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The Potential of Cohesive Silicone for Facial Prosthetic Use: A Material Property Study and a Clinical Report

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Abstract

Purpose: Prosthetic reconstruction of a facial defect can help to reduce disfigurement and restore the social functioning of the patient. Several methods for holding a prosthesis in place exist, including the use of osseointegrated implants and medical adhesive agents; however, since the treatment options for some patients may be restricted by various health conditions and other limitations, including allergies to adhesive agents, a history of radiation therapy, and financial issues, other options that suit individual demands are required. The objectives of this study were to test the hypothesis that adhesive characteristics could be bestowed on silicone elastomers by altering their catalyst/base silicone ratios (CBR) and to examine the effect of the thickness of the cohesive silicone layer of a prosthesis on its initial adhesive strength.
Materials and Methods: The adhesive strengths of specimens with CBRs ranking from 1/10 to 1/70 were examined by the rolling ball tack test. A tensile test was used to evaluate the tensile adhesive strengths of specimens made of layers of cohesive silicone (CBR 1/60) and normal silicone (CBR 1/10) with different thicknesses. Auricular prostheses containing cohesive silicone on the skin side were applied to a 50-year-old man with defects in both auricular regions and with reduced manual dexterity due to serious burns.
Results: The rolling distance was reduced with a decrease in CBR, and a thinner cohesive silicone (CBR 1/60) layer demonstrated a higher peak load. On clinical application, the adhesion of the auricular prosthesis containing cohesive silicone was improved by expanding the adhesive area and altering the thickness of the cohesive silicone layer, resulting in sufficient adhesion and easier handling than that achieved using an adhesive agent 1 year post delivery.
Conclusion: These results suggest that cohesive silicone can be used as a glueless retentive material for facial prostheses.

Reconstruction of facial defects is a challenging task for prosthodontists and anaplastologists. Patients with facial defects caused by head and neck cancer, trauma, or congenital conditions often experience esthetic and functional complications and emotional issues. Reconstruction helps these patients improve their appearance, ability to function, and self esteem and return to work and active life. To improve the quality of life of such patients,[1] various surgical and prosthetic reconstructions are being developed. A number of studies have reported excellent support and retention of facial prostheses using osseointegrated implants;[2–13] however, since patients who seek reconstruction may also suffer from various health conditions and be subject to personal preferences and restrictions, such as a history of radiation therapy or financial issues, further development of other options is required.

The main advantage of prosthetic reconstruction is that it is more suited to producing anatomically intricate structures than surgical reconstruction.[14] In addition to implants, several other retentive systems, such as adhesive agents, double-sided tape, surgical tape, and glasses, are available for holding facial prostheses in place.[2,8,15,16] Adhesive agents are the most commonly used method, and several studies of adhesive retention of facial prostheses have been conducted;[17–20] however, several clinical problems have been reported, including allergic skin reactions, wear and tear of the edges of the prostheses, and difficulty in cleaning up residual amounts of adhesive agent. Therefore, if the prostheses themselves possessed adhesive characteristics, the disadvantages of using adhesive agents could be overcome.

We hypothesized that A-2186F (Factor II, Inc., Lakeside, AZ), a silicone elastomer, would show adhesive characteristics

Table 1 Silicone specimens used in the rolling ball tack test

Catalyst/base silicone ratio (CBR)	Medical adhesive
1/10 (manufacturer-recommended CBR)	–
1/30	–
1/50	–
1/60	–
1/70	–
1/10	+

when its catalyst/base silicone ratio (CBR) was altered. A-2186F is approved for tissue contact for 29 days or fewer. The purposes of this study were to (1) examine the adhesive properties of silicone elastomers with various CBRs and the effect of the thickness of the cohesive silicone layer on the initial adhesive strength of prostheses and (2) to report on the clinical application of such prostheses in a preliminary case.

Material and methods

Rolling ball tack test

The rolling ball tack test measures the level of instantaneous adhesion. The silicone specimens used in this test are described in Table 1. Two gypsum molds (Advastone, GC, Tokyo, Japan) consisting of an upper portion and a lower portion containing a cavity ($26 \times 76 \times 0.45$ mm^3) and a microscope slide ($26 \times 76 \times 1.2$ mm^3; Superfrost, Matsunami, Osaka, Japan) were formed in a dental flask. The silicone sheets ($26 \times 76 \times 0.45$ mm^3) were prepared by packing each catalyzed silicone (A-2186F) into the gypsum molds, compressing them (4 MPa), and then leaving them at room temperature for 12 hours. Silicone with a CBR of 1/10 (manufacturer-recommended ratio) combined with a medical adhesive agent (Pros-Aide Adhesive) was used as the control. Two silicone specimens on two microscope slides were placed next to each other to make one long silicone specimen (152 mm).

The simplified rolling ball tack tester was fabricated according to the manufacturer's instructions (LTS/57, Bansei, Tokyo, Japan) (Fig 1). A 5.5-g carbon steel ball (JIS SWRCH 12A, Ohashi Steelball, Osaka, Japan) (11 mm diameter) was released and allowed to run down an inclined track made of cardboard (152-mm long at 20° angle). The distance the ball travelled along the horizontal silicone specimens was then measured. The test was conducted five times for each pair of specimens, and three pairs of specimens were prepared for each group.

Tensile test

Tensile tests were performed to examine the effect of the thickness of the cohesive silicone layer on the tensile adhesive strength of the silicone. The cylindrical specimens produced for the test (30-mm diameter × 12-mm height), consisted of different thicknesses of cohesive silicone (CBR 1/60) in their lower section and normal silicone (CBR 1/10) in their upper section (Fig 2A). Normal silicone combined with a medical adhesive agent was used as a control. Two gypsum molds with cylindrical cavities (30-mm diameter, 12-mm height) were formed in a dental flask. To fabricate the silicone specimens (30-mm diameter × 12-mm height), catalyzed normal silicone and a plaster spacer (30-mm diameter × 4- or 8-mm height; to fill the space to be occupied by the cohesive silicone) were packed into the gypsum molds, compressed (4 MPa), and left at room temperature for 12 hours. Later, cohesive silicone was added to the space previously occupied by the plaster spacer. The leg portion of a metal clip for a hook was embedded under the silicone and fixed in place using methyl methacrylate (MMA) resin (Provinice, Shofu, Kyoto, Japan).

To ensure the test was always performed under the same conditions, the left arm of the test subject (a healthy man) was cleaned and marked to ensure correct placement of the specimens, which were fixed at the same position using a fixing device made of MMA resin (Tray resin II, Shofu, Kyoto, Japan). After each specimen had been softly pressed onto the inside of the subject's arm for 5 seconds, their peak loads were recorded using a universal testing machine at a 20 mm/min crosshead speed (Instron 3342; Universal Material Testing Machine, Norwood, MA) (Fig 2B). The tests were performed a minimum of three times for each specimen, and three specimens were prepared for each group.

Clinical report

Before clinical application, a skin test for hypersensitivity to the cohesive silicone was performed on ten human subjects (mean age: 38.9 ± 14.6 years; range: 20 to 55 years). All subjects were fully aware of the design, objectives, and risks of the study and gave their written informed consent before participating. The authors received approval from the Ethics Committee of Tohoku University Graduate School to perform the study. Patches (10 mm × 10 mm × 10 mm) made of cohesive silicone (CBR 1/60) were prepared using gypsum molds with a

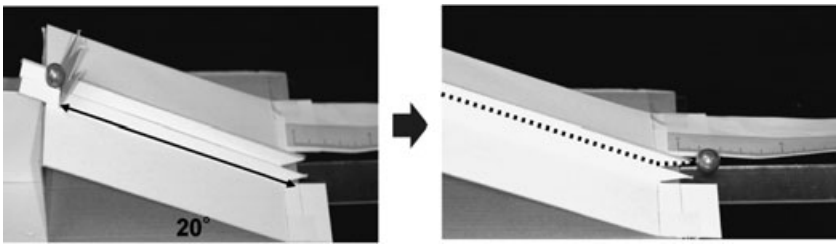

Figure 1 Rolling ball tack test. (Left: start, Right: stop).

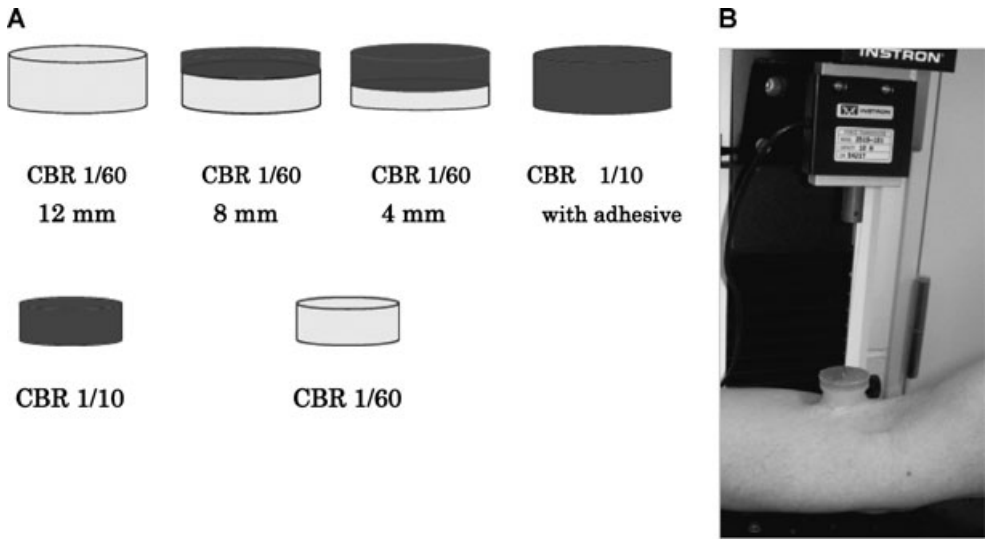

Figure 2 A. Silicone specimens used in the tensile test. The four types of silicone cylinder tested (all were 30 mm in diameter and 12 mm in height): (1) CBR 1/60-12 mm; (2) CBR 1/60-8 mm (CBR 1/10-4 mm); (3) CBR 1/60-4 mm (CBR 1/10-8 mm); (4) CBR 1/10 with adhesive. B. Tensile test.

10 mm × 10 mm × 10 mm cavity and placed on the inside of the left arms of the ten test subjects. Normal silicone (CBR 1/10) combined with a medical adhesive agent (Pros-Aide Adhesive) was used as a control. The results of the skin patch tests of the cohesive silicone and the silicone combined with medical adhesive agent showed no allergic reaction or irritation in the ten human subjects after 48 hours.

After we confirmed the safety of cohesive silicone for clinical application, auricular prostheses, in which the skin side was composed of cohesive silicone and the outer surface was composed of normal silicone, were fabricated by impression taking, wax prosthesis try-in, and processing, according to the same procedures used for the tensile test, and applied to a 50-year-old man. The patient suffered serious burns and had received split thickness skin grafts on nine occasions, resulting in defects on both auricles, scarring throughout the head, face, and neck region, and reduced manual dexterity (Fig 3). He had already worn prostheses held in place by a medical adhesive agent and a wig. He fully understood the design, objectives, and risks of the study and gave his written informed consent before participating in the clinical application. Instructions regarding the insertion, removal, and maintenance of the prostheses were given to the patient.

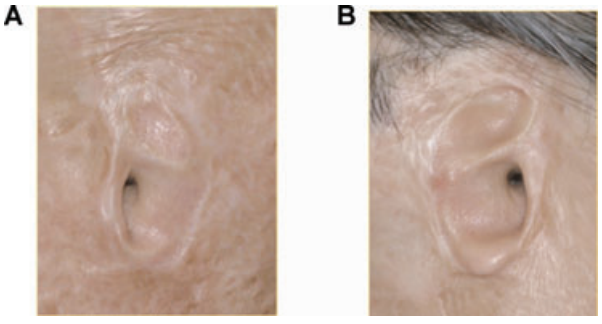

Figure 3 Side views of the patient's ear defects. The auricular lobes are almost completely absent (A: left side, B: right side).

Differences in tensile strength among the three groups were analyzed by the Kruskal Wallis test and Bonferroni's inequality post hoc test.

Results

Rolling ball tack test

The rolling distance decreased as the CBR was reduced (Fig 4). In particular, the specimens with CBR of 1/60 and 1/70 showed markedly decreased rolling distances (13.2 ± 1.7 mm and 7.0 ± 0.7 mm, respectively). Furthermore, there was no significant difference in rolling distance between the specimen with a CBR of 1/70 and that with a CBR of 1/10 combined with medical adhesive agent (control). The rolling distances of the specimens with CBR of 1/10 and 1/30 were over 140 mm.

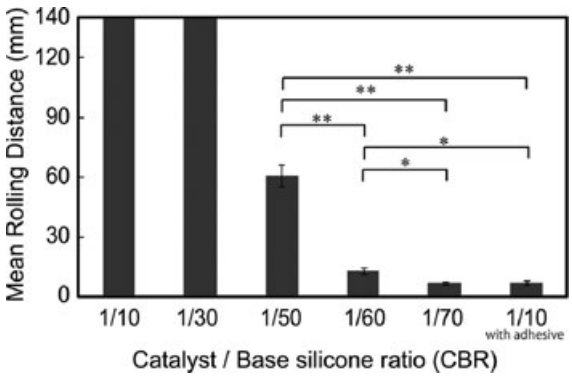

Figure 4 Results of the rolling ball tack test. (n = 3). *indicates a significant statistical difference at $p < 0.05$. ** indicates a significant statistical difference at $p < 0.01$.

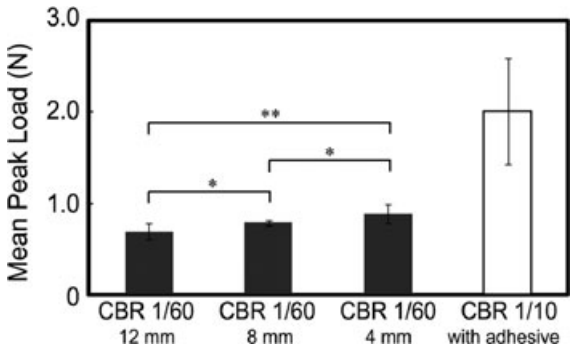

Figure 5 Results of the tensile test. Peak loads for the detachment of the specimens from the arm (n = 3). *indicates a significant statistical difference at $p < 0.05$. ** indicates a significant statistical difference at $p < 0.01$.

Tensile test

Since the cohesive silicone (CBR 1/60) was too soft to be used to produce the whole facial prosthesis, we decided it would be best used as an adhesive lining material within the normal silicone (CBR 1/10). Consequently, the specimens for clinical application were prepared by combining the cohesive and normal silicone, and tensile tests were carried out on human skin. Silicone specimens with layers of cohesive silicone (CBR 1/60) with various thicknesses demonstrated significantly different peak loads. The specimens with thinner cohesive silicone layers showed higher peak loads than those with thicker cohesive silicone layers (Fig 5). The peak loads for the cohesive silicone specimens (12 mm, 8 mm, and 4 mm), were 0.78 ± 0.09 N, 0.93 ± 0.18 N, and 1.09 ± 0.23 N, respectively, approximately half that of the control (2.00 ± 0.58 N). No detachment of the normal silicone from the cohesive silicone occurred during the test.

Clinical report

Based on the results of in vitro studies, we designed the auricular prostheses using a uniform and relatively thin cohesive silicone layer (CBR 1/60), which was able to adhere to human skin without medical adhesives (Figs 3 and 6A). In the first trial, problems were discovered during the first 3 months of observation, including insufficient adhesion, partial detachment of the normal silicone from the cohesive silicone, and difficulties associated with positioning of the prostheses by the patient. To solve these problems, the prostheses were improved by increasing the thickness of the cohesive silicone layer, expanding the adhesive area, and adding vinyl tubes to make positioning easier. The improved prostheses were then offered to the patient during the second trial (Fig 6B). At the follow up 1 year post delivery, improved adhesion, reduced distortion, no marginal breakage, and no detachment of the different types of silicone were observed (Figs 7 and 8). Although the adhesive ability of the prostheses decreased over time due to perspiration, moisture, and contamination, we found that it was possible to recover it by cleaning the prostheses with water and soap and then drying them. The patient appreciated the ease of handling of the prostheses containing cohesive silicone compared with that of those held in place with medical adhesives, based on his previous experience of having difficulty in removing the residual adhesive.

Discussion

This study demonstrated an increase in the instantaneous adhesion of silicone as its CBR decreased, the influence of the thickness of the cohesive silicone (CBR 1/60) layer on tensile adhesive strength, and the absence of allergic reactions to cohesive silicone in a patch test. During their clinical application, auricular prostheses containing cohesive silicone showed sufficient adhesion at the follow-up 1 year post delivery, suggesting the potential use of cohesive silicone as a glueless retentive material for facial prostheses.

Silicone elastomers are the most commonly used materials for maxillofacial prostheses due to their physical properties, ability to accept intrinsic and extrinsic coloring, and similarity to the texture and elasticity of skin. A platinum silicone elastomer was used in the present study. In this elastomer, the crosslinking process is promoted by the platinum-catalyzed hydrosilation of the silicone, dramatically changing the physical properties of the polymer, such as its viscosity and

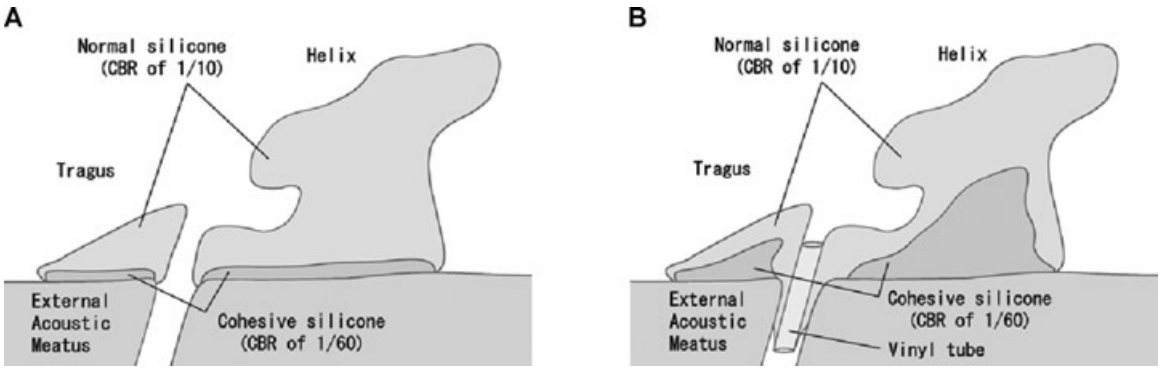

Figure 6 Longitudinal sectional scheme of the auricular prostheses. **(**A) In the first trial, a relatively thin and uniform cohesive silicone layer was employed. (B) In the second trial, the thickness of the cohesive silicone layer was increased, and a vinyl tube was added as a guide rod.

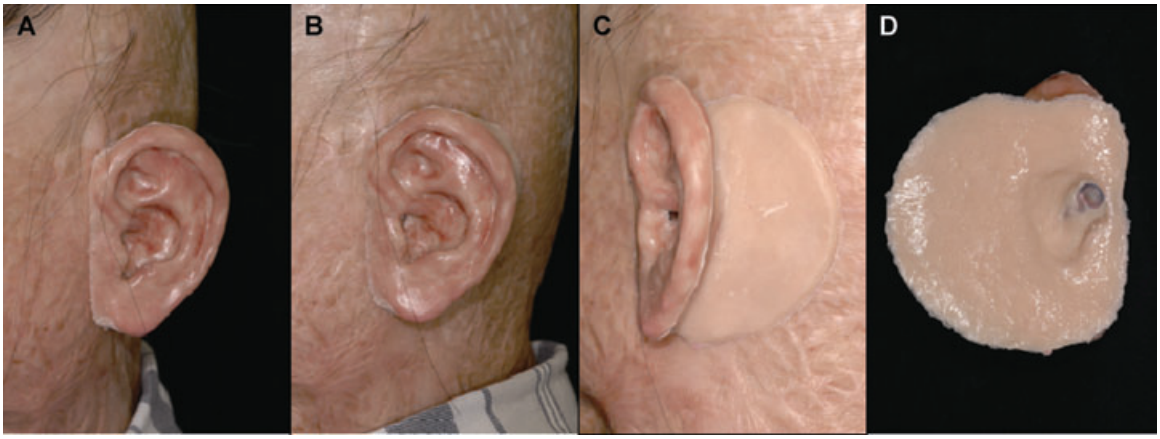

Figure 7 Left side view: placement of the auricular prosthesis (A to C) and skin-side view (D).

adhesiveness.[21] Although this study did not examine the mechanism by which adhesiveness was induced, it was assumed that having smaller amounts of catalyst in the cohesive silicone led to a lower crosslink density in the silicone elastomer, resulting in an increase in its softness and adhesiveness. The use of silicones with lower functional group content may also increase their adhesion.

Pressure-sensitive adhesive materials are defined as materials that are viscous at room temperature and become attached to an adherend on light pressure. One advantage of this type of material is that it does not remain on the adherend and exhibits no cohesion failure during removal. Other practical advantages of pressure-sensitive adhesive materials include permanent adhesion, the ability to tack (instantaneously adhere), and reliable retention. In this study, we refer to silicone with pressure-sensitive adhesive characteristics as "cohesive silicone" and evaluated its instantaneous adhesion using the rolling ball tack test and tensile tests.

According to the results of the rolling ball tack test, silicone with a CBR of 1/70 demonstrated the greatest instantaneous adhesion; however, because of difficulties associated with its molding and handling, silicone with a CBR of 1/60 was selected for clinical application. The rolling distance for silicone with a CBR of 1/60 (13.2 ± 1.7 mm) was shorter than that for medical-use plaster (Transpore; 3M ESPE, St. Paul, MN) (47.5 ± 12.0 mm) in our preliminary experiment, implying its potential for practical use.

This is the first report to examine the clinical application of pressure-sensitive adhesive silicone as a material for facial reconstruction. In the first clinical trial, 3-month observation revealed insufficient adhesion and partial detachment of the cohesive silicone from the normal silicone of the prostheses. The possible causes were an inadequate adhesive area and mobility of the skin during mandibular movement. In the second trial, the prostheses were improved based on these findings, and their adhesive properties were maintained without breakage or detachment for 1 year post delivery. These results indicated that (1) increasing the adhesive area of the prostheses increased its adhesion, and (2) altering the thickness of the cohesive silicone layer as a means of increasing the flexibility (mobility) of the application site appeared to promote adhesion and prevent detachment of the cohesive and normal silicone. In addition, reducing the weight of the silicone may be an effective way of maintaining the adhesion of cohesive silicone.

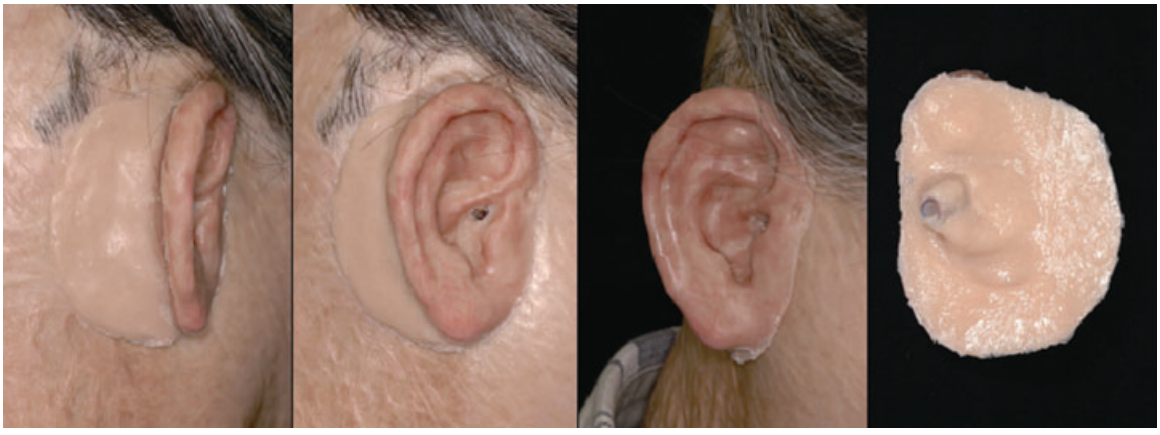

Figure 8 Right side view: placement of the auricular prosthesis (A to C) and skin-side view (D).

The retention and durability of prostheses are extremely important factors for patient satisfaction and rehabilitation success.[6] Moreover, surface porosity and the use of adhesives often cause fungal and bacterial colonization. Therefore, further studies are needed to address the following issues: (1) the surface structure of prostheses; (2) deterioration, fatigue, and retention during long-term use; (3) application to other regions of the face, to a larger number of patients, and to patients who have allergies to medical adhesives; and (4) elucidation of the adhesive mechanism of the material.

The treatment of facial defects is determined by various factors, including the systemic status of the patient, whether the patient has a history of radiation therapy, the size and site of the defect, and the cost of rehabilitation.[14] Despite the limitations of the present study, short-term observation of one clinical application and in vitro experiments demonstrated that cohesive silicone (CBR 1/60) showed (1) sufficient retention for practical use without causing allergic reactions, (2) no marginal breakage of the prostheses, and (3) easier handling compared to prostheses requiring adhesives. The beneficial characteristics of cohesive silicone, such as its ability to adhere to human skin without bonding agents and ease of handling, are favorable for patients who are allergic to adhesive agents and have decreased manual dexterity, respectively. Moreover, cohesive silicone has the potential to be applied to prostheses for other parts of the body, such as the breasts. These results make cohesive silicone an attractive candidate for use as a glueless retentive prosthesis material. Future studies would be useful to investigate the bond strength of this material using the peel test to examine its utility for clinical application.

Conclusions

In the present study, we produced silicone with increased adhesive properties by decreasing its catalyst/base silicone ratio and demonstrated that it has the potential to be used as a glueless retentive material for facial prostheses. These results make cohesive silicone an attractive candidate for further investigation as a glueless retentive material for maxillofacial prostheses.

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