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The Compliance of Temporary Soft Lining Materials-An in vivo & vitro study

Dr. N.Shanmuganathan, Dr.T.V.Padamanabhan, Dr.R.Subramaniam, Dr.S.Madhankumar

***Abstract*- Objective:** The purpose of this study was to evaluate the change in clinical compliance of the three selected soft lining materials during use (in vivo) and also to analyze the leached out component during use. (In vitro)

Methods and materials: Three soft-liner materials (Visco-gel, Coe-soft, GC Soft liner) were studied. Three circular depressions were made on the intaglio surface of the posterior palatal seal region, and they were filled with the three selected soft lining material and marked as A, B, C. Modified penetrometer was used to test the clinical compliance of the material over a period of 2 hrs, 24 hrs, 1 week and 4 weeks after the denture was inserted. An in vitro study was conducted to find out the leachable components, both qualitatively and quantitatively with the use of high performance liquid chromatography and the clinical findings were correlated.

Results: Paired t-test was applied to analyze the data. It was found that compliance of Visco-gel reduced the most in the 1st week which was followed by GC Soft liner over a period of 4 weeks followed by Coe Soft. In vitro study revealed that initial loss of ethanol was shown by HPLC test which caused the reduction in compliance.

Conclusion: The results of this study indicated that physical property of the materials mainly depend on the type of plasticizer used and not ethanol that is present in most of the tissue conditioners. It could also be inferred that the use of plasticizer with large molecular size like benzyl salicylate, would preserve the physical property of the material over a longer period of time.

***Index Terms*-** Soft-liners, Clinical Compliance, High performance liquid chromatography

I. INTRODUCTION

The inflammation and accompanying edema of the soft tissue underlying ill-fitting dentures have been the concern for many years. In the past, management of these patients, and those with congenital or acquired abnormalities, systemic disturbances or a combination of these, using hard and rigid polymers was very difficult if not impossible. The use of material designed to recondition abused denture supporting tissues and to restore a normal healthy state was reported by Chase [12]. Since then, these class of dental materials have stimulated several clinical and laboratory studies and there are many products designed to produce, tissue conditioning of the soft tissues underlying dentures". Clinicians who have long been aware of these materials can be effective in relieving the pain, discomfort and inflammation associated with this situation. In these conditions, tissue conditioners are used to treat the abused mucosa. These materials will confirm to the anatomy of the residual ridge and gel in that position and continue to flow slowly after application. The purpose of the soft liner is to absorb some of the energy produced by masticatory impact that would otherwise be transmitted through the denture to the soft mucosal tissues.

The soft relining material can be either temporary or permanent. The temporary soft relining material which set intra-orally inside the mouth, can be used for a short period (up to several weeks) to improve the comfort and fit of the complete denture until it can be remade or permanently relined. After a few weeks they begin to foul smell and debond from the denture. Hence this material has to be replaced often. The permanent soft relining material (processed soft liners) is used in a patient who is wearing a complete denture and experiencing chronic soreness with their dentures, may be because of heavy bruxism or poor oral health. These materials are processed in the laboratory in a manner similar to denture base. They may remain resilient up to a year. After which they tend to debond from the denture base or become porous and foul smelling.

These soft lining materials are mainly made up of polyethyl methacrylate or polymethyl methacrylate resin added with plasticizer such as Dibutyl Phthalate or Ethanol. During use, these materials may become more rigid and inelastic due to loss of alcohol. The most important characteristic physical property of resilient denture liners is their elastic modulus. The reciprocal of the elastic modulus is called compliance, which is also referred to compressibility of the material. A compliance measurement gives the flexibility of the material. Reduction of these properties as a result of constant use in an oral cavity has been its great disadvantage. Hence this study was done to assess the resilient property and the loss of this property during intraoral use and to analyze the leachable component of these materials by in vitro to correlate with loss in the resilient property of these materials.

II. MATERIALS AND METHODS

Ten completely edentulous patients were selected randomly among the patients attending the Dept of Prosthodontics in the Saveetha Dental College, Chennai for replacement of their missing teeth. Convenience sampling technique was adopted for selecting the patients. The inclusion criteria included patients from both the genders, having completely edentulous area in both the maxillary and mandibular arch. All the individuals who were selected for this study had extracted their teeth before one year, with complete healing of the ridge, and it was also ensured that no pathological conditions existed in the oral cavity at the time of this study. Consent of the patient was obtained after explaining the purpose of the study and its procedures that would be followed during its conduct.

Clinical phase: Ten patients were selected and complete dentures were constructed in the conventional methods. On all the ten selected maxillary dentures, three circular depression, in the right (A) , centre (B) and left (C) on the intaglio surface of the posterior palatal region measuring about 4mm diameter x 2mm depth in dimensions were made(figure-1). This region was selected due to the space available for the placement of test sample as done by David M Casey et al.[10] These depressions were filled with the following selected soft lining materials (Table 1) and placed in the oral cavity (figure-2).

(Table 1)

Product	Code	Manufacturer	Powder/ Liquid Ratio by weight	Composition	
				Powder	Liquid
Visco-gel	VG	DeTreyDivision, Dentsply Ltd, Weybridge, Surrey, England	1.25	PEMA(86.2%) PMMA(13.8%)	BPBG(86.9%) DBP(8.2%) EtOH(4.9%)
COE Soft	CS	Coe Laboratories Inc	1.34	PEMA(100%)	BS(35.1%) DBP(49.7%) EtOH(15.2%)
GC Soft-Liner	GC	G-C Dental Industry Co,Tokyo,Japan	1.25	PEMA(100%)	BPBG(80.9%) DBP(4.3%) EtOH(14.8%)

PEMA: Polyethyl methacrylic; PMMA: Polymethyl methacrylic; BPBG: butyl pthalyl butyl glycolate; DBP: dibutylpthalate; BS: benzyl salicylate; EtOH: ethyl alcohol. In which the right (A) was filled with Visco-gel, centre (B) was filled with COE Soft and left (C) was filled with GC Soft Liner.

Method of testing: The dentures were then tested for clinical compliance of each of the three samples of soft liner material using modified penetrometer and measured separately. This test was done after a period of 2 hrs, 24 hrs, 1 week and 4 weeks, after the denture was inserted. Modified flat end penetrometer needle probe was used to test the clinical compliance of the tested materials. Clinical compliance of each material, Visco-gel, Coe Soft and GC Soft liner were measured separately. The tests were performed according to Nicholas J.A Jepson et al.[9] A load of 30g was held constantly for five seconds, strain cured in during loading, recovery were recorded. Test was performed on three separate points on each specimen.

III. LAB PHASE

An in-vitro study was conducted to find out the leachable components, both qualitatively and quantitatively. This test was done to correlate with the clinical findings. The technique, HPLC (High performance liquid chromatography) was used for analyzing the molecules that are dissolved in a solvent. These solvents were qualitatively and quantitatively analyzed to find the leachable components of the specimen. Three samples of the relining material were made to the dimension 8.5mm in diameter and 2mm thickness(figure-3) according to Hironori Tsuchiya et al[11].These samples were placed in nano purified water (figure-4). Selectively the samples were removed from each test material after a period of 2 hrs, 24hrs, 1week, and 4 weeks and analyzed. The high performance liquid chromatography is a method used for separating molecules dissolved in a solvent. The solvent is qualitatively and quantitatively analyzed to find the leached out components of the specimen.

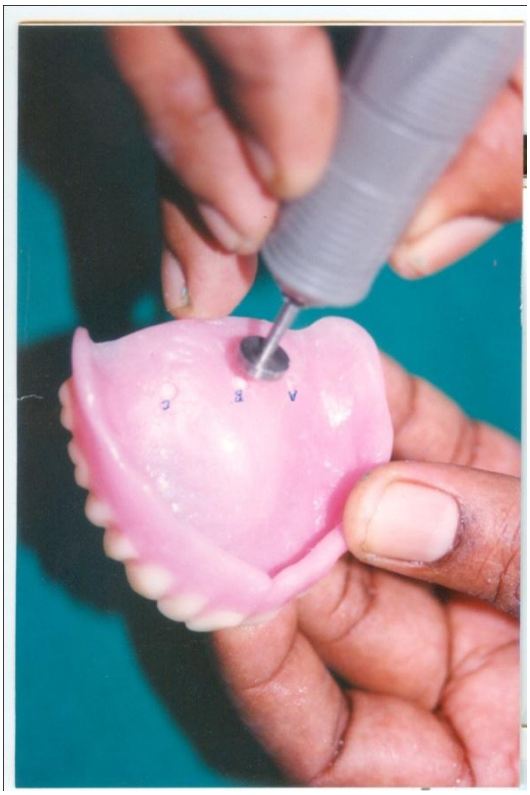

Figure 1: three circular depression created on the intaglio surface

Figure 2: depressions filled with selected three different soft lining materials

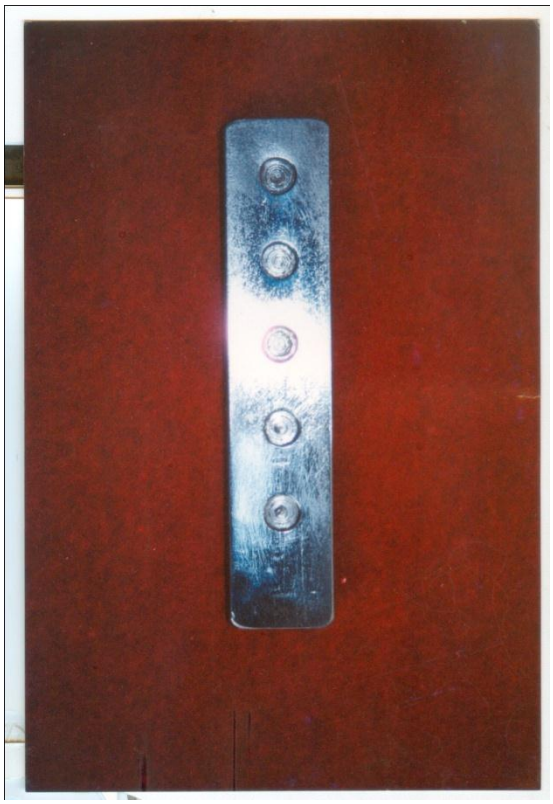

Figure 3: Dyes made for preparing the samples

Figure 4: All the three samples immersed in the nano purified water

Similar study has been done by Minoru Kawaguchi et al[13] using the HPLC test to study the amount of leachable monomers of a light activated reline resin. The different solutes will interact with stationary phase to differing phase, due to difference in size, adsorption, partitioning etc. These differences allow the mixture components to be separated from each other and studied separately. This instrument consists of a column with a fritted bottom that holds the stationary phase. The mixture to be separated is loaded on to the top of the column. The different component in the solvents passes through the column at different rates due to difference in their partitioning behavior. The different solutes are studied using UV detector at different times when it passes through the column.

Qualitative analysis: Identification of different components of the samples was made by comparing retention time of different analysts with that of the standard.
Quantitative analysis: Quantization was done by comparison of the sample chromatogram with that of the standard. In this study, the peak height of the chromatogram was taken in to consideration.

IV. Results

Data were analyzed with IBM SPSS 19.0 version software. The descriptive statistics with ten numbers of samples in all the groups were shown in the table number 1 with their mean and standard deviation.
Table: 1 The table shows the mean and standard deviation of clinical compliance at 2 hours,24 hours, 1 week and 4 weeks for all the three groups. In group A, the mean value in 2 hours was 3.785 and it was decreased in the 4 week to 0.489. The same trend was shown in group B and group C.

Table:1

Descriptive Statistics			
	N	Mean	Std. Deviation
Group A-2hrs	10	3.78520	.112252
Group B 2hrs	10	4.78380	.009271
Group C 2hrs	10	4.60800	.102940
Group A 24hrs	10	3.39120	.026097
Group B 24hrs	10	4.75200	.010893
Group C 24hrs	10	4.2321	.01022
Group A 1wk	10	1.44760	.010113
Group B 1wk	10	3.92930	.010371
Group C 1wk	10	2.76970	.010371
Group A 4wks	10	.48920	.006579
Group B 4wks	10	1.78330	.010371
Group C 4wks	10	.59290	.010225

Table 2: Paired sample t test was implemented to find out the significance between the groups A, B, and C during the time duration of 2 hours, 24 hours, 1 week and 4 weeks respectively.

Table: 2

Paired t-test			
Groups	T	Df	Sig. (2-tailed)
Group A-2hrs - Group B 2hrs	-27.490	9	.000
Group B-2hrs - Group C 2hrs	-26.584	9	.000
Group C 2hrs - Group A-2hrs	22.341	9	.000
Group A 24hrs - Group B 24hrs	-128.142	9	.000
Group B 24hrs - Group C 24hrs	89.648	9	.000
Group C 24hrs - Group A 24hrs	98.790	9	.000
Group A 1wk - Group B 1wk	-504.466	9	.000
Group B 1wk - Group C 1wk	292.305	9	.000
Group C 1wk - Group A 1wk	412.865	9	.000
Group A 4wks - Group B 4wks	-307.413	9	.000
Group B 4wks - Group C 4wks	252.371	9	.000
Group C 4wks - Group A 4wks	28.984	9	.000

- The identified p value was .0001

Table 3: The following table shows the mean and standard deviation of the three types of softliner during the duration of 2 hours, 24 hours, 1 week and 4 weeks respectively.

Table :3

Descriptive Statistics			
	N	Mean	Std. Deviation
VG 2 ETOH	6	.14050	.019398
CS 2 ETOH	6	.82000	.028014
GC 2 ETOH	6	.46183	.021321
VG 24 ETOH	6	.95900	.019647
VG 24 DBP	6	.14050	.018534
CS 24 ETOH	6	1.33967	.017189
CS 24 DBP	6	.45883	.019198
GC 24 ETOH	6	.46567	.024841
GC 24 DBP	6	.04617	.020913
VG 1W ETOH	6	2.16967	.018403
VG 1W DBP	6	.45083	.024045
VG 1W BPBG	6	1.16000	.018243
CS 1W ETOH	6	2.84867	.019997
CS 1W DBP	6	.95850	.025758
CS 1W BS	6	1.15850	.020226
GC 1W ETOH	6	2.95567	.023526
GC 1W DBP	6	.35967	.018085
GC 1W BPBG	6	1.05283	.028273
VG 4W ETOH	6	3.75050	.025774
VG 4W DBP	6	1.36500	.022680
VG 4W BPBG	6	2.16183	.023259
CS 4W ETOH	6	4.66283	.027007
CS 4W DBP	6	1.76067	.022367
CS 4W BS	6	1.86350	.023287
GC 4W ETOH	6	4.95533	.023636
GC 4W DBP	6	1.05283	.036141
GC 4W BPBG	6	2.36617	.029158

Table4: Paired sample t test was implemented to find out the significance between the soft liners with the time duration of 2 hours, 24 hours, 1 week and 4 weeks respectively. The table shows there was a significant difference between the three soft liners in the time period of 2 hours, 24 hours, 1 week and 4 weeks with the p value of .0001.

Table :4 Paired t-test

	t	df	Sig.(2-tailed)
VG 2 ETOH - CS 2 ETOH	-50.389	5	.000
VG 2 ETOH - GC 2 ETOH	-19.750	5	.000
GC 2 ETOH - VG 2 ETOH	19.750	5	.000
VG 24 ETOH - CS 24 ETOH	-33.817	5	.000
VG 24 ETOH - GC 24 ETOH	65.166	5	.000
CS 24 ETOH - GC 24 ETOH	85.758	5	.000
VG 24 DBP - CS 24 DBP	-30.522	5	.000
CS 24 DBP - GC 24 DBP	37.467	5	.000
GC 24 DBP - VG 24 DBP	-7.446	5	.001
VG 1W ETOH - CS 1W ETOH	-67.720	5	.000
CS 1W ETOH - GC 1W ETOH	-9.746	5	.000
GC 1W ETOH - VG 1W ETOH	77.877	5	.000
VG 1W DBP - CS 1W DBP	-32.927	5	.000
CS 1W DBP - GC 1W DBP	35.483	5	.000
VG 1W DBP - GC 1W DBP	7.817	5	.001
GC 1W BPBG - VG 1W BPBG	-8.592	5	.000
VG 4W ETOH - CS 4W ETOH	-59.107	5	.000
CS 4W ETOH - GC 4W ETOH	-15.576	5	.000
GC 4W ETOH - VG 4W ETOH	74.064	5	.000
VG 4W DBP - CS 4W DBP	-25.659	5	.000
CS 4W DBP - GC 4W DBP	63.990	5	.000
GC 4W DBP - VG 4W DBP	-15.559	5	.000
VG 4W BPBG - GC 4W BPBG	-13.366	5	.000

V. DISCUSSION

It is admitted that ill fitting dentures are bane to the patients and dental professionals. This may be due to poor fabrication of the dentures, prolonged use of the dentures and also due to systemic conditions like diabetes. These poor fitting dentures often abuse the basal tissue. The reaction may range from simple denture stomatitis to hyperplasia. The hard tissues may undergo accelerated resorption. The reason for this could be due to the pressure on the mental foramen; sharp bony spicules; thin, atrophic mucosa; bony undercuts, particularly in the mylohyoid region; irregular bony resorption; poor fit of the denture base; incorrect occlusal relationship; bruxism; and/or debilitating disease.[1] It is wise to decide whether the treatment should include remaking the prosthesis rather than simply relining a prosthesis for short-term benefit without a plan for long –term success. Research site the use of tissue conditioners to treat an abused mucosa during 1960s.[2-4] These materials stay intact to the anatomy of residual ridge and gel in that position and continue to flow slowly after application and distribute stress on denture –bearing tissues[3-6].These tissue conditioners have plasticizer or ethanol which being a low molecular weight compound is usually leached out in the saliva over a period of time. This leaching out may result in reduction in softness of the material, which may have a negative impact on the tissues. These materials are very porous; porosity of these materials imparts the quality of shock absorption. The adverse effect of the porosity is that it forms a nidus for easy colonization with fungi and other microorganisms. So prolonged therapy is usually not possible with this class of material. The other disadvantage is the marginal leakage between these liners and the denture base. Extensive study has been done regarding these physical properties and the influence of bacterial colonization and its manifestation on the tissue liner. But studies to elicit the change of physical properties of these materials in the oral environment have not been dealt much. Hence this study was conducted to measure the change in compliance of selected tissue conditioners i.e.; Visco gel, Coe soft, GC Soft-liner and correlate it with the type and amount of chemicals leached out from the tissue conditioners over a period of time. The clinical compliance of Coe soft, Visco gel, GC Soft liner were measured individually using the modified penetrometer. The manufacture's recommended period of use in the oral cavity is between 3-4 weeks and so it was decided to test the specimens at 2hrs, 24hrs, 1 week and 4 weeks. Concurrent with this study, evaluation of the chemicals leached out from the test samples was studied using High performance liquid chromatography (HPLC). The results of this study that all the three test materials have similar initial compliance when tested at 2 hrs had the mean value of compliance at 2 hrs Group A (Visco gel) – 3.785, Group B (Coe soft) – 4.783 and Group C (GC Soft liner) – 4.608.

There was a significant change in compliance over a period of 4 weeks for each of the tested materials. Group B (Coe soft) showed the least change (mean value 1.781) there was a

statistically significant difference of change in compliance when the material Group A, B & C were compared with each other. When the change in compliance between the material Group A and C were compared at a time period of 2-24 hrs there was no significant difference (t value- 0.41). The HPLC analysis showed that ethanol leached out first in all the three samples which was seen in the 2 hrs test results with the mean value of 0.1405 for Visco gel, 0.8200 for Coe soft and 0.4618 for Soft liner. Dibutyl phthalate was seen to leach out in all the three samples and was present in the 24 hrs test sample, the mean value for Visco gel was 0.1405 with a t-value of 74.23. The Coe soft had a mean value of 0.4588 with a t-value of 83.73 and GC Soft liner had the mean value of 0.0461 with the t-value 100.86.

Butyl pthalyl butyl glycolate leached out at 1week from the two test samples. The mean value for Visco gel was 1.1600 with the SD of .018243 and GC Soft liner was 1.0528 with the SD of .028273. Benzyl salicylate leached out at 1 week from Coe soft, the mean value was 1.1585 with the SD of .020226. Butyl pthalyl butyl glycolate leached out at 4 weeks from the two test samples. The mean value for Visco gel was 2.1618 with the SD of .023259 and for GC Soft liner it was 2.3661 and .029158. Benzyl salicylate leached out at 4 weeks from Coe soft and had the mean value of 1.8635 with the SD - .023287. The amount of ethanol, Dibutyl phthalate, butyl pthalyl butyl glycolate, benzyl salicylate increased from leaching out at 2 hrs to 4 weeks was measured.

Similarly there was an increase in the amount of Dibutyl phthalate from leaching at 24 hrs to 4 weeks. Butyl pthalyl butyl glycolate and benzyl salicylate was last to leach out and increased from 1 week to 4weeks.Correlating the above said tests for the various test specimens, it was found that the initial loss of ethanol between 2 hrs- 24 hrs 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 1 week, 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 to a period of 4 weeks retreated the same result i.e. loss of plasticizer like butyl pthalyl butyl glycolate produced more change than loss of benzyl salicylate. This result can be inferred as the loss of ethanol and Dibutyl phthalate for all the three test samples were similar. These changes could be due to the difference in molecular size. Benzyl salicylate being larger molecule would be leached out slower than butyl pthalyl butyl glycolate which would be leached out faster and hence lead to deterioration of the physical properties as found by H.Murata et al.[13]

Differences in base-line properties between materials probably reflect the combined effects of varying polymer composition, ethanol concentration, plasticizer type, and powder: liquid ratio. Reductions in compliance tended to reflect a material's baseline softness- the higher the baseline initial compliance, the greater the reduction. Baseline values of compliance and the differences in these values between materials were both significantly reduced such that at 28 days there were only small differences in compliance values that ranged from 0.14 mm/ N for CC to 0.5mm/ N for VG. Several authors have described that the viscoelastic properties best suited to their specific use as tissue conditioners or functional impression or temporary reline materials. These properties concern various combination of softness, elastic recovery, and plastic flow but have often been described only in relation to the gel formed after initial mixing. Continued changes in these properties over time are clearly important to their actual effectiveness. These were modified over time through a rapid reduction in compliance and increase in elastic recovery, a combination of properties ideally suited to its use as a functional impression material. The combination of high initial compliance and elastic recovery seen for CC and to a lesser extent CS would indicate a soft elasticity appropriate to tissue conditioning.[7-8]

VI. CONCLUSION

The study identifies that the use of a simple, modified penetrometer enabled a clear and reproducible characterization of the viscoelastic properties of four temporary soft lining materials.[10] These changes would be attributed to the loss of ethanol and plasticizers. Initial loss of ethanol which was shown by HPLC test was also the cause for reduction in compliance. But loss of plasticizers let too drastic reduction in clinical compliance. This was more apparent when butyl phthalate butyl glycolate was the plasticizer used in the soft liner where as the material using benzyl salicylate as the plasticizer showed less change than earlier ones.

Hence it can be concluded that physical property of the material mainly depends on the type of plasticizer used and not ethanol that is present in most of the tissue conditioners. It can also be inferred that use of plasticizer with large molecular size like benzyl salicylate, would preserve the physical property of the material over a longer period of time.

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AUTHORS

First Author: Dr. N.Shanmuganathan,
Professor, Department of Prosthodontics
Faculty of Dental Sciences, Sri Ramachandra University
Chennai – 600 116, India
Phone: +91 9840231829
Email: shansdr@yahoo.co.in

Second Author: Dr.T.V.Padamanabhan
Professor and HOD, Department of Prosthodontics
Faculty of Dental Sciences, Sri Ramachandra University
Chennai – 600 116
India

Third Author: Dr.R.Subramaniam
DEAN, Noor-ul Islam Institue of Dental sciences
Kerala, India

Forth Author: Dr.S.Madhankumar
Senior Lecturer, Department of Prosthodontics
Faculty of Dental Sciences, Sri Ramachandra University
Chennai – 600 116
India