Dental Traumatology

Dental Traumatology 2013; **29**: 378–382; doi: 10.1111/edt.12010

Postfabrication thickness of single- and double-layered pressure-formed mouthguards

Emine Sen Tunc[1], Turkan Egilmez Ozdemir[2], Selim Arici[3]

[1]Department of Pediatric Dentistry, Faculty of Dentistry, University of Ondokuz Mayıs, Samsun, Turkey; [2]Samsun Oral-Dental Health Center, Samsun, Turkey; [3]Department of Orthodontic Dentistry, Faculty of Dentistry, University of Ondokuz Mayıs, Samsun, Turkey

Key words: mouthguard; sports dentistry; thickness

Correspondence to: Emine Sen Tunc, Department of Pediatric Dentistry, Faculty of Dentistry, University of Ondokuz Mayıs, 55139 Samsun, Turkey
Tel.: +90 362 312 19 19 3783
Fax: +90 362 4576032
e-mail: sentunc@yahoo.com

Accepted 2 August, 2012

Abstract – *Aim*: The thickness of a mouthguard (MG) plays an important role in its primary function of preventing injuries. Multi-layered MGs have recently come into prominent use due to the disadvantages associated with single-layered MGs. Whereas researchers have evaluated the postfabrication thickness of single-layered MGs, the effects of fabrication procedures on multi-layered MGs are unknown. This study aimed to evaluate postfabrication thickness of various single-layered and double-layered pressure-formed MGs. *Materials and methods*: Mouthguards were fabricated using stone models produced from impressions of a phantom model maxillary arch. A total of 50 MGs were fabricated from ethylene vinyl acetate (EVA) sheets and divided into 10 groups of five according to the sheet(s) used in fabrication. The initial thickness of each sheet was recorded prior to fabrication. Following fabrication, MG thickness was measured at seven sites per MG. Data were analyzed using independent *t*-tests and one-way ANOVA followed by Tukey's test. *Results*: Mean reduction in MG thickness was 36–38% for single-layered MGs and 32–34% for double-layered MGs. Significant differences in thickness were seen between measured sites for all MG groups ($P < 0.05$). Maximum thinning occurred at the incisal edge of the central incisor, whereas minimum thinning was observed in the molar crown fissure sites for all groups. *Conclusion*: Clinicians should take into account the effects of fabrication on MG thickness. A loss of thickness of approximately 50% should be expected in critical areas of both single-layered and double-layered MGs made from EVA.

Sporting accidents are one of the most common causes of orofacial injuries (1, 2). The prevention of such injuries increases in importance as more children are encouraged to participate in sports (3). Mouthguards (MGs) are designed to reduce the severity and number of sports-related orofacial injuries (4) by absorbing and distributing forces incurred during sporting activities (5, 6).

There are three main types of MGs: stock, mouth-formed and custom-fabricated (7). Of these, custom-fabricated MGs are considered superior in terms of adaptation, retention, and comfort and for their minimal interference in both breathing and speech (8). Custom-fabricated MGs are constructed from thermoplastic material by either vacuum-forming or pressure-forming over a stone or plaster model of the patient's dentition. The former procedure shaped using low to moderate heat and a vacuum, whereas the latter relies on extremely high temperature and high pressure (7, 9, 10). The lamination cannot be achieved vacuum-forming; however, pressure-forming is capable of producing a chemical fusion of more than one layer of thermoplastic material (7). Pressure lamination has other advantages over vacuum lamination, including better internal adaptation of the material over the cast and subsequent adaptation of the MG in the mouth, with negligible deformation (9). Moreover, because pressure-formed MGs can be constructed from multiple layers, MG thickness can be adjusted through additional lamination (5, 10, 11). This technique allows for sport-specific design, such as the incorporation of hard inserts over the incisors for use in sports involving balls or projectiles and the use of a more shock-absorbing material for collision sports (12).

Mouthguard thickness has been a subject of ongoing discussions. Several authors have stated that the ideal MG should be as thin as possible while providing adequate protection and maximum respiratory efficiency (8, 13, 14). Recent studies have evaluated dimensional changes occurring during MG fabrication as a result of various factors, including pressure, heat, cast height, and sheet color (11, 15–17); however, these studies only examined MGs fabricated using single-layer techniques. Therefore, the aim of this study was to evaluate the final thickness of single- and double-layered MGs fabricated from ethylene vinyl acetate (EVA) sheets of varying thicknesses under standard fabrication conditions.

Materials and methods

Materials

All MGs were fabricated from natural-transparent EVA sheets (Drufosoft; Dreve-Dentamid, Unna, Germany) of 2, 3 and 4 mm in thickness and 120 mm Ø using a Biostar pressure-thermoforming unit (Great Lakes Orthodontics, Ltd., Tonawanda, NY, USA). All MGs were fabricated as described by Padilla.

Fabrication procedures

A total of 15 single-layered and 35 double-layered MGs were prepared and divided into 10 groups ($n = 5$) according to the thickness of the EVA sheet(s) used. Groups 1–3 used single sheets only and Groups 4–10 used double layers, as follows:

Group 1: 2 mm; Group 2: 3 mm; Group 3: 4 mm; Group 4: 2 + 2 mm; Group 5: 2 + 3 mm; Group 6: 3 + 2 mm; Group 7: 3 + 3 mm; Group 8: 3 + 4 mm; Group 9: 4 + 3 mm; Group 10: 4 + 4 mm.

Mouthguards were fabricated using stone models produced from impressions of the maxillary arch of a dental phantom model with an overall height of 2.5 cm. All MGs were produced to the same specifications, with the labial flange located within 2 mm of the vestibular reflection and the palatal flange approximately 10 mm above the gingival margin.

Fabrication was initiated by placing an EVA sheet on the pressure chamber gasket and locking it into place using a clamping frame. Once in place, a code was entered into the computer interface to initiate a preset heating session. The total heating time of 100 s for 2 mm, 110 s for 3 mm, and 120 s for 4 mm sheets was used. The pre-established heating temperature was 220°C for all sheets. The heating element was positioned over the EVA material, and the sheet was softened using the self-contained heat source. At the end of the heating period, the heating element was swung away from its location over the EVA sheet and returned to its resting position, and the pressure chamber containing the EVA material was flipped onto the platform containing the stone model. Once positioned over the model, the chamber was locked, allowing air to enter the chamber. The air pressure was set at approximately 5×10^5 Pa for all sheets. As the pressure in the chamber increased, the EVA sheet adapted to the shape of the model. Once pressurizing was completed, the EVA was allowed to cool. Following cooling, the air was released from the pressure chamber, the chamber was opened, and the EVA-enveloped model was removed. After further cooling and setting (a minimum of 30 min.), the MGs were removed from the model using light tensile force, trimmed, and labeled. In Groups 4–10, a second layer of EVA was adhered to the first using the same fabrication procedures described earlier.

Measurements

Prior to fabrication, each EVA sheet was measured at seven locations, and the average of these measurements was recorded in mm as the initial thickness. Following MG fabrication, thicknesses were measured at seven sites on the right side of the MG using a modified version of the technique originally described by Geary and Kinirons (17). For anterior region, incisal edge, midpoint on labial and lingual aspects of upper right central was measured. Mesiobuccal cusp, deepest part of fissure, midpoint on labial and lingual aspects of upper right first molar were measured at posterior region. To accurately assess MG thickness, dimensional measurements were obtained using an electronic digital thickness gauge (Guanglu, Guangxi, China) capable of detecting minute differences (resolution: 0.01 mm, 0.0005″). All measurements were performed by one of the authors (TE), who was blinded to the thickness of the EVAs used, and the measurement data (mm) for each group were used in statistical analysis (Fig. 1). Thinning rate was calculated using the following formulae:

Thinning rate = 100 − (mean value of thickness after fabrication/mean value of orginal thickness (s) × 100).

Statistical analyses

Data were analyzed using SPSS version 16.0 (SPSS Inc., Chicago, IL, USA). Independent *t*-tests were used to compare differences in initial and final thicknesses within each group and to examine the effects of initial thickness on postfabrication thickness. One-way analysis of variance (ANOVA) was used to evaluate any differences in thickness between different sites within a MG. Post hoc comparisons were made using the Tukey's HSD test. For all statistical analyses, the critical level of alpha was set at 0.05.

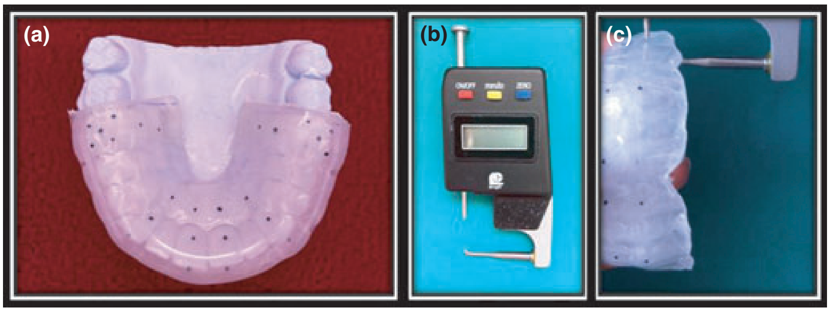

Fig. 1. Figure shows measurement procedure. (a) Fabricated mouthguard (MG); (b) measurement device; (c) Thickness measurement of a MG.

Results

Initial EVA thicknesses and postfabrication thicknesses of MGs (mm) are presented in Table 1. Overall reductions in thicknesses ranged from 36% to 38% for the single-layered MGs and 32–34% for the double-layered MGs. Differences in initial and postfabrication thicknesses were statistically significant for all groups ($P < 0.05$).

Thinning rates varied according to the sites measured that range 2–59% (Table 2). The highest thinning rate was shown in incisal edge for both single-layered and double-layered MGs (53–59%). Also, mean values for postfabrication thickness at the different measurement sites are shown in Table 2. Significant differences were seen between the measured sites in all groups. MG thickness was significantly greater at the molar crown fissure, and significantly lower at the incisal edge, than at all other sites tested for all groups ($P < 0.05$).

No statistically significant differences were found between Groups 5 and 6 or between Groups 8 and 9, suggesting that the order of sheets used in lamination did not affect postfabrication MG thickness (Table 3).

Discussion

Mouthguard fabrication procedures have undergone only relatively minor changes over the last 30 years. Early custom-made MGs were vacuum-formed from single sheets of EVA polymer on dental models (18). However, problems related to vacuum formation led to the introduction of pressure lamination, a method that provides excellent fit, determinable and uniform thickness and an extensive range of color combinations as a result of its high pressure, high temperature, and extra lamination (5, 10, 18). Information regarding the actual postfabrication thickness of pressure-laminated MGs is scarce; whereas single-layered pressure- and vacuum-formed MGs are known to be affected by fabrication conditions, how multi-layered MGs are affected is unknown. Geary and Kinirons (17) have asserted that the stretch patterns of additional layers of EVA may not follow that of original layer.

Table 1. Initial and postfabrication thicknesses (mm) and thinning rates of mouthguardS (MGs)

Groups	Initial thickness (mean ± SD)	Postfabrication thickness (mean ± SD)	Thinning rates (%)
Group 1 (2 mm)	2.11 ± 0.04	1.30 ± 0.28	38%
Group 2 (3 mm)	3.03 ± 0.05	1.94 ± 0.54	36%
Group 3 (4 mm)	4.07 ± 0.05	2.61 ± 0.79	36%
Group 4 (2 + 2 mm)	4.05 ± 0.04	2.74 ± 0.66	32%
Group 5 (2 + 3 mm)	5.14 ± 0.05	3.40 ± 0.76	34%
Group 6 (3 + 2 mm)	5.17 ± 0.05	3.44 ± 0.75	33%
Group 7 (3 + 3 mm)	6.03 ± 0.05	4.02 ± 1.01	33%
Group 8 (3 + 4 mm)	7.08 ± 0.05	4.70 ± 1.15	34%
Group 9 (4 + 3 mm)	7.12 ± 0.07	4.77 ± 1.16	33%
Group 10 (4 + 4 mm)	8.14 ± 0.05	5.35 ± 1.31	34%

Table 2. Mean measurements (mm) and thinning rates (%) of seven different measurement sites on different mouthguards (MGs) groups

	Measurement sites						
	Upper right central			Upper right first molar			
MG groups	Midpoint on labial aspect of tooth	Incisal edge	Midpoint on lingual aspect of tooth	Midpoint on buccal aspect of tooth	Mesiobuccal cusp	Fissure (deepest part)	Midpoint on lingual aspect of tooth
Group 1	1.17 ± 0.04^{b} (%45)	0.91 ± 0.02^{a} (%57)	1.38 ± 0.02^{d} (%35)	1.26 ± 0.10^{c} (%40)	1.13 ± 0.06^{b} (%46)	1.81 ± 0.05^{e} (%14)	1.41 ± 0.05^{d} (%31)
Group 2	1.69 ± 0.18^{b} (%44)	1.28 ± 0.11^{a} (%58)	2.24 ± 0.15^{c} (%26)	1.75 ± 0.16^{b} (%42)	1.61 ± 0.10^{b} (%47)	2.95 ± 0.03^{d} (%3)	2.08 ± 0.10^{c} (%31)
Group 3	2.25 ± 0.06^{b} (%45)	1.67 ± 0.09^{a} (%59)	3.29 ± 0.09^{d} (%19)	2.13 ± 0.13^{b} (%48)	2.09 ± 0.07^{b} (%49)	3.88 ± 0.06^{e} (%5)	2.97 ± 0.16^{c} (%27)
Group 4	2.36 ± 0.06^{b} (%42)	1.87 ± 0.06^{a} (%53)	3.02 ± 0.08^{d} (%25)	2.78 ± 0.04^{c} (%31)	2.41 ± 0.08^{b} (%39)	3.97 ± 0.01^{e} (%2)	2.83 ± 0.19^{c} (%30)
Group 5	2.90 ± 0.08^{b} (%44)	2.35 ± 0.10^{a} (%54)	3.85 ± 0.08^{d} (%25)	3.39 ± 0.04^{c} (%34)	2.96 ± 0.02^{b} (%42)	4.68 ± 0.52^{e} (%9)	3.71 ± 0.12^{c,d} (%28)
Group 6	2.96 ± 0.07^{b} (%43)	2.35 ± 0.14^{a} (%55)	3.89 ± 0.13^{d} (%25)	3.36 ± 0.17^{b,c} (%35)	3.20 ± 0.41^{b,c} (%48)	4.73 ± 0.32^{e} (%9)	3.64 ± 0.04^{c,d} (%30)
Group 7	3.28 ± 0.11^{b} (%46)	2.58 ± 0.11^{a} (%57)	4.62 ± 0.06^{e} (%29)	4.10 ± 0.03^{d} (%32)	3.67 ± 0.09^{c} (%49)	5.74 ± 0.08^{f} (%5)	4.21 ± 0.11^{d} (%30)
Group 8	3.90 ± 0.17^{b} (%45)	3.09 ± 0.14^{a} (%56)	5.55 ± 0.08^{e} (%22)	4.67 ± 0.10^{c} (%34)	4.08 ± 0.05^{b} (%42)	6.56 ± 0.16^{f} (%7)	5.09 ± 0.05^{d} (%28)
Group 9	4.10 ± 0.14^{b} (%43)	3.19 ± 0.11^{a} (%55)	5.74 ± 0.09^{e} (%19)	4.65 ± 0.09^{c} (%35)	3.98 ± 0.07^{b} (%44)	6.62 ± 0.20^{f} (%7)	5.16 ± 0.15^{d} (%28)
Group 10	4.44 ± 0.16^{b} (%46)	3.49 ± 0.20^{a} (%57)	6.59 ± 0.07^{e} (%19)	5.27 ± 0.06^{c} (%35)	4.55 ± 0.15^{b} (%44)	7.27 ± 0.19^{f} (%11)	5.85 ± 0.15^{d} (%28)

Differences in superscript letters indicate statistically significant differences within rows ($P < 0.05$).

Table 3. Mean postfabrication thickness of 2 + 3, 3 + 2 and 3 + 4, 4 + 3 mm groups (mm)

Group 5 (2 + 3 mm)	Group 6 (3 + 2 mm)	Group 8 (3 + 4 mm)	Group 9 (4 + 3 mm)
3.40 ± 0.76	3.44 ± 0.75	4.70 ± 1.15	4.77 ± 1.16

Independent *t*-test showed no significant difference between Group 5–6 and Group 8–9 ($P > 0.05$).

Thinning is an inevitable consequence of the thermoforming process (11). In the present study, although single-layered MGs showed greater thinning than double-layered MGs, thinning did not exceed 38% among single-layered MGs and 34% among double-layered MGs. In other words, additional lamination did not significantly affect thinning rates. The loss of material thickness of custom-made MGs during manufacturing has been reported to range from 25% to 52% (7, 14, 15, 17). Differences reported among studies may be related to differences in fabrication procedures, measurement sites, and measurement methods.

In terms of energy absorption and transmitted forces, cusps and incisal edges have been identified as critical areas. The thermoforming process can directly influence the thickness of custom-made MGs especially at critical areas either by thinning of the material during heating or by stretching of the material on pull-down (5). The present study found maximum thinning at the incisal edge of the incisors, ranging from 53% to 59%, followed by thinning at the midpoint of the labial aspect of the incisors, ranging from 42% to 46%. These findings support those of Geary and Kinirons (17), Del Rossi and Leyte-Vidal (11), and Park et al. (15), who reported thinning at the incisors ranging from 47% to 60%. Our study showed maximum thinning in the posterior region to occur at the mesiobuccal cusp of upper right first molar, which showed a loss of thickness ranging from 39% to 49%, which is similar to thinning rate that reported by Geary and Kinirons (17).

For all groups, thinning rates were comparatively lower at posterior crown fissures and ranged from 2% to 14%. These results are indicative of the importance of adjusting MG occlusion to mimic standardized bite pressure – a procedure that was not performed due to *in vitro* nature of this study. Without a balanced occlusion, a greater MG thickness, especially on molar occlusal surfaces, can impair speech and breathing as well as inducing a general feeling of discomfort (8, 19).

No statistically significant differences were found between Groups 5 and 6 or between Groups 8 and 9 in our study. These results indicate that the order of sheets used in lamination does not affect postfabrication MG thickness. It is possible that this finding may be related to the small difference in thickness between the sheets used. Given the importance of this issue in terms of MG adaptation, future studies may address the issue of initial sheet thickness in connection with MG adaptation.

The actual postfabrication thickness of a MG is a critical issue. Given that the primary function of an MG is the prevention of injury, several studies have evaluated MGs in terms of their protective effects (5, 15, 20–22). Material thickness plays a role in the preventive function of the MG; as the thickness of the material increases logarithmically, transmission of the force of impact decreases logarithmically (15). Along with energy absorption, player comfort should be taken into consideration in determining the thickness required for an MG. Overly thick MGs may meet with resistance from athletes if they cause discomfort or interfere with speech or respiration (23). The effects of MG thickness on orofacial structures such as lips, cheeks, and temporomandibular joints are also an issue of concern. A thick MG considerably increases the tension between lips and cheeks, thus increasing the possibility of an injury. An MG that is so thick as to prevent the mouth from closing is also dangerous, given the role of the lips and cheeks in protecting the teeth from direct impact forces. Moreover, given that the interocclusal space in the mandibular rest position generally ranges from 2 to 3 mm, MGs thicker than 2–3 mm could be neurophysiologically inappropriate (22). Appropriate MG thickness may also be affected by the type and level of sports and age of the player using the MG (14, 22, 24, 25); in other words, rather than relying on a standardized thickness, appropriate MG thickness should be decided on an individual basis. The findings of the present study may be used by clinicians to predict the actual final thickness of MGs fabricated for use in different clinical conditions.

Conclusion

Within the limitations of this *in vitro* study, the following conclusions can be drawn.

1. Single-layered MGs showed greater thinning than double-layered MGs, but thinning did not exceed 38% among single-layered MGs and 34% among double-layered MGs. So, additional lamination did not significantly affect thinning rates.
2. Clinicians should take into account the effects of fabrication on MG thickness. To aspects of protective thickness, a loss of thickness of approximately 50% should be expected in incisal/cuspal regions or both single-layered and double-layered MGs made from EVA.
3. Comparatively lower thinning rates should be expected at posterior crown fissures, for both single-layered and double-layered MGs made from EVA. Thus, to avoid developing resistance to MG use, proper occlusal adjustment should be done.
4. The sheets used in lamination did not affect postfabrication MG thickness. However, in future studies may address the issue of initial sheet thickness in connection with MG adaptation.

References

1. Hecova H, Tzigkounakis V, Merglova V, Netolicky J. A retrospective study of 889 injured permanent teeth. Dent Traumatol 2010;26:466–75.
2. Thelen DS, Bårdsen A. Traumatic dental injuries in an urban adolescent population in Tirana, Albania. Dent Traumatol 2010;26:376–82.

3. Johnston T, Messer LB. An in vitro study of the efficacy of mouthguard protection for dentoalveolar injuries in deciduous and mixed dentitions. Endod Dent Traumatol 1996;12:277–85.
4. Lieger O, von Arx T. Orofacial/cerebral injuries and the use of mouthguards by professional athletes in Switzerland. Dent Traumatol 2006;22:1–6.
5. Westerman B, Stringfellow PM, Eccleston JA. EVA mouthguards: how thick should they be? Dent Traumatol 2002;18:24–7.
6. Takeda T, Ishigami K, Shintaro K, Nakajima K, Shimada A, Regner CW. The influence of impact object characteristics on impact force and force absorption by mouthguard material. Dent Traumatol 2004;20:12–20.
7. Padilla RR. A technique for fabricating modern athletic mouthguards. J Calif Dent Assoc 2005;33:399–408.
8. Duarte-Pereira DM, Del Rey-Santamaria M, Javierre-Garcés C, Barbany-Cairó J, Paredes-Garcia J, Valmaseda-Castellon E et al. Wearability and physiological effects of custom-fitted vs self-adapted mouthguards. Dent Traumatol 2008;24:439–42.
9. Choy MM. A comparison of custom-made mouthguards. Hawaii Dent J 1998;29:28.
10. Padilla RR, Lee TK. Pressure-laminated athletic mouth guards: a step-by-step process. J Calif Dent Assoc 1999;27:200–9.
11. Del Rossi G, Leyte-Vidal MA. Fabricating a better mouthguard. Part I: factors influencing mouthguard thinning. Dent Traumatol 2007;23:149–54.
12. McCrory P. Do mouthguards prevent concussion? Br J Sports Med 2001;35:81–2.
13. Guevara PA, Ranalli DN. Techniques for mouthguard fabrication. Dent Clin North Am 1991;35:667–82.
14. ADA Council on Access, Prevention and Interprofessional Relations; ADA Council on Scientific Affairs. Using mouthguards to reduce the incidence and severity of sports-related oral injuries. J Am Dent Assoc 2006;137:1712–20.
15. Park JB, Shaull KL, Overton B, Donly KJ. Improving mouth guards. J Prosthet Dent 1994;72:373–80.
16. Del Rossi G, Lisman P, Signorile J. Fabricating a better mouthguard. Part II: the effect of color on adaptation and fit. Dent Traumatol 2008;24:197–200.
17. Geary JL, Kinirons MJ. Post thermoforming dimensional changes of ethylene vinyl acetate used in custom-made mouthguards for trauma prevention–a pilot study. Dent Traumatol 2008;24:350–5.
18. Westerman B, Stringfellow PM, Eccleston JA. Beneficial effects of air inclusions on the performance of ethylene vinyl acetate (EVA) mouthguard material. Br J Sports Med 2002;36:51–3.
19. Gardiner DM, Ranalli DN. Attitudinal factors influencing mouthguard utilization. Dent Clin North Am 2000;44:53–65.
20. Bemelmanns P, Pfeiffer P. Shock absorption capacities of mouthguards in different types and thicknesses. Int J Sports Med 2001;22:149–53.
21. Tran D, Cooke MS, Newsome PR. Laboratory evaluation of mouthguard material. Dent Traumatol 2001;17:260–5.
22. Maeda M, Takeda T, Nakajima K, Shibusawa M, Kurokawa K, Shimada A et al. In search of necessary mouthguard thickness. Part 1: from the viewpoint of shock absorption ability. Nihon Hotetsu Shika Gakkai Zasshi 2008;52:211–9.
23. Francis KT, Brasher J. Physiological effects of wearing mouthguards. Br J Sports Med 1991;25:227–31.
24. Scott J, Burke FJ, Watts DC. A review of dental injuries and the use of mouthguards in contact team sports. Br Dent J 1994;176:310–4.
25. Takeda T, Ishigami K, Ogawa T, Nakajima K, Shibusawa M, Shimada A et al. Are all mouthguards the same and safe to use? The influence of occlusal supporting mouthguards in decreasing bone distortion and fractures. Dent Traumatol 2004;20:150–6.