Tokuyama Dental Corporation

Durable soft reline material

“Sofreliner Tough Soft”

Technical Report

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1. Introduction

Tokuyama Dental has developed proprietary technology for bonding acrylic resin and silicone at room temperature. Tokuyama Dental sells three types of silicone-based soft denture reline products that incorporate this technology; Sofreliner Soft, Sofreliner Medium Soft, and Sofreliner Tough. All three offer simple relining and are ideal for use in both direct and indirect techniques.. Each has its own unique clinical characteristics and has won high regard for denture treatment in an aging society.

In 2003, Tokuyama Dental released Sofreliner Tough, characterized by its high durability, with a Shore A hardness of 45. However, our aging society faces increasing challenges, with difficult denture treatment cases growing ever more common. Clinicians have demanded a product that provides even greater softness and durability.

In response, Tokuyama Dental developed a material with the world's leading tear strength of products having similar softness for this application. This revolutionary development led to the birth in November 2010, of Sofreliner Tough Soft.

This report discusses the technical background, features, and properties of this product.

2. Product description

2.1 Configuration

Paste

- α, ω-divinyl polydimethylsiloxane
- Dimethyl hydrogen polysiloxane
- Silicon dioxide
- Platinum catalyst

Primer

- Ethyl acetate
- Adhesive polymer

Polisher

- Form Correction Coarse Point (Black)
- Finishing Wheel (Brown)

2.2 Color

Pink, 1 color

2.3 Indicated cases

In cases like the ones below, Sofreliner Tough Soft minimizes pain (by providing cushioning and pressure distribution), improves suction, stabilizes the denture, and maintains the ability to chew. It is also ideal for use as a temporary reline and for mucosal tissue conditioning.

- Cases involving thin submucosal tissue having poor elasticity
- Case involving extremely deformable mucosa
- Cases involving sharp edges in the alveolar bone (alveolar elevation)
- Cases involving conspicuous undercuts in the ridge
- Cases in which the patient has difficulty wearing ordinary hard dentures.

2.4 Usage

The standard operating procedure for this product is briefly described below.

① Remove the denture surface to be relined.

② Apply the Sofreliner primer and allow to dry.

③ Apply the Sofreliner paste.

④ Hold the denture (to cure the paste) in the oral cavity for at least 5 minutes, or cure at room temperature (23°C) for at least 20 minutes.

⑤ Correct the form and polish.

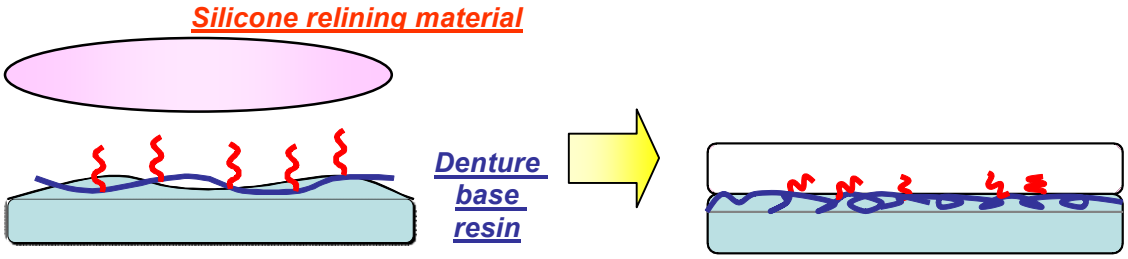
⑥ The procedure is complete.

3. Background technology

3.1 Adhesion technology

Achieving both softness and durability requires high material strength and high bond strength. Tokuyama Dental's Sofreliner series uses an adhesive consisting primarily of a methacrylate polymer (adhesive polymer), in which silicone chains with reactive functional groups (SiH groups) are grafted. Based on this adhesive, the products provide a high bond strength both in direct and indirect techniques.

The adhesion mechanism is illustrated below.

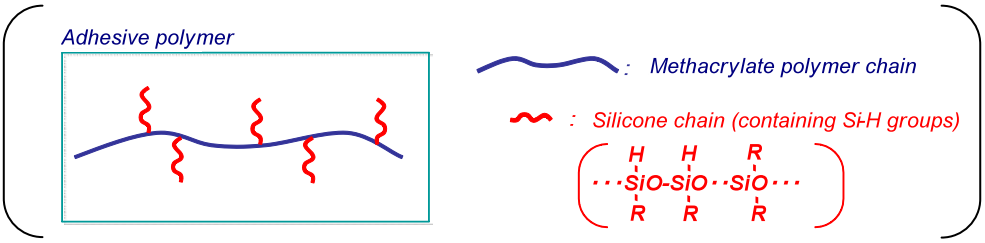


First stage

The adhesive is applied to the resin denture base and dried. (The PMMA chains entangle.)

Second stage

The silicone relining material is applied and cured.
(Hydrosilylation reaction)



4. Properties

4.1 Basic properties

We assessed some of the basic properties for Sofreliner Tough Soft and other products from various manufactures. Table 1 shows the products evaluated.

Table 1: List of products

<table>
<tr><th>Product name</th><th>Manufacturer</th><th>Classification</th><th>Material</th></tr>
<tr><td>Sofreliner Tough Soft
(Tough S)</td><td rowspan="4">Tokuyama Dental</td><td>Long-term soft reline material
Short-term soft reline material</td><td rowspan="12">Silicone</td></tr>
<tr><td>Sofreliner Tough Medium
(Tough M)</td><td rowspan="11">Long-term soft reline material</td></tr>
<tr><td>Sofreliner Medium Soft
(MS)</td></tr>
<tr><td>Sofreliner Soft (SS)</td></tr>
<tr><td>Reline Ultra Soft (US)</td><td rowspan="3">GC</td></tr>
<tr><td>Reline Extra Soft (ES)</td></tr>
<tr><td>Reline Soft (S)</td></tr>
<tr><td>Evatouch Super</td><td>Neo Dental Chemical Products</td></tr>
<tr><td>Mollosil Plus</td><td>Detax</td></tr>
<tr><td>Mucopren Soft</td><td>Kettenbach</td></tr>
<tr><td>Ufi-Gel</td><td>VOCO</td></tr>
<tr><td>TissueCare</td><td>Tokuyama Dental</td><td rowspan="7">Short-term soft reline material</td><td rowspan="7">Acrylic</td></tr>
<tr><td>Shofu Tissue Conditioner II
(Shofu TC II)</td><td>Shofu</td></tr>
<tr><td>GC Tissue Conditioner
(GCTC)</td><td rowspan="2">GC</td></tr>
<tr><td>Soft-Liner</td></tr>
<tr><td>Coe-soft</td><td>GC America</td></tr>
<tr><td>Visco-gel</td><td rowspan="2">Dentsply</td></tr>
<tr><td>Lynal</td></tr>
</table>

4.1-1 Shore A hardness

We measured Shore A hardness, including change in hardness after immersion of the material in water at 37°C and change in hardness after immersion in oil (olive oil) at 37°C, for Tough S and other long- and short-term soft reline material products from various manufacturers. Tables 2 and 3, Figures 2 and 3 show the results.

Table 2: Change in Shore A hardness (after immersion in water at 37°C)

Product	Initial	1 week	2 weeks	3 weeks	4 weeks
Tough S	24	24	25	25	25
Reline US	22	25	29	32	37
Reline ES	34	37	42	45	51
Reline S	56	58	61	61	62
Evatouch	45				
Mollosil Plus	32				
Mucopren Soft	37				
Ufi-Gel	31	34	34	34	36
TissueCare	11	12	13	13	14
Shofu TC II	8	12	16	19	21
GCTC	10	12	15	19	22
Soft-Liner	10	19	24	29	33
Coe-soft	9	16	18	18	19
Visco-gel	8	18	24	28	32
Coe-soft	9	16	18	18	19
Lynal	21	24	25	26	27

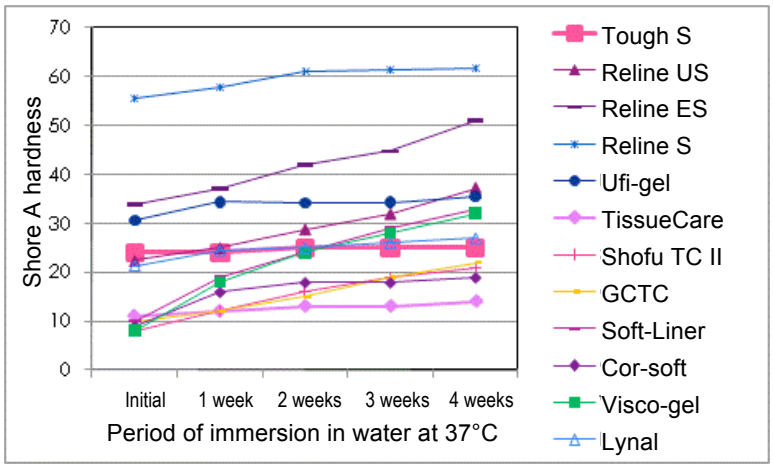


Figure 2: Change in Shore A hardness (after immersion in water)

Table 3: Change in Shore A hardness (after immersion in oil at 37°C)

Product	Initial	1 week	2 weeks	3 weeks	4 weeks
Tough S	24	25	26	26	26
Reline US	23	27	36	38	40
Reline ES	31	34	35	34	35
Reline S	9	14	14	13	14
Ufi-Gel	16	34	44	49	59
TissueCare	20	35	50	56	66
Shofu TC II	14	21	23	23	24
GCTC	15	24	30	32	34
Soft-Liner	8	18	24	28	32
Coe-soft	24	29	29	31	32
Visco-gel	25	26	26	26	26
Coe-soft	23	27	36	38	40
Lynal	31	34	35	34	35

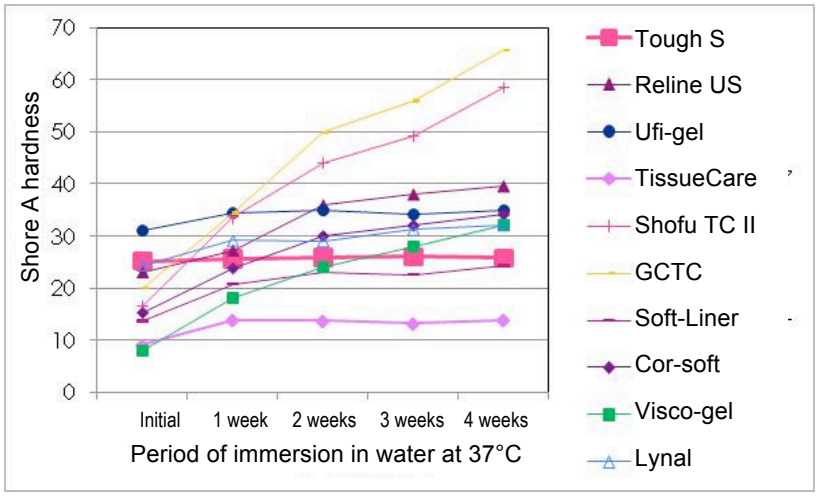


Figure 3: Change in Shore A hardness (after immersion in oil)

Tough S and Ufi-gel, silicone-based products, show little change in hardness compared to other products. The acrylic-based short-term soft reline products (tissue conditioners) and the silicone-based Reline products (US, ES, S) show significant change in hardness, with gradually hardening tendencies.

The results confirm that Tough S has the second lowest hardness (after Reline US) of the silicone-based soft relining materials, and that it retains its softness.

4.1-2 Tear strength

We measured the tear strength for Tough S and other long-term soft reline products. Table 4, Figure 4 shows the results.

Table 4: Tear strength

No.	Product	Tear strength N/mm	Standard deviation	Shore A hardness (for reference)
1	Tough S	9	2.2	24
2	Tough M	23	4.1	43
3	MS	4	0.5	33
4	SS	4	0.5	23
5	Reline US	4	0.2	25
6	Reline ES	10	7.7	37
7	Reline S	9	0.7	55
8	Evatouch	6	0.8	45
9	Mucopren Soft	19	7.3	37
10	Mollosil Plus	13	1.8	32
11	Ufi-Gel	18	2.7	31

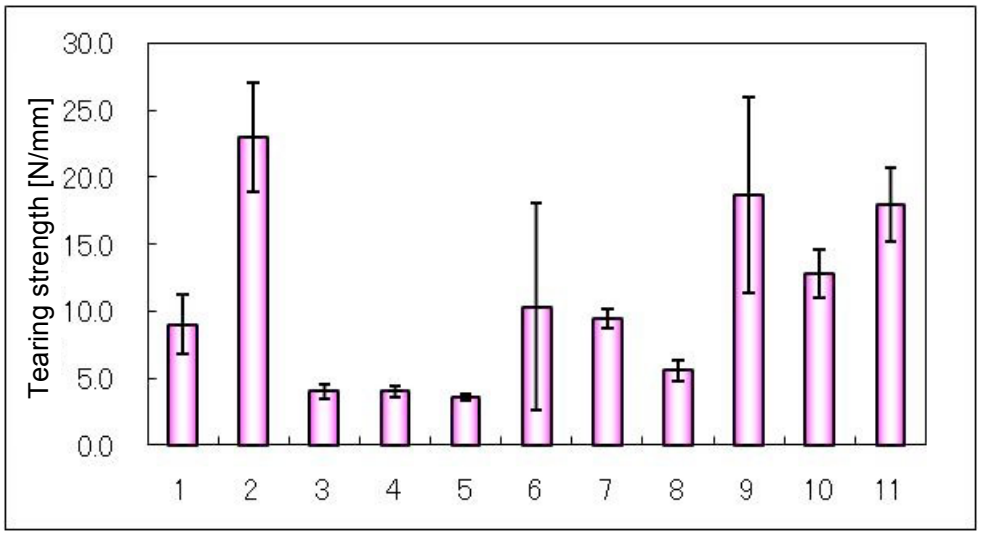


Figure 4: Tear strength

The tear strength of Tough S is more than twice that of SS and nearly three times that of Reline US. All of these products are roughly equivalent in Shore A hardness values. Reline ES, Reline S, and Mollosil Plus, all of which have tear strength values that are roughly equivalent to Tough S, have high hardness values.

These results show that Tough S provides both softness and strength.

4.1-3 Bond durability

① Thermal shock durability test

After thermal cycle tests at 4°C and 60°C, we assessed the bond strength for Tough S and other long-term soft reline products and calculated the cohesive failure ratio for all samples. Table 5 shows the results. Here, Figure 5 shows interfacial and cohesive failures.

Table 5: Results of bond durability test after cyclic thermal shock

Product	Initial	After 3,000 cycles	After 10,000 cycles
Tough S	100%	100%	100%
Tough M	100%	100%	100%
MS	100%	100%	100%
SS	100%	100%	100%
Reline US	100%	60%	20%
Reline ES	100%	—	20%
Reline S	100%	—	40%
Evatouch	100%	100%	40%
Mollosil Plus	100%	—	40%
Mucopren	100%	0%	0%

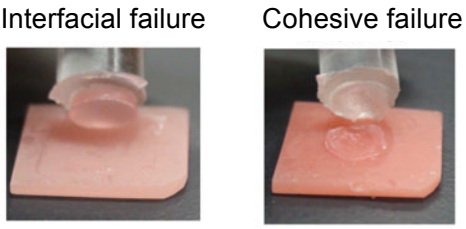


Figure 5: Failure modes

A rate of approximately 10 cycles of thermal shock loading per day corresponds to 3,650 cycles per year. Thus, 3,000 thermal cycles corresponds to approximately one year, while 10,000 thermal cycles corresponds to slightly less than three years.

Initially, all products were free of interfacial failures, and strong bonding was confirmed for all. After the thermal cycle tests, the interfacial failure rate for the Sofreliner series remained at 0%; the rates for products from other manufacturers increased, demonstrating the high bond durability of the Sofreliner series.

② Load durability test

After cyclic loading, we assessed the bond strength for Tough S and other long-term soft reline products, calculating the interfacial failure ratio for all samples. Table 6 shows the results. Here, 300,000 cycles corresponds to approximately 2 years.

Table 6: Results of bond durability test after cyclic loading

Sample	Initial	Cyclic loading
		After 300,000 cycles
Tough S	0%	0%
Tough M	0%	0%
MS	0%	0%
SS	0%	0%

Data from the load durability test also demonstrated the high bond durability of the Sofreliner series.

4.1-4 Wear resistance

We assessed wear resistance to evaluate the resistance of the relining materiasl against surface roughness and degradation. Figure 6 shows the results for Sofreliner Tough S, MS, and SS.

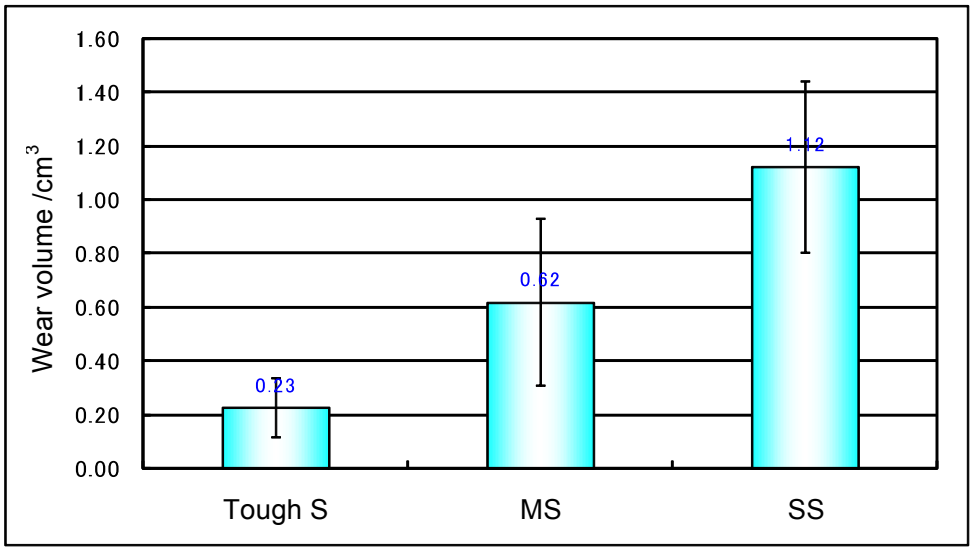


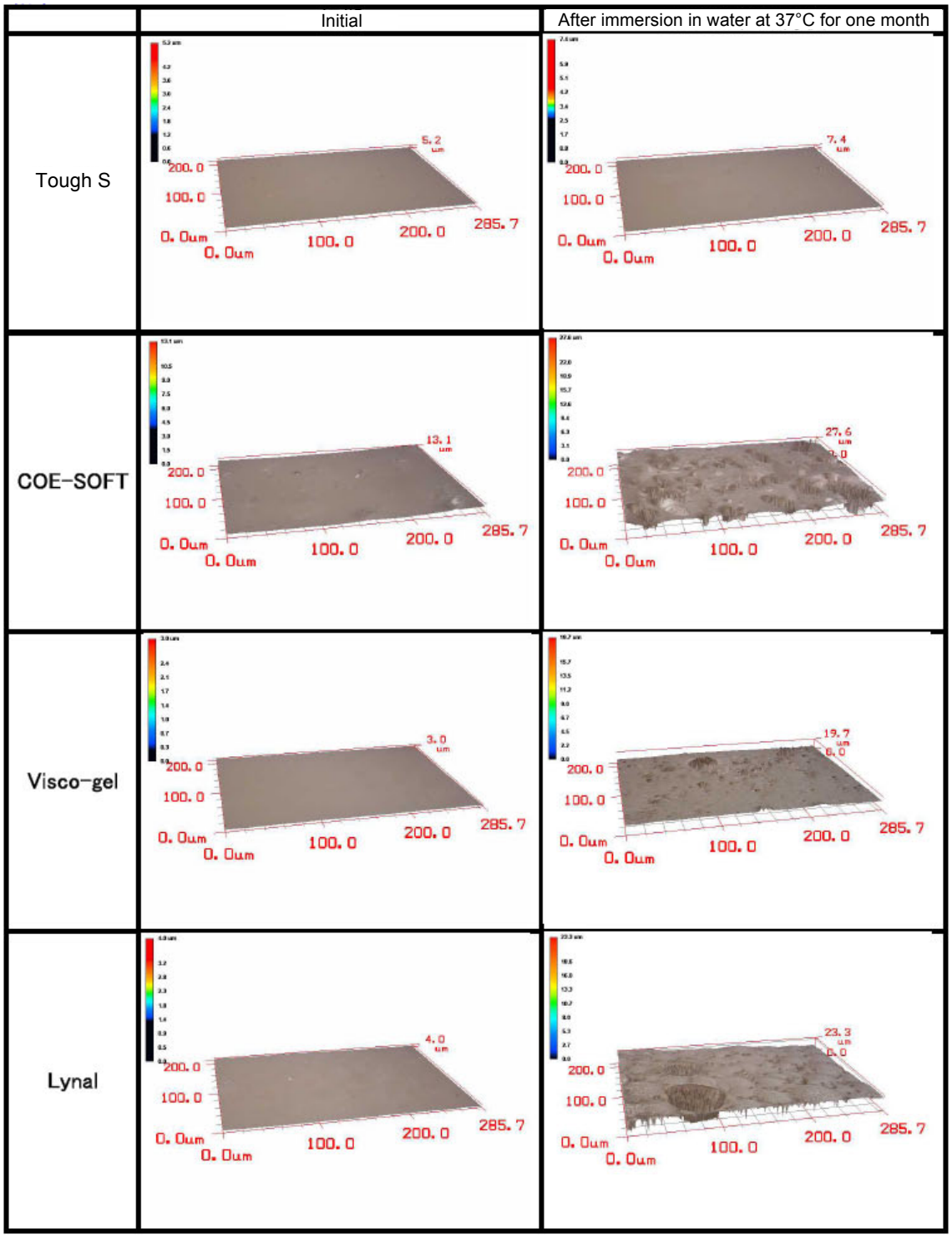
Figure 6: Results of wear resistance test

As shown in Figure 6, the wear volume of Tough S proves to be approximately 1/5 of SS and 1/3 of of MS, demonstrating that Tough S offers better wear resistance than conventional products.

Based on this result, we believe Tough S to have a higher resistance to surface roughness and a higher durability than SS, with an equivalent softness.

4.1-5 Changes in surface texture

To evaluate surface texture in use, we examined the surface texture of the cured body for Tough S and short-term soft reline products with a laser microscope before and after immersion of the samples in water at 37°C for one month. Figure 7 shows the results.



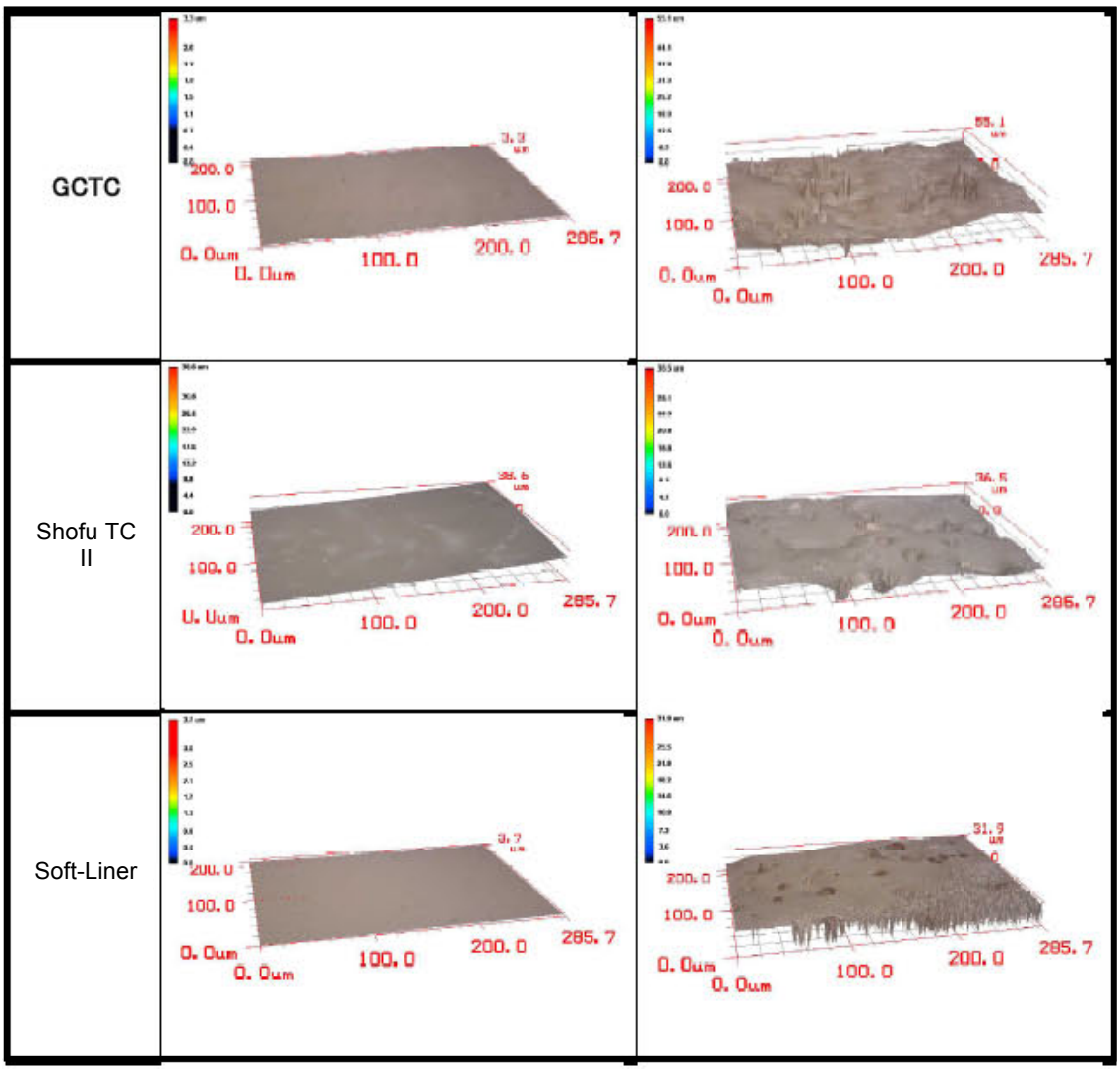


Figure 7: Change in surface texture (microscopic observation)

Compared to acrylic-based short-term soft reline products, which undergo surface roughening due to plasticizer elution, Tough S, a silicone-based short-term soft reline material, changes very little. The results confirm that Tough S offers advantages over acrylic-based short-term soft reline products, with low degradation and high deposition resistance.

4.1-6 Stain resistance

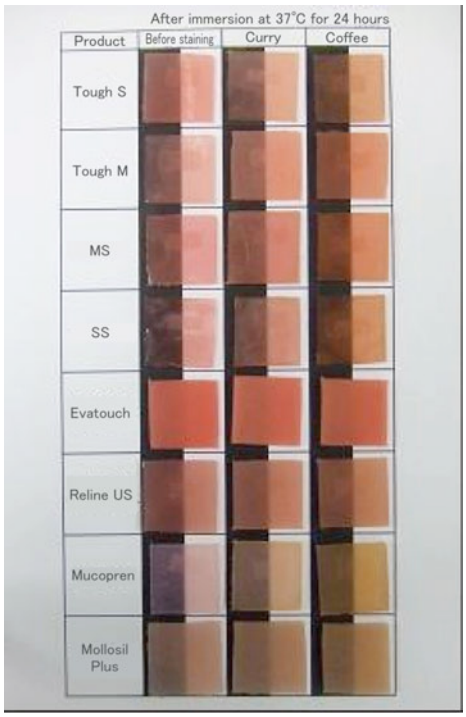
Tables 7 and 8, Figures 8 and 9 show the results of staining tests with curry and coffee.

① Long-term soft reline materials

Table 7: Results of staining tests
(Long-term soft reline materials)

Product	ΔE*	
	Curry	Coffee
Tough S	5.2	4.4
Tough M	4.7	3.5
MS	6.5	4.9
SS	6.8	4.7
Evatouch	4.0	2.6
Reline US	3.5	3.6
Mucopren	6.7	8.5
Mollosil Plus	7.0	5.0

<For reference>



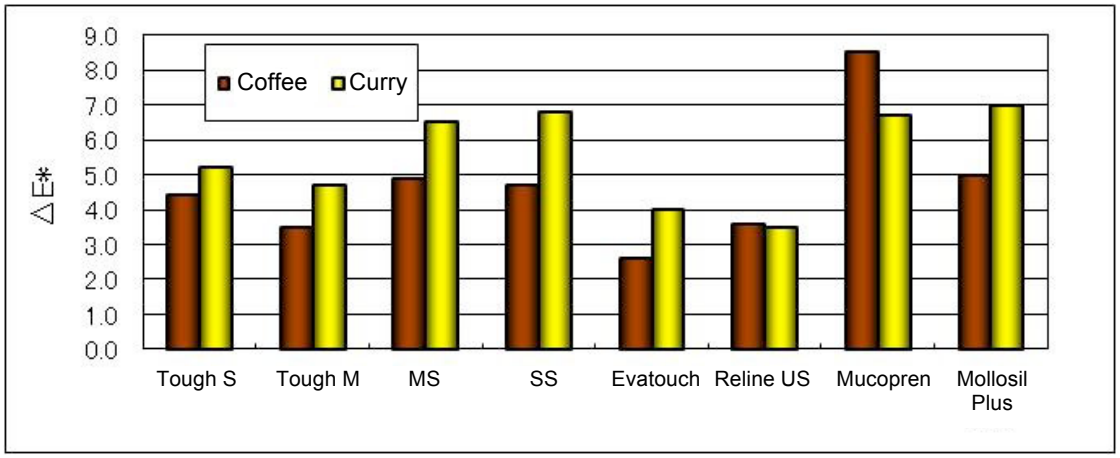


Figure 8: Results of staining test (Long-term soft reline materials)

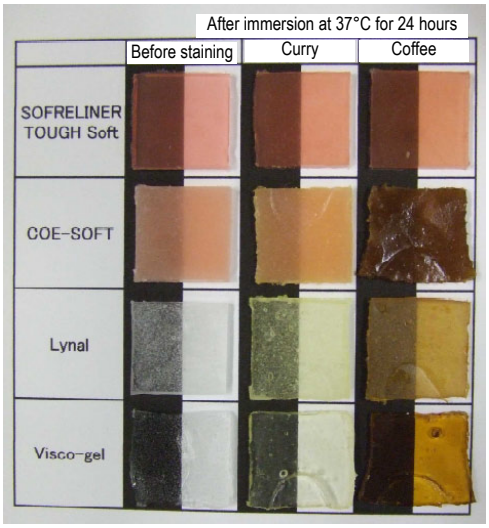
Silicone is strongly resistant to staining by nature. Tough S shows low staining that is equivalent to Tough M.

② Short-term soft reline materials

Table 8: Results of staining test
(Short-term soft reline materials)

Product	ΔE*	
	Curry	Coffee
Tough S	5.2	4.4
TissueCare	24.2	29.9
Shofu TC II	35.2	32.7
COE-SOFT	24.3	27.8
Visco-gel	8.7	15.5
Lynal	19.7	18.3

<For reference>



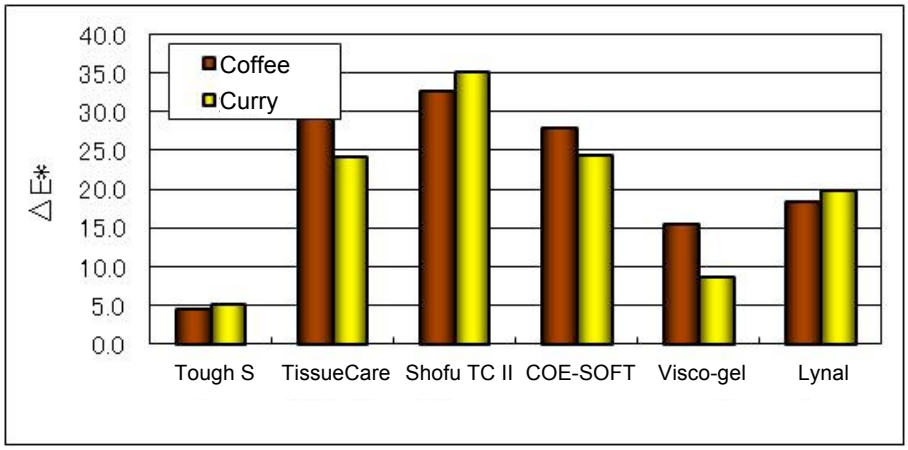


Figure 9: Results of staining test (Short-term soft reline materials)

The results show Tough S undergoes significantly less staining than acrylic-based short-term soft reline products. Since most short-term soft reline products are acrylic-based, this property provides a significant advantage when using Tough S as a short-term soft reline material.

4.1-7 Immersion test in denture cleansers

We performed Immersion cleansing tests in denture cleansers for Sofreliner Tough S, Tough M, and SS. Table 9 shows the denture cleansers used. Table 10, Figures 10 and 11 show the results.

After testing for 4 months, we observed degradation (e.g., discoloration) only with Pika (blue).

However, as shown in Figure 12, Tough S discolored to a very dark shade in the first week of the immersion test in Pika (blue). The discoloration following immersion in Pika (blue) also occurs with Sofreliner MS and SS, but not with Sofreliner Tough M. The discoloration is believed to occur due to the degradation of the platinum catalyst.

Thus, while Tough S is suitable for use with most denture cleansers, users should be informed of discoloration when used with Pika (blue).

Table 9: Denture cleansers

Product name	Type	Manufacturer
Pika (blue)	Enzyme, oxygen	Shofu/Rohto Pharmaceutical
Pika (red)	Hypochlorite	
Polident	Oxygen	Glaxo
Toughdent		Kobayashi Pharmaceutical
Partialdent		
DENTURE CLEANER		Sunstar
Physio Clean Kirari (tablet)		Nissin
Clean Soft	Enzyme	Kamemizu Chem. Ind.
Physio Clean Kirari		Nissin
Spa Dent	Crude drug	
Partialdent Sanitizer	Surfactant	Kobayashi Pharmaceutical
Super Sera Coat		Nippon Zettoc
Labarraque-D	Ultrasonic	Sundental
Clean Denture Max	Ultrasonic	
Water	Control	—

Table 10: Results of immersion test in denture cleansers

Product name	1 week	2 weeks	3 weeks	4 weeks	1 month	2 months	3 months	4 months
Pika (blue)	△	×	×	×	×	×	×	×
Pika (red)	○	○	○	○	○	○	○	○
Polident	○	○	○	○	○	○	○	○
Toughdent	○	○	○	○	○	○	○	○
Partialdent	○	○	○	○	○	○	○	○
DENTURE CLEANER	○	○	○	○	○	○	○	○
Physio Clean Kirari (tablet)	○	○	○	○	○	○	○	○
Clean Soft	○	○	○	○	○	○	○	○
Physio Clean Kirari	○	○	○	○	○	○	○	○
Spa Dent	○	○	○	○	○	○	○	○
Partialdent Sanitizer	○	○	○	○	○	○	○	○
Super Sera Coat	○	○	○	○	○	○	○	○
Labarraque-D	○	○	○	○	○	○	○	○
Clean Denture Max	○	○	○	○	○	○	○	○
Water	○	○	○	○	○	○	○	○

* ○ (Circle): no discoloration, △ (Triangle): slight discoloration, × (Cross): discoloration

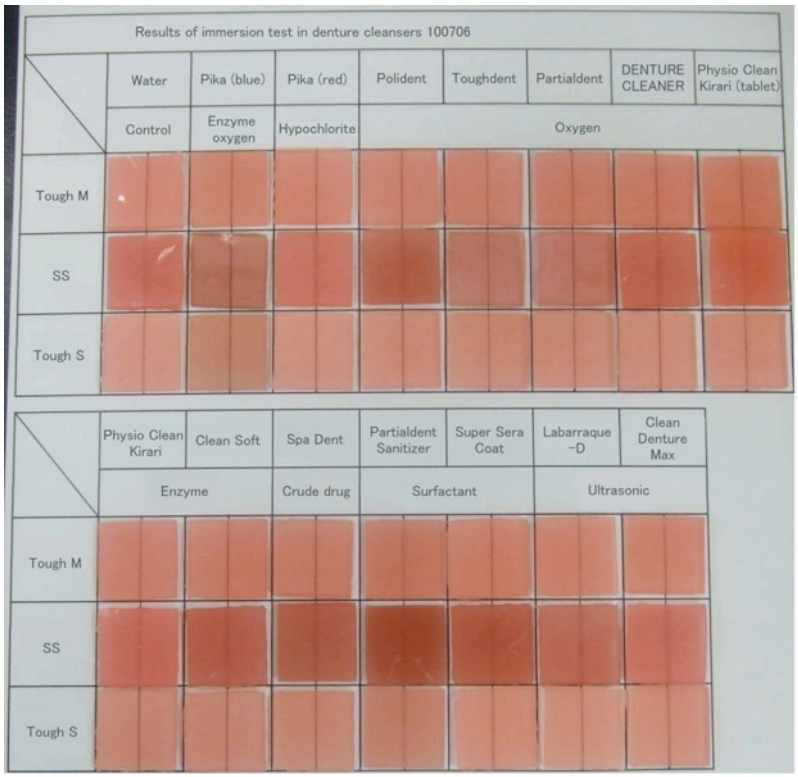


Figure 10: Results of immersion test in denture cleansers (1 week)

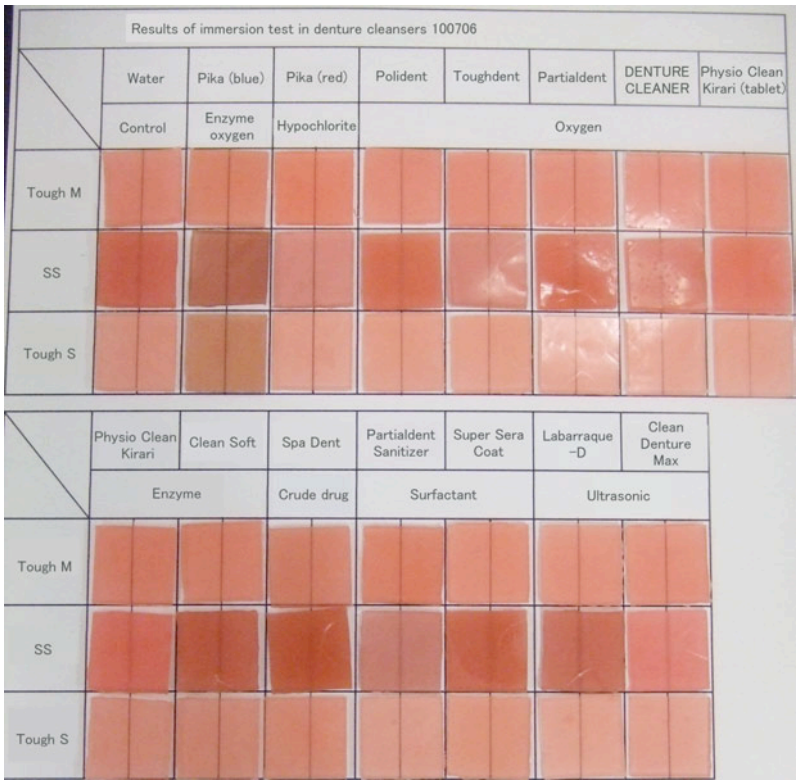


Figure 11: Results of immersion test in denture cleansers (4 months)

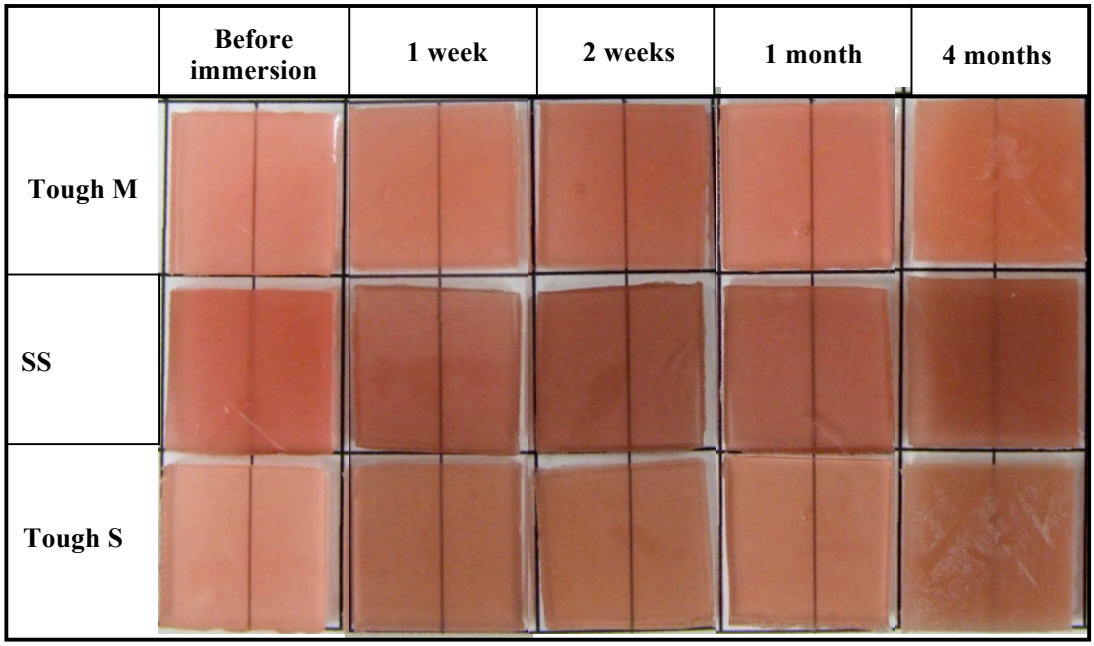


Figure 12: Photographs of samples immersed in Pika (blue)

4.2 Operability

4.2-1 Handling time

We measured the handling times. Table 11 shows the results.

Table 11: Handling time

Product	Handling time
Tough S	2'15"
Tough M	2'30"
MS	2'30"
SS	2'30"
Reline US	2'45"
Reline ES	2'25"
Reline S	2'10"
Evatouch Super	4'50"
Mollosil Plus	1'30"
Mucopren Soft	2'30"
Ufi-Gel	2'50"

With the exception of Evatouch Super, which required a relatively long handling time of 4 minutes and 50 seconds, the handling times for most products are approximately 2 to 3 minutes. Significantly longer handling times than other products may inconvenience users. These results confirm handling times for Tough S are equivalent to those of other products.

4.2-2 Dispensing paste

We assessed the load required to dispense the paste from the cartridge. Table 12,Figures 13 and 14 show the results

Table 12: Load for dispensing paste

Product	Specified tip	Load for dispensing paste /N	
		Specified tip	Yellow tip
Tough S	XS (yellow)	46	46
Tough M		46	46
MS	S (pink)	76	100
SS		85	95
Reline US	L (green)	45	70
Reline ES		55	95
Reline S		75	100
Ufi-gel	S (pink)	53	75

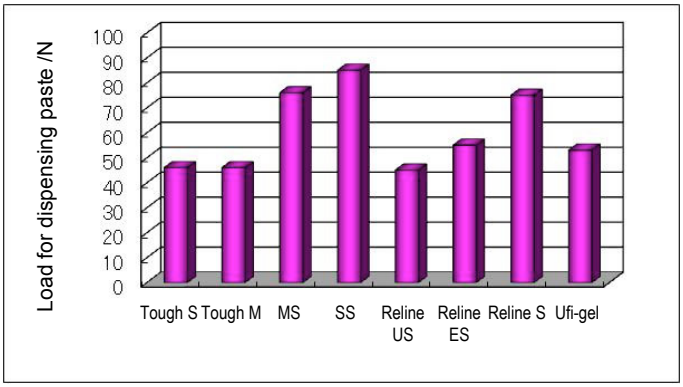


Figure 13: Load for dispensing paste (with specified tip)

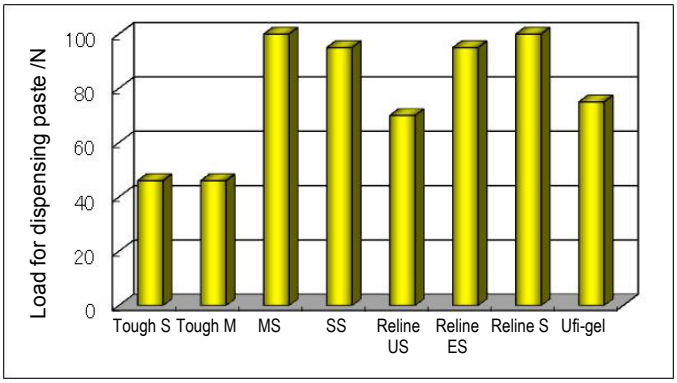


Figure 14: Load for dispensing paste (with XS tip)

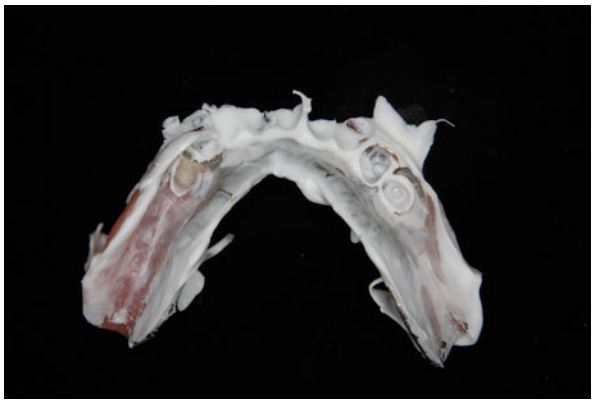
When the specified tip is used (Figure 13), Tough S can be dispensed with the smallest load (approximately half the load for SS) of all the listed products. In addition, since Tough S supports the smallest tip (XS), it offers additional advantages over Reline US (with S tip). Although the two products yield equivalent results, the amount of paste remaining in the tip of Tough S is less.

As shown in Figure 14, if we compare the load using the XS tip, Tough S and Tough M can be dispensed with minimal load, indicating excellent paste dispensing performance.

5. Clinical cases/Dr. Matsumura

<Case 1>

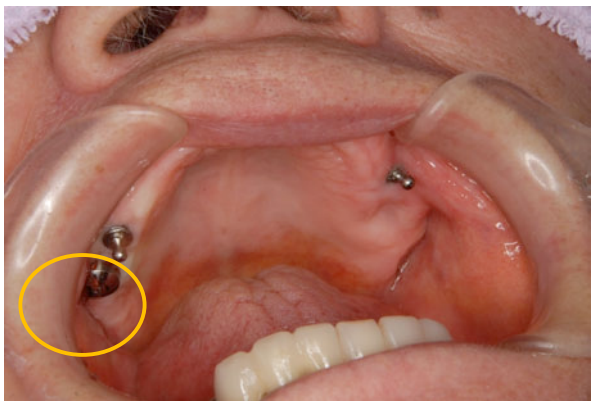
Mismatching mandibular partial denture base (slightly loose, jammed by food bolus)



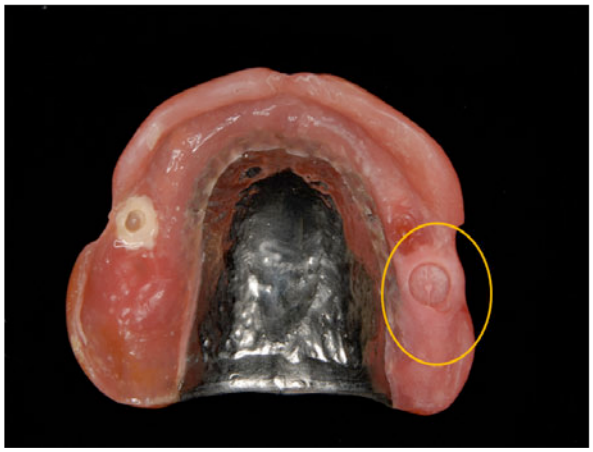
The resin portion of the partial denture is relined with Tough S.

<Case 2>

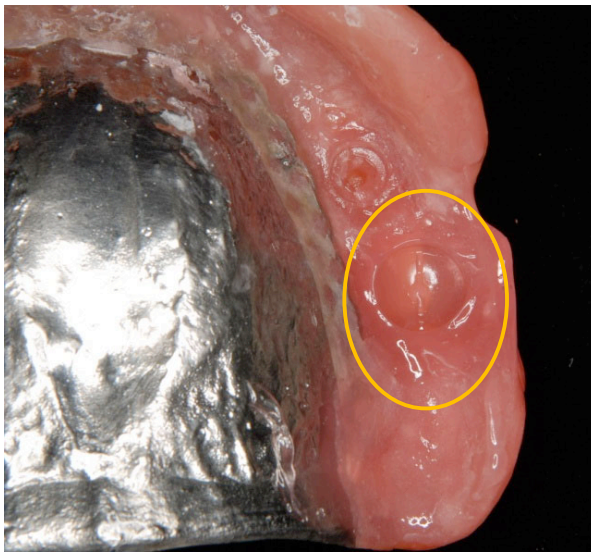
After second implant surgery



Relined with a tissue conditioner (2 weeks)



After the tissue conditioner is removed and relined with Tough S.



6. Summary

The technical data for Sofreliner Tough Soft, released in November 2011, confirms the following features:

- ○ Among silicone-based long-term soft reline products, Sofreliner Tough Soft is softer than most and offers a high tear strength, providing both softness and strength.
- ○ Sofreliner Tough Soft shows little change in hardness and surface texture, with low degradation.
- ○ Sofreliner Tough Soft offers excellent bond durability.
- ○ The paste can be dispensed with modest pressure.
- ○ Sofreliner Tough Soft offers excellent stain resistance compared to acrylic-based soft reline products.
- ○ Sofreliner Tough Soft discolors in Shofu Pika (blue) in similar fashion to Sofreliner MS and SS. Users should be informed of this characteristic.

7. References

(None) 16