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Thermoforming Technique for Suppressing Reduction in Mouthguard Thickness

Mutsumi Takahashi[1]*, Yogetsu Bando[2,3]

[1]Department of Physiology, The Nippon Dental University School of Life Dentistry at Niigata, Niigata, Japan
[2]Graduate School of Health and Sport Science, Nippon Sport Science University, Tokyo, Japan
[3]Bando Dental Clinic, Ishikawa, Japan
Email: *mutsumit@ngt.ndu.ac.jp

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Abstract

Wearing a mouthguard reduces the risk of sports-related injuries, but the material and thickness of the mouthguard has a substantial impact on its effectiveness and safety. The aim of this study was to establish a thermoforming technique in which the model position is moved just before formation to suppress the reduction in thickness. Mouthguards were vacuum formed using ethylene-vinyl-acetate sheets with a thickness of 2.0, 3.0, and 4.0 mm. The working model was trimmed to the height of 25-mm at the maxillary central incisor and 20-mm at first molar. The model was placed with its anterior rim positioned 40-mm from the front of the forming table. Two forming methods were compared: 1) the sheet was formed when it sagged 15-mm at the top of the post under normal conditions (control); and 2) the sheet frame at the top of the post was lowered and the model was covered when the sheet sagged 15-mm, the rear side of the model was pushed forward 20-mm, and the mouthguard was formed (MP; model position). Sheet thickness after fabrication was determined for the incisal edge, labial surface, and buccal surface using a specialized caliper accurate to 0.1-mm. The difference in the reduction in thickness depending on the forming methods and sheet thicknesses were analyzed by two-way ANOVA and Bonferroni's multiple comparison tests. Reduction in thickness was greater for thicker sheets, and the reduction in thickness for the MP was less than that for the control. The reduction in labial for the MP was an exception; the reduction in thickness was only about half that of the control. The thermoforming technique of moving the model forward just before vacuum formation was effective for suppressing the mouthguard thickness reduction, which in thickness of the labial side can be reduced to about half of the normal forming method.

Keywords

Mouthguard, Thermoforming, Thickness, Moves the Model Position,

Vacuum Formation

1. Introduction

Wearing a mouthguard can reduce the risk of injury during sports; however, the efficacy and safety of mouthguards depend on the mouthguard material and thickness [1]-[6]. A standard method for fabricating custom-made mouthguards is to thermoform a thermoplastic elastomer sheet. Although this method is simple, the drawback is that it reduces the mouthguard thickness [7] [8], and it is difficult to achieve the necessary thickness for shock absorption because the mouthguard is formed by only a single thermoplastic sheet. In contrast, laminated mouthguards can provide the necessary thickness on the anterior part and occlusal surface without being affected by dentition or occlusion. However, because laminated mouthguards are more expensive and require longer fabrication time compared with single-layer mouthguards, laminate mouthguards may not be suitable for all athletes. Therefore, the change in shape of the mouthguard material during thermoforming should be investigated to determine the most effect forming method and equipment, and to develop a thermoforming method that can ensure the required thickness with a single layer.

Several methods have been investigated for suppressing the reduction in thickness of mouthguards [9]-[18], including heating [9] [10] [13], adjusting the model angle [14], using a V-shaped grooved sheet [11] or notched sheet [16], and moving the model position just before forming [15] [17] [18]. The results showed that moving the model position just before vacuum forming yielded the required thickness more effectively than the heating method or adjusting the model angle, and was easier than using a V-shaped grooved sheet or a notched sheet [17] [18].

The aim of this study was to establish a thermoforming technique that suppresses reduction in thickness. Therefore, we examined the dependence of the change in mouthguard thickness after formation on the thickness of the thermoplastic sheet when applying the thermoforming method in which the model position is moved just before vacuum forming.

2. Materials and Methods

Ethylene-vinyl acetate sheets (Sports Mouthguard, 127 × 127 mm, clear; Keystone Dental Inc., Cherry Hill, NJ) with thicknesses of 2.0, 3.0, and 4.0 mm were used. A working model was fabricated using a silicone rubber (Correcsil; 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 gypsum was allowed to harden for 60 min, and then it was removed and trimmed with a model trimmer (MT-6, Morita Co., Tokyo, Japan) to a height of 25 mm at the incisal edge of the maxillary central incisor and to a height of 20 mm at the mesiobuccal cusp of the maxillary first molar [19]-[24]. The model was then dried thoroughly for more than 48 h in an air-conditioned room at approximately 22.0˚C.

Sheets were formed using a vacuum forming machine (Pro-form; T&S Dental & Plastics Co., Inc., Myerstown, PA). The model was placed with its anterior rim positioned 40 mm from the front of the forming table. The following two forming methods were compared: 1) the conventional method, in which the sheet was formed when it sagged 15 mm below the level of the sheet frame at the top of the post under ordinary use (control); and 2) the sheet frame at the top of the post was lowered and the model was covered when the sheet sagged 15 mm, the rear side of the model was pushed forward 20 mm, and the mouthguard was formed (MP). **Figure 1** shows the MP method. The vacuum time was 30 s for both methods. The sheet was cooled for at least 24 h in an air-conditioned room. The sheet was formed after being heated in the forming machine, and a radiation thermometer (CT-2000N, Custom Co., Tokyo, Japan) in the vacuum unit confirmed cooling to room temperature. Six specimens were produced for each condition from one working model [20] [21] [22] [23] [24].

The thicknesses of the fabricated mouthguard sheets were determined using a specialized caliper accurate to 0.1 mm (21-111, YDM Co., Tokyo, Japan) without a spring, so as to prevent distortion during measurement [19]-[24]. Measurement points for the thickness of the incisal portion were defined at the left and right central incisor positions as follows: five equally spaced points from the proximal to the distal end of the incisal edge; and 10 points on the labial surface (including five equally spaced points from the cervical to incisal edge along a line located one-third of the distance from the proximal edge corresponding to the five points along a line located one-third of the distance from the distal edge). Measurement points for the molar portion were defined at the left and right first molars as follows: there were 10 points on the buccal surface, including five equally spaced points from the cervical bulge to the tip of the cusp along a line located one-third of the distance from the proximal end corresponding to the five points along a line located one-third of the distance from the distal end (**Figure 2**) [9] [10] [13] [21] [22] [23] [24] [25]. Measurements were performed once for each specimen.

IBM SPSS 24.0 software (SPSS Japan Inc., Tokyo, Japan) was used for statistical analysis. The Shapiro-Wilk test for normality of distribution and Levene's test for homogeneity of variance were used to analyze the distribution of thickness after formation for each method and the sheet material thicknesses. Normality and equality of variance were found for each item. The data were analyzed by two-way analysis of variance (ANOVA) and Bonferroni's multiple comparison tests. Significance was set to $p < 0.05$, and the power was set to 0.8 for all analyses. Overall, a significant difference was considered to be present when both items were satisfied [20] [21] [22] [23] [24].

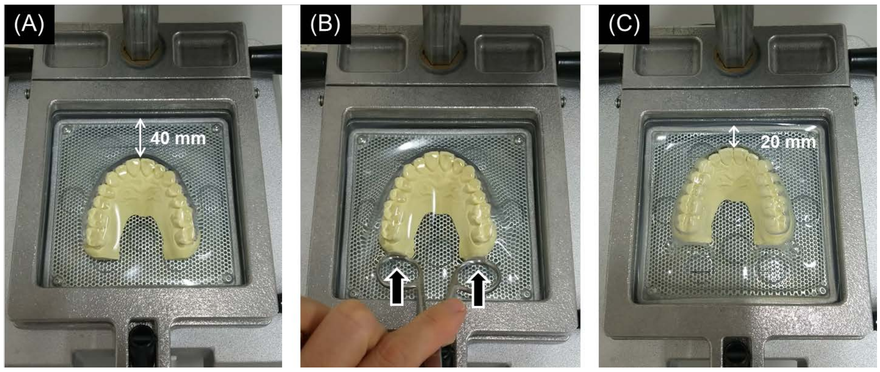


Figure 1. The MP method. (A) The sheet frame at the top of the post was lowered and the sheet covered the model when the sheet sagged by 15 mm; (B) The rear side of the model was pushed forward 20 mm; (C) The vacuum switch was turned on to form the sheet.

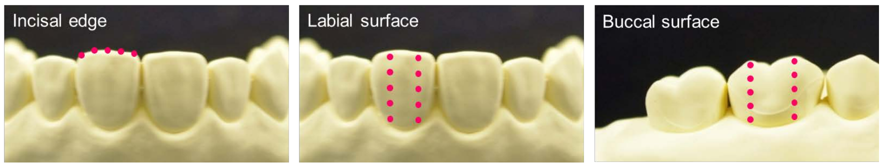


Figure 2. Measurement points for the mouthguard thickness corresponding to the model.

3. Results and Discussion

Two-way ANOVA results for the difference in the reduction of mouthguard thickness are summarized in Table 1. At all measurement points, the main effects of the forming method and sheet thickness were significant, and their interaction was also significant. Based on the results, simple main effect tests were performed prior to multiple comparisons among levels.

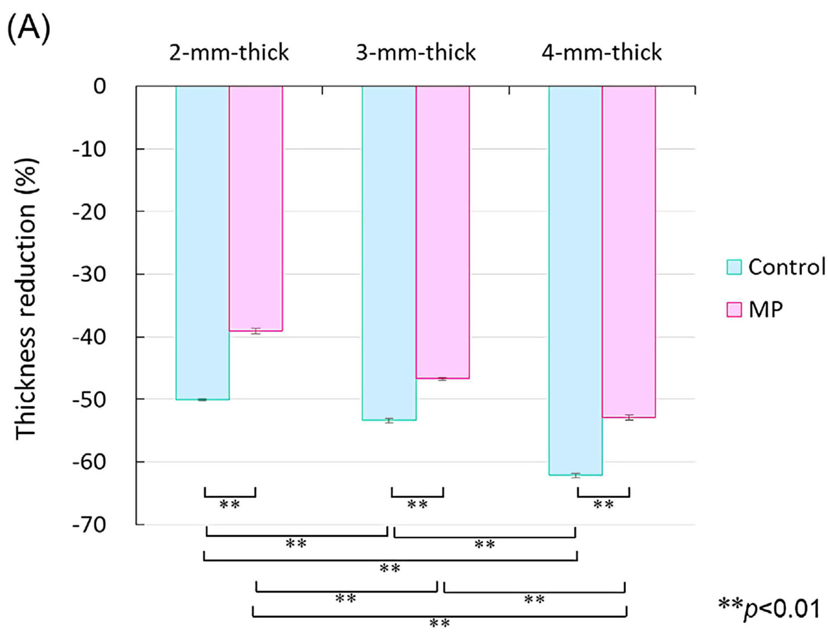
Multiple comparison test results are shown in Figure 3. The reduction in thickness after formation was significantly lower for the MP method than the control method at all measurement points ($p < 0.01$). The difference in the thickness after forming due to the sheet material thickness depended on the forming method and measurement points. In the control method, the reduction in thickness increased as the sheet thickness increased at all measurement points. In contrast, in the MP method the reduction in thickness increased as the thickness of the sheet increased on the incisal edge and buccal surface but sheet thickness had no effect on the labial surface. The reduction in thickness for the labial side in the MP method was only about half that of the control.

Custom mouthguards are fabricated by flasking, injection molding, or thermoforming [26] [27] [28] [29]. Flasking and injection molding are superior because they produce mouthguards with an appropriate thickness. However, thermoforming has the advantage that the fabrication process is simple and mouthguards can be fabricated without additional time-consuming processes and technical skills [13] [24] [26]. Vacuum-forming devices and pressure-molding devices are used for thermoforming, and devices with various functions, such as semi-automatic operation and the ability to create indentations in the occlusal surface, are being developed [26] [30] [31]. Accordingly, many researchers and clinicians use forming devices for mouthguard fabrication [22] [26] [32]-[37]. However, because the reduction in thickness after formation can be as much as 35% - 60%, it is difficult to obtain sufficient thickness with a single thermo-formed layer [5] [23] [24] [32] [33] [34] [38]. This has led to the investigation of

Table 1. Results of two-way ANOVA for thickness after formation.

Source	*df*	SS	MS	*F* value	*p* value
Incisal edge					
Forming condition (A)	1	731.703	731.703	1859.473	<0.001**
Sheet thickness (B)	2	1021.736	510.868	1298.266	<0.001**
A*B	2	29.360	14.680	37.306	<0.001**
Error	30	11.805	0.394		
Labial surface					
Forming condition (A)	1	5150.454	5150.454	6815.776	<0.001**
Sheet thickness (B)	2	233.704	116.852	154.634	<0.001**
A*B	2	330.451	165.225	218.648	<0.001**
Error	30	22.670	0.756		
Buccal surface					
Forming condition (A)	1	1690.580	1690.580	2881.398	<0.001**
Sheet thickness (B)	2	384.354	192.177	327.543	<0.001**
A*B	2	15.707	7.854	13.386	<0.001**
Error	30	17.602	0.587		

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



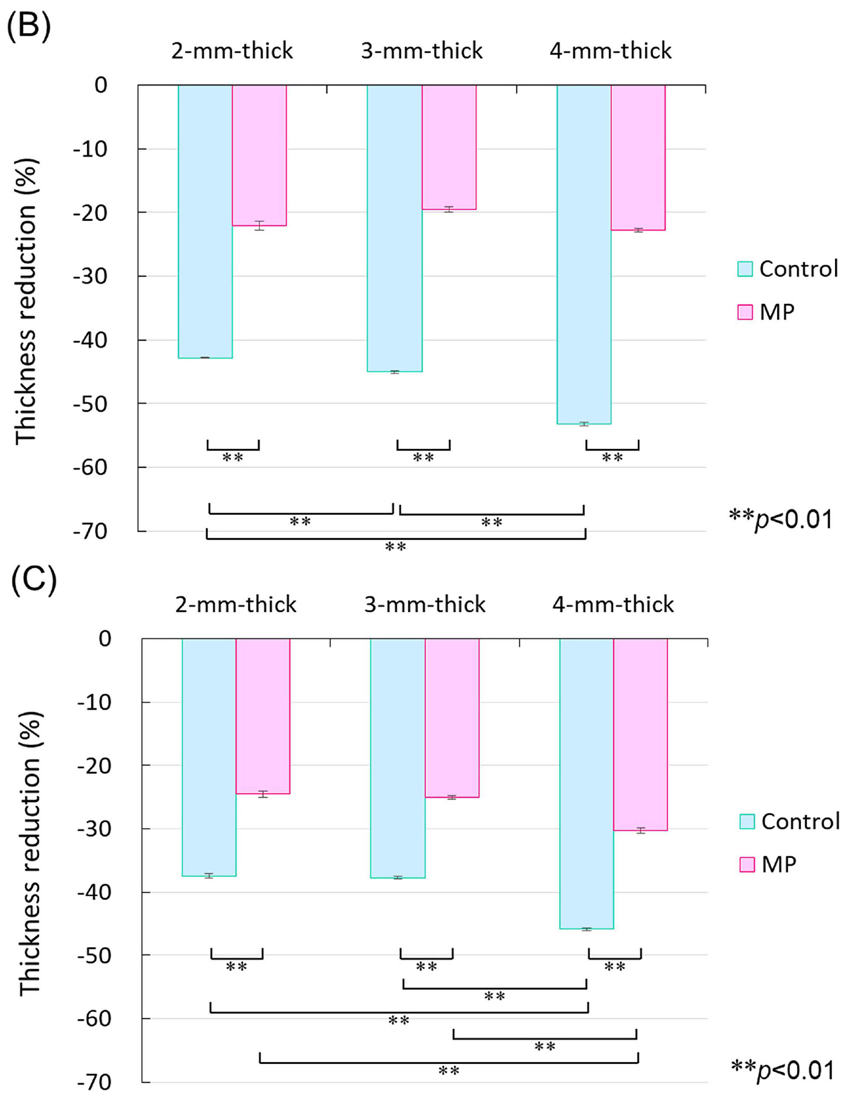


Figure 3. Reduction in mouthguard thickness according to the forming condition and the sheet thickness at measurement points in the incisal portion ((A) incisal edge; and (B) labial surface) and the molar portion ((C) buccal surface). The reduction in thickness was greater for thicker sheets, and the reduction in thickness for the MP method was less than that for the control method. The reduction in labial for the MP method was an exception; the sheet thickness did not affect the reduction in thickness.

fabrication methods for mouthguards that do not affect mouthguard fit and can control mouthguard thickness during thermoforming. The MP thermoforming method controls thickness by moving the model position just before forming [26]. Therefore, we investigated the feasibility of applying the MP technique by examining the forming conditions [15] [17] [18]. The thickness of the mouthguard sheet is reduced during model formation because the sheet is three-dimensionally stretched along the model form. If the length of the original sheet is insufficient for the amount of deformation of the sheet (*i.e.*, the sum of the distance from the model rim to the sheet frame and the model height), the mouthguard thickness will decrease [24] [39]. In the MP technique, the thickness of the labial surface and the buccal surface were maintained by suppressing the stretching of the sheet during model formation [15] [17] [18]. In contrast, the palate side, which affects the feeling of wearing mouthguards, became thinner [17]. We furthermore examined the effect of changing the distance the model moved and found that moving the model a distance of more than 20 mm was most effective at preserving thickness [17]. And, the pressure molding machine achieved the same thickness as the vacuum forming machine [17]. From these, it was inferred that this thermoforming method could be obtained with a sufficient thickness with a single layer. This method can greatly reduce fabrication time and cost compared with laminated mouthguards. Moreover, it is expect that the method will allow high-quality mouthguards to be provided to athletes quickly. In the present study, the difference in the reduction of mouthguard thickness after vacuum forming was examined depending on the sheet material thickness using the MP technique. The results of this study showed that preserving thickness will be a criterion for the application of single-layer and laminated mouthguards and for selecting mouthguard materials.

The results of this study showed that reduction in thickness tended to increase as the thickness of the sheet increased in the control. In general, the reduction in sheet thickness is greater for thin sheets [19]. However, the reduction in thickness after formation is strongly affected by the position of the model on the forming table; when the distance from the model rim to the sheet frame is large, the reduction in thickness tends to be greater for thick sheets than for thin sheets [39]. In this study, the distance from the sheet frame to the front edge of the model was 40 mm. Thus, as in the previous study [39], the thick sheet showed a greater reduction in thickness when using the control method. In contrast, for the MP method, the reduction in mouthguard thickness due to sheet thickness varied according to the measurement point. At the incisal edge and buccal surface, the reduction in thickness increased as the thickness of the sheet increased, as in the control. However, on the labial surface, the thickness of the sheet material did not affect the thickness of the mouthguard. This result would have arisen from the model form. The incisal portion is the highest part of the model and is the first point of contact with the softened sheet. Because the softened sheet starts to thin from the point of contact with the model [23], the reduction in thickness was larger than the other measurement points for the control and MP methods, and the difference between the methods was small. The buccal side is not easily affected by the forming method because the model form is low and wide [19]. Thus, the effect of the sheet material thickness on the buccal surface was the smallest for the control method, and smaller than at the incisal edge for the MP method. In the MP method, the softened sheet makes contact with the labial surface of the model without stretching and is then vacuum formed, thereby suppressing any reduction in thickness during model formation. Therefore, the effect of the sheet material thickness can be considered small.

The results of this study suggest that moving the model position just before vacuum formation suppressed the reduction in mouthguard thickness. In particular, the decrease in the labial side thickness was half or less (about 20% of the original sheet) that for the conventional method, regardless of sheet thickness. The target mouthguard thickness could be achieved more reliably by applying the MP method using a 3-mm-thick sheet compared with the conventional forming method using a 4-mm-thick sheet. Furthermore, the MP method using a 4-mm-thick sheet provided a sufficient thickness with only a single layer. In summary, the results show that the MP forming method is a simple, effective method for achieving sufficient mouthguard thickness. In future work, the relationship between the moving distance of the model and the height of the model should be investigated.

4. Conclusion

The thermoforming method of moving the model forward just before vacuum formation suppressed the reduction in mouthguard thickness, which decreases reduction in thickness of the labial side by about half compared with the conventional thermoforming method regardless of the thickness of the mouthguard sheet.

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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