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Influence of Continuous Use of a Vacuum-Forming Machine for Mouthguard Thickness after Thermoforming: Effect of the Time Interval between Repeat Moldings

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Abstract

Mouthguards can reduce the risk of sports-related injuries, but the sheet material and thickness have a large effect on their efficacy and safety. This study was intended to predict the changes in thickness of molded products by clarifying the effect of the time interval between repeat moldings during the continuous use of a vacuum-forming machine. Ethylene vinyl acetate mouthguard sheets were used for thermoforming with a vacuum-forming machine. The working model was trimmed to a height of 23 mm at the maxillary central incisor and 20 mm at maxillary first molar. Five molding conditions were investigated: 1) molding was carried out after the sag at the center of the softened sheet was 15 mm (control); 2) sheet heating was started 5 min after the molding of the control (AF5-Re1); 3) sheet heating started 5 min after the molding of AF5-Re1 (AF5-Re2); 4) sheet heating started 10 min after the molding of the control (AF10-Re1); and 5) sheet heating started 10 min after the molding of AF10-Re1 (AF10-Re2). Sheet thickness after fabrication was determined for the incisal edge, labial surface, cusp, and buccal surface using a special caliper accurate to 0.1 mm. Thickness differences of the molding conditions were analyzed by two-way analysis of variance. Significant differences between the control and AF5-Re1 were observed at all measurement points ($p < 0.01$), but not between the control and AF10-Re1. AF10-Re2 became thinner than AF10-Re1 ($p < 0.01$). Reproducible molding results were obtained by waiting 10 min between the first and second moldings, but the third molded mouthguard was significantly thinner, despite this 10 min wait interval.

Keywords

Mouthguard, Thermoforming, Thickness, Vacuum Formation, Continuous Use

1. Introduction

Mouthguards are effective for lowering the risk of injuries such as tooth fracture during sports activities. However, it is important to choose the appropriate sheet material and control the thickness of the material as these have a large effect on the efficacy and safety of mouthguards [1] [2] [3] [4] [5]. For example, the anterior part of the sheet is prone to large variability in thickness during fabrication, and thus ensuring proper control of thickness of this part is necessary in order to produce effective mouthguards [6] [7] [8].

The optimal thickness of a mouthguard is difficult to control when using a conventional forming method with a single layer of thermoplastic sheet material. In contrast, methods used to produce laminated mouthguards are more effective and are not affected by dentition or occlusion. The laminating technique also enables the thickness or the design of different parts of mouthguards to be easily modified [6] [7] [8]. However, a disadvantage of laminated mouthguards is their greater cost and time required for fabrication. There is therefore a need for a mouthguard fabrication method that suppresses the reduction in thickness after molding yet allows use of the same equipment for the fabrication of all mouthguards.

The physical properties of mouthguard sheets during thermoforming have been studied in prior research [6] [9]. Specifically, it was a temperature change and its distribution during heating of the sheet, and an influence of the sheet extrusion direction on the mouthguard thickness, and so on. As a result, it was clarified that the sheet temperature is not uniform, the thickness decreases as the temperature increases, and the sheet shrinks in the extrusion direction during sheet heating. The forming machine remains hot immediately after the formation process, and sheet sag occurs more rapidly when the machine is used continuously, producing thinner mouthguards. We therefore examined changes in mouthguard thickness during continuous use of a vacuum-type forming machine [10]. We found that the thicknesses of mouthguards are affected if there is a 5 min time interval between each mouthguard molding process whereas stable forming was achieved by setting the interval to 10 min. However, the temperature of the forming machine gradually changes between the first, second, and third moldings. The purpose of this study was to predict the changes in thickness of molded products by clarifying the effect of the time interval between repeat moldings during the continuous use of a vacuum-type molding machine.

2. Materials and Methods

Ethylene vinyl acetate (EVA) mouthguard sheets (Sports Mouthguard®, 127 × 127 × 4.0 mm, clear; Keystone Dental Inc., Cherry Hill, NJ) were used. We took a silicone rubber impression (Correcsil®, Yamahachi Dental Mfg., Co., Aichi, Japan) from a maxillary dental model (D16FE-500A-QF, Nissin Dental Products Inc., Kyoto, Japan) and filled the impression with dental gypsum (New Plastone®, GC Co., Tokyo, Japan) to create a working model. After hardening for 1 h, the gypsum model, was demolded and trimmed (Model trimmer MT-6®, Morita Co., Tokyo, Japan) to a height of 23 mm at the cutting edge of the maxillary central incisor and 20 mm at the mesiobuccal cusp of the maxillary first molar. The working model was left to dry for more than 48 h at about 19.0˚C in an air-conditioned room [6] [7] [8] [9] [10].

We produced EVA molded mouthguards by using a vacuum forming machine (Ultraformer®, Ultradent Products Inc., South Jordan, UT). During molding, the working model was placed at the center of the vacuum unit. Five molding conditions were investigated: 1) molding was initiated after the sag at the center of the softened sheet was 15 mm below the clamp (control); 2) sheet heating was started 5 min after the molding of the control, and molding was carried out after the sag at the center of the softened sheet was 15 mm below the clamp (AF5-Re1); 3) sheet heating was started 5 min after the molding of AF5-Re1, and molding was carried out after the sag at the center of the softened sheet was 15 mm below the clamp (AF5-Re2); 4) sheet heating was started 10 min after the molding of the control, and molding was initiated after the sag at the center of the softened sheet was 15 mm below the clamp (AF10-Re1); and 5) sheet heating was started 10 min after the molding of AF10-Re1, and molding was carried out after the sag at the center of the softened sheet was 15 mm below the clamp (AF10-Re2). Under each condition, vacuum forming was conducted for 30 s, and six samples were produced under each condition.

The sheet temperatures of the heated and non-heated surfaces were measured under each condition at 5 points with a radiation thermometer accurate to 0.1˚C (CT-2000N, Custom Co., Tokyo, Japan). The measurement points were the center (C) and 40 mm from each corner [anterior (A, B) and posterior (D, E)] (Figure 1). The heating time was measured until the sheet sagged by 15 mm. The

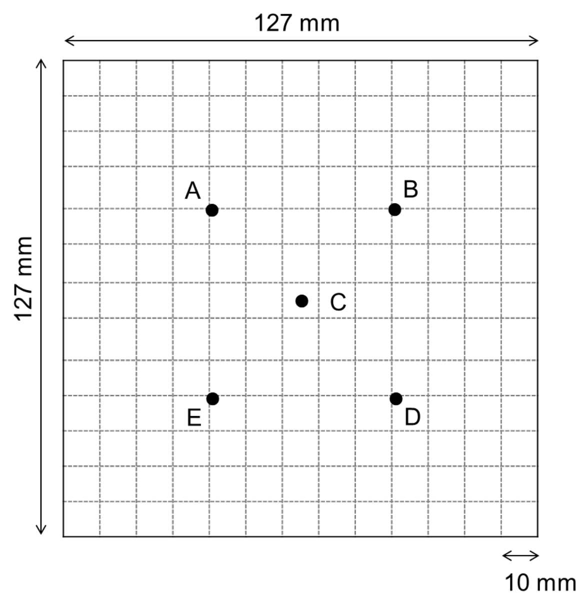

Figure 1. Temperature measurement points on the surface of the sheets (A-E). A, B: anterior, C: center, D, E: posterior.

sheet was allowed to cool for at least 24 h at a constant temperature of approximately 19.0˚C and it was then removed with scissors (HSB 630-10, Karl Hammacher GmbH Co., Cologne, Germany).

Using calipers accurate to 0.1 mm (21-111, YDM Co., Tokyo, Japan) with the spring removed to prevent measurement error, we measured the mouthguard sheet thickness [6] [7] [8] [9] [10]. Measurement points for the incisal portion were defined at the left and right central incisor positions as follows: 5 points were spaced equally from the proximal to the distal end of the incisal edge; 10 points were on the labial surface, including 5 points spaced equally from the cemento-enamel junction to the incisal edge along a line located one-third of the distance from the proximal edge corresponding to the 5 points along a line located one-third of the distance from the distal edge. Measurement points for the molar portion were defined for the left and right first molars as follows: 4 points were on the cusp, including the proximal and distal buccal cusps and distal lingual cusps; and 10 points were on the buccal surface, including 5 points spaced equally from the cemento-enamel junction to the tip of the cusp along a line located one-third of the distance from the proximal end corresponding to the 5 points along a line located one-third of the distance from the distal end. One measurement was taken for each sample and used in the analysis to determine mean thickness.

IBM SPSS 24.0 software (SPSS Japan Inc., Tokyo, Japan) was used for statistical analysis. For each condition, the thickness distribution after formation was tested for normality using the Shapiro-Wilk test and for homogeneity of variance using Levene's test. Normality and equality of variance were found for each item. The data were then analyzed by two-way analysis of variance (ANOVA) with Bonferroni's correction for multiple comparisons. The level of significance was set to $p < 0.05$, and the power was set to 0.8 for all analysis. Overall, a difference was considered significant if both criteria were satisfied.

3. Results and Discussion

The temperature on the sheet surface and the heating time under each condition are listed in **Table 1**. The heated surfaces were had a higher temperature than

Table 1. Mean temperature and standard deviation on the surface of the sheets and the heating time for a sheet sagging distance of 15 mm.

Heating condition	control			AF5						AF10					
				Re-1			Re-2			Re-1			Re-2		
Measurement point	A, B	C	D, E	A, B	C	D, E	A, B	C	D, E	A, B	C	D, E	A, B	C	D, E
Heated surface (˚C)	119	135	97.2	141.5	147.2	128.8	144.7	149.4	130.1	127.2	135.1	105.5	139.8	142.7	127.1
Non-heated surface (˚C)	81.7	84.2	81	85.4	91	81.2	86.2	90.3	83.5	83	88.3	82.6	84.4	88	82.3
Heating time	4 min 00 sec			3 min 20 sec			3 min 20 sec			3 min 50 sec			3 min 30 sec		

the non-heated surfaces. The highest temperature was at the center, followed by the anterior and posterior regions of each sheet. The sheet temperatures of the heated surface of AF5-Re1 at the center, anterior, and posterior regions were higher than the control by 12.2˚C, 22.5˚C, and 31.6˚C, respectively. In contrast, the increase in temperature of the non-heated surface of AF5-Re1 compared with the control was less than 6.8˚C. The temperature differences between corresponding parts of AF5-Re1 and AF5-Re2 were small (less than 4˚C). The sheet temperature of AF10-Re1 was 4.7˚C - 8.3˚C higher than that of the control at the anterior and posterior sites on the heated surfaces but the same at the other points. The sheet temperatures of the center, anterior, and posterior regions of the heated surface of AF10-Re2 were higher than those of AF10-Re1 by 7.6, 12.6, and 21.6˚C, respectively, similar to the temperatures observed for AF5-Re2. Compared to the control, the required heating time (the time required for a sheet to sag 15 mm) was shorter by 10 s for AF10-Re1, by 30 s for AF10-Re2, and by 40 s for AF5-Re1 and AF5-Re2.

The two-way ANOVA results for the differences in mouthguard thickness due to molding conditions are summarized in Table 2, and the multiple comparison test results are shown in Figure 2. Significant differences between the control

Table 2. Results of two-way ANOVA for thickness after formation.

Source	df	SS	MS	F value	p value
Incisal edge					
Molding interval (A)	1	0.051	0.051	302.222	<0.001**
Repeat number (B)	2	0.373	0.186	1095.801	<0.001**
A*B	2	0.044	0.022	128.938	<0.001**
Error	30	0.005	0		
Labial surface					
Molding interval (A)	1	0.026	0.026	50.526	<0.001**
Repeat number (B)	2	0.506	0.253	499.364	<0.001**
A*B	2	0.014	0.007	14.276	<0.001**
Error	30	0.015	0.001		
Cusp					
Molding interval (A)	1	0.059	0.059	60.695	<0.001**
Repeat number (B)	2	0.559	0.279	286.344	<0.001**
A*B	2	0.088	0.044	44.909	<0.001**
Error	30	0.029	0.001		
Buccal surface					
Molding interval (A)	1	0.258	0.258	406.934	<0.001
Repeat number (B)	2	0.689	0.344	542.297	<0.001
A*B	2	0.159	0.08	125.437	<0.001
Error	30	0.019	0.001		

df: degree of freedom. SS: sum of squares. MS: mean square. **: statistically significant, with $p < 0.01$.

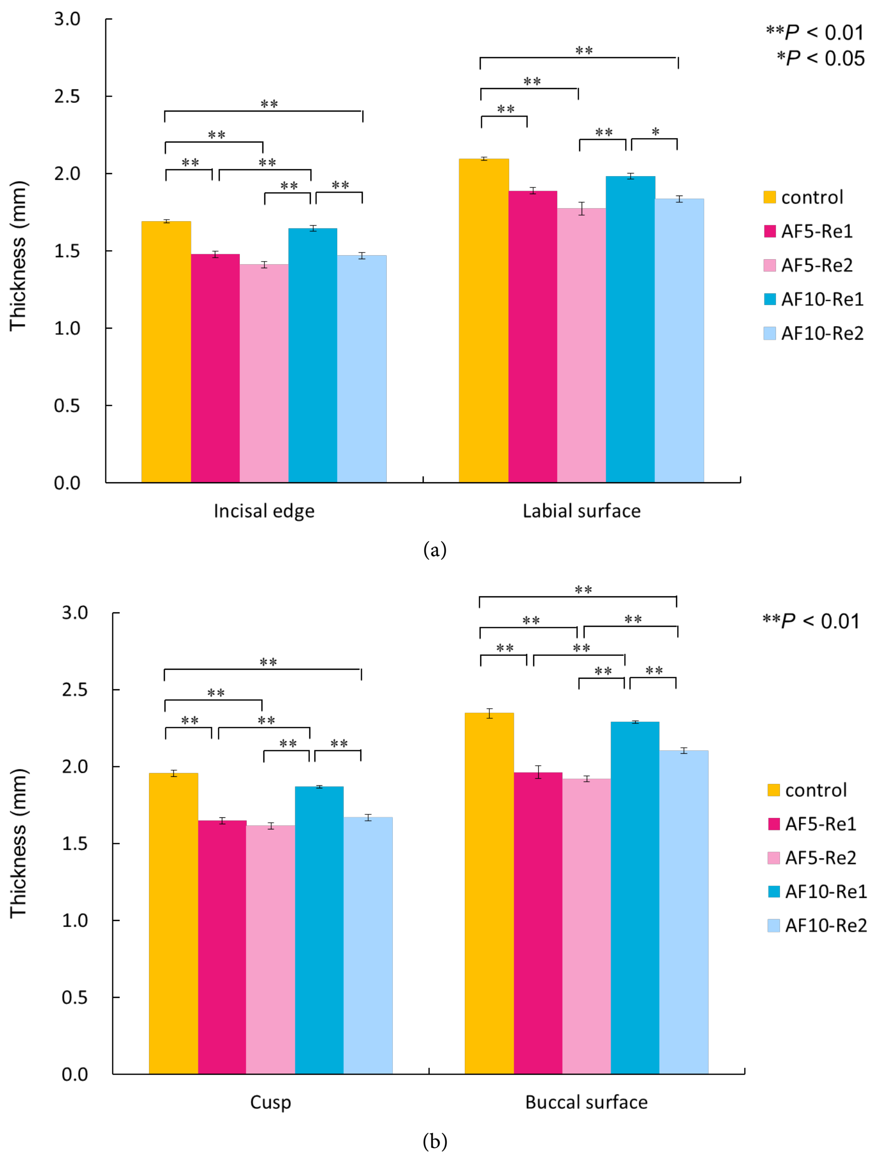

Figure 2. (a) Comparison of mouthguard thickness (mean ± SD) at the anterior part according to the molding interval and repeated numbers; (b) Comparison of mouthguard thickness (mean ± SD) at the posterior part according to the molding interval and repeated numbers.

and AF5-Re1 were observed at all measurement points ($p < 0.01$), but not between the control and AF10-Re1. No significant difference was observed between AF5-Re1 and AF5-Re2, whereas there was a significant difference between AF10-Re1 and AF10-Re2. AF5-Re1 and AF10-Re2 had similar thicknesses.

The timing required to mold a mouthguard is conventionally judged by either the sagging distance, the sheet's softening temperature, or the heating time. This timing is often recommended by the manufacturers because it is specific to that machine model and for the type and thickness of sheet used [11] [12] [13]. Judging the timing from the sagging distance is simple and so is applicable to many vacuum forming machines [6]-[13]. When mouthguards are produced using a vacuum forming machine with a 4.0-mm-thick EVA sheet, that a sheet sagging distance of 15 mm were corresponded to optimal heating conditions, and thus the timing required to achieve this sagging provided the temperature window for good molding with EVA (80˚C - 120˚C) [14]. We adopted this guideline (time required for a 15 mm sag) in the current study.

Previous studies have investigated the change in shape in mouthguard sheets during thermoforming using an elastomer sheet and a forming device [6]-[14]. The forming machine remains hot immediately after formation, and thus sheet sag occurs more rapidly when the machine is used continuously, thereby producing thinner mouthguards [10]. During the next molding, this heat affects the softening of the sheet. An interval of 10 min between moldings is required to achieve consistent molding, but the temperature of the forming device gradually increases from one molding to the next. The present study aimed to predict the change in thickness of the molded product by clarifying the effect of the interval between moldings with continuous use of a vacuum-type molding machine.

Decreases in the thickness of molded mouthguards during the first stage of thermoforming have been previously reported [9] [11] [12] [14]. The sheet slowly softened, resulting in uniform softening and only a slight decrease in the thickness of the mouthguard. In contrast, a significant decrease in the thickness was observed when there was rapid sagging of the sheet; furthermore, the sheet did not reach a sagging distance of 15 mm as the timing of the proper molding, until the temperature of the non-heated surface reached the softening temperature even though the heated surface temperature was already above the softening temperature.

The present study showed that AF5-Re1 became thinner than the control because the fluidity of the elastomer was increased by continuous heating until the sheet reached the softening temperature of the non-heated surface. Each region of the AF5-Re1 and AF5-Re2 sheets achieved the same temperature at the same heating time and thus their thicknesses were equal. It has been reported that the elasticities of EVA sheets decrease when heated above 120˚C, causing a decrease in the shock absorbing capacity of the sheet material. The sheet temperatures of AF5-Re1 and AF5-Re2 were 20˚C above the moldable temperature range for EVA, raising concerns regarding the physical properties of the sheet. Consequently, this molding method cannot be recommended because of its effect on both the thickness and physical properties of the molded body. On the other hand, the heating time required to observe a 15 mm sag with AF10-Re1 was 10 s less than that required for the control, the temperature differences between the sample and the control were small, and thus the effects of the processing conditions on the thickness of the molded product were small. Furthermore, the heating time required for AF10-Re2 was 30 s less than that required for the control, the temperature of each region of the sheet was comparable to that of AF5-Re1, and AF10-Re2 became thinner than the control or AF10-Re1. In other words, it was found that the thickness differences after formation depends on the sheet temperature; the thickness became thin when the sheet temperature was higher than the control, or the thickness was same when the sheet temperature was same as the control. Taken together, our results show that stable molding can be obtained by setting an interval of 10 min or more between the first and second moldings, but this method cannot be recommended because the thickness of the third molding decreases significantly.

In this study, the temperature of each part of the molding machine (vacuum unit, sheet frame, and heater) before molding under each condition was measured with a radiation thermometer (CT-2000N). The temperature of the vacuum unit and sheet frame during continuous use were similar between the control and test conditions. However, the temperature of the heater differed greatly between conditions: it was essentially at room temperature (21˚C) for the control, whereas for AF5-Re1, AF5-Re2, AF10-Re1, and AF10-Re2 the heater temperature was about 124˚C, 196˚C, 51˚C, and 113˚C, respectively. We therefore speculate that an increase in the temperature of the heater promotes softening of the heated surface and accelerates sagging of the sheet. Furthermore, the temperature difference between the heated surface and the non-heated surface increased as the heater temperature increased, suggesting that mouthguard thicknesses will decrease between the first and second stages of thermoforming.

Our results indicate that when a vacuum forming machine is used continuously, the second molding can be pressed at an appropriate softened state by performing the molding operation about 10 min after the first molding, providing stable molding results. However, when heating is continued until the non-heated surface reaches the softening temperature during the third and subsequent moldings, the heated surface increases to a temperature at which sheet deterioration occurs. Therefore, this approach cannot be recommended as a molding method. To avoid overheating the heated surface during molding, we recommend that the forming operation be performed after the heater has cooled to room temperature.

4. Conclusion

When the vacuum forming machine is continuously used, stable molding results are obtained when the second molding is done after 10 min, but thinning is remarkable when the third molding is done further after 10 min. We are planning to investigate the influence on the mouthguard thickness by continuous use of the pressure molding machine, because the thickness reduction after pressure molding is larger than that of vacuum formation.

Supported

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Conflicts of Interest

The authors report no conflict of interest.

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