Change in the Mechanical Behaviour of Facial Elastomers after Weathering and Chemical Disinfection

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Abstract: ***Weathering and chemical disinfection are some of the parameters that lead to the deterioration of the facial elastomers over a period of time, especially the mechanical properties; tensile and tear strength. This study evaluated the effect of weathering and chemical disinfection on the tensile strength of two commercially available Room Temperature Vulcanizing silicone; M511 and A2000. The sample size of n=80 (n=40, each material) fabricated in a custom-made mold. The samples were suspended outdoor in Indian climatic conditions for a year and disinfected daily using commercially available disinfectant. The tensile strength tabulated before and after weathering, chemical disinfection using Universal Testing Machine (Instron) in the unit of Kg/cm2. Statistical analysis done using student paired t test showed significant difference (p-value=0.000**). A2000 showed better results compared to M511, therefore, giving us a clear choice between the two materials.***

Keywords: Facial elastomers, Weathering, Chemical disinfection, Tensile strength

1. Introduction

The replacement of missing parts such as nose, eyes, ears or the construction of a device to re-establish facial or cranial contour requires the utmost clinical skill, perception and technical know-how of available materials. Thus stringent reassessment of materials used in the fabrication of the prosthesis in the field of maxillofacial prosthetics seems indispensable(1,2).

Today there is a wide range of material available for fabrication of maxillofacial prosthesis, ranging from materials like; poly(methyl methacrylate), poly(vinyl chloride), chlorinated polyethylene, polyurethanes and silicone(3,4). But, resin polymers and elastomers are the mainstay of modern maxillofacial prosthetic reconstruction and have been tested and used frequently as they meet the requisites like biocompatibility, durability, color stability and ease of manipulation. (3,4)

Acrylic resin can be successfully employed for prosthesis catering specific type of facial defects, particularly those in which diminutive movements occur during function such as ocular defects. But they have drawbacks like; rigidity making it a bad choice for movable areas, porosity, water sorption and high thermal conductivity which produces discomfort during cold climates. Whereas silicone elastomers have a range of properties from rigid plastics through elastomers to fluids. They exhibit good physical properties over a range of temperatures. (2,5)

Silicone elastomers were first used for external prostheses by Barnhart (1960) and have since become the material of choice becauseof its chemical inertness, strength, durability, and ease of manipulation(2,6). Silicone is a combination of organic and inorganic compounds and chemically they are termed as polydimethylsiloxane. The inorganic backbone makes the unique difference of this material as siloxane bonds Si—O—Si in the main chains, as well as Si—C bonds where side groups are bonded to silicone, are extremely flexible and have a great freedom of motion. This is reflected in their lower viscosity, lower surface tension, lower melting point and glass transition temperatures, and is responsible for the elastomeric behaviours of many polysiloxanes. Silicone and methyl chloride react to form dimethyldichlorosilane. When water is added to dimethyldichlorosilane, a fluid polymer, polydimethylsiloxane (PDMS), is formed that is white and translucent and of varying viscosity, which is determined by the length of the polymer (7,8).

Silicone elastomers are of two types – Room temperature vulcanizing silicone (RTV) and Heat temperature vulcanizing silicone (HTV). The Room temperature vulcanizing silicone (RTV) is preferred over heat temperature vulcanizing silicone (HTV) due to its limitations such as, its white opaque finish that gives the prosthesis lifeless like appearance and its inability to accept extrinsic colors readily. Moreover, it requires high temperature for vulcanization, use of metal molds is necessary(9). The quality of silicone elastomer materials depends greatly on two basic components, one being poly (dimethylsiloxane) PDMS chains and the other silica fillers(2).

Although polymeric materials are highly versatile, their performance is still far from ideal, as most of them have disadvantages such as low thermal stability and its low resistance to solar radiation. They can last up to 24 months. Upon usage silicone suffers deterioration in physical and mechanical properties. Silica fillers, the polymer chains, their interactions with the surrounding environment, skin secretions and disinfecting solutions may affect the performance of silicone during service, necessitating replacement of the prosthesis (2,9).

Maxillofacial silicone elastomer should exhibit properties comparable to those of replaced facial tissues and maintain these properties during service. Among the ideal properties desirable for maxillofacial prosthesis those include biological, physical and mechanical properties and processing characteristics; mechanical properties like tensile strength and tear strength are the most important(3,7).The tensile strength and tear strength are essential for the longevity of the maxillofacial prosthesis.

The tensile strength gives an overall strength of the material. The tensile strength of maxillofacial prosthesis includes both the elastic and plastic elongation. It implies the extent to which the prosthesis can be stretched before failure, under tension and their ability to tolerate the movement of facial muscles [1,2]. Thus it also gives an idea about the flexibility of the material [1,2,3].

The factor which brings dramatic change to the properties of the material is their exposure to the environment and chemical disinfection procedures. The quality and measure of these undesirable changes may vary depending on the geographic location, climatic conditions, and the environment in which the prosthesis is worn. The main environmental factors that cause polymer degradation are sunlight, moisture, and temperature[10,11].

Weathering can indicate the polymer's outdoor performance as well as an estimate of its in-service lifetime and how it affects the mechanism of degradation. Artificial weathering can approximate the outdoor performance of polymers and in many cases is used to predict the lifetime of polymers under service conditions[10].

Moreover, different climatic conditions can be observed in different geographic location and during different seasons all year round as studies by Weins[12], Al Harabi et al.[14], Hatamleh et al.[11] and Eleni et al.[13].All these studies cannot be taken into consideration as India have a very diverse range of seasons.

The use of chemical disinfectant solution is another factor that leads to deterioration of the mechanical and chemical properties of the silicone elastomer. It is possible that silicone could be affected only on the surface rather thanthe bulk due to disinfection[15]

Disinfection is essential for facial prosthesis not only for protection from microorganisms of the prosthesis itself but also of the surrounding tissue. Patients have to disinfect their maxillofacial prosthesis every day for about 3 minutes in order to maintain optimum hygiene. There are mechanical as well as chemical methods for sterilization and disinfection of maxillofacial prosthesis, where mechanical methods include tooth brushing with water and chemical methods include disinfectant solutions like 4% chlorhexidine gluconate, neutral soap 4.8% (w/w) sodium hypochlorite solution --- etc[16,17].

Mechanical methods cause surface abrasions, that are undesirable for aesthetic and biological reasons, and furthermore, this method is not sufficient to eliminate the microorganisms completely. Thus, the use of chemical methods is chosen over it, where a disinfectant solution is used. Many chemical antimicrobial agents, such as effervescent denture cleansing tablets and other commercially available antimicrobial solutions like neutral soap, sodium hypochlorite solutions --- etc havebeen used to disinfect maxillofacial elastomers [18,19].

There is no literature regarding the effect of weathering and chemical disinfection on the degradation of maxillofacial silicone elastomers. Both the parameters are of deterioration over a period of time, especially in terms of mechanical properties like tensile and tear strength.

Taking into consideration this paucity of literature thisstudy is conducted with an aim to evaluate the effect of weathering and chemical disinfection on the tensile strength of M511 and A2000 silicone elastomers focusing onthe year- round climatic conditions of India.

The null hypothesis states that there is no effect of weathering and chemical disinfection on the tensile of two different maxillofacial silicone elastomer.

2. Materials and Method

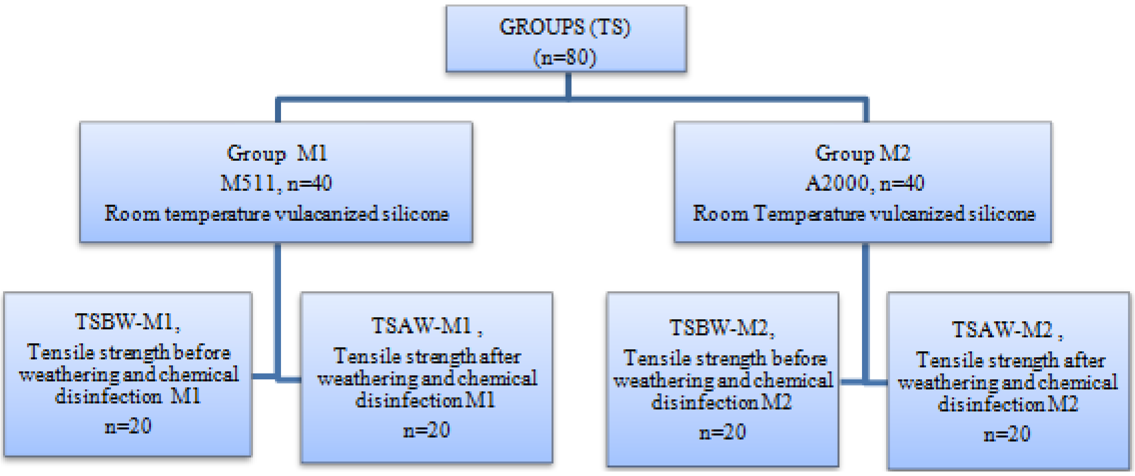
This in-vitro study was carried out in the Department of Prosthodontics, Sharad Pawar Dental College, Sawangi (M), Wardha and PRAJ Metallurgical Laboratory, Pune to evaluate the effect of weathering and chemical disinfection on the tensile strength of two maxillofacial silicone elastomers (dermatologically tested) [19-21].
Following materials and methodology was used:-
A) Materials used in the study:

- M511 Room Temperature Vulcanizing Silicone (FACTOR II, Arizona, U.S.A)
- A2000 Room Temperature Vulcanizing Silicone (FACTOR II, Arizona, U.S.A)
- Commercially available Disinfectant – Neutral soap (Johnson and Johnson, India)

B) Custom Made Equipments:

- Custom Made Metal Molds – 1 (Nagpur Engineering Works)
- Dumbbell -shaped mold (Evaluation of tensile strength): comprises of 10 dumbbell- shaped slots

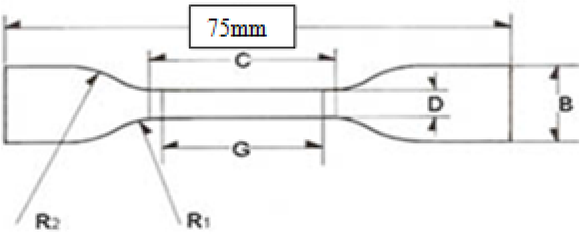
Methodology used in the study
The total sample size for evaluating the tensile strength was 80. The samples were grouped:



Fabrication of Samples Includes the Following Steps:

A) Fabrication of samples for evaluating tensile strength (Figures: 1 and 2):
The steps for fabrication of samples for tensile strength were same for both the maxillofacial silicone elastomers and were as follows:

B) Schematic Diagrammatic representation of samples for tensile strength:
Custom made metal molds of dimensions 75mm x 12.5mm x 4mm (ASTM ISOStandardization 37) were fabricated to produce dumbbell-shaped samples of the material, maxillofacial silicone elastomers M511 and A2000[22].



- The master mold was made using stainless steel and was then polished.
- The stainless steel mold was used because samples prepared in stainless steel mold exhibitbetter physical properties than dental stone[23].
- Mold contains 10 dumbbell-shaped slots of dimension 75mm in length, 4mm in width (75mm x 12.5mm x 4mm (ASTM ISOStandardization no.37).
- It's a two-piece mold, base with the dumbbell shaped slots and a lid over it which can be screwed.
- The mold was closed with a lid and tightening screws were used to fix the lid over the mold. This was for easy retrieval of the samples.
- The mold was kept in the hot air oven for half an hour at 100°C for initial curing of material M1 (M511) as recommended by the manufacturer[20].

C) Manipulation of the material:

- Maxillofacial silicone elastomer was weighed on the digital weighing machine.
- Silicone and the catalyst were mixed in a ratio of 1:10 parts mentioned by the manufacturer for 5 minutes at room temperature.
- Both part A and part B are mixed till a homogenous mixture is obtained.
- The samples were then retrieved after 24 hours and the excess elastomer was removed using a sharp scalpel and/or scissors.

Treatment for the samples

The samples (control group, n=40) before weathering and chemical disinfection were tested within 24 hours after the preparation and then were stored in distilled water.

a) Outdoor Weathering of the samples : (Figure 3)

- The samples were weathered outdoor by suspending them from a glass fibre on a stand as shown in (figure3).
- During the exposure, the samples were left uncovered and were exposed to all the three seasons, i.e. summer, monsoon and winter very discretely observed in the state of Maharashtra, India.
- The samples were adjusted to an angle of 5° from the horizontal to avoid standing water on the stand and to maximize the amount of sunlight exposure on the samples[10,13,14].
- The samples were exposed for about 10 hours daily and were then brought back in the room for the rest of the hours.

b) Chemical Disinfection of the samples :

- After the samples were brought back in the room, each sample was disinfected by wiping it with cotton dipped in neutral soap(Johnson and Johnson soap, India).

Testing of Samples

a) Evaluation of tensile strength

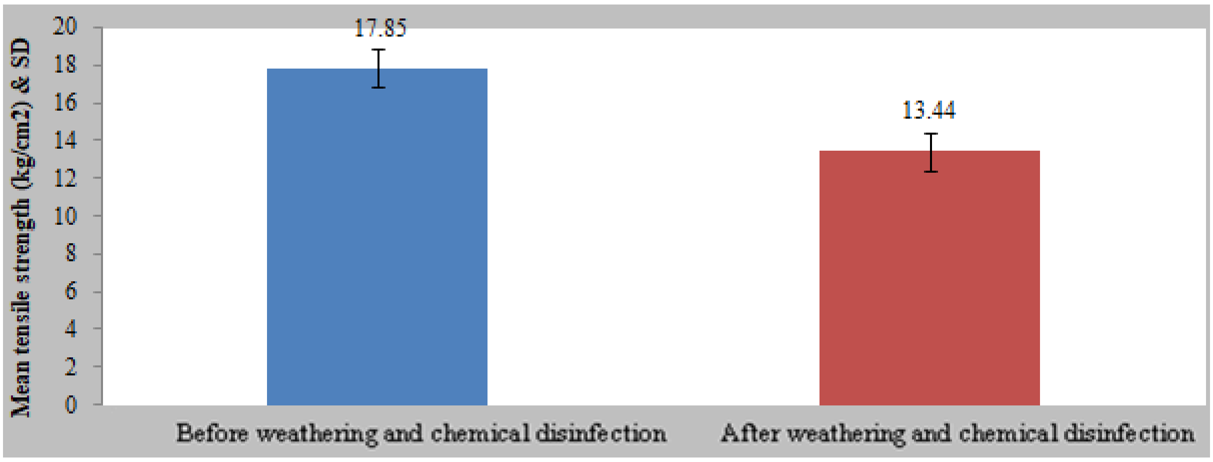
Universal testing machine (Instron) was used. Each sample of both the maxillofacial silicone elastomer M511 and A2000 were placed in the fixtures of the universal testing machine at a crosshead speed of 50mm/minute. The maximum tensile load was applied to break the sample. Tensile strength was calculated as maximum tensile load (Kg) divided by cross-sectional area (cm^2). All the samples were tested likewise.

3. Observation and Result

In order to derive conclusions from the study conducted, analysis and interpretation of the data obtained, by means of biostatistics using Students Paired t tests. Following results were obtained (table 1-4, graphs 1-4).

Table 1: Comparison of tensile strength of group M1 before and after weathering and chemical disinfection Student's Paired t test

Weathering and chemical disinfection (kg/cm^2)	Mean	N	Std. Deviation	Std. Error Mean	Mean Difference	t-value	p-value
Before	17.85	20	4.62	1.03	4.40±3.13	6.29	0.0001, S**
After	13.44	20	5.17	1.15			

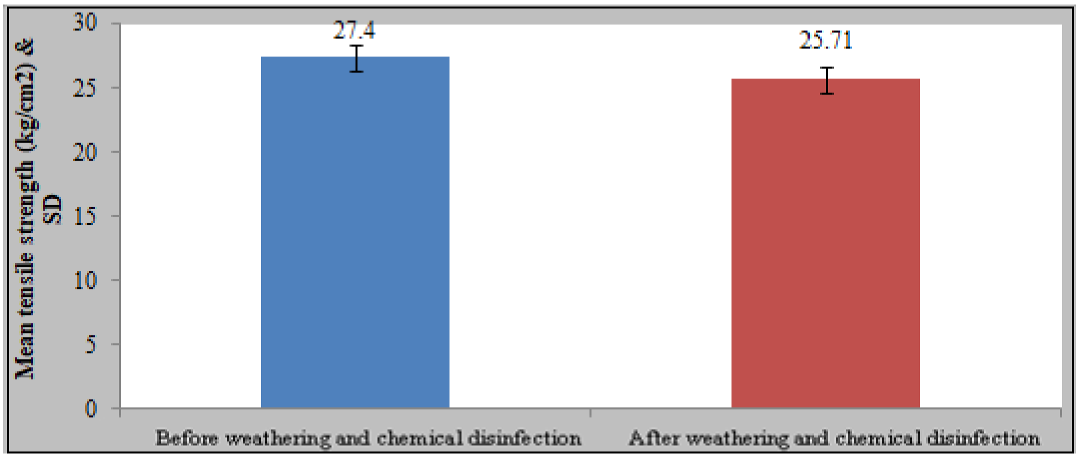


Graph 1: Comparison of tensile strength of group M1 before and after weathering and chemical disinfection

Inference: Mean tensile strength before and after weathering and chemical disinfection was 17.85±4.62 and 13.44±5.17. By using Student's paired t test statistically significant difference in mean tensile strength before and after weathering and chemical disinfection (t=6.29, p-value=0.0001**) (** shows highly significant value) was noted.

Table 2: Comparison of tensile strength of group M2 before and after weathering and chemical disinfection Student's paired t test

Weathering and chemical disinfection (kg/cm^2)	Mean	N	Std. Deviation	Std. Error Mean	Mean Difference	t-value	p-value
Before	27.4	20	3.52	0.78	1.69±2.95	2.56	0.019, S*
After	25.71	20	2.99	0.66			



Graph 2: Comparison of tensile strength of group M2 before and after weathering and chemical disinfection

Inference: Mean tensile strength before and after weathering and chemical disinfection was 27.40±3.52 and was 25.71±2.99. By using Student's paired t test statistically significant difference in mean tensile strength before and after weathering and chemical disinfection (t=6.29, p-value=0.019*) (* shows significant value) was noted.

Table 3: Comparison of tensile strength of group M1 and M2 before weathering and chemical disinfection Student's unpaired t test

Group (kg/cm^2)	N	Mean	Std. Deviation	Std. Error Mean	Mean Difference	t-value	p-value
M1	20	17.85	4.62	1.03	9.55±1.30	7.34	0.0001, S**
M2	20	27.4	3.52	0.78			

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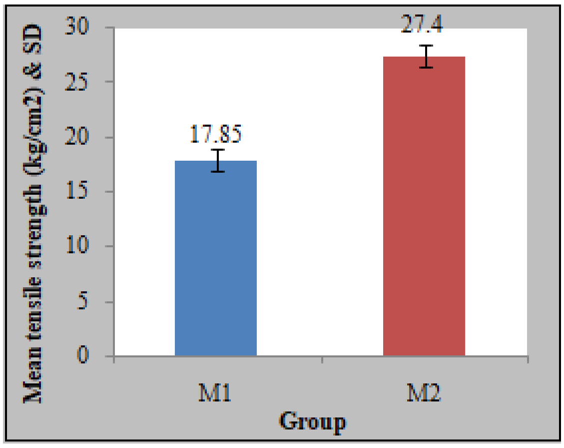
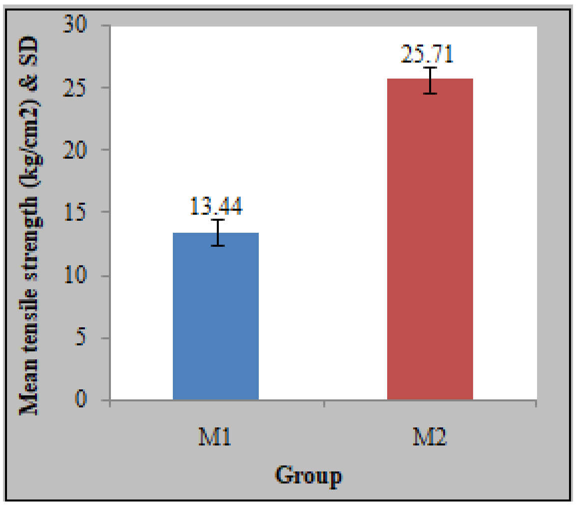


Graph 3: Comparison of tensile strength of group M1 and M2 before weathering and chemical disinfection

Inference: Mean tensile strength before weathering and chemical disinfection in group M1 was 17.85±4.62, and M2 was 27.40±3.52. By using Student's unpaired t-test statistically significant difference was found in mean tensile strength among two groups (t=7.34, p-value=0.0001**) (** shows significantly higher value).

Table 4: Comparison of tensile strength of group M1 and M2 after weathering and chemical disinfection
Student's unpaired t test

Group (kg/cm^2)	N	Mean	Std. Deviation	Std. Error Mean	Mean Difference	t-value	p-value
M1	20	13.44	5.17	1.15	12.26±1.33	9.17	0.0001, S**
M2	20	25.71	2.99	0.66			



Graph 4: Comparison of tensile strength of group M1 and M2 after weathering and chemical disinfection

Inference: Mean tensile strength after weathering and chemical disinfection in group M1 was 13.44±5.17 and in group M2 was 25.71±2.99. By using Student's unpaired t-test statistically significant difference was found in mean tensile strength among two groups (t=9.17, p-value=0.0001**) (** shows highly significant value).

4. Discussion

The use of maxillofacial prosthetic materials is increasingly be used to improve functional and esthetic deficiencies in patients with major facial defects [24,25]. The maxillofacial material should possess physical and mechanical characteristics comparable to those of the human tissues and ideally maintain those characteristics during service[26,27]. High tensile strength, tear resistance, and color stability are important properties of successful maxillofacial materials.

Mechanical properties like tensile strength, tear strength and color stability of silicone elastomers are clinically very important properties[11,28]. The tensile strength of the silicone elastomer indicates the overall strength and how far the material stretches before it breaks. Whereas, tear strength relates to the problem of the prostheses tearing while in use, particularly at the fine edges of the prosthesis[10,11].

Testing of tensile strength is an essential step toward the acceptance of the silicone elastomer, as they are important and essential for the longevity of the prosthesis[29].

Several types of materials can be used to fabricate maxillofacial prostheses; these include polyvinyl chloride, polymethyl methacrylate, polyurethanes, chlorinated polyethylene and silicones. Silicones are characterized by acceptable tear and tensile strengths, chemical inertness, high elongation, ease of fabrication and adequate bonding to underlying materials[30,31,32].

Because of the material's clinical inertness, strength, durability, ease of manipulation and adequate bonding to underlying materials; silicone elastomers have become the material of choice for the maxillofacial prosthesis. However, silica fillers, the polymer chains and the interactions between them, and the surrounding environment may affect their performance during service, necessitating replacement of the prosthesis[9,33,34].

Exposure of the prosthesis to various environmental conditions and routine cleansing protocol are the two major factors which can be responsible for the deterioration of the material when the prosthesis is in service[11].Very few are available which have evaluated the role of these two factors of maxillofacial silicone. Especially the combined effect of two has never been evaluated.

This study evaluates the combined effect of both natural weathering and chemical disinfection on the tensile strength of two commonly used maxillofacial silicone elastomers; M511 and A2000. The null hypothesis that there is no effect of weathering and chemical disinfection on the tensile strength of the two maxillofacial silicone elastomer was rejected.

In the present study, the silicone materials tested were Platinum-based Room Temperature Vulcanizing silicone, M511, and A2000. All the systems cross-link using addition reaction and are dermatologically evaluated [19-21].

Both the materials in this study showed deterioration of tensile strength after natural weathering and chemical disinfection after one year exposure toIndian climatic conditions. (Table 1, 2).

Mean tensile strength of group M1 (Table 1) was found to be less than M2 (Table 2) both before and after natural weathering and chemical disinfection for one year (Table 3,4).The reduction of these values was more significant for M1 group suggesting A2000 is a better material when compared to M511.

The tensile strength of the material are degraded by the surrounding environment, skin secretion, disinfecting solutions --- etc[6]. Steven Haug et al.[36]in his study concluded that environmental variables affected the tensile and tear strength of the maxillofacial materials. Weins[12] compared accelerated aging in the weatherometer with outdoor weathering and concluded that accelerated aging appeared to alter the mechanical properties sooner and with greater magnitude than outdoor weathering.

Environmental conditions; i.e., weathering induces significant changes in the extension of cross-linking and strongly affects the tensile and tear strength of polymers [13,37].

The main structural modifications in irradiated polymers are changes in their molecular weight distribution – due to main chain scission, cross-linking, end linking – and the production of volatile degradation products. All these phenomena tend to modify the material's tensile and tear strength as suggested by P.N.Eleni and his mathematical models [10,13].

Prosthesis hygiene is an important factor for maintaining the health of soft tissue underneath and for keeping the prosthesis in good condition. As they are in direct contact with tissues and body fluids for an extended period of time, microbes can colonize and form a biofilm. This may lead to severe skin infections and degradation of the maxillofacial material used. Patients are usually directed to disinfect their maxillofacial prosthesis daily in order to maintain proper hygiene. For this purpose, different chemical solutions such as hypochlorite cleansers, neutral soaps, efferent tablets---etc are used[16,17].

Nevertheless, the daily use of disinfectants, using aggressive chemical solutions reduces the service life of the prosthesis and raises the need for its replacement. Therefore, the disinfecting solution must be selected with caution in order to avoid deterioration of the material[38].

Neutral soap has been routinely used for the disinfection of acrylic orbital prosthesis to avoid the irritation of the sensitive tissues around the eye cavity. However, lately, neutral soap was proposed for the disinfection of other maxillofacial prostheses also, as they are chemically inert. In a study conducted by Perivoliotis D, et al. and Eleni et al.[15,17], they suggested that neutral soap was the least degrading to the polymers of silicone elastomer and showed milder alterations in the bulk of the materials when compared to other cleansing solutions. Hence in our study neutral soap was used as a disinfecting solution.[16,38].

Disinfection of elastomers alters the surface characteristics and the bulk of the material due to extraction of some compounds from the matrix. Chemical cleansing agents increase the absorption and solubility of the silicone. This leads to an increase in the porosity of the material promoting water absorption, altering its physical and mechanical properties. These alterations in the structure of elastomers affect its tensile strength; similar results were found by Steven Haug in his study where he suggested that the tensile strength of maxillofacial elastomers deteriorated by the use of a cleansing agent. Therefore, the effects of chemical disinfection were also tested in this study[15,17,39].

Molds used in the fabrication of prosthesis also play a major role in deciding the quality of the prosthesis. They not only provide final shape but also interact with silicone material and affect the properties of the material[23].

M511 has not been studied in literature for the combined effect of natural weathering and chemical disinfection. However, P.N Eleni (2009) studied M511 for effect of weathering and the values stated that it became softer due to the photo-oxidative reaction. [13] In the present study due to the added effect of chemical disinfection and difference in methodology, direct comparison with other studies is not possible.

The studies which evaluated the tensile strength of M511 are by Muhanad M. Hatamleh[30] which investigated the mechanical property M511. The values of tensile strength obtained in his study were in agreement with the present study. However, they haven't studied weathering.

The studies which evaluated the tensile strength of M511 where weathering was a parameter are by P.N.Eleni et al[10] conducted a study in Athens, where they found that after a yearlong exposure of outdoor weathering of M511 the tensile strength of the material deteriorated. A similar study was conducted by same authors in Thessaloniki in the year 2011 where the results found were same[10,13].The results of both studies are similar to the present study were also M511 showed degradation in tensile strength after weathering which is in agreement with our study. However, direct comparison of the value cannot be done due to the difference in methodology, climatic and geographical conditions.

The striking difference in environmental conditions in India where this study is carried out is that it is a country with 3 distinct seasons annually which are summer, winter and monsoon. This makes it important to study the material in the respective location so that the serviceability of the particular material can be predicted. This helps us to choose one material over the other.

A2000 was tested for tensile strength by Pinar Cevik [40](2016), he evaluated the mechanical properties of silicone elastomer, A2000. The control group value of tensile strength was higherthan the value observedin our study this was due to the difference in methodology. And the effect of weathering and chemical disinfection has never been evaluated before.

A recent study conducted by A.Rahim et al[41] on maxillofacial elastomer; M511 and A2000 stated that A2000 shows better tensile strength. These values are from a control group which is in agreement with our study.

This study shows (Table 3,4) that the tensile strength of group M1 significantly reduced by approximately 4.41 before and after weathering. For M2 the reduction was only approximately 1.69. Thus, it showed that the effect of weathering and chemical disinfection on the tensile strength of M2 was lower than that of M1. The difference was statistically significant (p-value=0.000**).

In this study among both the groups the tensile strength of A2000 silicone elastomer is more than that of M511 silicone elastomer. This result might be because of post-polymerization cross-linking as a result of energy from light irradiation, causing modifications in the polymer network structure.

After natural weathering and chemical disinfection, A2000 showed better results compared to M511, therefore, giving us a clear choice between the two materials.

In this study, an effort was made to isolate factors like weathering and chemical disinfection, contributing to the aging of silicone facial prostheses; however, during service, silicone prostheses are exposed to all these factors but with different period and concentration. Nevertheless, the sole effect of different factors were investigated, and mixed conditioning proved to affect the silicone prostheses materials severely.

As it is an in-vitro study the result may vary or may not correlate with situations clinically so future studies in this field should involve testing of material after its application or use on the patient so that realistic results are obtained.

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Figure 1: Preparation of samples for evaluation of tensile strength

Figure 2: Dumbbell-shaped sample for evaluation of tensile strength

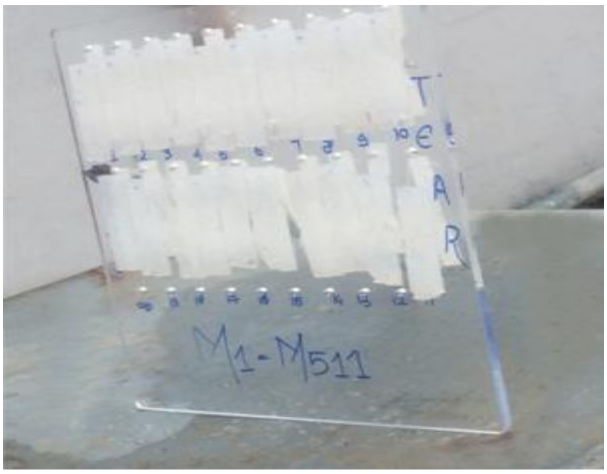

Figure 3: Outdoor weathering of samples