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Effect of Extraoral Aging Conditions on Mechanical Properties of Maxillofacial Silicone Elastomer

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Abstract

Purpose: The purpose of this study was to investigate the effect of extraoral human and environmental conditions on the mechanical properties (tensile strength and modulus, elongation, tear strength hardness) of maxillofacial silicone elastomer.
Materials and Methods: Specimens were fabricated using TechSil-S25 silicone elastomer (Technovent Ltd, Leeds, UK). Eight groups were prepared (21 specimens in each group; eight tensile, eight tear, five hardness) and conditioned differently as follows (groups 1 through 8): Dry storage for 24 hours; dry storage in dark for 6 months; storage in simulated sebum solution for 6 months; storage in simulated acidic perspiration for 6 months; accelerated artificial daylight aging under controlled moisture for 360 hours; outdoor weathering for 6 months; storage in antimicrobial silicone-cleaning solution for 30 hours; and mixed conditioning of sebum storage and light aging for 360 hours. The conditioning period selected simulated a prosthesis being in service for up to 12 months. Tensile and tear test specimens were fabricated and tested according to the International Standards Organization (ISO) standards no. 37 and 34, respectively. Shore A hardness test specimens were fabricated and tested according to the American Standards for Testing and Materials (ASTM) D 2240. Data were analyzed with one-way ANOVA, Bonferroni, and Dunnett's T3 post hoc tests ($p < 0.05$). Weibull analysis was also used for tensile strength and tear strength.
Results: Statistically significant differences were evident among all properties tested. Mixed conditioning of simulated sebum storage under accelerated artificial daylight aging significantly degraded mechanical properties of the silicone ($p < 0.05$).
Conclusions: Mechanical properties of maxillofacial elastomers are adversely affected by human and environmental factors. Mixed aging of storage in simulated sebum under accelerated daylight aging was the most degrading regime. *Clinical significance*: Accelerated aging of silicone specimens in simulated sebum under artificial daylight for 12 months of simulated clinical service greatly affected functional properties of silicone elastomer; however, in real practice, the effect is modest, since sebum concentration is lower, and daylight is less concentrated.

Facial defects can result from congenital abnormalities, surgical resection of tumors, trauma, or a combination of these occurrences.[1,2] They often result in devastating cosmetic, functional, and psychological consequences, and require difficult and challenging procedures for maxillofacial surgeons and prosthetists. Surgical reconstruction of such defects is often limited by insufficient residual soft and hard tissue and vascular compromise. Thus, a facial prosthesis presents the only attractive and practical alternative, when esthetic and functional demands cannot be surgically fulfilled.[3,4]

Silicone elastomers have been widely used for constructing maxillofacial and other prosthetic devices where soft tissue and anatomic (form) reconstruction is needed. They are usually comprised of poly(dimethylsiloxane) (PDMS) elastomers. The PDMS chains, silica fillers, and the interactions between these components affect the overall strength and serviceability of the silicone elastomers.[5–7]

Silicones have many desirable properties including biocompatibility, ease of manipulation, low viscosity, and patient accommodation properties (i.e., nontoxic, easily cleansable, lightweight, compatible with adhesives).[8] Moreover, they have high tensile strength, high elongation, and sufficient bonding to underlying substrates.[9–12] Despite their wide use, they are far from ideal. The longevity of maxillofacial prostheses is dependent on the prosthesis material and the patient's attitude toward the prosthesis,[13] and it can be directly associated with the effectiveness of the prosthesis in achieving its objectives.[14] Silicone-based maxillofacial prostheses require replacement every 6 to 18 months, as they suffer deterioration in physical and mechanical properties and discoloration upon service.[13,15]

Many studies have investigated the properties of silicone elastomers after storage in simulated sebum solution or acidic perspirations,[16,17] exposure to artificial daylight or radiation,[18–22] storage in silicone-cleaning solutions,[23] or outdoor weathering.[24–26] However, direct comparisons between these treatments are not possible, as studies varied in silicone elastomers tested, conditioning treatments (composition and duration), and specimen fabrication and testing standards used. Whereas MDX 4-4210 silicone (MDX 4-4210, Dow Corning, MI) was not affected by accelerated light aging,[20] Epithan-3 polyurethane (Epithane-3, Daro products, Butler, WI) decomposed by the end of light radiation.[17] While mechanical properties of Episil silicone (Episil, Dreve Dentamid, Unna, Germany) were enhanced after 6 months storage in acidic perspiration,[16] Epithane-3 and Cosmesil (Cosmedica, Cardiff, UK) depolymerized after 24 hours of chlorine storage.[17]

A recent study showed that color stability of TechSil S25 maxillofacial silicone (heat-temperature vulcanizing, HTV) was unacceptable ($\Delta E > 3.0$, range from 3.48 to 9.89 for pigmented and 3.89 to 10.78 for unpigmented) when subjected to six of seven accelerated conditionings with clinical relevance in both severity and duration.[27] Unpigmented TechSil S25 (Technovent Ltd, Leeds, UK) had an inherent color instability, adding to its overall color change. Silicone specimens stored in sebum and exposed to accelerated light aging exhibited the greatest color changes.[27] However, the literature lacks comprehensive data on silicone serviceability and properties under clinically related extraoral aging conditions. Therefore, the aim of this study was to investigate the effect of extraoral human and environmental conditions on the mechanical properties of new maxillofacial silicone elastomer, and to rank the conditions. Our null hypothesis stated that maxillofacial silicone elastomer properties are not affected by extraoral aging conditions.

Materials and methods

TechSil S25 silicone elastomer, an addition platinum-catalyzed silicone elastomer, was used throughout the study. The material is provided as rubber and hardener with a mixing ratio of 9:1 gm. It was processed in dental stone molds and cured in a dry heat oven at 100°C for 2 hours.

Hard wax patterns (Associated Dental Products Ltd, Swinton, UK) of the test specimen designs (tensile, tear, hardness) were invested in dental stone (Class 1, Dentsply, Surrey, UK) to construct the molds. After the stone set, the patterns were removed, and the molds were ready for specimen construction.

The silicone elastomer was mixed manually for 5 minutes followed by mechanical mixing under vacuum for 5 minutes (Multi Vac 4, Degussa, Hanau, Germany).[28] Then it was poured into the molds with the aid of vibration. Twenty-one specimens (eight specimens for each tensile and tear test, and five specimens for hardness) were evaluated for each conditioning mode.

Table 1 Study groups

Group (n = 21)*	Exposure mode	Exposure duration
1	Control	24 hours
2	Storage in the dark (time passage)	6 months
3	Sebum solution	6 months
4	Acidic perspiration	6 months
5	Accelerated daylight aging	360 hours
6	Outdoor weathering	6 months
7	Antibacterial silicone-cleaning solution	30 hours
8	Mixed aging (sebum storage under light)	360 hours

*Each group had 21 specimens divided between the mechanical tests performed (eight specimens for each tensile and tear test, and five specimens for hardness test).

The specimens tested were exposed to seven conditions with different exposure times (Table 1). Group 2 specimens were suspended with stainless steel ligature wires in a sealed glass container and stored in the dark at room temperature (23 ± 2°C) and 50 ± 5% relative humidity for 6 months (time passage). Group 3 specimens were stored in simulated sebum for 6 months. The sebum was prepared by dissolving 10% palmitic acid with 2% glyceryl tripalmitate into 88% linoleic acid (all w/w).[16,17] Accordingly, 244.45 ml of sebum was made by dissolving 25 g palmitic acid with 5 g glyceryl tripalmitate into 244.45 ml of linoleic acid (density 0.9 g/ml). The sebum was freshly reprepared after the first 3 months.

Group 4 specimens were stored in simulated acidic perspiration for 6 months (pH 5.5). The solution contained the following (per liter 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 (ISO) specification ISO 105-E04:96.[29] The solution was freshly reprepared after the first 3 months.

For the light aging group (group 5), accelerated daylight aging was achieved using filtered Xenon light of 150 klx and 475 W/m^2 irradiance (Suntest Chamber CPS, Heraeus Instruments, Hanau, Germany). A complete weathering cycle lasted for 120 minutes, including 18 minutes of wet weathering by controlled flow of distilled water (29 ± 2°C), followed by 102 minutes of dry weathering (36 ± 2°C). The relative humidity was approximately 70%, and air pressure was 700 to 1060 hPa. The Xenon light was applied for the whole duration of aging (360 hours). Group 6 specimens were suspended from wooden racks using stainless steel ligature wire, and the assembly was placed on the roof of the Manchester Dental School (Manchester, UK) for 6 months (July 2008 through December 2008). At the end of the treatment period, the specimens were removed, cleaned for 15 minutes in distilled water in an ultrasonic cleaner (Transonic T310, Camlab Ltd, Cambridge, UK), stored for 24 hours at room temperature (23 ± 1°C), and then tested. Average monthly outdoor weathering conditions

Table 2 Monthly average radiation and climatic data during outdoor weathering

Date	Mean temp (°C)	Min temp (°C)	Max temp (°C)	Wind speed (knots)	Rainfall (mm)	Global radiation (kJm^2)	Sunshine (hrs)
July 2008	16.2	12.3	20.0	7.9	3.5	16397.5	4.7
August 2008	16.1	12.7	19.4	7.7	2.9	11873.8	2.6
September 2008	13.1	9.2	17.0	5.8	3.1	9421.4	3.4
October 2008	9.3	5.8	12.8	8.5	4.6	5947.7	3.0
November 2008	6.6	4.0	9.0	7.7	1.8	2605.4	1.8
December 2008	2.6	−0.9	6.1	6.2	2.5	2161.9	2.2

Data source: Met office. Woodford location, Greater Manchester, England.

are presented in Table 2. Group 7 specimens were stored in a commercially available antimicrobial silicone-cleaning solution (B-200–12, Daro Inc., Lakeside, AZ) for 30 hours.

Group 8 specimens were stored in simulated sebum solution in the aging chamber of the aging machine and exposed to accelerated artificial daylight for 360 hours. The aging machine used filtered Xenon light of 150 klx and 475 W/m^2 irradiance (Heraeus Instruments).

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

The experimental procedures were conducted according to specifications for vulcanized rubber established by the ISO and the American Standards for Testing and Materials (ASTM). Specimens were tested after 24 hours of conditioning at room temperature (23 ± 1°C) and at 50 ± 5% relative humidity.

Tensile tests were conducted according to ISO 37.[30] Type 2 dumbbell-shaped specimens were produced. TS, elongation percentage at break, and tensile modulus at 100% elongation were measured with a computer-operated Zwick universal testing machine (Zwick/Roell Z020, Leominster, UK). The thickness of each specimen was measured using a digital caliper (Mitutoyo, Tokyo, Japan) from three points (at the center and at each end of the test length), and the mean thickness was used for cross-sectional area calculations. The separation between the tensile grips was 20 mm, and each specimen was inserted into the tensile-testing grips, with the end tabs being gripped symmetrically so tension was distributed uniformly over the cross-section. Tensile tests were performed at a 500 mm/min crosshead speed. Specimens that broke outside the narrow portion or yielded outside the test length were discarded. The tensile strength and elongation percentage (EP) were calculated automatically by the software, using equations 1 and 2, respectively.

$$\mathrm{Ts} = \frac{\mathrm{F_b}}{\mathrm{Wt}} \tag{1}$$

$$\mathrm{EP} = \frac{\mathrm{L_b} - \mathrm{L_o}}{\mathrm{L_o}} \times 100\% \tag{2}$$

where F_b = force recorded at break (N), W = width of the narrow portion of the specimen (mm), t = thickness of the test length (mm), L_o = initial test length (20 mm), L_b = test length at break (mm).

The tensile modulus was obtained from the plotted stress-strain curve when a specimen was subjected to 100% strain,[31] using SigmaPlot software (version 11, SPSS Inc., Chicago, IL). Tear test was performed according to ISO 34-1[31] on trouser-shaped specimens. A cut in the test specimen was made (40-mm long) at the center of the width of the test specimen. Test specimen trouser legs were inserted symmetrically and in axial alignment with the direction of the pull in each grip. The depth of insertion was 30 mm, ensuring the specimen was adequately gripped. Specimens were tested at a 100 mm/min strain rate with the Zwick machine. The tear strength, expressed in kiloNewtons per meter of thickness (kN/m), was calculated according to equation 3:

$$\mathrm{Ts} = \frac{\mathrm{F}}{\mathrm{d}} \tag{3}$$

where F = the median force (N) calculated, d = median thickness (mm) of the test piece.

Indentation hardness was determined with a Shore A durometer (MFG Co., New York, NY) on 25 × 25 × 6 mm^3 specimens, according to ASTM specification D 2240.[32] The Shore A durometer was held in a vertical position, and the presser foot was applied parallel to the surface of the specimens. The readings were obtained 5 seconds after firm contact was achieved. For each specimen, nine readings were taken with a 6-mm distance maintained between readings and of the edge of test specimen. Then the average value was calculated.

Data relating to each property were subjected to Levene's test of homogeneity of variance ($\alpha = 0.05$), to determine whether equal variances could be assumed ($p > 0.05$). Accordingly, one-way ANOVA and Bonferroni post hoc tests (SPSS Inc.) were used to analyze significant differences between test groups (equal variances assumed) within properties (tensile strength, elongation percentage, tear strength). Dunnett's T3 multiple comparison test was used to analyze significant differences between test groups ($p < 0.05$) for tensile modulus (equal

Table 3 Mean (SD) values of different properties of TechSil S25 silicone elastomer after exposing to different conditions

	Groups							
Properties	Control 1	Time passage 2	Sebum 3	Acidic perspiration 4	Light aging 5	Outdoor weathering 6	Cleaning solution 7	Mixed (light and sebum) 8
Tensile strength (MPa)	4.85 (0.38)[a]	4.45 (0.47)	3.90 (0.50)	4.22 (0.83)	4.64 (0.78)	4.33 (0.73)	4.81 (0.65)	3.70 (0.73)[b]
Tensile modulus (MPa)	0.64 (0.09)[a]	0.67 (0.14)	0.64 (0.16)	0.81 (0.15)	0.29 (0.07)[b]	0.24 (0.03)[b]	0.23 (0.03)[b]	0.56 (0.10)
Elongation (%)	941.25 (94.47)[a]	776.92 (87.63)	712.08 (112.46)[b]	620.21 (72.66)[b]	997 (126.8)	891.45 (113.18)	1091.98 (132.66)	784.06 (151.37)
Tear strength (kN/m)	6.64 (1.61)[a]	6.22 (1.37)	4.75 (1.24)	4.51 (1.43)	5.98 (0.94)	5.51 (1.05)	4.12 (0.97)[b]	3.24 (1.36)[b]
Shore A hardness	25.86* (0.87)[a]	25.07 (0.37)	20.96 (1.38)[b]	29.30 (1.04)[b]	27.59 (1.40)[b]	27.11 (0.48)[b]	24.80 (0.68)	20.43 (0.74)[b]

Within each property, superscript letters indicate significant differences between paired groups ($p < 0.05$) when compared to its control specimens.
*Average value of the 35 specimens fabricated.

variances not assumed). For the hardness property, a *t*-test for paired data (release 16, SPSS Inc.) was performed ($p < 0.05$). Pearson's correlation and quadratic regression analyses were used to evaluate possible correlation between tensile strength and Shore A hardness ($\alpha = 0.05$) after different treatment conditions using SigmaPlot (version 11, SPSS Inc.).

Two-parameter Weibull analysis was carried out to calculate the cumulative failure probability of the strength measurements (both tensile and tear) via following steps:

Step 1: The strength results were (either tensile or tear) ranked in ascending order, and the mean rank was calculated using the following formula:

$$\mathrm{Pf(i)} = \mathrm{i}/(\mathrm{N} + 1)$$

where i is the rank order, and N is the total number of specimens in the group.

Step 2: The Weibull parameters were defined by performing the simple linear regression (X, Y). X = ln (strength)

$$\mathrm{Y} = \ln(\ln(1/(1 - \text{Mean rank})))$$

The slope of the regression line represented the Weibull modulus, "m." The characteristic strength, $\sigma 0$, was obtained from the line intercept on the Y-axis in $\sigma 0 = e\,(-Y/m)$.

Step 3: The Weibull probability distribution was created using the formula:

$$\mathrm{Pf} = 1 - \exp\{-(x/\sigma 0)m\}$$

where Pf = Weibull probability distribution; x = tensile or tear strength; σ = characteristic strength (the point where the regression line intersects the Y-axis); m = Weibull modulus (the slope of the regression line).

Results

Statistically significant differences were evident among all properties tested. Mixed conditioning of simulated sebum storage under accelerated artificial daylight aging significantly degraded mechanical properties of silicone in comparison with the control group ($p < 0.05$).

Means and standard deviation values are presented in Table 3. The tensile strength ranged from 3.70 to 4.85 MPa, the tensile modulus ranged from 0.23 to 0.81 MPa, the elongation at break ranged from 620.21 to 1091.98%, the tear strength ranged from 3.24 to 6.64 kN/m, and the Shore A hardness varied from 20.43 to 29.30.

Figure 1 shows a correlation between tensile strength and Shore A hardness after different treatment conditions. Tensile strength correlated statistically significantly with Shore A hardness ($p = 0.049$, r = 0.837).

The Weibull modulus (m), the 95% confidence intervals, the characteristic failure strength, the correlation coefficient r, and the stress for 5% failure probability for both tensile strength and

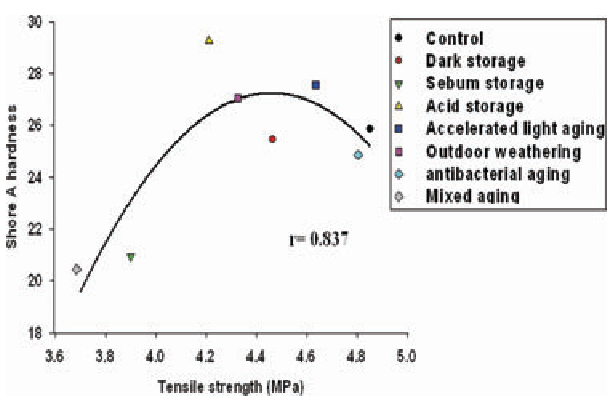

Figure 1 Changes in Shore A hardness as function of tensile strength after different treatments.

Table 4 Weibull parameters of tensile strength for the groups. Different lowercase letters indicate significant difference.

Tensile strength								
	Groups							
Parameters	Control	Dark storage	Sebum storage	Acid storage	Accelerated light aging	Outdoor weathering	Antibacterial	Mixed aging
Weibull modulus (m)	11.85 a	9.06 b	7.31 c	4.68 d	5.35 d	5.44 d	7.12 c	4.32 d
95% Confidence interval for Weibull modulus	10.07 – 13.63	7.49 – 10.63	5.34 – 9.28	3.88 – 5.49	3.87 – 7.23	4.07 – 6.82	5.09 – 9.16	2.98 – 5.67
Characteristic failure strength (MPa)	8.69	6.42	4.86	3.47	4.24	4.00	5.41	2.98
Correlation coefficient (r)	0.989	0.985	0.966	0.986	0.957	0.970	0.961	0.955
Stress for 5% failure probability	8.89	6.61	5.04	3.67	4.45	4.20	5.61	3.17

tear strength are shown in Tables 4 and 5. For tensile strengths, statistical significances were presented in the Weibull modulus values of the groups in comparison to the control group ($p < 0.05$). The correlation coefficient values (r) were in the range 0.87 to 0.99. The Weibull probability distributions are presented in Figures 2 and 3.

Discussion

The actual performance of silicone elastomers under extraoral factors can be evaluated by exposure tests simulating conditions involving sterilization, hygienic maintenance procedures, biological skin fluid absorption, and outdoor exposure.[11] TechSil S25 showed comparable functional (mechanical) properties to commonly used silicone elastomers.[33] However, its properties were affected by human and environmental factors; accordingly, we rejected the null hypothesis.

TechSil S25 is an addition HTV vinyl-blocked (CH-CH_2) PDMS, which undergoes cross-linking in the presence of a platinum catalyst. HTV silicones have the advantages of excellent thermal stability and physical properties along with color stability in comparison to room-temperature vulcanizing (RTV) silicones.[11]

Conditioning of silicone elastomers can induce changes in physical and chemical structures, potentially resulting in significant alterations in their functional properties. Acids,[17] catalyst contaminants,[34] and climate characteristics, including sunlight radiation, temperature, moisture,[35] dust, and pollutants[17] affect silicone properties.

TechSil S25 is an addition platinum-cured vinyl-blocked (CH-CH_2) PDMS, which undergoes cross-linking with the aid of a hydride functional siloxane copolymer, in the presence of a platinum catalyst. The curing process was accelerated at 100°C in a dry oven for 2 hours. At elevated temperatures, cross-linking occurs, and volatile decomposition products from the catalyst are removed, resulting in optimal mechanical and physical properties. Silicone was mechanically mixed under vacuum to ensure homogeneous mixtures and pore-free specimens.[28]

Tensile strength and tear strength, elongation at break, and hardness of TechSil S25 significantly changed in comparison to control properties, and the change varied according to the aging performed. Variations are likely due to differences in structural stability of the PDMS chains as a result of cross-linking densities and conditioning type.[16,17,35] However, specimens stored in the dark for 6 months maintained the same properties recorded

Table 5 Weibull parameters of tear strengths for the groups. Different lowercase letters indicate significant difference.

Tear strength								
	Groups							
Parameters	Control	Dark storage	Sebum storage	Acid storage	Accelerated light aging	Outdoor weathering	Antibacterial	Mixed aging
Weibull modulus (m)	3.64 a	3.89 a	3.55 a	2.95 a	5.99 b	5.02 b	4.01 a	1.71 c
95% Confidence interval for Weibull modulus	2.63 – 4.64	3.05 – 4.72	2.22 – 4.88	1.33 – 4.57	4.47 – 7.52	2.23 – 7.81	2.64 – 5.51	1.09 – 2.34
Characteristic failure strength (MPa)	3.49	3.62	2.93	2.44	5.19	4.26	3.05	1.37
Correlation coefficient (r)	0.964	0.978	0.936	0.876	0.969	0.874	0.943	0.939
Stress for 5% failure probability	3.75	3.87	3.16	2.67	5.42	4.49	3.25	1.60

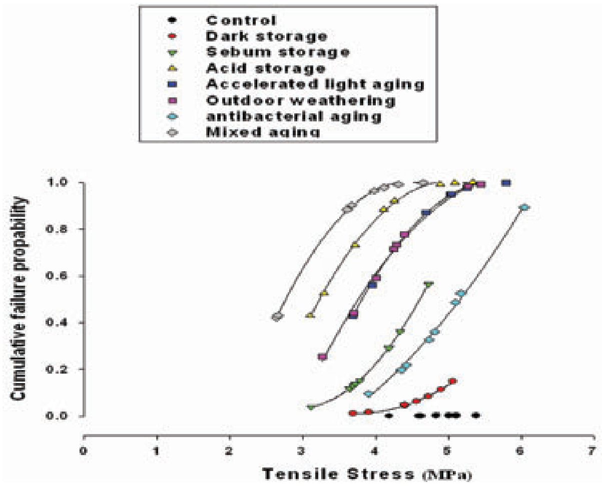

Figure 2 Weibull probability distribution of tensile stress.

at baseline, evidently due to the absence of physical or mechanical conditioning. Nevertheless, this result may be silicone-type dependent and, in partial agreement with other studies, as some silicone elastomers degraded with time in the absence of any conditioning.[23]

The results of each tensile strength and tear strength test varied among the groups. Such data are often presented in studies in the form of mean value and standard deviation; however, this does not give the true strength value due to experimental variations among studies and, therefore, could lead to misinterpretation of testing materials. Weibull analysis provides a better solution by giving the failure probability evaluation at any stress level. The Weibull modulus (m) is a measure of scatter, which represents the coefficient of variation of the measured result.[36] A lower m value means a wider scatter of results.

Tensile strength was only degraded after mixed aging of sebum storage under accelerated daylight aging for 360 hours.

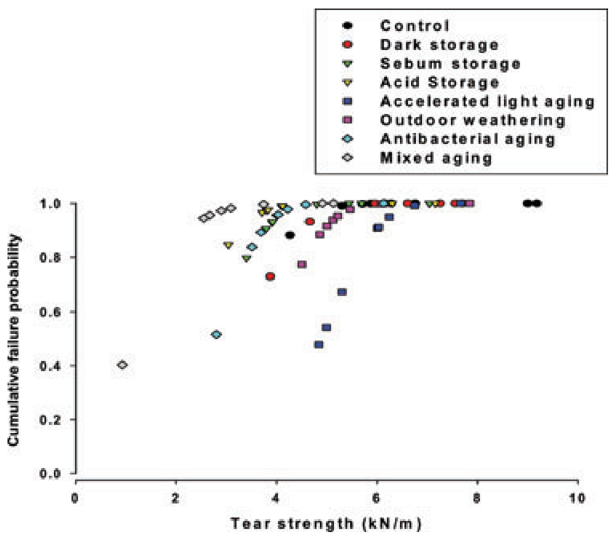

Figure 3 Weibull probability distribution of tear stress.

Degradation or enhancement of silicone physical properties is usually caused by structural modifications in the distribution of the polymer molecular masses caused either by polymer chain scission, intensified cross-linking, or increased density causing the polymer to either become softer or harder.[20,37]

Accelerated daylight aging produces denser elastomeric structures as it enhances cross-linking between chains. 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.[38] Sebum fatty acids tend to interact with silicone, breaking chain bonds and decomposing the elastomer.[16] This degradation effect is accelerated with light radiation, leading to softer and weaker elastomer. Silicone elastomers depolymerize by contact with concentrated acids and bases in a phenomenon known as reversion, which takes place when the silicone is heated in a totally encapsulated space with the presence of water and acid catalyst residues.[38]

Elongation at break decreased after storage in either simulated sebum solution or acidic perspiration. While the effect of sebum is described above, the catalytic effect of the acidic environment on the cross-linking reaction leads to the decomposition of polymer network junctions in the silicone, which break at lower forces; however, cross-link density can be accurately identified by swelling experiments in organic solvents.[35]

The other important property is the marginal integrity and durability of the silicone prosthesis during clinical service. TechSil S25 silicone elastomer tear strength significantly degraded after being stored in antimicrobial silicone-cleaning solution or mixed aging, indicating that the silicone material became inelastic and brittle, and ruptured at very low deformations.[12] Such degradation is likely caused by an accelerated breakdown of the silicone chains by the fatty acid with the enhancement of radiation from accelerated lighting for a long time; however, light aging tends to increase cross-linking, but too high levels of cross-linking result in inelastic brittle materials.

The antimicrobial silicone-cleaning solution, while in use, decomposes into carbon monoxide, carbon dioxide, and sulfur dioxide (Daro Products, Antimicrobial soap B-200-1, 2007). It is highly likely that such decomposition products affected the tear strength of the silicone elastomer, as traces of carbon monoxide, amines, sulphur, organo tin-compounds, and nitrogen oxide inhibited the cure of MDX4–4210 silicone elastomer, which is basically similar to TechSil S25.[34] However, tensile strength decreased, but not statistically significantly with the cleaning solution.

The hardness of silicone elastomers is controlled by the surface characteristics of the polymer network and by the density of cross-links.[16] For TechSil S25, Shore A hardness significantly increased after immersion in acidic solution and exposure to accelerated light aging. On the other hand, hardness decreased significantly after immersion in simulated sebum solution or with the aid of accelerated light aging. This can be due to an interaction of the fatty acids with the surfaces of the silicone.[16,17]

There were no significant differences in mechanical properties between artificial-daylight aging and outdoor weathering groups. Furthermore, they had similar effects on properties when compared to control specimens. Accordingly, the settings used for the aging device can effectively simulate environmental factors affecting silicone prostheses in the period of July to December in England; however, data from one exposure in a single location are not suitable for estimating the durability of silicone elastomer. Also climatological changes preclude the use of a single exposure test to predict the mean degradation rate of a natural or synthetic substance; thus, several years of repeated exposures would be required to obtain a reliable average test result for a specific location.[25]

All treatment conditions tested had no enhancing effect on the tensile strength and tear strength of TechSil S25, indicating that the serviceability of the TechSil S25-based silicone prostheses is likely to be diminished upon use, and the term "one-time prosthesis," which lasts for the whole life of the patient, is still unrealistic.[14] However, acidic perspiration, daylight aging, and outdoor weathering significantly increased hardness of the silicone, within the acceptable hardness ranges previously reported. On the other hand, and regardless of treatment conditioning of silicone specimens, tensile strength correlated statistically significantly with Shore A hardness ($p = 0.049$, $r = 0.837$).

The current conditioning procedures subjected specimens to concentrated media of acidic perspiration, sebum, and lighting conditions that might be greater than normal conditions. In this study, an effort was made to isolate factors contributing to the aging of silicone facial prostheses; however, during service, silicone prostheses are exposed to all these factors but with different periods and concentrations. Nevertheless, the sole effects of different factors were investigated, and mixed conditioning proved to affect the silicone prostheses materials most severely.

Conclusions

Within limitations of this in vitro study, it can be concluded that:

(1) TechSil S25 silicone elastomer properties were enhanced or adversely affected by different environmental factors.
(2) Shore A hardness was the most sensitive property, as it was enhanced after acidic perspiration, accelerated daylight aging, and outdoor weathering; however, hardness degraded after storage in simulated sebum with or without accelerated daylight aging.
(3) Mixed aging via storage in simulated sebum under accelerated daylight aging for 360 hours was the most degrading factor, as tensile strength and tear strength and hardness of TechSil S25 silicone elastomer were all adversely degraded.

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