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RESEARCH AND EDUCATION

Effects of mixing method, thixotropic agent, and polymerization procedure on porosities in silicone elastomers used for facial prosthesis fabrication

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ABSTRACT

Statement of problem. Air entrapment during silicone mixing and processing can result in porosities in maxillofacial prostheses, compromising esthetics, mechanical properties, and hygiene. However, the combined effects of mixing method, thixotropic agent (TA), and polymerization pressure on the presence of porosities have not been fully clarified.

Purpose. The purpose of the present study was to evaluate the effects of polymerization pressure, mixing method, and TA amount on the pore formation of a facial silicone material.

Material and methods. Cylindrical silicone specimens (N=96) were fabricated using 2 mixing methods (manual or mechanical), 4 TA levels (0, 1, 2, 3 drops), and 2 polymerization conditions (with or without pressure). Porosity, pore number, and maximum pore diameter were measured by using microcomputed tomography. Data were analyzed with 3-way analysis of variance (α=.05).

Results. Pressurization markedly reduced the porosity and pore number, regardless of the mixing method or TA amount ($P<.001$). Without pressure, mechanical mixing produced significantly fewer pores than manual mixing ($P<.001$). In manual mixing without pressure, adding TA decreased the pore number but increased the maximum pore diameter. No significant effect of TA was observed with mechanical mixing ($P=.102$).

Conclusions. Polymerization under pressure was the most effective method of minimizing porosities. In situations where pressure cannot be applied, mechanical or manual mixing with limited TA can reduce pore incorporation in silicone prostheses. (J Prosthet Dent 2026;135:829-835)

Facial prostheses are used to prosthetically restore facial defects or deformities caused by tumors or traumatic injuries.[1,2] Polydimethyl siloxane (PDMS), a flexible silicone elastomer, is the most commonly used material for facial prostheses.[3–6] Most commercially available products consist of 2 components, a base and a catalyst, which are mixed together before use.[7] Air incorporation during mixing and processing produces porosities in silicone elastomers, warranting procedures for reducing them.[8,9] Air pores impair esthetics, reduce mechanical properties, and create suitable environments for bacterial invasion.[10,11] In addition, compatibility, color, form, and natural appearance are important for facial prostheses.[12] Silicone elastomers are translucent; intrinsic pigments are added for reproducing human skin color during mixing, whereas extrinsic pigments are colored on the external surface after polymerization. Intrinsic pigments are more durable and less affected by the environment than extrinsic pigments.[13] Hatamleh et al[10] investigated porosity in facial prosthesis silicone elastomers associated with different mixing methods and reported that the number and percentage of air pores were reduced by mechanical mixing and increased when intrinsic pigments were added. Although these studies have reported on porosities by using different mixing methods

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Clinical Implications

Air is often incorporated during the mixing and pouring of silicone materials for facial prostheses, impairing the esthetics and mechanical properties and creating favorable environments for bacteria colonization. The present results indicated that if pressurization is not feasible, pores can be reduced by mechanical mixing without a thixotropic agent or by manual mixing with 1 drop of thixotropic agent.

and materials, the authors are unaware of studies that have been conducted on silicone elastomer A-2186 (Factor II Inc), one of the most popular facial elastomers.[14]

A thixotropic agent (TA) containing 100% silicone polyether copolymer has been used to improve operability.[15,16] The addition of a TA has been reported to increase the viscosity of silicone by changing the spatial distribution, increasing interparticle attractions and the entanglement density of the chains.[16] The manufacturer recommended adding 1 to 2 drops of TA to increase the appropriate viscosity of the 10 g base silicone materials. Kurtoglu et al[17] reported the effect of TA of A-2186 on the mechanical properties and that 2 to 5 drops of TA increased the tensile and tear strength but decreased shore-A hardness and elongation. Although increasing the viscosity by using TA has been reported to help reduce the air pores that would be embedded inside the mixture,[15,18,19] the authors are unaware of reports that have demonstrated a clear effect of TA on pore reduction in silicone elastomers.

The feasibility of pressurized polymerization depends on the size of the facial prosthesis. Dental stone has been the most commonly used material for fabricating molds, and small-sized facial prostheses can be invested in metal flasks to minimize the risk of dental stone mold fracture during the packing process. However, for large prostheses, appropriately sized metal flasks are not available, and only dental stone molds, which cannot withstand pressurization during polymerization, can be used.[20] This clinical limitation may lead to increased porosity in the definitive silicone prosthesis, underscoring the need for alternative methods such as optimized mixing techniques or material modifications to minimize air entrapment during fabrication under nonpressurized conditions.

The present study aimed to evaluate the influence of mixing method, TA amount, and polymerization pressure on the porosity, pore number, and maximum pore diameter of A-2186 silicone elastomer. The null hypotheses were that no significant differences would be observed with respect to polymerization, mixing method, or TA amount.

MATERIAL AND METHODS

The facial prosthetic materials tested were a silicone elastomer (A-2186; Factor II Inc), TA (A-300–8; Factor II Inc; available at: https://www.factor2.com/Thixotropic_Agent_p/a-300–8.htm), and an intrinsic pigment

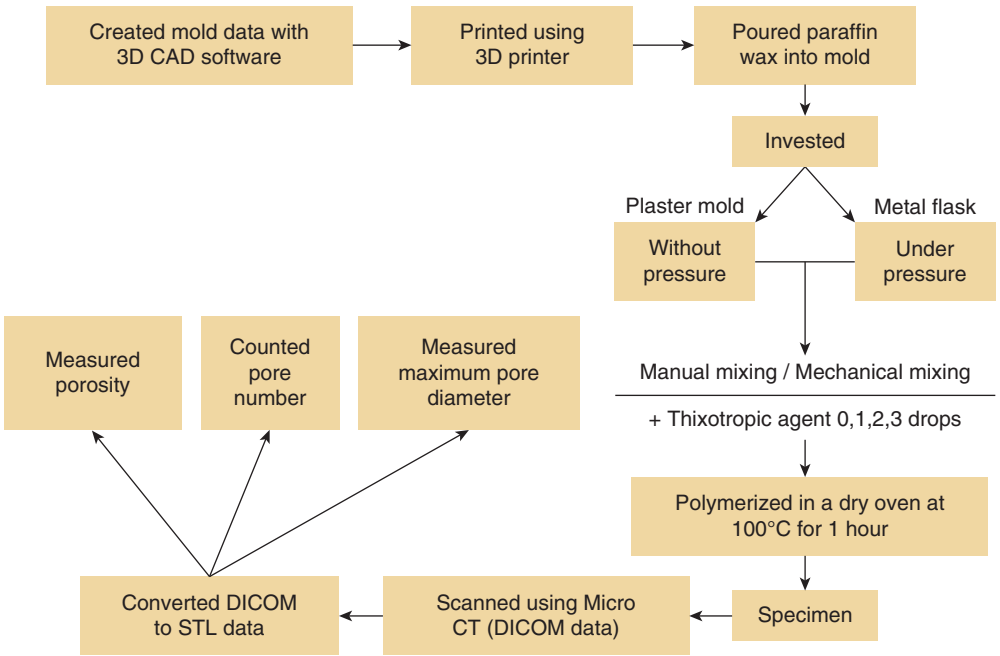

Figure 1. Study workflow. 3D, 3-dimensional; CAD, computer-aided-design; DICOM, digital imaging and communications in medicine; Micro CT, microcomputed tomography; STL, standard tessellation language.

(Functional Intrinsic II Bisque; Factor II Inc). The experimental workflow is shown in Figure 1.

Cylindrical specimens were designed (Ø30×10 mm) using a 3-dimensional (3D) computer-aided design (CAD) software program (Freeform Modeling Plus v12; Geomagic) and fabricated with a 3D printer (Object30 prime; Stratasys) using photopolymerized acrylic resin (VeloClear RGD810; Stratasys) with a layer thickness of 14 μm in high-quality mode. Wax patterns were created by pouring molten paraffin wax (GC Corp) into the molds, which were subsequently invested. For the pressurized condition, 3 wax patterns were invested in metal flasks with a Type 3 dental stone (Zoostone; Shimomura Gypsum) and a Type 4 dental stone (Fuji Rock; GC Corp) for the double investing method (silicone only contacted the Type 4 dental stone); then the wax was removed, and the mold was fabricated under pressure. In the absence of pressure, the mold was made of Type 4 dental stone (Fuji Rock; GC Corp) without any flasks. Three grams of the catalyst and 3 drops of the intrinsic pigment (0.069 g) were added to 30 g of the silicone elastomer base and then mixed. For each condition, 0, 1, 2, and 3 drops of TA (0.018 g/drop) were added to 10 g of silicone base. Two mixing methods were used: manual mixing on a mixing pad for 5 minutes or mechanical mixing using a vacuum mixer (Smart mix; Amann Girrbach AG) for 3 minutes after premixing for 30 seconds. Then, the prepared silicone materials were injected into the flasks using a 5-mL plastic syringe with manual pressure to prevent air contamination on the surface of the specimen. The flasks were closed under pressure without any gaps and fixed using a flask press. For the nonpressure condition, the dental stone molds were closed together carefully without any gaps, ensuring no breakage of the molds. Each mold was stored for 1 hour at 100 °C in a dry oven (HO-1; GC Corp) for polymerization. Then, the molds were allowed to cool to room temperature (23 ±2 °C) for 24 hours, deflasked, and the specimens trimmed. Six specimens were tested for each condition: the amount of TA (0, 1, 2, and 3 drops), manual or mechanical mixing, and with or without pressure during polymerization. A total of 96 specimens were prepared under 16 different conditions. The fabrication order of specimens was randomized using a computer-generated random sequence to avoid systematic bias.

Each specimen was scanned using microcomputed tomography (Scan Xmate-E090; Comscan Techno) at a tube voltage of 71 kV, tube current of 113 μA, magnification ×1.3, number of laminations of 2 times, and lamination rate of 3.0 frames/second; thereafter, the Digital Imaging and Communications in Medicine (DICOM) data were created and transferred into a 3D visualization software program (Zedview 9.3; LEXI), and standard tessellation language (STL) data were obtained.

The porosity, number of pores, and maximum pore diameter were evaluated. The STL data of each specimen were transferred to a 3D CAD software program (Freeform Modeling Plus v12; Geomagic), and the volumes of the entire specimen (Vi) and embedded pores (Vp) were calculated. Porosity (P%) was calculated by using the following formula: P%=Vp/Vi×100.

The number of pores was counted in a 3D view by using a 3D visualization software program (Zedview v9.3; LEXI). To determine the maximum pore diameter, STL data were transferred to 3D data editing software program (Artec Studio v11; Artec Group), the largest pore diameter was measured 3 times by using the measurement function, and the average diameter was obtained.

The porosity, number, and maximum pore diameter were statistically analyzed (GraphPad Prism software program v9.1.0; GraphPad). Because the porosity under the pressure condition was concentrated at less than 0.1%, the specimens were classified into 2 groups (<0.1% and ≥0.1% porosity), and the distribution of the number of specimens was compared with the chi-squared test (α=.05). Three-way analysis of variance (3-way ANOVA) with 3 fixed factors (pressurization, mixing method, TA) and their 3-way interactions were conducted to analyze the differences in means for porosity, pore number, and maximum pore diameter. The Tukey test was used for post hoc multiple comparisons (α=.05).

RESULTS

The pores without TA were almost spherical, whereas they were irregularly shaped when TA was added (Fig. 2). Tables 1 to 3 present the results of 3-way ANOVA for porosity, pore number, and maximum pore diameter.

For porosity, significant interactions were observed between the pressure condition and both the amount of TA and mixing method (P<.001) (Table 1). Under pressure, porosity remained negligible (<0.1%) across all mixing methods and TA levels (Table 4). Without pressure, manual mixing produced higher mean ±standard deviation porosity than mechanical mixing (from 0.73 ±0.13% to 2.10 ±1.17% versus from 0.05 ±0.07% to 0.87 ±0.52%, P<.001). Within manual mixing without pressure, 2 drops of TA produced the highest porosity (2.10 ±1.17%), which was significantly greater than the 0-drop condition (0.73 ±0.13%, P<.001).

For pore number, significant interactions were observed among the TA, mixing method, and pressurization (P<.001) (Table 2). With pressure, pore numbers were near 0 for all conditions (Table 5). Without pressure, mechanical mixing produced drastically fewer pores than manual mixing (5.7 ±7.4 versus 1002.8 ±108.5, P<.001). In manual mixing without pressure, adding 1 to 3 drops of TA significantly reduced the pore numbers than 0 drops (1002.8 ±108.5 versus from 242.3 ±105.9 to 283.5 ±69.3, P<.001).

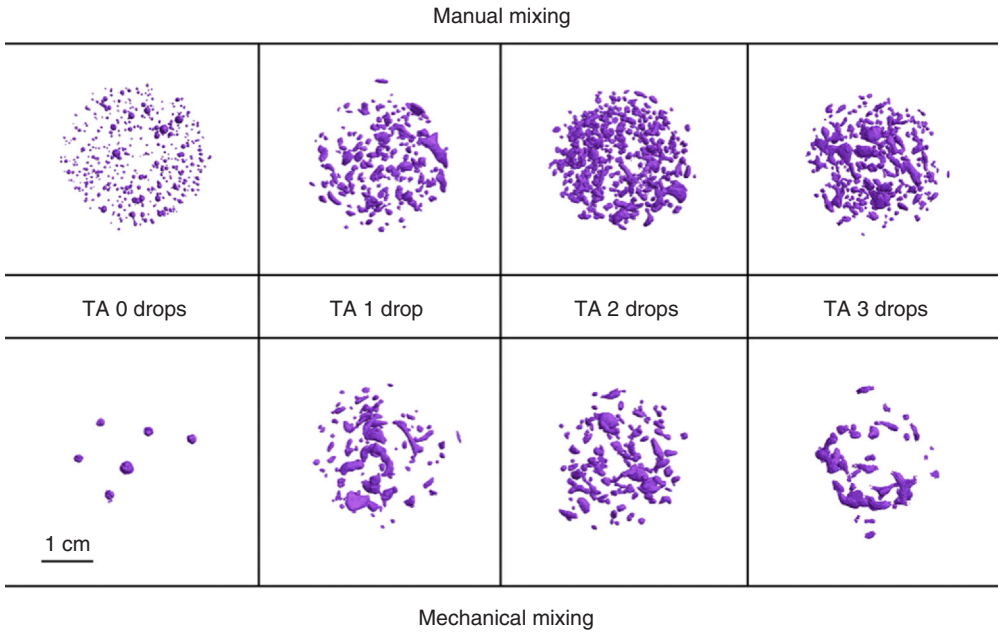

Figure 2. Shape of pores without pressure, (Original magnification, ×1.3). Purple part represents pores. TA, thixotropic agent.

Table 1. Results of three-way analysis of variance for porosity

Source	*df*	Sum of Squares	Mean Square	F	*P*
TA	3	3.700	1.233	7.230	<.001[x]
Mixing method	1	5.260	5.260	30.84	<.001[x]
Pressurization	1	24.06	24.06	141.0	<.001[x]
TA × Mixing method	3	0.278	0.093	0.544	.654
TA × Pressurization	3	3.805	1.268	7.435	<.001[x]
Mixing method × Pressurization	1	5.185	5.185	30.40	<.001[x]
TA × Mixing method × Pressurization	3	0.311	0.104	0.608	.612
Within specimens	80	13.64	0.171		

TA, thixotropic agent; [x], $P<.05$ shows statistically significant difference.

Table 2. Results of three-way analysis of variance for pore number

Source	*df*	Sum of Squares	Mean Square	F	*P*
TA	3	506322	168774	36.69	<.001[x]
Mixing method	1	890313	890313	193.6	<.001[x]
Pressurization	1	1539507	1539507	334.7	<.001[x]
TA × Mixing method	3	758122	252707	54.94	<.001[x]
TA × Pressurization	3	503185	167728	36.46	<.001[x]
Mixing method × Pressurization	1	888388	888388	193.1	<.001[x]
TA × Mixing method × Pressurization	3	753396	251132	54.60	<.001[x]
Within specimens	80	367977	4600		

TA, thixotropic agent; [x], $P<.05$ shows statistically significant difference.

Table 3. Results of three-way analysis of variance for maximum pore diameter

Source	*df*	Sum of Squares	Mean Square	F	*P*
TA	3	163.5	54.51	38.09	<.001[x]
Mixing method	1	3.908	3.908	2.731	.102
Pressurization	1	782.7	782.7	546.9	<.001[x]
TA × Mixing method	3	0.296	0.099	0.069	.976
TA × Pressurization	3	168.9	56.30	39.34	<.001[x]
Mixing method × Pressurization	1	5.895	5.895	4.120	.004[x]
TA × mixing method × Pressurization	3	2.791	0.930	0.650	.585
Within specimens	80	114.5	1.431		

TA, thixotropic agent; [x], $P<.05$ shows statistically significant difference.

For maximum pore diameter, the interactions were significant between pressure and TA ($P<.001$) and between pressure and mixing method ($P=.004$) (Table 3). Under pressure, maximum pore diameters were negligible in all groups (Table 6). Within manual mixing without pressure, TA addition significantly increased the

Table 4. Results of porosity with different amounts of TA

	Under Pressure		Without Pressure	
Amount of TA	**Manual Mixing %**	**Mechanical Mixing %**	**Manual Mixing %**	**Mechanical Mixing %**
0 drops	0.02 ±0.04^{e}	0 ±0^{e}	0.73 ±0.13^{c,d,e}	0.05 ±0.07^{d,e}
1 drop	0 ±0^{e}	0 ±0^{e}	1.41 ±0.35^{a,b,c}	0.63 ±0.2^{c,d,e}
2 drops	0 ±0^{e}	0 ±0.01^{e}	2.1 ±1.17^{a}	0.87 ±0.52^{b,c,d}
3 drops	0 ±0^{e}	0 ±0^{e}	1.65 ±0.78^{a,b}	0.6 ±0.22^{c,d,e}

TA, thixotropic agent. Data presented as mean ±standard deviation. Same superscript letters denote subgroups not significantly different (Tukey test, *P*>.05).

Table 5. Results of pore number with different amounts of TA

	Under Pressure		Without Pressure	
Amount of TA	**Manual Mixing n**	**Mechanical Mixing n**	**Manual Mixing n**	**Mechanical Mixing n**
0 drops	1.2 ±2.7^{d}	0 ±0^{d}	1002.8 ±108.5^{a}	5.7 ±7.4^{d}
1 drop	0 ±0^{d}	0 ±0^{d}	255.2 ±123^{b}	109.7 ±32.4^{c,d}
2 drops	0 ±0^{d}	0.3 ±0.8^{d}	242.3 ±105.9^{b,c}	77.5 ±39.8^{d}
3 drops	0 ±0^{d}	0 ±0^{d}	283.5 ±69.3^{b}	51 ±21.7^{d}

n, pore number; TA, thixotropic agent. Data presented as mean ±standard deviation. Same superscript letters denote subgroups not significantly different (Tukey test, *P*>.05).

Table 6. Results of maximum pore diameter with different amounts of TA

	Under Pressure		Without Pressure	
Amount of TA	**Manual Mixing mm**	**Mechanical Mixing mm**	**Manual Mixing mm**	**Mechanical Mixing mm**
0 drops	0.28 ±0.66^{d}	0 ±0^{d}	1.84 ±0.37^{d}	1.21 ±0.68^{d}
1 drop	0 ±0^{d}	0 ±0^{d}	6.43 ±0.92^{b}	5.97 ±1.35^{b,c}
2 drops	0 ±0^{d}	0.65 ±1.52^{d}	7.72 ±2.42^{a,b}	6.29 ±1.12^{b}
3 drops	0 ±0^{d}	0 ±0^{d}	9.12 ±2.5^{a}	8.05 ±1.19^{a,b}

TA, thixotropic agent. Data presented as mean ±standard deviation. Same superscript letters denote subgroups not significantly different (Tukey test, *P*>.05).

pore diameter compared with 0 drops (1.84 ±0.37 mm versus from 6.43 ±0.92 to 9.12 ±2.5 mm, *P*<.001). A similar trend was observed in mechanical mixing without pressure (1.21 ±0.68 mm versus from 5.97 ±1.35 to 8.05 ±1.19 mm, *P*<.001).

Pressurization was the most influential factor, significantly reducing porosity, pore number, and maximum pore diameter (*P*<.001) (Tables 1–3). Among 48 specimens polymerized under pressure, only 1 (2.1%) exhibited porosity ≥0.1%, whereas 43 of 48 specimens (89.6%) without pressure exceeded this threshold (chi-squared, *P*<.001) (Table 7). Under pressure, both the mixing methods and TA levels showed nearly no influence, with pore numbers near 0 and negligible pore diameters.

Under nonpressurized conditions, mixing method exhibited a marked effect. Mechanical mixing produced significantly fewer pores than manual mixing (5.7 ±7.4 versus 1002.8 ±180.5, *P*<.001) (Table 5). The porosity values for mechanical mixing ranged from 0.05% to 0.87%, compared with 0.73% to 2.1% for manual mixing. Maximum pore diameters also tended to be smaller with mechanical mixing (approximately 6 to 8 mm) than with manual mixing (up to 9.12 ±2.50 mm). Under pressurization, however, the mixing method did not affect any of the outcomes.

The influence of TA was evident only in manually mixed specimens without pressure, where significant interactions were observed (Tables 1–3). Adding TA significantly reduced the pore number (0 drop: 1002.8 ±180.5 versus 1 drop: 255.2 ±123.0, *P*<.001) but increased the maximum pore diameter (0 drop: 1.84 ±0.37 mm versus 3 drops: 9.12 ±2.50 mm, *P*<.001). No consistent differences in porosity were found among 1 to 3 drops; however, 2 drops produced the highest mean porosity (2.1 ±1.2%). In contrast, under mechanical mixing or pressurization, the addition of TA had little to no measurable effect.

Overall, pressurization minimized porosity regardless of the mixing method or TA level. In the absence of pressure, mechanical mixing effectively reduced pore

Table 7. Comparison of porosity with and without pressure by using chi-squared test

	Total		0.01% Porosity or More		Under 0.01% Porosity		*P*
	n	**%**	**n**	**%**	**n**	**%**	
Under pressure	48	50	1	1.04	47	48.96	<.001
Without pressure	48	50	43	44.79	5	5.21	
Total	96	100	44	45.83	52	54.17	

n, number of specimens.

incorporation, while manual mixing demonstrated a trade-off: TA addition decreased the pore numbers but resulted in fewer, larger pores.

DISCUSSION

The present study evaluated the effects of pressure condition on the polymerization, mixing methods, and amount of TA on the pore formation of silicone elastomer A-2186.

The null hypotheses that no significant differences would be observed with respect to polymerization, mixing method, or TA amount were rejected.

Facial prostheses should be fabricated in metal flasks because pressurization during polymerization was found to be the most effective method of reducing air pores. The pressure polymerized group demonstrated that the porosity was mainly concentrated below 0.01% ($P<.001$) and that pores were rarely mixed into the silicone material under pressure with either mixing method. When comparing the presence and absence of pressure, the porosity, pore number, and maximum pore diameter significantly increased ($P<.001$), except for mechanical mixing and 0 drops of TA. Even when TA was added and the silicone elastomer was layered by manual mixing, which tends to create pores, it was possible to remove the pores by applying pressure. The interaction between the amount of TA and the polymerization pressure was also significant ($P<.001$). Under pressurized conditions, the TA had little influence on the porosity, as the pressure effectively eliminated entrapped air, regardless of viscosity. However, under nonpressurized conditions, the amount of TA strongly affected both the number and size of the pores, suggesting that TA was particularly important in large facial prostheses where pressurization was not feasible.

In the specimens without pressure, the porosity and pore number were significantly higher with manual mixing than with mechanical mixing (0 drop: $P<.001$, 1 drop: $P=.03$, 2 drops: $P=.006$, and 3 drops: $P<.001$, respectively). Hatamleh et al[10] reported that the pore number and porosity were lower in mechanical mixing than in manual mixing. The present study also indicated similar results when comparing mechanical and manual mixing without pressure. Thus, in the absence of pressure, mechanical mixing is considered an effective method for reducing the porosities and number of pores. Hatamleh et al[11] also reported that mechanical mixing alone did not eliminate air pores when the vacuum was released or during pouring into molds. Moreover, in the present study, the maximum pore diameter increased with the addition of TA, regardless of the mixing method. These results can be explained by the fact that air pore formation can be related to high silicone viscosity, heat polymerization, and the amount of catalyst used.[11] Other factors such as polymerization temperature and the amount of catalyst may also influence pore formation; however, no differences were identified in the present study, and future research is warranted to explore these aspects further.

Regarding the amount of TA, no significant difference was found with pressurization; however, without pressure, the porosity ($P=.019$) and maximum pore diameter ($P<.001$) increased, and the pore number significantly decreased ($P<.001$). TA enables skin color 3D reproduction by increasing the viscosity of the elastomer. Porosity is generally related to the viscosity of the material because air may be trapped within the material during the packing of the mold owing to the high surface tension of fluid silicone.[7,9] Kurtoglu et al[17] reported that the addition of 2 or more drops of TA decreased the mechanical properties of silicone elastomers, and the manufacturer recommends adding 1 to 2 drops of TA to increase the viscosity. In the present study, the amount of TA was set to 0, 1, 2, and 3 drops per 10 g of base silicone. With more than 3 drops of TA, the viscosity became too high, and it was difficult to manually mix continuously for 5 min. In contrast, the number of pores formed by manual mixing increased significantly in the absence of TA; however, the maximum pore diameter was small. Although the addition of TA significantly reduced the number of pores ($P<.001$), no significant difference was observed between drops 1 and 3 ($P=.098$). The results of the present study demonstrated that if pressurization was not possible, pores could be reduced by mechanical mixing without TA or by manual mixing with 1 drop of TA. The interaction between the amount of TA and the mixing method was significant, indicating that the effect of TA on the porosity was based on the type of mixing. Specifically, the addition of TA had a minimal impact under mechanical mixing but significantly influenced pore formation under manual mixing. The present results also indicated that air pores were evident on the surface of the silicone without TA and were eliminated by vacuum during the mechanical mixing process. The results suggested that viscosity modification by TA played a more critical role in the absence of mechanical homogenization. In addition, the maximum diameter increased significantly with an increase in the amount of TA, suggesting that TA affected pore formation. When manual mixing with TA was used, large irregularly shaped pores were mixed. If the viscosity was low, the tension around the interface between the silicone and air pores was balanced and the pores became spherical. When the silicone viscosity increased owing to an increased amount of the TA, irregularly shaped pores were created owing to unbalanced surface tension, contributing to deformation.

Limitations of the present study included that only 1 silicone material (A-2186) was tested with a single intrinsic pigment type. A-2186 is a room-temperature-vulcanizing (RTV) platinum silicone elastomer in which the polymerization reaction is cross-linked by the

addition of platinum and polymerized with no reaction byproducts. Other RTV silicones include condensation cross-linking and silicone-to-silicone medical adhesives using acetoxy polymerization.[3] Therefore, the effects of TA on the porosity of various silicone elastomers with different polymerization reactions should be evaluated. In addition, further studies are warranted to examine the amount of pigment and the pigment color types in air pores because Hatamleh et al[10] reported that pigmentation increased the number and percentage of pores. In the present study, a single pouring technique (syringe injection) was used to pour silicone into the mold, which may have affected the formation and distribution of pores. Future studies are warranted to investigate the influence of various pouring techniques on this phenomenon. One of the biggest problems affecting facial prosthesis longevity is discoloration caused by environmental factors such as ultraviolet (UV) rays, air pollution, and disinfection.[12] To limit discoloration caused by UV, opacifiers are often used for facial prostheses.[2] Whenever feasible, pressurization should be considered a fundamental requirement for minimizing air pore formation. Further research is warranted to clarify the effect of opacifier on air pores in situations where pressure cannot be applied.

CONCLUSIONS

Based on the findings of this in vitro study, the following conclusions were drawn:

1. Air pores were significantly reduced when pressurized, regardless of the mixing method and amount of TA.
2. Without pressurization, the porosities were significantly reduced by mechanical mixing. The maximum pore diameter increased significantly when the TA was added.
3. In manual mixing without pressure, the pore number decreased significantly when TA was added; however, the maximum pore diameter increased, and no significant difference was observed in the porosity between 0 and 1 drop compared with mechanical mixing.

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