)	2 (2,2)	3.08 (±0.97)	-0.52 (-0.92,-0.11)*	2.13 (±0.51)	-0.98 (-1.53, -0.42)*	7.5 (1.5, 13.0)	0.45 (0.24, 0.84)*	0.5 (0.0, 1.5)	0.10 (0.05, 0.19)**
6 months	2 (2,3)	4 (3,4)	1 (1,2)	2 (1,2)	1 (1,1)	2 (2,2)	2.71 (±0.84)	-0.95 (-1.45, -0.44)**	2.35 (±0.66)	-0.80 (-1.34, -0.25)**	2.5 (1.5, 9.0)	0.32 (0.17, 0.62)*	0.0 (0.0, 1.0)	0.03 (0.01, 0.08)**

NM, not mentioned.

3.4. Changes in reported oral impacts and main problems

The percentage of participants with an oral impact is illustrated in **Table 4**. At baseline, all participants had at least one oral impact, with all participants reporting eating problems. The major problems were an ill-fitting LCD, food impaction underneath the denture, and pain from the denture. Three days after denture relining, the prevalence of oral impact significantly decreased due to improved denture fit. However, denture pain emerged in both groups beginning at 7 days. In the HL group, individual patients' complaints relating to an ill-fitting denture remained stable over time, and their complaints about denture pain continuously decreased. In contrast, in the DIL group, denture pain occurred on and off for 6 months, and the number of participants with ill-fitting dentures significantly increased at 1 month. After 6 months, ill-fitting dentures were reported in 60% and 20% of the DIL and HL groups, respectively.

3.5. Clinical properties of the materials

Changes in the material properties are listed in **Table 5**. After mixing, the DIL was pink, resilient, and non-adjustable. The DIL became hard and adjustable after 7 days. At 1 month, the DIL color partly changed from pink to white, was completely hard, had visible porosities, and was slightly detached peeled off around the denture border. At 3 months, the DIL was white-opaque with a perceivable odor, detaching material was visible at the denture border, and in the detached areas, plaque accumulated slightly. At 6 months, the DIL was yellow-white with visibly detached material and plaque accumulation in the affected areas. In contrast, the HL was hard and adjustable immediately after mixing. Its properties remained stable for over six months, at which time the material was slightly detached, mostly at the denture border.

4. Discussion

To our knowledge, this is the first RCT study to compare DIL and HL on denture retention and stability, masticatory function, and the OHRQoL of the patients who wear CD. Our findings revealed that DIL and HL application increased denture retention and stability of the LCD, with a slightly higher score in the HL group. Masticatory performance in the DIL group significantly improved at 3 days, with the highest performance at 6 months. In contrast, the HL group significantly improved at 1 month, with the highest performance at 3 months. Applying a denture liner significantly improved the participants' OHRQoL by reducing the frequency and severity of the oral impacts. However, at 6 months, oral impacts were still present in 80–100% of the participants in the DIL group and 40% in the HL group. Based on these results, the null hypothesis was rejected.

The retention and stability scores of the LCD on day 3 were slightly lower than those of the HL group. This may be due to the different compositions and setting processes of the two materials. The main components of DIL are polyethyl methacrylate, plasticizer, and ethyl alcohol[20]. As a result, continuous leaching of the plasticizer and alcohol from the DIL, together with water absorption and solubility, could result in dimensional changes to the material[19]. Thus, DIL could become less adapted to the underlying tissue over time. Similar to that of PEMA-based soft lining materials, DIL formation likely consists of a dual process of polymer chain entanglement by non-crosslinked polymers, which is temporary but makes the material resilient, and a crosslinked polymer that allows the material to harden over the long term. In contrast, the conventional hard den-

Table 4. Percentage of participants who reported oral impacts and the main problems.

Denture liner types	Time points	Reported oral impacts: %	Main problems: %		
			Ill-fit denture	Food impact	Pain from denture
DIL (n=15)	**Baseline**	100.0	86.7	53.3	26.7
	3 d	80.0*	40.0	13.3	40.0
	7 d	93.3	40.0	26.7	46.7
	1 m	80.0*	60.0	33.3	13.3
	3 m	93.3	60.0	30.0	53.3
	6 m	100.0	60.0	50.0	6.7
HL (n=10)	**Baseline**	100.0	90.0	40.0	30.0
	3 d	60.0*	30.0	20.0	60.0
	7 d	50.0*	30.0	20.0	30.0
	1 m	40.0*	30.0	20.0	10.0
	3 m	40.0*	30.0	20.0	20.0
	6 m	40.0*	20.0	20.0	0.0

Significant reduction from baseline at *P < 0.05.

Table 5. Median (Q1, Q3) of the material properties.

Properties	Baseline	7 d	1 m	3 m	6 m
DIL					
Physical integrity	4 (4,4)	3 (3, 4)	2 (2, 3)	2 (2, 2)	2 (2, 2)
Surface texture	3 (3, 4)	3 (2, 3)	2 (2, 3)	2 (2, 2)	2 (2, 2)
Adhesion to denture base	4 (4,4)	4 (4,4)	3 (3, 4)	2 (2, 3)	2 (2, 2)
Color stability	4 (4,4)	3 (3, 4)	3 (2, 3)	2 (1, 2)	2 (1, 2)
Odor	4 (4,4)	4 (4,4)	3 (3, 4)	2 (2, 3)	2 (2, 2)
Plaque accumulation	4 (4,4)	4 (4,4)	4 (3, 4)	3 (2, 3)	2 (2, 2)
Hygiene	4 (4,4)	4 (4,4)	4 (3, 4)	3 (2, 3)	3 (2, 3)
Resilience	Present	Declined	Absence	Absence	Absence
Fungal colonization	Absence	Absence	Absence	Absence	Absence
HL					
Physical integrity	4 (4,4)	4 (4,4)	4 (4,4)	4 (4,4)	3 (3, 4)
Surface texture	3 (3, 4)	3 (3, 4)	3 (3, 4)	3 (3, 4)	3 (2, 3)
Adhesion to denture base	4 (4,4)	4 (4,4)	4 (4,4)	4 (4,4)	3 (3, 4)
Color stability	4 (4,4)	4 (4,4)	4 (4,4)	4 (4,4)	3 (3, 4)
Odor	4 (4,4)	4 (4,4)	4 (4,4)	4 (4,4)	3 (3, 4)
Plaque accumulation	4 (4,4)	4 (4,4)	4 (4,4)	4 (4,4)	3 (3, 4)
Hygiene	4 (4,4)	4 (4,4)	4 (4,4)	3 (3, 4)	3 (3, 4)
Resilience	Absence	Absence	Absence	Absence	Absence
Fungal colonization	Absence	Absence	Absence	Absence	Absence

4=excellent, 3=good, 2=fair, 1=poor.

ture lining material contains a benzoyl peroxide initiator that functions in HL autopolymerization, allowing the material to become hard promptly after mixing. Therefore, HL may possess greater dimensional stability and tissue adaptability, leading to greater retention and stability than DIL.

After DIL application, masticatory performance significantly increased but returned to baseline within 1 month. The initial masticatory function improvement could be due to a markedly improved denture fit. Therefore, the patients were able to better control their dentures. After 1 week, dimensional instability and unstable occlusal balance caused by alcohol and plasticizer leaching may have decreased masticatory performance[11]. As found in previous studies on the patients who wear CD[17,29], viscoelastic resilient denture liners showed the lowest masticatory improvements, followed by the elastic silicone denture liners. The hard acrylic dentures demonstrated the least deformation. Masticatory performance in the DIL group improved at 3 months, possibly because of the relative dimensional stability of the material and the patient's adaptation to mastication while wearing the denture after final denture adjustments[30]. In contrast, HL gradually improved masticatory performance because its hardness and dimensional stability after mixing allow for denture adjustment immediately. Therefore, the patients who were CD continuously adjust to their CD and achieve their greatest masticatory performance 3 months sooner compared with patients in the DIL group.

The OIDP score results indicated that DIL and HL application significantly improved the OHRQoL of the patients who wear CD from baseline to 6 months. These results are consistent with those of previous studies on the patients who wear CD, whose LCD was relined with silicone, and their OHRQoL was determined using the OHIP-EDENT[13,14]. In the DIL group, a slight oral impact caused by denture pain persisted during the first week due to localized hardening of the material. At 3 days, pain occurred from the knife-edge material portion that extended into tissue folds or tissue irregularities on the residual ridge. At 7 days, pain occurred from the material portion that extended into the tissue undercut areas. The tissue fitting surface of the denture was clinically adjusted by an investigator (T.P.) when the participants complained of pain from their dentures. At 1 month, an adverse oral impact that was unrelated to denture pain emerged. This was due to the denture being ill-fitting as a result of a dimensional change in the material plasticizers and alcohol have leached over time. Denture pain reoccurred at 3 months because the overall material hardened[19]. After denture adjustments, pain was rarely reported at 6 months. In contrast, HL immediately hardens and is adjustable at the time of application. Thus, denture pain was noticed immediately and corrected during the lining visit. To summarize, DIL caused pain during its dimensional change and hardening, and over time, the denture became dimensionally stable but ill-fitting. In contrast, HL caused pain that was relieved by adjusting the denture immediately. The dentures lined with HL were less likely to become ill-fitting due to dimensional stability over time compared those lined with DIL. Considering the reported oral impacts, DIL use as a tissue conditioner and functional impression material may be limited to seven days. Furthermore, its function as a hard denture liner begins at three months.

After DIL application, the patient-reported negative oral impact due to an ill-fitting denture increased from 3 days to 6 months. However, the Kapur score for LCD retention and stability remained unchanged. These results imply that the objective assessment of denture retention and stability may be less sensitive to changes than subjective patient-reported outcomes. An ill-fitting denture was reported at 1 month because the patients felt that their denture was less adapted to the underlying tissue. However, the fit was better than that at baseline. Although both DIL and HL reduced the frequency and severity of negative oral impact, they did not completely eliminate these problems. For patients with persistent complaints of an ill-fitting denture and food impaction underneath the denture, fabrication of a new denture or implant-retained overdenture should be considered[31].

Although the DIL improved the patient's masticatory function and OHRQoL for up to 6 months, its service life may be limited by changes in the material's properties. At 3 months, DIL demonstrated visible detachment especially at the denture border, surface roughness and porosity, perceivable odor, and color change. Instead of being a long-term hard denture liner, the DIL can be used as a tissue conditioning material, functional impression material, or resilient denture liner with a limited service life of approximately 1 month. When a longer service life of up to 6 months is desired, HL improved denture retention and stability, masticatory function, and the OHRQoL. Despite being soft for 1 week, the DIL required more frequent denture adjustments than the HL due to the denture pain that occurred while the material hardened. A DIL or HL may not reduce the number of dental visits. However, they improve the retention and stability of an existing denture and should be considered as an interim option while fabricating new dentures.

The present RCT confirmed that there is a cause-effect relationship between the type of denture lining materials and the outcomes. The outcomes were measured repeatedly to identify the appropriate service life for each denture liner. However, this study had some limitations. Confounding factors associated with denture retention and stability, such as viscosity and the patients' saliva flow rate, were not considered. In addition, some material properties, such as the dimensional change and bond strength of the denture liner to the acrylic-based denture were not evaluated. The efficacy of the DIL was not compared with that of conventional long-term resilient denture liners, such as silicone and conventional plasticized acrylic resin. Thus, an in vitro study investigating physical and antimicrobial properties of DIL should be performed to verify these clinical findings. Future studies that investigate the clinical performance of DIL compared with that of other conventional soft denture lining materials are warranted.

5. Conclusion

Based on our results, we conclude that DIL improves denture retention and stability, masticatory performance, and the OHRQoL of the patients who wear CD. However, the adverse oral impact persisted in patients who received DIL, mainly due to denture pain and an ill-fitting denture. Clinical changes in the DIL properties were visible at 3 months, whereas the HL texture remained relatively stable for up to 6 months.

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Conflict of interest statement

There are no conflicts of interest to declare.

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