

To evaluate the Tensile Bond Strength, Viscoelasticity, and Material Leachability of Three Commercially Available Temporary Soft Liners - A Comparative in Vitro Study.

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Abstract:

Introduction: The clinical adhesion failure is the most critical problem because of the failure of the optimal bond between denture base and the soft liner.

Aims and Objectives: To evaluate and compare the tensile bond strength, viscoelastic property and leach ability of commercially available for temporary denture soft liners.

Materials and Methods: Inpresent studythe tensile bond strength, clinical compliance and leachability of different materials like Visco Gel (Group A),

COE Soft(Group B) and GC (Group C)was measured at specific time periods i.e. 2hrs, 24hrs, 1week, and 4weeks by using modified penetrometer and high performance liquid chromatography unit.

Statistical Analysis: ANOVA, Turkey Honestly test and Students paired T- test were used for mean values for comparison between different study groups and to compare the mean values between different time intervals.

Results: Group A has shown the least tensile bond strength initially and at the end of 4 weeks followed by Group B and Group C. There was a statistically significant difference of change in compliance when the material of Group A, B and C were compared. The amount of ethanol, di-butyl pthalate, butyl pthalyl butyl glycolate/ benzyl salicylate leached out increased from 2hrs — 4weeks. Increase in the amount of di-butyl pthalate leached out from 24hrs — 4weeks. Butyl pthalyl butyl glycolate/ benzyl salicylate was last to leach out and increased from 1week to 4weeks.

Conclusion: Dentists should select better denture liners for best bond strength and viscoelastic property for their patients subject to their individual needs.

Key words: Soft liners, Tensile Bond Strength, Complete denture, Viscoelastic property.

Introduction:

The success of complete denture depends on the comfort, esthetics and function in the patient's mouth. The soft denture bearing mucosa is confined between the hard denture base and bone causes chronic soreness especially in heavy bruxism habits anddiabetic patients. Soft liners acts as shock absorbers to reduce and distribute the stresses on the denture bearing tissues because of their viscoelastic properties and have been known to be clinically effective. [1],[2],[3] Plastic acrylic soft liners tend to become hard and lose their resiliency because of leaching of plasticizers during storage. One of the serious problems with soft denture liners is the failure of adhesion which causes bacterial growth, thus leading to functional failure of prostheses. [4] Therefore, it is very important to optimize the strength of the soft lining material to denture base. [5],[6],[7],[8]

So, present study was conducted to evaluate the tensile bond strength, clinical compliance and leachable components of Visco gel, Coe soft, GC temporary soft lining materials over period of time and the reason for changes in these properties were also studied.

Aims and Objectives:

The purpose of the study was to evaluate and compare

- 1. The tensile bond strength by using universal testing machine.
- 2. Viscoelastic property (compliance) by using modified penetrometer.
- 3. Leachable components of soft liners by using high performance liquid chromatography unit of three commercially available temporary denture soft liners.

Materials and Methods:

Materials:

1. Visco Gel (Group A) (Figure 1d)

Composition- Powder-PEMA (86.2%), PMMA (13.8%). Liquid- Butyl Pthalyl Butyl Glycolate (86.9%), Dibutyl pthalate (8.2%), Ethyl Alcohol (4.9%).

2. COE Soft (Group B) (Figure 2c)

Composition- Powder-PEMA (100%) Liquid- Benzyl Salicylate (35.1%), Dibutyl pthalate (49.7%), Ethyl Alcohol (15.2%).

- **3. GC Soft liner** (**Group C**) (Figure 3c)Composition- Powder-PEMA (100%). Liquid- Butyl Pthalyl Butyl Glycolate (80.9%), Dibutyl pthalate (4.3%), Ethyl Alcohol (14.8%).
- 4. Wet mouth liquid is used as a storage medium Shown in Figure 3b.Composition:Sodium cmc, Glycerin

Methodology:

For evaluation of tensile bond strength of soft liners, the fabrication of aluminum dies for standardized sample with help of milling machine was done with dimensions of 40mm length, 12mm breadth and 18mm width. In preparing the specimens of PMMA blocks, putty index was made from preformed

aluminum dies which in turn were used for the fabrication of the wax mold shown in Figure 1a, 1b and 1c.

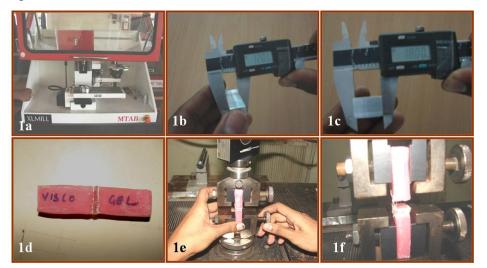


Figure 1a: Milling machine. **Figure 1 b and c:** Aluminum rectangular block used for fabrication of acrylic block **1d:** PMMA blocks of soft liner in between **1e:** Sample placed in universal testing Machine for tensile bond strength test. **1f:** Shows bond failure.

32 specimens for each of the 3 lining materials were prepared for testing clinical compliance, aluminum dies of dimension of 8cm diameter, 30mm thickness and four depressions equidistant from each other with dimensions of 25mm diameter × 4mm depth **shown in** Figure 2a, 2b and 2c.

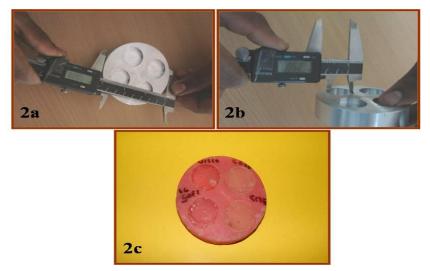


Figure 2a, 2b and 2c: Aluminum circular plate with diameter of 8cm with 4 equally spaced circular depressions of 25mm diameter each and depth of 4mm Sample for testing compliance of three different soft liners.

12 samples of heat cure circular acrylic plates were fabricated. The samples were stored in wet liquid (storage medium) Figure 3a and 3b. For chemicals leached out the aluminum plate of 30 mm lengths, 12mm width with 3 depressions (4mm diameter and 2mm depth)equidistant from each other was fabricated and was used for standardization for the samples shown in Figure 4a and 4b. The three different commercially available soft lining materials and the samples were stored in wet liquid (storage medium).

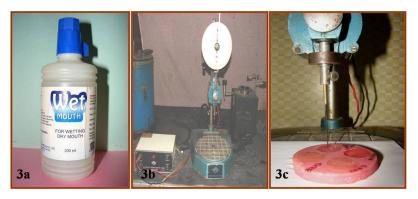


Figure 3a: Wet mouth liquid used as storage medium for samples 3b: Modified penetrometer 3c: Test for compliance.



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Section A-Research paper

Figure 4a and 4b: Aluminum die used for fabrication of acrylic block with depth =2mm, diameter =4mm and length =30mm for HPLC test. 4c: High performance liquid chromatography unit.

HPLC (high performance liquid chromatography unit) was used for analyzing the molecules that are dissolved in a solvent. The solvent is qualitatively and quantitatively analyzed to find out the leached out components of the specimen shown in Figure 4c. The test samples were removed from the acrylic plates and were placed in test tube containing wet liquid (solvent) for a specified period of time, and test analysis were performed at different time intervals. Similar study has been done by **Minoru Kawaguchi et al**^[10] using the HPLC test to study the amount of leach able monomers of a light activated reline resin.

The manufactures recommended period of use in the oral cavity is between 3-4 weeks. Hence it was decided to test the specimens at 2hrs, 24hrs, 2weeks and 4weeks and the samples were stored in wet liquid (storage medium). They were then deformed at the rate of 2 mm/minute using a Lloyds Universal testing machinelinked to an IBM compatible computer shown in Figure 1d, 1e and 1f.

The compliance of these materials were studied at the specific periods i.e. 2hrs, 24hrs, 1week, and 4weeks, using modified penetrometer as done by **Nicholas J.A. Jepson et al.**^[9] The modified penetrometer used in the study was simple and easy to use. A load of 50g was held constant for 5secondsshown in Figure 3c, strain during loading and recovery were recorded.

Statistical Analysis:

One way ANOVA followed by Turkey Honestly test was used forthe comparison between different study groups. Students paired T- test was used to compare the mean values between different time points within each study group. In this study **p< 0.05** was considered as the level of significance.

Results:

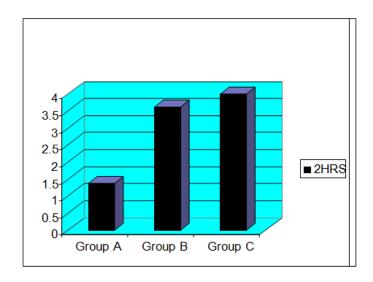
Tensile Bond Strength:

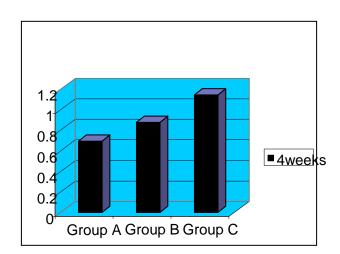
The tensile bond strength of Group A, B and C was tested for a time duration ranging from 2hrs - 4 weeks. The measurement unit used was Kgf/cm square shown in Table 1.

Sample		Group A	in kgf/cm²	2		Group B	in kgf/cn	n^2	Group C in kgf/cm ²			
	2hrs	24hrs	2	4	2hrs	24hrs	2	4	2hrs	24hrs	2	4
			weeks	weeks			weeks	weeks			weeks	weeks
1.	1.198	0.874	0.852	0.654	3.938	1.841	1.114	0.899	4.156	1.831	1.554	1.502
2.	1.232	0.867	0.745	0.750	3.580	1.822	1.282	0.780	4.386	1.780	1.487	0.922
3.	1.559	0.798	0.780	0.550	3.656	1.883	1.371	0.920	4.280	1.824	1.375	0.998
4.	1.352	0.816	0.894	0.740	3.784	1.887	1.187	0.850	3.828	1.670	1.558	1.022
5.	1.512	0.858	0.712	0.680	3.476	1.874	1.354	0.890	3.780	1.545	1.452	1.300
6.	1.380	0.872	0.736	0.672	3.484	1.742	1.284	0.894	3.976	1.788	1.480	1.042
7.	1.180	0.832	0.814	0.785	3.281	1.684	1.358	0.872	3.766	1.824	1.384	1.224
8.	1.418	0.862	0.794	0.696	3.686	1.692	1.412	0.868	3.685	1.838	1.288	1.112

Table: 1 Tensile bond strength at different time intervals for Visco Gel (Group A), COE SOFT (Group B) and GC Soft liner (Group C)

The mean standard deviation of tensile bond strength between the values at 2hrs with that of specified times i.e. 24hrs, 2week and 4weeks and similarly between the values at 24hrs with the values at 2week and 4weeks as well as 2week values compared with 4th week values of various Groups A, Group B and Group C shown in Table 2.Group A has shown the least tensile bond strength initially as well at the end of 4 weeks followed by Group B and Group C shown in Graph 1 and 2.





Graph 1: Tensile bond strength of three test groups after 2hrs

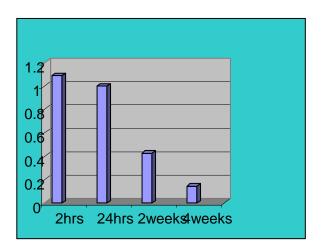
Graph 2: Tensile bond strength of three test groups after 4weeks

Time Duration	Group	Mean± S.D	P-Value
2hrs	Group A	1.354±0.142	
	Group B	3.611±0.203	<0.0001(sig)
	Group C	3.982±0.262	
24hrs	Group A	0.847±0.028	
	Group B	1.803±0.085	<0.0001(sig)
	Group C	1.762±0.103	
2 week	Group A	0.791±0.061	
	Group B	1.295±0.101	<0.0001(sig)
	Group C	1.447±0.093	
4week	Group A	0.691±0.072	
	Group B	0.872±0.043	<0.0001(sig)
	Group C	1.140±0.191	
2hrs to 24hrs	Group A	0.506±0.155	
	Group B	1.808±0.178	<0.0001(sig)
	Group C	2.220±0.250	
2hrs to 2 weeks	Group A	0.563±0.176	
	Group B	2.314±0.279	<0.0001(sig)
	Group C	2.535±0.264	
2hrs to 4weeks	Group A	0.663±0.198	
	Group B	2.739±0.204	<0.0001(sig)
	Group C	2.842±0.362	
24 hrs to 2week	Group A	0.056±0.077	
	Group B	0.508±0.157	<0.0001(sig)
	Group C	0.315±0.148	
24 hrs to 4week	Group A	0.156±0.071	
	Group B	0.932±0.093	<0.0001(sig)
	Group C	0.622±0.224	

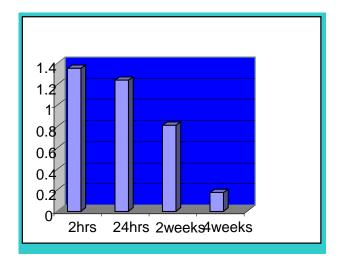
Table: 2 Mean standard deviation and test of significance of mean values among different study groups for tensile bond strength at different time intervals

Clinical Compliance:

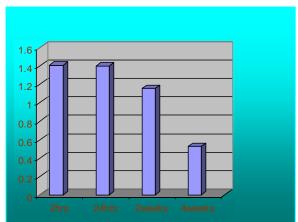
The clinical compliance of Visco Gel (Group A), Coe Soft (Group B) and GC (Group C) Soft liner for a time duration ranging from 2hrs – 4 weeks is measured in unit used was mm/30gms shown in Table3. The mean and standard deviation of clinical compliance atdifferent time intervals i.e 2hrs, 24hrs, 1week and 4 weeks in all the three groups are shown in Graph 3, 4 and 5 and Table 4. In Group A the mean value in 2hrs is 1.091 and it decreased in the 4th week to 0.144. The same trend is seen in Group B and Group C.



Graph 3 Mean values of Compliancefor (Group A) Visco Gel at different time intervals



Graph 4 Mean values of Compliancefor (Group B) GC Soft liner at different time intervals



Graph 5 Mean values of Compliancefor (Group C) Coe Soft at different time intervals

S. No	2	24	2	4	2	24	2	4	2	24	2	4
	hrs	hrs	week	week	hrs	hrs	week	week	hrs	hrs	week	week
1.	1.12	1.00	0.426	0.146	1.405	1.401	1.156	0.525	1.31	1.247	0.818	0.170
2.	1.05	0.99	0.423	0.142	1.409	1.399	1.159	0.529	1.36	1.240	0.813	0.175
3.	1.09	1.001	0.428	0.143	1.410	1.402	1.157	0.527	1.34	1.241	0.814	0.173
4.	1.10	1.003	0.429	0.145	1.414	1.392	1.158	0.528	1.33	1.243	0.817	0.170
5.	1.20	0.997	0.428	0.146	1.407	1.394	1.115	0.522	1.30	1.249	0.810	0.179
6.	1.07	1.004	0.425	0.141	1.411	1.395	1.167	0.523	1.40	1.248	0.815	0.178
7.	1.06	0.995	0.430	0.147	1.408	1.397	1.157	0.522	1.39	1.244	0.811	0.176
8.	1.04	1.005	0.421	0.144	1.404	1.396	1.155	0.526	1.37	1.243	0.815	0.172

Table: 3 Compliance of three different temporary soft lining materials of 8 samples for each test group at different time intervals (Units=mm/30gms)

Duration	Group	Mean±S.D	P-value
	Group A	1.091±0.051	
2 hrs	Group B	1.350±0.036	<0.0001(Significant)
	Group C	1.408±0.003	
	Group A	1.000±0.005	
24 hrs	Group B	1.240±0.003	<0.0001(Significant)
	Group C	1.400±0.003	
	Group A	0.426±0.003	
2 weeks	Group B	0.814 ± 0.003	<0.0001(Significant)
	Group C	1.158±0.004	
	Group A	0.144±0.002	
4 weeks	Group B	0.174±0.003	<0.0001(Significant)
	Group C	0.525 ± 0.003	

Table: 4 Mean and Standard Deviation of Compliance of three groups at different time intervals

The comparison of the clinical compliance of GroupA, GroupB and GroupC between the values at 2hrs with that of specified times i.e. 24hrs, 2week and 4weeks and similarly between the values at 24hrs with the values at 2week and 4weeks as well as 2week values compared with 4th week values shown in Table5.

In Group A, Group B and Group C there is a mean difference between 2hrs and 24hrs, 2weeks and 4weeks and between 24hrs and 2weeks, 4weeks and the mean difference between 2nd and 4th week is given in Table 5.

Changes in duration	Group	Mean± S.D	P-Value
2 hrs – 24hrs	Group A	0.092±0.052	
	Group B	0.106 ± 0.037	<0.0001(Significant)
	Group C	0.012 ± 0.006	_
2hrs – 2weeks	Group A	0.665 ± 0.050	
	Group B	0.536 ± 0.037	<0.0001(Significant)
	Group C	0.250 ± 0.004	
2hrs – 4 weeks	Group A	0.947 ± 0.050	
	Group B	1.176 ± 0.035	<0.0001(Significant)
	Group C	0.883 ± 0.004	
24hrs – 2 weeks	Group A	0.573 ± 0.006	
	Group B	0.430 ± 0.004	<0.0001(Significant)
	Group C	0.239 ± 0.006	
24hrs – 4 weeks	Group A	0.885 ± 0.006	
	Group B	1.070 ± 0.004	<0.0001(Significant)
	Group C	0.872 ± 0.004	_
2weeks -4 weeks	Group A	0.282±0.003	
	Group B	0.640 ± 0.006	<0.0001(Significant)

Group C	0.633±0.005	
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Table: 5 Mean and Standard Deviation of Compliance of three groups compared between different time intervals.

We found that Group A lost the initial compliance at a faster rate which was followed by Group C. The change in compliance of Group B was the least and it showed the maximum compliance at the end of 4 weeks.

There was a statistically significant difference of change in compliance when the material Group A, B and C were compared with each other. When the change in compliance between 2-24hrs of material A and C were compared there was no significant difference shown in Table 3.

HPLC Analysis Reading:

The High-performance liquid chromatography analysis report for Group A, B and C at the end of 2hrs, 24hrs, 2weeks and 4weeks shown in Table 6 to 10. Table 6 and 10 shows the HPLC analysis reading of the Visco gel, Coe Soft and GC Soft liner material at the end of 2hrs duration and it was found that ethanol was the only ingredient leached with mean value of 0.146, 0.827 and 0.464 respectively.

Table 7 and 10 shows the HPLC analysis reading of the Visco gel, Coe Soft and GC Soft liner material at the end of 24hrs duration and it was found that ethanol and Dibutyl pthalate were the only ingredients leached out with mean value of Visco gel is 0.962, 0.138, Coe Soft is 1.347, 0.460 and GC Soft liner material is 0.642, 0.042 respectively.

Table 8 and 10 shows the HPLC analysis reading of the Visco gel, Coe Soft and GC Soft liner material at the end of 2week duration and it was found that ethanol and Dibutyl pthalate and butyl pthalyl butyl glycolate were the ingredients leached out with mean value of Visco gel is 2.177, 0.454, and 0.475, Coe Soft is 2.848, 0.958, and 1.159 and GC Soft liner is 2.952, 0.360, and 1.046 respectively.

Table 9 and 10 shows the HPLC analysis reading of the Visco gel, Coe Soft and GC Soft linermaterial at the end of 4week duration and it was found that ethanol and Dibutyl pthalate and butyl pthalyl butyl glycolate were the ingredients leached out with mean value of Visco gel is 3.742, 1.356, and 2.162, Coe Soft is 4.670, 1.758 and GC Soft liner material is 1.864.4.958, 1.058, and 2.390 respectively.

HPLC ANALYSIS READINGS

				Visco G	el						
Samples	1	2	3	4	5	6	7	8			
ЕТОН	0.118%	0.123%	0.132%	0.155%	0.144%	0.167%	0.167%	0.165%			
DBP	NF	NF	NF	NF	NF	NF	NF	NF			
BPBG	NF	NF	NF	NF	NF	NF	NF	NF			
BS	NF	NF	NF	NF	NF	NF	NF	NF			
Coe Soft											
Samples	1	2	3	4	5	6	7	8			
ЕТОН	0.799%	0.791%	0.845%	0.816%	0.848%	0.835%	0.837%	0.648%			
DBP	NF	NF	NF	NF	NF	NF	NF	NF			
BPBG	NF	NF	NF	NF	NF	NF	NF	NF			
BS	NF	NF	NF	NF	NF	NF	NF	NF			
			G	C Soft li	ner						
Samples	1	2	3	4	5	6	7	8			
ЕТОН	0.469%	0.488%	0.479%	0.445%	0.459%	0.450%	0.431%	0.488%			
DBP	NF	NF	NF	NF	NF	NF	NF	NF			
BPBG	NF	NF	NF	NF	NF	NF	NF	NF			
BS	NF	NF	NF	NF	NF	NF	NF	NF			
TOH - E	Ethyl alco	hol, DBP	-Dibutyl p	phthalate,	BPBG B	utyl pthal	yl glycol:	ate and BS			
		D	anzyl cal	avilata N	T Not for	d					

Benzyl salicylate, NF-Not found

Table: 6 Leached out components after 2hrs for Visco Gel, Coe Soft and GC Soft liner

	Visco Gel												
Samples	1	2	3	4	5	6	7	8					
ЕТОН	0.951%	0.955%	0.989%	0.944%	0.964%	0.933%	0.980%	0.983%					
DBP	0.116%	0.114%	0.158%	0.165%	0.143%	0.129%	0.140%	0.142%					
BPBG	NF	NF	NF	NF	NF	NF	NF	NF					
BS	NF	NF	NF	NF	NF	NF	NF	NF					
				Coe Soft									

Samples	1	2	3	4	5	6	7	8
ЕТОН	1.364%	1.318%	1.342%	1.350%	1.353%	1.332%	1.354%	1.365%
DBP	0.430%	0.445%	0.443%	0.485%	0.480%	0.474%	0.452%	0.473%
BPBG	NF	NF	NF	NF	NF	NF	NF	NF
BS	NF	NF	NF	NF	NF	NF	NF	NF
			GO	C Soft lin	er			
Samples	1	2	3	4	5	6	7	8
ЕТОН	1.160%	1.165%	0.440%	0.470%	0.430%	0.480%	0.495%	0.498%
DBP	0.063%	0.012%	0.040%	0.041%	0.052%	0.028%	0.050%	0.051%
BPBG	NF	NF	NF	NF	NF	NF	NF	NF
BS	NF	NF	NF	NF	NF	NF	NF	NF

Table: 7 Leached out components after 24hrs for Visco Gel, Coe Soft and GC Soft liner

				Visco G	el					
Samples	1	2	3	4	5	6	7	8		
ЕТОН	2.170%	2.172%	2.194%	2.195%	2.186%	2.148%	2.164%	2.185%		
DBP	0.427%	0.454%	0.464%	0.463%	0.484%	0.455%	0.458%	0.430%		
BPBG	1.172%	1.150%	0.649%	0.167%	0.154%	0.153%	0.185%	0.170%		
BS	NF	NF	NF	NF	NF	NF	NF	NF		
Coe Soft										
Samples	1	2	3	4	5	6	7	8		
ЕТОН	2.855%	2.858%	2.819%	2.864%	2.873%	2.836%	2.842%	2.840%		
DBP	0.950%	0.952%	0.939%	0.975%	0.961%	0.998%	0.926%	0.960%		
BS	1.174%	1.170%	1.183%	1.142%	1.164%	1.155%	1.158%	1.129%		
BPBG	NF	NF	NF	NF	NF	NF	NF	NF		
			(GC Soft li	ner					
Samples	1	2	3	4	5	6	7	8		
ЕТОН	2.983%	2.980%	2.920%	2.954%	2.975%	2.936%	2.930%	2.937%		
DBP	0.380%	0.375%	0.364%	0.335%	0.380%	0.350%	0.348%	0.345%		
BPBG	1.010%	1.054%	1.060%	1.068%	1.073%	1.011%	1.026%	1.070%		
BS	NF	NF	NF	NF	NF	NF	NF	NF		

Table: 8 Leached out components after 2weeks for Visco Gel, Coe Soft and GC Soft liner

	Visco Gel											
Samples	1	2	3	4	5	6	7	8				
ЕТОН	3.760%	3.750%	3.752%	3.754%	3.785%	3.710%	3.715%	3.713%				
DBP	1.340%	1.375%	1.379%	1.356%	1.338%	1.358%	1.391%	1.385%				
BPBG	2.190%	2.195%	2.175%	2.130%	2.134%	2.150%	2.154%	2.185%				
BS	NF	NF	NF	NF	NF	NF	NF	NF				
	Coe Soft											
Samples	1	2	3	4	5	6	7	8				

ETOH	4.680%	4.685%	4.690%	4.678%	4.630%	4.678%	4.675%	4.640%			
DBP	1.750%	1.770%	1.730%	1.740%	1.760%	1.765%	1.793%	1.760%			
BS	1.890%	1.850%	1.854%	1.830%	1.885%	1.880%	1.865%	1.854%			
BPBG	NF										
Table: GC Soft liner											
Samples	1	2	3	4	5	6	7	8			
ЕТОН	4.950%	4.970%	4.975%	4.963%	4.910%	4.950%	4.980%	4.970%			
DBP	1.010%	1.015%	1.018%	1.070%	1.075%	1.085%	1.095%	1.094%			
BPBG	2.345%	2.450%	2.430%	2.350%	2.378%	2.365%	2.450%	2.350%			
BS	NF										

Table 9: Leached out components after 4weeks for Visco Gel, Coe Soft and GC Soft liner.

Variable	Groups	Mean±S.D	P-	Mean±S.D	P-value	Mean±S.D	P-value	Mean±S.D	P-value
		2 hrs	value	24 hrs	24 hrs	2 weeks	2 weeks	4 weeks	4 weeks
			2 hrs						
ЕТОН	Group A	0.146±0.020		0.962±0.020		2.177±0.016		3.742±0.027	
	Group B	0.827±0.023	<	1.347±0.016	<	2.848±0.017	<	4.670±0.022	<
	Group C	0.464 ± 0.021	0.0001	0.642±0.322	0.0001	2.952±0.025	0.0001	4.958±0.022	0.0001
			(sig)		(sig)		(sig)		(sig)
DBP	-	-	-	0.138±0.018		0.454±0.019		1.356±0.020	
				0	<	0.958±0.022	<	1.758±0.019	<
				0.460±0.020	0.0001	0.360±0.017	0.0001	1.058±0.037	0.0001
				0.042±0.016	(sig)		(sig)		(sig)
BS	-	-	-	-	-			2.162±0.024	
						0.475±0.045	<	1.864±0.020	<
							0.0001	-	0.0001
						1.159±0.018	(sig)		(sig)
						-			
BPBG	-	-	-	-	-	-		_	
						-	<	-	<
						1.046±0.027	0.0001	2.390±0.046	0.0001
							(sig)		(sig)

Table: 10- Mean and Standard Deviation of HPLC Analysis after 2 hrs, 24hrs, 2 weeks and 4 weeks.

Discussion:

Ill-fitting dentures can be due to difficulties and discrepancies encountered in the fabrication of the prosthesis, prolonged use and also due to alteration of tissues in systemic disorders. The reaction may range from simple denture

stomatitis to hyperplasia. To overcome this condition an alternative is the use of soft liners/tissue conditioners. [9],[10],[11]

The silicone rubber materials are basically composed of polymers of dimethylsiloxane that can be cross linked to give good elastic properties. [12] They are without any plasticizer content, so no leaching of plasticizer is present in silicones, they retain their viscoelasticity and softness for longer periods. The disadvantage in using silicone soft liners is presence of little or no chemical adhesion to PMMA denture base resin. Primo adhesives are supplied by manufacturers to aid in bonding of silicone soft denture liners with denture base resins. Therefore the bond strength depends upon the tensile strength and the adhesive used. Adhesion failure between silicone resilient denture lining materials and the denture base is commonly encountered in clinical practice. [13], [14] Kimoto S et al in 2006, [15] found that the bond strength of soft denture liners to PMMA denture base resins is weak and when separated the area become unhygienic. Clinically, the ability of denture reline materials to resist de-bonding and internal fracture is extremely important, so evaluation of bonding of different denture soft lining materials to PMMA denture base resins is gaining importance in the field of research.

The bond failure was determined by the tensile strength which is ultimate strength properties in tension. According to **McMordie R in 1989**, ^[16] clinically the stress exerted on the interface of two materials is more closely related to shear and tear. **Smith and Bates in 1965**, ^[17] and **Kawano F in 1992** ^[18] considered the tensile test a good method of investigating the bond strength of resilient lining materials, because it gives information on the strength of the bond in comparison to the tensile strength of the material.

In present study Visco gel, Coe soft and GC soft liner were studied over a period of

time and aluminum die was used as a standard. The compliance of these materials were studied at the specific periods i.e. 2hrs, 24hrs, 1week, and 4weeks, using modified penetrometer as done by Nicholas J.A. Jepson etal.^[9]

The derived value of compliance, offered a quantitative and reproducible description of the changes in the physical properties of the material.

The clinical compliance of Coe soft, Visco gel, GC Soft liner were measured individually using modified penetrometer. The manufactures recommended period of use in the oral cavity is between 3-4 weeks. Hence it was decided to test the specimens at 2hrs, 24hrs, 2weeks and 4weeks.

Concurrent with present study evaluation of the chemicals leached out from the test samples was studied using high performance liquid chromatography (HPLC). HPLC is used for analyzing the molecules that are dissolved in a solvent. The solvent is qualitatively and quantitatively analyzed to find out the leached out components of the specimen. The test samples were placed in artificial saliva (solvent) for a specified period of time, and test analysis were performed. Similar study has been done by **Minoru Kawaguchi et al**^[10] and **Aditi Sharma et al**^[19] using the HPLC test to study the amount of leach able monomers of a light activated reline resin.

Tensile bond strength was also compared between the above mentioned temporary soft lining materials placed between two acrylic rectangular blocks by using universal testing machine.

The results of present study show that all the three test material has maximum tensile bond strength when tested at 2hrs (Table 1, Graph 1). The mean value of tensile bond strength at 2hrs GroupA (Visco gel) was 1.354, Group B (Coe soft) was 3.611, and GroupC (GC soft liner) was 3.982(Table 2, Graph 1).

There was significant change in tensile bond strength for each test material over a period of 4weeks (Table 1 and 2, Graph 2) when the samples were immersed in artificial saliva which is consistent with study done by **Ayse Mese et al.**^[20] Group A (Visco gel) showed the least change mean value 0.691. This result can be inferred as absorption of fluid by the temporary soft lining materials as well as leaching of the components. It is well known that water sorption alters the dimensions of denture polymers. Water sorption is a diffusion process whereby water molecules penetrate the polymer network and displace the denture polymer chains. The displacement of the polymer chains causes an expansion

that is reversible as polymer dries. However, repeated wetting and drying can cause irreversible warpage. In addition to effecting dimensional changes, water molecules act as plasticizers and facilitate the movement of polymer chains which decreases the strength of the polymer as found by **Yutaka et al.**^[21]For clinical compliance, the results of this study show that all three test materials have similar initial clinical compliance when tested at 2hrs (Table 3). The mean values of clinical compliance at 2hrs GroupA (Visco gel) - 1.091, Group B (Coe soft)-1.350, GroupC (GC soft liner)-1.408 (Graph 3,4and 5 Table 4).

There was significant change in compliance over a period of 4weeks for each test material (Table 4). There was a statistically difference of change in compliance when the three groups were compared with each other. When the change in compliance between 2 to 24hrs of material Group A and C were compared there was no significant difference (Table 5).

The HPLC analysis show that ethanol leached out first in all the three samples which was seen in first 2hrs test results(Table 6), the mean value 0.146(Visco gel), 0.827(Coe soft), 0.464(GC soft liner) as shown in (Table 10). Dibutyl pthalate was seen to leach out in all the three samples and was present in 24hrs test samples (Table 7), the mean value (Visco gel)- 0.138, (Coe soft) 0.460), (GCsoft liner) 0.042 as shown in (Table 10).

Butyl pthalyl glycolate leached out at 2week from the two test samples (Table 8) with mean value (Visco gel) 1.159 and (GC soft liner) 1.058. Benzyl salicylate leached out at 2week from (Coe soft) the mean value is 1.159 as shown in (Table 10). Butyl pthalyl butyl glycolate leached out at 4weeks from the two test samples (Table 9) the mean value (Visco gel) -2.162, and (GC soft liner)-2.390 as shown in (Table 10). Benzyl salicylate leached out at 4weeks from Coe soft the mean value is 1.864 as shown in (Table 10).

The amount of ethanol, Dibutyl pthalate, butyl pthalyl butyl glycolate/ benzyl salicylate leached out increased from 2hrs – 4weeks. Similarly there was an increase in the amount of Dibutyl pthalate leached out from 24hrs – 4weeks. Butyl pthalyl butyl glycolate/ benzyl salicylate was last to leach out and increased from 1week to 4weeks.

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Correlating the above said tests for the various test specimens, it was found that the initial loss of ethanol between 2hrs-24hrs caused statistically insignificant change in compliance of all the three test samples.

On further testing it was found that loss of ethanol and plasticizer produced a significant change in compliance over a period of 2weeks, loss of butyl pthalyl butyl glycolate produced more significant change in compliance as seen in Visco gel and GC soft liner than the loss of benzyl salicylate as seen in the case of Coe soft. Further test at a period of 4weeks reiterated the same result i.e. loss of plasticizer like butyl pthalyl butyl glycolate produced more significant change in compliance as compared to benzyl salicylate.

This result can be inferred as the loss of ethanol and Dibutyl pthalate for all the three groups was similar. These results could be due to the difference in molecular size. Benzyl salicylate being larger molecule would leach out slower than butyl pthalyl butyl glycolate which would leach out faster and hence lead to deterioration of the physical properties as was found by **H.Murata et al in** 1998, [22] 2001^[23] and 2008^[24] and Wallaput S et in 2010. [25]

Conclusions:

The result in present study will help dentists in selecting better denture liners for their patients subject to their individual needs. In present study the physical properties of soft denture liners were reviewed under watersorption and solubility, tensile bond strength, leachability and viscoelasticity. Therefore, it is safe to say that silicone-based soft denture liners are better suitable to long-term clinical usage at particular time interval.

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Conflict of Interest:

There are no conflicts of interest

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