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Post thermoforming dimensional changes of ethylene vinyl acetate used in custom-made mouthguards for trauma prevention – a pilot study

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Abstract – It is important that mouthguards have an adequate thickness of material if they are to be effective in the prevention of trauma. The aim of this study was to quantify dimensional changes that occur on thermoforming ethylene vinyl acetate (EVA) sheets used in the construction of mouthguards. Fourteen batches of 3 mm thick sheet EVA were thermoformed 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. Thickness of thermoformed material was determined at anterior and posterior sites and measurements were compared to determine the magnitude and patterns of stretching collectively and within each processing condition. 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. A number of thermoforming conditions were demonstrated to have a significant effect on the degree to which the EVA material stretched. For the combination of materials and equipment tested in this study, current thermoforming practices may cause excessive thinning of EVA in critical areas including incisal edges and cusp tips, thereby reducing the protective effect for professionally made mouthguards. To optimize protection in vulnerable areas, it is important that clinicians distinguish between EVA sheet thickness and the cross-sectional dimensions achieved in the finished mouthguards. They need to be specific in their prescription of the thickness of material they require especially in critical areas.

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Introduction

It is recognized that mouthguards worn by participants during contact or dangerous sporting activities diminish the probability of permanent damage and disfigurement through orofacial trauma. Custom made mouthguards prescribed and fitted by dental professionals have been shown to be well tolerated by sports activists (1). Thermoformed ethyl vinyl acetate (EVA) predominates currently as a material of choice for construction of custom made devices. To maximize their protective effect, sufficient thickness of material must be developed over critical areas such as incisal edges of anterior teeth where risk of injury is increased (2). Eccelston (3) reported a direct relationship between material thickness and impact absorption. With regard to optimum cross-sectional thickness for EVA thermoformed mouthguards, Tran et al. (4) advocate that appliances should be at least 4 mm thick in order to optimize their protective qualities. The research of Westerman et al. (5) revealed a preference for 4 mm thickness over critical areas such as incisal edges and tooth cusps. Hoffman *et al.* (6) recorded a minimum layer thickness of 3 mm was required to provide an adequate protective effect for the mouthguards they tested.

Advantages in levels of protection for thicker mouthguards must of course be balanced with wearability. An optimally protective appliance is indicated when the player can accommodate comfortably the appliance under their lip and cheeks, can communicate coherently with team mates and is able to breathe without difficulty (1, 7). Some providers of EVA mouthguards overcome the thickness protection/wearability dilemma by offering a number of specifications to the sports activist (8). Other workers have suggested inclusions, materials sandwiched between or overlying the EVA to improve the protective qualities of the appliance and to maximize shock absorption for object specific impacts (9, 10).

It should not be assumed that all custom made mouthguards have optimal thickness profiles. Sheet EVA materials stretch noticeably as a result of current construction processes that use dedicated dental thermoforming instruments employing vacuum, air pressure or a combination of the two to maximize adaptation accuracy. As cross-sectional material thickness is linked to protective effect, this leads to the possibility that vulnerable structures remain under protected for some mouthguards in the event of a traumatic impact. Authors have speculated as to the degree of stretching in vacuum and pressure thermoforming procedures used in the formation of mouthguards (8). The current investigation is designed to determine and quantify, under a number of thermoforming conditions, the magnitude of stretching for the initial layer of one EVA material used in the construction of laminated or multilayered mouthguards.

Materials and methods

One dental model of the upper arch of a 13 year old was selected, duplicated and where necessary modified for all experimental thermoforming. An isolating layer of sodium alginate was applied prior to each thermoforming procedure.

A Drufomat (Dreve-Dentamid GMBH, Unna, Germany) thermoformer was used for all pressure formed groups with the Vacfomat (Dreve-Dentamid) employed for the vacuum thermoformed batch tested. Natural-transparent EVA discs or foils (Drufosoft; Dreve-Dentamid), 3 mm thick by 120 mm ∅ were used for all thermoforming procedures undertaken in the study. Fourteen batches of five units were thermoformed according to conditions identified in Table 1.

Each thermoformed unit was sectioned anteriorly through the long axis of the left central incisor and through the mesial cusps of the left first molar posteriorly. Post thermoformed dimensions were measured and recorded at 12 sites on each thermoformed sheet according to Table 2 (Fig. 1). Measurement sites were viewed directly under the light transmission microscope 100× of a Mitutoyo MVK-HI Hardness Testing Machine [Mitutoyo (UK) Limited, Hampshire, UK]. Measurements were made perpendicular to the fitting surface edge of the material at the measurement site or perpendicular to a tangent of the measurement point for curved surfaces, using the digital micrometer coordinate table (resolution 0.001 mm) of the testing apparatus. One author made all measurements. Measurement reproducibility was checked by comparison of original and duplicate readings of 10 measurement sites and expressed as the standard deviation according to Bland (11). Data were coded and analyzed using SPSS, version 12.0 (SPSS Inc., Chicago, IL, USA). The data were subjected to independent *t*-test, univariate analysis of variance and the multicomparison Scheffe test to detect differences between groups.

Results

Standard deviation of measurement error for sample thickness was found to be 2 μm, which was considered an acceptable level of precision for this study. Overall, sheets of 3-mm EVA stretched by 52% during the thermoforming processes tested. The material stretched by 72% at incisal sites, reducing thickness to less than 1 mm in this region. Mean values (mm) for thermoformed material thickness for the various measurement sites is shown in Table 3. Variance in thickness was significantly explained by the grouping factor, measurement site. The Scheffe test showed that thickness of EVA was significantly different at incisal edge, posterior buccal cusp and posterior lingual cusp sites compared with other locations. Therefore, EVA was less thick at incisal/cuspal sites compared with other sites and thicker at anterior lingual crown and posterior crown fissure sites.

Varying plasticizing (heating) times were found to have a significant effect on post thermoforming dimensions. Surprisingly, increasing plasticizing times actually reduced the degree of stretching of the material (Table 4). Increasing model height overall or by altering the inclination of the model together with shifting model position on the thermoforming machine were all found to increase significantly the degree of stretching on thermoforming the material (Table 5). No variation in material stretch patterns was observed for vacuum formed appliances or for models with tapering sides when compared with control thermoforming conditions.

Discussion

Rosemergy (8) in his detailed description for the construction of mouthguard appliances, stresses the importance of trimming model bases so that upper incisor teeth are vertical in relation to the base of the vacuum-forming unit and of keeping the model thin to minimize stretching of the material. Much earlier, Carmichael et al. (12) appreciated the problem and advocated embedding models in lead granules to help minimize stretching of the sheet material. A similar effect was achieved in the current study with batch number three specimens where the already relatively thin model (base to incisor height of 25 mm) was trimmed posteriorly to 15 mm. The current study verifies the claims of these workers to an association between increased model thickness and material stretching on thermoforming.

A number of technique descriptions for thermoformed, custom made, mouthguards suggest a one-layer EVA construction technique. Soporowski, Warunek and Willison, and Shaull KL recommended one sheet of between 3- and 4-mm thickness (13–15). Other workers use one layer in 3-mm thickness while de Wet, Badenhorst and Rossouw suggested one sheet of 2 mm, when making mouthguards for children (16–18). With the magnitude of stretching quantified in the current study, it is difficult to see that sufficient thickness of material in critical areas can be developed for appliances made using sheet thermoforming materials in such dimensions. More recently, multilayering is recognized as the requirement to achieve a defined thickness for mouthguard appliances (19).

Padilla and Lee in their step-by-step process for the construction of pressure laminated mouthguards (using a

Table 1. Control and variant (*in italics*) thermoforming conditions for 14 batches of five, 3 mm thick ethylene vinyl acetate thermoforming sheets

Batch Number	Model Height	Model Inclination	Model Position	Model Sides	Model pre-heat temperature	Plasticizing (heating) time (s)	Thermoforming Machine
1 (Control)	Central Incisors and second molars to base height = 25 mm	Bases trimmed parallel to occlusal plane	Centred on mounting platform of thermoformer	Perpendicular to model base	40°C	110*	Pressure former
2	*Central Incisors and second molars to base height = 35 mm*	Bases trimmed parallel to occlusal plane	Centred on mounting platform of thermoformer	Perpendicular to model base	40°C	110*	Pressure former
3	Central Incisors and second molars to base height = 25 mm	*Posterior tilt down by 10 mm*	Centred on mounting platform of thermoformer	Perpendicular to model base	40°C	110*	Pressure former
4	Central Incisors and second molars to base height = 25 mm	*Posterior tilt up by 10 mm*	Centred on mounting platform of thermoformer	Perpendicular to model base	40°C	110*	Pressure former
5	Central Incisors and second molars to base height = 25 mm	*Posterior tilt up by 20 mm*	Centred on mounting platform of thermoformer	Perpendicular to model base	40°C	110*	Pressure former
6	Central Incisors and second molars to base height = 25 mm	Bases trimmed parallel to occlusal plane	*Labial aspect of model placed at edge of mounting platform*	Perpendicular to model base	40°C	110*	Pressure former
7	Central Incisors and second molars to base height = 25 mm	Bases trimmed parallel to occlusal plane	*Distal aspect of model placed at edge of mounting platform*	Perpendicular to model base	40°C	110*	Pressure former
8	Central Incisors and second molars to base height = 25 mm	Bases trimmed parallel to occlusal plane	Centred on mounting platform of thermoformer	*Tapering towards centre of base*	40°C	110*	Pressure former
9	Central Incisors and second molars to base height = 25 mm	Bases trimmed parallel to occlusal plane	Centred on mounting platform of thermoformer	Perpendicular to model base	*20*°C	110*	Pressure former
10	Central Incisors and second molars to base height = 25 mm	Bases trimmed parallel to occlusal plane	Centred on mounting platform of thermoformer	Perpendicular to model base	*80*°C	110*	Pressure former
11	Central Incisors and second molars to base height = 25 mm	Bases trimmed parallel to occlusal plane	Centred on mounting platform of thermoformer	Perpendicular to model base	40°C	*140*	Pressure former
12	Central Incisors and second molars to base height = 25 mm	Bases trimmed parallel to occlusal plane	Centred on mounting platform of thermoformer	Perpendicular to model base	40°C	*170*	Pressure former
13	Central Incisors and second molars to base height = 25 mm	Bases trimmed parallel to occlusal plane	Centred on mounting platform of thermoformer	Perpendicular to model base	40°C	*200*	Pressure former
14	Central Incisors and second molars to base height = 25 mm	Bases trimmed parallel to occlusal plane	Centred on mounting platform of thermoformer	Perpendicular to model base	40°C	110*	*Vacuum former*

*Manufacturers recommended plasticizing time (Drufosoft processing brochure; Dreve-Dentamid GMBH, Unna, Germany, August 1997).

Table 2. Description of anterior and posterior measurement sites for 14 batches of five 3 mm thick ethylene vinyl acetate thermoforming sheets

Area of mouthguard	Measurement point description
Anterior – upper right central	
1	3 mm below labial gingival margin
2	Mid point on labial aspect of tooth
3	Incisal edge
4	Mid point on lingual aspect of tooth
5	3 mm below lingual gingival margin
Posterior – upper right first molar	
6	3 mm below buccal gingival margin
7	Mid point on buccal aspect of tooth
8	Mesio buccal cusp
9	Fissure (deepest part)
10	Mesio lingual cusp
11	Mid point on lingual aspect of tooth
12	3 mm below lingual gingival margin

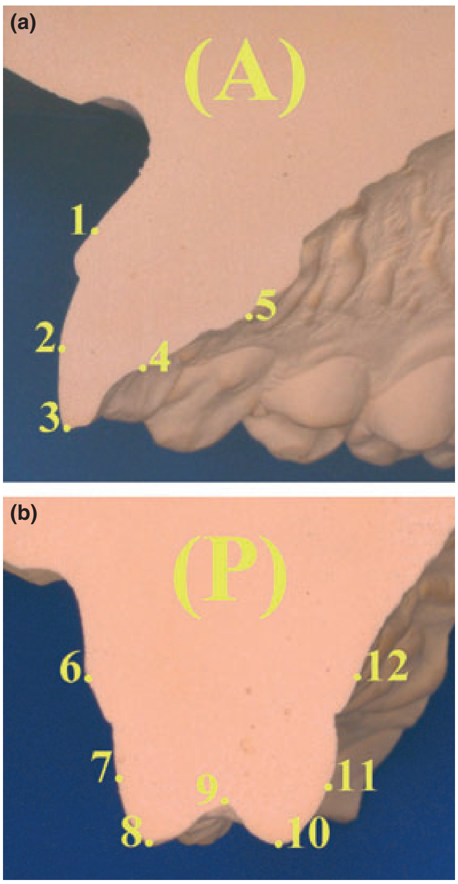

Fig. 1. (a) and (b) Cross sections through the long axis of the upper left central incisor (A) and mesial cusps of the first molar teeth (P) identifying anterior and posterior measurement sites for fourteen batches of five 3-mm-thick ethylene vinyl acetate thermoforming sheets.

similar forming machine to the one used in the current study), assert that two sheets of 3-mm material laminated together will produce a 4-mm-thick mouthguard (20). The stretching pattern for additional layers of material was not tested in the current investigation, however, the

Table 3. Mean 'post thermoforming' dimensions for 12 measurement sites on 70, 3 mm thick ethylene vinyl acetate thermoforming sheets

Measurement site on mouthguard	Mean measurement (mm)	95% CI
Anterior labial sub gingival	$1.52^{5,6*}$	1.45, 1.59
Anterior labial crown	$1.19^{2,3}$	1.13, 1.25
Incisal edge	0.83^{1}	0.77, 0.89
Anterior lingual crown	1.89^{8}	1.84, 1.95
Anterior lingual sub gingival	$1.86^{7,8}$	1.81, 1.91
Posterior buccal sub gingival	$1.80^{7,8}$	1.75, 1.86
Posterior buccal crown	$1.30^{3,4}$	1.24, 1.36
Posterior buccal cusp	0.99^{1}	0.92, 1.05
Posterior crown fissure	1.91^{8}	1.81, 2.01
Posterior lingual cusp	1.00^{1}	0.93, 1.06
Posterior lingual crown	$1.44^{4,5}$	1.38, 1.49
Posterior lingual sub gingival	$1.69^{6,7}$	1.64, 1.73

F (11, 828) = 150.05, $P < 0.001$.
*Differences in numerical values of suffixes indicate a significant difference at $P < 0.05$.

Table 4. Relationship of overall post thermoforming dimensions for 3 mm sheet ethylene vinyl acetate where thermoforming conditions significantly **decreased** stretching of the material

Thermoforming condition*	Dimensions (mm) $\bar{x}$ (95% CI)	t	P
Condition 12. Changing plasticizing time		2.83	0.01
(a) Control = 110 s	1.53 (1.38, 1.67)		
(b) Plasticizing time changed to 170 s	1.73 (1.60, 1.85)		
Condition 13. Changing plasticizing time		3.55	0.001
(a) Control = 110 s	1.53 (1.38, 1.67)		
(b) Plasticizing time changed to 200 s	1.81 (1.68, 1.94)		

*See Table 1 for thermoforming condition details.

unrealistic expectation of no thinning of the second layer of material over the incisal/cuspal regions would be required to realize this goal. Authors in the current investigation would speculate that, while stretching patterns of additional layers of EVA may not replicate the pattern observed for initial layers, because of altered topography in these regions, disproportionate stretching in these areas is likely still.

The current investigation highlights a number of variables that can result in altered dimensions for thermoformed EVA used in the construction of mouthguards. It is not, however, an exhaustive list. For example, arch forms of various sizes and depths or differences in sulcus contours or dimensions were not tested. The thermoforming instrument may have also an impact on the degree of stretching of the material. A trend for all variables that were assessed is the significantly reduced dimensions for incisal/cuspal sites compared with all other areas including the other labial zones. This is important as it is incisal edges of teeth that are most likely to be affected by trauma (2). Increased potential for trauma must exist also where an insufficient

Table 5. Relationship of overall post thermoforming dimensions for 3 mm sheet ethylene vinyl acetate where thermoforming conditions significantly **increased** stretching of the material

Thermoforming condition*	Dimensions (mm) $\bar{x}$ (95% CI)	t	*P*
Condition 2. Changing model height	1.53 (1.38, 1.67)	4.11	0.001
(a) Control = 25 mm	1.21 (1.10, 1.32)		
(b) Model height changed to 35 mm			
Condition 4. Changing model inclination	1.53 (1.38, 1.67)	3.55	0.001
(a) Control = horizontal	1.26 (1.16, 1.36)		
(b) Posterior of model elevated by 10 mm			
Condition 5. Changing model inclination	1.53 (1.38, 1.67)	4.40	0.001
(a) Control = horizontal	1.17 (1.04, 1.29)		
(b) Posterior of model elevated by 20 mm			
Condition 7. Changing model position	1.53 (1.38, 1.67)	2.76	0.01
(a) Control = Centred on thermoformer platform	1.31 (1.20, 1.42)		
(b) Distal edge of model placed at edge of thermoformer platform			

*See Table 1 for thermoforming condition details.

layer of material prevents cusp-to-cusp contact. Patrick, van Noort and Found (21) suggest mouthguards could be graded according to the degree of protection offered. Among criteria cited by these workers were dimensions for specific aspects on the appliance, 3 mm for labial aspects, 2 mm for occlusal aspects and 1 mm on palatal surfaces. In the light of the results in the current investigation, adequate coverage of the incisal/cuspal regions would seem to be of primary significance and should therefore be included in any specification designed to rank mouthguards according to protective effect. The current investigation highlights difficulties in achieving exact dimensions for specific areas for thermoformed appliances given that variations in processing technique can produce such a diverse magnitude of stretch patterns. It should however, using current thermoforming techniques, be reasonable to produce appliances with minimum dimensions in critical areas. Building up 3-mm thickness in vulnerable incisal/labial zones, however, can result in a material excess in other areas of appliances where stretching of the material was found to be much less. An example would be the palatal periphery where thermoformed EVA stretches much less but where optimum peripheral dimensions should be thin, of the order of 1 mm (21). This problem has led authors to advise differential trimming of individual layers that make up laminated mouthguards (8). Where increased stretching of the material is established, a practical alternative might be to plasticize and sandwich strips of thermoforming material over critical areas during the lamination process to ensure minimum dimensions are realized.

Authors in the current study speculated that softening further the material by increasing plasticizing or heating time would result in additional thinning of thermoformed EVA. However, the reverse was observed for samples heated for longer than recommended by the manufacturer. One explanation for this unexpected finding 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 as they transform from the elastic to a plastic state under the intense plasticizing heat source. As the model, in the technique under scrutiny, is placed directly below the material, this brings the two closer together during the plasticizing stage of thermoforming. When the manufacturer's recommended plasticizing time has elapsed, a gap of approximately 15–20 mm separates material from model. On activation of forming pressure the plasticized material is propelled at speed against the model. The momentum generated may be the cause of additional stretching. This effect is negated in the case of lengthy plasticizing times when continued heating causes the material to sag to the point of model contact, before forming pressure is exerted.

One dimension of EVA sheet material was tested in the current investigation. Further research could determine if the magnitude and patterns of stretching are similar for materials of differing thicknesses as well as for appliances made using multi-layered lamination techniques, made on different thermoforming instruments.

Conclusions

1. To achieve a specific minimum dimension in critical areas over the dental arch, it is likely that in excess of twice that thickness of sheet EVA must be used, for the combination of equipment, material and processing conditions tested in this study.
2. A significant pattern of increased stretching of thermoformed material is evident over incisal/cuspal regions of the dental model. Reduced cross-sectional bulk in this area on mouthguards may reduce protective efficacy, leaving mouthguard wearers' teeth more susceptible to injury.
3. In order to optimize protection in vulnerable areas, it is important that clinicians specify cross-sectional dimensions for finished mouthguards for trauma prevention.

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