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Research Article

In-Vitro Evaluation of Hardness Changes in Denture Soft Liners when Stored in Different Storage Media

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Abstract

Introduction: Complete dentures are a pair of acrylic plates simulating upper and lower alveolar ridges bearing a full set of maxillary and mandibular teeth that impart aesthetics to the face and rehabilitate the function of mastication for people who have lost all teeth.

Prolonged use of complete denture leads to pressure resorption of the alveolar ridges leading to denture instability. An unstable denture is incapable of even distribution of masticatory stresses leading to concentration of load at certain specific areas creating pressure points. These areas are often painful due to ulceration, inflammation or injury to oral mucosa from denture trauma.

Here comes in the role of denture reliners. Denture soft liners go a long way in enabling a dentist to ensure comfort and protection to a denture wearing patient with special needs.

Aim: To evaluate the changing hardness values of denture soft liners when stored for varying duration in different commonly available storage media.

Methodology: A total of 384 disc shaped samples of denture soft liners have been fabricated using ISO directives. These samples have been divided into groups I, II and III of 128 each, respectively made out of Mollosil (Detax, Germany), Reline Soft (GC, Japan) and Coe Soft (GC, Japan). Further, every group have been divided into subgroups A, B, C and D consisting of 32 samples each which have been stored in artificial saliva, tap water, RO water and distilled water respectively. Again 32 samples in each subgroup have been divided into batches of 8 and studied at 4 different time intervals of 32 hours post fabrication, 7 days post immersion, 30 days post immersion and 90 days post immersion in each storage medium.

Results: The data was analyzed using two way ANOVA. The mean Shore A hardness just after fabrication of the samples (Day 2) ranges between 38.4 ± 0.2 to 42.7 ± 0.4. When immersed in storage media, the values indicate increase in Shore A hardness and the minimum increase in hardness is seen in artificial saliva. The maximum increase in hardness is seen in tap water.

Conclusion: It was concluded that the hardness of GC Coe Soft showed minimum changes over time and the best material for storage according to this study is artificial saliva.

Keywords: *Denture Soft Liner; Storage Media; Hardness; Plasticizers; Complete Denture; Pressure Ulcers*

Introduction

Complete denture is a vital addition to the lifestyle of a person whose teeth have been lost due to periodontitis, trauma or age. A complete denture is a pair of acrylic appliances that resemble the maxillary and mandibular teeth and gingiva. The purpose of the same is to improve or restore facial aesthetics and masticatory function.

Regular use of complete dentures for a long period of time may cause ridge resorption and loss of retention and stability of the denture. The compromised fit of complete denture causes uneven distribution of the forces of mastication and lead to concentration of stresses at particular regions leading to formation of pressure points. Very often these areas ulcerate with lot of pain inflammation and inability to wear dentures. This in turn hampers the patient's nutrition and quality of life. This is where the role of denture soft liners creep in.

Soft denture reliners improve the fit and comfort of prosthesis.

It plays a great role in fulfilling the ultimate goal of dentistry which is restoring lost occlusion and mastication of an edentulous patient.

The use of soft liners in clinical dentistry was first identified in 1961 [1]. The general uses of denture reliner includes enhancement of the fit of dentures, alleviation of problems of speech in cleft palate patients, protection of underlying oral mucosa, preservation of the bone from resorption in alveolar ridge areas. Moreover denture soft liners enable patients to continue using the denture due to alleviation of pain on pressures points and it also aids in healing after placement of implants [2].

In view of the different uses of denture soft liners, certain ideal requisites for a material to be named as denture soft liners would be biocompatibility, odourlessness, non-irritability to oral tissues, ease of use in laboratories and chairside, dimensionally stable over time, able to retain the desired properties over time, a strong bonding to Polymethyl methacrylate for long term use, low solubility in water and saliva, low absorption of storage media, unsuitability for fungal growth, sufficient surface wettability and acceptable aesthetics [2].

Denture soft liners can grossly be divided into two groups, namely permanent soft liner and acrylic temporary soft liner. The acrylic temporary soft liners are also known as tissue conditioners. The permanent soft liners can be further divided into groups based on chemical nature of the material used. The groups are autopolymerized silicone, Heat polymerised silicone, autopolymerized acrylic resin and Heat polymerised acrylic resin [2].

According to ISO 10139 - 1:1991, Part I, a short term soft liners can be used for a period of 30 days whereas long term ones can retain their resilience for longer than 30 days and almost upto 1 year [3].

Silicone based denture soft liners can be either room temperature vulcanized (RTV) or heat cured (HTV). The room temperature vulcanized silicones are also known as auto polymerized soft liners. The auto polymerized soft liners are commercially available under names of Ufi Gel (VOCO, Germany), Mollosil (DETAX, Germany), Tokuyama soft (Tokuyama Dental, Japan), Mucopren soft (Kettenbach Dental, USA), Dentusil (Bosworth Company, USA), GC reline (GC, Japan) and so on. These materials are usually a set of two pastes. The catalyst paste usually consists of vinyl terminated poly dimethylsiloxane with a platinum counterpart. Vinyl terminated polydimethyl siloxane along with hydride terminated polydimethylsiloxane constitute the base paste. Both the pastes are mixed to trigger the hydrosilation reaction. These materials can be used 'chairside' due to low temperature requirements while curing. Their hardness is finally reached often 24 hours of curing which is significantly lower than the HTV silicones [2].

According to ISO 10139 - 2: 2009, liners are categorised as type A (soft) or type B (extra soft) when hardness is tested 24 hours after specimen preparation [4].

While in use, soft liners are in contact with saliva or soaked in storage media while not in use. This influences the hardness of the material due to leaching out of the plasticiser component as deduced from various studies conducted by esteemed researchers in the past [5].

Soft liners in general demonstrate certain disadvantageous physical properties like hardening over time, absorption of storage media, fungal growth if hygiene is not maintained and separation from acrylic base. These properties need improvement to save cost and precious time and of patient and dentist.

DN Mancuso., *et al.* (2009) conducted a study where they evaluated the change in hardness and colour of one resin based and one silicon based denture soft liners after accelerated ageing. They concluded that both the materials showed significant increase in hardness and change in colour after the ageing process [6].

Stability in hardness is an important property of denture soft liners since the primary function of the soft liner is to render softness and cushioning effect to the intaglio surface of a denture.

Hardness is the inherent physical property of a material that resists indentation or flexing when external force is applied.

The ISO and ASTM (American Society for Testing and Materials) proposed certain criteria for testing of hardness on denture soft liner samples. The proposed criteria include the use of Shore A method to determine the hardness of denture soft liners using standard measuring techniques.

Studies which involve aging of denture soft liner samples, must use sample thickness of greater than or equal to 6 mm. Samples which are thinner give unnecessarily high values leading to incorrect deductions [5].

The Shore A hardness values after 24 hrs of aging in distilled water at 37 degrees centigrade for soft liners is between 25 - 50 units while for extra soft liners, it's less than 25 units.

This study primarily focuses on the changing hardness or reduction of resilience in denture liners influenced by the storage media. It aims to deduce the best storage media from readily available ones for commonly used denture liners so that the foresaid purpose is served best. As studied previously by the researchers, when hardness of denture liners change, a failure in stress distribution function is seen which in turn damages the oral mucosa. Moreover, it also fails to adhere to the acrylic component well due to increased hardness.

Hence choice of the best storage media for long term efficiency of denture liners is an absolute necessity for preservation of money and time.

Materials and Methods

This study was conducted in Awadh Dental College and Hospital, Jamshedpur, to evaluate *in-vitro* changes in hardness of denture soft liners when stored in different storage media. Three commercially available denture soft liners have been used for comparison of hardness in this study post ageing in different storage media. All the denture liners are addition polysilicon resilient room temperature vulcanizing polyvinylsiloxane by nature. Various other materials have also been used as we progressed with this study. A detailed overview of the important materials and the method in which we progressed to create samples, age them in commonly used storage media and made the study significant is outlined here.

Materials

- Mollosil (Detax, Germany) (Figure 1)
- Reline Soft (GC, Japan) (Figure 2)

- Coe Soft (GC, Japan) (Figure 3)
- Artificial saliva (ICPA) (Figure 4)
- Tap water (Figure 5)
- RO Water (Figure 6)
- Distilled water (Figure 7)
- Vaseline.

Figure 1: *Mollosil (Detax, Germany).*

Figure 2: *Reline Soft (GC, Japan).*

Figure 3: *Coe-Soft (GC, Japan).*

Figure 4: *Artificial saliva (ICPA), 4th storage media.*

Figure 5: *Beaker of tap water, 1st storage media.*

Figure 6: *Beaker of RO water, 2nd storage media.*

Figure 7: *Beaker of distilled water, 3rd storage media.*

Instruments

- Green cloth (Figure 8)
- Metal mold (Figure 9)

Figure 8: *Green cloth.*

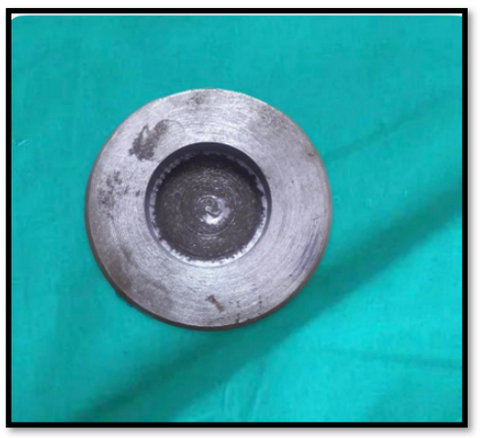

Figure 9: *Metal mold.*

- Glass slab
- Stainless steel spatula
- Beakers
- Type 2L mixing tips
- Mixing gun
- Silicone finishing point
- Scoop.

Equipments

Shore A Durometer (Figure 10).

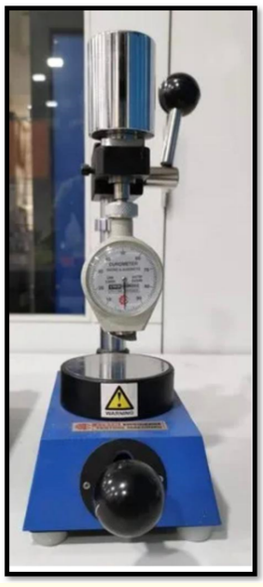

Figure 10: *Rubber Durometer for Shore A hardness testing.*

Methodology

Sample fabrication

Samples of different thickness underwent pilot testing in similar studies to reveal that the minimum thickness of a sample of denture soft liner to undergo Shore A Hardness testing is 6 mm and the testing must be done atleast 12 mm away from the edges of the sample. Keeping these references in mind, this study has used samples which are disc shaped and have a thickness of 8 mm and a diameter of 40 mm.

The samples were fabricated in uniform dimensions using a metal mold (Figure 11). Each material was manipulated in a way the manufacturers have instructed and polymerized accordingly.

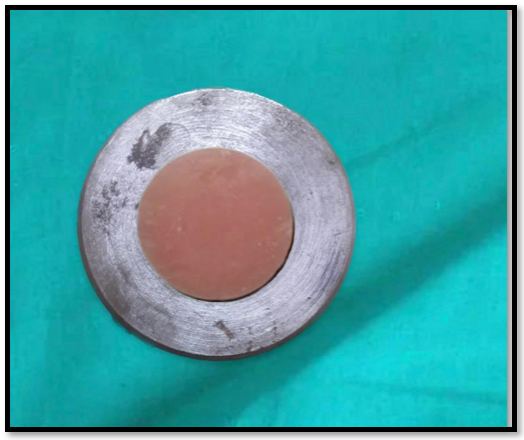

Figure 11: *Sample fabrication in metal mold.*

Division of samples

The sample size for this study has been estimated using the GPower software v. 3.1.9.4 [(Franz Faul, Universität Kiel, Germany).

Considering the effect size to be measured (f) at 45%, power of the study at 80% and the alpha error at 5%, the total sample size needed is 96. Each group will consist of 8 samples. [3 brands of soft liners x 4 storage media x 8 samples = 96 samples].

The study includes evaluation of hardness at 4 different time intervals, so the overall sample size required for the present study is 96 x 4 time intervals = 384 samples.

For conducting this study, a total of 384 disc shaped samples of denture soft liners have been fabricated using ISO 10139-2:2016 directives. These samples have been divided into groups I, II and III of 128 each, respectively made out of each brand of denture soft liner used in this study. Further, every group have been divided into subgroups A, B, C and D consisting of 32 samples each which have been stored in artificial saliva, tap water, RO water and distilled water respectively. Again 32 samples in each subgroup have been divided into batches of 8 and studied at 4 different time intervals of 32 hours post fabrication, 7 days post immersion, 30 days post immersion and 90 days post immersion in storage medium.

Group I: Mollosil self polymerizing denture soft liner has been used to fabricate 128 discs for the study of ISO specified dimensions each with the help of prefabricated metal mold. They have been then divided in to four subgroups of 32 samples each.

Subgroup IA: Out of the 32 disc shaped samples of Mollosil denture soft liner, 8 have been tested for hardness initially and rest of the 24 samples have been stored in artificial saliva at 37 degree centigrade to simulate oral conditions.

Subgroup IB: Out of the 32 disc shaped samples of Mollosil denture soft liner, 8 have been tested for hardness initially and rest of the 24 samples have been stored in tap water at 37 degree centigrade.

Subgroup IC: Out of the 32 disc shaped samples of Mollosil denture soft liner, 8 have been tested for hardness initially and rest of the 24 samples have been stored in RO water at 37 degree centigrade.

Subgroup ID: Out of the 32 disc shaped samples of Mollosil denture soft liner, 8 have been tested for hardness initially and rest of the 24 samples have been stored in distilled water at 37 degree centigrade.

Group II: Reline Soft self polymerizing denture soft liner has been used to fabricate 128 discs for the study of ISO specified dimensions each with the help of prefabricated metal mould. They have been then divided in to four subgroups of 32 samples each.

Subgroup IIA: Out of the 32 disc shaped samples of reline soft denture soft liner, 8 have been tested for hardness initially and rest of the 24 samples have been stored in artificial saliva at 37 degree centigrade to simulate oral conditions.

Subgroup IIB: Out of the 32 disc shaped samples of reline soft denture soft liner, 8 have been tested for hardness initially and rest of the 24 samples have been stored in tap water at 37 degree centigrade.

Subgroup IIC: Out of the 32 disc shaped samples of reline soft denture soft liner, 8 have been tested for hardness initially and rest of the 24 samples have been stored in RO water at 37 degree centigrade.

Subgroup IID: Out of the 32 disc shaped samples of reline soft denture soft liner, 8 have been tested for hardness initially and rest of the 24 samples have been stored in distilled water at 37 degree centigrade.

Group III: Coe Soft denture self polymerized denture soft liner has been used to fabricate 128 discs for the study of ISO specified dimensions each with the help of prefabricated metal mold. They have been then divided in to four subgroups of 32 samples each.

Subgroup IIIA: Out of the 32 disc shaped samples of Coe soft denture soft liner, 8 have been tested for hardness initially and rest of the 24 samples have been stored in artificial saliva at 37 degree centigrade to simulate oral conditions.

Subgroup IIIB: Out of the 32 disc shaped samples of Coe soft denture soft liner, 8 have been tested for hardness initially and rest of the 24 samples have been stored in tap water at 37 degree centigrade.

Subgroup IIIC: Out of the 32 disc shaped samples of Coe soft denture soft liner, 8 have been tested for hardness initially and rest of the 24 samples have been stored in RO water at 37 degree centigrade.

Subgroup IIID: Out of the 32 disc shaped samples of Coe soft denture soft liner, 8 have been tested for hardness initially and rest of the 24 samples have been stored in distilled water at 37 degree centigrade.

Method of testing

Each of the 384 samples have been tested with Rubber Durometer for Shore A Hardness. During all measurements, the samples have been placed on a horizontal base and the hardness tester has been slowly lowered until the indenting tip touches the sample surface (Figure 12). After 5 seconds of loading, the Shore A values have been recorded. These readings have been later compared amongst all groups and subgroups.

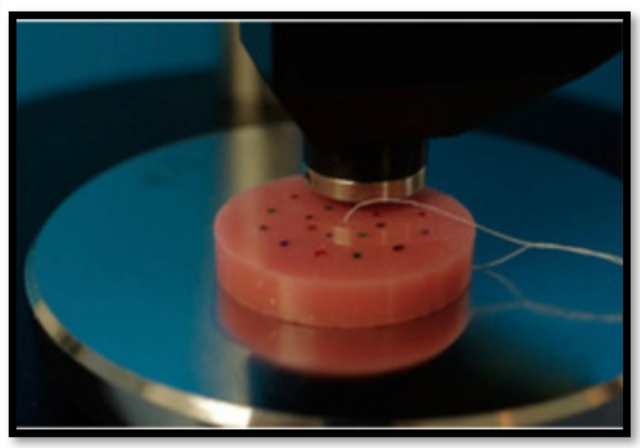

Figure 12: *Shore A hardness testing of sample.*

The data hence derived was analyzed statistically. The two ways of analyzing used were descriptive statistics and inferential statistics.

Descriptive statistics includes expression of Hardness in terms of mean and standard deviation (SD).

Two-way ANOVA test has been used to observe for the possible interaction between different brands of soft liners and storage media on the mean hardness values. It has been used to compare the mean hardness values between different storage media in each brand of soft liner group.

The level of significance [P-Value] have been set at $P < 0.05$.

Results

A total of 384 disc shaped samples of denture soft liners have been fabricated using ISO 10139-2:2016 directives. These samples have been divided into groups I, II and III of 128 each, respectively made out of each brand of denture soft liner used in this study. Further, every group have been divided into subgroups A, B, C and D consisting of 32 samples each which have been stored in artificial saliva, tap water, RO water and distilled water respectively. Again 32 samples in each subgroup have been divided into batches of 8 and studied at 4 different time intervals of 32 hours post fabrication, 7 days post immersion, 30 days post immersion and 90 days post immersion in storage medium.

After testing all the specimens stored in various storage media at the desired time intervals, significant results ($P < 0.001$) were deduced in respect to change in Shore A hardness. The samples when tested for hardness initially 32 hours after fabrication, values of hard-

ness ranging between 27.6 ± 0.7 Sh A degrees to 50.2 ± 4.0 Sh A degrees were found. Every material showed different hardness in different storage media and in different time intervals of storage. Mostly hardness was seen to be increasing with storage in all the denture soft liners considered in this study (Table 1-3).

	Day 2	Day 7	Day 30	Day 90
Artificial Saliva	40.4	41.1	42.2	42.7
Tap Water	41.6	45.1	45.5	45.9
RO Water	42.2	43.9	44.3	44.6
Distilled Water	41.8	42.2	43.3	43.4

Table 1: *Mean hardness changes (Shore A) for Mollosil.*

	Day 2	Day 7	Day 30	Day 90
Artificial Saliva	47.2	48.9	49.6	49.8
Tap Water	49.6	52.1	55.9	55.9
RO Water	49.9	53.3	51.8	51.9
Distilled Water	49.1	49.3	50.4	51.1

Table 2: *Mean hardness changes (Shore A) for GC reline soft.*

	Day 2	Day 7	Day 30	Day 90
Artificial Saliva	27.6	29.9	30.1	32.7
Tap Water	28.8	32.4	33.1	35.5
RO Water	31.7	31.9	32.8	34.3
Distilled Water	30.1	32.3	32.5	33.6

Table 3: *Mean hardness changes (Shore A) for GC Coe soft.*

For Mollosil, a steady increase in hardness was observed in the initial 7 days which was seen to be maximum in tap water whereas minimum in artificial saliva (Chart 1). After the span of 7 days, Mollosil samples showed very gradual increase in hardness, preserving most of its physical properties in consideration in that state (42.4 Sh A degrees - 45.1 Sh A degrees).

When the data of GC reline soft were analysed, they indicated a steady increase in hardness especially when stored in tap and RO water. Throughout the study GC Reline Soft has shown highest hardness values in all conditions. After the third time interval in consideration in this study, the hardness values achieved stability and did not increase any longer (Chart 2).

During initial testing at 36 hour interval after fabrication, GC Coe Soft was found to be softer than the materials mentioned before. It retained its softness the longest and showed minimal change even in the 90 days interval testing when compared to other materials. The least increase in hardness was observed in artificial saliva whereas other storage media proved to harden the material much more (Chart 3).

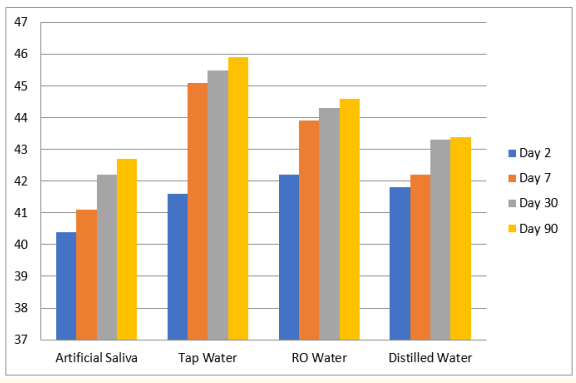

Chart 1: *Hardness changes (Shore A) mean ± standard deviation for Mollosil.*

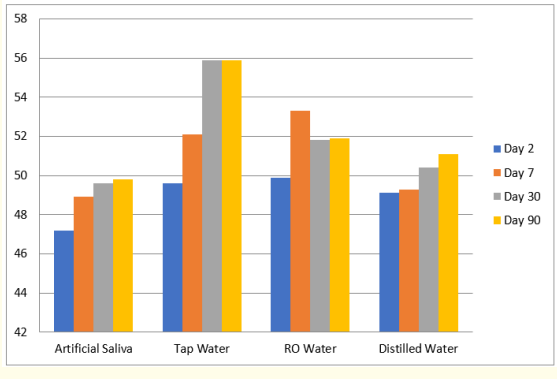

Chart 2: *Hardness changes (Shore A) mean ± standard deviation for GC reline soft.*

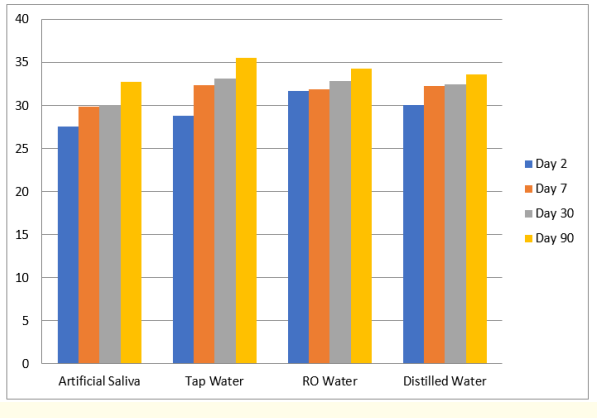

Chart 3: *Hardness changes (Shore A) mean ± standard deviation for GC Coe soft.*

The descriptive statistical data for mean Shore A hardness of the soft liners used in this study at different time intervals, when immersed in different storage media shows the mean Shore A hardness just after fabrication of the samples (Day 2) ranges between 38.4 ± 0.2 to 42.7 ± 0.4. When immersed in storage media, the values indicate increase in Shore A hardness which ranges between 39.9 ± 1.6 to 45.7 ± 0.9 (Table 4A).

Shore A Hardness	Media of Storage	n	Mean	SD
Day 2	Not relevant	24	38.4	0.2
	Not relevant	24	40	0.8
	Not relevant	24	42.7	0.4
	Not relevant	24	41.3	0.7
Day 7	Artificial Saliva	24	39.9	1.6
	Tap Water	24	43.2	1.3
	RO Water	24	41.3	1.4
	Distilled Water	24	30.3	1.5
Day 30	Artificial Saliva	24	40.6	0.9
	Tap Water	24	44.8	0.4
	RO Water	24	42.9	0.6
	Distilled Water	24	42.1	0.7
Day 90	Artificial Saliva	24	41.7	1.3
	Tap Water	24	45.7	0.9
	RO Water	24	43.6	1.2
	Distilled Water	24	42.7	1.2

Table 4A: *Statistical data for Shore A hardness (Descriptive Statistics).*

The minimum increase in hardness is seen in Artificial saliva which ranges between 39.9 ± 1.6 to 41.7 ± 1.3.

The maximum increase in hardness is seen in tap water which ranges between 41.3 ± 1.4 to 45.7 ± 0.9.

The gradual hardening of the soft liners with time has also been justified by this table where the mean Shore A hardness of the materials on Day 90 ranged between 41.7 ± 1.3 to 45.7 ± 0.9 which is much more than the initial hardness mentioned before.

Results from ANOVA show significant P values, all below 0.001 for all the data within the groups and also between the groups proving the null hypothesis false (Table 4B).

Discussion

Regular use of complete dentures for a long period of time may cause ridge resorption and loss of retention and stability of the denture. The compromised fit of complete denture causes uneven distribution of the forces of mastication and lead to concentration of stresses at particular regions leading to formation of pressure points. Very often these areas ulcerate with lot of pain inflammation and inability to wear dentures. This in turn hampers the patient's nutrition and quality of life. This is where the role of denture soft liners creep in.

Soft denture reliners improve the fit and comfort of prosthesis.

Shore A Hardness	Variation Criteria	Sum of Squares	df	MS	F	Sig (P)
Day 2	Between Group	360.3	4	90.1	132.6	0.0
	Within Group	77.3	63	1.2		
Day 7	Between Group	358.7	4	89.7	132.8	0.0
	Within Group	77.2	63	1.2		
Day 30	Between Group	336.5	4	84.2	133.1	0.0
	Within Group	71.1	63	1.1		
Day 90	Between Group	357.7	4	89.4	133.6	0.0
	Within Group	75.5	63	1.2		

Table 4B: *Statistical data for two way ANOVA.*

It plays a great role in fulfilling the ultimate goal of dentistry which is restoring lost occlusion and mastication of an edentulous patient.

The general uses of denture reliner includes enhancement of the fit of dentures, alleviation of problems of speech in cleft palate patients, protection of underlying oral mucosa and preservation of the bone from resorption in alveolar ridge areas.

The denture soft liners enable patients to continue using the denture due to alleviation of pain on pressures points and it also aids in healing after placement of implants. Kawano., *et al*. showed in his study that the softness of denture soft liners reduced the magnitude of impact caused on oral tissues by the forces of mastication [1].

According to ISO 10139 - 2: 2009, liners are categorised as type A (soft) or type B (extra soft) when hardness is tested 24 hours after specimen preparation. This time point was supported by many studies like the one following. Edgar Starckeet., *et al*. studied five tissue conditioners for hardness using Shore A Durometer with reading taken every 15 minutes in the first hour and then readings at two, four, six, eight and twenty four hours. The results indicated initial setting time as 15 - 20 minutes and final setting time as 24 hours. This is why initial hardness in this study has been tested more than 24 hours post fabrication of samples.

Soft liners seem to harden over time when under the influence of various factors like storage media, storage temperature, chemical exposure and so on. This fact provides the main basis of this study.

A reference study conducted by Mutluay., *et al*. suggests that changes in hardness is also influenced by temperature of storage. Higher storage temperatures lead to higher cross linking of bonds and polymerization of material leading to increased hardening. The results of this study comply with the one carried out by Mancuso., *et al*. where considerable increase in hardness was reported after thermocycling [6]. Mese and Guzel and Kim., *et al*. also arrived at a similar conclusion when dealing with specimens stored at 37 degrees centigrade [7]. A study by Khaledi., *et al*. proposed that besides storage media, chemicals that mimiced food items al the temperature inside oral cavity also resulted in increased hardness [8].

Soft liners in general demonstrate certain disadvantageous physical properties like hardening over time, absorption of storage media, fungal growth if hygiene is not maintained and separation from acrylic base. These properties need improvement to save cost and precious time and of patient and dentist.

Soft liners are to be kept in contact with fluids all the time as in saliva intraorally or soaked in storage media while not in use. This influences the hardness of the material due to leaching out of the plasticiser component as deduced from studies conducted by esteemed

researchers in the past. One such study was conducted by Samir Q., *et al*. which concluded that plasticisers leached out after soaking and thermocycling denture soft liners in water which led to its gradual hardening [9]. The conclusion was in agreement with the one obtained in this study. Polyzois., *et al*. conducted a study which also suggested that denture soft liners hardened over time when soaked in distilled water due to leaching out of plasticizers which ultimately compromised their clinical use [10].

So, to determine the best storage media for minimal hardness changes in denture soft liners, this study was conducted in Awadh Dental College and Hospital, Jamshedpur, to evaluate *in-vitro* changes in hardness of denture soft liners when stored in different storage media. Three commercial denture soft liners Mollosil (Detax, Germany), Reline Soft (GC, Japan) and Coe Soft (GC, Japan) have been used for comparison of hardness in this study post ageing in different storage media. All the denture liners are addition polysilicon resilient room temperature vulcanizing polyvinylsiloxane by nature.

The reason for selecting these particular brands of denture soft liners was that they were the most commonly used ones in day to day clinical practice in India. They are cost efficient, commonly available and easy to use. These materials do not require any lab procedures and can be easily used by the dentist while the patient is on the dental chair for treatment. This improves patient cooperation and time consumed in delivering the denture.

Samples of different thickness underwent testing in various studies like the one mentioned later, to reveal that the minimum thickness of a sample of denture soft liner to undergo Shore A Hardness testing is 6 mm and the testing must be done atleast 12 mm away from the edges of the sample. Keeping these references in mind, this study has used samples which are disc shaped and have a thickness of 8mm and a diameter of 40 mm. These dimensions were proposed in ISO 10139-2:2016 directive and supported by some studies. Siddiqui., *et al*. concluded in a study in 2010 that samples of soft liners being tested for Sore A hardness should be 6 mm or above in thickness since thinner samples when tested gave unrealistically high readings and gave room for higher chances of error.

Easily available media for storage were taken up like artificial saliva (ICPA), tap water, RO water and distilled water. These media were the ones commonly preferred in several other studies as mentioned here. HJ Wilson chose water bath as the storage media to check for hardness in Flexibase and Molloplast denture soft liners [11]. McCarthy., *et al*. also chose water as ageing medium for soft liners in his study. Aloul and Shen used artificial saliva to check for changes in various physical properties of denture soft liners [12].

A total of 384 disc shaped samples of denture soft liners have been fabricated using ISO 10139-2:2016 directives. These samples have been divided into groups I, II and III of 128 each, respectively made out of each brand of denture soft liner used in this study. Further, every group have been divided into subgroups A, B, C and D consisting of 32 samples each which have been stored in artificial saliva, tap water, RO water and distilled water respectively. Again 32 samples in each subgroup have been divided into batches of 8 and studied at 4 different time intervals of 32 hours post fabrication, 7 days post immersion, 30 days post immersion and 90 days post immersion in storage medium.

These specified time points have been used in various studies testing hardness of denture soft liners. McCarthy., *et al*. showed similar hardening of samples gradually when aged in water over a period of one hour, one day, three days and one week. The time periods considered in this study may have varied from McCarthy's study based on the fact that newer materials have better longevity and functionality that the ones available in the 1970s [13]. Similar to our study, Agnieszka Nowakowska., *et al*. used time points of 7 days, 30 days and 90 days post fabrication to study hardening of soft denture liners when stored in artificial saliva [14].

Each of the 384 samples have been tested with Universal Testing Machine for Shore A Hardness. During all measurements, the samples have been placed on a horizontal base and the hardness tester has been slowly lowered until the indenting tip touches the sample surface. After 5 seconds of loading, the Shore A values have been recorded. These readings have been later compared amongst all groups and subgroups.

The data hence derived was analyzed statistically. The two ways of analyzing used were descriptive statistics and inferential statistics. The reason for use of two types of statistical data were because descriptive statistics helped in showing the apparent and visible variations in the data received from hardness testing while inferential statistics aided in extrapolating the results of this hardness data obtained from tested samples to a larger extent. In short descriptive statistics reveals the character of a data set whereas inferential statistics helps us to test a hypothesis.

Two-way ANOVA test has been used to observe for the possible interaction between different brands of soft liners and storage media on the mean hardness values.

Two-way ANOVA had been used to compare the mean hardness values between different storage media in each brand of soft liner group.

The level of significance [P-Value] have been set at $P < 0.05$.

Significant statistical results in the study led to rejection of null hypothesis regarding stability of hardness of denture soft lining materials over time when stored in particular storage media.

GC Coe Soft demonstrated minimal changes in hardness when stored in artificial saliva whereas acceptable changes in hardness were seen when stored in tap water, RO water or distilled water. This may be because GC Coe soft had no methylmethacrylate monomer in its composition as proposed by Mary Anne Salcetti in the year 2022 in Spear Education Journal. Since GC Coe Soft is a relatively advanced newer material with improved physical properties as proved by this study, not many studies have been found to compare this result with. Hence the results of this study might prove to be a fruitful one in contributing to facts about this new material.

GC Reline Soft showed highest hardness throughout the study. Although an increase of 7 Shore A degrees was shown by GC Reline soft while Mollosil showed an increase of 9 Shore A degrees in artificial saliva. These materials had unstable hardness values when stored in RO or Tap water which improved a little in case of distilled water. The increasing hardness of these materials indicate increasing pressure on oral mucosa and increased discomfort to patient. Similar result was found by Bong Jun Kim., *et al*. where GC reline soft showed highest mean hardness after ageing for 28 days. Agnieszka Nowakowska., *et al*. also concluded that GC Reline soft was the hardest material but shower lower changes in hardness when aged compared to Megabase and Mucopren Soft [14].

GC Coe soft hence proves to be the suitable choice in terms of longevity above Mollosil and GC Reline soft. This fact has been supported in studies like the one conducted by Aditi S., *et al*. and Mary Anne Salcetti where GC Coe Soft has been shown to have the least bond strength leading to maximum softness when compared to other materials. Also the minimal use of PMMA monomer in it contributed to decreased hardening over time.

GC reline soft being a throughout harder denture liner than the others considered in the study, it may prove to be more suitable for patients with resilient oral tissue.

When compared for initial hardness with a reference study by Travaglini, similar results were found with this study. He found the hardness to be ranging between 50 - 65 Shore A degrees whereas this study found initial hardness to be ranging between 27 - 50 Shore A degrees. This slight difference in result in this study and the one conducted by Travaglini may be due to improvement in physical properties of denture soft liners over time.

When media of storage were taken into consideration, Artificial saliva proved to be the best choice in this study as statistical data indicated the minimal increase in hardness in all materials were observed when aged in artificial saliva. This same interesting reference maybe drawn when the results of this study is compared to that of one conducted by HK Tan., *et al*. in the year 2000 which concluded

that higher perborate containing denture cleansers hardened the soft liners quicker. In this study too we have seen similar trends leading to tap water containing higher minerals like perborate harden the soft liners much more than distilled water which is devoid of such minerals. Agnieszka Nowakowska studied hardening of denture soft liner samples in artificial saliva and arrived at similar conclusion to our study [14]. Aloul and Shen also studied changes in various physical properties of denture soft liners when aged in artificial saliva and arrived at similar conclusions as our study [12]. Malherios-Segundo., *et al*. concluded that denture soft liner samples hardened considerably when stored in artificial saliva [15].

Though similarity in conclusion might be present for this study with previously conducted similar studies, the results are not exactly the same. This maybe due to difference in specimen thickness, radius and conditions of aging. In this study the exact environment and all factors influencing the hardness of denture liners was impossible to reproduce in case of storage in artificial saliva.

The variety of materials and storage media were limited so generalisation with the entire group of materials maybe be a guiding factor but never exact.

Conclusion

This study aimed at examining the changes in hardness of denture softliners when stored in various storage media over its usage time. The conclusions derived after all statistical analysis of the results proved to be significant. The important conclusions drawn from this study were as described here.

The initial hardness of the denture soft liners ranged between 27.6 ± 0.7 Sh A degrees to 50.2 ± 4.0 Sh A degrees. During initial testing, GC Coe Soft was found to be softer than Mollosil or GC Reline Soft. It retained its softness the longest and showed minimal change even in the 90 days interval testing when compared to other materials. The least increase in hardness was observed in artificial saliva whereas other storage media proved to harden the material much more. The physical property of softness of most commercially available affordable denture soft liners were confirmed initially after polymerization. This ensures that denture soft liners considered in this study are fit to serve their clinical purpose.

Storage being an inevitable aspect of soft liner use in removable prosthesis, the best medium of it according to this study is artificial saliva, followed by distilled water, tap water and RO water when judged from the requirement of minimal changes in hardness. This study helped estimate the influence of storage media at room temperature on the longevity of denture soft liner use.

Amongst the readily available autopolymerizing silicon based denture soft liners available in the eastern Indian market, GC Coe soft demonstrated greatest longevity when change in hardness over time was considered. It preserved its softness the best compared to other materials in this study in the given experimental conditions.

Finally, this study indicated that the maximum amount of time these soft liners remained fit to serve their purpose is 3 months. Though it can be anticipated from the results of this study that GC Coe soft may have demonstrated longer preservation of physical property of hardness when compared to Mollosil and GC Reline soft had it been within the scope of this study.

All conclusions were limited by the *in-vitro* nature of this study and so the exact results may not be extrapolated to practical use of these materials.

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