Compliance of Resilient Denture Liners Immersed in Effervescent Denture Cleansers

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Purpose: **Six resilient denture liners (RDL) were exposed to two immersion effervescent denture cleansers to evaluate change in compliance over a simulated 1 year time interval.**

Materials and Methods: **Ten samples of each material, Molloplast B, Mollosil, MPDS-SL, Permasoft, Softline, and Sofreliner were exposed to either Fixodent or Efferdent denture cleanser. A cyclic load was applied in a squarewave fashion to derive a load displacement curve to measure compliance at 0, 7, 30, 180, and 360 simulated days.**

Results: **All 12 of the material/cleanser combinations demonstrated a significant change in compliance at each time interval relative to baseline. Mollosil had the greatest increase in flexibility from baseline, and MPDS-SL had the smallest increase in flexibility. In general, chairside materials demonstrated greater change in compliance from baseline compared to laboratory materials. Materials subjected to Fixodent cleanser, when averaged over time, were significantly more flexible than materials exposed to Efferdent cleanser.**

Conclusions: **Exposure of resilient soft liners to two common cleansers resulted in a significant increase in flexibility. This change in flexibility depended slightly, though significantly, on the type of cleanser, and appeared to be more significant with time. In general, chairside materials seemed to change more than laboratory-processed liners. The exception was Permasoft that was fabricated as a laboratory material but behaved like a chairside material.**

Clinical Significance: **The initiator of the polymerization reaction rather than the mode of polymerization may be more important in predicting a change in the flexibility of RDLs. Constituents within the oral environment may be more responsible for changes in RDL flexibility than denture cleansers.**

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INDEX WORDS: resilient denture liner, denture cleanser, immersion effervescent denture cleanser, compliance, modulus of elasticity, viscoelasticity, flexibility

ENORMOUS challenges arise in restoring patients with long-standing edentulism. While the percentage of edentulous patients in the population is decreasing, the total number of edentulous patients will increase slightly from 33.6 million to 37.9 million in 2020 as the overall population increases.[1]

Patients present with advanced alveolar bone loss leading to sharp bony undercuts or extreme sensitivity due to submucosal exposure of the inferior alveolar nerve. Compromised alveolar support,[1-4] whether congenital or acquired, increases the technical difficulty in construction as well as the subsequent use of a removable prosthesis. When a denture is made and still does not meet the needs of a patient due to morphological or physical issues, a resilient denture liner (RDL) may be an effective solution.[5-11]

Commonly used RDLs are typically either acrylic or silicone based. Generally, silicones demonstrate greater resistance to change in physical properties when exposed to solid or liquid chemical components and are more elastic. A drawback of silicone materials is their greater propensity for bond failure between the RDL

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and the acrylic denture base. Acrylic materials demonstrate greater abrasion resistance and bond strength, but lose elasticity and dimensional stability as the plasticizing agent leaches from the RDL.[3,12-16]

Some investigators theorize that a laboratory-processed RDL exhibits more complete polymerization than a chairside RDL, providing increased resistance to solubility in oral fluids and improved physical and mechanical properties.[17,18] Laboratory studies in which acrylic-based soft denture lining materials are immersed in distilled water, artificial saliva, or denture cleansers show a smaller reduction in flexibility compared with clinical studies that are characterized by a more rapid and pronounced reduction in compliance.[6-10]

The defining characteristic of RDLs is their modulus of elasticity. Compliance, defined as the reciprocal of the modulus of elasticity, could also be referred to as flexibility.[4] This definition of compliance does not completely account for the viscoelastic nature of the material. The rebound of the material should coincide with the release of the applied force.

Compliance is the strain of an elastic body expressed as a function of force producing the strain, describing the softness or flexibility of a material and its ability to recover its shape as easily as it is deformed.[19,20] Pesun et al[21] describe the inverse relationship predicting the reduced compliance of an RDL with use; the greater the baseline compliance value, the greater the reduction in compliance. The reduced compliance in both clinical and laboratory testing of acrylic-based liners is presumed to relate to a loss of ethanol and plasticizers.[4,22-27]

The assumption has been that clinical success of an RDL material relies on the ability of the liner to recover its shape and readapt to the ridge after the initial application of a load in a time-dependent manner.[4-11,28] Tan et al,[29] Dootz et al,[30] and Davenport et al[31] found increased flexibility of the silicone-based laboratory-processed material Molloplast B when it was immersed in water. Water may increase flexibility most in the first 30 days of exposure to an aqueous environment. Passerini and Craig[32] showed that residual water on polylactide microspheres acts as a plasticizing agent based on the decrease measured in glass transition temperature.

Parker et al[33] demonstrated the relationship between osmotic potential and water uptake of soft lining materials. Water uptake that occurred in all three materials tested, was reduced measurably when the materials were exposed to either 0.45 M or 0.9 M saline solutions. Waters et al[34,35] described an association between the silica filler used in silicone RDLs and water absorption, but they were unable to demonstrate significant differences in absorption when the proportion of silica filler was altered.

Evaluating an RDL's ability to change shape clinically over time requires nondestructive tests. If RDL materials are to viscoelastically dampen the load placed on the mucosal tissues, then tests must account for the dynamic nature of these tissues and of the stresses placed on them. Nondestructive tests can be performed on viscoelastic materials by applying and releasing force at a specific rate to measure the displacement and rebound of the material with time.[36,37]

The rate at which the force is applied and released is based on the average dentate human chewing cycle. While reduced masticatory efficiency is expected with complete denture prostheses, Hayakawa et al[38] reported that after relining a mandibular complete denture prosthesis with an RDL, chewing strokes were reduced by one-fourth ($p = 0.020$), and chewing time was reduced by one-third ($p = 0.010$). The average time interval between initiation and termination of a single masticatory cycle was measured at 835 milliseconds for males and 973 milliseconds for females.[39] A cyclic load with force applied for 0.5 second followed by a release of force maintaining only a small amount of pressure for 0.5 second would then be reasonable to simulate functional use by complete denture wearers.

The purpose of this study was to measure the compliance of resilient soft relining materials using cyclic loading and unloading to determine the effect of multiple cleaning procedures.

Materials and Methods

The sample thickness was standardized for all six materials using four 1.1 mm thick sheets of pink base plate wax, which were invested in type III gypsum with flasks used for denture processing. Twenty samples (25 mm × 25 mm × 4.4 mm) of each material were constructed. Molloplast B, MPDS-SL, and Permasoft were processed under heat with pressure applied to the denture flasks to simulate laboratory processing. Mollosil, Softline, and Tokuyama's Sofreliner were processed at room temperature with pressure

Table 1. Resilient Denture Lining Materials

Processed Under Heat and Pressure (Laboratory)

MPDS-SL: Lai Labs, 12101 16th Ave. S, Burnsville, MN 55337. Experimental material dispensed in a gel state and polymerized under heat and pressure in a laboratory.

Molloplast B: Buffalo Dental Manufacturing Company, 99 Lafayette Dr., Syosset, NY 11791. Provided premixed in a jar of predetermined weight. The material is polymerized under heat and pressure in a laboratory setting. Considered the "gold standard" for comparing RDL materials.

Permasoft® Soft Denture Liner, Austenal, Inc., 4101 W 51st St. Chicago, IL 60632. The powder consists of polyethylmethacrylate and the liquid consists of dibutyl phthalate, ethyl acetate, and ethyl alcohol. The ratio of powder to liquid can be manipulated by the operator from 2:1 to 3:1 (2.5:1 used in current study) depending on the desired softness of the liner. The powder and liquid are hand mixed. The manufacturer provides instructions for polymerization of the RDL in either a chairside or laboratory manner.

Processed in the Absence of Heat and Pressure (Chairside)

Mollosil® Plus (soft relining material—cold curing), Detax, GmbH & Co. KG, Postfach 10 02 25 D-76256 Ettlingen, Germany. The manufacturer does not provide specifics as to the contents of its RDL. The silicone material is dispensed with an auto-mix cartridge with a working time of 1.5 minutes, and a setting time of 6.5 minutes (includes the working time).

Softline ™ Chairside Silicone Soft Relining Material, Microselect, 6665 Amador Plaza Rd. Dublin, CA 94568. The lining material consists of a mixture of polydimethyl, polymethyl, vinyl siloxane, polydimethyl, polymethyl, hydrogen siloxane, silica. The specifics for the primer are not provided. The material is dispensed in an auto-mix cartridge with a working time of 1 minute and a setting time of 4 minutes.

Sofreliner MS (medium soft silicone based soft denture liner), Tokuyama America, Inc., 1875 S Grant St., Ste 570, San Mateo, CA 94402. The lining material consists of polyorganosiloxane (66%), silicone resin powder (28%), and silicone dioxide (6%). The primer consists of methylene chloride (99.5%) and polymethylmethacrylate with polyorganosiloxane (0.5%). The material is dispensed with an auto-mix cartridge with a working time of 1–1.5 minutes, and a setting time of 5 minutes. The manufacturer provides instructions for polymerization of the RDL in either a chairside or laboratory manner.

applied to the denture flasks maintaining equivalent thickness to simulate a chairside polymerization (Table 1).

Tests measuring compliance for resilient materials have been standardized in the Minnesota Dental Research Center for Biomaterials and Biomechanics (MDRCBB).[21,40] The closed loop servo-hydraulic testing system (MTS Systems, Eden Prairie, MN) was calibrated by lifting the metal table into contact with the steel ball. The servo-hydraulic actuator was programmed to produce a squarewave, in which the load of 3 lbs was applied for 0.5 second and released for 0.5 second (Fig 1).

The squarewave compliance-testing device was designed to evaluate the dynamic, viscoelastic nature of RDLs in a laboratory setting[21] and in a clinical setting.[40] A servo-hydraulic actuator subjects the RDL sample to cyclic loading and unloading in 0.5-second intervals to simulate masticatory movements (Fig 1). Each sample was randomly assigned for exposure to a specific denture cleanser for the duration of the study. Ten samples of each material were selected prior to the start of the study to be exposed to either Fixodent (Procter & Gamble Co., Mason, OH) or Efferdent (Warner-Lambert Co., Morris Plains, NJ) denture cleanser.

At baseline (i.e., before immersion in cleaning materials) compliance testing was completed as described by Pesun et al.[21] Each sample was measured three times at each of three locations marked on the sample for repeated measurement throughout the study (Fig 2). All samples were subjected to five squarewave cycles prior to recording data, to minimize variation between measurements (Fig 3).

Data were recorded by a Nicolet 310 Storage Oscilloscope (Nicolet Instrument Corporation, Madison,

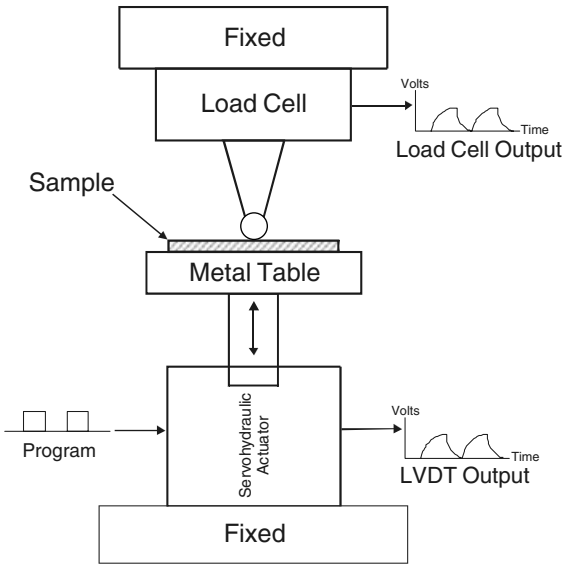

Figure 1. Schematic of MDRCBB's closed-loop servo-hydraulic testing device used to test for compliance.

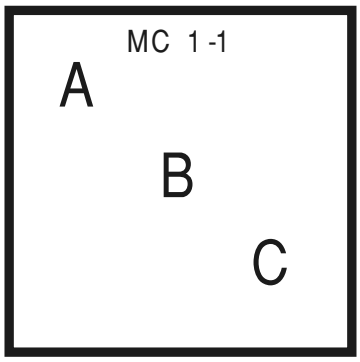

Figure 2. Representation of compliance measurement positions on individual samples.

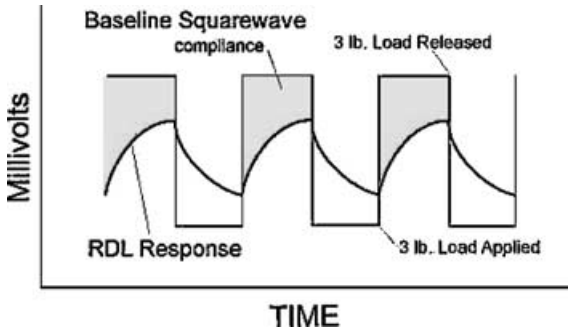

Figure 4. Representation of squarewave with response of RDL superimposed.

WI), specifically, a curve plotting load versus time was created. The data for each sample were related to the data obtained through squarewave testing of the metal table without a sample present. The area between the two curves was computed by subtracting the curve obtained with the RDL from the baseline squarewave using DASH 300 (data acquisition) software (Fig 4). The resulting value is the compliance.

Once compliance was measured on the untreated baseline samples, each RDL sample was exposed to an immersion effervescent denture cleaning agent (Table 2) for simulated 1-week, 1-month, 6-months, and 1-year intervals, where the simulated time interval was based on the time required for the chemical reaction of the denture cleanser to run to completion. Each specimen was immersed in a denture cleaning agent for 15-minute cycles as recommended by the manufacturer.

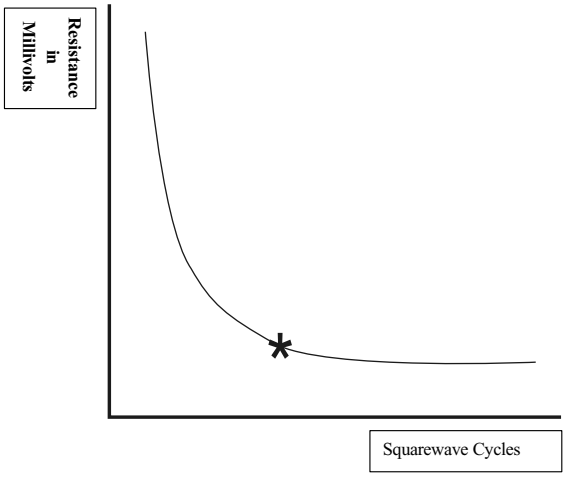

Figure 3. Representation of the starting point for collection of data after the completion of the five initial squarewave cycles.

Compliance was measured upon the completion of each simulated time period.

Cleaning tablets were placed into 50°C distilled water.[41] Exposure to the immersion effervescent denture cleansers was controlled to allow all surfaces of the sample to be in contact with the cleanser. A Fixodent® (Procter & Gamble, Cincinnati, OH) denture bath and an acrylic sample positioner were used to ensure (Fig 5) consistent concentration of denture cleanser in contact with the RDL samples. Acrylic was chosen for the sample positioner due to its compatibility with denture cleaning agents.

Materials were compared at baseline using a mixed linear model analyzed using the MIXED procedure in SAS version 6.12, and summarized as an analysis of variance (ANOVA). Variance components were estimated using the restricted likelihood method. The independent variable was the RDL material, and the dependent variable was the compliance measurement at baseline. The components of variation, or random effects, were variation between batches of the same material, variation between the samples made from a batch, variation between locations of the measurement within a sample, and variation between replicate measurements at a location.

Measurements taken after immersion were analyzed using sample and location change relative to baseline measurements. The focus of the analysis was to compare the change in compliance of the six materials, to compare the specific cleansers according to the change in compliance relative to baseline, and to trace the path of change over time relative to baseline. A mixed linear model using unbalanced repeated measures ANOVA was analyzed in JMP version 3.1. The independent variables were the individual RDL, the cleanser, time, and their interactions. The dependent variable was change in RE from baseline averaged over the replicate measurements.

Significant differences were defined as those having $p \leq 0.05$ in the ANOVA calculations. Post hoc tests used

Table 2. Immersion Effervescent Denture Cleansers

Efferdent Warner-Lambert Co., 182 Tabor Road, Morris Plains, NJ
Ingredients provided by the manufacturer include sodium bicarbonate, potassium monopersulfate compound, EDTA, sodium perborate monohydrate, sodium sulfate, polytetrafluoroethylene anhydrous, sodium lauryl sulfoacetate, sodium saccharin powder, and a flavor blend synthetic.
Fixodent Denture Cleanser with Proguard The Procter & Gamble Company, 8700 Mason Montgomery Road, Mason, OH 45040
Ingredients listed from the Material Safety Data Sheet (MSDS): sodium perborate monohydrate, potassium monopersulfate, tetraacetyl ethylene diamine, with the remaining ingredients considered common denture cleaner excipients.

the relevant error terms from the ANOVA to compute standard errors. For each specific effect, the threshold of significance for post hoc tests was Bonferronized according to the number of pairwise comparisons made (e.g., with materials and 15 pairwise comparisons, therefore, the Bonferronized threshold was $0.05/15 = 0.0033$).

For an alpha (type I error rate) of 5%, the sample size of 10 per group, or 60 samples tested in each cleaning solution, provided 95% power to detect differences among the six groups in the following two patterns: in pattern A, five groups have an equal mean compliance and the other group has a compliance difference of at least 17 compliance units; in pattern B, the six groups fall into two clusters of three groups each with equal compliance values within each cluster, and the difference between the two clusters is at least 13 compliance units.

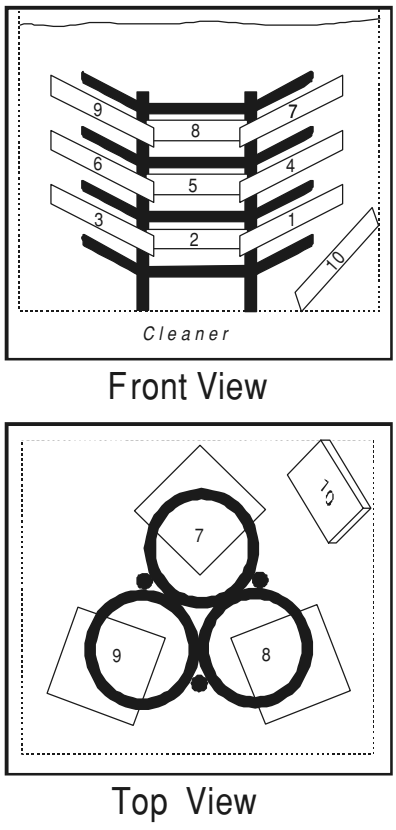

Figure 5. Schematic of sample positioning device.

Results

Analysis of compliance change from baseline found significant differences between materials averaged over times (material main effect; $p < 0.0001$). Average change in compliance of Mollosil was significantly greater ($p = 0.0004$) than all other materials, while the average change in compliance of MPDS was significantly less ($p = 0.005$) than all other materials. Molloplast B, Softline, and Tokuyama showed no significant differences, and the difference between Permasoft and Tokuyama was not significant. Comparing changes from baseline at each time point (averaged over material and cleansers), each time point is significantly different from all others (time main effect; $p < 0.0003$) (Fig 6).

The cleanser main effect averaging over materials and time intervals approaches significance ($p = 0.05$); however, the two-way interaction of cleansers and time after baseline (averaging over materials) was highly significant ($p = 0.0001$). In particular, the adjusted mean change in compliance for Efferdent is lower than for Fixodent except at the 30-day interval (Fig 7).

Materials processed in a laboratory manner differed from the materials processed at room temperature ($p = 0.003$). The average compliance change for chairside materials was greater than the average compliance change for laboratory materials by a difference of 15.7 (standard error: 1.83). The change for Permasoft, however, is not consistent with the changes recorded for Molloplast B or MPDS-SL. Grouping the materials

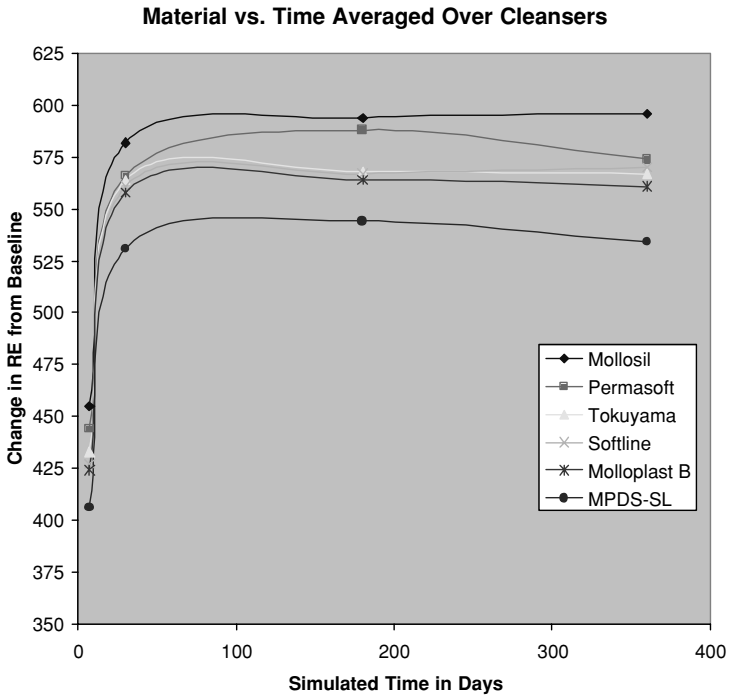

Figure 6. The change from baseline in compliance for the materials versus time averaged over cleansers.

according to the process by which the polymerization reaction is initiated, either by heat or chemical, shows a more profound difference (Table 3). The average compliance change for chemically polymerized materials was greater than the average compliance change for materials polymerized with heat by a difference of 25.5 (standard error: 1.9) increasing the significance to $p < 0.0001$.

Discussion

The purpose of a resilient denture liner is to dampen and distribute occlusal loads in function. The material must compress when a load is applied and recover when it is released, and must maintain the desired resiliency over time. The MDRCBB's closed loop servo-hydraulic squarewave testing device was used to mimic the cyclic application and release of load that takes place during mastication. All six materials, independent of cleanser, demonstrated increased flexibility or decreased compliance as time passed.

The increase in the RDL's flexibility in this study is considerably greater than was found in a concurrent clinical study.[40] The average change in compliance from baseline in this study was 570 at 6 simulated months (180 days), whereas the average change in compliance from baseline during the clinical trial was 360 at 6 months of exposure to the oral environment and cleaning regimen. The difference in measured change in compliance is due to the use of an RDL sample unsupported by an acrylic denture base.

Isolating the effect of a denture cleanser on an independent RDL sample will increase the measured change in compliance in the following two ways:

1. Increasing the surface area exposed to the cleaning solution, causing increased flexibility due to the uptake of water as six sides are exposed rather than one or two surfaces for an RDL attached to an acrylic denture base, and
2. Bending the edges of the sample in a direction opposite the downward force of the squarewave compliance testing device's stylus.

Parr and Rueggeberg[42] compared the physical properties of Permasoft processed in either a laboratory manner or a chairside manner. The conclusion was that the mode of polymerization did not influence the physical properties of Permasoft

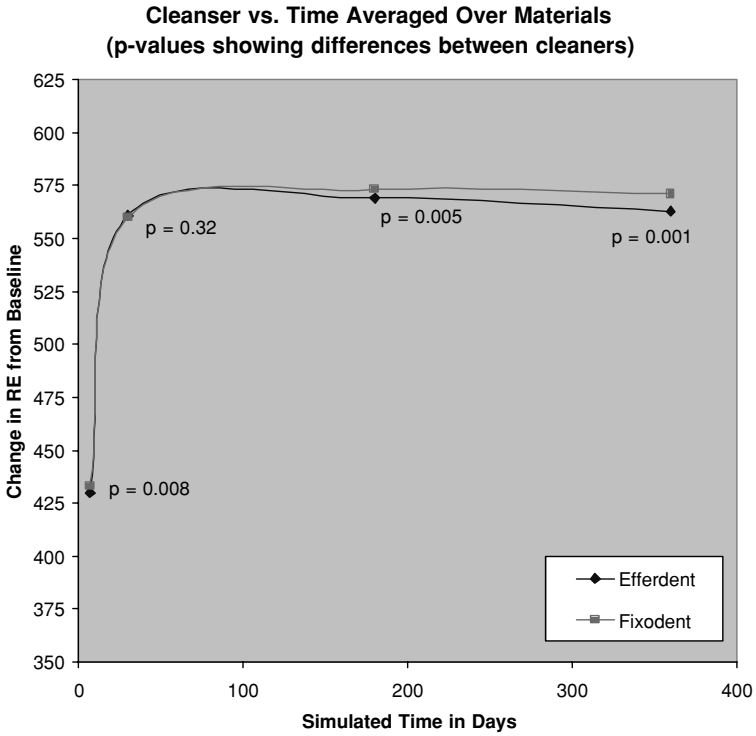

Figure 7. The change from baseline in compliance of the average of materials in cleansers versus time.

and that the plasticizing effect of water could explain the insignificant difference resulting from the mode of polymerization.

The goal of the current study was to measure the change in compliance relative to the baseline measurements. Because it is not possible to use an immersion effervescent denture cleanser without water, emphasis was placed on standardizing the potential osmotic effect of the colloidal solution containing the denture cleanser. Future research should measure the change in compliance related directly to exposure of the RDL to distilled water only.

Permasoft and Tokuyama's Sofreliner each came with manufacturer's instructions for processing in either a chairside or a laboratory manner. Both materials, although processed differently, demonstrated changes in compliance similar to the other chairside materials tested. Thus, the initial stages of the initiator and accelerator of the polymerization reaction may provide a more relevant distinction in classifying RDLs.

Increased polymerization of a laboratory-processed RDL is thought to provide increased resistance to solubility in oral fluids and improved physical and mechanical properties.[17,18] The decreased polymerization of an RDL processed in a chairside manner may be advantageous in allowing more space for water uptake. The result of greater water uptake is an increased plasticizing

Table 3. Chairside Materials Versus Laboratory Materials

Outcome	*Average Lab-Average Chair*	*Standard Error*	*p-Value*
Compliance	-15.7* (-25.5)*	1.83 (1.9)	0.003 (<0.001)

In each column above, the first number represents the value obtained with Molloplast B, MPDS-SL, and Permasoft considered to be laboratory materials, and Mollosil, Softliner, and Tokuyama's Sofreliner as chairside materials. The second number, in parentheses, represents the change in value after switching Permasoft from the laboratory materials to the chairside materials.
*Negative number indicates that the value for the chairside material is greater than the value for the laboratory material. A positive number would indicate that the value for the chairside material is less than the value for the laboratory material.

action and, therefore, increased flexibility when exposed to denture cleansers and oral fluids.

The difference between the two denture cleansers changed significantly with time after baseline (i.e., the cleanser-by-time interaction was significant); however, the differences between cleansers were small and are likely to be clinically irrelevant. Given their basic similarity in formulation, the only difference between the two cleansers that could arise would be related to the Proguard Sealer. The Proguard sealer contains tetraacetyl ethylene diamine to minimize the adherence of foreign materials to a removable prosthesis. The inhibition of bacterial or, more importantly, fungal infection would contribute greatly to the potential for long-term clinical use of a resilient denture liner.

Within the constraints of a laboratory study, Mollosil exposed to the Fixodent denture cleanser demonstrated the greatest change in compliance. Materials processed in a chairside manner immersed in Fixodent with Proguard demonstrated a greater change in compliance. The questions that remain are: How much flexibility is desirable in a soft denture liner? Is it better if a material is able to recover quickly, or is it better to be softer? These questions must be addressed in future clinical studies.

Conclusions

1. Exposure of resilient soft denture liners to two common cleansers resulted in a significant decrease in compliance (increase in flexibility). Mollosil had the greatest change in flexibility, and MPDS-SL had the smallest change in flexibility.

2. The greatest change in compliance relative to baseline occurred within the first 7 simulated days, followed by a large change in 30 simulated days, then demonstrating minimal change thereafter.

3. Materials exposed to Fixodent with Proguard demonstrated decreased compliance (increased flexibility) at every time interval except 30 days, relative to materials exposed to Efferdent.

4. The initiator of the polymerization reaction predicted resilient denture liners behavior better than the descriptors chairside versus laboratory processed.

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