

Color stability and colorant effect on maxillofacial elastomers.

Part I: Colorant effect on physical properties

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Statement of problem. The average clinical life span of a maxillofacial prosthesis is approximately 6 months, at which point it needs to be refabricated, mainly because of degradation of the color and physical properties of the prosthesis.

Purpose. This first part of a 3-part study evaluated the effect of coloring agents on the physical properties of maxillofacial elastomers.

Methods and material. Five dumbbell-shaped and 5 trouser-shaped specimens were fabricated for each of the combinations of the 3 elastomers (Silastic medical adhesive type A, Silastic 4-4210, and Silicone A-2186) and 6 colorants (dry earth pigments, rayon fiber flocking, artist's oil paints, kaolin, liquid cosmetics, and no-colorants), for a total of 180 specimens. Evaluations of hardness and tear strength were made with the trouser-shaped specimens. Evaluations of the ultimate tensile strength and the percentage elongation were made with the dumbbell-shaped specimens. A within elastomer analysis compared the 6 colorants using a 1-way analysis of variance for each of the 4 physical properties. When significant differences were observed, the Student-Newman-Keuls multiple range test was used to identify differences between groups at a significance level of .05.

Results. Physical properties of maxillofacial elastomers were changed by the incorporation of coloring agents. Dry earth pigments, kaolin, and rayon flocking acted as a solid filler without bonding to the Silicone, and artists' oils and liquid cosmetics acted as a liquid phase without bonding to the silicone matrix.

Conclusion. No clearly superior colorant-elastomer combination was demonstrated in all the tests in this study. (J Prosthet Dent 1999;81:418-22.)

CLINICAL IMPLICATIONS

The clinician must possess a thorough understanding of the benefits and shortcomings of each of the materials used in the fabrication of a maxillofacial prosthesis before making a decision regarding their use in patient treatment. In this study, the liquid colorants tended to decrease hardness and tensile strength while increasing tear strength and percent elongation. Dry colorants tended to decrease tensile strength and increase hardness.

The use of silicone elastomers for facial prostheses was first presented in 1960 by Barnhart.¹ Since that time, silicone elastomers have become the material of choice for maxillofacial prostheses because of the material's clinical inertness, strength, durability, and ease of manipulation.² The primary goal of maxillofacial prosthetics is to restore the patient's appearance to allow improvement in self-esteem and help the patient lead as normal a life as possible. It follows that fabricating a prosthesis with optimal physical properties and esthetics and maintenance of its appearance and properties over its service lifetime is of major importance. The principle reason for replacement of facial prostheses is a degradation in appearance because of changes in color

and physical properties. In 1980, Yu et al³ evaluated the effect of dry earth pigments on the physical properties of Silastic 4-4210 material. To date, the effects of many popular coloring agents on the physical properties of popular maxillofacial polymers have not been evaluated.

The purpose of this in vitro study is to report on the interactions between elastomers, colorants, and weathering as they influence properties that are related to the effective life span of these prostheses. This first part in a 3-part investigation examines the influence of common colorants on the physical properties of 3 maxillofacial polymers.

MATERIAL AND METHODS

Four of the more commonly used intrinsic coloring agents based on a recent survey of both the American Academy of Maxillofacial Prosthetics and the American Anaplastology Association were evaluated:⁴ dry earth

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Table I. Representative values of colorants added to 200 g of silicone

Dry earth pigments	Dark buff	0.04063 g
	Medium brown	0.10563 g
	Red brown	0.01625 g
	Blue	0.00813 g
Rayon fiber flocking	Tan	0.300 g
	Yellow	0.060 g
	Pink	0.240 g
	White	0.090 g
	Light buff	0.720 g
Artist's oil paints	Brown	0.030 g
	Red	0.030 g
	Flesh hue	0.667 g
	Burnt sienna	0.167 g
Kaolin	Deep cadmium-barium yellow	0.050 g
	Georgia kaolin	0.488 g
Liquid cosmetic	Alabaster beige	1.047 g

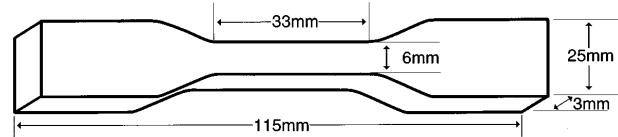
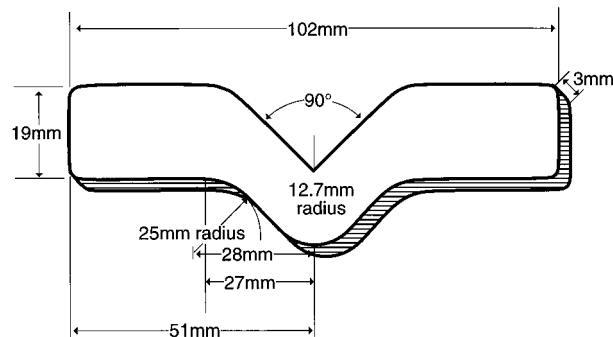
pigments, rayon fiber flocking, artist's oil paints and kaolin (Factor II, Inc, Lakeside, Ariz.), and 1 recently introduced method⁵ that uses liquid facial cosmetic (Estée Lauder Polished Performance Liquid Make-up, Alabaster Beige 18-N, Estée Lauder, New York, N.Y.).

The maxillofacial elastomers evaluated were 3 of the more commonly used elastomers based on that same survey: Silastic medical adhesive type A (Dow Corning Corp, Midland, Mich.), Silastic 4-4210 (Dow Corning Corp), and Silicone A-2186 (Factor II, Inc). All elastomer-colorant combinations were evaluated for tear strength, percentage elongation, and ultimate tensile strength with a universal testing machine (Instron Corp, Canton, Mass.). Hardness was measured with a shore type A durometer (Shore Mfg Co, Jamaica, N.Y.).

Ten specimens of each elastomer-colorant combination (5 dumbbell-shaped specimens to evaluate ultimate tensile strength and percentage elongation; 5 trouser-shaped specimens to measure hardness and tear strength) were fabricated in improved dental stone molds (Silky-Rock, WhipMix Corp, Louisville, Ky.) according to the American Society for Testing and Materials (ASTM) specifications No. D412⁶ (Fig. 1) and No. D624 (die C)⁷ (Fig. 2).

A total of 180 specimens were fabricated; there were 60 of each of the 3 elastomers. Within each elastomer category, there were 6 colorant categories (the 5 colorants and 1 without colorants) of 10 specimens each. Within each colorant category, there were 2 specimen shapes (dumbbell and trouser) of 5 each.

Each of the materials were handled in strict compliance with the manufacturer's instructions. To achieve maximum consistency among specimens within an elastomer colorant category, all specimens were fabricated during 1 processing. For the 2-part room temperature vulcanizing systems Silastic 44210 and Silicone A-

**Fig. 1.** ASTM No. D412 specifications for dumbbell-shaped specimens.**Fig. 2.** ASTM No. D624 (die C) specifications for trouser-shaped specimens.

2186, 182 g of base were mixed with 18 g of catalyst to achieve the recommended ratio of 10:1. Two hundred grams of medical adhesive A (a 1-part room-temperature vulcanizing material) was used directly from the tube. Colorants then were added in the following amounts to the 200 g of silicone to achieve concentrations similar to those found in clinical prostheses as described by Over⁵ and Moore (Moore DJ. Personal written communication. 1987) and to serve as representative values (Table I).

Colorants were mixed with the elastomers by hand using wooden tongue blades in 5-quart paper paint pails for 5 minutes. Each mixture (both the 1- and 2-part systems) was de-aired under a vacuum of at least 30-in. of mercury for 20 minutes. The mixture was then placed in the stone molds, which had been coated with 2 applications of tinfoil substitute (Al-Cote, Dentsply Trubyte, York, Pa.) and allowed to dry. Care was taken not to incorporate air bubbles into the mold space or mixture. The mold was closed and clamped with a 1-in web-type ratcheting clamp (Pony clamp, Adjustable Clamp Co, Chicago, Ill.). The molds were then placed in a 100°F dry oven (Imperial Radiant Heat Oven, Labline Instruments, Inc, Melrose Park, Ill.) to polymerize for 16 hours. After polymerization, molds were carefully separated, specimens were removed and flash was trimmed away with a sharp scalpel.

Testing procedures

Evaluations for hardness were made on the trouser-

shaped specimens. These specimens then were used for testing tear strength. Dumbbell-shaped specimens were used to perform tests on the ultimate tensile strength and percentage elongation. All tests were performed at ambient room temperature and humidity after the specimens were held in these conditions for at least 24 hours.

Shore A hardness test

In accordance with ASTM specification No. D-2240,⁸ 3 specimens were stacked on one another in random order to obtain the required 6 mm thickness and were placed on a hard horizontal surface. The shore A durometer was held in a vertical position, and the pressor foot was applied to the surface of the specimens as rapidly as possible without shock. Readings were made 1 second after firm contact was achieved. Five sites were measured per specimen (12 mm distance between each site and a 6 mm distance from the edge of the specimen). The specimen at the bottom of the stack was removed, a new specimen placed on the top, and the procedure was repeated to obtain readings for that specimen. This process was repeated until all 5 specimens for that group were evaluated. The mean of the 25 measurements was recorded as the hardness of that group.

Tear strength test

Tear strength is defined as the maximum force (Newtons) required to break the specimen divided by the thickness of the specimen. Specimen thickness (approximately 3 mm, depending on the degree of mold closure) was measured at the intersection of the trouser leg with a vernier caliper with digital readout (Mitutoyo Digimatic CD-6, Mitutoyo Corp, Tokyo, Japan). The specimen was placed in the jaws of the testing machine and stretched at a rate of 500 mm/min. From these measurements, the tear strength of that specimen was calculated. The value reported for a treatment group was the mean of the values obtained from the 5 specimens in that group.

Ultimate tensile strength test

The ultimate tensile strength is defined as the force required to break the dumbbell-shaped specimen, divided by the cross-sectional (width \times thickness of the reduced section) area of the unstretched specimen. The thickness measurement (approximately 3 mm, depending on the degree of mold closure) was made at the center of the reduced section of the specimen using a vernier caliper with digital readout. The width of the reduced section was 6 mm, which was the width of the mold. In keeping with ASTM D-412 specifications, the specimen was placed in the jaws of the universal testing machine and stretched at a rate of 8.5 mm/min. The maximum load before breaking (in Newtons) was

obtained, and tensile strength of that specimen was calculated. The mean tensile strength value for the 5 specimens in that group was reported as the ultimate tensile strength for that group.

Percentage elongation test

Benchmarks were placed on the dumbbell-shaped specimen 25 mm apart before testing, and the additional distance between the benchmarks at fracture was recorded. This additional distance at fracture, divided by the original distance of the unloaded specimen, then multiplied by 100, was recorded as the percentage elongation of that specimen. The mean value obtained for all specimens in the group was reported as the percentage elongation for that group.

Statistical analysis

Because colorants were added as representative values, even though all 3 silicones received the same weight of each colorant material, they may not have achieved the same clinical color. To achieve the same clinical color, more or less colorants may have been added. The only relevant silicone physical property comparisons would require that each silicone elastomer be colored to achieve the same clinical color. Because this was not the intent of the study, only within elastomer comparisons were made. A within elastomer analysis comparing the 6 colorants using a 1-way analysis of variance (ANOVA) for each of the 4 physical properties was performed. When significant differences were observed, the Student-Newman-Keuls multiple range test was used to identify differences among colorants at a significance level of .05.

RESULTS

Only statistically significant percentage differences between each colorant condition and no-colorant are reported, and all nonsignificant differences between colorant conditions and no-colorant will be listed. Accompanying figures reveal significant differences among the various colorant conditions.

Hardness

The addition of liquid cosmetic to medical adhesive A decreased the hardness of the elastomer by approximately 4% (Fig. 3). Dry earth pigments slightly increased the hardness of type A by 2.6%. ($P < .05$). Addition of rayon flocking increased hardness by approximately 19%, and the addition of the other colorants had no significant effect.

The addition of artist's oils and liquid cosmetic to Silastic 4-4210 decreased hardness by approximately 7%, whereas the addition of kaolin and rayon flocking increased the hardness by 19%. Dry earth pigments had no significant effect on the hardness of Silastic 4-4210 material. When liquid cosmetic was added to Silicone

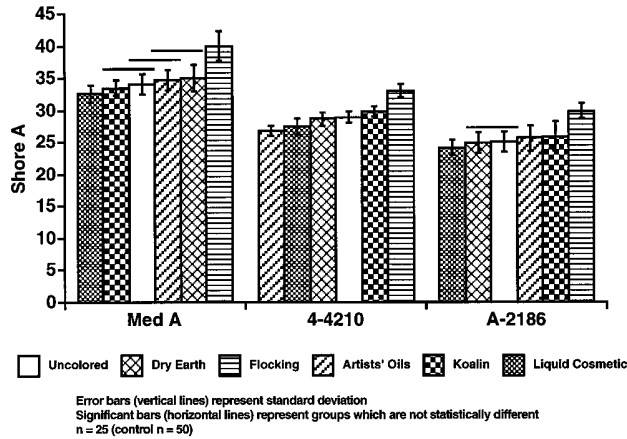


Fig. 3. Effects of colorants on hardness.

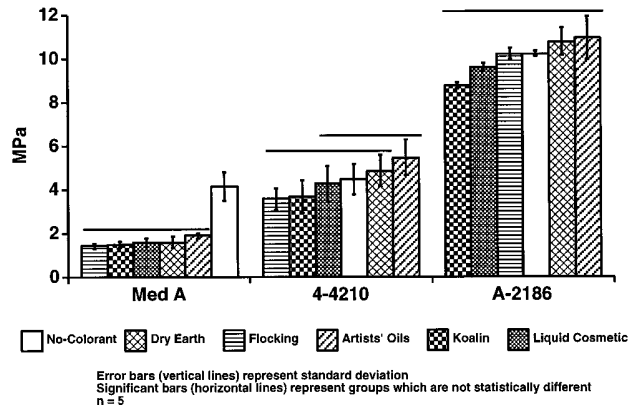


Fig. 5. Effects of colorants on ultimate tensile strength.

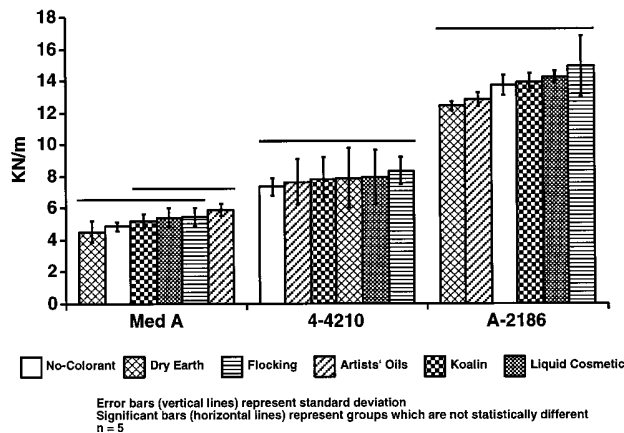


Fig. 4. Effects of colorants on tear strength.

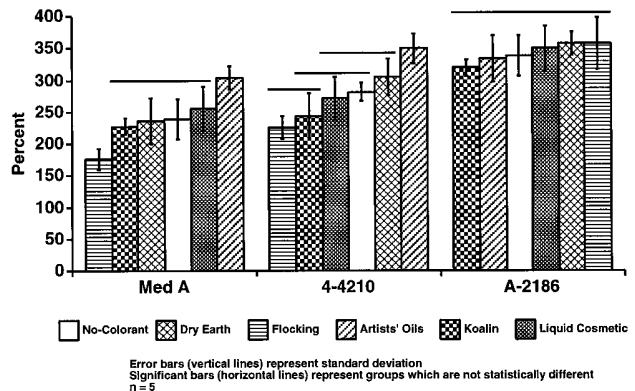


Fig. 6. Effects of colorants on percentage elongation.

A-2186 material, the hardness was decreased by 3.6%. Artist's oil pigments and kaolin only slightly increased the hardness of Silicone A-2186 material by 3.6%, whereas rayon flocking again increased the hardness by more than 19%. Dry earth pigments had no effect on the hardness of this elastomer.

Tear strength

The addition of artist's oil pigments to medical adhesive type A increased tear strength by 21% (Fig. 4). Addition of the other pigments had no statistically significant effect. Colorant additions to Silastic 4-4210 and Silicone A-2186 materials had no statistically significant effect.

Ultimate tensile strength

Ultimate tensile strength of medical adhesive type A was decreased significantly by the addition of all coloring agents with a range of 54.6% to 66% (Fig. 5). No significant difference was found with the addition of

coloring agents to Silicone A-2186 or Silastic 4-4210 materials.

Percentage elongation

The addition of rayon flocking decreased the percentage elongation of medical adhesive type A by 26.6% compared with the no-colorant group and Silastic 4-4210 material by almost 20% (Fig. 6). Artist's oils increased the percentage elongation of medical adhesive type A by 26.6% and Silastic 4-4210 by 24%. The addition of other colorants had no significant effect on the percentage elongation of the 2 materials. No significant effect could be seen on the percentage elongation by the addition of any colorant to Silicone A-2186 material.

DISCUSSION

The ideal elastomer-colorant combination should not only allow satisfactory esthetics, but also provide appropriate physical properties. The addition of the

colorant could enhance the physical properties of the elastomer used to fabricate a maxillofacial prosthesis, but the ideal colorant should not degrade the properties. Artist's oil paints and liquid facial cosmetic use a vehicle for the colorant, which allows the colorant to be handled in liquid form. However, the material eventually hardens, most likely through evaporation or absorption of the vehicle. The physical property data seem to indicate that these additional ingredients could act as a liquid phase without bonding to the silicone matrix, because the ingredients tended to cause a decrease in hardness and tensile strength. The ingredients' action as a plasticizer is supported by increases in tear strength and percentage elongation.

The silicone elastomers used in maxillofacial prostheses are actually resin matrix composites whose properties depend in part on the addition of inorganic fillers. These filler components are typically microfine silica that is bonded to the resin matrix with an organosilane in a manner similar to that used with restorative resin composites. The addition of significant amounts of other fillers, organic or inorganic solids, to the silicone-resin matrix without provisions for bonding these fillers to the matrix can actually degrade the physical properties of the silicone-resin composite.

Both kaolin and dry earth pigments affected the initial physical properties of the prosthesis. By acting as a solid filler without bonding to the silicone, these particles decreased the tensile strength and increased the hardness of the silicone. The addition of rayon fiber flocking to the elastomer acted as a fibrous solid filler, which increased the hardness by as much as 19% in this study.

CONCLUSIONS

The following conclusions were drawn from this study:

1. The addition of colorants changed the physical properties of the silicones. Dry earth pigments, kaolin,

and rayon flocking appeared to act as a solid filler without bonding, and artist's oils and liquid cosmetics appeared to act as a second liquid phase without bonding to the silicone resin matrix.

2. No clearly superior colorant-elastomer combination was demonstrated in any of the tests.

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