

In Vitro Changes in Hardness of Sealed Resilient Lining Materials on Immersion in Various Fluids

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Abstract

Purpose: During clinical use, resilient lining materials undergo changes in hardness that make them ineffective. The aims of this investigation were (1) to determine the effect of a resilient lining sealer on the hardness of four resilient denture liners; and (2) to determine the effect of the sealer on hardness after immersion in various solutions.

Materials and Methods: Two sets of specimens of four resilient liners, Coe-comfort (CC), PermaSoft (PS), Tokuyama soft reline (TK), and Total-Soft (TS), 6-mm diameter by 4-mm thickness, were fabricated. Two coats of Permaseal, a soft reline sealant, were applied to one set of specimens of each material according to manufacturers' instructions. Sealed and unsealed samples were divided into four groups ($n = 10$). Each group was immersed in one of the following solutions: artificial saliva at 37°C, Efferdent, Efferdent with once daily scrubbing with a soft toothbrush, and 50% ethanol. Shore A hardness numbers were obtained at 0, 1, 3, 7, 30, and 90 days. A two-way ANOVA test was performed using materials (treated and untreated) and immersion solution as independent variables. The percentage change in hardness after the 90-day immersion period was the dependent variable.

Results: The results show that the application of sealant significantly improved the durability of CC, PS, and TS in immersion solutions by maintaining hardness close to preimmersion values or delaying the softening effect of the solutions. The hardness of sealed and unsealed TK showed the significantly ($p < 0.05$) lowest change after immersion in the test solutions. Ethanol caused the most severe decrease in hardness of all solutions, followed by saliva. Immersion in Efferdent and daily brushing after immersion in Efferdent showed only a mild effect on the hardness of the soft reline agents.

Conclusion: The use of a sealer can play an important role in the preservation of the hardness of some resilient lining materials.

Resilient lining materials are used for obtaining a uniform distribution of stress at the denture/tissue interface¹ and to improve the retention of the denture.² There is clear evidence that many patients prefer soft relined dentures and that the resilient lining materials are associated with improvement in comfort and masticatory effectiveness.³ Disadvantages of chairside resilient lining materials are that they harden prematurely, discolor, and tend to pick up odors and plaque over time.¹⁻³ Resilient lining materials deteriorate by water uptake and leaching

of plasticizers.² These processes can lead to hardening or softening depending upon the formulation of the material.⁴ During clinical use, resilient lining materials are exposed to different chemicals present in a patient's diet. Changes in viscoelasticity and other physical properties of resilient lining materials occur on immersion in various solutions that have been used in an attempt to simulate intraoral conditions.⁵ The composition of storage media is known to influence changes in viscoelasticity of denture base materials over time.^{6,7}

A denture reline sealer, Permaseal (Austenal, Inc. Chicago, IL), has been recommended for use by the manufacturer of one resilient lining material, PermaSoft (PS) (Austenal, Inc.), for preserving its physical properties. A recent clinical study⁸ has reported that application of Permaseal prevented changes in hardness of PS over a 4-week period. Change in hardness over time has been used by several investigators⁹⁻¹¹ as a measure of preservation of the viscoelasticity of resilient lining materials.

The objective of this study was to determine the effectiveness of a soft denture sealing material, Permaseal, in preserving the hardness (prevent hardening/softening) of soft reline materials. These objectives were achieved by (1) determining the effect of Permaseal on the hardness of four resilient denture liners; and (2) determining the effect of Permaseal on hardness after immersion in three solutions (saliva, Efferdent, ethanol). The combined effect of daily brushing and immersion was also investigated. The three immersion liquids were selected because (1) saliva is in constant contact with the resilient lining materials in the oral cavity; and (2) the routine use of immersion denture cleaners such as Efferdent is recommended as an effective way to minimize plaque accumulation and reduce candidiasis;^{8,12-14} (3) the combined effects of brushing and immersion in denture cleansing agent is also a recommended method of cleaning, and brushing is thought to damage the lining material;^{12,13} and (4) alcohol is consumed routinely by many patients.¹⁵ One study has shown that resilient lining materials deteriorate faster clinically than in immersion studies in which artificial saliva and distilled water were used.⁵ This suggests that other chemical agents with more severe effects may play a role in the deterioration of resilient lining materials *in vivo*.

Materials and methods

The resilient lining materials investigated were Coe-comfort (CC), PS, Tokuyama soft reline (TK), and Total-Soft (TS). The resilient lining materials and their manufacturers are listed in Table 1. In the first experiment, samples of each material (6 mm diameter by 4 mm thickness) were fabricated in a custom-made poly(vinyl siloxane) mold and divided into two groups of ten samples. Two liberal coats of the soft denture liner sealer Permaseal were applied to one group of specimens, according to manufacturers' instructions. Samples were stored at 37°C and 100% relative humidity. Twenty-four hours after fabrication, Durometer hardness measurements were made of sealed and unsealed samples using Shore A hardness instrument (Model # 104640, Shore Instrument and Mfg. Co., Inc., New York, NY).

To determine the effect of immersion in experimental solutions, two groups of specimens of each material (sealed and unsealed), were fabricated as described above. One group each of sealed and unsealed specimens were divided into four subgroups, and each subgroup ($n = 10$) was subjected to one of four treatment regimens: immersion in artificial saliva (Oralube, Perth, Australia), immersion in Efferdent (Pfizer Co., Morris Plains, NJ), immersion in Efferdent with daily scrubbing with a soft toothbrush (Oral B, Iowa City, IA), and immersion in 50% ethanol (Fisher Scientific, Fair Lawn, NJ). The saliva solution was maintained at 37°C and the other solutions were maintained

Table 1 Materials and their manufacturers

Material	Treatment	Manufacturer
Coe-comfort	Untreated	GC America, Inc., Chicago, IL
Coe-comfort	Sealed	GC America, Inc.
PermaSoft	Untreated	Austenal, Inc., Chicago, IL
PermaSoft	Sealed	Austenal, Inc.
Tokuyama soft reline	Untreated	Tokuyama Corp., Tokyo, Japan
Tokuyama soft reline	Sealed	Tokuyama Corp.
Total-soft	Untreated	Stratford Cookson Co., Westbury, NY
Total-soft	Sealed	Stratford Cookson Co.,

at room temperature. Durometer hardness measurements were made using a Shore A hardness instrument. Shore hardness values were obtained from ten samples for each material/solution condition before immersion (control), at 1, 3, 7, 30, and 90 days. These time points were selected to demonstrate both short- and long-term changes in hardness. Statistical analysis of the Shore A hardness numbers was carried out using statistical software (JMP Software Rel. 5.1, SAS Institute, Inc., Cary, NC). A two-way ANOVA test was performed using treated and untreated materials and immersion solution as independent variables. The percentage change in hardness after the 90-day immersion period was the dependent variable.

Results

Effect of sealer on hardness of resilient lining materials

Shore A hardness measurements of the sealed and unsealed soft lining materials before immersion are listed in Table 2. Of the materials investigated, CC reline material had the lowest hardness number ($p < 0.05$). This material also showed a significant increase ($p < 0.05$) in hardness upon application of sealer. The hardness measurements of PS and Tokuyama did not differ significantly from each other. Sealing of these materials appeared to have no effect on the Shore hardness. TS had a significantly higher Shore A hardness ($p < 0.05$) than all

Table 2 Shore A hardness of permanent soft lining materials

Soft lining material	Shore a hardness before sealing	Shore a hardness after sealing
Coe-comfort (CC)	11.2 (2.6)*	17.1 (2.9)*
Permasoft (PS)	29.3 (4.6)†	29.7 (3.5)‡
Tokuyama soft reline (TK)	26.9 (3.3)†	28.7 (2.7)‡
Total-Soft (TS)	40.0 (7.7)	41.7 (9.8)

Standard deviations are in parenthesis.

*Materials with a statistically significant difference in hardness before and after sealing ($p < 0.05$).

†Materials with no statistically significant difference in hardness between unsealed materials ($p < 0.05$).

‡Materials with no statistically significant difference in hardness between sealed materials ($p < 0.05$).

the other resilient lining materials investigated. Application of sealant did not significantly alter its hardness.

Effect of sealer on hardness after immersion in various test solutions

The results show that application of the sealant significantly improved the durability of CC, PS, and TS in saliva and Efferdent by maintaining hardness values close to preimmersion values. The hardness of sealed and unsealed TK showed the significantly ($p < 0.05$) lowest change after immersion in the test solutions. Ethanol showed the most severe effect on hardness of all solutions, followed by saliva. Immersion in Efferdent and daily brushing after immersion in Efferdent showed only a mild effect on the hardness of the soft reline agents. The interaction of material and solution also showed a highly significant effect ($p < 0.0001$).

Changes in hardness caused by immersion in the test solutions are graphically depicted in Figures 1-8. When immersed in saliva, unsealed CC showed rapid softening of close to 50% in 3 days, and the final decrease in hardness was close to 40% (Fig 1). Sealing resulted in a 20% decrease in hardness after day 1, followed by hardening; the final hardness of sealed CC is close to the preimmersion hardness (Fig 2). Unsealed PS and TS showed minor changes in hardness 24 hours after immersion and then recovered to values close to preimmersion hardness. The sealed PS and TS behaved in a manner similar to their respective unsealed materials. For TK, the unsealed material gained about 13% to 15% hardness in saliva, while the sealed material showed an initial softening followed by stabilization at 4% softer than before immersion. In Efferdent (Figs 3 and 4), unsealed CC showed an initial hardening of 14% followed by a

slight softening; the final hardness was close to preimmersion hardness. Sealing resulted in an increase in hardness throughout the immersion period. The final hardness value was close to the preimmersion hardness. Sealing resulted in a final increase in hardness of 18%. Unsealed PS gained approximately 30% hardness after day 1, then softened to about 10% higher hardness than the preimmersion hardness. Sealed PS showed little change after 24 hours, but the hardness at the end of immersion was similar to unsealed samples. TK sealed and unsealed showed little change in hardness throughout the immersion period. The unsealed TS material gained hardness throughout the immersion period to about 55% increase after immersion. Sealed TS softened initially, and then gradually hardened to values 10% less than its initial hardness.

Daily brushing after immersion in Efferdent (Figs 5 and 6) changed the behavior of TS considerably. The increase in hardness seen for unsealed TS (Fig 4) was not observed when brushing was applied. Unsealed CC, TK, and TS showed slight hardening effect, while unsealed PS had little change on immersion. For sealed materials, the initial increase in hardness was higher, but the hardness after 90 days was similar to values before immersion.

Immersion in ethanol (Figs 7 and 8) produced a severe softening of the unsealed CC, PS, and TS, with the Shore A hardness of all three decreasing to zero after 7 days. With sealing, the deterioration was more gradual; CC showed a 17% decrease in hardness after 7 days, and complete softening was observed at 30 days. Softening of PS and TS was also more gradual; zero hardness was reached after 80 days of immersion. Unsealed TK hardened to values approximately 10% higher than the initial hardness while sealed TK remained relatively unchanged.

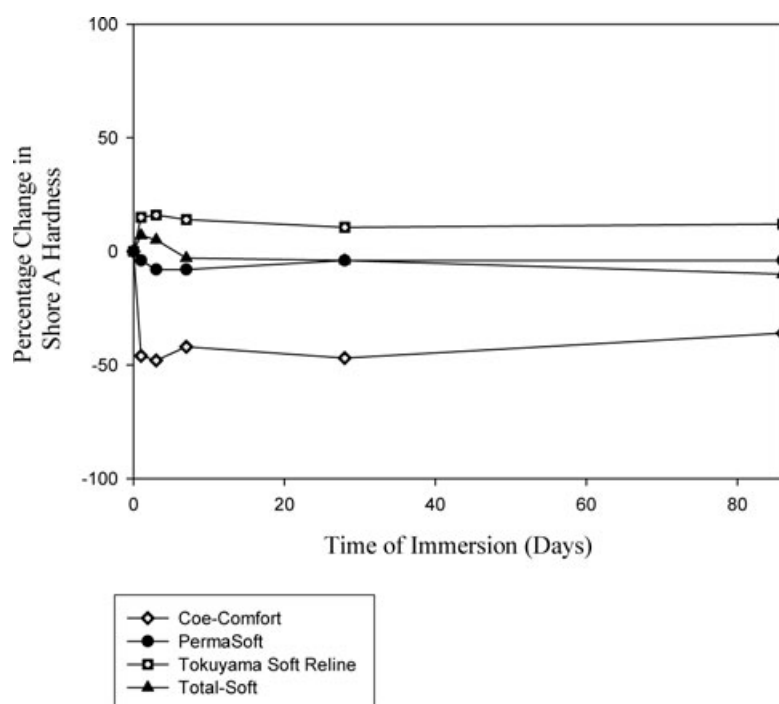


Figure 1 Percentage change in hardness of unsealed soft reline materials on immersion in saliva.

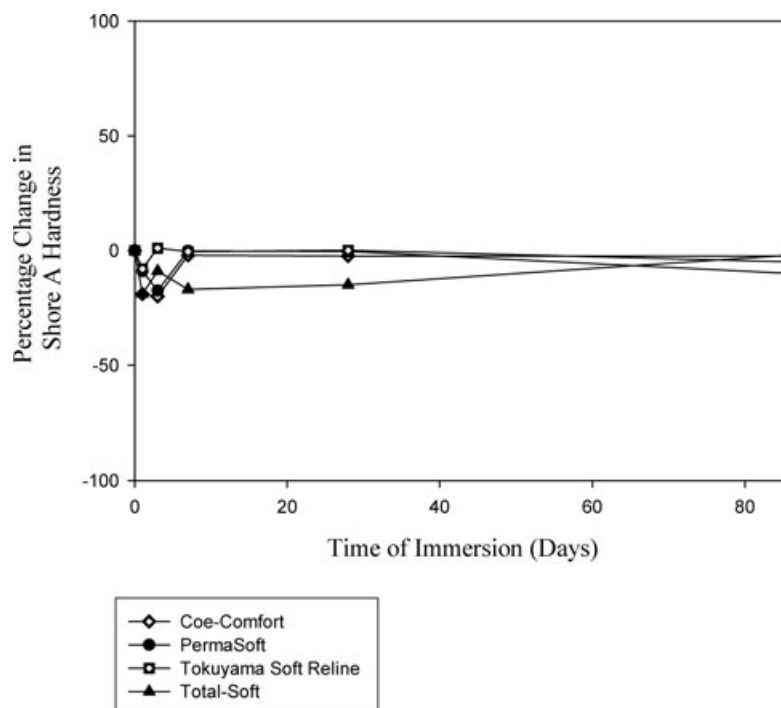


Figure 2 Percentage change in hardness of sealed soft reline materials on immersion in saliva.

Discussion

Shore A hardness of the resilient denture relining materials investigated vary significantly. The hardness of CC was significantly lower and of TS was significantly higher than all other materials tested. PS and TK were not significantly different

from each other in hardness. The effect on hardness of sealing the resilient lining material also varies among test materials. There was a significant increase in hardness of CC on sealing, while the other materials showed only modest increases in hardness upon sealing. These differences in hardness and response to sealing are due to differences in composition of the relining

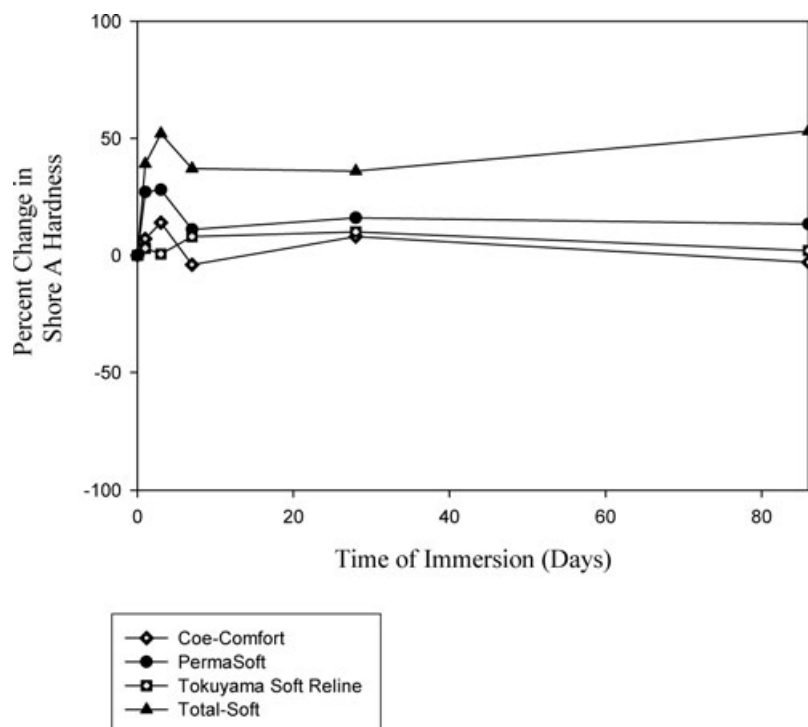


Figure 3 Percentage change in hardness of unsealed soft relining materials on immersion in Effident.

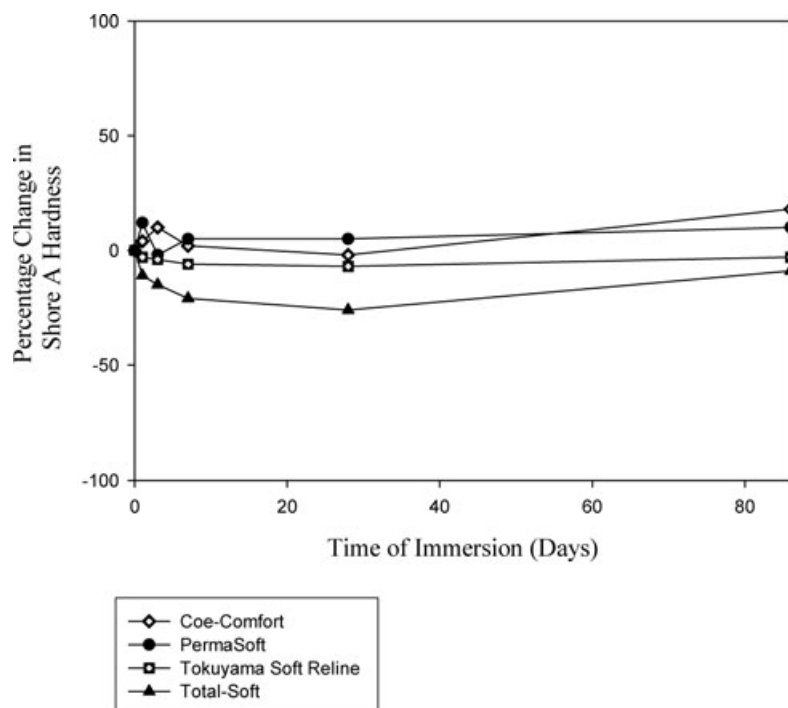


Figure 4 Percentage change in hardness of sealed soft reline materials on immersion in Effident.

materials. Although CC, PS, and TS are based on methacrylate polymers, there are wide differences in the type and content of plasticizer. TK is a room temperature vulcanizing (RTV) silicone rubber-based material.¹⁶ These differences in composition would be expected to lead to differences in response to sealing with Permaseal.

Upon immersion in artificial saliva, the net change in hardness of unsealed materials over the period under observation ranged from 0% to 40%. CC showed a significant decrease in hardness, PS showed a zero net change in hardness, and the other materials showed minor increases in hardness. Sealing of the resilient lining materials eliminated the softening effect

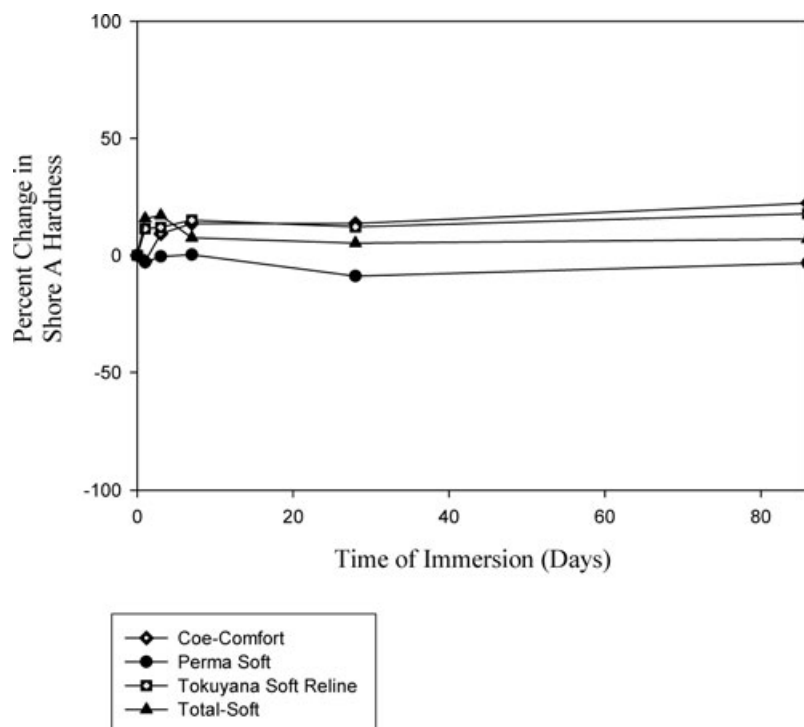


Figure 5 Percentage change in hardness of unsealed soft reline materials on immersion in Effident with brushing.

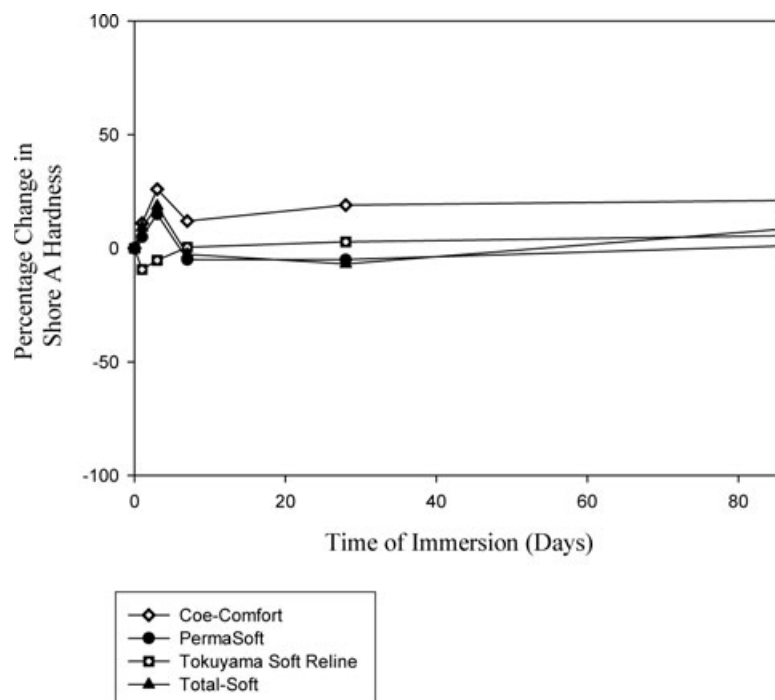


Figure 6 Percentage change in hardness of sealed soft reline materials on immersion in effident with brushing.

of saliva for CC. All unsealed materials hardened on immersion in Effident within 3 days of immersion. Immersion of unsealed materials in ethanol produced the greatest softening effect on three of the materials and a slight increase in TK. The severe effect of ethanol on the hardness of reline materials is in agreement with other studies.¹⁵ This suggests that patients'

alcohol consumption may lead to a more rapid deterioration of the resilient lining materials. It is presumed that any change in hardness of the reline material is undesirable, because the sealant is placed to preserve the properties of the materials.

Immersion in chemical cleansers like Effident is the recommended method of cleaning resilient lining materials.^{12,13}

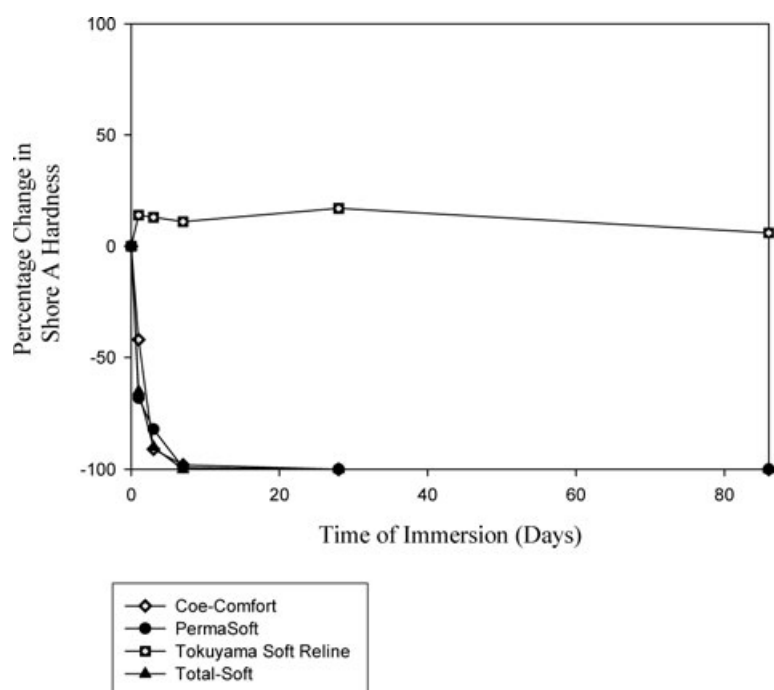


Figure 7 Percentage change in hardness of unsealed soft reline materials on immersion in ethanol.

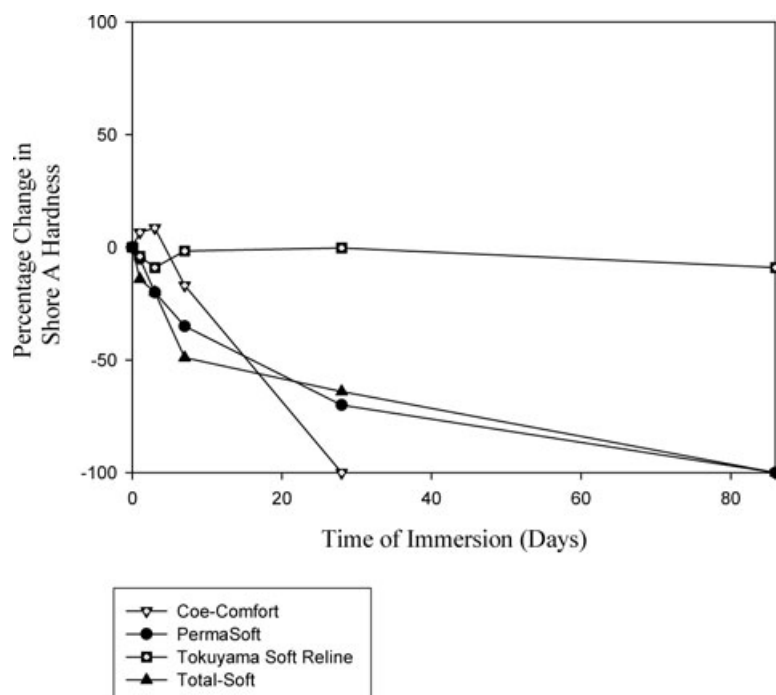


Figure 8 Percentage change in hardness of sealed soft reline materials on immersion in ethanol.

Unsealed reline materials hardened to different degrees in Efferdent. For TS, the hardness after the immersion period was significantly higher ($p < 0.05$) than before immersion. Specimens that were brushed daily did not show this hardening effect, except CC.

Acrylic-based denture reline materials are known to degrade over time by water uptake and leaching out of plasticizers, which are usually low molecular weight esters such as dibutylphthalate.¹⁷ An increase or decrease in hardness may be observed depending on the formulation of the material^{4,7} and the duration of immersion. Thus, in clinical use, over time, denture reline materials may undergo a change in physical properties resulting in an alteration in hardness, viscoelasticity, and resiliency. Changes in hardness makes resilient liners less effective in providing the “cushioning effect” necessary for relieving inflammation and trauma of the underlying denture bearing area.^{4,18} Changes in hardness due to leaching out of plasticizers can be eliminated by incorporating forms of methacrylate such as n-butyl and ethyl methacrylate, which copolymerize into a more plastic mass but do not leach out.¹⁶ It is possible that the methacrylate-based materials that show smaller changes in hardness have some of the higher methacrylates functioning as plasticizers.

Sealing of the resilient lining materials was effective in reducing changes in hardness. All materials showed smaller net changes in hardness upon immersion in artificial saliva and Efferdent upon sealing, compared to the unsealed state. On immersion in alcohol, sealing slowed the rate of softening of CC, TS, and PS. TK, which showed zero net change in hardness in the unsealed state, remained unchanged by sealing. The three other resilient lining materials in this study (CC, PS, TS) are methyl methacrylate-based, and contain dibutyl phthalate, which can leach out with use, resulting in softening. It should

be noted that CC is a tissue conditioner, and is intended for use for shorter periods than the other materials. Although it is methacrylate-based like PS and TS, it would be expected to contain higher quantities of plasticizer.

The results of the present study show that sealing of the resilient material may be effective in preserving the hardness during use. Sealing may therefore be beneficial in prolonging the usefulness of resilient lining material. The sealant used, Permaseal, is composed of vinyl polymer in methyl ethyl ketone.¹⁹ It is expected that on application of the sealant, the organic solvent evaporates, leaving behind a surface layer of reduced permeability that is more resistant to the degradation of the polymer that occurs in the presence of saliva and ethanol.

This *in vitro* investigation provides information on the changes in hardness that occur upon immersion of sealed and unsealed resilient lining materials in different solutions. In clinical use, the materials may undergo additional changes in hardness that may be caused by temperature fluctuations in the oral cavity, as well as pH changes. Reports in the literature indicate that resilient lining materials deteriorate faster clinically than in immersion studies in which artificial saliva and distilled water were used.^{3,4}

A soft reline sealant is provided by only one of the resilient liner manufacturers investigated in this study; however, all the materials except TK showed some improvement in maintaining their hardness upon sealing. TK is effective in the unsealed state in minimizing changes in hardness with use.

Conclusions

The application of a denture soft reline seal significantly increased the Shore A hardness of CC, but did not alter the hardness of other materials investigated.

Application of the soft reline sealer reduced the softening effect of saliva on the methacrylate-based soft reline materials. Unsealed reline materials used in the study all gained in hardness on immersion in Efferdent, a denture cleansing agent. Daily brushing of the soft reline material reduced this hardening effect. Immersion of all the soft reline materials in ethanol resulted in severe progressive softening, which was reduced or delayed by application of the sealant. The silicone-based reline material showed the lowest overall change in hardness in the test solutions.

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