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Original Research Articles

Title: Thinning factors influence on custom-made mouthguards thermoforming

Running head: Thinning factors during custom-made mouthguard thermoforming.

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Abstract

The aim of the present study was to clarify and quantify factors on thinning during a thermoforming using a special simulation model that has three different flat surfaces of 0 degree, 45 degree, and 90 degree against a pressurizing force. Air pressure type samples were made by EVA and acrylic resin blank. Vacuum type samples were also made by EVA. Thickness Gauge was employed to measure the thickness. As results, pressure forming showed significantly larger thinning at 45 and 90 degree surfaces and smaller thinning at 0degree surface, 36 % in thinning rate by vacuum forming and 66% by the pressure forming at 90 degree surface, and 17 and 20 % at 45 degree surface, and 11 and 2% at 0 degree surfaces. Thinning rate of each surface at each heating time was significantly increased with an inclination against the pressure become steep. Promoted thinning by an increase in heating time on 0 degree surface, however, the reverse results of the thinning were restrained with an increase in heating time on 45 and 90 degree surface significantly were obtained. Thinning was increased with the increase in distance from the center in 0 degree surface and increased with the decrease in height in the vertical surface significantly. The air pressure, the material thickness in EVA (Drufosoft), difference in material color did not affect thinning rate. An acrylic resin material showed approximately 10% smaller thinning than EVA (Drufosoft). To retain enough thickness of 3 mm on 90 degree surface corresponding an incisal labial aspects for pressure laminate type, over 55 % reduction is taken into consideration, at least two 3-mm thickness materials should be laminated. On 0 degree surface showed at most 2 % reduction, occlusal thickness becomes almost 6 mm, careful occlusal adjustment to achieve 2 mm thickness should be requested.

1. Introduction

Positive effects of wearing a mouthguard have been indicated in various epidemiological surveys and experiments [1-5], and their usage appears to be increasing in many sports. However, a lot of preventable sports-related dental injuries still occur with a use of a conventional mouthguard [6]. These figures are shocking to us sports dentists. It is clear that when an impact force far exceeds a protective capability of the mouthguard, dental injuries will occur. However, an ordinal impact power in sports is estimated to be smaller than that found in traffic accidents [7]. Therefore, most sports-related dental injuries are assumed to be preventable by use of appropriate custom made mouthguard with adequate shape [8, 9], occlusal relationship [10, 11], design [12-14], and thickness [15-19], adaptability [20].

Thermoforming is softening material by heat and give a form by sucking or pressurizing. Thus, thermoforming at the time of a custom made mouthguard fabrication give a mouthguard sufficient adaptability. A vacuum type and a laminate type are often used as a custom made mouthguard. The vacuum type is a comparatively handy in fabrication, inexpensive, so suitable for the spread type and young players. The laminate type is produced with bonding two or more sheet materials with a high pressure and excels in adaptability and can create various designs. In both types, a sheet material is pressurized or vacuumed to mold against a model after softened sheet, so the completed mouthguards have moderate adaptability and wearability with a little fitting differences in two types. However, thickness decreases during thermoforming are a common knowledge and accompanied without fail. This decrease lowers the safety of the shock absorption ability [15-19]. In addition, it is necessary to consider a change in the thickness after usage [21, 22]. Therefore, a decrease in the thickness of the mouthguard material by thermoforming should be reduced.

Up to now, thickness changes of the mouthguard have been investigated using a dental stone model (Table 1). In 1994, Park et al. [23] studied thickness change of ethyl-vinyl-acetate (EVA) mouthguard. The authors mentioned using vacuum forming machine post thermoforming thickness decreased 25% at the top and 50% at the side for the mouthguards. And same authors also mentioned 70-99% of much larger decreased in the mouth-formed boil and bite mouthguards results from the uncontrolled biting force during the biting process for fitting. Afterwards, Yamada et al. [20] suggested a reduction in sheet thickness formed on the model surface parallel to a sheet surface was smaller than vertical to a sheet surface. Recently, Del Rossi and Leyte-Vidal [24] reported a high negative correlation between a model height and a thermoformed thickness. Takahashi et al. insisted color difference [25] and shape of mouthguard sheet [26] influence on thickness of post thermoforming. Recently, in the prestigious work of Geary and Kinirons [19], they have been evaluated dimensional changes that occur on thermoforming EVA sheets used in the construction of mouthguards over dental models under a number of common processing conditions including, model height, inclination, shape and model temperature, model position on thermoforming platform, plasticizing time and evacuation method. And they reported that sheets of 3-mm EVA stretched by half thickness during the thermoforming processes as an average of all measurement points. And the material stretched more at incisal site. Moreover, they figured that increasing model height overall or inclination were found to increase the degree of stretching and increasing plasticizing times reduced the degree of stretching of the material. Decreases in the thickness during the fabrication process found critical, especially in the area where the external impact is exerted the upper anterior region.

As results of these studies, changes in the thickness of formed sheet material are closely related to the working model conditions and many other factors. But, the influence of each factor on the thinning rate post

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thermoforming is still not clear. Moreover, to specify the magnitude of the possible processing factors using usual dental arch models seemed to be difficult. Because those models have an individual variation, pointed part, and curved surface made accurate measurement difficult. Then, we made a special simulation model that has three different flat surfaces of 0 degree (corresponds to an occlusal surface), 45 degree, and 90 degree (corresponds to a labial surface of an upper incisor) against a pressurizing force. The aim of the present study was to clarify and quantify factors on the thinning during thermoforming using the model. The involved factors were related to model condition, thermoforming condition, and mouthguard material itself.

2. Materials and methods

2.1 Mouthguard materials and forming machines

Air pressure type samples were made by thermoforming mouthguard material EVA (Drufosoft 1, 2, 3 mm, Dreve-Dentamid GMBH, Unna, Germany) and thermoforming acrylic resin（Erkodur 1 mm, 1.5 mm Erkodent ® Erich Kopp GmbH, Pfalzgrafenweiler, Germany）using air pressure machine (Drufomat Scan, Dreve-Dentamid GMBH, Unna, Germany). And vacuum type samples were made by thermoforming material EVA (Rinkai VF material 3mm, Rinkai Company, Ltd. T6okyo, Japan) and Vacuum former （Pro-form, Dental Resources, Inc., Minnesota, USA）.

2.2 Fabrication of samples

A special simulate model (Figure 1) was made from a hexahedron model (20×65×60 mm) made from a dental stone (New Fujirok, GC Co., Tokyo, Japan) by cutting down one side of the model to 45 degree

surface. Namely, the model had three surfaces of 0, 45, and 90 degrees against pressurizing direction. This model was used for making the samples. Three test mouthguards were made for each test condition using above mentioned materials and machines. Regarding measuring points, each center of three surfaces of 0, 45, and 90 degrees measured to compare the model inclination effect. To see the influence of position on a forming plate, 10 mm, 20 mm, and 30 mm from the center in the 0 degree surface were added as measuring points. To see the influence of the height in the vertical surface, 5 mm upper and below points on 90 degree surface were added to measure. In another test condition, the most important or critical surface which thought to be corresponding buccal surface of incisors, the center point on 90 degree surface data were used to analyze.

Regarding the air pressure thermoforming procedure for the 3-mm thickness Drufosoft material, manufactures recommended conditions, heating time of 135 sec. and approximate 0.6 MPa air pressure was employed. After 30 minutes under pressure and cooling time, thermoformed sheet was removed. Necessary changes were made to the basic condition according to each material and the examination parameter. Namely, about influence of heating time: Increase in heating time of 155 sec and 175 sec were considered, about influence of air pressure: Smaller values of 0.4 and 0.5 MPa were employed, about color effect: Black, neon yellow and white were compared with clear in 3 mm thickness sheet, about thickness effect: 1 and 2-mm were compared with 3-mm in clear sheet, about material difference hard and soft: 1 and 1.5-mm thickness hard sheets which often use for making Hard & Space mouthguard [12, 27] were compared with Drufosoft. Regarding the vacuum thermoforming procedure, a sagged sheet distance of 20 mm from the original position was used referring to the report of Takahashi et al. [28]. So a heating time was set 75 sec. A Vacuumed sheet was removed after 30 min cooling time. To make heating condition constant, each heating was started after a confirmation of complete

cooling down, and a pre-heating of three minutes [29] in both forming machine. All tests and preservation of

mouthguard material were conducted in an air-conditioned room at 25°C.

2.3 Thickness measuring methods

Digital Thickness Gauge Model G（OZAKI MFG. CO., LTD. Tokyo, Japan, resolution: 0.01 mm）was

employed to measure the thickness. And measured four times in each formed material were conducted.

2.4 Analysis methods

An impact absorption ability of mouthguard is directly related to material thickness [15, 16]. Thus, post

thermoforming thickness was measured and analyzed in thickness (mm). However, the materials employed in this

study were different in thickness. So, to compare and analyze easily, both thinning rate (%) and post

thermoforming thickness of the each measuring condition were conducted.

Statistical comparisons for the thinning rate were made using a one-way or two-way analysis of variance

(ANOVA) test followed by a Tukey multiple comparison tests for further comparisons (P < 0.05) using software

(SPSS Ver.11, SPSS Japan Inc., Tokyo, Japan).

3. Results

Thinning rate (%) and post thermoforming thickness of each measuring condition are summarized in figure

2 to 9. Figure 4 to 9 shows data at the middle of 90 degree surface of most critical measuring point. The results of

the Tukey multiple comparison test are also shown in these figures. Statistical analysis (ANOVA) showed

significant differences in influence of thermoforming method.

3.1 Influence of thermoforming method (pressure or vacuum)

Pressure forming showed significantly smaller thinning 2.94 mm (2.08%) in comparison with the vacuum

forming 2.67 mm (11.11%) at 0 degree surfaces, but pressure forming showed significantly larger thinning 2.40

mm (19.97%) than vacuum forming 2.49 mm (16.92%) at 45 degree surface and 1.02m m (66.17%) than vacuum

forming1.91 mm (36.44%) at 90 degree surface (Figure 2).

3.2 Influence of heating time and inclination against a pressurizing force

Thinning rate at the center point of each surface showed an increase with an inclination against the pressure

become steep at any heating time significantly. However, the effect of heating time on the thinning rate was

different among three inclinations. Thinning was promoted with an increase in heating time on 0 degree surface,

but thinning was restrained with an increase in heating time on 45 and 90 degree surfaces significantly (Figure 3).

3.3 Influence of the distance from center on 0 degree surface

Thinning rate showed an increasing tendency with the increase in distance from the center in 0 degree

surface. But, the thinning rates were relatively small; the thinning was 2.94 mm (2.08%) at the center, 2.84 mm

(5.36%), 2.66 mm (11.42%), 2.63 mm (12.25%) at the 10, 20, 30 mm from the center respectively (Figure 4).

3.4 Influence of the height in vertical surface

Thinning rate showed an increase with a decrease in height in the vertical surface significantly. And the

thinning rates were not so small, 1.34 mm (55.28%) at the upper, 1.02 mm (66.17%) at the middle, 0.94 mm

(68.78%) at the lower (Figure 5).

3.5 Influence of air pressure

Thinning showed almost same values roughly 1.0 mm (66%) among three air pressures (Figure 6).

3.6 Influence of material thickness

Thinning in three different thicknesses of 3 mm, 2 mm and 1 mm showed 1.02 mm, 0.71 mm and 0.35 mm

respectively (approximately same values of 65%)(Figure 7).

3.7 Influence of material color

Thinning in four different colors of clear, black, neon yellow and white showed roughly same values of 1.02

mm, 1.02 mm, 1.04 mm and 1.01 mm respectively (approximately same values of 66%) (Figure 8).

3.8 Influence of material difference

Both thickness hard materials (acrylic resins) showed 0.65 mm and 0.45 mm respectively (approximately

56%) which was significantly smaller than soft material of EVA (Drufosoft) materials 1.02 mm (approximately

66%) (Figure 9).

4. Discussion

Post thermoforming mouthguard material thinning rate% in several measuring points of previous studies

and the present study at manufacture's recommendation heating time of 3mm EVA (Drufosoft) are summarized

in Table 1. First, we pay attention about vacuum forming results, Park et al.[23] first tested about thermoforming

thickness changes to provide information for a more protective yet more comfortable mouthguard in detail. The

authors mentioned the maintenance of thickness in custom made vacuum forming mouthguards is one of a major

merit. And several researchers have performed following studies. Guevara et al.[30] reported 3.0-mm thick EVA

sheets was decreased by 36% at the incisal labial surface. Yamada et al. [31]reported thickness changes were

about 36% at the buccal surface of the central incisor and 40% at the cusp of the first molar and −10% at the

central fossa of the first molar. Waked and Caputo suggested that the reductions at the molar lingual cusp were

62 % and at the incisal labial surface 49 % [21]. Takahashi et al. [32] mentioned the ratio of thickness changes of

the sheet fitted to the anterior teeth of the 2-mm sheets (40.0 %) was greater than that of the 4-mm sheets (32.5 %).

And the ratio of changes of the thickness of the sheet fitted to the posterior teeth did not differ between the 2-mm

(30.0 %) and the 4-mm sheets (27.5 %). Takahashi et al. in their another study [26] reported reductions were

roughly 42% at incisor labial center and 3% at first molar fissure. Second, we pay attention about air pressure

forming results, other studies or in above mentioned studies, some results about pressure forming machine have

been presented. Yamada et al. [31] reported about 50% at the buccal surface of the central incisor, 40% at the cusp

of the first molar, and −10% at the central fossa of the first molar. These figures about molar were mentioned the

same results of the vacuum forming machine. Waked and Caputo reported that the reductions at the molar lingual

cusp was 42 % and at the incisal labial surface were 45.2 % [21]. Del Rossi and Leyte-Vidal[24] reported post

thermoforming thickness was decreased by 46.7 to 60.0 % at labial incisor and 46.7 % at occlusal molars cusp.

Geary and Kinirons [19] reported that overall, sheets of 3-mm EVA stretched by 52% during the thermoforming

conditions tested. Incisal/cuspal sites were found to be significantly thinner when compared with all other locations measured. Namely, reductions were 59.6% at incisor labial center, 36.3% at first molar fissure, and 67% at molar lingual cusp.

Namely, the former studies insisted that the post thermoforming reductions were ranged between 33 and 50 % by vacuum and 45 to 60 % by pressure forming machine at the most critical area of upper incisal labial surface, and ranged between 28 and 62 % by vacuum and between 40 and 67% by pressure forming machine at the molar cusp, and ranged between -10 and 3 % by vacuum and between -10 and 36.3 % by pressure forming machine at the molar fossa or fissure, with showing higher values in pressure forming procedure. Almost appropriate results were obtained in the present simulation model study (Figure 2): 36 % in thinning rate by vacuum forming and 66% by the pressure forming at 90 degree surface, and 17 % and 20 % at 45 degree surface, and 11 % and 2% at 0 degree surface. The pressure forming showed significantly larger thinning at 45 and 90 degree surfaces and smaller thinning at 0 degree surface. Thus, thermoforming method differences did affect post thermoforming thicknesses. A fundamental pressure is different between vacuum and pressure forming machine, stretching is affected by this characteristic. However, these results contain not clarified causes that cannot be disregarded and should be clarified for mouthguard safety.

Two major factors at the time of thermoforming might involve in thinning of the custom made mouthguard [19, 23], excluding the viewpoint of the difference of a material characters: One factor is a thinning of material itself by heating process. On activation of forming pressure, the plasticized material is propelled at speed against the model. So, the other factor is thought to be related in a material stretching at forming (a positive molding; the stretching of heated material over a model). The issues related to stretching because of increased traveling

distance should be considered: (a) a gap of separates material from a model at the time of forming start depend on the heating time and model height difference [19]; (b) a heating process make the central area of the EVA sheet sag, however, surrounding materials do not sag so much, so the traveling distance of the surrounding materials is bigger than the central area; (c) a ring using for a mouthguard sheet holding not to come off the sheet at the thermoforming make the material near the ring more stretch than the central area (The fixed portion becomes a fulcrum and the stretch thought to be increased in this area); (d) the greatest amount of stretch takes place along the vertical sections of model that have the greatest depth or distance travel [23], a greater decrease in thickness should be expected on the side of the teeth because with positive molding; (e) and a fundamental pressure difference affect stretching. These factors might act complexly and influence post thermoforming thickness.

In the present study, thinning rate of each surface at each heating time was significantly increased with an inclination against the pressure become steep (Figure 3), a reason of this phenomenon thought to be occurred by the difference in traveling distance of softened material depending on the difference of the angle on the model. This result regarding inclination effect was equal to Geary and Kinirons study [19] with the explanation: Increasing the inclination of the model was all found to increase significantly the degree of stretching on thermoforming the material. However, an analysis about the influence of heating time and inclination of the model surface on the thinning rate at the same time presented a quite complex relation which cannot be discussed separately (Figure 3). This crosswired influence of heating time and inclination is paid attention most in the present study. Basically, softening further the material by increasing heating time thought to be result in additional thinning of thermoformed materials all over the model. However, the present study, both the expected results on o degree surface and the reverse results on 45 and 90 degree surfaces were observed for samples. The

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expected result of the thinning by an increase in heating time on 0 degree surface was simply promoted with increase in heating time. The heating process make the central area of the EVA sheet begins to sag as the material warms up, as the material sags, it also may thin. So the prolonged heating time made the material thinner. This thinner portion of the EVA sheet then comes to the model surface of 0 degree center resulted in making a distance to travel short. So the post thermoforming thickness on 0 degree surface was affect strongly by prolonged heating time of thinning material itself, but did not affected traveling distance. On the other hands, the reverse results of the restrained thinning with increase in heating time on 45 and 90 degree surface significantly were obtained. These results were almost the same results of the study [19] . The authors maintained that the explanation for the reverse phenomenon may be related to EVA/model proximity at the point where forming pressure is applied to press the material against the model. EVA thermoforming materials sag more by longer heating time, this brings the two closer together. And above mentioned other factors related in stretching were also diminished with this EVA/model proximity. So, prolonged heating time made the traveling distance short on 45 and 90 degree surface. Thus, the prolonged heating time caused the unexpected reverse results in thermoformed material thickness. However, this research did not examine the inclination of the model. In any event, at the conventional mouthguard fabrication process, the model is usually trimmed so that upper incisor teeth are vertical in relation to the base of the forming unit [33]. The phenomenon prolonged heating time made the mouthguard reduce small at 90 degree surface, this surface is corresponding to maxillary incisor labial surface need sufficient thickness, is quite important for the injury prevention and fabrication for sophisticated mouthguard with considering the extension of heating time should be profitable to improve a bonding strength and adaptability of laminated mouthguard [29].

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Thinning was small compare to other area and increased with the increase in distance from the center in the 0 degree surface significantly. As already mentioned, heating makes the central area of sheet sag, so a traveling distance becomes relatively long with the increased distance from the center on 0 degree surface. Thus, it would be better to place the critical area of anterior teeth of model on to the vicinity of center of forming unit. And the material reduction was small on 0 degree surface, so too thick material on occlusal surface should be adjusted to refrain from uncomfortable, muscular overturgescence, and load increase to temporomandibular joint and so on.

Thinning was increased with the decrease in height on 90 degree surface significantly. Park et al. [23] mentioned that a greater decrease in thickness should be expected on the sides of the teeth as compared with the occlusal surface because with positive molding (the stretching of heated material over a mold) the greatest amount of stretch takes place along the sections of material that have the greatest depth or distance to travel. These finding are also corresponding to association between increase model thickness and material stretching on thermoforming [19, 24]. With the magnitude of stretching quantified in this study, it is difficult to retain sufficient thickness in critical area of anterior labial surface with fabricating EVA mouthguard using 3 or 4mm thickness or more less, laminate type mouthguards are recommended to achieve an appropriate thickness for safety [34-36] and partially laminate technique over anterior teeth [37]. And surface of 90 degrees or less would be expected more reduction, so the model should be trimmed maxillary incisor teeth are vertical in relation the base of the forming unit. However, though it contradicts current common sense, it would be necessary to consider that both sides of a labial surface of maxillary incisor teeth and an occlusal surface are trimmed to 45 degrees for the pressurizing power to assume an even thickness [38].

The air pressure differences did not affect thinning rate. 0.4 MPa pressure were employed as the smallest

value, but this pressure is in other pressure forming machine (Erkopress), this result imply that 0.4 MPa is pressure of the tolerance for laminate mouthguards fabrication. And it is appropriate to form at 0.6 MPa air pressure with Drufomat to obtain proper adaptability and adhesiveness [29] with no over load to the machine.

In the present study, the material thickness in the EVA (Drufosoft) did not affect thinning rate. However, the result is a little bit different from a previous study [32]. Namely, Takahashi et al. suggested that the ratio of thickness changes of the sheet fitted to the anterior teeth and palate on the 2-mm sheets was greater than that of the 4-mm sheets with showing no difference at the posterior teeth. This study was performed using vacuum forming machine, so the different result seemed to be obtained. In any event, the fact that material thickness in the EVA did not affect post thermoforming thicknesses is quite profitable to preconceive the thickness after completing mouthguard.

The difference in material color did not affect thinning rate in the present study. However, Takahashi et al. [25] mentioned that the thickness of post vacuum forming was affected by color difference. This study was employed vacuum forming technique, so the different result might be obtained. Rossi et al. indicate that by using dark-colored mouthguard material, one can achieve superior adaptation and thus produce a more firmly fitting mouthguard [39]. It seems that it influences post thermoforming thickness by the difference of color when the radiation method is used as a heating method. Drufomat employs a heating method of an electrothermal line. Thus, the difference of color did not influence the thickness. Selecting thermoforming machine for color mouthguard material should be careful.

Both thickness hard materials showed approximately 10% smaller thinning rate than EVA material of Drufosoft. A hard material is used to fabricate the high safety mouthguard of Hard & Space mouthguard [12, 27].

The reduction rate in the hard material was smaller than EVA (Drufosoft) material. Thus, selecting hard material thickness needs a consideration about player's level, age, and sport event difference and so on with considering appropriate final labial thickness of 3mm not to disturb players' comfortable. This result thought to be originated in the difference of the material characteristic. Original shore hardness and weight of EVA (Drufosoft) and hard material were roughly 82 and 97, 1.06g and 1.24g / 100 mm square 1-mm thickness sheet respectively. A hard material might not expand easily.

Patrick, van Noort and Found [3] have suggested necessary thickness for specific aspects on the mouthguard, 3 mm for labial aspects, 2 mm for occlusal aspects and 1 mm on palatal surfaces. Most of sports dentists and we authors are all for these suggestion for mouthguard thickness. The mouthguard should provide maximum protection against oral trauma such as broken or avulsed teeth, soft tissue lacerations and concussions. Mouthguards need sufficient safety ability with comfortable and easy to wear. To achieve these goals mouthguards need enough thickness in labial surfaces of the anterior teeth to reduce a direct impact force and occlusal surface to establish full balance occlusion and to reduce an indirect force applied to mandibular lower surface. Westerman et al. [17]reported that a direct relationship between material thickness and impact absorption. With regard to optimum cross-sectional thickness for EVA mouthguards, Tran et al. [18]advocated that appliances should be at least 4 mm thick in order to optimize their protective qualities. The research of Westerman et al. [15] revealed a preference for 4 mm thickness over critical areas such as incisal edges and tooth cusps. Maeda et al.[16] mentioned, from the viewpoint of energy absorption ability, the minimum thickness required for a mouthguard is 4 mm. Appropriate thickness in occlusion is definitely required to establish full balanced occlusion which benefit for protecting mandibular bone [11] and anterior teeth from the viewpoint of occlusion [10].

As Geary and Kinirons [19] insisted, to optimize protection in vulnerable areas, it is important that clinicians distinguish between original EVA sheet thickness and the thickness achieved in the finished mouthguards. A multilayering is recommended as the requirement to achieve an enough thickness for mouthguard protection in many cases. Therefore, to retain above mentioned enough thickness for mouthguards in fabricating pressure laminate type, with considering decrease in thickness while thermoforming, over 55 % reduction is taken into consideration on 90 degree surface, at least two 3-mm thickness materials should be laminated for the incisal labial aspects in theory. On the other hand, on 0 degree surface center showed at most 2 % reduction, in other words occlusal surface thickness becomes almost 6 mm with the lamination, careful occlusal adjustment to achieve 2 mm occlusal thickness and not to leave excess material related to uncomfortable and muscle hypertonia should be important. And optimal design first and second layer outline should be requested for 1 mm on palatal surfaces.

While the aim of present study was to clarify and quantify effects of each factors that may contribute to thinning of custom made mouthguards thermoforming, we limited the scope of our investigation to only those factors related to influence of the inclination against a pressurizing force, distance from center in the horizontal surface, height in vertical surface, heating time, air pressure, thermoforming method (pressure or vacuum) , mouthguards material itself, material thickness, material color and material hardness were employed. Future research should certainly examine these factors, difference in soft material and equipment used, condition of material reservation, difference of environment of temperature and convection at thermoforming, deterioration in heating part, temperature of machine when softening begins, a working model dryness degree, model placement position on thermoforming plate, separating agent, and effect of multi-layered lamination technique , so that

construction guidelines can be revised if necessary and the thinning that occurs during the fabrication process can be kept to a minimum. However, our results still have strength in fabricating sophisticated mouthguard with enough protection. To retain an enough thickness (3 mm for labial aspect, 2 mm for occlusal aspect and 1 mm on palatal surface) for pressure laminate type, more than half reduction is taken into consideration on incisal labial aspect; at least two 3-mm thickness materials are required for this aspect, while considering the fact of too thick occlusal and palatal materials after lamination. Optimal design in first and second layer and careful fabrication with considering other thinning factors is indispensable for a good mouthguard.

5. Conclusion

The aim of the present study was to clarify and quantify the factors on thinning using a special model that has three different flat surfaces of 0 degree, 45 degree, and 90 degree against a pressurizing force. As results, pressure forming showed significantly larger thinning at 45 and 90 degree surfaces and smaller thinning at 0 degree surface. Thinning rate of each surface at each heating time was significantly increased with an inclination against the pressure become steep. The promoted thinning by an increase in heating time on 0 degree surface (center) and the reverse results of the thinning was restrained with increase in heating time on 45 and 90 degree surface significantly were obtained. Thinning was increased with the increase in distance from the center in 0 degree surface and increased with the decrease in height in vertical surface significantly. The air pressure, the material thickness in EVA (Drufosoft), difference, in material color did not affect thinning rate. And a hard material showed smaller thinning than EVA (Drufosoft).

Conflict of interest

The authors declare no conflict of interest.

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Figure legends

Figure1: A special simulate model with three different flat surfaces of 0 degree, 45 degree, and 90

degree against a pressurizing force with numbered measuring points (Digital Thickness Gauge

measurement in lower right).

Figure 2: Influence of thermoforming method (pressure or vacuum). Pressure forming showed

significantly larger thinning at 45 and 90 degree surfaces and smaller thinning at 0degree surface,

36 % in thinning rate by vacuum forming and 66% by the pressure forming at 90 degree surface, and

17 % and 20 % at 45 degree surface, and 11 % and 2% at 0 degree surfaces.

Figure 3: Influence of heating time and inclination against a pressurizing force. Thinning rate was

significantly increased with an inclination against the pressure become steep at each heating time.

Thinning was promoted with an increase in heating time on 0 degree surface; however, the reverse

results of the thinning were restrained with an increase in heating time on 45 and 90 degree surface

significantly.

Figure 4: Influence of the distance from the center on 0 degree surface. Thinning rate showed the

increasing tendency with the increase in distance from the center.

Figure 5: Influence of the height in the vertical surface. Thinning rate showed an increase with the

decrease in height in the vertical surface significantly.

Figure 6: Influence of air pressure. Thinning rate showed almost same values roughly 66% among

three air pressures.

Figure 7: Influence of material thickness. Thinning rate in three different thicknesses showed

approximately same values of 66%.

Figure 8: Influence of material color. Thinning rate in four different colors showed roughly same

values of 66%.

Figure 9: Influence of material difference. Hard materials showed roughly 56% thinning rate which

was significantly smaller than soft material of Drufosoft EVA materials (roughly 66%).
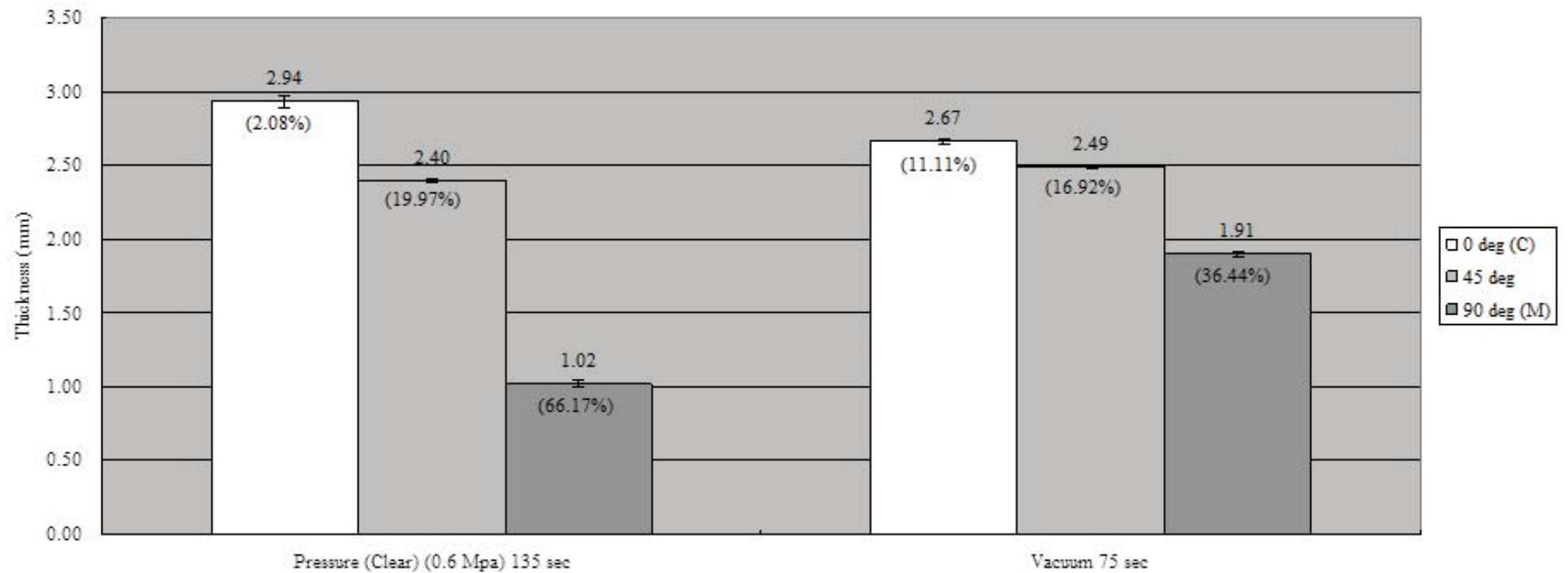
Pressure or suck force

40 mm

(1)(2)(3)(4)

(5)

(6)
(7)
(8)

90°

20 mm

65 mm
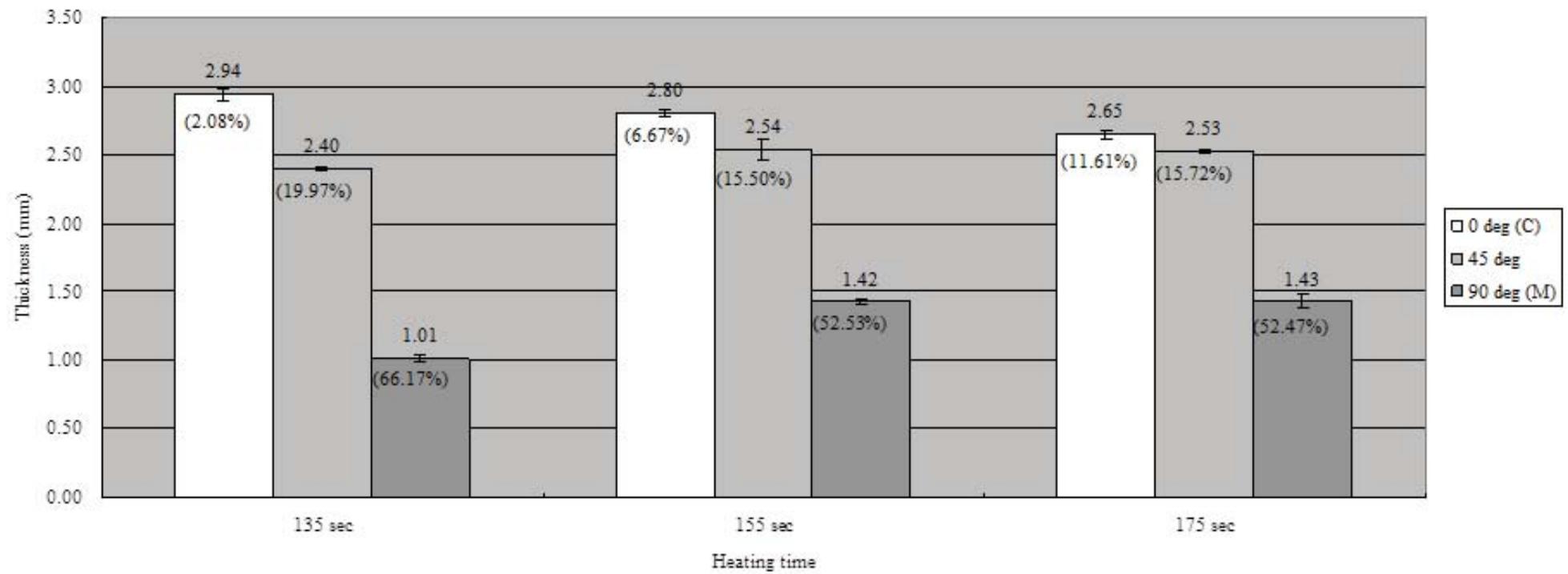
45°

60 mm
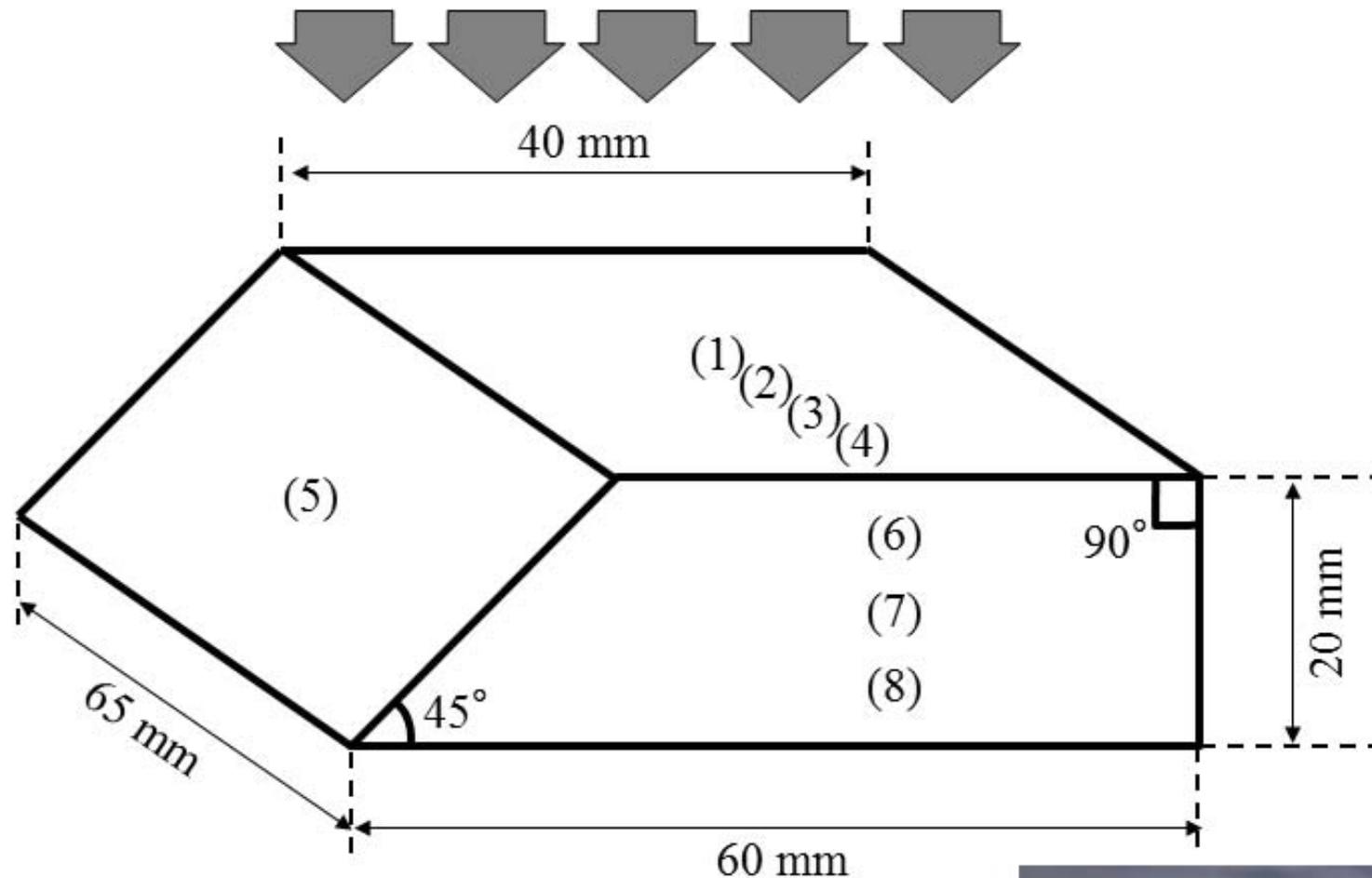
Measuring points:
- (1)(2)(3)(4) on 0 degree surface
  (Center (C), 10 mm, 20 mm, 30 mm from the center)
- (5) on 45 degree surface
- (6)(7)(8) on 90 degree surface
 (Upper (U), Middle (M), Lower (L))
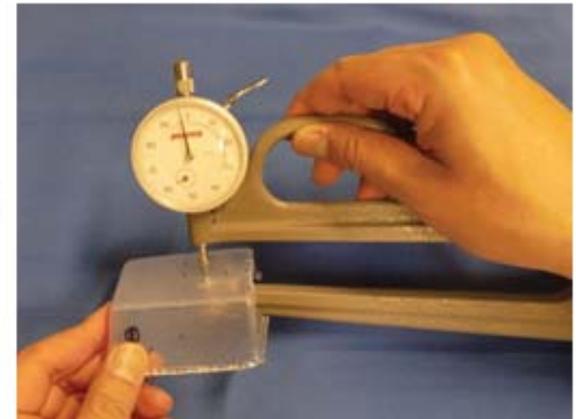
		Pressure（Clear)			Vacuum		
		0 deg	45 deg	90 deg	0 deg	45 deg	90 deg
Pressure (Clear)	0 deg		*	*	*	*	*
	45 deg			*	*	*	*
	90 deg				*	*	*
Vacuum	0 deg					*	*
	45 deg						*
	90 deg						

*: p<0.05

Thickness (mm) vs Heating time

2.94 (2.08%) — 2.40 (19.97%) — 1.01 (66.17%) — 2.80 (6.67%) — 2.54 (15.50%) — 1.42 (52.53%) — 2.65 (11.61%) — 2.53 (15.72%) — 1.43 (52.47%)

Legend: 0 deg (C), 45 deg, 90 deg (M)

		135 sec			155 sec			175 sec		
		0 deg (C)	45 deg	90 deg (M)	0 deg (C)	45 deg	90 deg (M)	0 deg (C)	45 deg	90 deg (M)
135 sec	0 deg (C)		*	*	*	*	*	*	*	*
	45 deg			*	*	*	*	*	*	*
	90 deg (M)				*	*	*	*	*	*
155 sec	0 deg (C)					*	*	*	*	*
	45 deg						*	*	-	*
	90 deg (M)							*	*	-
175 sec	0 deg (C)								*	*
	45 deg									*
	90 deg (M)									

*: $p < 0.05$
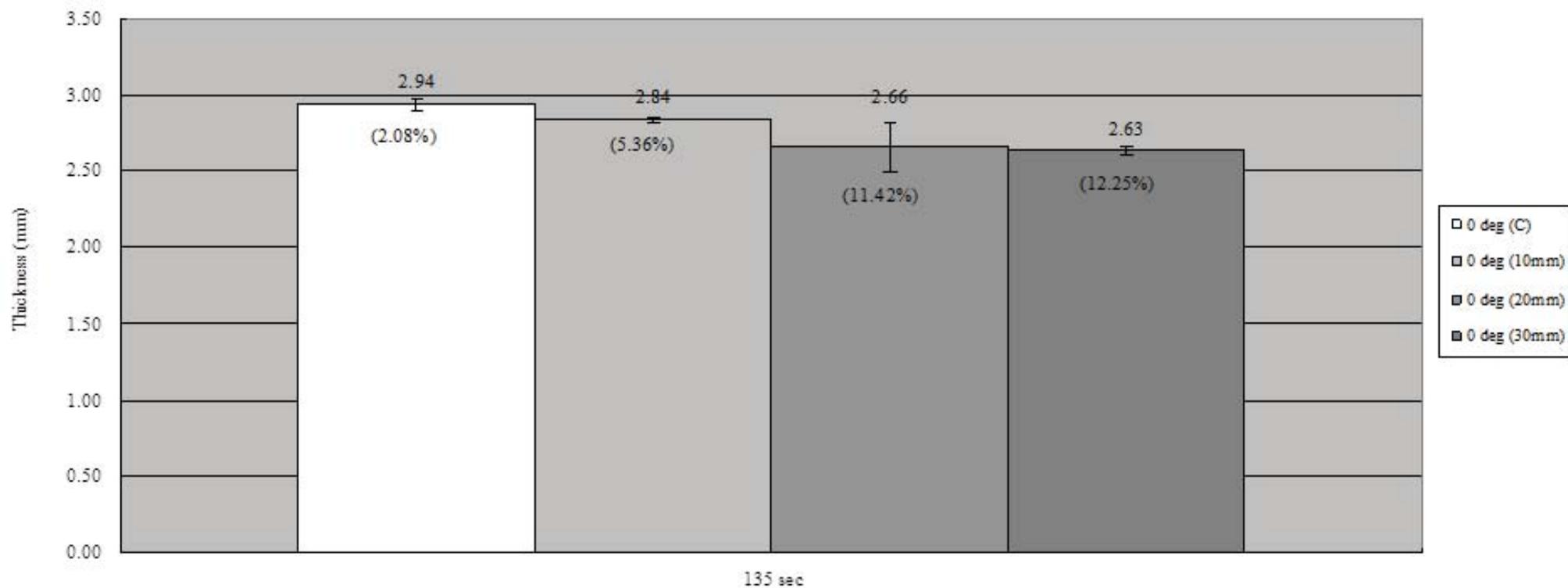
	0 deg (C)	0 deg (10mm)	0 deg (20mm)	0 deg (30mm)
0 deg (C)		-	*	*
0 deg (10mm)			*	*
0 deg (20mm)				-
0 deg (30mm)				

*: p<0.05
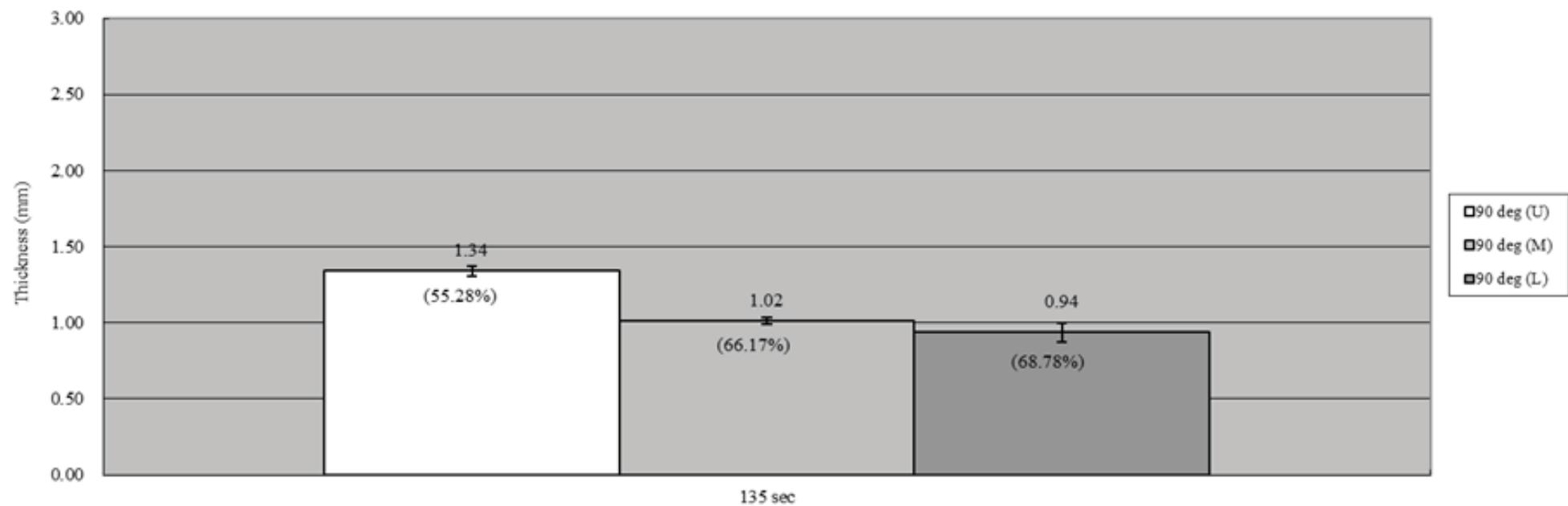
	90 deg (U)	90 deg (M)	90 deg (L)
90 deg (U)		*	*
90 deg (M)			*
90 deg (L)			

*: p<0.05
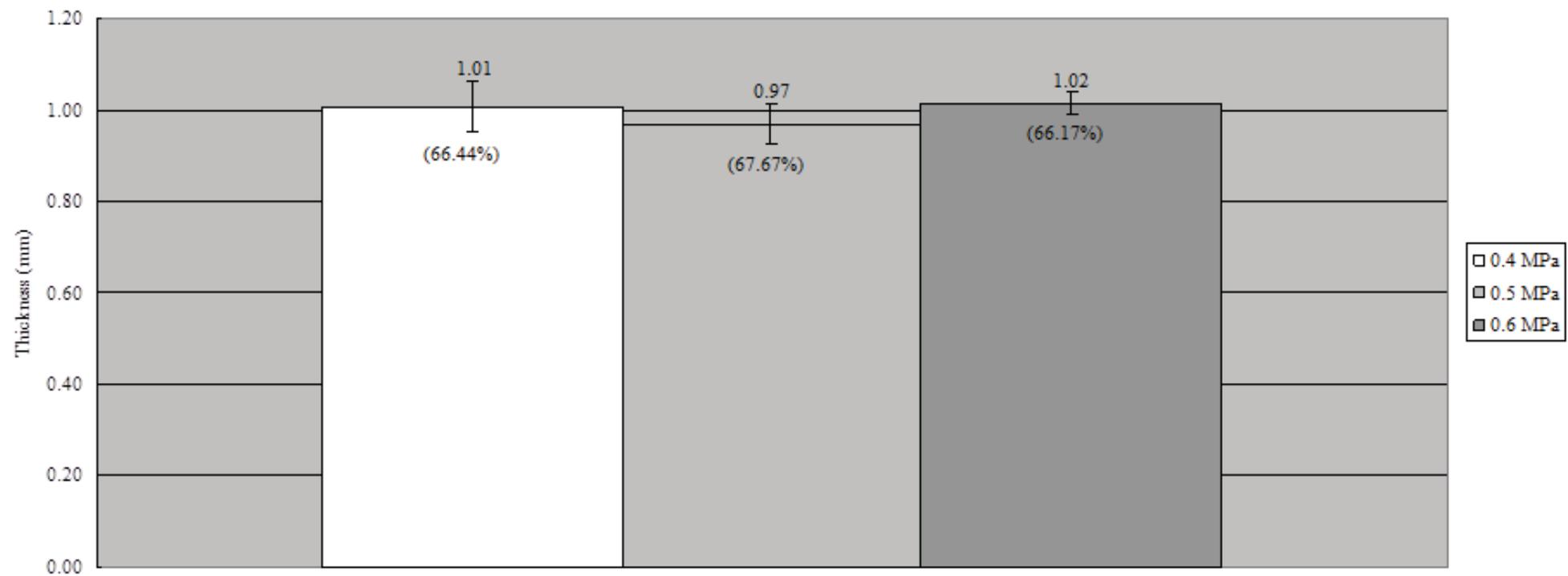
	0.4 MPa	0.5 MPa	0.6 MPa
0.4 MPa		-	-
0.5 MPa			-
0.6 MPa			
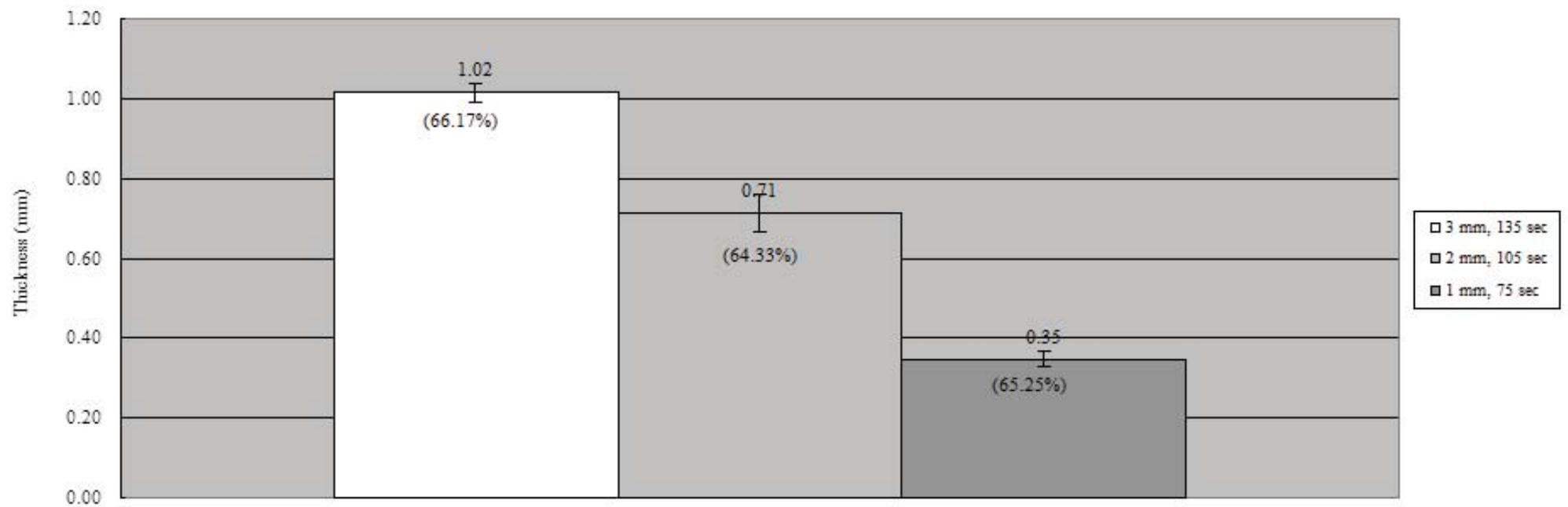
	3 mm, 135 sec	2 mm, 105 sec	1 mm, 75 sec
3 mm, 135 sec		-	-
2 mm, 105 sec			-
1 mm, 75 sec			
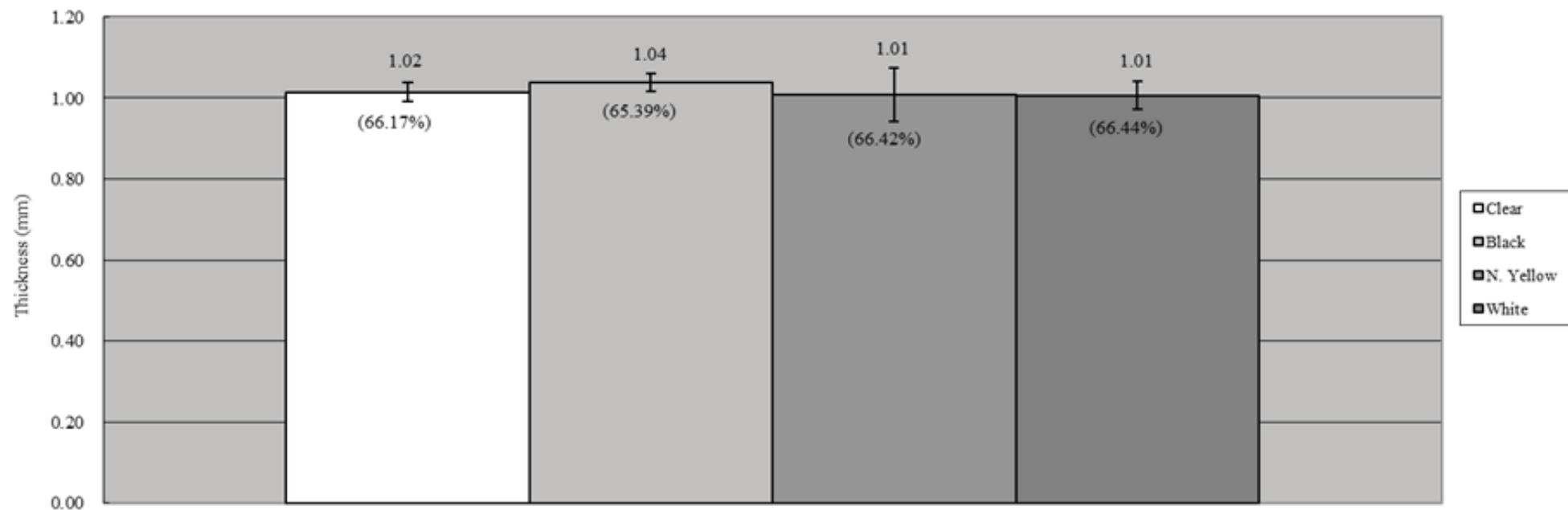
	Clear	Black	N. Yellow	White
Clear		-	-	-
Black			-	-
N. Yellow				-
White				
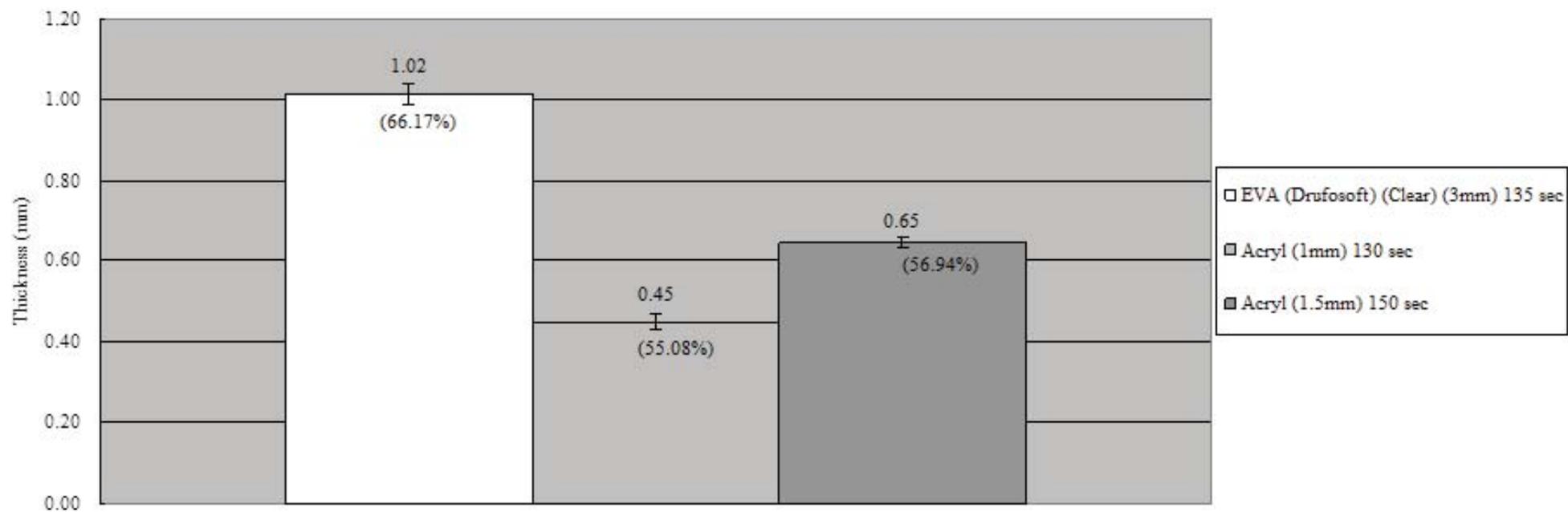
	EVA (Drufosoft) (Clear) (3mm) 135 sec	Acryl (1mm) 130 sec	Acryl (1.5mm) 150 sec
EVA (Drufosoft) (Clear) (3mm) 135 sec		*	*
Acryl (1mm) 130 sec			*
Acryl (1.5mm) 150 sec			

*: p<0.05

Table 1. After thermoforming mouthgurd material thinning rate%

FirstAuthor (Year)	Ref. No.	Model	Thermoforming method	Measurment site		
Park (1994)	27	Dental model	Vacuum	50% (side)	25% (top)	
Guevara (2001)	34	Dental model	Vacuum	36% (incisal labia lsurface)		
Yamada (2003)	35	Dental model	Vacuum	36%(insisor labial surface)	40% (cusp of molar), -10% (central fossa molar)	
Waked (2005)	25	Dental model	Vacuum	49% (incisal labial surface)	62% (molar lingual cusp)	
Takahashi (2008)	36	Dental model	Vacuum	32.5-40.0 % (anterior teeth)	27.5-30.0 % (posterior teeth)	
Takahashi (2012)	30	Dental model	Vacuum	42% (incisor labial center)	3% (first molar fissure)	
Present study	-	Simulation model	Vacuum	36.44% (90 degree surface)	16.92% (45 degree surface)	11.11% (0 degree surface)
Yamada (2003)	35	Dental model	Pressure	50%(insisor labial surface)	40% (cusp of molar), -10% (central fossa molar)	
Waked (2005)	25	Dental model	Pressure	45.2% (incisal labial surface)	42% (molar lingual cusp)	
Del Rossi (2006)	28	Dental model	Pressure	46.7-60.0% (labial incisor)	46.7% (molars cusp)	
Geary (2008)	23	Dental model	Pressure	59.6% (incisor labial center)	36.3% (first molar fissure), 67% (molar lingual cusp)	
Present study	-	Simulation model	Pressure	66.1% (90 degree surface)	19.97% (45 degree surface)	2.08% (0 degree surface)
				Present study: at manufacture's recommendation heating time (3mm EVA)		