Application of addition-cured silicone denture relining materials to adjust mouthguards

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The purposes of this study were to examine the shock absorption capability of addition-cured silicone denture relining materials and the bonding strength of addition-cured silicone denture relining materials and a commercial mouthguard material to determine its applicability to mouthguard adjustment. Two addition-cured silicone denture relining materials and eleven commercial mouthguard materials were selected as test materials. The impact test was applied by a free-falling steel ball. On the other hand, bonding strength was determined by a delamination test. After prepared surface treatments using acrylic resin on MG sheet surface, 2 types of addition-cured silicone denture relining materials were glued to MG surface. The peak intensity, the time to peak intensity from the onset of the transmitted force and bonding strength were statistically analyzed using ANOVA and Tukey’s honest significant difference post hoc test (p<0.05). These results suggest that the silicone denture relining materials could be clinically applicable as a mouthguard adjustment material.

Keywords: Mouthguard, Impact test, Silicone, Delamination test

INTRODUCTION

Mouthguards have recently received considerable attention because they reduce the incidence and severity of sport-related oral injuries to the teeth, alveolar bone, soft tissue and temporomandibular joints¹–⁶. In particular, mouthguards have significantly contributed to the prevention of such oral injuries in contact sports. The Federation Dentaire Internationale issued the policy statements that national dental associations promote to the public and to oral health care professionals the benefits of sports mouthguards, including the prevention of orofacial injuries⁷.

Mouthguard materials should have the ability to absorb and disperse impact energy to avoid concentrating force around an impact point, and should be durable throughout the season⁶,⁷. Most mouthguards currently comprise ethylene-vinyl acetate copolymer (EVA). Thermoplastic elastomers including EVA generally include a molecular component that crosslinks with rubber to prevent the plastic from becoming deformed and a flexible component that provides rubber-like elasticity. High shock absorption capacity and durability depend on these properties. The safety of using EVA in the oral cavity has been established and the Food and Drug Administration has approved EVA for such use⁸.

Durability has been investigated in vitro, but not in vivo. Thus, although the mechanisms of changes in mouthguard fit have not been evaluated, the accuracy of fitted mouthguards decreases with repeated usage over time clinically.

Mouthguards require modification or adjustment every time dentition, a dental device, or occlusal status changes, particularly among school-age children, those who require orthodontic treatment, or those presenting with trauma. Mouthguards become deformed over time due to repeated insertion into and removal from the mouth and by repeated bite and impact forces that decrease fit accuracy and lower retention⁹. Mouthguards can also become perforated or damaged, requiring adjustment, relining or replacement in many clinical situations. Moreover, the athletes who request repairing at the chairside have recently been increasing because of competition schedule and economic burden. However, re-fabrication is necessary for mouthguards in many cases because it is difficult to repair mouthguards at the chairside. Yagi et al. reported that softening mouthguards in hot water and then pressing them against the dentition improves fit and retention¹⁰. However, the results have been less than satisfactory because of unsuitable margins and insufficiently thick materials. When heating is used to improve fit accuracy and retention, deformation of the mouthguard material is a concern. Relining materials are currently used to

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adjust fit accuracy of dentures. We thus considered using a common silicone material in dentistry in order to improve the fitness and retention of mouthguards without heat. A previous study found that the impact absorption capacity of some silicone compounds is as high as that of conventional mouthguard materials.

We therefore used addition-cured silicone lining materials in this study, and compared their shock absorption properties with those of conventional thermoforming mouthguard materials in order to determine their applicability to mouthguard adjustment.

However, dental silicone and EVA are generally hard-to-bond materials because surface polarity is low. A fundamental study previously attempted to bond dental silicone to EVA. The results suggested insufficient bond strength for clinical application. It was necessary to develop a bonding method to apply dental silicone as a mouthguard adjustment material. In addition, we attempted to bind dental silicone to EVA using available materials in the oral cavity. An adhesion system for acrylic resin and dental silicone has already been established. Moreover, bonding strength has been evaluated as having sufficient durability for clinical application, and the adhesion system has been used clinically. Recently, it was reported that some adhesives were designed to react with the molecular networks in polyvinyl siloxane and to chemically bond with both the elastomeric impression (or relining) materials and the acrylic resin, which consist of methyl acetate as the solvent and an adhesive conjoined monomer. Ona et al. reported that the bond strength of dental silicone and acrylic resin was sufficient. Although we used acrylic resin as a relining material without heat in dentistry, acrylic resin denture relining materials have a tendency to lose cushioning effects over time. Thus, acrylic resin denture relining materials may be unsuitable for long-term use because acrylic resin denture relining materials deteriorate due to elution of ethanol and plasticizers into oral saliva. Addition-cured silicone denture relining materials have heat resistance, water resistance and chemical resistance. Iwaki et al. reported that ST has high flexibility. The period of use (recommended by manufacturers) for addition-cured silicone denture relining material conforms to the refabricating period for mouthguard. Therefore, we devised a concept for applying acrylic resin to the binding of dental silicone to EVA. We considered the following two methods as a means of embedding acrylic resin to the surface of EVA: (i) heat-pressing acrylic resin polymer like retention anchor by utilizing thermoplastic property of EVA and (ii) polymerization of acrylic resin on the surface of EVA just after mixing polymer and monomer.

In the present study, we also evaluated the effects of embedding acrylic resin on bond strength between EVA mouthguard materials and dental silicone.

### MATERIALS AND METHODS

**Free-falling ball impact test**

1. **Materials**

Table 1 shows the commercial names, main components, manufacturers and lot numbers of the tested materials. Two addition-cured silicone denture relining materials were selected as test materials; Evatouch® Super (ES; Neo Dental Chemical Products, Tokyo, Japan) and

| Group                        | Products          | Abbreviation | Main composition                  | Batch number | Manufacturer                          |
|------------------------------|-------------------|--------------|-----------------------------------|--------------|---------------------------------------|
| Mouthguard sheet             | Erkoflex®         | ERK          | ethylene-vinyl acetate copolymer   | 10952        | ERKODENT, Pfalzgrafenweiler, Germany   |
| Auto-polymerization          | Evatouch® Super   | ES           | addition-cured silicone            | A4L1         | NEO DENTAL CHEMICAL PRODUCTS, Japan    |
| addition silicone            | SOFRELINER TOUGH | ST           | addition-cured silicone            | 1240Z4P      | Tokuyama Dental, Japan                 |
| resilient denture            |                   |              | silane coupling agent              | A2F1         | NEO DENTAL CHEMICAL PRODUCTS, Japan    |
| relining material            | SOFRELINER TOUGH Primer |            | adhesive monomer                  | 095043P      | Tokuyama Dental                        |
| Primer                       |                   |              |                                   |              |                                       |
| Acrylic resin polymer        | UNIFAST III       |              | poly methyl methacrylate          | 1410211      | GC, Japan                             |
| (powder)                     |                   |              |                                   |              |                                       |
| Acrylic resin monomer        | UNIFAST III       |              | methyl methacrylate               | 1410091      | GC                                     |
Sofreliner Tough M (ST; Tokuyama Dental, Tokyo, Japan).

2. Methods
Free-falling ball impact test in the present study was conducted as reported previously20 in order to allow comparisons with data with that study.

Specimens were disks of 2 mm thickness and a diameter of 50 mm, and were shaped using a stainless steel mold. All specimens were stored dry for 24 h at 23°C before testing.

The impact testing system consisted of a free-falling stainless steel ball (weight, 32.6 g; diameter, 20.0 mm), a 10-mm thick steel platform, and a base plate. Impact force was generated by releasing the ball from 600 mm above each specimen using a modified IM-201 impact testing machine (Tester Sangyo, Saitama, Japan) and the amount of impact force was measured using a load cell sensor system (Fig. 1). Three dynamic LMA-A-1KN-P compression load cells with a rated capacity of 1 kN (Kyowa Electronic Instruments, Tokyo, Japan) were located 120° apart on the base plate of the impact tester, and a steel platform was placed upon the load cells. Changes in force during the impact test were recorded on a personal computer through an EDX-100A amplifier (Kyowa Electronic Instruments) and the sum of the measured forces generated by the three load cells was recorded. The intensity of the first peak of the sum of the measured forces was taken as the maximum impact force (MIF) and the time taken to reach the MIF (MIF-t) was calculated based on the amount of transmitted force. Five specimens of each material were measured at room temperature.

The MIF without materials was 660.5±30.6 N, and the MIF-t without materials was 0.39±0.05 ms20).

Delamination test

1. Materials
Table 1 shows the commercial names, main components, manufacturers and lot numbers of the tested materials.

Two types of addition-cured silicone denture relining material (ES and ST) and a mouthguard sheet material including EVA as the main component were used in delamination testing. Primers attached to each silicone material were used. The commercial thermoforming mouthguard sheet material was Erkoflex® (ERK; Erkodent, Pfalzgrafenweiler, Germany). UNIFAST III (Shade Clear, GC, Tokyo, Japan) was selected as the auto-polymerized acrylic resin.

2. Methods
The method for delamination testing in the present study was based on a previously reported method13,21). Forty-eight specimens of each silicone material (ES and ST) were prepared and assigned to eight groups based on the following four treatments. Acrylic resin was placed on mouthguard sheets to create an adhesive area so that the center of the sheet had a width of 15 mm.

The flow chart of surface treatments was showed in Fig. 2.

Control: ERK was sprinkled onto acrylic resin polymer without heat treatment.

Treatment E: ERK was hot-pressed with sprinkling acrylic resin polymer on the surface of the ERK adhesive area at 130°C for 85, 300 and 600 s in order to embed the acrylic resin polymer.

Treatment A: Immediately after mixing acrylic resin polymer (powder) with monomer (liquid), acrylic resin was applied to the surface of ERK (Fig. 3).

Treatment EA: After treatment E, treatment A was carried out.

After each treatment, the adhesive areas of ERK were cleaned with ethanol, and each primer was attached to each silicone material.

Each silicone material was auto-mixed in a syringe and injected onto the surface of ERK. Then, injected silicone materials were pressed using a stainless-steel board with stainless-steel spacer (thickness, 2 mm). All specimens were stored dry for 24 h at 23°C. The laminated sheet was cut with a dumbbell-shaped cutter according to JIS K6251:2004 such that the adhesive area was at the center of the isthmus, and sectioned at the center of the isthmus. The final specimens for delamination, with an adhesive area of 4.0×7.5 mm, are shown in Fig. 4.

The size of the specimen was measured using a digital micrometer (Digimatic 293-421-20, Minimum reading: 0.001 mm; Mitutoyo, Kanagawa, Japan) before delamination test.
The T-peel test was used for delamination testing. The specimen was fixed to a universal test machine (1123, Instron, Canton, MI, USA) with a special jig to provide a firm grip. Delamination test was carried out with the universal test machine at a cross-head speed of 50 mm/min (Fig. 5). Changes in load before specimen fracture or break were recorded using material testing software (Series IX, Instron). Bonding strength was calculated as the maximum load divided by the width of each specimen.

Fracture patterns of the specimens were observed after delamination testing using a digital microscope (PROVIS AX-70, OLYMPUS). In addition, cross section views of specimens after delamination testing were observed using another type of digital microscope (VHX-1000, Keyence).
RESULTS

Free-falling ball impact test

1. Maximum impact force (MIF)

MIF values of the ES and ST specimens (mean±S.D.) were 410.9±8.6 and 334.1±9.3 N, respectively.

2. MIF arrival time (MIF-t)

Figure 6 shows the time-transmitted force curves for two materials. The amount of applied impact was the same for two sheets, but the load initially increased and decreased over time. The MIF-t of the ES and ST specimens (mean±S.D.) were 0.64±0.02 and 0.60±0.04 ms, respectively.

Delamination test

Table 2 and Fig. 7 show the results for bonding strength in delamination tests.

On two-way ANOVA, the interaction between two factors in ES and ST were confirmed (p<0.001). Hence, simple effects were statistically analyzed in post-hoc tests. Bonding strength in the treatment E group and the treatment EA group was significantly higher than that in the control group, regardless of heating time. Bonding strength in the treatment EA group was significantly higher than that in the treatment E group, regardless of heating time.

Figure 8 shows the surfaces of specimens after the delamination test under a digital microscope. Figures 9 and 10 show a cross-sectional view of specimens after delamination test under a digital microscope. Cohesive fractures in acrylic resin were observed in specimens from the treatment E group, while cohesive fractures of addition-cured silicone denture relining material were...
Fig. 8  Digital microscope images of the surface of treatment E specimens after delamination test. Site of EVA (upper side) and Site of silicone (lower side). Scale bar, 0.25 mm.

Fig. 9  Digital microscope images of the cross-sectional view of treatment E specimens after delamination test. Site of EVA (upper side) and Site of silicone (lower side). Scale bar, 100 μm.
observed in specimens from the treatment EA group. Interfacial fractures were observed in specimens from the treatment A and Control groups.

DISCUSSION

Most mouthguards are manufactured by vacuum forming and/or pressure forming with thermoplastic sheet materials, and mouthguard sheets comprising thermoplastic elastomeric materials such as EVA, polyolefin and polystyrene-polyolefin copolymer are now widely available. Some materials that were used in the lost wax method, such as silicone, are not currently used to make mouthguards because of the complexity of the fabricating process. Dental silicone materials have been used for impression taking, relining and registration of interocclusal relationships, but have not become commercially available as mouthguard materials. Most dental silicone materials comprise addition-cured silicone. The impact absorption capacity of addition-cured silicone denture relining materials is as high as that of conventional mouthguard materials according to the results of previous studies\(^{11}\). Therefore, we focused on addition-cured silicone denture relining materials for adjustment of mouthguards.

**Free-falling ball impact test**

The main purpose of wearing a mouthguard is to prevent injury, including those due to participating in sports. Mouthguard materials must therefore efficiently absorb, attenuate and disperse shock. The present study focused on shock absorption. Numerous studies have investigated the impact absorption properties of mouthguard materials, but these results cannot be directly compared because of differences in experimental systems. As Reza\textit{ et al.}\(^{11}\) found that the load cell system detected changes in overall transmitted impact force more effectively than film sensor systems, we selected the load cell system for the present study\(^{22}\). The free-falling ball impact test method used in the present study was adopted from a previous study\(^{20}\) in order to allow comparison of data for various mouthguard materials (EVA-, polyolefin- and polystyrene-polyolefin copolymer-based sheets). In the previous study, the control load in the impact test was 660 N, which is equal to the minimum impact tolerance of the maxilla. When compared with these findings, the conditions under which a stainless steel ball (diameter, 20 mm; weight, 32.6 g) fell above 600 mm were valid\(^{20}\). In general, the control load is established based on the resistance of human bones and teeth to impact, and the level of competition at which the mouthguard will be used. The impact tolerance of the maxilla among human facial bones is extremely weak\(^{23-25}\). Here, we focused on the maxilla and maxillary incisors, because trauma to primary and permanent dentition is common at maxillary incisors, and the maxilla is closest to maxillary incisors among human facial bones.

Yokota\textit{ et al.}\(^{11}\) found that the load absorbance of two commercial mouthguard materials was 38% and that of dental silicone materials was 34–49% when compared with a control group in regard to MIF. In addition, the MIF-t was 1.15–1.18-fold longer (commercial mouthguard sheets) and 1.03–1.32-fold longer (dental silicone materials) than that of the control group. Reza\textit{ et al.}\(^{11}\) reported that the load absorbance of commercial mouthguard sheets was 24–37% of control MIF. We previously reported that the load absorbance of various commercial mouthguard materials was 26–37% when compared to the control group with regard to MIF, and MIF-t of the commercial mouthguard sheets was 1.26- to 1.59-fold longer than that of the control group\(^{20}\). Our findings for MIF showed that the load absorbance of ES and ST were about 38 and 49%, respectively, when compared with the control group. The MIF-ts of ES and ST were about 1.64- and 1.54-fold longer than that of the control. The MIF of ST tended to be lower than those of ES and commercial mouthguard materials as compared with data from previous studies. Our results also revealed that the shock absorption of ES was equal to or greater than those of commercial mouthguard materials,
and that the shock absorption of ST was greater than those of commercial mouthguard materials. Within the limitations of present in vitro study, these results suggest that ES and ST may be clinically applicable as a mouthguard adjustment material.

**Delamination test**

The present results suggested that the bond strengths between ERK and two addition-cured silicone denture relining materials were significantly improved by applying treatment EA to the surface of ERK.

Depending on the direction of force applied to the adhesive interface of the materials, adhesion tests were classified into methods focusing on tensile, shear and peel strength. Moreover, bonding behavior of laminated materials has been evaluated using several test methods, including the T-peel, 180-degree peel, 90-degree peel, and floating roller methods. Here, we conducted the T-peel test, which is one of the most common test methods.

Mouthguards are used in the oral cavity. However, delamination testing was carried out at a temperature of 23°C under atmospheric pressure in order to focus on finding a bonding method. Delamination testing under conditions that mimic conditions similar to those in the oral cavity, and in the presence of artificial saliva, remains a challenge to be overcome in the near future.

Heating temperature was set at 130°C and heating time was set at 0 (=without heat treatment; Control and treatment A), 85, 300 and 600 s. For the thermoforming process, heating temperature and time for ERK recommended by the manufacturer are 130°C and 85 s, respectively. We used three heating times in order to examine the effects of heating time on the bonding strength between ERK and two addition-cured silicone denture relining materials.

The control group, which did not undergo treatment E or treatment A was too weak to be measured. As addition-cured silicone denture relining materials were not bonded to ERK with primer attached to each addition-cured silicone denture relining material, it was confirmed that some treatment of the ERK surface was necessary to improve the bonding strength between ERK and silicone materials.

1. Treatment E group

Bond strength in the treatment E group varied with heating time (p>0.05), but was insufficient. Acrylic resin was observed on the surfaces of both ERK and dental silicone in specimens after treatment E (Fig. 8). Bead-shapes were clearly observed, as polymer beads were incompletely melted in specimens in the treatment E group (Fig. 9). Bond strengths were considered to be insufficient due to fracturing of the acrylic resin layer due to non-polymerization in specimens after treatment E.

2. Treatment A group

Treatment A group was too weak to be measured. Although the acrylic resin layer in specimens in the treatment A group was polymerized, interfacial fractures were observed in the boundary between the acrylic resin layer and the surface of ERK (Fig. 9).

3. Treatment EA group

We attempted to mutually resolve the problems with both surface treatments by combining them (treatment E and treatment A). Bond strength in the treatment EA group with ST was high at 2.40–2.55 kN/m. ST specimens had a higher adhesive strength than ES specimens. Since fracture of silicone materials were observed in both ST and ES, it was presumed that the difference in the tear strength of the silicone materials was affected. Bonding strength in the treatment EA group was significantly higher than those in the treatment E group with ES and ST, regardless of heating time. Polymerized acrylic resin was clearly observed in specimens from the treatment A and treatment EA groups (Figs. 9 and 10). Fracture of addition-cured silicone denture relining materials was observed in specimens from the treatment EA group (Fig. 10). This suggests that the improvement in acrylic resin layer strength due to treatment A contributed to this observation, as compared with the results for treatment E.

Among previous studies, Yokota reported bond strengths of 0.51 kN/m when combining prototype adhesive and sandblasting. Ona et al. reported that bond strength between acrylic resin and dental silicone impression material ranged from 0.5 to 0.8 kN/m. The results of present study thus showed higher adhesive strengths when compared with previous studies.

Mouthguard sheets are heated before vacuum-forming of mouthguards in clinical settings. The sheets used in the present study were heated at 130°C for 85 s in order to fabricate mouthguards. Based on these results, it was considered possible to embed acrylic resin polymer on the surface of EVA during fabrication.

Addition-cured silicone denture relining materials may be clinically applicable for mouthguard adjustment in the near future based on their useful shock absorption properties and durability.

It remains necessary to confirm the properties of embedding resin polymer during the thermoforming process of mouthguard materials. Furthermore, it is necessary to investigate the shock absorption properties of multi-layer sheets of EVA, acrylic resin and addition-cured silicone denture relining material.

**CONCLUSION**

The capacity of silicone rubber to absorb shock was equal to or greater than that of commercial mouthguard materials. In addition, using currently available materials for the oral cavity, we succeeded in obtaining sufficient adhesion between EVA and addition-cured silicone denture relining materials, which are difficult-to-bond materials.

Within the limitations of present study, addition-cured silicone denture relining materials are clinically applicable for mouthguard adjustment.
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