The Influence of Water Storage on Durometer Hardness of 5 Soft Denture Liners Over Time

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Purpose: This laboratory study investigated the influence of water storage on the durometer hardness of 2 RTV and 3 HTV soft denture liners over a 1-year period.

Materials and Methods: Five soft denture liners were used: 2 HTV silicone rubber (Luci-Sof™ and Molloplast-B®), 1 RTV silicone rubber (Tokuyama), 1 HTV polyphosphazene (Novus™), and an RTV plasticized acrylic (PermaSoft®) that uses a surface sealer. They were processed following manufacturers' instructions, cured, and stored in tap water at 37°C. The water was changed every 2 weeks. Five durometer A hardness measurements were made at logarithmically spaced intervals of 16.7 minutes, 27.8 hours, 11.6 days, 34.7 days, 115 days, and 347 days. Repeated measures analysis of variance (MANOVA), one-way analysis of variance (ANOVA), Pillai trace statistic, the difference scores (last–first) among the groups, and the Tamhane T2 multiple comparison test were used to compare the groups over time, all on SPSS V. 7.5 and 9.0.

Results: The order of highest initial indentation hardness was Luci-Sof™, Molloplast-B®, Novus™ ($H_D = 38$ to 33). Tokuyama and PermaSoft® as a group were softer ($H_D = 18$ to 22). Tokuyama Soft Relining changed the least over 347 days, followed by Luci-Sof™, Novus™, Molloplast-B®, and PermaSoft® in that order ($p \leq 0.05$). Within the PermaSoft® group, sealer applied only once changed the least over 347 days, followed by no sealer, and then sealer applied every month ($p < 0.0005$).

Conclusions: After 347 days of water storage, Tokuyama had the lowest indentation hardness changes, followed by Luci-Sof™, Novus™, PermaSoft® with sealer applied once; Molloplast-B®, PermaSoft® without sealer; and PermaSoft® with sealer applied every month. All HTV soft denture liners had higher indentation hardness than RTV liners initially. After 347 days, PermaSoft® without sealer and with sealer every month became the hardest.

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SOFT DENTURE liners have been advocated for denture patients, because these liners may distribute occlusal forces more evenly and may allow undercuts to be engaged.[1-10] In patients presenting with missing posterior teeth or patients with maxillary defects resulting in oral-antral communication, the use of a soft liner may assist in retention while preventing force concentration on the residual anatomic structures.[4-7,11-15] Likewise, resilient liners have been advocated in overdenture therapy as a means of damping the forces of

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mastication.[16-20] Soft liners are made of materials from several chemical families. These materials undergo chemical changes over time as patients immerse their dentures in either the aqueous environment of the mouth or, when not in use, in tap water or denture cleanser. Hardening of the material is one of the major reasons for failure of some soft liners. Other complications include bonding failure, abrasion resistance, fouling by *Candida albicans*, odor, and change in color.[21]

Soft denture liners have been used for more than a century in dentistry.[22] There are 3 major groups: methyl/ethyl methacrylate,[23] silicone rubber,[24] and other materials such as polyphosphazene fluoroelastomers.[24] During the past decade, several new products have been commercially released. These products appear to have favorable initial properties, claim to maintain original softness, and promise longer usefulness. Parr and Rueggeberg[25,26] describe physical properties including durometer A hardness of materials immersed in water for 1 year. There are no studies that compare all of the new products with previously tested materials. The purpose of this laboratory study was to investigate the influence of water storage on the durometer hardness of 5 new soft liners over a study period of 12 months.

Materials and Methods

Five soft denture liners (2 HTV silicone rubber (Luci-Sof™ and Molloplast-B®), 1 RTV silicone rubber (Tokuyama), 1 HTV polyphosphazene (Novus™), and an RTV plasticized acrylic (PermaSoft®) that uses a surface sealer) were investigated in this study (Table 1). The materials were processed according to the manufacturers' instructions. Processing was accomplished in a denture flask against a flat gypsum surface, producing blocks of rubber 11 mm thick and 38 mm wide, dimensions that conform to the ASTM specifications.[27]

The manufacturer of PermaSoft® recommends the application of a sealer made of polyvinyl chloride/polyvinyl acetate copolymer dissolved in methyl ethyl ketone. In this study, for comparative purposes, PermaSoft® was tested (1) without using the sealer, (2) with 2 coats of sealer initially followed by air drying for 2 minutes, and (3) with 2 coats of sealer applied once per month for 11 months.

Specimens of all materials were immersed in a thermostatically controlled water bath at 37 ± 1°C. The tap water was changed every 2 weeks. Specimens were tested immediately after cleaning under flowing water and at intervals described below. A Shore A-2 Durometer (Shore Instrument & Mfg. Co., Inc., Jamaica, NY) with a hardened, spring-loaded steel rod centered 6 mm from the edge of the foot, was used with an external mass of 1 kg. The instrument was calibrated using the Shore 71430 Test Block Kit. Sites on the specimens in this study were separated by at least 3 mm to prevent overlapping indentations. Five hardness readings were made within 5 seconds of loading and this test was repeated at logarithmically spaced intervals of 10^3, 10^5, 10^6, 3×10^6, 10^7, and 3×10^7 seconds (16.7 minutes, 27.8 hours, 11.6 days, 34.7 days, 115 days, and 347 days, respectively).

Table 1. Materials Used

Soft Denture Liner Material	*Type of Soft Denture Liner & Curing Conditions*	*Manufacturer*	*Batch No.*
Luci-Sof™	Heat-cured silicone rubber (100°C, 2.5 hours, bench cool 15 minutes, cool water immersion 15 minutes)	Dentsply International (York, PA)	90455
Molloplast-B®	Heat-cured silicone rubber (100°C, 2 hours, slow cool immersed)	Detax GmbH & Co. (Ettlingen, Germany)	970530
Novus®	Heat-cured polyphosphazene rubber (74°C, 2 hours, 100°C, 0.5 hour)	The Hygenic Corp. (Akron, OH)	09993B
Tokuyama soft relining	Autopolymerized silicone rubber	Tokuyama American, Inc. (San Mateo, CA)	6645Y6
PermaSoft®	Plasticized acrylic (65°C water bath, 10 minutes)	Austenal, Inc. (Chicago, IL)	07014 (box) 815003 (powder) 097002 (liquid) 097004 (sealer)

Repeated measures analysis of variance (MANOVA) was used to compare the groups over time. The Pillai trace statistic was used because of its robustness. One-way analysis of variance (ANOVA) was used to compare the difference scores (last–first) among the groups. The hardness values at the last time period were also compared by ANOVA[28] and the Tamhane T2 multiple comparison test, all on SPSS V. 7.5 and 9.0 (SPSS Inc., Chicago, IL).

Results

The values of durometer hardness are plotted in Figure 1 for all 7 materials at the 6 time periods. The values varied from less than 20 to more than 40 on the 0–100 durometer hardness scale. MANOVA of all materials at all time periods demonstrated that the hardness of the materials changed significantly over time ($p < 0.0005$). Graphic analysis showed that all materials increased in hardness for the first 3 time periods, but differed in ensuing periods. PermaSoft® was the softest of the materials initially.

The order of highest initial indentation hardness was Luci-Sof™, Molloplast-B®, Novus™ ($H_D = 38$ to 33). Tokuyama and PermaSoft® as a group were softer ($H_D = 18$ to 22). Tokuyama Soft Relining changed the least over 347 days, followed by Luci-Sof™, Novus™, Molloplast-B®, and PermaSoft® in that order ($p \leq 0.05$). Within the PermaSoft® group, sealer applied only once changed the least over 347 days, followed by no sealer, and then sealer applied every month ($p < 0.0005$).

Univariate ANOVA demonstrated that overall changes in hardness from 16.7 minutes to 347 days differed significantly among the materials ($p < 0.0005$) (Table 2). *Post hoc* analysis (Tukey's HSD) revealed that PermaSoft® with sealant applied every month demonstrated the greatest change (+20) ($p < 0.0005$), while Tokuyama (+0.9) ($p > 0.05$) and Luci-Sof™ (−1.8) ($p > 0.05$) changed the least.

The variation demonstrated at 347 days was statistically significant ($p < 0.0005$), with the 3 PermaSoft® samples exhibiting the greatest variability (SD = 4.16). Because of the equal sample size in each group, it was determined that the ANOVA test was appropriate. *Post hoc* tests, using the Tamhane T2 method where variances differ, showed that Tokuyama and PermaSoft® with sealant applied once were significantly softer at 347 days than Luci-Sof® and PermaSoft® with sealant applied every month ($p \leq 0.05$) (Table 3).

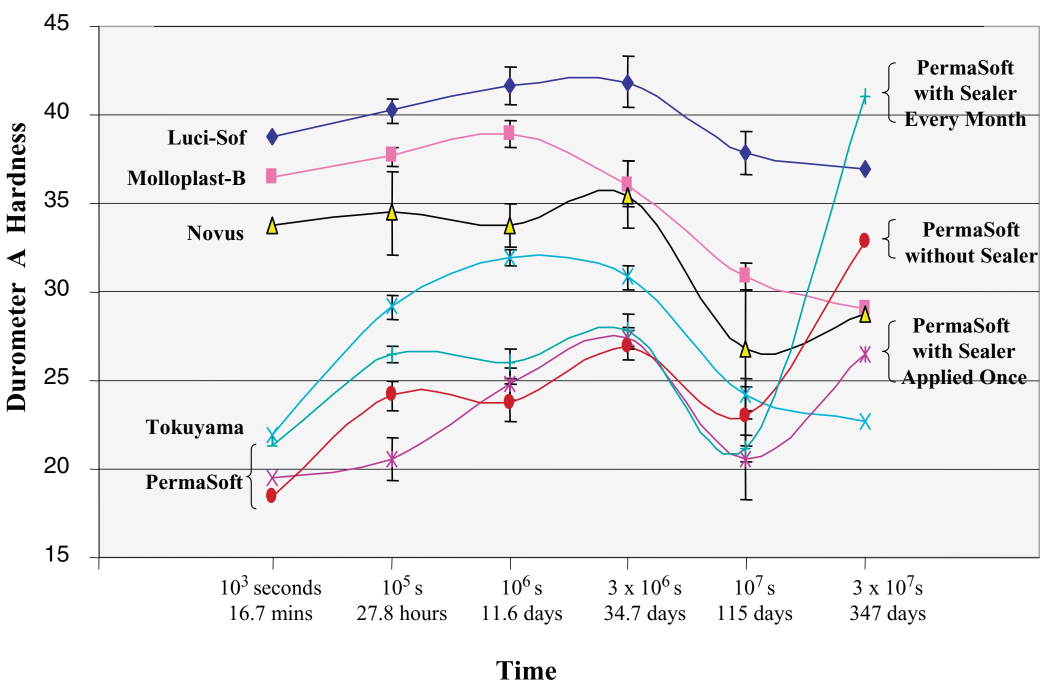

Figure 1. Durometer A hardness of soft denture lining materials over time (up to 347 days). Bars are standard deviations (n = 5).

Table 2. Differential Hardness From the First to the Last Time Periods

Material	*Differential Hardness (From First to Last Time Period)*
Molloplast-B®	−7.5 (1.2)
Novus™	−5.1 (2.2)
Luci-Sof™	−1.8 (1.9)
Tokuyama soft relining	+0.9 (0.82)
PermaSoft®	
with sealer applied once	+7.0 (2.9)*
with sealer applied every month	+20.0 (2.6)*
without sealer	+14.6 (3.8)*

*$p < 0.0005$ (standard deviation).
|Indicates no significant difference $p \leq 0.05$.

Discussion

Tokuyama soft relining is an RTV and, while initially softer, hardened considerably by 34.7 days. This was likely due to continued polymerization of the elastomer. The material softened during the remainder of the test period, approaching the initial hardness by the end of the study period. The likely explanation for this is water sorption or plasticization. All 3 HTV materials in this study (Luci-Sof™, Molloplast-B®, and Novus™) had higher initial indentation hardness values. These materials behaved similarly to Tokuyama, starting softer, hardening by 34.7 days, and then becoming softer during the remainder of the test period.

Parr and Rueggeberg[25] tested physical properties including durometer A hardness of 2 silicone-based denture liners, Tokuyama and Luci-Sof™ after 1 day, 1 week, 1 month, 6 months, and 1 year of water storage at 37°C. They, too, found that Luci-Sof™ was harder than Tokuyama at all intervals, but both materials did not soften after 1 year as they did in the present study. Different conditions prevailed, however. The present study was not a closed system, with tap water changed every 2 weeks (to simulate the patient's immersion of dentures in tap water overnight). Parr and Rueggeberg used distilled water, apparently without replacing it, for the entire period.

Changes in hardness for PermaSoft® with sealer applied once, applied every month, or with no sealer applied, may have been affected by 4 mechanisms: (1) continued polymerization of the acrylic, (2) loss of plasticizer,[17,29-34] (3) water sorption,[29-32,34] and/or (4) the buildup of 11 double coats of sealer on the surface. Regardless, all PermaSoft® specimens hardened significantly ($p < 0.0005$) by 347 days. It should be noted that the test conditions used did not subject the specimens to the same abrasion, wear, or cyclic loading experienced in the mouth, so survival of the coating in the clinical situation may be different than in this *in vitro* study.

In another study by Parr and Rueggeberg[26] for both groups of PermaSoft® with sealer applied once and stored in water, indentation hardness values increased significantly at all intervals. For both wet groups of Permasoft® with sealer applied once, indentation hardness values increased significantly at all intervals. These results were consistent with the present study.

Table 3. Mean Durometer Hardness After 347 Days (3×10^7 Seconds) in Water

Material	*Durometer Hardness at 347 Days*
PermaSoft® with sealer every month	41.20
Luci-Sof™	36.95
PermaSoft® without sealer	32.90
Molloplast-B®	29.10
Novus™	28.70
PermaSoft® with sealer applied once	26.40
Tokuyama soft relining	22.70

|Indicates no significant difference $p \leq 0.05$.

Jepson et al[35] found that the acrylic-based soft liner (Palasiv 62) displayed significant reductions in compliance values after 120 weeks, whereas the silicone rubber material (Molloplast-B®) did not. Kazanji and Watkinson[36] studied silicone (Molloplast-B®) and plasticized acrylic materials (Softic 49, Coe Super-Soft, Coe Soft, and Flexibase) stored in water for 6 months and found that Molloplast-B® became softer while Coe Super-Soft became harder. Jepson et al found that laboratory immersion yielded consistent but slower changes compared to the clinical situation.

Most *in vitro* research studies test for changes up to a 1-year period. The average service time of a soft liner is 1–2 years. Extension beyond 1 year should be considered. Test conditions used for *in vitro* studies do not subject the materials to the aqueous environment, microorganisms, abrasion, temperature cycling, material thickness, and cyclic loading. The properties of soft denture liners in the clinical situation still differ from laboratory testing. Future research in a well-controlled clinical trial will be fruitful.

Conclusions

After 347 days of water storage, the indentaton hardness of Tokuyama changed the least, followed by Luci-Sof™, Novus™, PermaSoft® with sealer applied once; Molloplast-B®, PermaSoft® without sealer; and PermaSoft® with sealer applied every month. All HTV soft denture liners had higher indentation hardness than RTV liners initially. PermaSoft®, a plasticized acrylic, was the softest of the group initially but became harder between 115 and 347 days. This hardening was more pronounced when no sealer or multiple layers of sealer were applied.

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