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Computerized Color Formulation for African-Canadian People Requiring Facial Prostheses: A Pilot Study

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Abstract

Purpose: The aim of this study was to investigate the effectiveness of spectrophotometry and a computerized color formulation system to predict pigment formulas for color mixing silicone elastomer to match the skin color of African-Canadian people.
Materials and Methods: In a prospective study, reflectance spectrophotometery was used to measure the skin color of 19 African-Canadian subjects. The spectral data for each subject was used in a computerized color formulation system to predict colorants required to mix silicone elastomer to match each subject's skin color. Delta-E values were recorded for each silicone sample in comparison to the subject's skin measurement. An analysis of variance was used to determine significance among variables, and a Tukey HSD post hoc test was used to assess paired comparisons.
Results: Delta-E decreased with iterative mixes of colored silicone for each subject, and pigment loading increased with iterative mixes. Delta-E values for the third iterative mix (fourth and final sample) ranged between 1.49 and 8.82.
Conclusion: Spectrophotometry and computerized color formulation provide a foundation in the color matching procedure for facial prostheses that offers objectivity to an otherwise subjective task. Through further study of spectrophotometry and computerized color formulation, and with the development of pigment databases appropriate for the African-Canadian population, it may be possible to establish a precise and repeatable color matching system that predicts required colorants and controls metamerism.

Color matching for facial prostheses has historically presented challenges to the clinician. Due to the variability and subjectivity of the common approach of trial and error with hand mixing, numerous attempts have been made to quantify the process in order to establish a predictable, precise, and repeatable color matching system that controls metamerism. While investigations into color matching for facial prostheses have predominately addressed color matching for Caucasian skin, less has been reported on color matching for the African-Canadian population.[1-3]

Coloring facial prosthetic material involves adding pigments to silicone elastomer until an acceptable color match is achieved. Typically, a base color is mixed, followed by several colored glazes that are applied instrinsically or extrinsically.[4] The color challenge is even more pronounced when one considers the issue of translucency. Achieving appropriate translucency with silicone elastomer is a critical component in color matching for facial prostheses.[5]

Numerous color order systems have been described. When mixing color for a predictable result, it is necessary to control the hue, saturation (chroma), and translucency of the silicone elastomer. Metamerism is a frequently observed problem with color matching for facial prostheses.[6] Computerized color formulation systems offer the ability to control the degree of metamerism observed. To predict the colorants required for a particular skin color, spectrophotometery, colorimetry, and color formulation begin to provide a solution.

Colorimetry and spectrophotometry have long been standards in manufacturing and laboratory science. These technologies have been used to quantify color by recording tristimulus and spectral data of reflected light. Colorimetry uses tristimulus values to define a color in 3D color space. Alternately, spectrophotometry can define a color based on either tristimulus or spectral data.[6] Spectrophotometry offers the advantage of producing a spectral curve (light reflectance in the visible light spectrum 400–700 nm), which is necessary to perform

computerized color formulation. Reflectance spectrophotometry has been widely used in studies of skin color and pigmentation.[7-11] Similarly, spectrophotometry and colorimetry have also been used to measure and monitor color differences of in vitro specimens in facial and dental prosthetic materials;[12,13] however, reports on the application of that same technology in the clinical treatment of the maxillofacial prosthetic patient has been limited.

A number of attempts have been made to develop a means of quantifying pigment formulas for facial prostheses through weight and volume measurements. Shade guides are often developed based on these measurements.[1,14] While this is helpful, each patient exhibits his or her own characteristic skin color, which necessitates the customization of pre-established prosthetic shades. Fewer attempts have been reported to quantify an individual patient's skin hue precisely as a foundation for establishing pigment formulas.

Gillman used spectral reflectance data to define the pigments of human skin for three races.[15] Spectral reflectance values were also obtained for pigment colorants used in facial prostheses. Gillman's objective was to match spectral curves of human skin pigments with those of pigment colorants used in facial prostheses. Gillman also describes the potential to reduce the effect of metamerism by approximating the spectral curves of the skin and pigments.

Aina et al addressed coloration techniques for dark-skinned individuals.[3] This study describes the development of a shade guide specific to what the authors termed "Negro patients" in an attempt to establish a technique for color matching silicone to black skin. Twenty shades were developed for matching silicone to three values of black skin (dark, medium, and light). The shades were established by combining known weight proportions of any of seven stock pigments to Silastic 399 silicone elastomer. Pigment colors included black, brown, umber, red, sienna, yellow, and white.

Koran et al used reflectance spectrophotometery to quantitatively measure skin color of three races.[16] These data were to serve as the foundation for the development of a computerized program for pigment selection in facial prostheses. Koran notes the dependence on the human eye for interpretation and discrimination of color in current color-matching methods; this is further complicated by the effect of metamerism. Given this, the need for a repeatable, quantifiable color matching system that controls metamerism in prosthetic work is noted. Like Gillman,[15] Koran et al[16] described the potential for minimizing the challenge of metamerism by matching spectral curves of skin to pigment, independent of a light source. The mean spectral curve for the white group showed the greatest overall reflectance (lightest value), then the Asian group, and finally the black group. In this study the spectral curves of the black group revealed considerable variability in skin color and the largest standard deviation for luminous reflectance and excitation purity (chroma). Wasserman[9] explained that variance of skin color among different ethnicities is due to the epidermal melanin concentration.

Only one study could be identified in the literature where spectrophotometric data were used to establish pigment formulas through direct transfer of the spectral data to computerized color formulation software. Troppmann et al[2] described the use of a computerized color formulation system with spectrophotometry to effect a clinically acceptable base color in silicone elastomer. Spectral reflectance readings were taken of patients' skin, and pigment formulas were determined by color formulation software. An iterative procedure was described whereby delta-E (ΔE: color difference) decreases with successive corrections to the formula indicating a closer match between the spectral curve of the patient's skin and that of the silicone sample. The system described by Troppmann is the same system used for the present pilot study.[2]

The aim of this study was to investigate the effectiveness of using a computerized color formulation system in conjunction with a silicone elastomer to target skin color for African-Canadian people. This paper addresses the methodology of creating a pigmented silicone swatch using a computerized color formulation system.

Materials and methods

In a prospective study, 19 African-Canadian volunteers underwent a non-invasive skin color matching procedure by one of two operators using a handheld reflectance spectrophotometer (Miniscan XE model No. 45/O-S, Hunter Labs Inc., Reston, VA) (Table 1) (Fig 1).[2] Using a technique similar to that described by Troppmann et al, the skin of the right or left supine forearm of each subject was measured using the spectrophotometer, and a colored silicone sample was prepared using the pigment database and color formulation software described by Troppmann et al[2] (EasyMatch Plastics, Hunter Labs, Inc.). The pigment database in the study is comprised of nine ferro paste pigments (white, black, red, yellow, blue, red-brown, buff, umber, and flesh) (Factor II, Inc., Lakeside, AZ). Three illuminants were selected in the color formulation software: daylight (D_{65}), incandescent (A), and fluorescent (F). The CIELAB L*a*b*

Table 1 Details of Miniscan XE model No. 45/O-S, Hunter Labs, Inc

Instrument geometry	0/45°
Standard observer	10°
Instrument aperture	5 mm
Instrument defined illuminant	D65
Light source	Xenon
Color tolerancing system	CIE L*a*b*

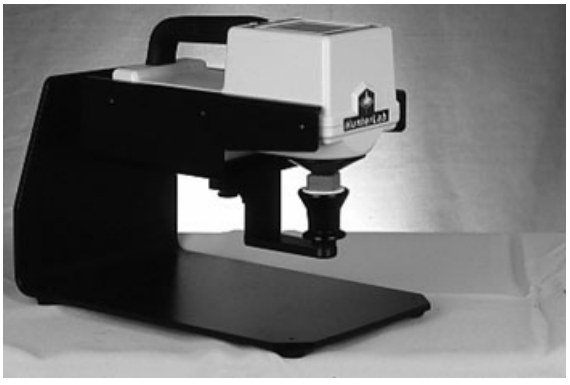

Figure 1 Miniscan XE reflectance spectrophotometer.

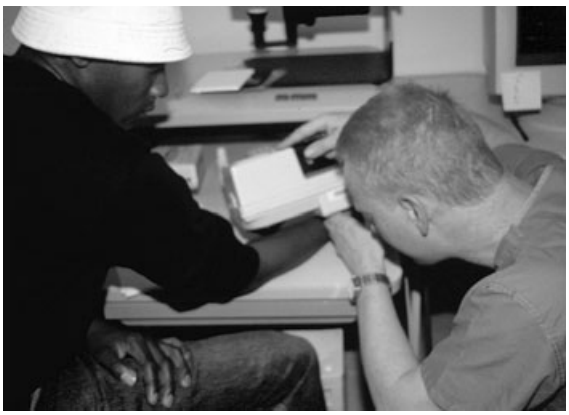

Figure 2 During color readings, the spectrophotometer was held lightly against the skin to prevent light from escaping, while avoiding excessive pressure on the skin.

color tolerance was used for this pilot study. Ethics approval for the study was obtained through the University of Alberta, Edmonton, Alberta, Canada.

Prior to taking a skin color measurement, the spectrophotometer was calibrated according to manufacturer's instructions using white and black ceramic tiles. Calibration of the spectrophotometer was performed every 4 hours. The subject was seated in the room for at least 15 minutes and allowed to acclimate to room temperature; then, a skin color reading was taken. During color readings the spectrophotometer was held lightly against the skin to prevent light from escaping, while avoiding excessive pressure on the skin (Fig 2).

An area of skin on the supine forearm was chosen, as it provides a flat, easily accessible area of skin and can be considered to be representative of a patient's base skin color.[4] Areas of skin with blemishes, varied coloration, freckles, or excessive vasculature were avoided. Three readings were recorded of the selected skin area and averaged to create one skin color reflectance measurement. Based on the spectral data from the skin measurement, a pigment formula was calculated by the computer and used to produce a colored silicone sample (Fig 3). Formulas were defined by pigment weight (Table 2).

Silicone samples were created by adding ferro paste pigments to the silicone elastomer, resulting in each swatch having a mass of approximately 5 g and measuring 25 × 25 × 5 mm^3. To produce a pigment formula, the pigment loading (0.156%), number of pigments (4), pigment weight (0.035 g), and total weight (22.435 g) were defined to establish the initial formula.

Based on the pigment database, the least metameric formula calculated by the formulation software was used. Paste pigments were measured on a Mettler Toledo AB104 balance (Mettler Toledo, Greifensee, Switzerland) with a weight tolerance to 000.0000 g. The balance was calibrated prior to use according to manufacturer's instructions. Constant amounts of silicone elastomer (20.0 g) (A-2186F, Factor II, Inc.), kaolin (0.4 g) (Georgia kaolin, Factor II, Inc.), and catalyst (2.0 g) (A-2186F catalyst, Factor II, Inc.) were added to the measured pigment for each formula. Silicone and catalyst were measured on a Mettler Toledo BB600 balance with a weight tolerance to 00.00 g. The mixture was blended to achieve a homogenous color.

The silicone was de-aired using the spatulating technique.[4] The silicone was placed carefully into the mold to avoid entrapment of air, and the mold was closed and cured at 72°C (Isotemp Curing Unit, Fischer Scientific, Ottowa, ON, Canada) for 20 minutes (Fig 4). Samples were removed and allowed to cool to room temperature.

The cured silicone sample was measured for spectral reflectance using the spectrophotometer. Three measurements were taken, and the mean reflectance values were stored in the computer. The reflectance values of the sample were compared with the original skin color reflectance values to yield a ΔE value ($\Delta E = \sqrt{(\Delta L^*)^2 + (\Delta a^*)^2 + (\Delta b^*)^2}$. A numerical value of color difference, that is, a higher ΔE, represents greater color difference. A computerized correction procedure was executed to yield a new four-pigment formula according to which a second silicone sample was prepared in the same manner as the first. This correction procedure was repeated twice more, resulting in four samples per subject. Each subsequent sample was compared to the subject's original skin color, and a ΔE value was recorded for each sample. The formula correction procedure is additive and is accomplished by increasing the pigment weight of specific pigments. The weight of the silicone, kaolin, and catalyst remained constant for each sample; therefore, with each correction, pigment loading increased, thereby increasing opacity.

Table 2 An example of data collected for one subject

Subject 7	Original skin	Pigment	Mix 1 (g)	Mix 2 (add)	Mix 2 (total g)	Mix 3 (add)	Mix 3 (total g)	Mix 4 (add)	Mix 4 (total g)
		Red-brown	0.0031	0.0018	0.0049	0.0011	0.0060	0.0001	0.0061
		Blue	0.0150	0.0000	0.0150	0.0007	0.0157	0.0021	0.0178
		Yellow	0.0137	0.0089	0.0226	0.0013	0.0239	0.0009	0.0248
		White	0.0031	0.0000	0.0031	0.0000	0.0031	0.0000	0.0031
Pigment weight			0.0349		0.0456		0.0487		0.0518
Pigment loading (%)			0.156		0.20315		0.21693		0.23071
ΔE			9.47		5.81		3.5		2.17
L∗	49.03		53.88		53.99		52.49		50.27
a∗	6.26		1.96		3.86		6.61		7.66
b∗	16.66		9.77		14.85		16.23		15.55

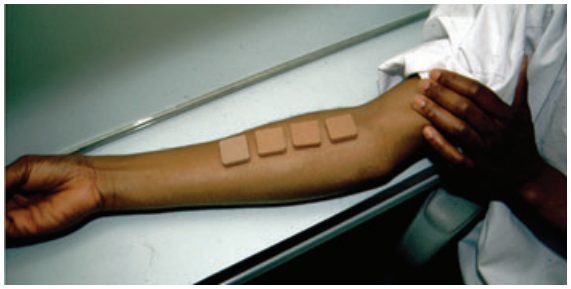

Figure 3 Based on the skin measurement, a color formula was calculated by the computer and used to produce a colored silicone sample (one sample is comprised of four silicone swatches).

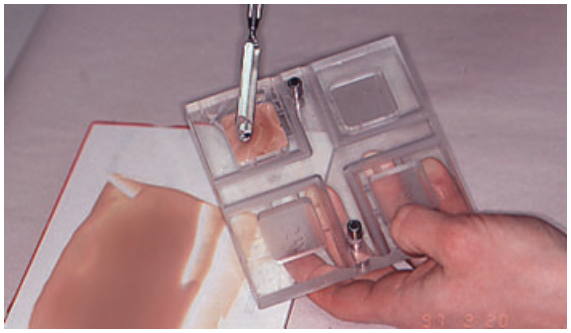

Figure 4 The silicone was placed carefully into the mold to avoid entrapment of air, and then the mold was closed and clamped.

For each of the 19 subjects, data from the original skin color reading and four silicone samples were recorded (L*a*b* values and spectral curves). Four silicone samples were produced for each subject, resulting in a total of 76 samples. For each sample, individual pigment weights, percent pigment loading, and total pigment weight were recorded. Additionally, the pigment that was added with each computerized correction was recorded (Table 2). Delta-E values derived from the comparison of the spectral curves of the original skin color reading (standard) and trial silicone color match (sample) were recorded for each mix, 1, 2, 3, and 4, respectively, for each of the 19 subjects, resulting in a total of 76 ΔE values (Fig 5). An analysis of variance was used to determine whether the sample mixes were significantly different from each other, and a Tukey HSD post hoc test was used to assess paired comparisons.

Results

The ΔE values for all four swatches for each of the 19 subjects are shown in Figure 6. The mean ΔE value showed a decrease with each iterative mix (Fig 7). For example, the mean ΔE value for swatch 1 was 10.9721, and for swatch 4 was 4.4879. A p-value <0.001 was obtained for the ΔE value among all four mixes. Multiple comparisons between mixes revealed significant differences between mixes one and two and between mixes two and three; however, no significant difference was found between mixes three and four (Table 3). It was observed that for 7 of the 20 subjects, the third sample had a lower ΔE

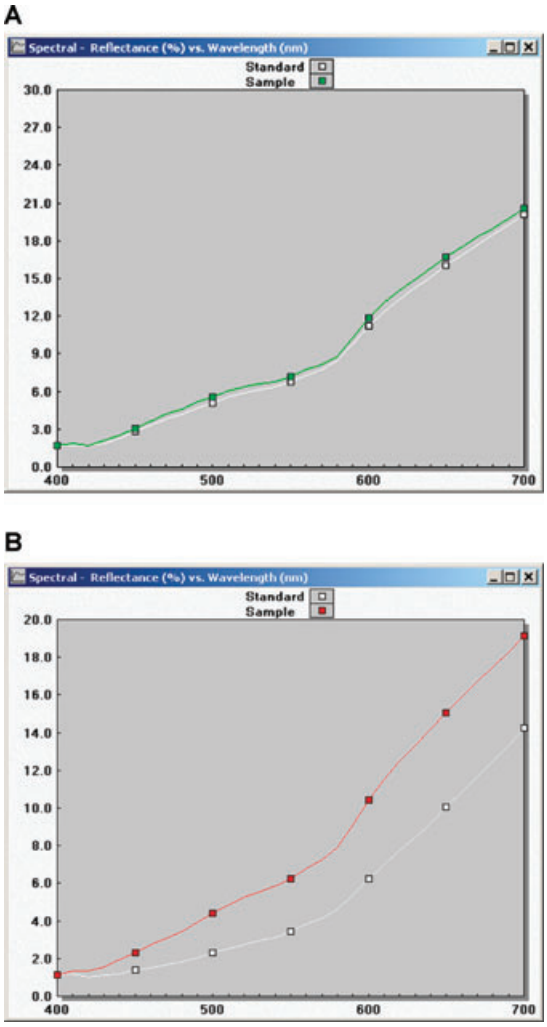

Figure 5 (A) Closely approximated spectral curves represent a closer match in color. The white curve represents the original skin color measure (standard); the green curve represents a trial silicone color match (sample). (B) Spectral curves that represent a greater color difference between the original standard (white) and the trial color sample (red).

than that of the final sample, indicating less of a color difference relative to the subject's skin (Fig 6). The ΔE values for swatch 4 ranged from 1.49 to 8.82, with a mean value of 4.4879 (SD: 2.2980).

Table 3 Multiple comparisons (Tukey HSD) between swatches in mixes 1, 2, 3, and 4

				95% Confidence interval	
Swatch (I)	Swatch (J)	Mean difference (I – J)	Sig.	Lower limit	Upper limit
1	2	3.2026	0.0005	2.1058	4.2995
2	3	2.2647	0.0005	1.1679	3.3616
3	4	1.0168	0.081	−8.002E-02	2.1137

The mean difference is significant at the 0.05 level.

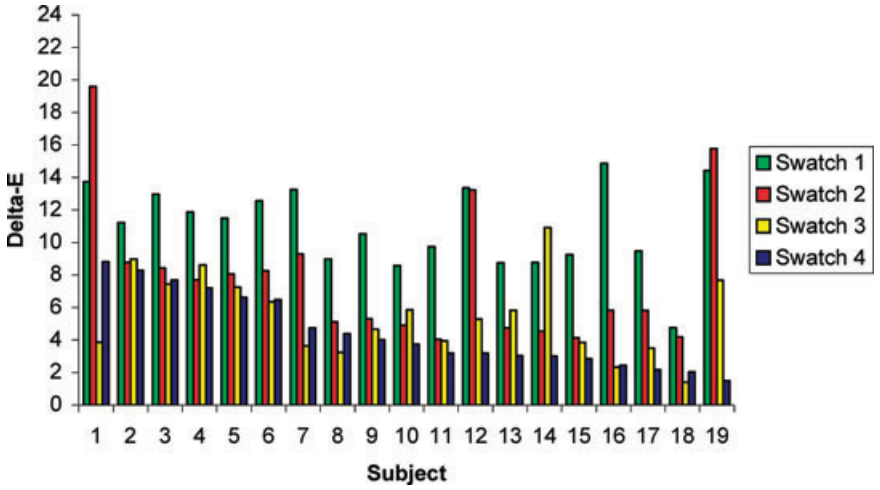

Figure 6 The ΔE value for each swatch for all 20 subjects.

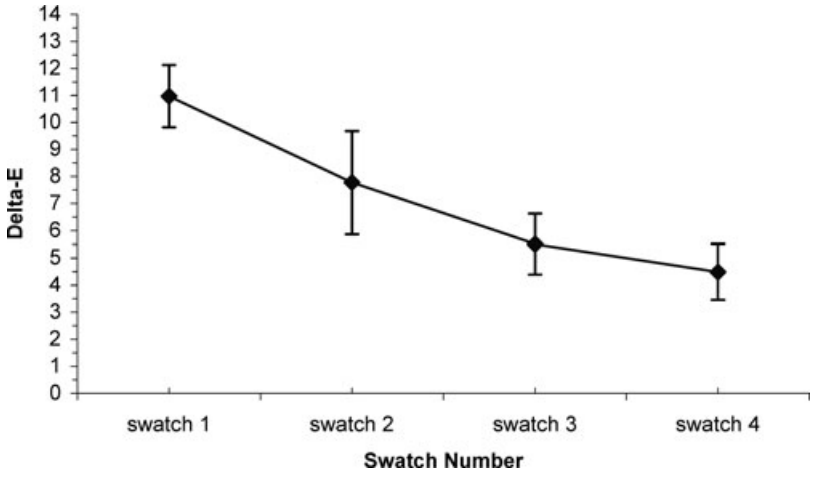

Figure 7 Decrease in ΔE with increasing swatch number. Shown are the means and 95% confidence intervals for each swatch.

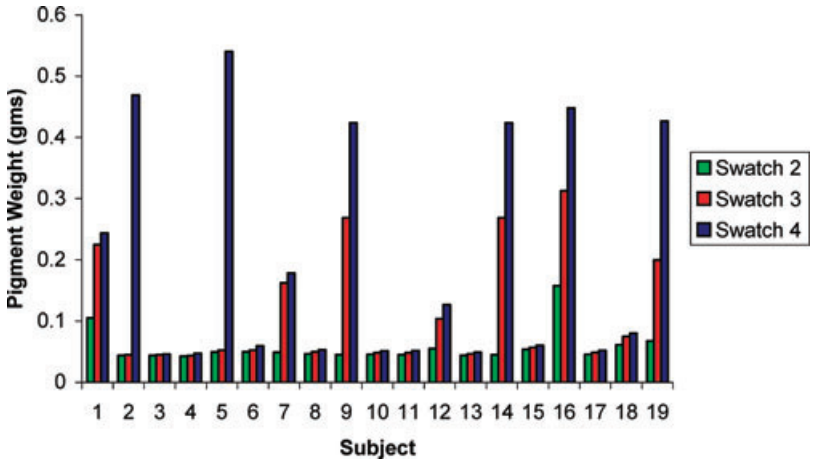

Figure 8 Pigment weight of each swatch for each of the twenty subjects. Swatch 1 is omitted as all subjects started with the same pigment weight (0.035 g). For each of the subjects, the total pigment weight of each swatch was recorded.

For each of the subjects the total pigment weight of each swatch was recorded (Fig 8). In five subjects, a substantial increase in pigment weight (range: 0.0015–0.2266 g) was noted after mix three. The total mean pigment weight of each swatch increased with successive corrections (Fig 9). The largest increases occurred between the third and fourth swatch. The fourth swatch had a total mean pigment weight of 0.1818 g (CI: 0.1007, 0.2629). The mean pigment loading for swatch 4

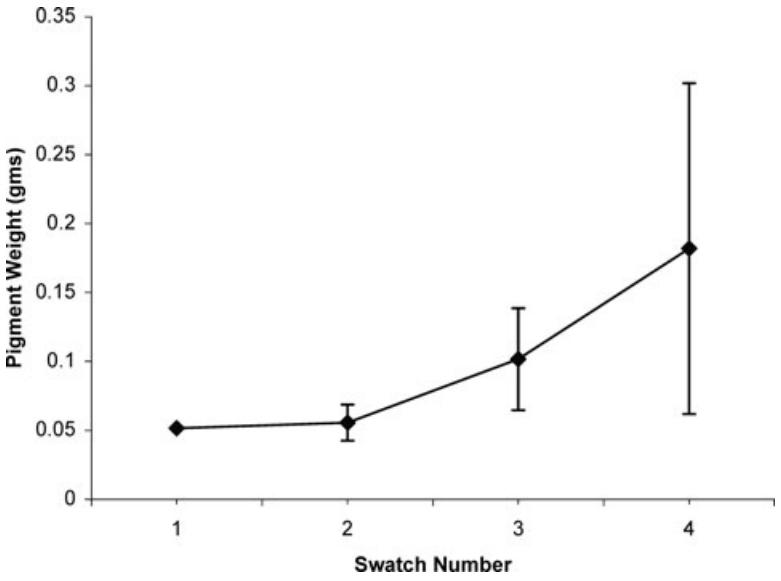

Figure 9 Increase of pigment weight (g) with increasing swatch number. Shown are the mean and 95% confidence intervals for each swatch. The total mean pigment weight of each swatch increased with each successive correction. The largest increases occurred between the third and fourth swatch.

was 0.5909% (CI: 0.3104, 0.8714). Generally, increasing the pigment loading for each of the four swatches in all 20 subjects resulted in a lower ΔE value (Fig 7). The pigment loading for swatch 4 ranged from 0.20404 to 1.96035%.

Eight of the nine original ferro paste pigments were consistently selected by the color formulation software program to create the samples. These were red-brown, blue, yellow, white, black, red, and buff. For 11 subjects, the best four-pigment combination identified by the software revealed a predominance of four pigments: red-brown, blue, yellow, and white. The other combinations identified were red-brown, yellow, black, and white (3 subjects); buff, red, black, and white (2 subjects); buff, blue, yellow, and white (2 subjects); and red, yellow, black and white (1 subject).

The L*a*b* values for the target skin area and each sample mix for each subject were noted. The combinations of pigments identified from the target skin color provided a range of L*a*b* values (Table 4) (Fig 10A). The final L*a*b* values for swatch 4 are shown in Figure 10B.

Table 4 Combinations of pigments identified from the target skin color and the ranges of L*a*b* values of each

Pigment color	No. of subjects	Range of values		
		L*	a*	b*
Red-brown, blue, yellow, white	11	41.84–55.72	4.09–8.51	14.56–18.32
Red-brown, yellow, black, white	3	31.82–34.74	7.46–8.51	9.79–16.30
Buff, red, black, white	2	38.72–41.02	8.04–8.08	14.12–16.37
Buff, blue, yellow, white	2	41.56–42.19	7.45–7.48	16.05–16.57
Red, yellow, black, white	1	48.46	5.40	16.20

Discussion

Facial prostheses are constructed to replace parts of the face that cannot be reconstructed with the patient's own tissues. For a prosthesis to be considered successful, it must appear realistic. An exact color match plays a critical role in the success of the prosthesis and the overall rehabilitation of the patient. Color matching the silicone to the skin, given the effects of metamerism, presents a considerable challenge.

The use of instrumentation and computerized color formulation offers a degree of objectivity to an otherwise subjective color matching procedure. Further, computerized color formulation enables the clinician to better understand the effects of metamerism with coloration of silicone elastomer and may offer a solution toward establishing a precise and repeatable color matching system that predicts required colorants and controls metamerism.

While studies reported in the literature offer interesting insight into the color matching procedure for facial prostheses, in particular for individuals of various races, each investigation incorporates different methodologies and instrumentation in the pursuit of quantifying the color matching process. With the differences in instrumentation used to quantify color, we are still presented with the challenge of identifying a universal means of quantifiably color matching silicone for the patient population requiring facial prosthetic treatment.

One is only able to draw conclusive comparative evidence from data where the spectral instrumentation, the illuminant, and the observer are identical. This is a limitation of the pool of literature dedicated to this area of study. In the review of the literature, there was little opportunity to compare data between studies due to the variability of the criteria employed. The present study can be compared to the study by Troppman et al

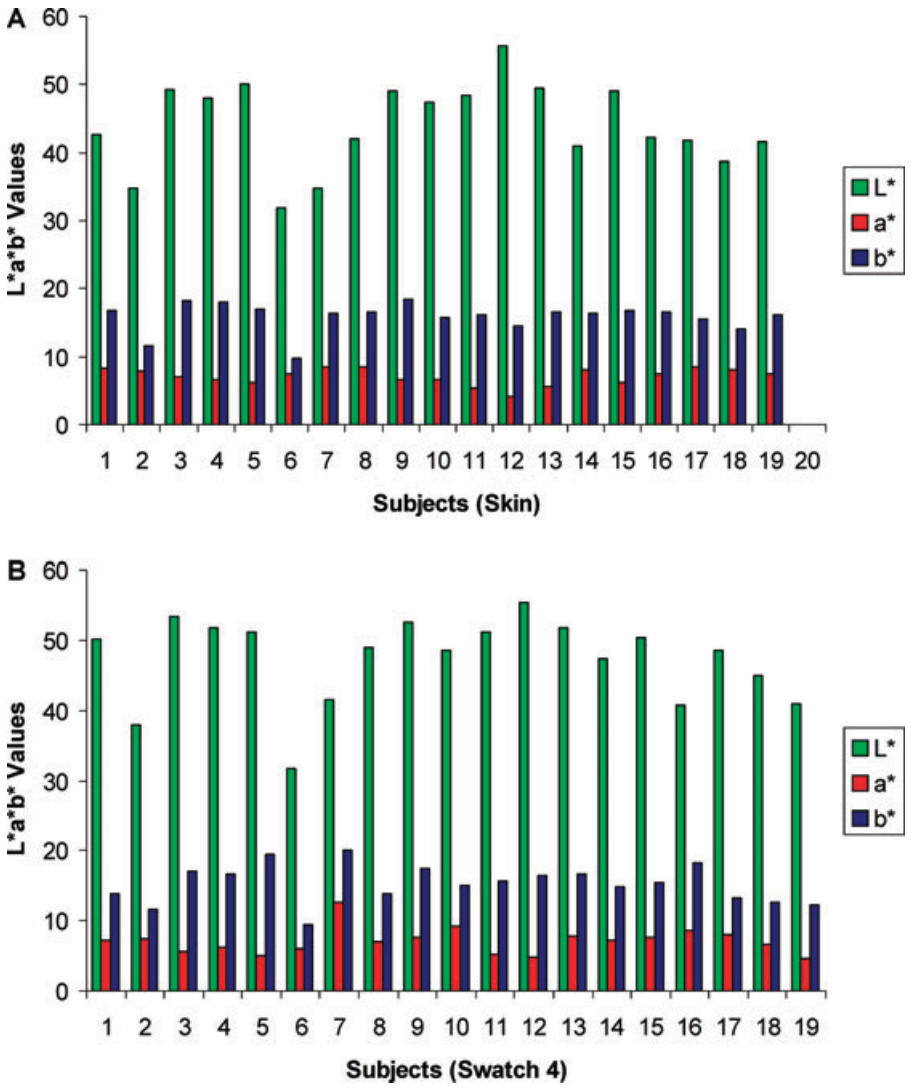

Figure 10 (A) L*a*b* values for 19 subjects' target skin area. (B) L*a*b* values for silicone swatch mix 4 for 19 subjects.

because the spectral instrumentation, the illuminant, and the observer were identical;[2] however, due to differences in sample size and subjects, it remains difficult to draw conclusive evidence of the effectiveness of this system based solely on the report by Troppmann et al. It is interesting to note that Troppmann et al observed a mean ΔE of 2.9 for the Caucasian group, and the mean ΔE observed for the African-Canadian population in the present study was 5.5 for the third silicone sample.

For color formulation procedures, ΔE is used as a guideline to determine how closely two colors match. Troppmann et al[2] and Seelaus and Troppmann[4] describe a ΔE value of 1.75 or less as an arbitrary usability tolerance for clinical application of color formulation. A formally-established tolerance for a clinically acceptable ΔE for silicone elastomer has not been reported in the literature. Douglas and Brewer[17] reported visual levels of acceptance for red varying and yellow varying metal ceramic crowns of 1.1 and 2.1 ΔE, respectively. Further research is necessary to determine the clinically acceptable ΔE value for facial prosthetic restorations for patients of various races.

In this study, only one of the 19 subjects recorded a ΔE value of less than 2.0 for swatch 4. In the study by Troppmann et al, ΔE values of the final swatch for five Caucasians ranged between 2.25 and 3.33.[2] All ΔE values for swatch 4 in this study were less than the first swatch, and most ΔE values decreased with successive swatch number, indicating that the color formulation software performed the way it was designed to work. There was no statistical significance between the ΔE values for samples 3 and 4 (Table 3). This begins to address the need to define a clinical tolerance for ΔE and indicates that a fourth sample may not be required for clinical application.

For seven of the subjects, swatch 3 revealed a lower ΔE value than swatch 4 and ranged between 1.41 and 7.44 (Fig 6). The mean difference between swatch 3 and swatch 4 for these seven subjects was 1.87 (SD: 1.72), supporting the theory that only three swatches would be required in clinical practice.

The software was designed to increase the pigment weight with each iterative mix to achieve a new formula (Fig 8) and result in a lower ΔE value. The greatest increases in pigment weight occurred between the third and fourth mix for five subjects. Generally, increasing the pigment weight (g) for each of the four swatches in all 19 subjects resulted in a lower ΔE value.

Troppman et al[2] found that the pigment loading for Caucasians after the final correction mix (mix 3) ranged between 0.15% and 0.25% of the total batch weight and was considered an acceptable range for imitating skin; however, in this study, 8 of the 19 African-Canadian subjects for mix 4 had a pigment loading above 0.25% (range: 0.26492–1.9604). The mean pigment loading for mix 4 was 0.590948% (CI: 0.310428, 0.871468) and above the range considered acceptable by Troppmann et al.[2]

In this study, five combinations of ferro paste pigments were identified for the 19 subjects. For 11 subjects whose skin color measurements ranged between 41.84 and 55.72 (L*), 4.09 and 8.51 (a*), and 14.56 and 18.32 (b*) (mean: L* 47.67, a* 6.73, b* 16.73), the system identified the pigments red-brown, yellow, blue, and white (Table 4).

Three subjects were considered to be very dark-skinned based on the operators' subjective visual assessment prior to recording the color reading. Their L*a* b* values ranged between 31.82 and 34.74 (L*), 7.46 and 8.51 (a*), and 9.79 and 16.30 (b*) (mean: L*: 33.75, a*: 7.97, b*: 12.58). For these subjects, the software identified the pigments red-brown, yellow, black, and white. The other three combinations provided too few subjects for assessment. Further study is required with a larger group of subjects to determine if it is possible to relate skin color to particular pigment formulas in establishing a classification of race-specific skin colors. The operators noticed a broad range of system results in predicting pigments with these individuals, perhaps indicating that the system is challenged within these darker skin tolerances. With review of the data, individuals with lower L* values (darker), revealed generally higher ΔE values on the system's first attempt to match the color, which may indicate that some relationship exists between skin color values and functionality of the computerized system.

Ideally, a low ΔE value of swatch 4 should be achieved with a low pigment weight to provide the optimum color match to the target skin area with a degree of translucency that is usable clinically. In this study, eight subjects had a high pigment weight (i.e., above 0.25% of total batch weight as specified by Troppman et al[2]) (Fig 8), of which three achieved a low ΔE value (Fig 6: subjects 14, 16, & 19). The inability to isolate kaolin as an independent variable in the system may have contributed to higher opacity. Kaolin was calibrated with the base silicone when the system was created and was a fixed component of each formula. Further study is required to test the effectiveness of a computerized system independent of the Kaolin effect.

Conclusion

Overall, the color formulation system performed similarly on African-Canadian subjects to that of Caucasians in a previous study (i.e., the ΔE value decreased, and the pigment weight increased with each iterative mix and successive swatch number); however, the ΔE values revealed limited consistency, and a broad range of ΔE values were recorded. The computerized formulations achieved a low ΔE as a consequence of high pigment loading that may compromise the clinical match of prosthesis to skin. High pigment loads did not always achieve a lower ΔE.

Where the ΔE value is low, but the pigment load is high, a visual assessment between the pigmented silicone and the target skin area may identify that the silicone is too opaque for clinical use. Therefore, it is important that this computerized color formulation system is used as a tool that may assist in managing the effects of metamerism, and to complement the subjective clinical assessment of the prosthodontist, because the degree of opacity of silicone is critical to a successful prosthetic appearance. Further research is necessary to examine the reliability and predictability of the system as assessed by persons knowledgeable in the creation of facial prostheses.

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