

Controlling Softened State of Mouthguard Sheet during Thermoforming to Ensure Thickness

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Abstract

Mouthguard thickness is affected by the softened state of the sheet during thermoforming. The aim of this study is to establish an effective method for controlling the softened state of the sheet to prevent the mouthguard thickness from decreasing during mouthguard fabrication using a vacuum-forming machine. Mouthguards were thermoformed using an ethylene-vinyl acetate sheet (thickness: 4.0 mm) and a vacuum-forming machine. The working model was trimmed to the anterior height of 25 mm and the posterior height of 20 mm. The following two heating methods were compared: 1) the sheet was formed when it sagged 15 mm below the level of the sheet frame at the top of the post (condition T); and 2) the sheet frame was lowered to and heated at 50 mm below its usual height and the sheet was formed when it sagged 15 mm below the level of the sheet frame (condition L). For each heating method, the vacuum was applied immediately (T0, L0) or 5 s (T5, L5) after the sheet frame was lowered to the forming unit. The sheet surface temperature immediately before the vacuum was applied under each condition was measured. The differences in mouthguard thickness due to forming conditions were analyzed by one-way ANOVA and Bonferroni's multiple comparison tests. The temperature difference between the center and the posterior depending on the condition decreased in the order T0 > T5 > L0 > L5, and that was 20°C or higher for T0 and T5, and 10°C or less for L0 and L5. At the incisal edge and the cusp, L0 and L5 were significantly thicker than T0. No significant differences were observed between conditions L0 and L5 at any measurement points. For the labial and buccal surfaces, significant differences in thicknesses among all conditions, except L0 and L5, were observed and were in the order T0 < T5 < L0 and L5. This study was suggested that the lowering the sheet frame and heating was more effective than adjusting the va-

cuum timing for uniform softening of the sheet.

Keywords

Mouthguard, Vacuum Formation, Softened State, Thickness, Thermoforming

1. Introduction

Wearing a mouthguard during sports is effective in preventing and reducing trauma, and the material and thickness of the mouthguard greatly affect its effectiveness and safety [1] [2]. For mouthguards fabricated from ethylene vinyl acetate (EVA) resin, which is a common mouthguard material, thicknesses of more than 3 and 4 mm are necessary for the anterior and posterior portions, respectively, to decrease the effects of impact force [3] [4].

When fabricating a mouthguard by thermoforming, the heating state of the sheet affects the thickness of the mouthguard [5] [6] [7]. When a mouthguard sheet is heated by a forming machine with conventional methods, there are temperature differences between different parts of the sheet. In addition, the sheet is partially stretched when it makes contact with the model and the thickness is greatly reduced when the unevenly softened sheet is formed [5] [6]. Therefore, a method for softening the sheet as uniformly as possible with a forming machine was examined, and it was found that heating the sheet by lowering the sheet frame suppressed the unevenness in softening compared with conventional heating methods [8]. In addition, inverting the sheet during heating [7] or delaying the vacuum-forming timing by several seconds [9] also suppressed thinning.

The aim of this study is to establish an effective method for controlling the softened state of the sheet to prevent the thickness of the mouthguard from decreasing during mouthguard fabrication using a vacuum-forming machine.

2. Materials and Methods

A working model was fabricated using a silicone rubber (Correasil, Yamahachi Dental Mfg. Co., Aichi, Japan) impression taken from a maxillary dental model (D16FE-500A-QF, Nissin Dental Products Inc., Kyoto, Japan) into which dental gypsum (New Plastone, GC Co., Tokyo, Japan) was poured. The model was trimmed to heights of 25 mm at the incisal edge of the maxillary central incisor and 20 mm at the mesiobuccal cusp of the maxillary first molar using a wet model trimmer (Model Trimmer MT-6, Morita Co., Tokyo, Japan). The model was dried thoroughly for more than 48 h in an air-conditioned room before use.

Mouthguards were thermoformed using an EVA sheet (Sports Mouthguard, Keystone Dental Inc., Cherry Hill, NJ; 127 × 127 × 4.0 mm, clear) and a vacuum forming machine (Pro-form, T&S Dental & Plastics Co., Inc., Myerstown, PA). The model position was 40 mm from the front of the forming unit. The follow-

ing two heating methods were compared: 1) the sheet was formed when it sagged 15 mm below the level of the sheet frame at the top of the post under normal conditions (condition T); and 2) the sheet frame was lowered to and heated at 50 mm below its usual height and the sheet was formed when it sagged 15 mm below the level of the sheet frame (condition L) (**Figure 1**). For each heating method, the vacuum was applied immediately (T0, L0) or 5 s (T5, L5) after the sheet frame was lowered to the forming unit. The vacuum time was 30 s for all forming conditions. The model was left in place for at least 24 h before the mouthguard was removed. Six specimens were formed for each set of conditions; thus, a total of 24 mouthguards were fabricated. In addition, the sheet surface temperature immediately before the vacuum was applied under each forming condition was measured with a radiation thermometer (CT-2000D, Custom Co., Tokyo, Japan). Measurement points were the center (C) and 35 mm from each corner (anterior portions, A and B; posterior portions, D and E) (**Figure 2**).

The thickness of the thermoformed mouthguard was measured using a specialized caliper accurate to 0.1 mm (21-111, YDM Co., Tokyo, Japan) without a



Figure 1. Sheet frame position of the vacuum forming machine.

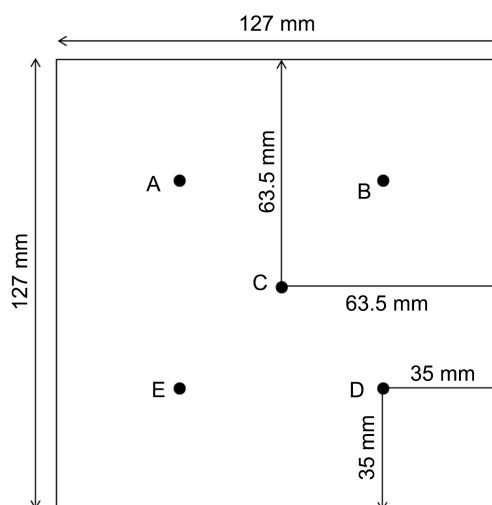


Figure 2. Temperature measurement points at the sheet heated surface (A-E). A, B: anterior; C: center; D, E: posterior.

spring, so as to prevent distortion during measurement [5]-[10]. The measurement points were the left and right central incisors (10 points on the incisal edge and 20 points on the labial surface) and the first molars (8 points on the cusp and 20 points on the buccal surface) according to previous studies [11] [12] [13] (Figure 3). The measurements were taken once for each specimen.

For all measurements, the differences in mouthguard thickness due to forming conditions were analyzed using statistical analysis software (IBM SPSS 24.0, SPSS Japan Inc., Tokyo, Japan). The Shapiro-Wilk test for normality of distribution and Levene's test for homogeneity of variance were also used. Each measurement exhibited normality and equal dispersion; accordingly, analysis was performed using one-way analysis of variance (ANOVA) and Bonferroni's multiple comparison tests. All analytical methods were performed with a significance level of 5% and a detection power of 80%, and a difference was considered significant when both were satisfied.

3. Results and Discussion

Table 1 shows the sheet surface temperature of the heated surface immediately before the vacuum was applied under each forming condition. Under all conditions, the temperature decreased in the order center > anterior > posterior. The temperature difference between the center and the posterior depending on the condition decreased in the order T0 > T5 > L0 > L5, and the difference was 20°C or higher for T0 and T5, and 10°C or less for L0 and L5. At the center of the sheet, 5 s after lowering the sheet frame, the temperature decreased by 22.1°C under condition T and 10.2°C under condition L.

Table 2 shows the results of one-way ANOVA, and Figure 4(a) and Figure 4(b) show the results of multiple comparison tests for the difference in mouthguard thickness depending on the forming conditions. Differences in mouthguard thickness depending on the heating method of the sheet were observed at

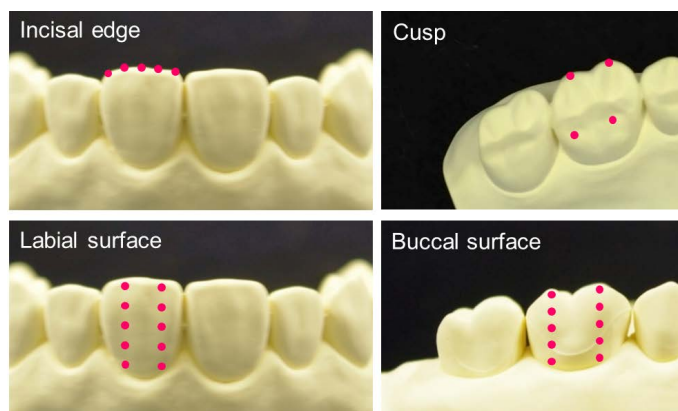


Figure 3. Measurement points for the mouthguard thickness corresponding to the model. The measurement points are the left and right central incisors (10 points on the incisal edge and 20 points on the labial surface) and the first molars (8 points on the cusp and 20 points on the buccal surface).

Table 1. Mean temperature (°C) of the heated surface immediately before vacuum application under each condition.

Forming condition	Measurement point		
	A, B	C	D, E
T0	136.3	145.1	117.7
T5	118.5	123.0	101.2
L0	96.1	97.8	90.6
L5	86.6	87.6	83.2

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

Source	<i>df</i>	SS	MS	<i>F</i> -value	<i>P</i> -value
Incisal edge					
Forming condition	3	0.328	0.109	274.658	<0.001**
Residual	20	0.008	0.000		
Total	24	72.512			
Labial surface					
Forming condition	3	0.974	0.325	618.212	<0.001**
Residual	20	0.011	0.001		
Total	24	112.527			
Cusp					
Forming condition	3	0.246	0.082	151.909	<0.001**
Residual	20	0.011	0.001		
Total	24	85.946			
Buccal surface					
Forming condition	3	0.898	0.299	720.197	<0.001**
Residual	20	0.008	0.000		
Total	24	141.896			

df: degree of freedom. SS: sum of squares. MS: mean square. ** $P < 0.01$: denotes statistically significant difference.

all measurement points, and the thicknesses obtained under condition L were significantly thicker than those obtained under condition T ($P < 0.01$). Differences in the mouthguard thickness depending on the timing of the vacuum application were observed on the labial and buccal surfaces under condition T, and the thicknesses obtained under condition T5 were significantly thicker than those obtained under condition T0 ($P < 0.05$). No significant differences were observed between conditions L0 and L5 at any measurement points. For the labial and buccal surfaces, significant differences in thicknesses among all conditions, except L0 and L5, were observed and were in the order T0 < T5 < L0 and L5.

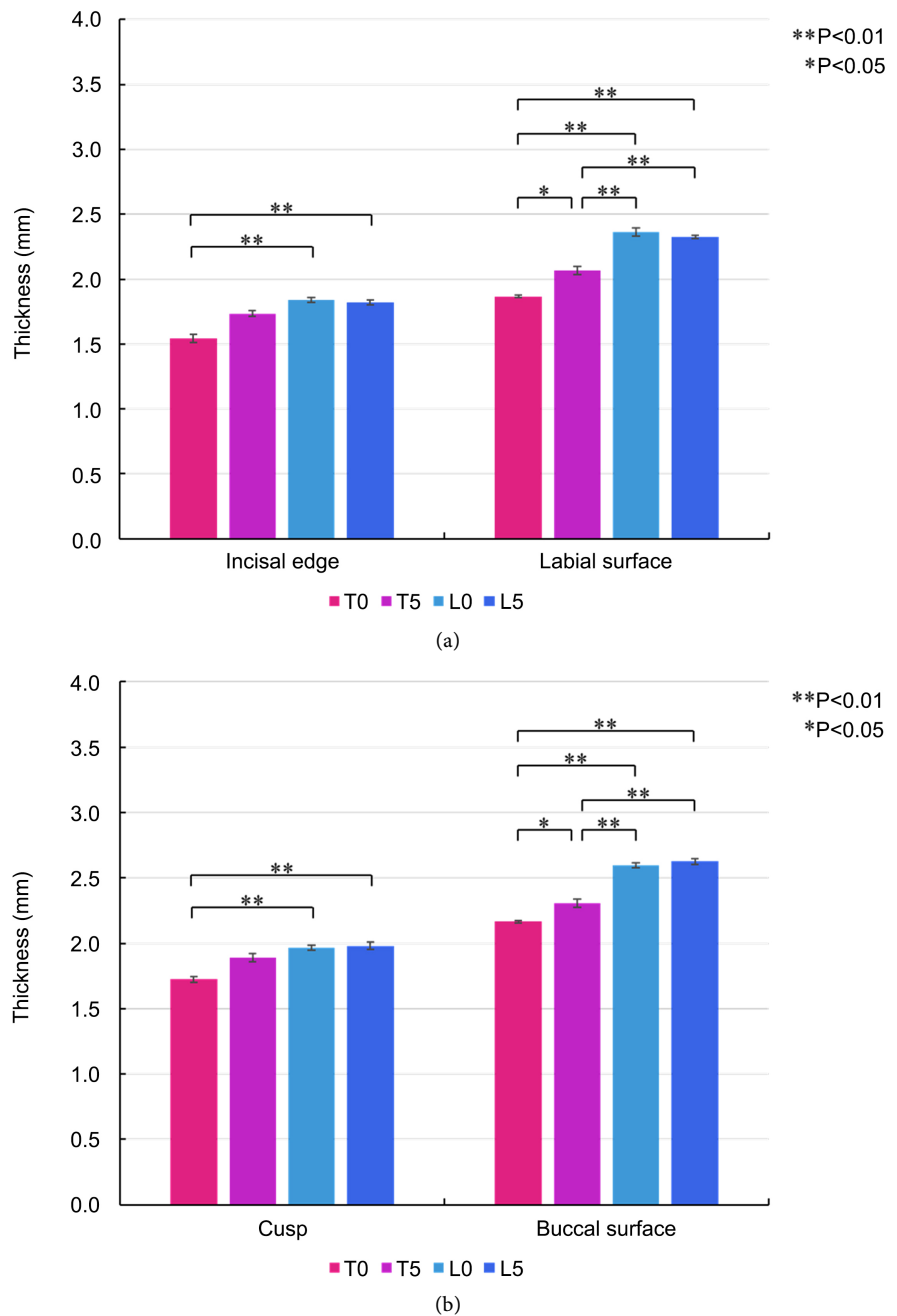


Figure 4. (a) Mouthguard thickness at measurement points on the anterior portion. Measurements are expressed as means \pm SD; (b) Mouthguard thickness at measurement points on the posterior portion. Measurements are expressed as means \pm SD.

The thickness of the mouthguard sheet decreases in two stages during thermoforming [8] [10]. In the first stage, when the sheet is heated by the forming machine, the thickness of the entire sheet decreases as the sheet softens. The second stage occurs during formation and is affected by the model form and the softened state of the sheet. The softened state of the sheet is affected by the design of the forming machine. Most forming machines have a one-sided heating design, which causes a temperature difference between the heated and non-heated

surfaces [5] [6]. The sufficiently softened portions are stretched during pressure welding rather than the insufficiently softened portions, resulting in a large decrease in thickness. In contrast, if the sagging distance of the sheet is increased or the heating time is long to avoid this, the first-stage thickness decrease increases, and overheating may cause deterioration of the sheet [14]. These facts show that the sheet can be softened uniformly at an appropriate softening temperature to suppress the thickness reduction of the mouthguard and retain the characteristics of the mouthguard material.

To soften the sheet uniformly, we focused on a method that uses ordinary equipment and does not require the inconvenience of handling a heated sheet. By increasing the distance between the forming machine heater and the sheet, the sheet was softened slowly and the temperature differences over the sheet were reduced [6]. On the other hand, a method of delaying the vacuum timing for a few seconds as suppresses thickness reduction was reported [9]. In this method, the sheet hangs under its own weight over the model until the vacuum is applied, and the sheet is elongated further after the vacuum is applied. It was considered that this was because the initial elongation of the heated sheet was inhibited. However, we expected that the sheet temperature and the softened state would change until the vacuum is applied, and this may suppress the decrease in the mouthguard thickness. Therefore, in this study, we compared the changes in thickness for lowering the sheet frame and heating, for adjusting the vacuum timing, and for both.

The temperature difference between the center and posterior of the sheet was 27.4°C (difference of 23.3%) for T0 and 21.8°C (difference of 21.6%) for T5, whereas it was 7.2°C (difference of 7.9%) for L0 and 4.4°C (difference of 5.3%) for L5. Therefore, the sheet was softened more uniformly when the sheet frame was lowered and heated, regardless of the timing of the vacuum application. In addition, the temperature of each part of the sheet decreased by 16°C - 22°C for T5 and 7°C - 10°C for L5 5 s after lowering the sheet frame to the forming unit. The effect of the vacuum application timing on the temperature was greater when the frame was at the top of the post (T0 and T5). T0 is the conventional vacuum forming process, but the temperature of the center of the heated surface was as high as 145°C, which exceeds the appropriate softening temperature range of EVA (80°C - 120°C) [14]. However, the temperature of the non-heated surface when the sheet sagged 15 mm was 96°C at the center but 75°C at the posterior, and partial softening was insufficient. The non-heated surface temperature for T5 was measured 5 s after the sheet sagged 15 mm, which is close to the vacuum timing of T5, and the center was 92°C and the posterior was 89°C. Thus, the non-heated surface was sufficiently softened and the temperature difference from the heated surface was smaller than for T0. Consequently, the mouthguards formed under T5 were thicker than those formed under T0 on the labial and buccal surfaces, possibly due to the softened state of the sheet. The incisal edge and the cusp are the parts where the thickness of the sheet is greatly

reduced, and the sheet comes into contact with these points when the sheet frame is lowered. Therefore, these thicknesses would be difficult to change by the vacuum timing.

On the other hand, if the sheet frame is lowered and heated, the sheet takes longer to stretch under its own weight, and the time from the time it until the sheet sags by 15 mm also increases [8]. Under the conditions in this study, it took 3 min and 28 s for condition T and 5 min and 25 s for condition L until the sheet sagged 15 mm. That is, when the sheet frame was lowered and heated, it took more than 1.5 times longer than usual to soften the sheet. Under condition L0, the sheet temperature of the non-heated surface immediately before vacuum application was 89°C at the center and 85°C at the posterior. Since the temperature difference between the heated and non-heated surfaces was less than 10°C, it was considered that the softening was almost uniform. Under condition L5, the temperature of the non-heated surface of the sheet was measured approximately 5 s after the sheet sagged 15 mm as 86°C at the center and 83°C at the posterior. Thus, the temperature difference between the heated and non-heated surfaces was smaller than that for condition L0, and the softening was more uniform. When the sheet sags, it extends from the part where softening started and becomes thinner. Therefore, if there is uneven softening during sagging, the decrease in the thickness of the softened part becomes larger. The same applies to the reduction of the sheet thickness during formation, where the sheet becomes more elongated and thinner at the softened part. In other words, the slow sagging caused by the weight of the sheet allowed uniform softening of the entire sheet, suppressing the thickness reduction due to the partial stretching in the first and second stages. There were no significant differences in the thicknesses between conditions L0 and L5 at any measurement points. Therefore, lowering the sheet frame (*i.e.*, increasing the distance between the sheet and the heater) and softening the sheet slowly softened the EVA sheet uniformly to an appropriate temperature. However, the temperature difference between the various parts of the sheet caused by the vacuum timing was about 10°C, which was within the appropriate softening temperature range of the EVA, and it did not affect the mouthguard thickness.

4. Conclusion

Within the equipment and experimental environment used in this research, it was shown that adjusting the vacuum timing and lowering the sheet frame during heating controlled the heating of the sheet during thermoforming by vacuum formation. Lowering the sheet frame during heating was more effective for uniform softening of the sheet and helped maintain the thickness of the mouthguard. Additionally, combining lowering the sheet frame and adjusting the vacuum timing allowed more uniform softening of the sheet, but it did not affect the mouthguard thickness. In the future, additional studies are needed to derive the amount of deformation that occurs in two stages from the theoretical equa-

tion in order to predict the reduction in the sheet thickness during thermoforming.

Conflicts of Interest

The authors report no conflict of interest. This study was supported by Nippon Dental University Intramural Research Fund.

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