Materials Sciences and Applications, 2022, 13, 469-478
https://www.scirp.org/journal/msa
ISSN Online: 2153-1188
ISSN Print: 2153-117X

Dependence of Thermoformed Mouthguard Thickness on Model Height in Single-Layer and Laminated Mouthguards

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How to cite this paper: Takahashi, M. and Bando, Y. (2022) Dependence of Thermoformed Mouthguard Thickness on Model Height in Single-Layer and Laminated Mouthguards. *Materials Sciences and Applications*, **13**, 469-478.
https://doi.org/10.4236/msa.2022.138028

Received: June 30, 2022
Accepted: July 25, 2022
Published: July 28, 2022

Abstract

The height of the working model affects the mouthguard thickness. The aim of this study was to clarify the difference in the effect of model height on the thickness between single- and double-layered mouthguards. Mouthguards were thermoformed using ethylene-vinyl-acetate sheets and a pressure molding machine. Working models were three hard gypsum models with the height of the anterior part trimmed to 25 mm (model A), 30 mm (model B), and 35 mm (model C). Three molding conditions were compared: a single-layered mouthguard using a 4.0-mm thick-sheet (S4); a double-layered mouthguard using a 3.0-mm-thick sheet on the first-layer and a 2.0-mm-thick sheet on the second-layer (L32); and a double-layered mouthguard using 3.0-mm-thick sheets on first- and second-layers (L33). Analysis was performed by two-way ANOVA and a simple main effect test for the differences in the mouthguard thickness depending on the model height and the molding condition. Under all molding conditions, the labial and buccal thicknesses tended to become thinner as the model height increased, and models B and C were thinner by about 6% - 7% and about 14% - 16% than model A, respectively. The cusp thickness was not affected by the model height in L32 and L33, but in S4, models B and C were thinner about 14% or more than model A. Significant differences were observed among molding conditions, and S4 < L32 < L33 in all models ($P < 0.01$). This study suggested that the degree of the decrease in mouthguard thickness due to the increase the model height was similar for the single- and double-layered mouthguards on the labial and buccal sides, and increasing the model height by 5 mm and 10 mm decreased the thickness by about 6% - 7% and about 14% - 16%, respectively. At the cusp, only the single-layered mouthguard was affected by the model height.

Keywords

Mouthguard, Thermoforming, Thickness, Working Model

1. Introduction

Mouthguards are worn to prevent or reduce trauma to the stomatognathic and facial areas during sports [1] [2] [3] [4], and their effect depends on factors including the thickness, impact absorption capacity, and fit [1] [2] [4]. Thermoforming is a simple production method for custom-made mouthguards and is often chosen by clinicians. However, the thickness of the thermoformed mouthguard is substantially less than the original sheet thickness [5] [6] [7]. Therefore, a laminated mouthguard is recommended to achieve the desired protective effect [8] [9] [10].

To predict the thickness after molding, it is necessary to understand the effect of factors, including the characteristics of the molding device, the shape change of the sheet during thermoforming, and the effect of the model shape. Most studies on the thickness change of the mouthguard after molding have been on single-layered mouthguards [6] [7] [9], and there are few on laminated mouthguards [10] [11]. The laminated mouthguard thickness may be affected by factors such as the thickness of the sheet material used, the trimming form of the first layer, and the model form. The mouthguard thickness depends on the sheet material thickness used for the first and second layers [10]. In addition, the shape change of the second layer sheet was less than that of the first layer, and it became almost uniform [11]. However, there is insufficient information available to estimate the thickness of the finished product.

The aim of this study was to clarify the difference in the effect of model height on the thickness between single- and double-layered mouthguards. The null hypothesis is that the effect of model height on the thickness of each part of the mouthguard is similar between the single- and double-layered mouthguards.

2. Materials and Methods

Mouthguards were thermoformed using ethylene-vinyl acetate resin sheets (EVA) (Sports Mouthguard, Keystone Dental Inc., Cherry Hill, NJ; circular diameter 120 mm, clear) and a pressure molding machine (Model Capture, Shofu Inc., Kyoto, Japan). A working model was fabricated using a silicone rubber (Correcsil, Yamahachi Dental Mfg. Co., Aichi, Japan) impression taken 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]. The gypsum model was trimmed using a model trimmer (MT-6, Morita Co., Tokyo, Japan) to obtain the following three models: model A, with a height of 25 mm at the incisal edge of the maxillary central incisor and a height of 20 mm at the mesiobuccal cusp of the maxillary first molar; model B, with heights 5 mm greater than model A; and model C, with heights 10 mm greater than model A (**Figure 1**) [12]. All models were dried thoroughly for more than 48 h in an air-conditioned room, and then coated with a separating agent (at varnish TF, Shofu Inc.) [13] [14]. The following three molding conditions were compared: condition S4, in which a single-layered mouthguard was molded from a 4.0-mm-thick sheet; condition L32, in which a double-layered mouthguard was formed with a 3.0-mm-thick sheet molded on the first layer and a 2.0-mm-thick sheet molded on the second layer; and condition L33, in which a double-layered mouthguard was formed with 3.0-mm-thick sheet molded on the first and second layers. The first-layer sheets for conditions L32 and L33 were trimmed so that the labial side of the anterior teeth covered the alveolar part, the buccal side of the molars covered the cervical region, and the palatal side covered the incisal edge and the occlusal surface (**Figure 2**) [9]. The molding operation was performed according to the manufacturer's instructions. The pressure level was 0.3 MPa. During the sheet heating, the sheet surface temperature was measured with a radiation thermometer (CT-2000N, Custom Co., Tokyo, Japan) [9] [15] [16], and the sheet frame was lowered and covered the model when the temperature reached 100˚C. Subsequently, the pressure chamber was closed and pressure molding was performed. The pressurization time was 10 min. A total of 54 mouthguards (3 model heights × 3 molding conditions × 6 repetitions) were thermoformed.

To measure the mouthguard thickness, a specialized caliper without a spring (21-111, YDM Co., Tokyo, Japan) able to measure up to 0.1 mm was used [7] [12] [13] [14]. The mouthguard was cut, and the thickness of each section (labial surface, cusp, and buccal surface) was measured (**Figure 3**). The measurement was performed once for each sample.

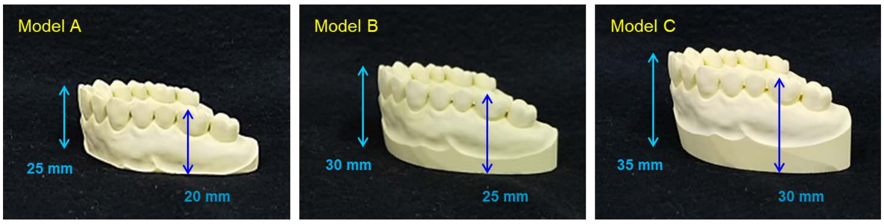


Figure 1. Working model. Model A, with a height of 25 mm at the incisal edge of the maxillary central incisor and a height of 20 mm at the mesiobuccal cusp of the maxillary first molar; model B, with heights 5 mm greater than model A; and model C, with heights 10 mm greater than model A.

Figure 2. Molding and trimming of the first-layer sheet.

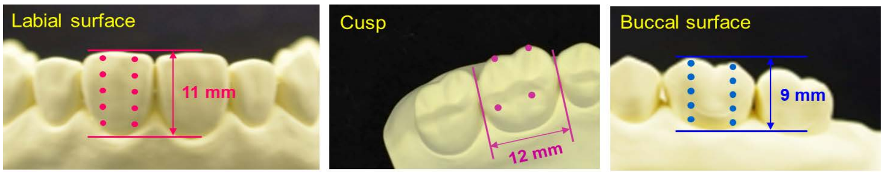


Figure 3. Measurement points for the mouthguard thickness corresponding to the model (20 points on the labial surface, 8 points at the cusp, and 20 points on the buccal surface).

Statistical analysis software (IBM SPSS 24.0, SPSS Japan Inc., Tokyo, Japan) was used for statistical processing. For all measured values, the Shapiro-Wilk test was used for the normality test, and Levene's test was used for the homoscedasticity test. Because normality and homoscedasticity were observed for each item, analysis was performed by two-way analysis of variance (ANOVA) and simple main effect test (the Bonferroni method) for the differences in the mouthguard thickness depending on the model height and the molding condition. All 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

Table 1 shows the results of two-way ANOVA for the mouthguard thickness according to the model height and molding condition. At all measurement points, the main effects of the model height and molding condition were significant, and their interaction was also significant. Based on the results, simple main effect tests were performed by the Bonferroni method.

Figure 4 shows the results of the simple main effect test for the differences in the mouthguard thickness depending on the molding conditions. Significant differences were observed among molding conditions at all measurement points, and the differences were in the order of conditions S4 < L32 < L33 in all models ($P < 0.01$).

Figure 5 shows the results of a simple main effect test for the labial mouthguard thickness according to the model height. In addition, a data table of the reduction rate of models B and C with respect to the thickness of model A is shown. The difference in thickness depending on the model height was significantly different among all conditions, except between models A and B for condition S4, and the thickness decreased as the model height increased ($P < 0.01$, $P < 0.05$). The thickness of model B was reduced by about 0.14 mm for conditions S4 and 0.20 mm for conditions L32 and L33 compared with model A, and the thickness reduction rate of model B with respect to model A was about 6% - 7% under all molding conditions. The thickness of model C was reduced by about 0.30 mm for condition S4, about 0.45 mm for condition L32, and about 0.50 mm for condition L33 compared with model A, and the thickness reduction rate of model C with respect to model A was about 15% - 16% under all molding conditions.

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

Source	*df*	SS	MS	*F*-value	*P*-value
Labial surface					
Model height (A)	2	2.016	1.008	3388.717	<0.001**
Molding condition (B)	2	11.063	5.531	18598.979	<0.001**
A*B	4	0.158	0.039	132.811	<0.001**
Error	45	0.013	0.000		
Cusp					
Model height (A)	2	0.293	0.146	370.098	<0.001**
Molding condition (B)	2	29.499	14.749	37322.760	<0.001**
A*B	4	0.144	0.036	91.080	<0.001**
Error	45	0.018	0.000		
Buccal surface					
Model height (A)	2	1.349	0.675	2863.781	<0.001**
Molding condition (B)	2	9.058	4.529	19227.296	<0.001**
A*B	4	0.058	0.014	61.529	<0.001**
Error	45	0.011	0.000		

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

Labial surface

Model A	S4	L32	L33
S4			
L32	**		
L33	**	**	

Model B	S4	L32	L33
S4			
L32	**		
L33	**	**	

Model C	S4	L32	L33
S4			
L32	**		
L33	**	**	

**P<.01

Cusp

Model A	S4	L32	L33
S4			
L32	**		
L33	**	**	

Model B	S4	L32	L33
S4			
L32	**		
L33	**	**	

Model C	S4	L32	L33
S4			
L32	**		
L33	**	**	

**P<.01

Buccal surface

Model A	S4	L32	L33
S4			
L32	**		
L33	**	**	

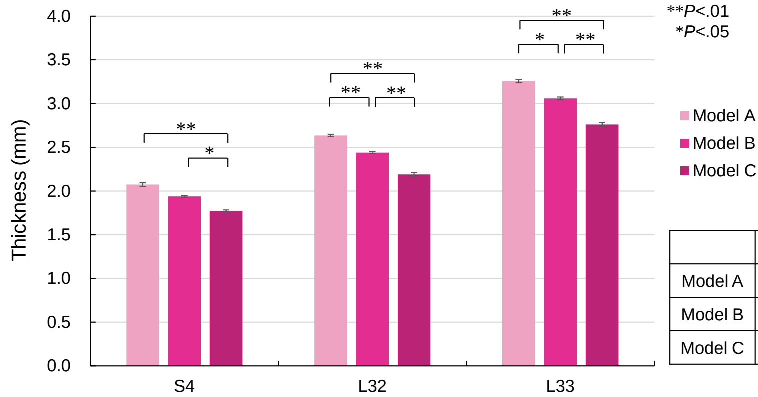
Model B	S4	L32	L33
S4			
L32	**		
L33	**	**	

Model C	S4	L32	L33
S4			
L32	**		
L33	**	**	

**P<.01

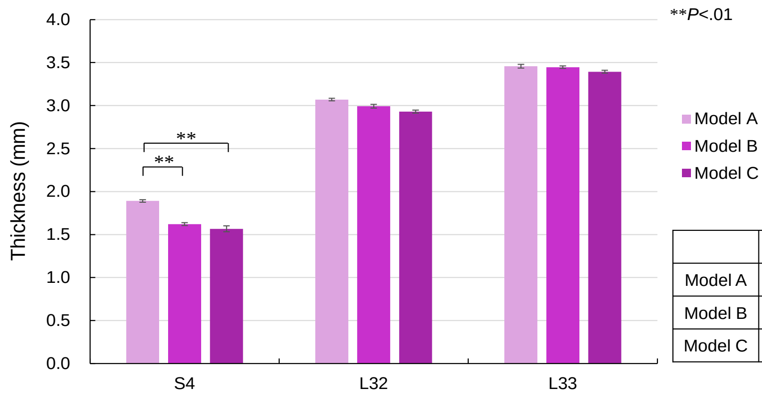
Figure 4. Results of simple main effect tests (the Bonferroni method) according to molding condition for each model.

Figure 6 shows the results of a simple main effect test for the mouthguard thickness at the cusp according to the model height. In addition, a data table of the reduction rate of models B and C with respect to the thickness of model A is shown. The differences in thickness depending on the model height were observed between models A and B and between models A and C for condition S4,



	S4	L32	L33
Model A	—	—	—
Model B	-6.5%	-7.3%	-6.2%
Model C	-14.5%	-15.8%	-15.2%

Figure 5. Mouthguard thickness on the labial surface according to the model height and molding condition, and a data table of the reduction rate of models B and C with respect to the thickness of model A. Measurements are expressed as mean value ± SD.

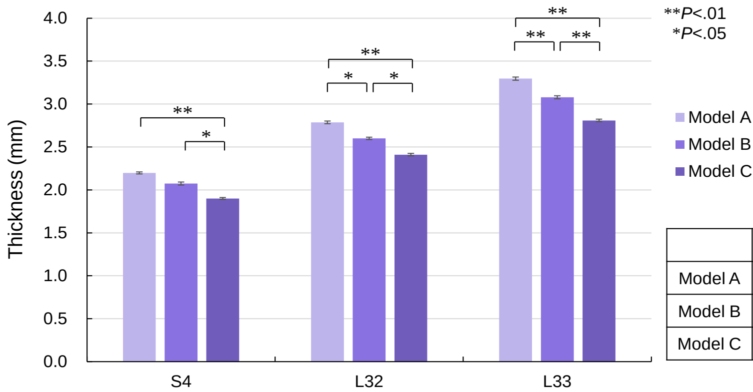


	S4	L32	L33
Model A	—	—	—
Model B	-14.3%	-2.5%	-0.3%
Model C	-17.2%	-3.7%	-1.9%

Figure 6. Mouthguard thickness at the cusp according to the model height and molding condition, and a data table of the reduction rate of models B and C with respect to the thickness of model A. Measurements are expressed as mean value ± SD.

and the thickness decreased significantly as the model height increased ($P < 0.01$). For condition S4, the thicknesses of models B and C decreased by 0.27 mm and 0.33 mm, respectively, compared with model A, and the thickness reduction rates were about 14% and about 17%, respectively. In contrast, there was no significant difference for conditions L32 and L33 depending on the model height, and the thickness reduction rates of models B and C with respect to model A were only a few percent.

Figure 7 shows the results of a simple main effect test for the buccal mouthguard thickness according to the model height. In addition, a data table of the reduction rate of models B and C with respect to the thickness of model A is shown. The difference in thickness depending on the model height was significantly different among all conditions, except for between models A and B for condition S4, and the thickness decreased as the model height increased ($P < 0.01$, $P < 0.05$). The thickness of model B was reduced by about 0.13 mm for condition S4, about 0.19 mm for condition L32, and about 0.22 mm for condition L33 compared with model A, and the thickness reduction rate of model B



	S4	L32	L33
Model A	—	—	—
Model B	-6.0%	-6.7%	-6.6%
Model C	-13.7%	-13.6%	-14.7%

Figure 7. Mouthguard thickness on the buccal surface according to the model height and molding condition, and a data table of the reduction rate of models B and C with respect to the thickness of model A. Measurements are expressed as mean value ± SD.

with respect to model A was about 6% - 7% under all molding conditions. The thickness of model C was reduced by about 0.30 mm for S4, about 0.38 mm for L32, and about 0.49 mm for L33 compared with model A, and the thickness reduction rate of model C with respect to model A was about 14% - 15% under all molding conditions.

Mouthguard thickness is one factor that affects the prevention of sports injuries in the maxillofacial and oral region during sports [1] [2] [4]. Lamination is an effective mouthguard fabrication method for controlling the mouthguard thickness [8] [9] [10], which is crucial for proper shock absorption. In this study, the difference in the effect of the model height on the mouthguard thickness between single- and double-layered mouthguards was investigated. This was expected to clarify by what percentage the mouthguard thickness is reduced according to the model height in the thermoforming of the mouthguard and will help to predict the mouthguard thickness after molding.

For condition S4, a 4.0-mm-thick sheet was used, which is frequently used in single-layered mouthguards [9] [12] [14]. In laminated mouthguards, the shape change of the second-layer sheet pressed against the first-layer sheet is smaller than that of the first-layer sheet [10] [11], so the result may depend on the thickness of the second-layer sheet. Therefore, molding conditions using 2.0- and 3.0-mm-thick sheets were investigated. Because the thickness of the sheet material used under each molding condition was different, the heating condition of the sheet was determined by measuring the surface temperature of the sheet with a radiation thermometer according to previous studies [9] [15] [16]. The sheet was molded when it reached 100˚C, which is the proper softening temperature for EVA sheets [17].

The results from this study show that the effect of the model height on the mouthguard thickness depended on the measurement site. The thickness changes of the single- and double-layered mouthguards due to the increase in the model height were the same on the labial and buccal surfaces but were different on the cusp. Therefore, the null hypothesis was rejected.

The thickness of the mouthguard by thermoforming is affected by the thickness of the original sheet material [9]. That is, the thicker the original sheet, the thicker the mouthguard after molding. The total thickness of the sheet material under each molding condition in this study was 4.0 mm for S4, 5.0 mm for L32, and 6.0 mm for L33. Therefore, a significant difference was observed in the thickness of the mouthguard according to the thickness of the sheet material used, and the differences were in the order of conditions S4 < L32 < L33 in all models.

The labial thickness of the mouthguard tended to decrease as the model height increased under all molding conditions. The degree of the decrease in the thickness due to the increase in the model height was the same for conditions S4, L32, and L33. The reduction rate in the thickness with respect to model A was about 6% - 7% for model B and 15% - 16% for model C. That is, the single- and double-layered mouthguards were similar. If there are undercuts or irregularities on the model, the sheet in these areas is stretched more during pressure welding and tends to become thinner [9] [12] [13] [18]. These areas would be tended to fluctuate depending on molding conditions. In the model form in this study, the labial surface stands upright on the basal plane (*i.e.*, no undercut), and there is almost no unevenness on the surface. Therefore, the reduction rate in the thickness due to the model height was hardly affected by the molding conditions.

Only for condition S4, the mouthguard thickness at the cusp decreased as the model height increased. Because the model at the cusp was convex, the single sheet for condition S4 and the first layer for conditions L32 and L33 would have a larger sheet elongation than the second-layer sheet. The occlusal surface for conditions L32 and L33 was evened out by the first layer of pressure welding. Therefore, the second layer was almost horizontal, although it had a gentle slope with respect to the basal plane of the model, and thus the sheet did not extend easily during pressure welding. This is probably why conditions L32 and L33 were not affected by the model height. That is, it would be recommended that the first layer of the laminated mouthguard cover the occlusal surface.

The buccal thickness tended to decrease as the model height increased under all molding conditions. The degree of decrease in mouthguard thickness due to the increased model height was similar for conditions S4, L32, and L33 and showed a trend similar to that for the labial thickness. That is, the thickness reduction rate with respect to model A was about 6% - 7% for model B and about 14% - 15% for model C, which was similar for single- and double-layered mouthguards. Because the buccal side of the model was almost smooth like the labial side, and it was a gentle slope with respect to the basal plane, the thickness due to the model height was probably only slightly affected by the molding conditions.

This study showed that the difference in the degree of decrease in the thickness of the single- and double-layered mouthguards due to the increase of the model height tended to be affected by the unevenness of the model. In other words, the labial and buccal thicknesses, where the sheet was pressed against the smooth surface of the model, were not affected by the molding conditions. The mouthguard thickness of the labial and buccal sides decreased by about 6% - 7% when the model height increased by 5 mm and further decreased by about 7% or more when the model height increased by another 5 mm. On the other hand, for the single-layered mouthguard, the cusp thickness that was pressed against the convex part of the model decreased by about 14% or more when the model height increased by 5 or 10 mm, whereas for the double-layered mouthguards, the thickness was not affected by the increase in the model height.

4. Conclusion

This study suggested that the degree of the decrease in mouthguard thickness due to the increase in the model height was similar for the single- and double-layered mouthguards on the labial and buccal sides, and increasing the model height by 5 mm and 10 mm decreased the thickness by about 6% - 7% and about 14% - 16%, respectively. At the cusp, only the single-layered mouthguard was affected by the model height and increasing the model height by 5 mm and 10 mm decreased the thickness by about 14% and about 17%, respectively. In addition, under the condition that a thick sheet material was used, the thickness of the mouthguard after molding could be secured more. That is, it was clarified that the thickness of the mouthguard depends on the thickness of the original sheet material. In future research, it will be necessary to investigate the design of laminated mouthguards considering the effect of the undercut amount of the model and the sheet material thickness.

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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