Materials Sciences and Applications, 2023, 14, 325-335
https://www.scirp.org/journal/msa
ISSN Online: 2153-1188
ISSN Print: 2153-117X

Effect of Molding Technique That Move Model Position Just before Formation in Production of Laminated Mouthguard

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How to cite this paper: Takahashi, M. and Bando, Y. (2023) Effect of Molding Technique That Move Model Position Just before Formation in Production of Laminated Mouthguard. *Materials Sciences and Applications*, **14**, 325-335.
https://doi.org/10.4236/msa.2023.146020

Received: May 1, 2023
Accepted: June 12, 2023
Published: June 15, 2023

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Abstract

Many molding techniques have been researched to ensure the thickness of custom mouthguards. The aim of this study was to clarify the effect on the thickness of a laminated mouthguard of a molding technique in which the model position is moved forward just before molding. Mouthguards were molded using a 3.0-mm-thick ethylene vinyl acetate mouthguard sheet and a pressure molding machine. The molding method was the normal molding method (condition C) and the molding technique (condition MP) in which the model position was moved 20 mm forward just before molding. Regarding the molding of the first layer (F) and the second layer (S), the following four molding methods based on the combination of conditions C and MP were compared; FC-SC, FC-SMP, FMP-SC, and FMP-SMP. Differences in mouthguard thickness due to molding conditions for the first and second layers were analyzed by two-way ANOVA and Bonferroni's multiple comparison test. Significant differences were observed among all molding conditions on the labial surface, and the thicknesses were in the order FC-SC < FC-SMP < FMP-SC < FMP-SMP. FMP-SMP was 4.67 mm thick, which was 1.39 mm thicker than FC-SC. FC-SC was the thinnest at the cusp, and a significant difference was observed between other molding conditions. On the buccal side, significant differences were observed between all conditions except FC-SMP and FMP-SC, and the thicknesses were in the order FC-SC < FC-SMP, FMP-SC < FMP-SMP. The results of this study suggested that the labial and buccal sides of laminated mouthguards could be made 1.4 and 1.2 times thicker when a molding technique that moves the model position just before formation was used for the first and second layers. The reduction in thickness was suppressed by approximately 23.2% and approximately 10.7% on the labial and buccal sides, respectively, compared with the normal molding method.

Keywords

Laminated Mouthguard, Thermoforming, Molding Technique, Thickness

1. Introduction

Mouthguards are an oral appliance worn to prevent or reduce maxillofacial trauma during sports [1] [2] [3] [4]. The effectiveness of mouthguards depends mainly on their thickness, shock absorption capacity, and conformability [1] [2] [4]. Custom mouthguards are highly adaptable, can be adjusted to any thickness, and their impact absorption capacity can be tailored by the materials used. It is now possible to use 3D printers to increase the thickness of any part of the mouthguard [5]. However, the equipment is expensive, and thermoforming remains the main method for fabricating mouthguards.

The greatest problem with using thermoforming to fabricate mouthguards is the reduction in the thickness after molding. The softened thermoplastic elastomer is pressed against the uneven working model and partially stretched, resulting in a significant reduction in thickness from the original thickness [6] [7] [8]. The decrease in the thickness of the anterior teeth of the mouthguard is particularly pronounced, and it is difficult to secure the thickness of 3 - 4 mm required for shock absorption with a single sheet [6] [7] [8] [9] [10]. To address this problem, a new molding method is needed [9] [10] [11] [12] [13] or a laminated mouthguard should be used [9] [14] [15]. The thickness of a thermoformed mouthguard is affected by the type of molding machine, the thickness and color of the sheet material, the heating condition of the sheet, and the shape of the model [9] [11] [16] [17] [18]. However, most of this information is on single sheets, and there are few reports on laminated mouthguards [15] [19] [20] [21]. For laminated mouthguards, the shape change of the sheet that is pressed as the second layer is less than that of the first layer and is almost uniform [15] [19] [21]. The extrusion direction of the sheet also affects the thickness [19]. For example, when fabricating a laminated mouthguard using two 3-mm sheets, if the extrusion direction of the sheet is formed perpendicular to the model midline, the labial side of the mouthguard can reach a thickness of 3 mm or more, whereas the thickness is less than 3 mm if the extrusion direction is not considered. In addition, when the model height increases by 5 or 10 mm, the thickness of the labial and buccal sides of the laminated mouthguard can decrease by ≥6% and ≥14%, respectively [20]. Thus, even if a laminated mouthguard is selected, it is often difficult to achieve the thickness required for shock absorption by using a normal molding method.

The purpose of this study was to clarify the effect on the thickness of a laminated mouthguard of a molding technique in which the model position is moved forward just before molding. The null hypothesis was that the thickness of the laminated mouthguard was not affected by the molding method.

2. Materials and Methods

The material is an ethylene vinyl acetate resin mouthguard sheet (Sports Mouthguard, Keystone Dental Inc., Cherry Hill, NJ; circular diameter 120 mm, clear). A pressure molding machine (Model Capture Try, Shofu Inc., Kyoto, Japan) was used for molding. A working model was fabricated using a silicone rubber (Correcsil, Yamahachi Dental Mfg. Co., Aichi, Japan) impression of 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 [12] [19] [20] [21].

The working model was trimmed to a height of 25 mm at the incisal edge of the maxillary central incisor and 20 mm at the mesial buccal cusp of the maxillary first molar [12] [19] [20] [21]. The model was coated with a separation agent (at varnish TF; Shofu Inc.) [10] [11] [17] [18] [19] [20] [21]. The model position was set so that the front edge of the model was 40 mm from the leading edge of the forming table.

The two molding methods were as follows. 1) The sheet was molded when the sheet sagged 15 mm from the sheet frame under ordinary use (condition C). 2) The sheet frame was lowered when the sheet sagged 15 mm, and then the rear side of the model was pushed to move it forward 20 mm and the sheet was molded (condition MP) (**Figure 1**).

The four molding conditions were as follows. 1) Both the first and second layers were molded under condition C (FC-SC). 2) The first layer was molded under condition C and the second layer was molded under condition MP (FC-SMP). 3) The first layer was molded under condition MP and the second layer was molded

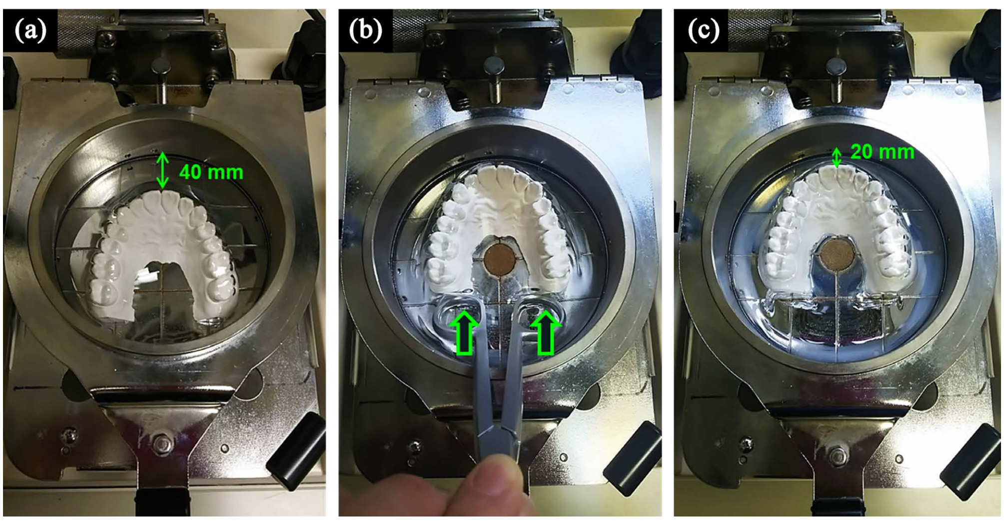

Figure 1. MP molding method (condition MP). The sheet frame was lowered when the sheet sagged 15 mm, and then the rear side of the model was pushed to move it forward 20 mm and the sheet was molded.

under condition C (FMP-SC). 4) Both the first and second layers were molded under condition MP (FMP-SMP). The first layer was trimmed to cover the labial side and incisal edges of the anterior regions, and the buccal and occlusal surfaces of the posterior regions (**Figure 2**) [9] [19] [20] [21]. The molding operation was performed according to the manufacturer's instructions with a pressurization time of 10 min. Six samples were prepared for each condition and one model was used for molding.

The thickness of the mouthguard sheet was measured using a specialized caliper without a spring (21 - 111, YDM Co., Tokyo, Japan), which can measure up to 1/10mm [8] [10] [12] [18] [19] [20] [21]. The measurement sites were the labial surface, the cusp, and the buccal surface (**Figure 3**). Measurement was performed once for each sample.

Statistical analysis software (IBM SPSS 24.0, SPSS Japan Inc., Tokyo, Japan) was used for statistical processing. The Shapiro-Wilk test for normality and Levene's test for homoscedasticity were used for all measurements. Normality and homoscedasticity were shown for each item. First, the differences in the thickness of the first layer mouthguard due to the molding method were compared using Student's t-test. Subsequently, the differences in mouthguard thickness due to molding conditions for the first and second layers were analyzed by two-way analysis of variance and Bonferroni's multiple comparison test. All

Figure 2. Molding and trimming of the first-layer sheet. The first layer was trimmed to cover the labial side and incisal edges of the anterior regions, and the buccal and occlusal surfaces of the posterior regions.

Figure 3. Measurement points for the mouthguard thickness on the corresponding parts of the model. Anterior portion were defined each 10 points on the labial surface at the left and right central incisors. Posterior portion were defined four points on the cusp and 10 points on the buccal surface at the left and right first molars. (a) Labial surface, (b) Cusp, (c) Buccal surface.

analyses were performed with a significance level of 5% and a detection power of 80%, and differences were considered significant when both were satisfied. The sample size with a power of 80% or more was calculated using the formula $n = (1571/(100 \times d^2)) + 1$, where n is the sample size and d is the effect size. The sample size was determined to be six.

3. Results and Discussion

Figure 4 shows a comparison of the thickness of the first layer mouthguard for different molding conditions. A significant difference was observed on the labial and buccal surfaces, and the thicknesses were greater for condition MP than for condition C ($P < 0.01$). The thicknesses for condition MP were approximately 1.4 and 1.2 times greater on the labial and buccal surfaces, respectively, than those of condition C. The thickness at the cusp for condition MP was significantly greater than that for condition C ($P < 0.05$), but the difference was only approximately 1.1 times.

Table 1 shows the results of a two-way analysis of variance of the thickness of the laminated mouthguard according to the molding conditions of the first and second layers. The main effects of the first and second layers were significant for the labial surface. The main effects and interactions of the first and second layers were significant for the cusps and buccal surface. Based on the results, a simple main effect test was performed using the Bonferroni method.

Figure 5(a) shows a comparison of the thickness of the labial surface of the laminated mouthguard for the different molding conditions for the first and

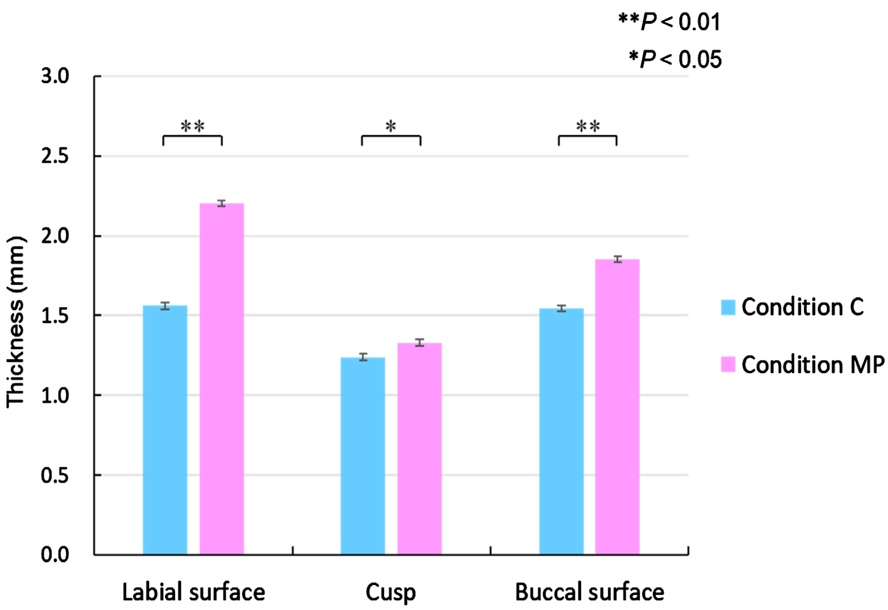

Figure 4. Comparison of the mouthguard thicknesses obtained with different forming methods for the first-layer sheet. Measurements are expressed as mean value ± SD. Condition C; normal molding method, Condition MP; molding technique in which the model position was moved forward just before molding. $^{**}P < 0.01$, $^{*}P < 0.05$: denotes statistically significant difference by the Student's t-test.

Table 1. Results of two-way ANOVA for the thickness of laminated mouthguard due to the molding condition.

Source	*df*	SS	*F*-value	*P*-value
Labial surface				
First layer (A)	1	3.604	8754.049	<0.001**
Second layer (B)	1	1.771	4302.672	<0.001**
A × B	1	0.001	3.279	0.085
Error	20	0.000		
Cusp				
First layer (A)	1	0.168	657.997	<0.001**
Second layer (B)	1	0.093	361.580	<0.001**
A × B	1	0.021	82.101	<0.001**
Error	20	0.000		
Buccal surface				
First layer (A)	1	0.697	2706.812	<0.001**
Second layer (B)	1	0.549	2132.184	<0.001**
A × B	1	0.010	38.851	<0.001**
Error	20	0.000		

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

second layers. A significant difference was observed among all molding conditions, and the thicknesses were in the order FC-SC < FC-SMP < FMP-SC < FMP-SMP ($P < 0.01$). The thickness for FMP-SMP was approximately 1.39, 0.76, and 0.53 mm greater than those of FC-SC, FC-SMP, and FMP-SC, respectively. The corresponding suppression rates of thickness reduction were approximately 23.2%, 12.7%, and 8.8%, respectively.

Figure 5(b) shows the results of a simple main effect test on the thickness of the cusp of the laminated mouthguard according to the molding conditions of the first and second layers. Significant differences were observed between FC-SC and FC-SMP, FMP-SC, and FMP-SMP, and the thicknesses of FC-SMP, FMP-SC, and FMP-SMP were greater than that of FC-SC ($P < 0.01$). No significant difference was observed among FC-SMP, FMP-SC, and FMP-SMP. The suppression rates of thickness reduction of FC-SMP, FMP-SC, and FMP-SMP were less than about 5.2%compared with FC-SC.

Figure 5(c) shows the results of a simple main effect test on the thickness of the buccal surface of the laminated mouthguard according to the molding conditions of the first and second layers. A significant difference was observed between all molding conditions except between FC-SMP and FMP-SC ($P < 0.01$). The thickness for FMP-SMP was approximately 0.64, 0.30, and 0.26 mm greater

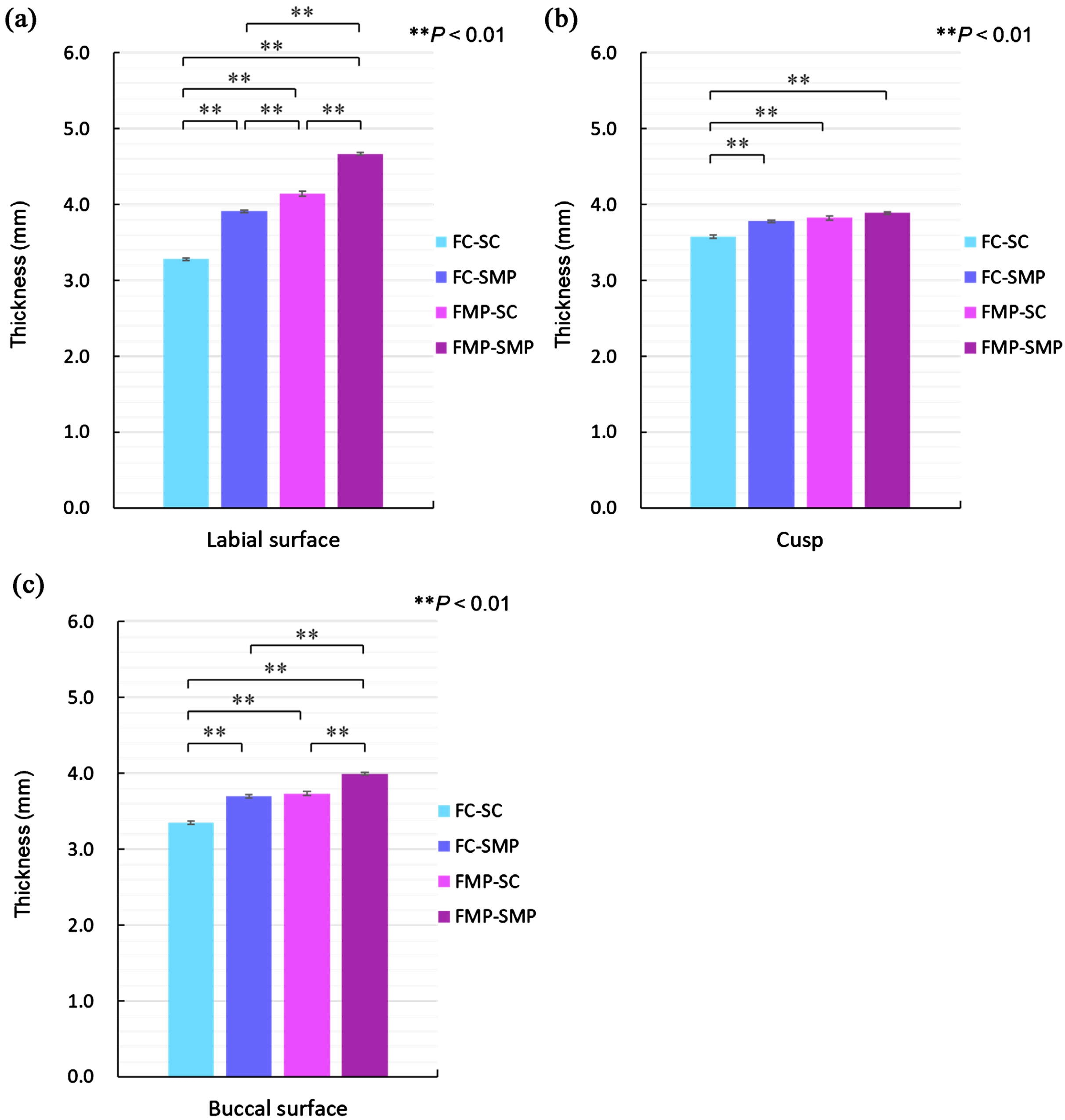

Figure 5. Effect of molding conditions for the first and second layers on the thickness of laminated mouthguards. Measurements are expressed as mean value ± SD. $**P < 0.01$: denotes statistically significant difference. (a) Labial surface, (b) Cusp, (c) Buccal surface.

than those of FC-SC, FC-SMP, and FMP-SC, respectively. The corresponding suppression rates of thickness reduction were approximately 10.7%, 5.0%, and 4.4%, respectively.

The results of this study showed that the thickness of the laminated mouthguard was affected by the molding method. Compared with the normal molding method, the reduction in thickness was suppressed significantly by using the molding technique in which the model position is moved just before formation for only the first layer, only the second layer, or both first and second layers.

Therefore, the null hypothesis was rejected.

Mouthguards should have a thickness of approximately 3 - 4 mm in order to protect the oral region from excessive external forces that occur during sports [22] [23]. Because the thickness of mouthguards is directly proportional to their ability to protect facial tissues from injury [1] [2], some sports require thicker oral appliances. Laminated mouthguards are an effective type of mouthguard that can prevent injuries because they can provide an appropriate thickness based on the needs of the athlete and the characteristics of their mouth [9] [14] [15]. The molding technique for thermoforming mouthguards in which the model is moved forward has been examined in order to determine how to suppress the reduction in thickness of the sheet material during molding [9] [12] [13]. In this method, a thickness of 3 mm or more can be achieved on the labial side of the mouthguard by molding a single sheet with a thickness of 4.0 mm only when all of the following conditions are satisfied: the model height does not exceed 25 mm; there is no undercut on the model labial side; and the extrusion direction of the sheet is perpendicular to the midline of the model. However, in actual clinical practice, there are many cases in which these conditions cannot be met, so laminate mouthguards are often selected.

In the present study, the thickness of the sheet after molding of the first layer was significantly thicker under condition MP at all measurement sites. This result was similar to previous studies in which the MP method was investigated [12] [13]. In this method, the sheet is flexed by moving the model forward before molding, and the tensile stress of the sheet during pressure welding is relieved, so it possible to increase the thickness of the molded body. When the softened sheet was placed over the model, the sheet stretched more on the convex part of the model [9], and thus the effect of the MP method on the thickness of the cusp was smaller than that on the outside of the model (labial and buccal surfaces).

There were significant differences in the thickness of the labial side of the laminated mouthguard among all conditions, and the MP method was effective in suppressing the decrease in mouthguard thickness. When the second layer is pressure-welded, there are fewer parts that are partially extended compared with the first layer [19], and thus the thickness obtained with the FMP-SC molding conditions was likely to be significantly greater than that obtained with the FC-SMP molding conditions. Therefore, the differences in thickness of laminated mouthguards fabricated under these conditions may reflect the differences in thickness of the first layer. This trend is similar to the previous study [19] that investigated the effects of the extrusion direction of the sheet in the production of laminated mouthguards. The present results suggest that it may be possible to increase the labial thickness of laminated mouthguards by applying the MP method to only the first layer, only the second layer, and both the first and second layers. The thickness was increased by approximately 1.3 times (approximately 4.14 mm thick), 1.2 times (approximately 3.91 mm thick), and 1.4 times (approximately 4.67 mm thick), respectively, compared with the ordinary molding method.

The thickness of the cusp of the laminated mouthguard obtained under FC-SC molding conditions was significantly thinner than that obtained under other molding conditions. The cusp is a convex part of the model, and thus the thickness of the first layer is greatly reduced. However, because the convex part of the model is covered by the pressure welding of the first layer creating a smoother form, the shape change of the second layer is less than that of the first [19]. In the present study, the cusp thickness of FC-SC was significantly thinner than that under other conditions, which may reflect the difference in the decrease in the thickness of the first layer. No significant difference was observed among the three conditions in which the MP method was applied, possibly because the cusp is less affected by the relaxation of the tensile stress of the sheet, which decreases as the model moves forward.

Differences in the thickness on the buccal side of the laminated mouthguard due to molding conditions were similar to those on the labial side, but no significant difference was observed between the FC-SMP and FMP-SC conditions. This was because the height of the model on the buccal side was lower than that on the labial side, and the surface was not perpendicular to the moving direction of the model. For athletes who need the buccal side of the mouthguard to be thicker, a thickness of approximately 4.00 mm (approximately 1.2 times that of the normal molding method) can be achieved by applying the MP method for both the first and second layers. In other words, the molding method should be selected according to the athlete's competition and event.

4. Conclusions

This study was investigated to clarify the effect on the thickness of a laminated mouthguard of a molding technique in which the model position is moved forward just before molding, and the following results were obtained.

1) The labial and buccal sides of laminated mouthguards could be made 1.4 and 1.2 times thicker when this molding technique was used for the first and second layers, compared with the normal molding method.

2) The reduction in thickness was suppressed by approximately 23.2% and approximately 10.7% on the labial and buccal sides, respectively, when this molding technique was used for the first and second layers, compared with the normal molding method.

3) When this molding technology was applied only to the second layer, compared to the case where this molding technology was applied to both the first and second layers, the suppression rate of thickness reduction was about half (approximately 12.7% on the labial side and approximately 5.0% on the buccal side).

This information is important for predicting the thickness of mouthguards after molding and selecting the fabrication equipment and molding method. In the future, the shape change of the thermoplastic sheet due to the molding method should be investigated in order to obtain knowledge that will assist in the design of laminated mouthguards.

Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

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