Original Article

Effect of the simulated Indian and Mediterranean climates on the Shore A hardness of maxillofacial silicone

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Abstract

Purpose: The purpose of this study was to assess and compare the effect of the simulated Indian and Mediterranean climates on the Shore A hardness of a commercially available nonpigmented room temperature vulcanizing maxillofacial silicone.

Materials and Methods: Sixty specimens were fabricated from A-2000 silicone material (Factor II), using a stainless steel mold of dimension 20 mm × 2 mm. The initial Shore A hardness was noted using a digital durometer. Thirty samples were subjected to the simulated Mediterranean climate (Group I), and the remaining thirty samples were subjected to the Indian tropical climate (Group II) in an accelerated weather chamber to simulate 1 year of clinical use. Final Shore A hardness was noted. A one-way ANOVA and Bonferroni *post hoc* tests were performed for the Shore A hardness at $P < 0.05$.

Results: The mean initial Shore A hardness for both the groups was 24.9833. After accelerated weathering, Group I showed mean Shore A hardness of 33.0000 whereas Group II showed mean Shore A hardness of 38.0000.

Conclusions: The Shore A hardness of Factor II, before and after accelerated artificial weathering, was statistically significant at 0.05 level ($P < 0.05$).The change in Shore A hardness was greater in the simulated tropical climate group (Group II) as compared to the simulated Mediterranean climate group (Group I) but within clinical limits.

Keywords: Accelerated weathering, maxillofacial silicone, Mediterranean climate, Shore A hardness, tropical climate

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INTRODUCTION

External maxillofacial prosthesis, restore anatomically, functionally, and cosmetically the regions of the maxilla, mandible, or face, which are missing or altered by disease, accident, or congenitally malformed.[1] Silicone materials have become the materials of choice for the fabrication of facial prostheses.[2] Two major drawbacks associated with maxillofacial silicones are the degradation of physical properties and discoloration of the prostheses in a service environment.[2-5]

The wearing time for facial prostheses averages only from 3 months to 1 year, as they undergo major alterations in

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their structure and appearance during their use mainly due to exposure to solar irradiation, air pollution, temperature changes, and humidity.[6]

Since there is no report in literature comparing the effect of a warmer, more humid Indian environment, to a cooler and drier Mediterranean climate on the degradation rate of maxillofacial silicones, the study aims at mimicking the environmental conditions that affect the Shore A hardness of the prosthesis, through simulated accelerated weathering.

The null hypothesis was that the change in the Shore A hardness of the room temperature vulcanizing (RTV) nonpigmented maxillofacial silicone in the simulated Indian climate would be comparable to that in the Mediterranean climate.

MATERIALS AND METHODS

A-2000 silicone elastomer is a two component, 1:1 mixing by weight, [Figures 1 and 2] and low viscosity platinum RTV silicone (Factor II, Lakeside, USA). All the specimens were made of the same material.

The sample size was calculated based on the following formula:

$$N = \frac{2\sigma^2 \times (Z\alpha + Z\beta)^2}{\Delta^2}$$

σ ⟶ Standard deviation
Δ ⟶ Difference of mean

Taking values from the key article and based on the result obtained from using the formula, a sample size of 30 per group was decided. A total of 60 specimens were prepared and utilized for the study. The specimens were distributed into two groups with each group having 30 specimens.

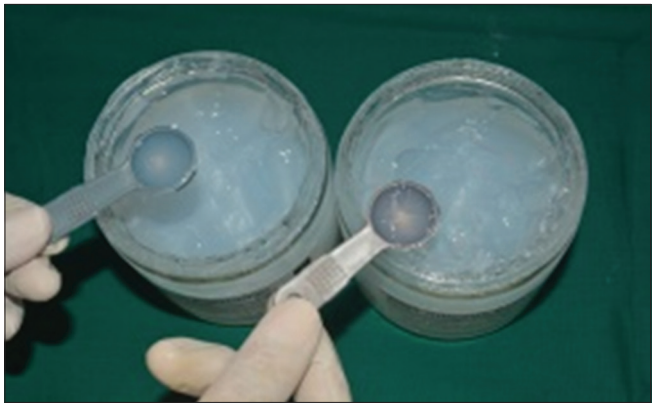

Figure 1: Base and catalyst ratio 1:1 by weight

Distribution of specimens

- Group I – Thirty nonpigmented silicone specimens subjected to the simulated Mediterranean environmental conditions
- Group II – Thirty nonpigmented silicone specimens subjected to the simulated Indian environmental conditions.

The flowchart of the methodology can be shown in Figure 3.

Description of the specimen

Each silicone test specimen of dimension 20 mm in diameter and 2-mm thickness was made using a metallic cylindrical matrix [Figure 4].

Fabrication of stainless steel mold

A rectangular metal plate with 15 cylindrical matrices of dimension 20 mm in diameter and 2 mm in thickness was cut from a stainless steel plate. Two glass slabs were used: one below and one on the top of the rectangular plate with 15 cylindrical matrices. This was done to get the uniform size of the test specimen and to retrieve the samples without distortion.

Fabrication of specimens

The A-2000 silicone elastomer is available as a base (Part A) and a catalyst (Part B) which are to be mixed in a ratio of 1:1 by weight or volume. Base and catalyst were taken in a ratio of 1:1 by weight. The base and catalyst were measured in a digital precision weighing scale using a plastic spoon to maintain 1:1 by weight ratio [Figure 1]. These components were mixed on a white ceramic tile using a stainless steel spatula to obtain a homogeneous mixture [Figure 2]. The mix was poured in a dappen dish, followed by a vacuum deaeration at 0.9 bars for 5 min as per manufacturer instructions to eliminate the

Figure 2: Base and catalyst mix for the nonpigmented room temperature vulcanizing group

smaller bubbles [Figure 5]. The mix was then inserted in the matrices, and a spatula was passed on the surface to regularize the thickness [Figure 6].

A-2000 elastomer being a RTV silicone was kept undisturbed overnight to set. The specimens were then retrieved, and the flash was removed carefully with a scissor [Figure 7]. The 20-mm diameter and 2-mm thickness of the specimen obtained were verified using a digital Vernier caliper [Figure 4]. The specimens were stored in black plastic boxes [Figure 8].

Accelerated aging protocols

Thirty samples from Group I were placed in the accelerated weather chamber [Figure 9] with ultraviolet B (UVB)-313 lamp for 192 h and subjected to alternating light and dark cycles. The light cycle lasted for 8 h and included an irradiance of 310 nm of 0.63 W/m^2/nm, humidity of 50%, and a chamber temperature of 60°C ± 3°C with condensation. The dark cycle lasted for 4 h with a temperature of 50°C ± 3°C with condensation and irradiance at 310 nm of 0.63 W/m^2/nm. These parameters were selected keeping in mind tropical climatic conditions.

For the Mediterranean climate, 30 samples from Group II were placed in the accelerated weather chamber with UVB-313 lamp for 192 h and subjected to alternating light and dark cycles. The light cycle lasted for 4 h and included an irradiance of 310 nm of 0.63 W/m^2/nm, humidity of 50%, and a chamber temperature of 60°C ± 3°C with condensation. The dark cycle lasted for 4 h with a temperature of 50°C ± 3°C with condensation and irradiance at 310 nm of 0.63 W/m^2/nm.

These tests were in accordance with IS 15907:2010 with IS no 1969:1985, which provided the standard methods for the determination of hardness of high-density polyethylene [Figure 10].

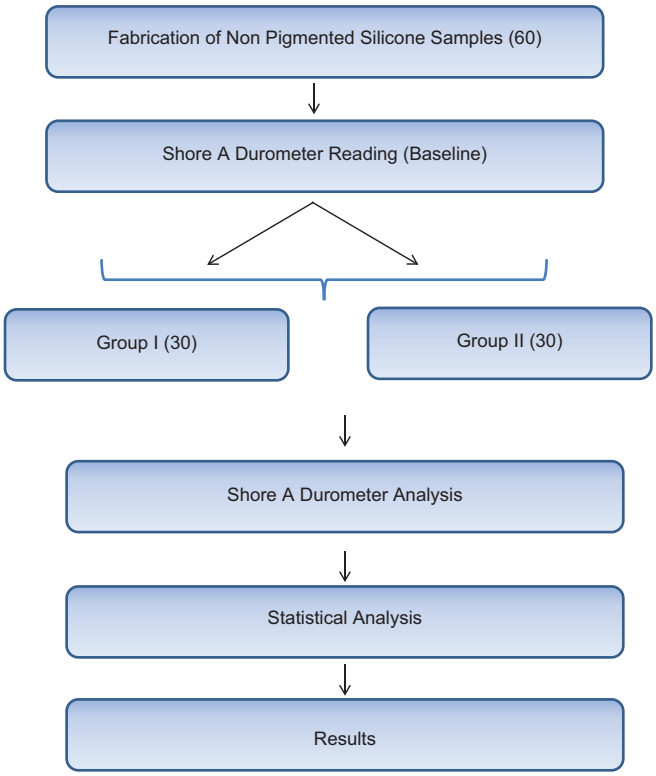

Figure 3: Flowchart of the methodology

Figure 5: Vacuum deaeration at 0.9 bars for 5 minutes

Figure 4: Nonpigmented room temperature vulcanizing silicone specimens of specified dimensions

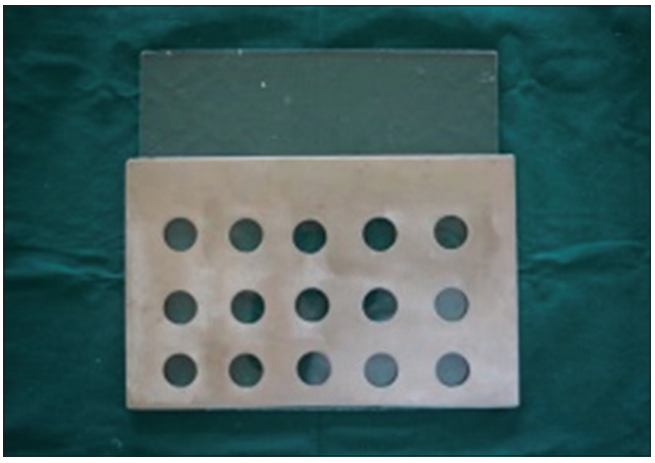

Figure 6: Dispensing the nonpigmented room temperature vulcanizing silicone material in the mold

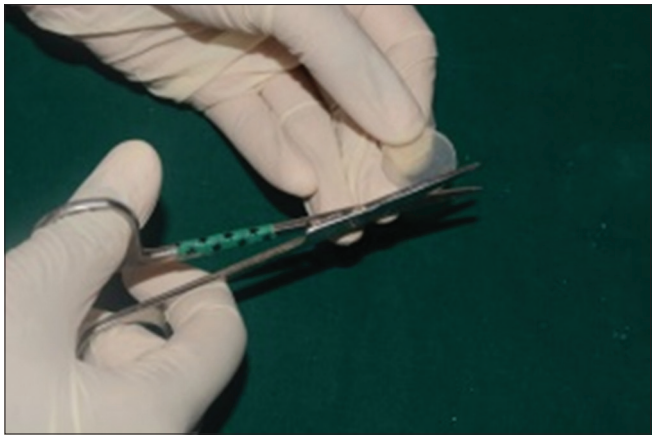

Figure 7: Flash trimmed using a sharp pair of scissors

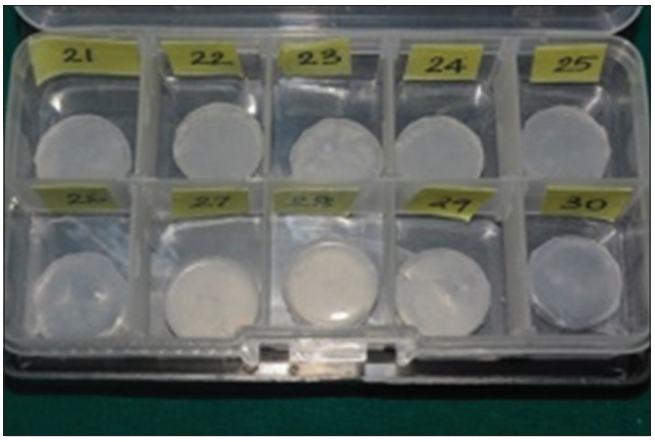

Figure 8: Specimens stored in black plastic boxes

Figure 9: QUV accelerated weathering Tester (Q Labs, USA)

Figure 10: Accelerated aging protocol in accordance to IS 15907

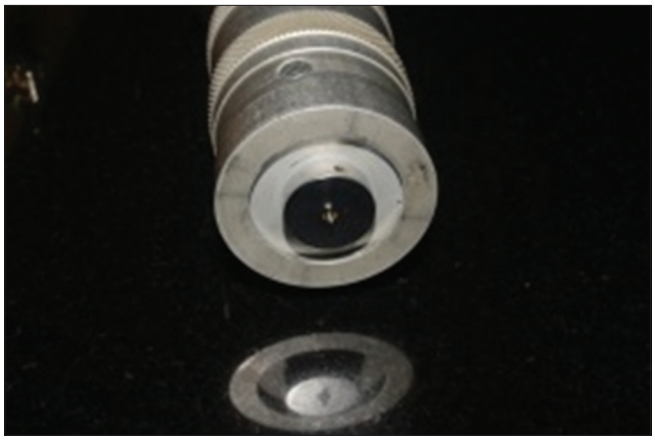

Figure 11: Presser foot of the digital durometer

Figure 12: Shore A durometer readings noted

Hardness test

The Shore A hardness of the prepared specimens was tested before and after artificial weathering using a digital durometer. This method is based on the penetration of a needle on the surface of the material. The digital durometer was placed in a vertical position, and the presser foot was applied perpendicular to the surface of the specimens as rapidly as possible without shock [Figure 11]. Readings were noted, 1 s after firm contact of the needle with the surface of the material was achieved. The results from six readings taken at six different positions on the surface (6 mm apart) for each specimen were noted, and the average was

calculated [Figure 12]. The absolute differences were then calculated using the measured values before and after each procedure for each sample. Three samples were placed over each other and measured to achieve 6 mm in thickness, in accordance to the American Standards for Testing and Materials (ASTM) D2240 specifications.

The readings were submitted for statistical analysis.

OBSERVATION AND RESULTS

In the present study, the initial Shore A hardness measurements of all the 60 specimens were made using a digital Shore A durometer (ABS instruments Pvt. Ltd., Chennai, Tamil Nadu, India), and the readings were recorded. The samples were divided into two groups, containing 30 specimens each. Group I was subjected to the simulated Mediterranean climate whereas Group II was subjected to the simulated tropical climate using accelerated weathering in a weathering chamber. The Shore A hardness was measured again using the digital durometer. The results obtained have been tabulated and shown in Tables 1 and 2, respectively.

- The statistical software, namely Statistical Package for Social Sciences (SPSS Software: IBM, Armonk, NY, USA) version 20 was used for the analysis of the data, and Microsoft office Word and Excel 2010 have been used to generate graphs and tables
- One-way ANOVA was carried out to determine whether there was a difference in the Shore A hardness before and after accelerated weathering. The same test compared the change in hardness in the Mediterranean group and the tropical group
- The level of statistical significance was determined by the "*P*" value. If the $P < 0.05$, it was assumed that there is a real difference. Conceptually, the *P* values are used to assess the degree of dissimilarity between two or more sets of measurements or between one set of measurements and a standard.

The Bonferroni test (*post hoc* test) was used to compare the mean Shore A hardness change within the Mediterranean and tropical group taken two at a time (pairwise) to assess where a significant mean difference exists.

The results are summarized in Tables 3-5 along with appropriate graphical representations of the same.

The Bonferroni test showed that the change in Shore A hardness for Group I and Group II was statistically significant at 0.00 level ($P < 0.05$).

Table 1: Shore A hardness values for Group I after accelerated weathering (Mediterranean climate)

Sample number	Initial hardness	After weathering
1	24	32
2	25	33
3	25	33
4	24	33
5	25	34
6	26	34
7	26	34
8	24	32
9	25	32
10	25	33
11	24	32
12	26	34
13	26	34
14	25	33
15	24	33
16	26	33
17	25	33
18	25	33
19	25	33
20	25	34
21	26	34
22	26	33
23	25	32
24	24	32
25	25	33
26	24	32
27	25	33
28	25	33
29	24	32
30	26	34

Table 2: Shore A hardness values for Group II after accelerated weathering (Tropical climate)

Sample number	Initial hardness	After weathering
31	26	39
32	24	37
33	25	38
34	25	38
35	24	37
36	25	37
37	24	38
38	25	37
39	26	38
40	26	39
41	25	39
42	25	38
43	25	38
44	25	38
45	26	38
46	24	39
47	25	38
48	26	39
49	26	38
50	24	37
51	25	38
52	25	37
53	24	37
54	26	39
55	26	39
56	24	39
57	24	38
58	25	38
59	25	38
60	24	37

Table 3: Descriptive statistics for the change in Shore A hardness for different groups

	n	Mean±SD	SE	95% confidence interval for a mean		Minimum	Maximum
				Lower bound	Upper bound		
Initial hardness	60	24.9833±0.74769	0.09653	24.7902	25.1765	24.00	26.00
After weathering (Group I)	30	33.0000±0.74278	0.13561	32.7226	33.2774	32.00	34.00
After weathering (Group II)	30	38.0000±0.74278	0.13561	37.7226	38.2774	37.00	39.00

CI: Confidence interval, SD: Standard deviation, SE: Standard error

Table 4: Comparison of change in Shore A hardness before and after accelerated weathering in different groups

	Sum of squares	df	Mean square	*F*	Significant
Between Groups	3693.008	2	1846.504	3324.560	0.001
Within Groups	64.983	117	0.555		
Total	3757.992	119			

Figure 13 shows the comparison of change in final Shore A hardness after accelerated weathering.

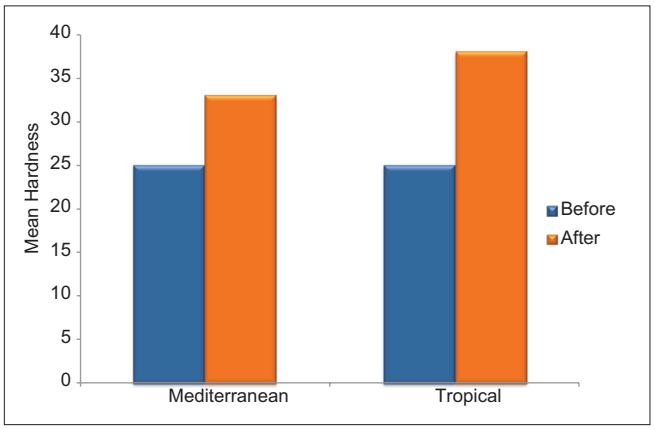

Figure 13: Comparison of change in final Shore A hardness after accelerated weathering

DISCUSSION

Facial defects often result in devastating a cosmetic, functional, and psychological consequence, which makes it challenging for maxillofacial surgeons and prosthodontists to rehabilitate. Thus, a facial prosthesis presents the only attractive and practical alternative, when esthetic and functional demands cannot be surgically fulfilled.[7,8]

Silicone elastomers have been widely used for the construction of maxillofacial prosthesis. They are usually comprised polydimethylsiloxane (PDMS) elastomers. The PDMS chains, silica fillers, and the interactions between these components affect the overall strength and serviceability of the silicone elastomers.[9-11] Despite their wide use, they are far from ideal. The longevity of maxillofacial prostheses is dependent on the prosthesis material and the patients' attitude toward the prosthesis,[12] and it can be directly associated with the effectiveness of the prosthesis in use.[13] Silicone-based maxillofacial prostheses require replacement every 3–12 months,[6] as they suffer degradation of their mechanical and esthetic properties due to the weathering of polymers.[3-5,12,14] The main environmental characteristics that cause degradation are sunlight, temperature, moisture, wind, dust, and pollutants.[3] Weathering parameters in the present study simulate silicone prosthesis in service for 12 months. Each day, patients wear their prostheses for 8–12 h during which it is expected to be exposed to at least 2 h of daylight, normal environmental conditions, while the prosthesis is on the defect site.

India experiences seasonal variations in the form of winter, summer, monsoon, and postmonsoon (autumn) seasons during 1 year. The years' coldest months are December and January when temperatures average around 15°C–25°C. In summer, temperatures average around 32°C–40°C. Mediterranean climates experience warm (but not hot) and dry summers and mild-to-cool wet winters. The temperature ranges from −3°C to 25°C.

The parameters for the simulated Indian weather were alternating light and dark cycles where the light cycles lasted for 8 h and included an irradiance of 310 nm of 0.63 W/m^2/nm, humidity of 50%, and a chamber temperature of 60°C ± 3°C with condensation. The dark cycles lasted for 4 h, with a temperature of 50°C ± 3°C with condensation, and irradiance at 310 nm of 0.63 W/m^2/nm. For the Mediterranean climate, the light cycles lasted for 4 h and included an irradiance of 310 nm of 0.63 W/m^2/nm, humidity of 50%, and a chamber temperature of 60°C ± 3°C with condensation. The dark cycles lasted for 4 h with a temperature of 50°C ± 3°C with condensation and irradiance at 310 nm of 0.63 W/m^2/nm. Thus, the artificial weathering conditions used in the study simulate the Indian tropical and Mediterranean environmental conditions.

Weathering of polymers leads to significant changes in their mechanical and physical properties. When photo-oxidative degradation occurs the following steps might happen:

- Initiation: Formation of free radicals. The formation proceeds by a radical chain process initiated either by dissociation caused by the collision of a photon with sufficient energy with a polymer molecule or as the

Table 5: Comparison of change in mean Shore A hardness based on groups

		Mean Difference	STD. Error	Sig. Lower Bound	95% Interval Confidence Upper Bound
Initial Hardness					
After Weathering Group I	-8.01667*	0.16665	0.001	-8.4214	-7.6119
After Weathering Group II	-13.01667*	0.16665	0.001	-13.4214	-12.6119
After Weathering Group I					
After Weathering Group II	-5.00000*	0.19243	0.001	-5.4674	-4.5326

result of some impurity present, for example, trace metals from the polymerization catalyst

- Propagation: Reaction of free polymer radicals with oxygen, production of polymer oxy radicals and peroxy radicals, and secondary polymer radicals, resulting in chain scission
- Termination: Reaction of different free radicals with each other resulting in further cross-linking.

The main structural modifications in irradiated polymers are changes in their molecular weight distribution, due to main chain scission, cross-linking and end linking, and the production of volatile degradation products. These phenomena tend to modify the material's physical properties.[5] The changes in physical properties affect the polymer structural network in different ways. The density of the structural network increases during cross-linking due to the formation of bonds between the existing monomers or between the chains.[5] Therefore, cross-linking leads to the formation of harder materials. On the other hand, when chain scission is the dominant mechanism, the fracturing bonds within the main chain or between two different chains incur a decrease in density of the structural network, and the materials become softer.[5] In irradiated polymers, both the above mechanisms take place; therefore, it is critical to investigate which of them is dominant, to explain the structural analysis.

The hardness of silicone elastomers is controlled by the surface characteristics of the polymer network and by the density of cross-links. Silicone elastomers undergo cross-linking once exposed to high-energy radiation, and the amount of cross-linking is proportional to the radiation dose and duration.[15] Sebum fatty acids, perspiration tends to interact with silicone, breaking chain bonds, and decomposing the elastomer by a phenomenon called as "reversion."[16] This degradation effect is accelerated with light radiation, leading to softer and weaker elastomer. Thus, the actual performance of silicone elastomers under extraoral factors can be evaluated by exposure tests simulating conditions involving sterilization, hygiene maintenance procedures, biological skin fluid absorption, and outdoor exposure.

This study evaluated the change in hardness of a commercially available nonpigmented RTV maxillofacial silicone when exposed to accelerated weathering that simulated the Indian and Mediterranean climates for 1 year.

RTV maxillofacial silicone was tested in this study, as it is commonly used due to its ease of manipulation. RTV of the maxillofacial silicone elastomer is known to show lesser progressive hardening of the elastomer as compared to the heat vulcanization technique.[17]

Factor II shows favorable properties compared to other commercially available maxillofacial silicones due to its high tear strength, softness, and ease of manipulation as reported by Tariq Aziz, Mark Waters, and Robert Jaggers.[18] Thus, it was chosen as a material of choice to conduct the study.

The maxillofacial prosthesis should demonstrate reasonable tensile strength and yet be flexible and soft enough to respond adequately with facial movement.

The hardness of the maxillofacial material is a measure of its flexibility. The ideal hardness is similar to that of the missing facial tissue. In this study, the initial shore hardness obtained was 25A, and after simulated accelerated weathering, it was 33A for the Mediterranean climate and 38A for the tropical climate, which is in agreement with other researchers and within the clinically acceptable limit. Considering that facial features are composed of soft and hard textures, Lewis and Castleberry stated that 25–35 Shore A indentation units were ideal, but 10–45 units were acceptable.[19] Sweeney *et al*.[20] considered a desirable range of hardness to be 48–52 Shore-A units. Conroy *et al*.[21] considered that 25–55 Shore-A units were the correct range of hardness.

As no difference was found in the hardness of the samples cured against polished metal, untreated stone, and stone sealed with cold-mold seal material,[22] our samples were cured in a polished metal mold comprising 15 compartments in the desirable dimensions.

In the present study, black plastic boxes were used to store the specimens.[23] This was done to rule out the light transmission affecting aging.

The experimental procedures were conducted according to the specifications for the vulcanized rubber established by the International Standards Organization and the ASTM. Specimens were tested after 24 h of conditioning at room temperature.

Limitations

Although the study was carried out following the standard protocols, it has some limitations as follows:

1. The present study was an *in vitro* simulation of the clinical usage of prostheses and the photochemical insult that they are subjected to. The actual clinical use of the prostheses in daily life can be different and variable
2. A single brand of RTV maxillofacial silicone material was used in the study. Further research with various other silicone materials is indicated
3. The evaluation was done for nonpigmented silicone samples. Extrinsic and intrinsic pigments could affect Shore A hardness as well. Further research is warranted
4. India has different climatic conditions in different regions; the simulation did not account for these variations.

Clinical implications

- Silicone elastomers have been used over the years for the fabrication of maxillofacial prostheses. The prosthesis has to be refabricated on an average every 3–12 months, mainly due to the degradation of their mechanical and esthetic properties due to the weathering of polymers
- Accelerated artificial weathering simulates the natural environmental conditions in which an extraoral prosthesis is used, thus denoting the service life of the prosthesis in use
- The hardness of the maxillofacial material is a measure of its flexibility. The ideal hardness is similar to that of the missing facial tissue whose hardness ranges from hard to soft and flexible. This study provided an insight into the appropriate use of the maxillofacial silicone at various sites
- There is currently no report in literature comparing the effect of a warmer, more humid Indian subcontinental environment, to a cooler and relatively drier Mediterranean climate on the degradation rate of maxillofacial silicones.

CONCLUSION

Within the limitations of this study, the following conclusions can be drawn:

1. The Shore A hardness of a RTV maxillofacial silicone, before and after accelerated artificial weathering was statistically significant at 0.05 level ($P < 0.05$)
2. The change in Shore A hardness was greater in the simulated tropical climate group (Group II) as compared to the simulated Mediterranean climate group (Group I) but within clinical limits.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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- Add up to a maximum of 15 references at a time.
- If the reference is correct for its bibliographic elements and punctuations, it will be shown as CORRECT and a link to the correct article in PubMed will be given.
- If any of the bibliographic elements are missing, incorrect or extra (such as issue number), it will be shown as INCORRECT and link to possible articles in PubMed will be given.