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A Spectrophotometric Analysis on Color Stability of Maxillofacial Silicone Elastomer Exposed Under Different Human And Environmental Conditions – An In Vitro Study

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Abstract: *Aim: The aim of the study was to evaluate the color stability of maxillofacial silicone elastomer (Cosmesil M511) after exposing them to five different human and environmental aging conditions.*
Material and methods: Sixty disk- shape maxillofacial silicone Cosmesil M511 (Principality Medical Ltd., South Wales, UK) (Part A: Part B = 10:1) specimens were prepared and equally divided into 5 groups. Dark room (control) (group A),outdoor weathering (group B), acidic perspiration (group C), neutral soap (group D) and disinfectant (group E) along with subgroups in each groups dark brown, medium brown and light brown using the principality skin shade P416, P406 and P418. The conditioning period for Group A, B, C are 3 months; group D and E for 30 hours. Color change (ΔE) was measured at the end of the conditioning period using spectrophotometer. Data was analysed with One-way analysis of variance (ANOVA) and Tukey's Post – Hoc tests. The probability value .05 is considered as significant level.
Results: Four of the five treatment conditions induced perceivable color change (ΔE > 3). Specimens stored in outdoor weathering (Group B) condition for 3 months exhibit high (ΔE = 5.68), which was greater (p < 0.05) than that produced by disinfectant (Group E) (ΔE = 5.37). All groups exhibited detectable color change expect for dark room (Group A).
Conclusion: There is inherent color stability of the three skin shades (dark brown, medium brown and light brown) which added to the overall color change of the silicone prosthesis. Visual perceptible and clinically unacceptable color change occurred when exposed to various extra oral aging conditions expect dark room condition. It can be said Cosmesil M511 have color instability under extra oral aging conditions.
Keywords*: color stability, maxillofacial silicone elastomer, spectrophotometer, outdoor weathering, acidic perspiration, neutral soap, disinfectant*

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I. Introduction

Facial irregularities and defects can compromise the appearance, function and well-being of a person[1]. Maxillofacial prostheses are used to restore congenital, developmental, and acquired defects of the head and neck into natural appearing replicas of the missing parts, thus, providing a suitable appearance and better function[2]. There is no ideal facial prosthetic material, although there have been developments in the last few decades, and silicone rubbers have established the current state-of- the-art material regardless of the improvements in reconstructive and plastic surgery[3]

Color stability is the property of a material that permits color to conserve over a period of time in a given environment[4] .The limited service of the facial prosthesis is a result of rapid degradation of the elastomer and its colour instability. The wearing time for facial prosthesis average from 3 months to 1 year. Deterioration is mainly caused by environmental exposure to ultraviolet (UV) light, air pollution, and change in humidity and temperature. Cleaning and the application of adhesives and cosmetic additives may also alter the physical properties and color stability of the material [5,6,7].

Takamata[8] et al. conducted a 6 months study to evaluate color change of silicone maxillofacial materials after exposure to sunlight. Polyzois et al.[9], Lemon et al.[10] Betty et al.[11], Goiato et al.[12] conducted some studies in different parameter using different maxillofacial prosthetic materials.

In support to the previous studys, this current in vitro study was intended to evaluate the color variation in silicone elastomers used for fabrication of maxillofacial prosthesis after subjecting the specimens to extra-oral aging conditions like; outdoor weathering, acidic perspiration and disinfectant solutions. A computerized spectrophotometer will be used to evaluate the color stability of the material.

II. Material And Methods

This invitro study was carried out in Department of Prosthodontics and Crown & Bridge, Sree Balaji Dental College, Pallikaranai, Chennai from September 2017 to December 2017. A standard custom made disc shaped stainless steel mold measuring 8mm in diameter, 3mm in thickness were fabricated to prepare the specimens. The stainless steel molds were invested in the dental flask using dental stone. After the stone set, the molds were removed, thus created a use for fabrication of specimens. Ninety disc shaped specimens was prepared. Maxillofacial elastomer Cosmesil M511 (part A: Part B = 10:1) was used for the study. The manipulation and polymerization of the maxillofacial silicone elastomers will be done strictly as per the manufactures instructions. The elastomers was mixed in a glass plate. Intrinsic stains namely P416, P406 and P418 were used to create Indian skin tone (dark brown, medium brown, light brown). Separating medium was applied over the invested mold for easy removal of the specimens. After polymerization the specimens were removed from the mold carefully and any excess flash will be trimmed away with scissor. A total of 60 specimens were selected and divided into 5 groups. The Groups were divide as - Group A (dark room), Group B (outdoor weathering), Group C (acidic perspiration) Group D (neutral soap), Group E (Disinfectant). Each groups were equally divided into 3 subgroups according to the skin color (light brown, medium brown and dark brown). Each subgroup has 4 specimens (table- 1). Conditioning period for groups A, B, C were 3 months (September – December) and groups D and E for 30 hours. Group A specimens were stored in dark room under room temperature. Group B were exposed to sunlight with covering. Group C were stored in simulate acidic perspiration for 3 months. The solution contained the following (per litre of distilled water): 0.5 g L-histidine monohydrochloride monohydrate, 5 g sodium chloride, and 2.2 g sodium dihydrogen orthophosphate dehydrate. The solution was prepared according to International Organization for Standardization specification, ISO 105-E04:96. Group D specimens were stored in neutral soap (Dove soap). Group E specimens were were stored in disinfectant solution (Clinsodent effervescent denture cleaning tablet) both for 30 hours. Color variation of each specimen were measured using spectrophotometer (MINOLTA) (fig – 2). Specimens were gently cleaned, rinsed in water before color measurement. Color measurements were recorded before and at the end of conditioning periods for all groups. (Fig -1)

The conditioning periods were selected to simulate silicone prosthesis in service for 12 to 18 months. Each day, the patient wear their prosthesis for 8 to 12 hours, during which it is expected to be exposed to a least 1 hour of daylight, normal environmental conditions, and continuous perspiration while the prosthesis is on defect site. In addition, before sleeping, patients spend an average of 5 minutes cleaning their prosthesis. Therefore, 1 months of service equals 30 hours of daylight aging, 10 to 15 days of storage in acidic perspiration and 150 minutes to storage in cleaning solution.

Group (n = 60)	**Dark brown**	**Medium brown**	**Light brown**
A. Dark room	4	4	4
B. Outdoor weathering	4	4	4
C. Acidic perspiration	4	4	4
D. Neutral soap	4	4	4
E. Disinfectant	4	4	4

Table no 1 – Study Table

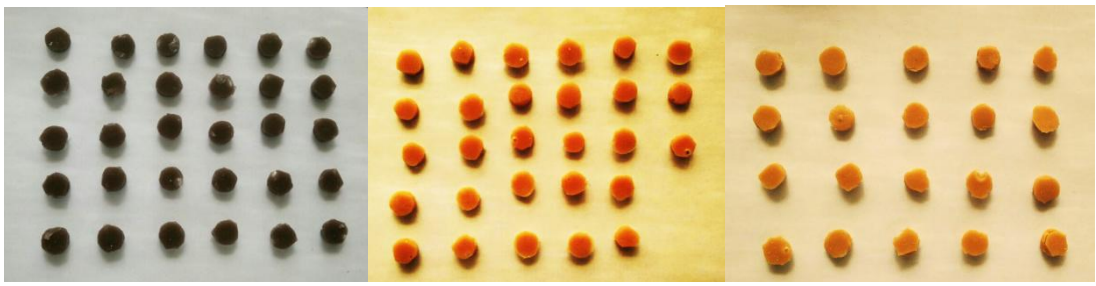


Fig1 – Study Specimens

Fig 2 – Spectrophotometer CM- 3600D (MINOLTA)

III. Statistical Analysis

The collected data were analysed with IBM.SPSS statistic software 23.0 version. Mean and standard deviation (S.D). One-way analysis of variance (ANOVA) and Tukey's Post – Hoc tests were used to test the significant difference between the five treatments conditions ($p \leq .01$ or $p \leq .05$) for each sub group (dark brown, medium brown and light brown). ΔE^* values of each specimens were calculated. Values of $\Delta E^* \leq 3$ were considered clinically acceptable.

IV. Result

As suggested by Fontes at al. [13] values more than 3 reflected unacceptable color change clinically. Any ΔE^* value more than 3 was considered to be a visually perceptible color change from the baseline reading.

Table 2 and 3 shows the mean difference of ΔE^*, SD and p value of group A, group B, group C, group D and group E. The ANOVA test shows that the groups are statistically significant ($p \leq 0.01$).

Table no 2

	N	Mean	Std. Deviation	Minimum	Maximum
Dark room	12	.5675	.20724	.25	.90
Outdoor weathering	12	2.7425	1.69027	.34	5.68
Acidic Perspiration	12	.7817	.35365	.37	1.54
Neutral Soap	12	1.9642	1.63533	.58	5.93
Disinfectant	12	1.9483	1.61147	.83	5.37
Total	60	1.6008	1.48893	.25	5.93

Table no 3

	Sum of Squares	Df	Mean Square	F	Sig.(p)
Between Groups	39.540	4	9.885	5.958	.0005
Within Groups	91.258	55	1.659		
Total	130.798	59			

Table no 4 – results shows that there is statistical significance differences between the groups.

Tukey HSD

(I) Groups		Mean Difference (I-J)	Std. Error	Sig.	95% Confidence Interval	
					Lower Bound	Upper Bound
Dark room	Outdoor weathering	-2.17500*	.52587	.001	-3.6581	-.6919
	Acidic Perspiration	-.21417	.52587	.994	-1.6973	1.2690
	Neutral Soap	-1.39667	.52587	.074	-2.8798	.0865
	Disinfectant	-1.38083	.52587	.079	-2.8640	.1023
Outdoor weathering	Dark room	2.17500*	.52587	.001	.6919	3.6581
	Acidic Perspiration	1.96083*	.52587	.004	.4777	3.4440
	Neutral Soap	.77833	.52587	.580	-.7048	2.2615
	Disinfectant	.79417	.52587	.560	-.6890	2.2773

Acidic Perspiration	Dark room	.21417	.52587	.994	-1.2690	1.6973
	Outdoor weathering	-1.96083*	.52587	.004	-3.4440	-.4777
	Neutral Soap	-1.18250	.52587	.178	-2.6656	.3006
	Disinfectant	-1.16667	.52587	.188	-2.6498	.3165
Neutral Soap	Dark room	1.39667	.52587	.074	-.0865	2.8798
	Outdoor weathering	-.77833	.52587	.580	-2.2615	.7048
	Acidic Perspiration	1.18250	.52587	.178	-.3006	2.6656
	Disinfectant	.01583	.52587	1.000	-1.4673	1.4990
Disinfectant	Dark room	1.38083	.52587	.079	-.1023	2.8640
	Outdoor weathering	-.79417	.52587	.560	-2.2773	.6890
	Acidic Perspiration	1.16667	.52587	.188	-.3165	2.6498
	Neutral Soap	-.01583	.52587	1.000	-1.4990	1.4673

Table 5, 6, 7, 8, 9, 10, 11, 12, 13 and 14 shows the One Way ANOVA test of group A, B, C, D and E was done along with the subgroups. The group shows that group A along with subgroups is not statistically significant ($p > .05$). Group B along with the subgroups shows that it is highly statistically significant ($p \leq 0.01$). Group C shows that it is statistically significant ($p \leq 0.05$). Group D is highly significant ($p \leq 0.01$). Similarly group E shows statistical significance ($p \leq 0.05$).

Table no 5

Delta E

	N	Mean	Std. Deviation	Minimum	Maximum
Dark	4	.6175	.14338	.48	.80
Medium	4	.4150	.20486	.25	.71
Light	4	.6700	.21587	.42	.90
Total	12	.5675	.20724	.25	.90

a. Groups = Dark room

ANOVA

Delta E

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	.145	2	.073	1.994	.192
Within Groups	.327	9	.036		
Total	.472	11			

a. Groups = Dark room

Table no 6

Delta E

	N	Mean	Std. Deviation	Minimum	Maximum
Dark	4	1.6375	.48911	1.20	2.10
Medium	4	1.9400	1.08729	.34	2.77
Light	4	4.6500	1.31004	2.76	5.68
Total	12	2.7425	1.69027	.34	5.68

a. Groups = Outdoor weathering

Table no 7

Delta E

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	22.014	2	11.007	10.524	.004
Within Groups	9.413	9	1.046		
Total	31.427	11			

a. Groups = Outdoor weathering

Table no 8

Delta E

	N	Mean	Std. Deviation	Minimum	Maximum
Dark	4	.5875	.32623	.37	1.07
Medium	4	1.1450	.28290	.90	1.54
Light	4	.6125	.08770	.50	.70
Total	12	.7817	.35365	.37	1.54

a. Groups = Acidic Perspiration

Table no 9

ANOVA
Delta E

	Sum of Squares	Df	Mean Square	F	Sig.
Between Groups	.793	2	.397	6.129	.021
Within Groups	.582	9	.065		
Total	1.376	11			

Table no 10

Delta E

	N	**Mean**	**Std. Deviation**	**Minimum**	**Maximum**
Dark	4	1.2750	.73559	.58	1.95
Medium	4	.9400	.19613	.66	1.09
Light	4	3.6775	1.81119	1.70	5.93
Total	12	1.9642	1.63533	.58	5.93

a. Groups = Neutral Soap

Table no 11

ANOVA
Delta E

	Sum of Squares	**df**	**Mean Square**	**F**	**Sig.**
Between Groups	17.838	2	8.919	6.932	.015
Within Groups	11.580	9	1.287		
Total	29.417	11			

a. Groups = Neutral Soap

Table no 12

Delta E

	N	Mean	Std. Deviation	Minimum	Maximum
Dark	4	1.0400	.14306	.83	1.15
Medium	4	1.2875	.38030	.89	1.78
Light	4	3.5175	2.09554	1.15	5.37
Total	12	1.9483	1.61147	.83	5.37

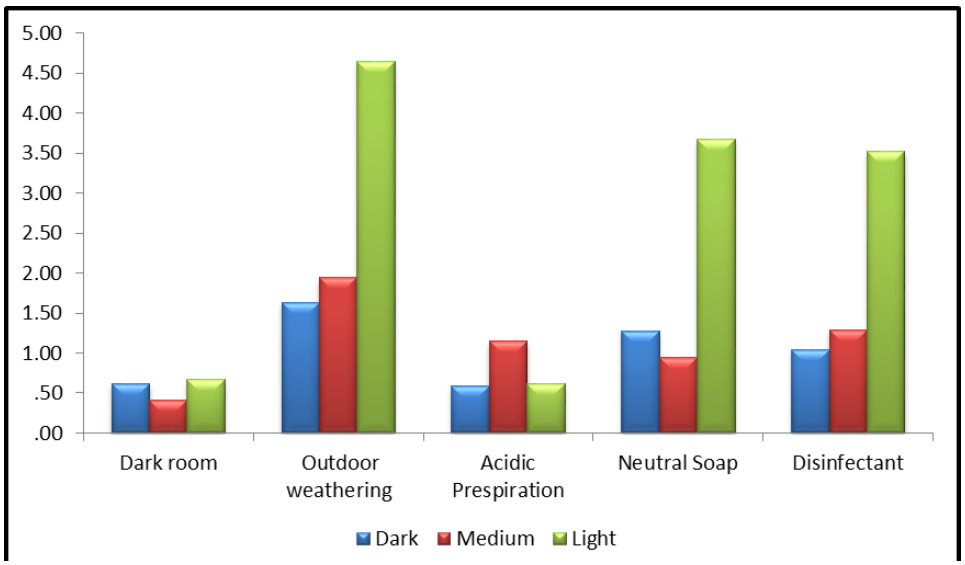
a. Groups = Disinfectant

Table no 13.

ANOVA
Delta E

	Sum of Squares	**Df**	**Mean Square**	**F**	**Sig.**
Between Groups	14.896	2	7.448	4.904	.036
Within Groups	13.669	9	1.519		
Total	28.565	11			

a. Groups = Disinfectant



Graph – 1

Graph 1 shows that outdoor weathering and light skin shade shows high color change with dark skin shade and dark room the most color stable.

V. Discussion

Most of the maxillofacial prosthesis have to be remade because of color instability. These have been demonstrated by Jani and Schaaf [7] in their study where the patient have their prosthesis remade within 1 year. In a questionnaire study of patient satisfaction by Markt et al.[14] patients desired prostheses that last longer and have color stability. Similar study regarding patients were also done by Chen[5] et al.

The present study was done from September to December. The highest temperature of Chennai recorded from the month of September to December was 36 ◦ C in September and the lowest was 21 ◦ C in December. The highest amount of rainfall recorded during these time period was 90 mm in the month of November[15].

There are two system to measure color. Munsell color system and CIE L*a*b* color system. CIE L*a*b* color system by ADA quantifies the color alterations using a mathematical equation expressed by ΔE* and obtained with the variation of three coefficients (L*a* and b*) where, L* = Color luminosity (ranging from 0- black to 100- white)

a* = Ranges from 90 to 70 and represent the greenness on the positive axis and redness on the negative axis

b* = Ranges from 80 to 100 and represents yellowness (positive b*) and blueness (negative b*).

The color change was calculated using the equation:

ΔE = ([ΔL *] 2 + [Δa *] 2 + [Δb *] 2) ½

Cantor et al. [4] reported that spectrophotometry was used to evaluate the color of maxillofacial elastomers.

Betty et al. [11] evaluated the color stability of maxillofacial silicone elastomers under ultra violet light concluded that there was color changes in the prosthesis. Lemon et al. [10] Kiat-amnuay et al.[16] Akash et al.[17] Siddharth et al.[18] conducted studies under different condtions using spectrophotometer.

In CIELAB system according to Seghai et al. [19] and Kuehni and Marcus [20] ΔE*equal to 1 is considered visually detectable 50% of the time, whereas a ΔE* greater than 2 is detectable 100% of the time. In this study, ΔE* greater than 2 was used as a baseline and considered to be visually detectable.

The silicone elastomer with light brown skin shade during outdoor weathering were considered visually detectable. The result of the present study showed that specimens subjected to outdoor weathering for three months with light brown shade have high significant color change. Study conducted by Hatamleh et al. [21] stated that this significant color change can be attributed to the presence of UV light irradiation present in the solar radiation which may have enhanced cross- linking, along with accelerated interaction of the fatty acids with silicone, breaking down the chain bonds, and decomposing the elastomer. Similar studies were conducted by Takatama et al.[8] and Polyzois et al. [22]

Specimens subjected to disinfectant solution with light brown skin shade have significant color change. Pesqueira et al. [23] shows that there was significant color change in the elastomers Efferdent effervescent tablet. This disinfectant contains sodium perborate monohydrate which mainly works through an oxygen - liberating mechanism that purposely loosens debris and remove stains.

Specimens subjected to neutral soap with light skin shade have significant color change. The neutral soap used in this study was commercially available dove soap with ph 7. Eleni [24] showed that neutral soap causes more color change than disinfectant solution sodium hypochlorite.

Specimens subjected to acidic perspiration with medium skin shade have significant color change. Hatamleh et al. [21] showed that there was significant color change in the specimens subjected to acidic perspiration for 6 months irrespective of the material used which was similar to the present study. This significant color change can be attributed to the catalytic effect of the acidic environment on the cross – linking reaction, which lead to the formation of additional polymer network in the silicone.

Specimens subjected to dark room showed stability of color. One year study conducted by Bankoglou et al. [25] showed that there was significant color changes in the specimens unlike the present study.

The wear of the color of the maxillofacial silicone prosthesis is not by virtue of a single cause or aging condition. In fact, it is due to the collective effect of various causes such as environmental exposure, humidity, UV radiation, air pollutants, exposure to facial secretions, and the method of disinfection. Apart from these external factors, certain internal factors such as the composition of the silicone, degree of cross- linking, mode of curing, extrinsic and intrinsic stains used; all play an important role in conserving or degrading the color of the silicone prosthesis.

VI. Limitation Of The Study.

1. Manipulation of the maxillofacial silicone elastomer was done by mechanical hand mixing. Further studies are required for the comparison of the color stability of silicone elastomers between mechanical hand mixing and vacuum mixing.
2. Evaluation of the color stability of the materials was done based on intrinsic staining only. Further studies are required for the evaluation of color stability based on extrinsic staining (with and without sealant application), addition of pigments, and flockings which also play an important role in the color stability of maxillofacial silicone elastomer.
3. The study was done using only one material to check stability. Further studies in cooperating different other materials is required for future knowledge and understanding.
4. The study was done for three months and less extra oral aging conditions were used. Further studies are required using different extra oral aging conditions.
5. Visual assessment of skin shade may be an error in accurate shade matching.

VII. Conclusion

Within the limitation of this in vitro study and the result obtained, the study can be concluded that –

1. Specimens subjected to dark room for 3 months have the least color change irrespective of the shade used whereas specimens subjected to outdoor weathering have high significant color change.
2. Darker brown skin shade after exposing to different aging conditions produced the least color change followed by medium skin shade. There was strong inherent color instability of light brown skin shade specimens.
3. The color stability of Cosmesil M511 RTV silicone elastomer was unacceptable when subjected to five different extra oral aging conditions used in the study.

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