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Thickness and fit of mouthguards according to a vacuum-forming process

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Abstract The purpose of this study was to examine the difference in the thickness and the fit of mouthguards fabricated with a vacuum-forming method of the mouthguard sheet material. The material used in this study was Sports Mouthguard (3.8 mm thickness). Two forming conditions were performed. In the first condition, the sheet was lowered over the working model after the vacuum was applied, and in the other trial, the sheet was lowered over the working model before the vacuum was applied. The sheets were formed using a vacuum former when the heated sheets hung 1.5 cm from the baseline. We measured the thickness and the fit of the mouthguard at the areas of the central incisor and first molar in both conditions. The difference of the thickness at the areas of the central incisor and first molar and the forming condition was analyzed by Two-way ANOVA. The difference of the fit according to the forming conditions was analyzed by the Mann–Whitney *U* test. The results showed that the thickness of the mouthguard differed at the areas of the central incisor and first molar, but the thickness of the mouthguard did not differ according to the forming conditions. The fit of the mouthguard at the central incisor and first molar was significantly different between the forming conditions ($P < 0.01$ and $P < 0.05$). These results suggested that the fit of the mouthguard was the best without any deficiency of thickness when the vacuum was applied first and then the sheet was pressed onto the working model. These results may be useful in fabricating proper mouthguards.

Key words: mouthguard; vacuum-forming; thickness; fit

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The mouthguard has been considered as the primary appliance for minimizing oral risks of trauma to hard and soft tissue or minimize the severity of orofacial trauma (1–10). The thickness of the mouthguard influences its preventive effects from injuries. The thickness of the mouthguard also influences the comfort of fitting as well as the ability to speak, which will affect whether one continues to use mouthguards or not (11). Therefore, it is necessary to evaluate the thickness of the mouthguard. Additionally, the mouthguard should be properly fitted to the wearer's mouth and accurately adapt to the wearer's oral structures to provide adequate protection (12, 13). If a mouthguard does not achieve the best possible adaptation when formed, this loss of retention and fit is likely to occur sooner rather than later. With the loss of proper fitting, mouthguards will need to be replaced sooner and more frequently than those offering superior adaptation qualities (14).

There have been some reports concerning the necessary thickness (15–18). The mouthguard sheet over the facial surface of anterior teeth requires a thickness of 3 to 4 mm, and the sheet over the buccal surface of posterior teeth and the occlusal surface needs a thickness of 2 to 3 mm (15). Hoffman et al. (16) reported that a minimum layer thickness of 3 mm was required. Tran et al. (17) suggested that appliances should be at least 4 mm thick to optimize their protective qualities. Westerman et al. (18) reported a preference for 4 mm thickness over critical areas such as incisal edges and tooth cusps. In our previous study, we investigated elongation and the thickness of the mouthguard under different heating conditions and clarified that the thickness of the sheet becomes thinner as heat is applied to the sheet, and it is difficult to maintain the proper thickness (19). Regarding the fit of the mouthguard, Yonehata et al. (20) reported that the best fit of custom-made mouthguards was achieved when the working cast was thoroughly dried and heated before the vacuum-forming process. Del Rossi et al. (14) indicated that dark-colored sheets of the co-polymer ethylene vinyl acetate (EVA) achieved superior adaptation during the fabrication process compared with light-colored or transparent material. Maeda et al. (21) showed that mouthguard retention is closely related to the accuracy of fit at the cervical undercut area rather than the outline location.

Fabrication of custom-made mouthguards can be performed by a vacuum-forming process or a pressure-forming process. Because of the limited heat and pressure that is used in the fabrication process, the vacuum-formed mouthguard results in a final product with an uneven thickness, and reduced thickness in comparison with the pressure-laminated mouthguard (12, 22). Therefore, pressure-laminated mouthguards, ones which the manufacturer can control the final thickness of the mouthguard, are recommended. However, vacuum-forming machines are easier to use and are more cost-effective than pressure-forming machines (20).

The purpose of this study was to examine the difference of the thickness and the fit of the mouthguard according to the forming process of the mouthguard sheet using a vacuum-forming machine.

Materials and methods

The material used in this study was Sports Mouthguard® (Meinan Dental Trading Co., Tokyo, Japan, 127 × 127 × 3.8 mm). A working model was made by taking an impression of a maxillary dentate model (500A; Nissin Co., Tokyo, Japan) using silicon rubber replicate impression paste (rema Sil®; InterGlobe Co., Osaka, Japan), and then gypsum (New Plastone®; GC Co., Tokyo, Japan) was poured into the impression. The removal of the model from the impression was performed 60 min after pour. The working model was trimmed using a wet type model trimmer (Model trimmer MT-6®; Morita Co., Tokyo, Japan) to a height 20 mm at the point of the anterior teeth and 15 mm at the point of the posterior teeth. The sheets were formed using a vacuum former (Ultra Former®; Ultradent Products Inc., South Jordan, UT, USA). The completely dried working model was put on the center of the former, and the heated sheet was pressed onto it. Each sheet was heated until the center was displaced by 1.5 cm from the baseline. The displacement distance was measured using a laser pointer fixed to a three dimension coordinate measuring instrument (No.192-201; Mitutoyo Co., Kanagawa, Japan) (23). The vacuum former allowed the cool down for each sheet. The temperature of the former was measured using an infrared thermometer (CT-2000D; Custom Co., Tokyo, Japan), and a new sheet was started to form after the temperature of the former became equally to the room temperature (about 2 h after the previous sheet forming). Two forming conditions were examined: the first condition measured the sheet after it was lowered over the working model after the vacuum was applied (VP), and the other condition measured the sheet after it was lowered over the working model before the vacuum was applied (PV). The sheets were pressed onto the working model for 2 min, and then cooled for 1 h. Ten samples were examined for each condition.

The thickness of the mouthguard was recorded using a measuring device (No.21-111; YDM Co., Tokyo, Japan). The spring of the measuring device was removed to prevent distortion of the material sheet during measurement. The thickness of the mouthguard was measured at specific sites on the central incisor and the first molar. The mouthguard thickness at the central incisor was measured at 10 points of the labial surface of the central incisor. The measurement points were equally divided into lines from the incisal edge to the cervical using the mesiodistal center of the central incisor. The 10 points measured were classified into three parts: the incisal part (3 points at the incisal edge side), the central part (4 points at the central), and the cervical part (3 points at the cervical side), and the mean value of the thickness of the right and left central incisors was calculated and used for analysis. The mouthguard thickness of the first molar was measured at 6 points on the buccal surface of the first molar: the cusp, central, and cervical parts of the mesiobuccal and distobuccal cusp. The mean value of the thickness of the right and left first molars was calculated, and then the mean value of the mesiobuccal and distobuccal cusp was calculated and used for analysis. The differences of the thickness of the central incisor and the first molar according to the measurement parts and the forming conditions were analyzed by Two-way ANOVA and the *Post hoc* test (Tukey method or Scheffé method).

The thickness of the occlusal surface of the first molar was also measured. The mean value of the thickness of the 10 points which were divided into lines from mesiobuccal cusp to mesiolingual cusp was calculated, and that of the distal cusp was also calculated. Then, the mean value of the thickness of the right and left first molars was calculated, and then the mean value of the mesial and distal cusp was calculated and used for analysis. The difference of the thickness of the occlusal surface of the first molar by the forming conditions was analyzed by the Mann–Whitney *U* test.

Additionally, the fit of the mouthguard to the working model was examined. The mouthguard was cut in a sagittal direction at the center of the right and left central incisors toward the frontal direction at the right and left mesial cusps of the first molar. The mouthguard was fitted to the working model, and pictures of the cross-section of the mouthguard were taken with a fixed digital camera incorporating a ruler. The pictures were observed using PHOTOSHOP® (Adobe Systems, San Jose, CA, USA), and the distance between the mouthguard and the cervical margin of the working model was measured. The difference of the distance between the mouthguard and the cervical margin according to the forming conditions was analyzed by the Mann–Whitney *U* test.

Results

Table 1 shows the results of Two-way ANOVA of the central incisor. There were statistically significant differences among the measurement sites ($P < 0.01$ or $P < 0.05$), and the thickness on the side of the incisal area was smaller than that on the side of the cervical area. Statistically significant differences were not found on the same measurement sites between the forming conditions (Fig. 1). The mean value of the thickness of the central incisor was 2.27 mm for the VP condition and 2.21 mm for the PV condition.

Table 1. The results of Two-way ANOVA (Central incisor)

Source	df	MS	*F* value	*P* value
Measurement part (A)	1.248	0.808	201.653	0.000
Forming condition (B)	1	0.058	0.903	0.355
A*B	1.248	0.026	6.606	0.013
Error (A)	22.456	0.004		
Error (B)	18	0.064		

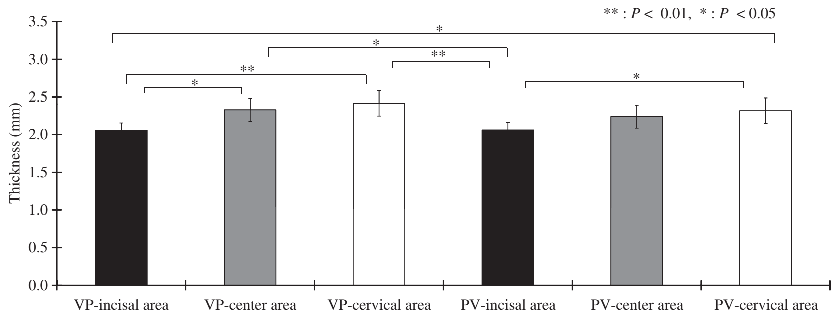

Fig. 1. The thickness of the central incisor under the two forming conditions on each measurement part.

Table 2 shows the results of Two-way ANOVA of the first molar. There were statistically significant differences among the measurement sites ($P < 0.01$) (Fig. 2). The material thickness on the side of the cusp area was smaller than that on the side of the cervical area. Statistically significant differences were not found between the forming conditions (Fig. 3). The mean value of the thickness of the first molar was 2.58 mm for the VP condition and 2.59 mm for the PV condition.

The thickness of the occlusal surface of the first molar was not different between the conditions of VP and PV (Fig. 4). The mean value of the thickness of the occlusal surface of the first molar was 2.91 mm for the VP condition and 2.90 mm for the PV condition.

The fit of the mouthguard to the working model at the central incisor was significantly different between the two forming conditions ($P < 0.01$) (Fig. 5). The mean value of the distance between the mouthguard and the cervical margin was 0.41 mm for the VP condition and 0.56 mm for the PV condition. The fit of the mouthguard to the working model at the site of the first molar was also significantly different between the two forming conditions ($P < 0.05$) (Fig. 6). The mean value of the distance between the mouthguard and the cervical margin was 0.32 mm for the VP condition and 0.37 mm for the PV condition.

Table 2. The results of Two-way ANOVA (First molar)

Source	df	MS	*F* value	*P* value
Measurement part (A)	1.497	2.646	615.738	0.000
Forming condition (B)	1	0.001	0.130	0.723
A*B	1.497	0.007	1.671	0.210
Error (A)	26.941	0.004		
Error (B)	18	0.012		

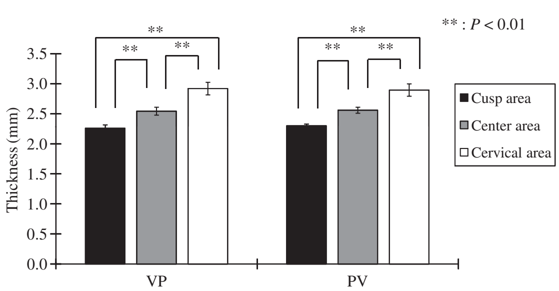

Fig. 2. The thickness of the first molar on each measurement part.

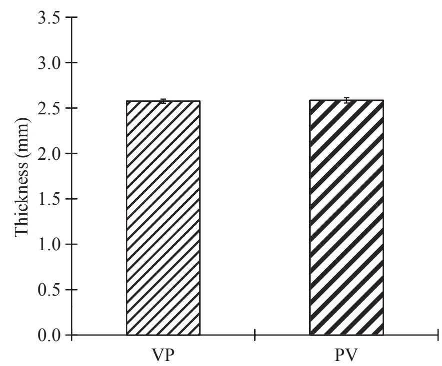

Fig. 3. The thickness of the first molar under the two forming conditions.

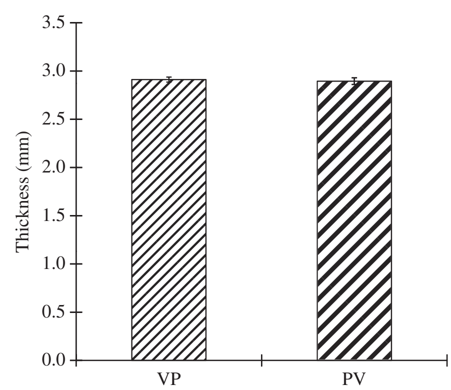

Fig. 4. The thickness of the occlusal surface of the first molar.

Discussion

It is important to maintain an uniform thickness of the mouthguard to prevent stomatognathic trauma during sports. And the mouthguard should fit well to function properly. In this study, we examined the differences of the thickness and the fit of the mouthguard according to the forming process of the mouthguard sheet using a vacuum-forming machine which resulted in different formation of the mouthguard under the forming conditions.

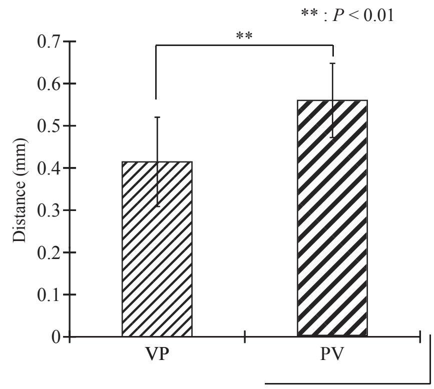

Fig. 5. The distance between the mouthguard and the cervical margin of the working model at the central incisor.

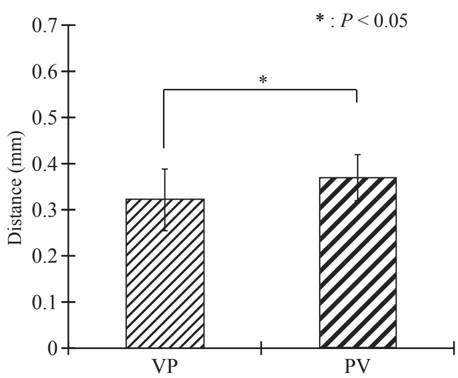

Fig. 6. The distance between the mouthguard and the cervical margin of the working model at the first molar.

The thickness of the mouthguard influences impact absorption and a preventive effect against stomatognathic injury (24). It is necessary to assess the thickness of the mouthguard, and choose the proper fabricating method to maintain the thickness of the mouthguard after forming. There have been some reports which investigated the thickness of the mouthguards (22, 25–28). Park et al. (25) reported that the average amount of thinning at the occlusal surface of the mouthguard was 25%, and that of the labial surface was 50%. Guevara et al. (26) described a 36% rate of thinning along the incisors. Del Rossi et al. (27) showed that the average amount of thinning that occurred at the occlusal surface overlying the molars was approximately 46%, and the amount of thinning along the labial surface of the central incisors and canines ranged between 47% and 60%. Geary et al. (28) revealed that the sheets of 3-mm EVA stretched by 52% during the thermoforming processes, and the material stretched by 72% at incisal sites, reducing thickness to <1 mm. These reports showed that fabricating the mouthguard resulted in a reduced thickness of itself. It is necessary to maintain the thickness of the mouthguard after fabrication.

To avoid becoming dislodged on impact, which is when protection is most needed, mouthguards must fit properly and firmly (12). It has been reported that an athlete's attitude toward wearing a mouthguard and usage pattern is influenced at least in part by comfort (proper fit) and the ability to speak and breathe (29–31). For the mouthguard to function as a shock absorber, comfort and proper fit are essential (32). Thus, the fit of the mouthguard is quite important as a chief factor in the effectiveness of the mouthguards.

Custom-made mouthguards can be either vacuum-formed or pressure-formed, and the vacuum-formed mouthguard is fabricated for daily use. Initially, the mouthguard sheet was placed on the frame of the vacuum former and locked into place using a clamping frame. The heating element was then positioned over the sheet and the sheet was then heated. When heating was properly achieved, the sheet was lowered onto the working model with a vacuum adaptor. Concerning this process, some reports introduced ways to lower the sheet onto the working model and then apply the vacuum adaptor (32, 33). Another report showed ways to switch the vacuum on and then lower the sheet onto the working model (34). It is conceivable that the forming process of the vacuum adaptor on the vacuum former would influence the thickness and the fit of the mouthguard, and clarifying the most effective forming process would be necessary to fabricate effective mouthguards. In this study, we examined the difference of the thickness and the fit of the mouthguard according to the forming process of the mouthguard sheet using a vacuum-forming machine.

The heating condition was set at a displacement distance of 1.5 cm from the baseline, because a displacement distance of 1.0 to 2.0 cm was regarded as the proper heating condition (35). The temperature of the surface of the mouthguard sheet was approximately 98.8°C when the displacement distance was 1.5 cm. There was a report showing that the appropriate heating temperatures of the ethylene vinyl acetate sheet are 80–120°C (36). The time to reach the 1.5 cm displacement distance was about 4 min 0 ± 4 s on the VP condition and 3 min 56 ± 9 s on the PV condition. There was not statistically significant difference on the heating time between the conditions of VP and PV.

As a result of statistical analysis of the central incisor measurements, the mouthguard thickness was significantly different among the measurement sites. The thickness of the incisal area was smaller than that of the cervical area. One reason for this result could be that the sheet first came in contact with the incisal area and then the sheet was extended from that area. The morphological features of the incisal area would also influence this result. The thickness of the central incisor on the same measurement sites did not differ between the two forming conditions. Therefore, the timing of the use of the vacuum adaptor will not influence to the thickness of the mouthguard at the anterior teeth area. As a result of statistical analysis of the first molar, the thickness was significantly different among the measurement sites. The thickness of the mouthguard at the site of the cusp area was smaller than that at the site of the cervical area. The reason for this result could be same as that of the anterior teeth area. The sheet first came in contact with the cusp area and then the sheet was extended from that area. The morphological features of the cusp area would also influence this result. The mouthguard thickness at the site of the first molar was not different between the two forming conditions. Therefore, the timing of the use of the vacuum adaptor will not influence the thickness of the mouthguard of the posterior teeth area.

The mouthguard thickness of the occlusal surface of the first molar was not different between the conditions of VP and PV. The timing of the use of the vacuum adaptor will not influence the thickness of the mouthguard of the occlusal surface of the posterior teeth area.

The fit of the mouthguard to the working model in the area of the central incisor and the first molar was statistically significantly different under various forming conditions. The fit of the mouthguard under the VP condition was superior to the PV condition. Regarding the VP condition, the softened mouthguard sheet should fit thoroughly over the working model with the aid of the vacuum already applied, hence a proper fit could be obtained. On the other hand for condition PV, the softened sheet first contacted with the working model and then the vacuum was adapted. Therefore, the pressure of the mouthguard sheet to the working model was weak, and the fit was inferior in comparison with the VP condition.

Concerning limitations of this study, the thickness of the mouthguard was not different according to the forming process, and the fit of the mouthguard was superior when the vacuum was first applied and then the sheet was pressed onto the working model. The results of this study suggested that initial vacuum application would be effective in fabricating properly fitted mouthguards without affecting thickness. Future research should examine the difference of the fit of the mouthguard by the angle and the position of the working model, and the difference of the thickness and the fit of the mouthguard when the heated side of the sheet contacted the working model first.

Conclusion

Mouthguards need adequate thickness and proper fit to be effective to prevent injury. In this study, we examined the differences of thickness and fit of the mouthguard according to the forming process of the mouthguard sheet using a vacuum-forming machine which resulted in different fit of the mouthguards due to the different forming conditions. The fit of the mouthguard was superior when the vacuum was first applied and then pressed the sheet onto the working model.

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