

1 Farrington T, Coward T, Onambele-Pearson G, Taylor RL, Earl P, Winwood K, 2016. The  
2 effect of model inclination during fabrication on mouthguard calliper-measured and CT-scan  
3 assessed thickness. *Dental Traumatology* [doi: 10.1111/edt.12213. [Epub ahead of print]]  
4

5 **Abstract.**

6

7 **Aim:** Excessive material thinning has been observed in the production of custom-made mouthguards  
8 in a number of studies, due to production anomalies that may lead to such thinning. This study  
9 investigated the effect of thinning material patterns of custom made mouthguards when the anterior  
10 angulation of dental model was increased during the thermoforming process.

11 **Materials & Methods:** A total of 60 samples of mouthguard blanks were thermoformed on identical  
12 maxillary models under four anterior inclination conditions (n=4×15); control 0°, 15°, 30°, and 45° .  
13 Each mouthguard sample was measured, using an electronic calliper gauge, at 3 anatomical points  
14 (anterior labial sulcus, posterior occlusion and posterior lingual). Mouthguards were then CT scanned  
15 to give a visual representation of the surface thickness.

16 **Results:** Data showed a significant difference ( $p < 0.005$ ) in the anterior mouthguard thickness  
17 between the four levels of anterior inclination, with the 45° inclination producing the thickest  
18 mouthguards, increasing the mean anterior thickness by 75% (2.8mm, SD: 0.16) from the model on a  
19 flat plane (1.6mm, SD: 0.34). Anterior model inclination of 30° and 45° inclinations increased  
20 consistancies between the thickest and thinnest mouthguards in the anterior region of these sample  
21 groups.

22 **Conclusion:** This study highlights the importance of standardising the thermoforming  
23 process, as this has a significant effect on the quality and material distribution of the resultant  
24 product. In particular, greater model inclination is advised as this optimises the thickness of  
25 the anterior sulcus of the mouthguard which may be more prominently at risk from sport-  
26 related impact.

## 27 INTRODUCTION

28 The primary function of a mouthguard is to protect the dentition and some of the surrounding  
29 structures from violent traumatic impacts during sporting activities [1-3]. Of all the types of  
30 mouthguards, stock, boil & bite and custom-made, it has been proposed that custom  
31 mouthguards provide a superior fit [1]. However, in the process of construction, when  
32 forming the mouthguard material over the dental model thinning occurs [4-6]. A common site  
33 of excessive material thinning has been reported in the anterior region of finished custom-  
34 made mouthguards, using current single layer techniques [3-6].

35

36 Reduction within thickness in EVA has been shown to affect the ability to dissipate impact  
37 forces, as it has been shown that there is a direct correlation between material thickness and  
38 attenuation of force [7, 8]. Westerman et al. [7] found that both 1 mm and 2 mm thickness of  
39 unformed ethylene vinyl acetate (EVA) offers lower protection in relation to energy  
40 absorption. They reported that a 2 mm thickness of mouthguard material was more than three  
41 times less effective of absorbing force than a 4 mm piece of material, (15.70 kN in  
42 comparison to 4.38 kN). Increasing the material thickness beyond 4 mm, with 5 and 6 mm  
43 blanks reducing transmission forces to 4.03 kN and 3.91 kN respectively, showing marginal  
44 differences and hence evidence of a plateau occurring in relation to force absorption.

45

46 Del Rossi et al. [6] and Geary et al. [4] observed material stretching and thinning of EVA  
47 when forming over the dental cast [4, 6]. Del Rossi et al. [6] examined model height and jaw  
48 size from impressions taken of the maxillary dentition of 15 subjects. For each subject three  
49 duplicate models were fabricated, and model heights created of 20mm, 25mm, and 30mm. A  
50 single 3 mm mouthguard blank was formed over each testing condition, and measurements  
51 were taken. In the anterior and canine region of the mouthguard they observed a mean

52 material thinning of: 47% (mean thickness 1.6 mm) with the model at 20 mm in height, 53%  
53 (mean thickness 1.4 mm) at 25 mm and 60% (mean thickness 1.2 mm) at a model height of  
54 30 mm. In the molar cusp measurement point the thickness was reported as a constant  
55 thickness of 1.6 mm for all three model heights [6]. Their findings suggested, as the model  
56 gets higher, the mouthguard material thins' in the labial (incisal) region thus to reduce these  
57 factors the model height should be kept as low as possible [6].

58

59 Geary et al. [4] examined more widely the variations in the manufacturing process that may  
60 cause stretching (thinning) of the EVA material, i.e. model height, shape, position on  
61 thermoforming platform, plasticizing time and dental model inclination. With relation to  
62 model height, Geary et al. [4] observed when the model height was increased from 25 to 35  
63 mm there was an additional thinning of the EVA material of 21% (from 1.53 to 1.21 mm)  
64 when using a 3 mm blank. This translates to an overall thinning of the material e.g. in the  
65 case of the 25 mm model height a mouthguard material thinning to 1.53 mm or by 49%, and  
66 with the model height at 35 mm with a material thinning of 1.21 mm or by 60% [4], this is  
67 comparable to findings observed by Del Rossi et al. [6] previously mentioned. Geary et al.  
68 [4] also altered the dental model position on the mounting platform (insert bowl) from the  
69 centre (1.53 mm), with the labial and then the distal aspects of the model placed on the  
70 outermost edge of the mounting platform, in two separate testing conditions. They observed  
71 that the model position on the mounting platform significantly ( $p < 0.01$ ) increased the  
72 stretching of the mouthguard material, from 3 mm to a mean of 1.53 mm for the control  
73 (centred model) and 1.31 mm for the model at the edge of the mounting platform, which  
74 represents a 49% and 56% material thinning respectively [4]. Geary et al. [4] studied the  
75 heating of the EVA material during the thermoforming process with regards to material  
76 thinning. They reported that by increasing heating time by 30 seconds, the amount of thinning

77 in the material was in fact reduced, theorising that the EVA material transforms from its  
78 elastic plasticised state to its plastic state, on contact with the dental model, earlier than it  
79 would have with a shorter heating time [4].

80

81 A number of studies have investigated variations in heating conditions, in relation to  
82 mouthguard thinning, when using a vacuum forming machine [9-11]. Mizuhashi et al [10,11]  
83 and Takahashi et al, [9] tested mouthguard material that was heated on both sides prior to  
84 forming [9, 11], the distance from the heat source is increased [9] and the heat source is  
85 turned off for a short duration prior to forming [9] and the mouthguard material is lowered  
86 over the model in two test conditions: (a) before (b) after the vacuum is applied [10].  
87 Mizuhashi et al, [10, 11] reported no significant change in finished mouthguard thickness in  
88 the anatomical measurement sites of interest, i.e. anterior (central incisor) and posterior (first  
89 molar), regardless of the thermoforming conditions. However, these authors did report a  
90 “*superior fit*” and retention of the mouthguards, using the following adaptations  
91 to recommended heating methods: when the vacuum is applied before the mouthguard  
92 material is lowered over the dental model [10]. When the heated surface came into contact  
93 with the surface of the dental model, in this case the material being heated to a 1.5 cm sag on  
94 both sides prior to forming [11], the mouthguard blank was lowered 50 mm from the heat  
95 source than ordinarily used. When the blank reached a 10 mm sag, the heat source was  
96 turned off until the blank reached a 15 mm sag before forming. Takahashi et al. [9]  
97 hypothesised by slightly lowering the mouthguard material from the heat source, this would  
98 create slower raise in material temperature which leads to a more uniform softening of the  
99 mouthguard blank prior to forming. Their results reported this final test condition also had a  
100 26% reduction in thinning, when using a 4 mm mouthguard EVA blank.

101

102 As variations in model height and heating methods have been previously examined, the  
103 present study investigated how manipulation of the inclination of a dentate model would  
104 modulate the distribution of the EVA material which was visually seen by CT scanning. It  
105 was hypothesised that by systematically increasing the anterior angulations of the dental  
106 model during the thermoforming process, there would be an increase in the thickness of the  
107 anterior sulcus section throughout the mouthguard which could increase impact protection.

**108 MATERIALS & METHOD.**

109 Ethical approval was sought and obtained prior to commencement of the study, from the ethics  
110 committee at the Department of Exercise and Sport Science, Manchester Metropolitan University.

111

**112 *Model Selection and Preparation.***

113 A suitable generic average sized model was pre-selected from demonstration models on which  
114 appliances are made for training purposes for clinicians. The single master model was duplicated to  
115 produce a group of 60 identical models on which the mouthguards were to be formed. Five random  
116 duplicate models were chosen from the group and were examined by Computed Tomography (CT)  
117 scanning technology (Scanner: GE Medical Systems)(Light Speed 16, Mode of Capture – Helical,  
118 Gantry Tilt – 0 Voxel Size – 0.7031 x 0.7031 x 0.5, Matrix Size – 256 x 256, KV – 120, Ma – 90,  
119 Reconstructed in 0.625 mm axial slices) to determine the degree of distortion/variability that that can  
120 occur during the duplication process. Robin's 3D - 3D Editor Software (Robin Richards, London,  
121 UK) was used to establish an algorithm technique to calculate the least square fit points between the  
122 two images surfaces [12]. The programme overlays two images as closely as possible to an average  
123 number of points (200). The difference between the two surfaces is expressed as a colour chart,  
124 which is assigned to a numerical value this can be set from 10.0 to 0.001 mm. Overall, there was a  
125 slight distortion of +/-0.2mm observed in the anatomical region between the five duplicate models  
126 (Figure 1). However, this was deemed to be within acceptable tolerances within dentistry [13].

127

128

&lt; INSERT FIGURE 1 HERE &gt;

129

130

131 A total of 60 mouthguards were segregated into four inclination conditions (n=15 per group)  
132 which consisted of 0° (flat), 15°, 30°, & 45°. The mouthguards were fabricated using 4mm

133 thick, EVA, 120 mm Ø (diameter) clear mouthguard blanks (Bracon Dental Laboratory  
134 Products, East Sussex, UK). A Drufomat Scan (Dreve Dentamid GMBH, Unna/Germany)  
135 was used for the pressure thermoforming process. This was used due to its audible marker  
136 that indicates when the mouthguard is to be pressure formed. This feature gives the study  
137 consistency as each blank is heated and blown down at the same point in time, thus reducing  
138 any further variability and potential experimental error.

139

#### 140 *Fabrication of Angle Blocks.*

141 Angulation blocks were fabricated using vacuum mixed Crystical R dental stone (BPB  
142 Formula, Nottinghamshire, UK). These were then trimmed on a Wehmer trimming machine  
143 (Model 108; Wehmer corporation, IL, USA), which is often used for orthodontic study  
144 models, due to the precision calibrated engraved protractor on the trimming table and an  
145 angulation tool for precision trimming of dental stone. The blocks were trimmed to gradients  
146 of 15°, 30° and 45° (Figure 2), and then inserted into the machine as shown in Figure 3. The  
147 angulation blocks inclinations were checked using a Cephalometric protractor/template  
148 (Ortho-Care Ltd, West Yorkshire, UK).

149

150 < INSERT FIGURE 2 HERE >

151

152 The insert bowl on which the model is normally placed during the forming process was  
153 removed to allow for the rotation of the model by 15°, 30°, and 45°, as the current system did  
154 not allow enough depth for inclination of the anterior section. For the purpose of this study,  
155 three removable plates were cast (Crystacal R) into the base of the “F insert” vessel, to form a  
156 stable base on which the models and angulation blocks could be seated. The new plates were  
157 made to heights of 27 mm for the 15°, 16 mm for the 30° and 12 mm for the 45°. Thus

158 accommodating the rotation of the model in the “F insert”, creating a constant 10 mm gap  
159 between the incisal tip of the dental model and the underside of the “plate reception” (Figure  
160 3).

161

162 &lt; INSERT FIGURE 3 HERE &gt;

163

164 Care was taken not to cover the vent hole in the F insert, which allows the air to escape  
165 during the thermoforming as this may alter the function of the pressure forming process. All  
166 models were treated with an isolating layer of sodium alginate (Isolant Cold Mould Seal,  
167 Dentsply, DeTrey GMBH, Germany) prior to forming the mouthguard, to allow easier  
168 removal of the formed EVA blank from the dental model once cooled. The Drufoformat Scan  
169 provides a barcode programming system that stipulates material specific heating and cooling  
170 times, dependant on blank thickness. Amongst the available settings, the ‘Drufoformat 4,0’  
171 program was selected, which involves 2.10mins heating, 7.00mins cooling at a 4.5 bar  
172 pressure, as it was comparable to the size and thickness of the 4 mm blank selected for this  
173 study. The audible beep by the machine indicated when to apply the pressure and how long  
174 to leave the mouthguard material to cool prior to releasing the pressure. All test samples were  
175 produced by the same operator and thermoforming machines manufacturers suggested  
176 program (as detailed above) to minimise any potential errors and variability during the  
177 forming process.

178

### 179 *Dimensional Measurements*

180

181 &lt; INSERT TABLE 1 HERE &gt;

182



183 An electronic calliper gauge (External Digital Caliper 442-01DC Series, Moore & Wright,  
184 UK) was used to measure the thickness of the finished mouthguards at the measurement  
185 points shown in Table 1. The callipers had a range resolution of 0.01 mm. Each anatomical  
186 point on the mouthguard was measured three times with a mean value obtained. After each  
187 measurement the gauge was zeroed. Callipers were calibrated by the use of a 4 mm steel  
188 calibration block, grade 1, ISO-DIN-BS (Cen Dev  $\mu\text{m}$  +0.02, Max Dev +0.02, Min Dev  
189 -0.11, Variation 0.13) (Alan Browne Ltd) and were used at every measurement session to  
190 check the accuracy of the gauges.

191

## 192 **CT Scans**

193 A mouthguard from each condition (Control , 15°, 30° & 45°) was scanned using a CT  
194 scanner (Make & Model: Scanner: GE medical Systems.)(Light Speed 16, Mode of Capture –  
195 Helical, Gantry Tilt – 0 Voxel Size –  $0.7031 \times 0.7031 \times 0.5$ , Matrix Size –  $256 \times 256 \times 97$ ,  
196 KV – 120, Ma – 90, Reconstructed in 0.625 mm axial slices). The scanned images were  
197 then transferred for further analysis using Robin's 3D - 3D Editor Software (V3.1.0.0) (Robin  
198 Richards, London, UK). Each image was scaled and the extraneous image noise (unwanted  
199 scanned information i.e. the surface the mouthguard was scanned on) from the image was  
200 also removed using the program's edit suite. The Houndsfield threshold of the scanned  
201 images were then scaled against the original measurements of the corresponding mouthguard,  
202 and the image was saved as an STL data file. The desired STL image was opened in Robin's  
203 Cloud - Polygon Mesh Manipulator program (V3.0.7). The image was sized and rotated to  
204 the desired orientation. A copy of each STL image was simultaneously opened. The surface of  
205 interest on the first image was highlighted using the 3D edit function within the program, and  
206 the foreground discarded.

207

208 Difference of surface command compared the background of the edited image (first) against the  
209 foreground of the second image, effectively comparing the fit surface of the mouthguard against its  
210 outer most surface, giving a single image, containing a colour map of thickness of the mouthguard  
211 (Figure 7). The comparison range on the output image was set at 4.000 mm. Finally, the comparison  
212 image was captured using Photoshop and saved as a JPEG file. Figure 7 served purely as a visual  
213 comparison of the thickness changes over the whole of the anterior section of the mouthguard in each  
214 testing condition.

215

### 216 *Statistical Analysis*

217 Statistical analysis was performed using PASW<sup>®</sup> Statistics 18 (SPSS Inc., Chicago, IL, USA).  
218 Sphericity checks were carried out using the Mauchly's test and Greenhouse-Geisser  
219 corrections applied where the assumptions were violated, i.e. sphericity not assumed. To  
220 identify any impact of dental model anterior inclination on the variability in mouthguard  
221 thickness, a repeated measures ANOVA was performed at each discrete anatomical  
222 measurement site. Post-Hoc pairwise comparisons, with Bonferroni corrections, were  
223 carried out where a main effect was identified. Data are presented as mean  $\pm$  STDEV unless  
224 otherwise specified. Statistical significance was accepted at  $\alpha \leq 0.05$ . Z-score analyses were  
225 also carried out on the outliers in Figures 4, 5 and 6.

226

### 227 **Results**

228 Measurements from all levels of inclination are reported in Table 2 and expressed in Figures  
229 4-6, values are expressed as mean thickness dimensions for the anterior, posterior-lingual,  
230 and occlusal regions.

231

232

< INSERT TABLE 2 HERE >

233

234 Anterior Section (Site A, Table 1):

235 The results showed that there was a highly significant difference, ( $p < 0.0001$ ), in anterior  
236 mouthguard thickness, between the varying degrees in anterior inclination of the dental  
237 model (Figure 4). Post-hoc pairwise comparisons showed a significant difference greater  
238 than  $p < 0.005$  in the anterior mouthguard thickness, between all four groups, when inclining  
239 the anterior region dental model by  $15^\circ$ ,  $30^\circ$  and  $45^\circ$ . In the anterior measurement section,  
240 there was a mean value decrease from baseline (flat) in thickness of the 4mm single laminate  
241 sheet by 60%,  $15^\circ$  inclination by 53%,  $30^\circ$  inclination by 40%, and  $45^\circ$  inclination by 30%  
242 respectively (Table 2).

243

&lt; INSERT FIGURE 4 HERE &gt;

244

245 Occlusal Section (Site B, Table 1):

246 The results showed that there was a highly significant difference,  $p < 0.0001$  in the occlusal  
247 mouthguard thickness, between the varying degrees of anterior inclination (Figure 5). The  
248 ANOVA showed a significant difference of  $p < 0.0001$  between all groups but the post hoc  
249 tests were used to identify where those differences were and showed non-significance for  
250 inclination groups  $15^\circ$  and  $30^\circ$  (Table 2 and Figure 5). In the occlusal measurement section,  
251 there was a mean value decrease from baseline (flat) in thickness of the 4mm single laminate  
252 sheet by 45%,  $15^\circ$  inclination by 55%,  $30^\circ$  inclination by 52%, and  $45^\circ$  inclination by 62%  
253 respectively (Table 2).

254

255

&lt; INSERT FIGURE 5 HERE &gt;

256

257 Posterior-Lingual Section (Site C, Table 1)

258 The results showed that there was a significant difference, ( $p < 0.0001$ ) in posterior-lingual  
259 mouthguard thickness, between the varying degrees in anterior inclination of the dental  
260 model (Figure 6). The ANOVA showed a significant difference of  $p < 0.05$ , in posterior-  
261 lingual mouthguard thickness between all groups but the post hoc tests were used to identify  
262 where those differences were and showed non-significance for inclination groups  $15^\circ$  and  $30^\circ$   
263 (Table 2 and Figure 6). In the posterior-lingual measurement section, there was a mean value  
264 decrease from baseline (flat) in thickness of the 4mm single laminate sheet by 37%,  $15^\circ$   
265 inclination by 42%,  $30^\circ$  inclination by 47%, and  $45^\circ$  inclination by 60% respectively (Table  
266 2).

267

268

&lt; INSERT FIGURE 6 HERE &gt;

269

### 270 *CT scans of mouthguards*

271 Four typical CT scanned images show the thickness typography of the finished mouthguards  
272 for each angulation group (Figure 7). As the mouthguard thickness increases, the mouthguard  
273 image changes from a light blue, denoting approximately 1.6 mm to a red which denotes a  
274 thickness of 2.8 mm (Figure 7). The scanned images are purely visual representations to  
275 illustrate the thickness distribution, over the whole anatomy of the finished mouthguard, for  
276 each test variable and degree of anterior inclination. The scanned image was scaled to the  
277 thickness of each of the selected mouthguards to set anatomical measurement points in the  
278 anterior sulcus and posterior occlusion.

279

&lt; INSERT FIGURE 7 HERE &gt;

280

281

**282 Discussion**

283 The thickness of a mouthguard has been shown to directly correlate with the rate at which  
284 energy is absorbed [7, 8], therefore it is imperative to obtain the optimal material thickness  
285 when manufacturing custom-made mouthguards and thereby increase their protective  
286 potential against orofacial trauma from impact in sport. A proposed solution to address the  
287 thinning problem, seen with finished mouthguards, is to laminate the material using one or  
288 more layers to increase the finished thickness of the mouthguard [4, 14]. However, the  
289 lamination technique, where a second mouthguard blank is formed over the initial formed  
290 mouthguard, can sometimes suffer from poor bond strength between two layers of  
291 mouthguard material leading to delamination of the finished mouthguards, especially with  
292 vacuum formed mouthguards [15]. Model selection for this study was verified by two studies,  
293 that of Mills, [16] and Uysal et al, [17]. Mills, [16], in a study where 230 males aged 17-21  
294 years were assessed. They reported a mean maxillary arch width of  $35.13 \pm .20$  mm in the  
295 inter-canine region,  $41.60 \pm .17$  mm in the region of the first premolars,  $47.05 \pm .18$  mm in  
296 the region of the second premolars and an arch length of  $32.79 \pm .20$  mm. Uysal et al. [17]  
297 also examined a mixed gender cohort of 150 participants (males 72, females 78) with a  
298 normal occlusion, the mean arch width in the inter-canine region was 34.4 (SD: 2.1) mm, 42.1  
299 (SD: 2.5) mm in the first pre-molar region and 50.7 (SD: 3.7) mm in the maxillary inter-  
300 molar width. The selected master model used in this study, had an arch width of 34.5 mm  
301 maxillary inter-canine, 40.5 mm maxillary inter first premolar width, 46 mm maxillary inter  
302 second premolar, 49 mm maxillary inter-molar width and arch length from the midline of the  
303 central incisors and the gingiva of the mesio-palatal first molar cusp is 32 mm, at the same  
304 measurement points respectively. From both Mills, [16] and Uysal et al, [17] studies the  
305 maxillary model measured within  $\pm 1.7$  mm at the same measurement points.

306

**307 *Influence of the Degree of Inclination on Thickness.***

308 By elevating the anterior section of the model by 15°, 30° and 45° there was a statistically significant  
309 ( $p < 0.005$ ) reduction in thinning in the anterior region of the mouthguard material during the forming  
310 process, Table 2 and was illustrated in Figure 7. A 45° anterior angulation of the dental model  
311 produced the mean thickest mouthguards in the anterior region 2.8 mm with a reduction of original  
312 laminate thickness of 30% (SD: 0.16). However, the anterior increase in thickness came predictably  
313 at the expense of the occlusal mouthguard thickness which reduced to 1.5 mm with a reduction of  
314 original laminate thickness of 62% (SD:0.10). In addition, the posterior-lingual region reduced to  
315 1.6 mm with a reduction of original laminate thickness of 60% (SD: 0.15).

316

317 In relation to the CT scans when the model was kept flat on the forming platform, the anterior flange  
318 of the mouthguard can be seen to be predominantly green, turning to blue towards the edge of the  
319 mouthguard flange (Figure 7). This indicates that the material is less than 2 mm thick in this region,  
320 and in the case of the blue, less than 1 mm. With the model held at a 15° angle, there is a greater  
321 proliferation of yellow, denoting that the thickness has increased to greater than 2 mm in this region.  
322 However, the edge of the anterior flange of the mouthguard is still green and therefore less than 2 mm  
323 in this region. When the model was placed at a 30° angle the lingual anterior flange the finished  
324 mouthguard is generally yellow, showing the mouthguard is above 2 mm in this region. Also, there is  
325 a greater degree of red in the gingival and inter dental spaces, indicating the material thickness has  
326 increased to approximately 3 mm in this region. Finally, when the model was placed at a 45° angle,  
327 Figure 7d, a greater prevalence of red/orange is seen denoting the finished mouthguard has increased  
328 thickness between 3-4 mm within this region (Figure 7).

329

330 It has been postulated that mouthguards could offer protection against concussion, through the shock  
331 absorbency quality of the mouthguard between the occlusion, preventing or lowering the transmission  
332 of traumatic impact forces from the mandible to the maxilla and subsequent cranial vault [18].

333 However, Benson, Hamilton, Meeuwisse, McCrory & Dvorak. [19] report there is no strong evidence  
334 to support as to whether mouthguards do reduce the risk of concussion. The current new technique  
335 reduced the mean occlusal thickness of the mouthguard from 2.2 mm, with the model flat on the  
336 forming table (0°), to 1.5 mm with the anterior of the model inclined to a 45° angle. The posterior  
337 lingual/palatal section of the mouthguard is a region of the oral cavity that would be at a much  
338 reduced risk of impact due to its inaccessibility. Therefore, we considered that the thickness of the  
339 mouthguard in this region could may be 'sacrificed' and redistributed to the anterior region of the  
340 mouthguard where the majority of the thinning is normally observed. What is more, anterior orofacial  
341 injuries are highly prevalent in sport, with this region most at risk of a traumatic impact from an  
342 opponent, via a punch, kick, elbow, or equipment i.e. ball, bat, handlebars, racquet [20-22].

343

344 The thinning of the mouthguard material within these specific anatomical regions may reduce  
345 the protective efficiency of the mouthguard and leave the wearer more susceptible to  
346 orofacial injury [4]. Conversely, the increase in material thickness has been shown to reduce  
347 force absorption, which would therefore increase the protective potential of the finished  
348 mouthguard [7]. Therefore, the 45° angulation of the model seems to be the optimum model  
349 rotation as it increases the anterior region of the mouthguard to a mean thickness of 2.8 mm,  
350 and the mean occlusal reduced thickness of 1.5 mm. However, a thicker mouthguard blank  
351 could potentially increase the occlusal surface. In other words, with increased angulation,  
352 despite the 'sacrificed' thickness in the posterior lingual/occlusal region, the mouthguard's  
353 ability to dissipate commutable impact forces between the mandibular and maxillary  
354 dentition and substructure is still maintained.

355

356 In the current study the thicknesses in the anterior region of the finished mouthguards were  
357 more consistent, (mean Coefficient of Variation = 5.9%) when the model was inclined at 45°

358 (Figures 4 – 6). Figure 4 shows at 0° there is a large variation between the upper and lower  
359 ends of the whiskers of the box plot chart. In contrast, with angles 15°, 30° & 45°, there is a  
360 much closer gap between the upper and lower extremes of the whiskers of the box plot,  
361 indicating greater consistency in these samples. This leads to the assumption that the  
362 inconsistency of anterior mouthguard thickness could may decrease if the proposed technique  
363 of angling the anterior section of the dental model by 45° was employed.

364

365 There seems to be very little published data on this subject matter for comparative analysis.  
366 Geary et al. [4] as part of their study examined model inclination and orientation variables  
367 that can affect mouthguard thinning. Geary et al. [4] took measurements in 12 anatomical  
368 regions, 5 in the anterior and 7 posteriorly. They examined both inclination of the anterior and  
369 posterior sections of the model by tilting 10 mm and 20 mm. This had the effect of stretching  
370 the material to 1.26 mm (P <0.001) in the first instance and to 1.17 mm (P <0.001) in the  
371 second. They reported a significantly higher degree of material thinning in the incisal anterior  
372 and cuspal posterior region of the finished sample mouthguard [4].

373

374 As one of their testing conditions, Geary et al. [4] tilted the dental model posteriorly by 10  
375 mm, effectively rotating the model, increasing the elevation of the anterior section of the  
376 dental model, as seen within this current study. Geary et al. [4] also inclined the anterior of  
377 the model, by tilting the posterior down by 10 mm. To achieve a comparison between  
378 Geary's study [4] and this current study, a model from the present study, that is believed to be  
379 a fair representation of the average size of maxillary dentition, was subjected to the same  
380 preparation technique by reducing the posterior portion of the models by 10 mm. When  
381 using an orthodontic cephalometric protractor (Ortho-Care Ltd, West Yorkshire, UK) this



382 would equate to a 9° inclination of the anterior section as opposed to the much higher  
383 angulation of 15°, 30° and 45° used in the current study.

384

385 The technique used in the current study used removable plates and angulations blocks, which  
386 employed greater accuracy and consistency during the manufacture of the test samples.  
387 However, this technique cannot be easily incorporated on all vacuum-forming machines. The  
388 dental model may therefore be placed in lead shot at the proposed angle of 45°, or  
389 alternatively when the initial model is cast, the angle of the impression tray can be based to  
390 achieve a 45° anterior inclination to save time and materials. In future thermoforming  
391 machine manufacturers may wish to include a forming table that can be angled, by as high as  
392 45°. In addition, future studies could test the proof of principle using thicker blanks of 5mm  
393 or 6mm, in terms of determining the optimal degree of angulation. Furthermore, it is our  
394 recommendation that the technique of anterior model inclination to reduce material thinning,  
395 be tested in laminated mouthguard production, since the properties of laminated models are  
396 expected to differ from those used in the present study.

**397 Conclusion**

398 Excessive thinning of the mouthguard material has been observed in a number of studies [4,  
399 5, 6, 9-11, 23] could be redistributed to areas at less risk of direct impact, through the  
400 angulation of the anterior section of the dental model. Correspondingly, the thickest section  
401 of mouthguard is created over the anatomical site of the dental model that is at greater risk of  
402 direct impacts i.e. the anterior sulcus. There is a significant increase in difference in thickness  
403 of mouthguards ( $P < 0.05$ ) when the anterior section of the dental models are elevated by  
404 varying degrees. The optimum increase of dental model angulation, in the anterior section,  
405 was by  $45^\circ$ , increasing the finished thickness of a mouthguard by as much as 75% in the  
406 anterior sulcus region. Even though there were slight reductions in other measurement sites  
407 these could possibly increase by using a thicker mouthguard blank. This technique whereby  
408 the dental model should be held with an anterior inclination can easily and at no extra cost be  
409 implemented to maximise the protective function of the mouthguard in the anterior region.

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