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Porosity and Color of Maxillofacial Silicone Elastomer

Muhanad M. Hatamleh, BSc, Mphil,[1,2] & David C. Watts, BSc, PhD, DSc[2]

[1] Department of Allied Dental Science, Faculty of Applied Medical Sciences, Jordan University of Science and Technology, Irbid, Jordan
[2] Biomaterials Research Group, School of Dentistry, The University of Manchester, Manchester, UK

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Correspondence
Muhanad M. Hatamleh, Biomaterials Research Group, School of Dentistry, Higher Cambridge St., The University of Manchester, Manchester M15 6FH, UK.
E-mail: muhanad.hatamleh@manchester.ac.uk

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Abstract

Purpose: Prosthesis color production and stability as a result of pore entrapment during mixing has not been investigated for maxillofacial silicone prostheses. The purpose of this study was to investigate pore numbers and percentages of a maxillofacial silicone elastomer mixed by two different techniques, using X-ray microfocus computerized tomography (Micro-CT), and to investigate the effect of porosity on color reproducibility and stability after two different aging conditions.
Materials and Methods: Sixty-four disk-shaped specimens were prepared (8-mm diameter, 3-mm thick) by mixing TechSil S25 silicone elastomer (Technovent, Leeds, UK) following two techniques: manual mixing ($n = 32$) and mechanical mixing under vacuum ($n = 32$). Half the specimens in each group were intrinsically pigmented, and the other half remained unpigmented. Pore numbers, volumes, and percentages were calculated using the Micro-CT, and then specimens of each subgroup were stored in simulated sebum for 6 months ($n = 8$), and exposed to accelerated daylight aging for 360 hours ($n = 8$). Color change (ΔE) was measured at the start and end of conditioning. Pore numbers and percentages were analyzed using one-way Analysis of Variance (ANOVA) and Dunnett's-T3 post-hoc tests ($p < 0.05$). Independent t-test was used to detect differences ($p < 0.05$) in ΔE between manually and mechanically mixed specimens, in both unpigmented and pigmented states and to detect differences ($p < 0.05$) in ΔE before and after conditioning within each mixing method.
Results: Mechanical mixing under vacuum reduced the number and percentage of pores in comparison to manual mixing, within pigmented and unpigmented silicone specimens ($p < 0.05$). Perceptible ΔE between manual and mechanical mixing techniques were 5.93 and 5.18 for both unpigmented and pigmented specimens, respectively. Under sebum storage, manually mixed unpigmented specimens showed lower ΔE ($p < 0.05$) than those that were mechanically mixed; however, pigmented silicone specimens showed the same ΔE ($p > 0.05$). After light aging, mixing method had no effect on ΔE of unpigmented specimens ($p > 0.05$). Furthermore, mechanically mixed pigmented specimens showed lower ΔE ($p < 0.05$).
Conclusions: Within silicone elastomers (whether pigmented or unpigmented), mechanical mixing under vacuum reduced pore numbers and percentages in comparison to manual mixing. For selected skin shade, pores affected the resultant color of prosthesis (color reproducibility). Additionally, silicone pores affected silicone color stability upon service. *Clinical significance:* In fabricating maxillofacial prostheses, mechanically mixing silicone under vacuum produces pore-free prostheses, tending to enhance their color production and stability.

Most dental materials are supplied in two or more parts, which are mixed together prior to their intended application. Air is often incorporated during mixing; resulting in porous structures of poor esthetics, reduced strength, rough surfaces, and a favorable environment for fluid absorption and microbial colonization.[1-5]

A material's mixing method, handling properties (manual vs. mechanical, with or without vacuum, and injection), along with its viscosity, greatly add to air bubble formation.[6-8] Mixing materials mechanically with the presence of air suction (vacuum) is effective in reducing pores, decreasing the number of unbounded particles within the mixture, and producing more homogeneous and dense mixtures.[8-12] Also, it saves more material than does manual mixing.[13]

Maxillofacial silicone elastomers (polydimethylsiloxane) are widely employed in constructing facial and body prostheses. Air bubbles are likely to be trapped while silicone ingredients (rubber, hardener, and pigments) are mixed.[14] Such pores adversely affect silicone prostheses' elasticity, elongation, tear resistance, and esthetics.[2] Furthermore, their porous fitting surfaces in contact with defect tissues allow colonization by *Candida albicans* and related *Candida* species, leading to serious consequences.[15,16] A questionnaire investigating opinions and experience of maxillofacial prosthetists and technologists (MPTs) in the United Kingdom regarding serviceability of maxillofacial silicone prostheses showed that 76.6% of MPTs stressed the importance of obtaining maxillofacial facial prostheses free from air bubbles.[17] The MPTs indicated that the most adverse effects of air bubbles were deterioration in prosthesis esthetics (83.7%), increased possibility of bacterial colonization (67.3%), and color loss (57.1%). Furthermore, 71.4% of the MPTs reported packing silicone mixtures under pressure to minimize air bubbles.

Color stability of a prosthesis is affected by the chemical stability of silicone and pigments, environmental climatic conditions, human body secretions, and prosthesis maintenance procedures.[18-22] The thresholds for perceptible and acceptable color difference of fair-skin-colored silicone specimens were reported to be 0.8 and 1.8, respectively.[23] The Commision Internationale de l'Eclairage, L*, a*, b* (CIELAB) perceptibility and acceptability thresholds for light-skin-colored maxillofacial silicone specimens are 1.1 and 3.0, respectively.[24]

While studies on maxillofacial silicone prostheses' color have focused on producing color-stable prostheses through investigating the use of opacifiers and different chemical structures of silicone elastomers, the method of mixing silicone specimens and pigmentation has been briefly considered. There have been no efforts to investigate maxillofacial silicone elastomer color under mixing methods due to limitations in methods of quantifying pores. The presence of pores within mixtures has been investigated by conducting invasive protocols of sectioning specimens into slices of controlled thickness, then investigating the slices using scanning electron microscopy[2] light or stereo microscopy.[8,25] Other protocols were noninvasive, using X-ray microfocus computerized tomography (Micro-CT)[4,7,26] in analyzing pores (number, size, volume, and percentage) of different materials including all-ceramic crowns[26] and encapsulated glass ionomer cements.[4] Although environmental and patient factors that affect silicone prostheses' functionality have been investigated thoroughly in the literature,[27-30] material handling properties of air bubble formation during mixing have not been evaluated. The aims of this study were to evaluate the porosity (number and percentage) in maxillofacial silicone elastomers mixed by two techniques, nondestructively using X-ray Micro-CT, and furthermore to investigate the effect of porosity on color reproducibility and color stability after two aging conditions. Accordingly, the three null hypotheses were: mechanical mixing under vacuum does not affect porosity in comparison to manual mixing (hypothesis 1); porosity does not affect silicone elastomer color (hypothesis 2); and porosity does not affect silicone elastomer color stability after conditioning (hypothesis 3).

Materials and methods

Sixty-four disk-shaped specimens were prepared (8-mm diameter, 3-mm thick) using TechSil S25 maxillofacial silicone elastomer (Technovent, Leeds, UK) and were heat cured in stone molds in a dry heat oven at 100°C for 2 hours. Half the specimens ($n = 32$) were manually mixed, and the other half were mechanically mixed under vacuum. Silicone was interruptedly mixed with a mechanical arm and under vacuum for 10 minutes. Every minute, the mixer was switched off, allowing the silicone to settle down in the bowl, then the mixer was switched on again.

Half the specimens ($n = 16$) for each mixing method were left clear (unpigmented), and the remaining specimens ($n = 16$) were colored using a preblended intrinsic rose-pink skin shade (P409, Principality Medical, Newport, UK). Five drops (0.05 g) were added to each 10 g silicone mix. A total of four groups ($n = 16$) were obtained (Table 1). Specimens were first scanned for porosity, and then color was measured before and after conditioning.

Micro-CT porosity measurements were initiated by scanning the specimens and then quantifying the pores. Specimen scanning was performed using an X-ray Micro-CT (SkyScan 1072, Skyscan, Kontich, Belgium), controlled by a PC workstation (Optilex 755, Dell Inc, Ireland). Scanning was conducted according to the parameters in Table 2, producing X-ray images. The images were reconstructed using *NRecon* software (Skyscan), providing 211 two-dimensional slices. These slices were analyzed using *CTAn*a software (Skyscan) providing a realistic three-dimensional model of each specimen (150.86 mm^3 total volume scanned), with various possibilities of rotating, slicing, and showing axial cross sections of specimens (Fig 1). Thresholding of specimens was conducted for measuring number, volume, and percentage of pores present in the silicone. This operation transformed the image to a binary one (black and

Table 1 Study groups

Groups ($n = 16$)	Description	Conditioning modes
1	Unpigmented, manually mixed silicone specimens	Within each group, two conditions were tested: sebum storage for 6 months ($n = 8$) and accelerated daylight aging for 360 hours ($n = 8$)
2	Pigmented, manually mixed silicone specimens	
3	Unpigmented, mechanically mixed silicone specimens	
4	Pigmented, mechanically mixed silicone specimens	

Table 2 Parameters used for microfocus computerized tomography scanning

Property	Value
Magnification	×18.71
Image thickness	14.21 μm
Rotation step	45°
Rotation angle	180°
Source	100 kV/98 μA
Exposure time	3.0 seconds
Scanning duration	30 to 35 minutes
Number of layers	211 ± 2
Specimen diameter = 8 mm, thickness = 3 mm, volume = 150.72 mm^3	

white). Image parts marked as white participated in all binary operations for correction and calculation of numerical characteristics. Porosity measurements were conducted by quantifying silicone pores for the volume scanned (S_V). The number of pores (P_N) is related to the total amount of pores in each volume. Pv stands for the volume of total pores, and porosity percentage ($P_{\%}$) of each volume was calculated according to Equation 1.[7]

$$P_{\%} = \frac{P_V}{S_V} \times 100. \tag{1}$$

Optical micrographs (×10) of the specimens were conducted using an optical microscope (Meiji Emz-TR, Meiji Techno, Tokyo, Japan). After conducting porosity measurements, eight specimens of each group (of the four main groups) were stored in simulated sebum for 6 months, and the remaining eight specimens were light aged for 360 hours (Table 1).

The simulated sebum solution was prepared by dissolving 10% Palmitic acid with 2% Glyceryl Tripalmitate into 88% of Linoleic acid (all w/w).[30,31] The sebum was freshly reprepared after the first 3 months. The accelerated artificial 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 Xenon light was applied for the duration of aging (360 hours).

Color measurements were performed using a colorimeter (Minolta Chroma Meter CR-221, Osaka, Japan) according to the CIELAB coordinates with a D65 standard light source. The L* parameter corresponds to the degree of lightness and darkness (100 ideal white, 0 ideal black); a* and b* coordinates correspond to red or green chroma (+a* = red, −a* = green), and yellow or blue chroma (+b* = yellow, −b* = blue), respectively. The colorimeter was calibrated using a standard white plate, which also served as a background when color was measured. Prior to color measurements, specimens were notch-marked and placed in a Teflon locating disk (external Φ = 26 mm, internal Φ = 8 mm, and thickness = 3 mm), to ensure readings were made at the same location on each specimen before and after conditioning. Color measurements were recorded at baseline and at the end of conditioning periods for all groups. Color change (ΔE) was calculated using the following equation:

$$\Delta E = [(\Delta L^*)^2 + (\Delta a^*)^2 + (\Delta b^*)^2]^{1/2},$$

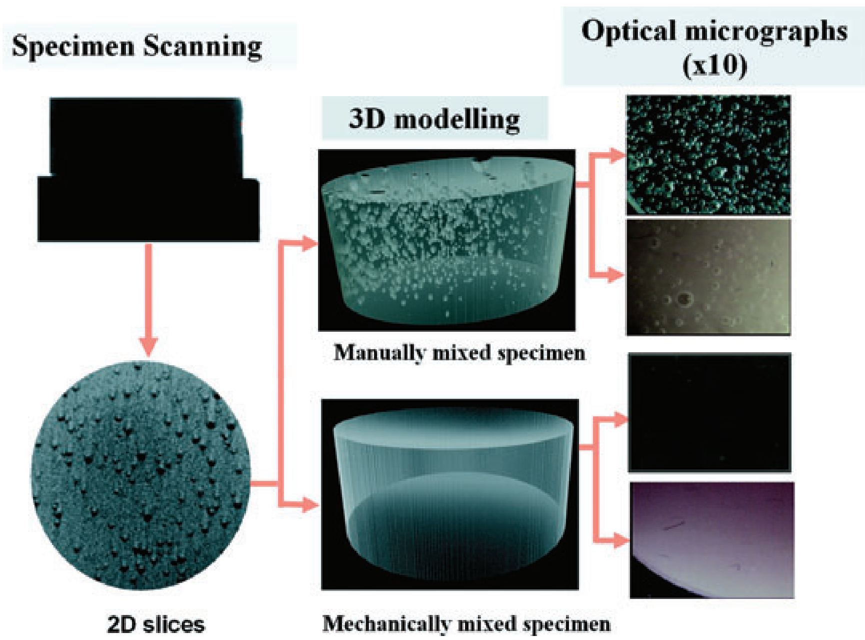

Figure 1 Diagram showing reproduction of three-dimensional models of silicone specimens (of both mixing methods), and optical micrographs (× 10) of pigmented (in pink) and unpigmented specimens of the mixing methods.

Table 3 Mean (SD) values of porosity variables for manual and mechanical mixing under vacuum

Group (n = 16)	Porosity measurements: Number of pores (P_N)	Pore volume (mm^3) (P_V)	*Porosity percentage ($P_{\%}$)
Manual mixing (unpigmented)	466.63^a (198.95)	0.97^a (0.60)	0.64^a (0.40)
Manual mixing (pigmented)	998.50^b (300.56)	2.15^b (0.73)	1.43^b (0.49)
Mechanical mixing under vacuum (unpigmented)	67.88^c (143.63)	0.11^c (0.11)	0.07^c (0.07)
Mechanical mixing under vacuum (pigmented)	107.13^c (158.56)	0.05^c (0.07)	0.03^c (0.05)

$^-$Within each porosity variable, different superscript letters indicate significant difference between groups ($p < 0.05$).
$^-$Volume of each specimen (S_v) = 150.85 mm^3.
*Porosity percentage ($P_{\%}$) = P_v / S_v × 100%.

where ΔL*, Δa*, and Δb* are the differences in the respective values before and after aging.

Specimens were gently cleaned with diluted aqueous liquid mild detergent (W5, Dublin, Ireland), then rinsed in water, and ultrasonically cleaned for 5 minutes (Transonic T310, Camlab Ltd, Cambridge, UK) before each color measurement. For porosity measurements, one-way ANOVA and Dunnett's T3 multiple post-hoc tests (release 16, SPSS, Chicago, IL) were applied to test significant differences between the four groups in pore number and percentage ($p < 0.05$). For color measurements, and to test the effect of pores on silicone color, independent *t*-test (release 16, SPSS) was used to detect statistically significant differences ($p < 0.05$) in color change (ΔE) between manually and mechanically mixed silicone specimens, in both unpigmented and pigmented states.

Also to test the effect of pores on color stability (durability), color changes were calculated after aging for each mixing method. Then, color change of manually and mechanically mixed silicone specimens were compared using independent *t*-test (release 16, SPSS) ($p < 0.05$).

Results

Porosity measurements are presented in Table 3. Mechanical mixing under vacuum reduced pore numbers and percentages in comparison to manual mixing, within pigmented ($p < 0.001$) and unpigmented silicone specimens ($p < 0.05$). Within mechanically mixed specimens, pigments did not affect porosity measurements ($p > 0.05$). Within manually mixed silicone specimens, pigmentation increased pore numbers and percentages ($p < 0.05$). Accordingly, the first hypothesis was rejected.

The effect of pores on color changes between manual and mechanical mixing methods (ΔE) is presented in Table 4. ΔE values were 5.93 and 5.18 for unpigmented and pigmented specimens, respectively; they were considered visually perceptible (ΔE > 3). There was no statistically significant difference in ΔE between pigmented and unpigmented specimens ($p > 0.05$). Accordingly, the second hypothesis was rejected.

The effect of pores on color stability (durability) after aging for each mixing method is presented in Table 5. For silicone specimens stored in sebum for 6 months, manually mixed specimens (in their unpigmented state) were more color stable than their respective mechanically mixed specimens (showed lower ΔE = 2.79, $p = 0.034$); however, pigmented silicone specimens showed the same color change regardless of mixing method ($p = 0.987$). For silicone specimens exposed to 360 hours of light aging, unpigmented silicone specimens showed the same color change ($p = 0.179$); however, mechanically mixed pigmented specimens showed lower color change than manually mixed specimens ($p = 0.003$).

Discussion

Fabrication of different facial and body prostheses involves mixing maxillofacial silicones using different techniques such as manual mixing, with or without vacuum; and mechanical mixing, with or without vacuum. This study investigated two mixing procedures: manual mixing without vacuum and mechanical mixing under vacuum.

The mixing technique of silicone, along with the method of pouring it into molds, might alter the number, size, and distribution of pores within silicone. It was reported that mechanical

Table 4 Mean (SD) values of color changes between manual and mechanical mixing methods (ΔE) of silicone elastomer

Groups (n = 16)	Mixing methods: Manual L	Manual a	Manual b	Mechanical L	Mechanical a	Mechanical b	ΔE
Unpigmented	45.66 (1.90)	−3.13 (0.18)	3.54 (0.66)	50.33 (3.67)	−3.46 (0.26)	4.79 (1.22)	5.93^a (3.17)
Pigmented	55.88 (2.25)	5.58 (0.89)	11.48 (0.64)	52.31 (1.66)	3.25 (0.43)	9.35 (0.52)	5.18^a (1.50)

^{a}homogeneous subsets ($p = 0.403$) using independent *t*-test.

Table 5 Mean (SD) values of color changes (ΔE) after conditioning with sebum and light aging. *P*-values indicate significant differences between manually and mechanically mixed silicone specimens according to independent *t*-test

	Baseline (n = 8)			After aging (n = 8)				
Conditioning	L	a	b	L	a	b	ΔE	*P*-value
Sebum unpigmented								
Manual	45.73 (2.43)	−3.17 (0.17)	3.67 (0.65)	44.02 (2.50)	−3.44 (0.10)	4.04 (0.79)	2.79 (1.62)	0.034
Mechanical	50.25 (4.36)	−3.40 (0.28)	3.87 (0.86)	48.71 (3.19)	−3.62 (0.12)	6.10 (1.34)	5.66 (3.07)	
Sebum pigmented								
Manual	55.37 (2.69)	5.48 (1.20)	11.52 (0.83)	54.14 (0.91)	4.59 (0.27)	10.2 (0.19)	3.49 (1.83)	0.987
Mechanical	51.89 (2.09)	3.37 (0.54)	9.44 (0.60)	49.88 (1.26)	2.38 (0.32)	7.58 (0.54)	3.48 (1.14)	
Light aging unpigmented								
Manual	45.59 (1.34)	−3.10 (0.20)	3.41 (0.69)	40.54 (2.65)	−3.09 (0.11)	2.34 (0.93)	5.48 (3.38)	0.179
Mechanical	50.41 (3.13)	−3.52 (0.23)	5.71 (0.72)	46.75 (5.80)	−3.61 (0.68)	2.29 (1.42)	8.55 (5.12)	
Light aging pigmented								
Manual	56.38 (1.74)	5.68 (0.48)	11.44 (0.43)	60.53 (2.36)	−3.21 (0.18)	9.84 (0.57)	10.28 (1.28)	0.003
Mechanical	52.74 (1.05)	3.12 (0.27)	9.26 (0.45)	56.48 (1.51)	−3.85 (0.14)	7.29 (0.42)	8.26 (0.95)	

mixing, combined with vacuum, produced silicone mixtures of statistically significantly lower pore numbers and percentage than with manual mixing.[7]

This study showed that mechanical mixing under vacuum reduced pore number and percentage in comparison to manual mixing, within pigmented and unpigmented silicone specimens. Furthermore, within manually mixed silicone specimens, pigmentation increased pore number and percentage; however, mechanically mixed silicone specimens were noticeably denser with less-prominent pores.

Pore reduction is a direct result of the technique used. Mechanical mixing employed a horizontal high-speed arm in a closed chamber under continuous air suction by an integrated vacuum, which reduced air bubbles in comparison to the manual spatulations of silicone in open surroundings. Furthermore, the silicone catalyst was thoroughly blended and incorporated into the silicone rubber, decreasing the number of unbounded particles within silicone, and forcing pores to the surface of the silicone. Mechanical mixing under vacuum has been investigated for bone cements[12] and elastomeric impression materials.[1,6,11] These reports suggested that such a technique reduced porosity and resulted in improved mechanical properties.

There was a statistically significant difference in pore numbers and volume between the two mixing methods, as higher numbers and larger pores were present in manual mixtures. This is in agreement with the literature, as previous studies showed that pore diameters within manual mixtures are larger than those of mechanical mixtures,[10] as mechanical mixing under vacuum eliminated large pores.[25] Mechanically mixed silicone had lower pore percentages than manually mixed silicone for unpigmented (0.64% vs. 0.07%) and pigmented (1.43% vs. 0.03%) silicone specimens.

Mechanical mixing was effective in eliminating pores and voids, and mechanically mixed high-viscosity materials had fewer pores than manually mixed materials.[1,9] Pore-free mixtures were not possible to obtain, despite mechanical mixing under vacuum.[8,10,32] It is likely that formation of pores is affected by the high silicone viscosity, heat-accelerated polymerization method, and the amount of catalyst used.[2]

Same color pigment was mixed with same silicone elastomer following the two mixing techniques: manual and mechanical mixing under vacuum. The color of both manually mixed specimens and mechanically mixed specimens was measured. It was expected that there would be no color difference between both specimens, as the same pigments and silicone materials were used, with different mixing methods. Results showed that color differences were 5.93 and 5.18 for unpigmented and pigmented specimens, respectively. This is indicative of pores' effect on the resultant color of silicone.

Furthermore, color differences greater than 3 are considered visually perceptible by the naked eye.[24] Accordingly, it can be stated that pores do affect color reproducibility, and mimicking of selected skin shade greatly depends on the silicone mixing technique.

In the CIE L*a*b* color space, the luminous reflectance (total amount of light reflected), dominant wavelength (actual color of specimen), and excitation purity (the amount of color chroma) of test specimens are calculated in accordance with the CIE chromatography diagram. Thus, it is likely that the presence of air voids within the manually mixed silicone specimens scattered the reflected light, affecting the total color of specimen.

On the other hand, and to investigate the effect of pores on color stability of silicone elastomer, color of specimens of both mixing methods was recorded at baseline and after aging. Regardless of silicone mixing method, and whether it is pigmented or not; all specimens exhibited color changes ($\Delta E = 2.79$ to 10.28). This might be due to the inherent color instability of silicone itself,[22,33] pigment loss, and/or severity of the aging conditioning employed.[20–22]

Color differences between the two mixing methods varied significantly whether silicone was pigmented or unpigmented and depended on type of aging conditioning used. For specimens stored in sebum, unpigmented, manually mixed specimens showed lower ΔE ($p < 0.05$) than the respective mechanically mixed specimens (2.79 vs. 5.66), and pigmented specimens showed the same color change ($p > 0.05$). For specimens exposed to light aging, pigmented mechanically mixed specimens showed lower ΔE ($p < 0.05$) than their respective manually mixed specimens (8.26 vs. 10.28), and unpigmented specimens showed the same ΔE ($p > 0.05$).

Conditioning of silicone elastomers can stimulate structural changes in physical and chemical properties, as it causes either polymer chain scission, intensified crosslinking, or increased density.[34] High-energy radiation of the accelerated daylight aging produces denser elastomeric structures, as it enhances crosslinking between chains, making the silicone more opaque. This might affect the chroma of the specimen color.[30] Sebum fatty acids tend to interact with silicone, breaking chain bonds and decomposing the elastomer, and leaching pigments out of the silicone.

There is no clear behavior of color loss upon service; but it can be stated that color stability among the two mixing techniques was affected by type of conditioning more than by mixing techniques. Pigmented silicone prostheses exposed to daylight can exhibit less color change if the silicone is mechanically mixed under vacuum; however, pore-free silicone prostheses are likely to be more color stable than porous prostheses. The Micro-CT scanning in investigating porosity analysis preserved the specimens and provided adequate data from a single scan;[4,26] however, its cost, artifact generation decreasing image quality, and high skill required might preclude its use.

Conclusions

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

1. Mechanical mixing under vacuum reduced porosity percentage within silicone elastomer whether pigmented or not, in comparison to manual mixing.
2. Mixing method affected the resultant color of the prosthesis.
3. Pores' effect on silicone elastomer color stability varies with presence of pigmentation and conditioning method.

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