

Evaluation of Surface Integrity and Softness of a Tissue Conditioner on Application of Two Different Surface Coatings at Different Time Intervals: An In Vivo Study

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ABSTRACT

Background: Tissue conditioners are required to function over relatively long time to treat inflamed, irritated, or distorted tissues. Most currently available materials have a short life span (three to four days).

Objectives: This in vivo study was designed to evaluate and compare the effect two different surface coatings on surface integrity and softness of tissue conditioner over a period of time.

Materials & Methods: In this in vivo study ten completely edentulous subjects with moderate ridges were selected. Maxillary and mandibular complete dentures were fabricated. Six troughs (3×5×2 mm) were prepared in maxillary denture. They were filled with chemically cured tissue conditioner and covered with different surface coatings. Dentures were inserted in the patient's mouth with proper instructions. The patients were recalled after one week and four weeks. The specimens were tested with Scanning Electron Microscope for surface integrity and with Shore A Durometer for softness. Statistical differences were determined with analysis of variance ($p < 0.05$).

Results: Statistically significant difference was noted between control, Monopoly and Permaseal coated tissue conditioner. Scanning Electron Microscope analysis indicated that the control group deteriorated by the end of the first week, whereas both Monopoly and Permaseal remained intact for up to one week. All groups showed some amount of deterioration by the end of four weeks.

Keywords: Tissue conditioner, Monopoly, Permaseal, Softness, Surface sealer.

INTRODUCTION

Resilient liners for dentures are used with the hope of minimizing pressure and trauma to the supporting tissues without sacrificing contact.^[1] Tissue conditioners should remain soft during use in order to maintain an adequate cushioning effect on the underlying soft tissues. The material should be resilient in order to absorb

masticatory loads without causing permanent deformation of the lining. The use of coating is one of approaches to preserve surface integrity, softness and is practiced for many years to reduce the growth of microorganisms in tissue conditioners.^[2] Gardner and Parr^[3] reported and recommended that coating the surface of a tissue conditioner with Monopoly, which is poly methyl methacrylate syrup made from one part clear heat cure polymer

Received: Jan. 21, 2016; Accepted: Mar. 6, 2016

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powder to ten parts auto-polymerized monomer, increases the life of the tissue conditioner up to one year. The coating remained clean and smooth, reduced the incidence of bacterial and fungal growth, and allowed the temporary liner to maintain its resilient characteristics for an extended period. Casey and Scheer^[4] compared three surface treatments of a tissue conditioner and found that surface treatment with Monopoly resulted in an improved glassy surface that lasted for thirty days intraorally. Two most important ideal features of clinically functioning tissue conditioners are surface integrity and softness. The wet environment of the oral cavity allows the ethanol and ester plasticizer to be leached into saliva and water is then absorbed by the polymeric phase of the gel. ^[5]The loss of plasticizer leads to gradual hardening of the material. The loss of surface integrity can irritate the denture bearing areas and create an environment for the colonization of oral micro-organisms.

Currently available tissue conditioners require replacement at short intervals, which is time consuming and expensive for both the dentist and patient. There is a need to improve the longevity of these tissue conditioners to overcome this problem. This in vivo study was designed to evaluate and compare the effect of different surface coatings on surface integrity and softness of a tissue conditioner over a period of time.

MATERIAL AND METHODS

Visco-Gel Temporary Soft Denture Liner, Dentsply DeTrey GmbH, Germany

Mono Poly Surface Sealer

Permasoft Sealer, Dentsply DeTrey GmbH, Germany
Heat Cure Acrylic Material (Dental Products of India, 9, Wallace Street, Fort, Mumbai, India)

Self Cure Acrylic Material (Dental Products of India, 9, Wallace Street, Fort, Mumbai, India)

Equipment Used For This Study:

Shore A Durometer (Model: SHR-MARK III, ASTM-D)

Scanning Electron Microscope (Hitachi, Model: 3400N)

Sputter Coater Machine (Emitech)

Straight Fissure Bur

Diamond Discs

Glass Beaker and Stirrer

Water Bath

This in vivo study was conducted to evaluate the effect of two different surface coatings, Mono Poly Surface Sealer (Monopoly) and Permasoft Sealer, Dentsply DeTrey GmbH, Germany (Permaseal) on the surface integrity and softness of a tissue conditioner, Visco-Gel Temporary Soft Denture Liner, Dentsply DeTrey GmbH, Germany (Visco gel) over a period of time.

Methodology

Selection of clinical material:

Seven male and three female completely edentulous patients with mean age of 55.1 years were selected randomly from the Department of Prosthodontics, for this study. Ethical clearance from institutional ethical committee, and informed consent was obtained from the subjects before starting the study. Patients with completely edentulous maxillary and mandibular arches and good general health status were included in the study. Patients with severe atrophy of the edentulous arches, unstable and non-retentive dentures, non-wearing of opposing mandibular prosthesis and decreased salivary flow were excluded from the study.

Preliminary impressions of the selected patients were made with Impression Compound using stock edentulous trays. Custom trays were made with self-cure acrylic resin, border molding was done with green stick modeling compound and final impressions were made with Zinc oxide Eugenol impression paste. After recording jaw relations and teeth arrangement trial was performed to verify the vertical, horizontal relations and esthetics. Patient's feedback and acceptance of the complete dentures were obtained. The dentures were then processed, delivered and post insertion instructions were given. Post insertion adjustments were done until the patients were free of tissue irritation and were comfortable with their dentures after which the patients' dentures were used for the study. Visco-gel (tissue conditioner) used in this study is supplied in powder and liquid form. Powder contains Poly ethyl methacrylate and liquid contains ethyl alcohol and citrate ester plasticizer.

Fig 1: Prepared Troughs in Maxillary Denture



Fig 2: Placement of Tissue Conditioner in the Troughs.

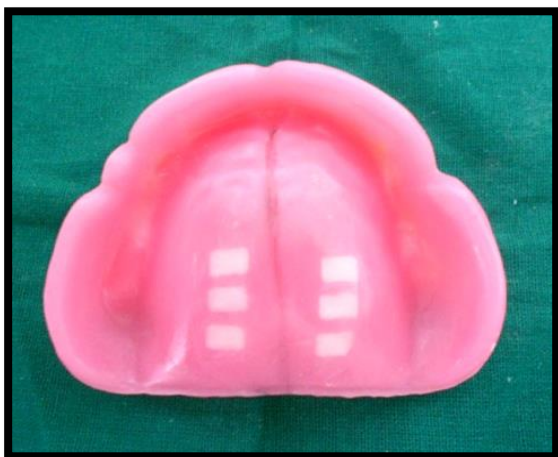


Fig 3: Application of Sealer.

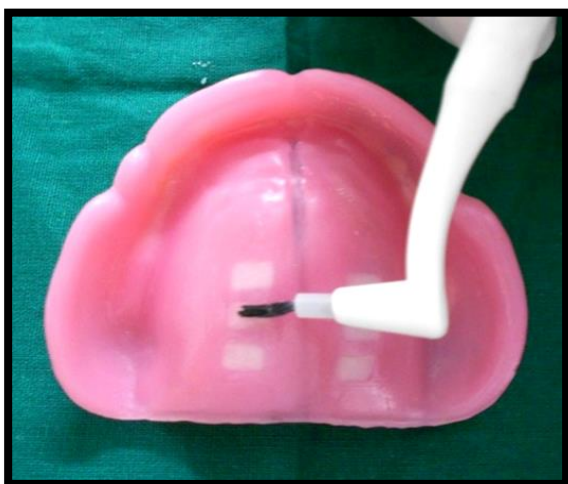


Fig 4: Retrieval of the Samples with Diamond Disc.



Fig 5: Maxillary Denture & Samples.

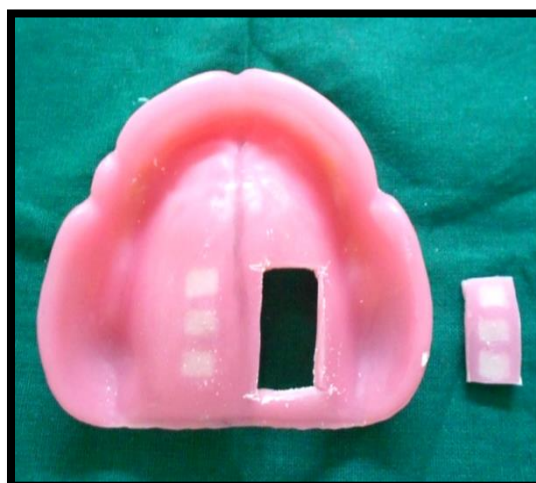


Fig 6: Separation of Individual Samples



Fig 7: Storage of Samples.



Fig 8: Shore A Durometer (SHR_MARK III, ASTM-D).



Fig 9: Scanning Electron Microscope (HITACHI Model: 3400N).



Fig 10: Sputter Machine (EMITECH).



Fig 11: Collected Samples.



Fig 12: Shore A Durometer with Specimen.



Fig 13: SEM Micrograph of Permaseal Coated Tissue Conditioner Surface Changes at 4th Weeks.

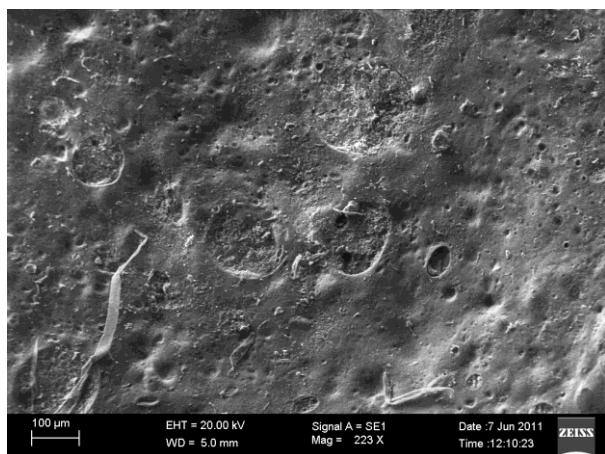
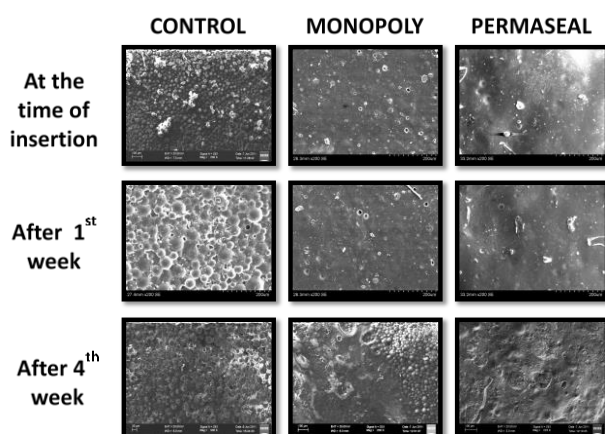


Fig 14: SEM Micrographs Of Tissue Conditioner Surface Changes At Different Intervals of Time.



Surface coatings used in this study are Monopoly and Permaseal. Mono poly is not commercially available but prepared according to the specific procedure described in the literature.^[6] Mono poly is a thin syrup-like mixture of semi set methyl methacrylate resin. One part of heat cured clear methyl methacrylate powder was mixed with ten parts of auto polymerizing clear orthodontic methyl methacrylate liquid. The powder and liquid are placed together in a glass beaker in a 130°F water bath and stirred for eight to ten minutes until the mixture starts to thicken. Mono poly is usually stored in a dark colored bottle in a refrigerator to extend its shelf life for future use. Perm seal is commercially available Permasoft Sealer, Dentsply. Its composition mainly consists of Methyl Ethyl Ketone (>60%). It is a clear, highly inflammable liquid with a characteristic “Ketone” odor.

Initially the tissue surface of the denture was prepared. A total of six troughs each 3×5×2 mm were prepared on the tissue surface of the maxillary denture [Figure.1]. Three troughs are prepared on the right and the left side on the tissue surface of the palate. Visco-gel tissue conditioner was mixed according to the manufacturer’s directions in a mixing jar with an agate spatula and placed in all the six troughs and the dentures were placed in the patient’s mouth and allowed to set for eight to ten minutes [Figure.2]. Of the three set surfaces on one side of the midline, first one was coated with Permaseal, second one with Mono poly and the third one was left uncoated which acts as control. Similarly the other three set surfaces were coated [Figure.3]. Prior to coating, the denture surface was dried with air and Mono poly sealer was applied to the tissue conditioner by using a good quality brush. It was then allowed to dry for four to five minutes. This procedure was repeated until two coats have been placed and dried. Permaseal was also applied similarly to the surface of the tissue conditioner.

These dentures were delivered to patients and instructed to wear for at least 8 hours in a day and store them in plain water for the remaining period of time. They were instructed to clean the dentures daily with a denture brush and to clean the six coated areas with a wet piece of gauge. Surface integrity and softness of the tissue conditioner and the health of each patient’s oral tissues were evaluated at the time of insertion, first week and fourth week post insertion.

Collection of Samples

At the end of first week, samples were collected from the maxillary denture. Three tissue conditioner loaded troughs on one side of the palate were removed with a diamond disc [Figures.4, 5 & 6] and that particular area was repaired using self cure acrylic resin material. The denture was delivered to the patient for further use and asked to report for evaluation at the end of fourth week. The samples were stored in distilled water [Figure.7] and evaluated for softness of control group, Monopoly and Permaseal coated group with Shore A Durometer (Model: SHR-MARK III, ASTM-D) [Figure.8] and surface integrity with Scanning

Table 1: Softness values of the uncoated tissue conditioner (control) compared to tissue conditioner coated with monopoly and Permaseal at the time of insertion.

S NO	CONTROL (shore A no)	MONOPOLY (shore A no)	PERMASEAL (shore A no)
1	25	22	20
2	24	22	20
3	25	20	20
4	23	20	18
5	22	23	19
6	26	21	20
7	27	23	22
8	28	23	22
9	29	24	21
10	27	20	19
MEAN	25.6	21.8	20
SD	2.221	1.476	1.155

*units are ASTM scale points

Table 2: Softness values of the uncoated tissue conditioner (control) compared to tissue conditioner coated with Monopoly and Permaseal1st week post insertion.

S NO	CONTROL (shore A no)	MONOPOLY (shore A no)	PERMASEAL (shore A no)
1	36	29	25
2	35	29	27
3	36	30	24
4	36	27	28
5	34	28	23
6	35	31	28
7	36	26	23
8	37	28	24
9	35	27	27
10	38	30	25
MEAN	35.8	28.5	25.4
SD	1.135	1.581	1.955

*units are ASTM scale points

Table 3: Softness values of the uncoated tissue conditioner (control) compared to tissue conditioner coated with Monopoly and Permaseal4th week post insertion.

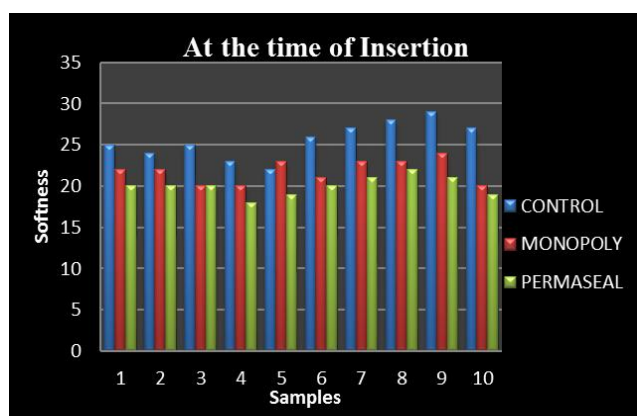
S NO	CONTROL (shore A no)	MONOPOLY (shore A no)	PERMASEAL (shore A no)
1	45	40	35
2	44	40	31
3	43	39	30
4	42	38	32
5	43	37	33
6	40	36	31
7	45	38	34
8	44	39	34
9	41	35	32
10	42	37	33
MEAN	42.9	37.9	32.5
SD	1.663	1.663	1.581

*units are ASTM scale points

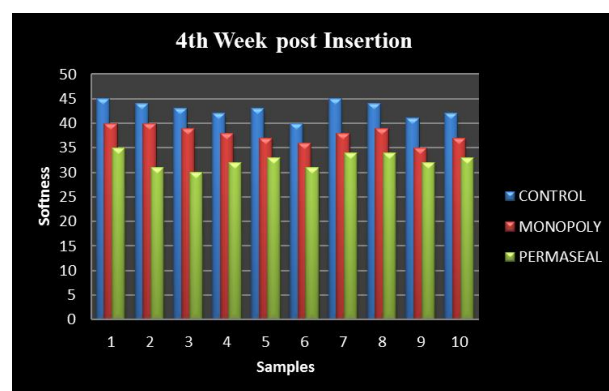
Table 4: Results of ANOVA and Tukey's post hoc analysis for softness values of all variables.

Time	Mean Differences and Standard Error			ANOVA	Tukey's
	Control & monopoly (1&2)	Control & Permaseal (1&3)	Monopoly & Permaseal (2&3)	F, p & values	significance
At the time of Insertion	3.8 (0.750)	5.6 (0.750)	1.8 (0.750)	F=29.037 P<0.00001	T(1&2)=0.000 T(1&3)=0.000 T(2&3)=0.059
1 st week	7.30 (0.712)	10.4 (0.712)	3.1 (0.712)	F=112.375 P<0.00001	T(1&2)=0.000 T(1&3)=0.000 T(2&3)=0.000
4 th week	5 (0.732)	10.4 (0.732)	5.4 (0.732)	F=101.029 P<0.00001	T(1&2)=0.000 T(1&3)=0.000 T(2&3)=0.0000

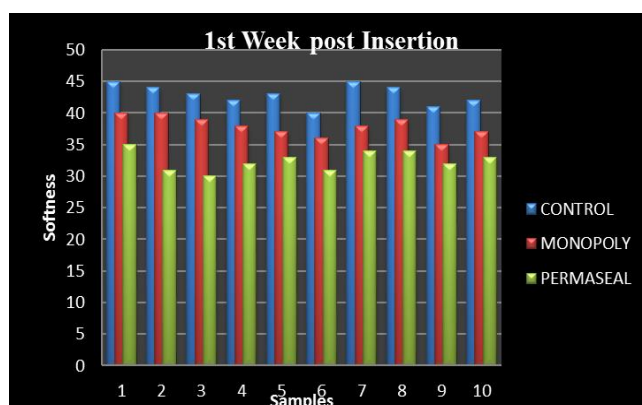
* The mean difference is significant at the 0.05 level.



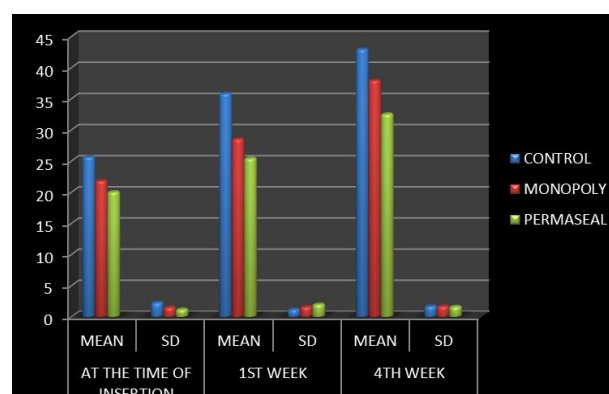
Graph 1: The basic data of the results obtained for softness of uncoated tissue conditioner (control), Monopoly and Permaseal coated tissue conditioner at the time of insertion.



Graph 3: The basic data of the results obtained for softness of uncoated tissue conditioner (control), Monopoly and Permaseal coated tissue conditioner 4th week post insertion.



Graph 2: The basic data of the results obtained for softness of uncoated tissue conditioner (control), Monopoly and Permaseal coated tissue conditioner 1st week post insertion



Graph 4: The comparison of Mean and Standard Deviation values of softness for uncoated tissue conditioner (control), Monopoly and Permaseal coated tissue conditioner at the time of insertion, 1st week and 4th week of post insertion.

Electron Microscope (Hitachi, Model: 3400N)[Figure.9].

The samples are dried with a tissue paper and tested for softness of the tissue conditioner with a Shore A Durometer. Durometer has a measurement range of 0 to 100 points on the ASTM (American Standards for Testing Materials) scale. Lower points on the scale indicate greater softness of the tissue conditioner. The tests were carried out at $20^{\circ}\text{C} \pm 2^{\circ}$ as per DIN 53505 or $76^{\circ}\text{F} \pm 6^{\circ}$ as per ASTM D 676-59T at $73.4^{\circ}\text{F} \pm 1.8^{\circ}\text{F}$ as per ASTM D 2240-75. The specimens were placed on a tester stand and three tests were carried out on each specimen and the mean value of these three readings was rounded off to a Shore number.

Specimens were coated with gold in Gold Sputter Machine [Figure.10] and observed for surface integrity at 200 X under Scanning Electron Microscope. At the end of fourth week, samples were collected stored in distilled water and evaluated for softness and surface integrity as done at first week [Figure.11, 12 & 13].

SEM analysis indicated that the surface integrity of the control specimens deteriorated by the end of the first week, whereas both Monopoly and Permaseal coated tissue conditioners remained intact for up to one week. All groups demonstrated some deterioration by the end of four weeks [Figure 14]. The values were tabulated and subjected to statistical analysis using one-way ANOVA and Tukey's post hoc analysis. In this present study, $p < 0.05$ is considered as level of significance.

RESULTS

The measured softness values, Mean and Standard Deviation of uncoated tissue conditioner (control), tissue conditioner coated with Monopoly and Permaseal at the time of insertion, after one week and four weeks of post insertion were tabulated in Tables 1, 2 and 3. It was observed that Shore A values were high with control group than the coated groups at the time of denture insertion, one week and four weeks post insertion. Table 4 represents the results of ANOVA and Tukey's analysis for softness values of uncoated tissue conditioner (control) compared to tissue conditioner coated with Monopoly and Permaseal at the time of insertion, 1week and 4weeks of post

insertion. $p < 0.00001$ implies that all the groups significantly differed as far as softness is concerned. As per the Tukey's analysis of variance for one way classification, statistically significant difference was found between control group and monopoly, control group and Permaseal and also between Monopoly and Permaseal at different time intervals.

DISCUSSION

The characteristics of a good tissue conditioner are (1) as low an ethanol content of the liquid as possible. (2) reasonable resilience consistent with a reasonable gelling rate to avoid distortion, under dynamic conditions.^[7] Hardening of tissue conditioners with age has been attributed to a sequence of three events: (1) ethanol loss (2) water absorption and (3) loss of plasticizer.^[8] Several studies were conducted in the past to enhance the life span of tissue conditioners, which include the preservation of surface integrity of tissue conditioner and maintenance of Visco elastic properties of tissue conditioner for a longer period of time.^[9]

Coating the porous surface of a tissue conditioner with a denture surface sealant increases the period of resiliency and over all longevity of the liners. This coating has the potential to provide greater stability and extended comfort from the prosthesis. One product proposed to improve the life span of tissue conditioners is Monopoly; a semi set methyl methacrylate syrup made up of one part clear heat cure polymer powder to ten parts of auto polymerized monomer.^[3]

In this present study, at the time of insertion the Mean softness value of control group was 25.6(Shore A no), Monopoly coated tissue conditioner was 21.8, and Permaseal coated tissue conditioner was 20 on ASTM scale. Lower points on the scale indicate greater softness of the tissue conditioner. At the end of first week and fourth week, the Mean softness value of control group are 35.8, 42.9, Monopoly coated group-- 28.5, 37.9, and Permaseal coated group – 25.4,32.5 on ASTM scale. This implies that the Monopoly coated and Permaseal coated tissue conditioners maintained softness for longer time compared to uncoated tissue conditioner.

The results of the present study coincides with Gardner and Parr,^[3] who reported that coating the surface of tissue conditioner increases the life of the material and also with Gronet, who suggested that the resiliency of the tissue conditioner coated with Permaseal or Monopoly is improved.^[9] This may be attributed to reduced leaching of the plasticizer, as well as the penetrant i.e. alcohol. In the present study, statistically significant difference was noted between control group, Monopoly, and Permaseal coated group at the time of insertion ($p < 0.00001$), one week ($p < 0.00001$) and four weeks ($p < 0.00001$) post insertion. The results suggested that the tissue conditioner coated with Monopoly and Permaseal surface sealers maintained softness for longer period of time compared to uncoated tissue conditioner (control). These findings coincide with the study conducted by Dominguez et.al in 1996 who stated that Monopoly coating acts as a barrier in preventing water absorption and the loss of plasticizer from the tissue conditioner.^[10]

In the present study, it was observed that the Permaseal coated tissue conditioner was more resilient and softer than Monopoly coated tissue conditioner. This finding coincides with the study conducted by Malmstrom in 2002, who found that application of Monopoly and Permaseal coating on GC tissue conditioner significantly reduced the surface deterioration and the loss of tissue conditioner softness.^[11]

In the present study, SEM analysis of control group, Monopoly coated group and Permaseal coated group have demonstrated deterioration of surface integrity by the end of four weeks. At the end of first week, surface integrity of Monopoly coated tissue conditioner and Permaseal coated tissue conditioner remained intact whereas the uncoated tissue conditioner demonstrated deterioration. SEM analysis indicated that the surface integrity is preserved in surface coated tissue conditioner because of lesser surface irregularities and decreased microbial colonization.

On the contrary, Ebandianet.al^[12] conducted an in vitro study on the softness of tissue conditioners coated with Monopoly at different time intervals and concluded that the Monopoly coating does not protect the softness of the tissue conditioners. The reason being that tissue conditioners with different

compositions, particle sizes, percentage of alcohol and plasticizers may lead to different treatments and interactions with surface coatings and affect the softness of the surface of the tissue conditioner. It seems that the in vitro and in vivo conditions of studies have different effects on results. The loss of ethanol and plasticizers are not identical for in vivo and in vitro conditions.

Clinical studies need to be conducted to confirm that surface coated tissue conditioners treat inflamed or abused tissues as effectively as uncoated tissue conditioners. Additional research on different brands of tissue conditioners coated with Permaseal and Monopoly is needed. Effect of tissue conditioner with surface coating on soft tissues needs to be studied for longer period of time.

Summary

This in vivo study was designed to evaluate and compare the effect of Monopoly and Permaseal surface sealers on surface integrity and softness of Visco-gel tissue conditioner over a period of time. In the present study, ten completely edentulous subjects were selected randomly from the Department of Prosthodontics and complete dentures were fabricated. On the intaglio surface of each subject's maxillary denture six troughs were prepared on right and left side of the palate and filled with Visco-gel tissue conditioner. Of the three tissue conditioner loaded troughs, one is coated with Monopoly surface sealant, the other with Permaseal and the third is left uncoated and is used as control group. The other side tissue conditioner loaded troughs were coated similarly. Softness of the samples of control group, Monopoly and Permaseal coated group were evaluated with Shore A Durometer (SHR-MARK III) and surface integrity with Scanning Electron Microscope (HITACHI) at the time of insertion, one week and four weeks after post insertion. The values were tabulated and subjected to statistical analysis using one-way ANOVA and Tukey's post hoc analysis.

Within the limitations of the present study, the following conclusions were drawn:

1. Monopoly and Permaseal coated tissue conditioner maintained softness for longer period of time compared to control group.

2. The softness of control group, Monopoly and Permaseal coated group decreased over a period of time.

3. Permaseal coated tissue conditioner was softer than Monopoly coated tissue conditioner over a period of time.

CONCLUSION

Surface integrity was maintained for a longer time when Permaseal and Monopoly coatings were applied to tissue conditioner than when left uncoated. Clinical studies need to be conducted to confirm that surface coated tissue conditioners treat inflamed or abused tissues as effectively as uncoated tissue conditioners. Additional research on other types of tissue conditioners coated with Permaseal and Monopoly is needed. Effect of tissue conditioner with surface coating on soft tissues needs to be studied for longer period of time.

CONFLICT OF INTEREST

No potential conflict of interest relevant to this article was reported.

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