Adhesion of Maxillofacial Silicone Elastomer to a Fiber-Reinforced Composite Resin Framework

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Purpose: Recently, fiber-reinforced composite resin (FRC) has been introduced as a framework material for maxillofacial silicone prostheses. The purpose of this research was to study the tensile bond strength between a room temperature–polymerized maxillofacial silicone elastomer and a unidirectional FRC. ***Materials and Methods:*** Three different bonding agents were compared. Specimens were loaded in tension mode according to ISO 22401 in a universal testing device with a crosshead speed of 10 mm/min until bonding failure occurred. The influence of the surface characteristics (ground vs intact) was also studied. ***Results:*** The highest tensile bond strength was seen with Gold Platinum Primer A-330-G, followed by Sofreliner primer. One-way analysis of variance revealed that the surface treatment of the FRC and the adhesive used had a significant effect on tensile bond strength between silicone and FRC ($P < .05$). Grinding enhanced adhesion, especially with Gold Platinum Primer A-330-G and Sofreliner primer. The fracture type also changed to more cohesive in nature. ***Conclusion:*** The FRC substructure can successfully be bonded to maxillofacial silicone elastomer by using primer containing methyl ethyl ketone and dichloromethane solvent. Bonding can be improved by roughening the FRC substrate via grinding. *Int J Prosthodont 2011;24:582–588.*

Silicone elastomers (polyvinyl siloxanes) are widely used for constructing facial and body prostheses and for soft relining of acrylic resin dentures. Facial epithesis prostheses are required for restoring craniofacial defects resulting from congenital or developmental abnormalities, trauma, or disfigurement because of maxillofacial surgery to remove tumors in the oral or nasal cavity. Facial prostheses may be made of silicone, acrylic resin, or a combination of both.[1–4] Large silicone facial prostheses are usually retained by implants with clip retention on a bar construction or with retentive magnets on the implants and prostheses.[5] These prostheses require a stiff clip carrier, usually made of acrylic resin. Rigid acrylic resin bases may cause patient discomfort; the margins of the prosthesis lack movement in facial expressions, and a large facial prosthesis can be rather heavy.

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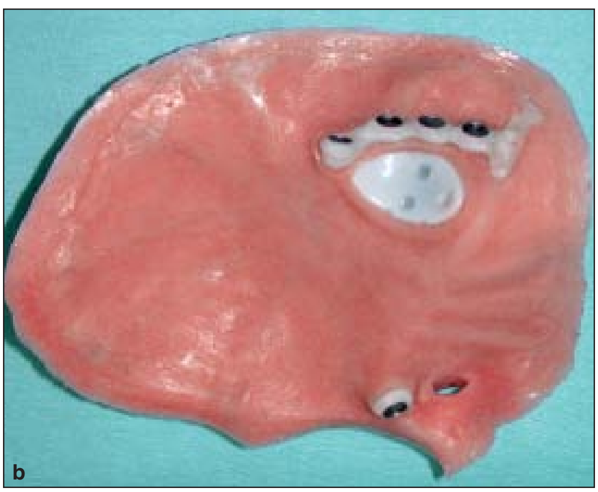
Glass fiber-reinforced composite resin (FRC) shaped as a framework substructure embedded into silicone elastomer has been used to overcome the disadvantages associated with traditionally fabricated silicone–acrylic resin facial prostheses (Fig 1).[6] FRCs have been used as reinforcement in different dental devices, such as removable dentures, fixed partial dentures, periodontal splints, orthodontic retainers, and endodontic posts[7,8] in reconstructive surgery,[9,10] and they also have recently been studied as an oral implant material as well.[11] Using an FRC framework to support the silicone material of a facial epithesis prosthesis requires adequate bonding of the silicone to the framework.

Resilient acrylic resin lining materials have been found to create stronger bonds to the acrylic resin denture base compared to silicone-based resilient lining materials. The low bond strength of acrylic resin to the denture base is explained by differences in the basic chemical structure between the silicone liners and the polymethyl methacrylate (PMMA)–based denture base polymer. There are many laboratory studies conducted on the bond strength of resilient lining materials to denture base materials, usually PMMA.[12–20] In one study, bond strengths between one addition facial silicone, one condensation-type facial silicone, and different acrylic resin denture base polymers were evaluated. The condensation-type silicone showed higher bond strengths with the denture base polymer.[21]

Fig 1a Application of silicone on the FRC framework.

Fig 1b Silicone facial prosthesis with FRC framework, magnets, and ocular prosthesis.

Fig 1c Completed facial prosthesis.



Mechanical surface treatment by airborne-particle abrasion or by grinding has been tested to improve the bonding of silicone to the acrylic resin or polyurethane substrate.[22–25] In one study, the shear bond strength between a resilient lining material was investigated. The resilient lining material showed stronger bonding to the FRC than to the PMMA surface.[26]

According to laboratory studies of bond strengths between maxillofacial silicone elastomers using different primers and acrylic resin, the bond strengths were suggested to be strong enough for clinical use, but the authors also concluded that further improvements in bonding ability are desirable.[17,27,28] Frangou et al[29] concluded that the most critical parameter of a bond-promoting primer is the compatibility and affinity of its composition with the selected silicone elastomer. On the other hand, the primer needs to have compatibility to bond to the acrylic resin substrate as well.

The purpose of this study was to evaluate the bond strength of three different primers to a room temperature–polymerized addition-curing facial prosthesis silicone and a continuous unidirectional glass FRC with a semi-interpenetrating polymer network polymer matrix.

Materials and Methods

The materials used in the study are listed in Table 1. The baseplates for substrates ($12 \times 12 \times 3$ mm^3) were composed of PMMA resin (Palapress, Heraeus Kulzer). The baseplates were made in silicone molds (Lab-Putty, Colténe/Whaledent) and heat cured at 60ºC for 15 minutes at 600 kPa (Ivomat Typ IPZ, Ivoclar).

The bonding surfaces of the PMMA baseplates were roughened by grinding (320-grit FEPA SiC paper, Struers), and unidirectional, resin-impregnated E-glass fiber rovings (everStick, Stick Tech) were attached with monomer resin (Stick Resin, Stick Tech) to cover the entire PMMA surface. The resin system of the fiber rovings was polymerized using a light-curing device (Kerr Demi, Kerr) for 40 seconds.

Table 1 Materials Used in the Study

Brand name	Composition	Manufacturer
Palapress	PMMA	Heraeus Kulzer
Stick Resin	Light-cured adhesive of bis-GMA and TEGDMA	Stick Tech
everStick C & B	Continuous unidirectional silanized E-glass fibers embedded in a resin matrix of bis-GMA-TEGMA and PMMA	Stick Tech
SILASTIC MDX 4-4210	Room temperature–vulcanized addition cure silicone; elastomer component: dimethylsiloxane polymer, reinforcing silica, and platinum catalyst curing agent: dimethylsiloxane polymer, inhibitor, and siloxane cross-linker	Dow Corning
Sofreliner Primer	99.5% methylene chloride, 0.5% PMMA polyorganosiloxane	Tokuyama Dental
Gold Platinum Primer A-330-G	Modified polyacrylates in methyl ethyl ketone and dichloromethane	Factor II
VMS Primer	2% vinyltrimethoxysilane, ethylacetate-based	Fluka Chemie

PMMA = polymethyl methacrylate; bis-GMA = bisphenol glycidyl methacrylate; TEGDMA = triethylene glycol dimethacrylate.

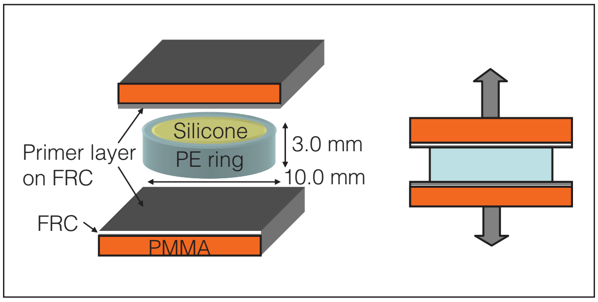


Fig 2 Schematic test setup. PE = polyethylene.

The bonding surfaces of half of the baseplates with FRC were ground (1,000-grit FEPA Waterproof SiC paper, Struers) to expose the glass fibers of the FRC. The other half of the baseplates was left as such (intact surface), ie, the FRC surface was covered with a thin layer of polymer bisphenol glycidyl methacrylate–triethylene glycol dimethacrylate–PMMA (bis-GMA–TEGDMA–PMMA). The surfaces of the baseplates were treated with primer according to the manufacturers' instructions as follows:

- Group 1: intact surface, A-330-G primer (Factor II), n = 10
- Group 2: intact surface, Sofreliner primer (Tokuyama Dental), n = 10
- Group 3: intact surface, VMS primer (Fluka Chemie), n = 10
- Group 4: ground surface, A-330-G primer, n = 10
- Group 5: ground surface, Sofreliner primer, n = 10
- Group 6: ground surface, VMS primer, n = 10

Maxillofacial silicone elastomer (MDX4-4210, Dow Corning) was weighed using a microbalance and mixed in a ratio of 10:1 in a mechanical speedmixer (Speedmixer model type DAC 150FV2-K, FlackTek). Silicone elastomer was applied into a polyethylene ring with a diameter of 10 mm (3-mm thick) onto each FRC substrate, and another FRC substrate plate was placed on top of the silicone-filled polyethylene ring (Fig 2). The silicone was post cured at 90°C for 2 hours.

The tensile bond strength between silicone resin and FRC was tested after a minimum of 24 hours, according to ISO 22401, using a universal material testing device (LRX, Lloyd Instruments) at a cross-head speed of 10 mm/min until bonding failure occurred. Fracture surfaces were visually categorized as adhesive, mixed, or cohesive. In the case of a cohesive failure equal to 50% of the surface, the failure was regarded as cohesive. Bond strengths were analyzed statistically using one-way analysis of variance and the Tukey post hoc test.

Results

The tensile bond strengths between FRC and the maxillofacial silicone elastomer are shown in Fig 3. With the intact FRC surface, A-330-G primer gave the highest bond strength (0.76 ± 0.26 MPa), Sofreliner primer presented the next highest bond strength (0.50 ± 0.11 MPa), and VMS primer gave the lowest bond strength (0.36 ± 0.16 MPa). The tensile bond strengths between the ground FRC surface and maxillofacial silicone elastomer showed significantly

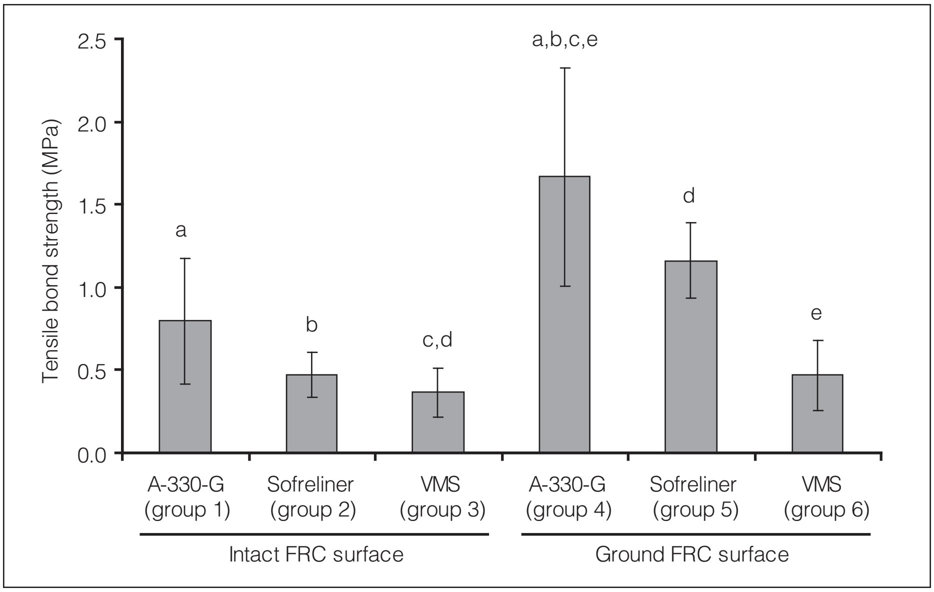


Fig 3 Tensile bond strength with the different primers according to surface structure. Groups with the same letters were significantly different from one another ($P < .001$).

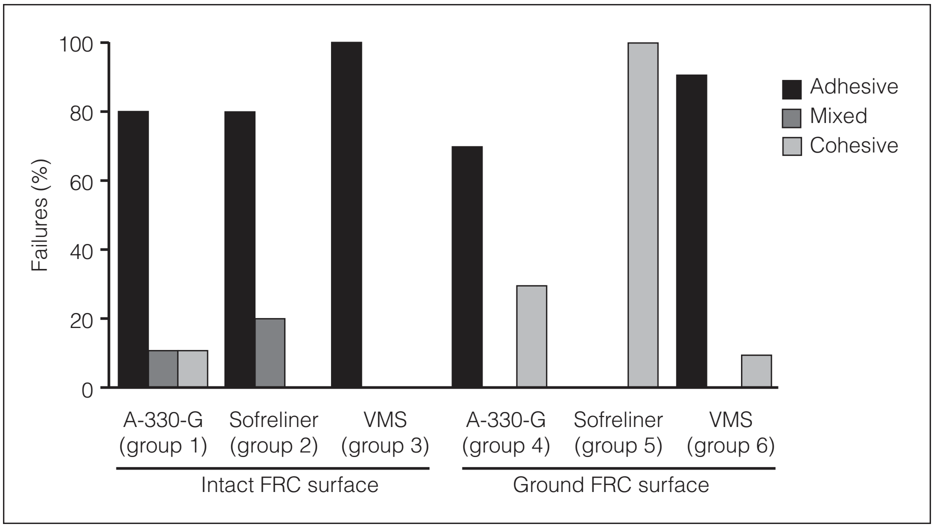


Fig 4 Fracture type at interface between silicone and primer according to primer and surface structure.

higher values with all primers. Grinding enhanced adhesion, especially with A-330-G and Sofreliner primers. With the ground FRC surface, A-330-G presented the highest bond strength (1.7 ± 0.70 MPa), followed by Sofreliner primer (1.16 ± 0.24 MPa). VMS primer showed the lowest bond strength (0.47 ± 0.21 MPa). When comparing the tensile bond strength between intact FRC surfaces and silicone elastomer to that of the ground FRC surfaces, the bond strengths were more than doubled with A-330-G and Sofreliner primers. Statistically significant differences between the groups according to the Tukey post hoc test ($P < .001$) are shown in Fig 3.

The results according to bonding failure type classified as adhesive, mixed, or cohesive are shown in Fig 4. With the intact FRC surface and using VMS primer, all (100%) of the bond failures between the silicone and FRC were adhesive. With Sofreliner primer, 80% of the bonding failures were adhesive, with the remaining 20% being cohesive. A-330-G primer showed 80% adhesive bonding failures, 10% mixed failures (ie, adhesive and cohesive failures on the same substrate), and 10% cohesive failures. Grinding the FRC surface led to more cohesive bonding failures. With the ground FRC surface, Sofreliner primer presented 100% cohesive failures, while A-330-G primer showed 30% cohesive failures, and VMS showed only 10% cohesive failures. All specimens remained intact at the FRC-PMMA interface. Analysis of variance revealed that the surface treatment of the FRC and the adhesive had a significant effect on the tensile bond strength between the FRC and silicone elastomer ($P < .05$).

Discussion

This study aimed to demonstrate the bonding properties of glass FRC to maxillofacial silicone elastomer. Most of the studies concerning bond strength between silicone elastomers and acrylic resin denture base polymers are performed using dental soft liners and denture base polymers. In general, the viscosity of the resilient dental liner is higher than that of maxillofacial silicone. The bond strength of maxillofacial silicones to a base material of the prosthesis has been tested using different types of bond tests, such as those testing peel bond strength, shear bond strength, and tensile bond strength. The wide variety of testing methods used in different studies makes direct comparison between the results difficult. Although maxillofacial prostheses are affected by various types of stresses and directions of stress forces, tensile bond strength was selected for this study. This selection was done to ensure even stress distribution at the adhesive interfaces, compared with the shear bond strength test. The existing reference data in the field of research at the research laboratory also justified the use of the tensile test.

The standardized test setup for tensile bond strength, according to ISO 22401, was used. It was found that the intact surface, ie, the substrate surface with a thin layer of polymer membrane, resulted in considerably lower bond strengths than those with the ground substrate surface. Grinding the FRC surface with 320-grit grinding paper caused a rough bonding site, providing good micromechanical retention for the silicone. In another study concerning the effect of surface treatment on bonding strength, airborne-particle abrasion treatment of an acrylic resin surface improved the adhesion between the maxillofacial silicone elastomer and acrylic resin.[23]

In the present study, grinding also exposed the glass surface of the glass fibers, which could have been used as a bonding surface, especially with silane coupling agents (group 6, VMS primer). In principle, silane primer reacts with the hydroxyl groups of the glass surface and forms a siloxane network for the elastomer silicone to be adhered. However, for unknown reasons, the results did not clearly show that this would have influenced the bond strengths. Silane, like other primers used in this study, improves surface wettability.[30] Therefore, penetration of silicone elastomer to the microscopic irregularities could have been more effective by using primers, and thus, the bond strengths should have been higher.

When the primers used in this study are compared, A-330-G provided the highest tensile bond strengths regardless of surface grinding. The polymer matrix of the presently used FRC was a combination of cross-linked thermoset and non–cross-linked thermoplastic polymers in the form of a semi-interpenetrating polymer network (semi-IPN).[31] The solvents of the A-330-G primer are methyl ethyl ketone and dichloromethane, which are known to be potentially good solvents to the PMMA phase of the semi-IPN polymer matrix.[32] The good bonding results were therefore most likely a result of the dissolution of the polymer matrix by the solvents of the A-330-G primer. This is in agreement with the results of Hatamleh and Watts,[27] who tested three different primers on shear and peel bond strengths between three new maxillofacial silicone elastomers and acrylic resin. They concluded that the silicone elastomers and primers used in the study gave serviceable bond strengths, and the optimum silicone/primer combination was Cosmesil Z004 (Principality Medical) with primer A-330-G.[27] Results showing that the bond strength between the silicone elastomer and acrylic resin is affected by type of silicone and primer were also shown in a study undertaken at Mahidol University, where the bond strength between maxillofacial silicones and autopolymerizing acrylic resin was studied using five different primers. Of the five primers tested, the highest bond strength to bond MDX4-4210 silicone to autopolymerizing acrylic resin was found with Epicon primer (Dreve Denfamid), followed by A-330-G.[33]

The solvent of VMS primer is ethylacetate, which has been previously tested to improve adhesion between silicones and acrylic resins. McCabe et al[19] concluded that a primer based on ethylacetate performed better than one based on toluene as the solvent. However, they did not compare the efficiency of these solvents to methyl ethyl ketone and dichloromethane. In the current study, VMS primer showed the lowest bond strengths between silicone and PMMA, suggesting that ethylacetate does not properly dissolve the surface of the polymer matrix of the FRC. Improving the dissolving ability of the polymers by solvents is based on increasing the temperature of the solvent and prolonging the contact time of the solvent to the polymer surface,[34,35] provided that the dissolving parameter of the primer or solvent of the primer matches that of PMMA.

The effect of these parameters with primer solvents requires further investigation. To the authors' knowledge, other studies using the standardized testing procedure concerning tensile bond strength between facial silicone and FRC have not been performed. However, Hatamleh and Watts[36] studied the pull-out strength of unidirectional glass fiber rovings embedded to maxillofacial silicone elastomer (Cosmesil). They concluded that resin-impregnated glass fiber rovings exhibited a strong bond to the silicone and that moderate interfacial porosity had no significant effect on the bond strength between silicone elastomer and the glass fiber bundles. In a recent study, the same authors compared mixing techniques for maxillofacial silicone. In that study, mechanical mixing resulted in reduced pore numbers and percentages compared to manual mixing.[37]

The tendency of more frequent cohesive bond failures between the FRC and silicone elastomer was seen with the ground FRC surface. This shows that the tensile bond strength between the silicone elastomer and the FRC was stronger than that of the maxillofacial silicone itself. A sufficient bond strength between the silicone elastomer and the FRC framework is vital to withstand the forces needed to remove the prosthesis from the suprastructure, especially for an implant-retained facial prosthesis.[12,13] Failure of the bond leading to local separation of the acrylic resin sleeve from the silicone is a frequent problem.[38] According to Hatamleh and Watts,[28] a tensile bond strength of 0.44 MPa is enough for bonding soft silicone liners to acrylic resin in intraoral prostheses relined with a soft reliner. In the current study, tensile bond strength between maxillofacial silicone and FRC for intact/ground surfaces was 0.50/1.16 MPa for Sofreliner primer and 0.76/1.67 MPa for A-330-G primer, which should withstand the static stress of an implant-supported facial prosthesis with clip and magnet retention. Obviously, during repeated removal of the prosthesis, the stress is dynamic in nature, and laboratory tests should be carried out using fatigue-type tests.

The materials used for fabrication of facial prostheses have improved to some extent over the years. Material researchers have attempted to develop new polymeric materials with enhanced mechanical properties, such as high tear strength, low hardness, and low viscosity.[39–41] Attempts also have been made to use layers of different types of silicones.[42] Research is ongoing to develop maxillofacial materials reinforced with polyhedral silsesquioxanes.[43] Chlorinated polyethylene elastomer (CPE) has been tested clinically as a low-cost substitute for silicone in maxillofacial prostheses. In a clinical trial by Kiat-amnuay et al,[44] the patients compared a CPE maxillofacial prosthesis to one composed of silicone elastomer. Overall, patients rated the silicone prosthesis higher than the CPE.[44] A survey among the American Anaplastology Association (AAA) and American Academy of Maxillofacial Prosthetics (AAMP) indicated that the majority of AAA and AAMP members were using room temperature–vulcanized silicone products.[45]

The average life span of silicone craniofacial prostheses is relatively short (mean: 1.5 to 2 years). The main reasons for remaking a craniofacial prosthesis include discoloration of the prosthesis (13.3%), attachment problems with the acrylic resin clip carrier to the silicone (25.3%), rupture of the silicone (13.3%), and poor fit (10.9%).[46] Problems concerning loss of bonding between the acrylic resin baseplate, the clips, and the silicone are some of the main reasons for remaking craniofacial prostheses.[47] An FRC framework supports a silicone maxillofacial prosthesis to adapt the margins of the prosthesis to the skin. The framework is lightweight yet still sufficiently stiff for use in the maxillofacial region. One of the most important characteristics of the FRC framework is that it is easy to repair; if the margins of the prosthesis have to be tightened or altered in any way, the FRC material can be cut off and new fiber material can be added in a corrected position to alter or tighten the margins of the prosthesis. Further studies concerning the use of FRC frameworks in facial prostheses are ongoing to clarify certain material-based and clinical aspects related to the use of FRC framework–supported silicone elastomer prostheses.

Conclusions

A glass FRC substructure can be successfully bonded to maxillofacial silicone elastomer using primer containing methyl ethyl ketone and dichloromethane solvent. Bonding can be improved by roughening the FRC substrate via grinding.

Acknowledgments

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