Farrington T, Coward T, <u>Onambele-Pearson G</u>, Taylor RL, Earl P, Winwood K, 2016. An
 investigation into the relationship between thickness variations and manufacturing
 techniques of mouthguards. *Dental Traumatology.* 32(1):14-21

5

6 ABSTRACT.

7

Background: The aim of the present study was to measure the finished thickness of a
single identical 4mm laminate mouthguard model from a large fabricated sample group
and to evaluate the degree of material thinning and variations during the fabrication
process.

12 Materials & Methods: Twenty boxes were distributed to dental technicians, each 13 containing 5 duplicated dental models (n=100), alongside 5×4 mm mouthguard blanks 14 and a questionnaire. The mouthguards were measured using electronic callipers 15 (resolution: ± 0.01 mm) at three specific points. The five thickest and thinnest 16 mouthguards were examined using a CT scanner to describe the surface typography 17 unique to each mouthguard, highlighting dimensional thinning patterns during the 18 fabrication process.

Results: Of the three measurement sites, the anterior sulcus of the mouthguard showed a significant degree of inconsistency (34% coefficient of variation), in finished mouthguard thickness between technicians. The mean thickness of the mouthguards in the anterior region was 1.62 ± 0.38 mm with a range of 0.77 to 2.80 mm. This inconsistency was also evident in the occlusion and posterior lingual regions but to a lesser extent (12.2% and 9.8% variations respectively).

25 <u>Conclusion:</u> This study highlights variability in the finished thickness of the 26 mouthguards especially in the anterior region specific point, both within and between 27 individuals. At the anterior region measurement point of the mouthguard, the mean

- thickness was 1.62mm, equating to an overall material thinning of 59.5% when using a
- 29 single 4mm laminate blank.

31

32 Mouthguards are used as an intervention against trauma from violent impact between 33 the upper and lower dentition, transferring forces to the surrounding structures. A 34 mouthguard blank, when used for a sports mouthguard, is fabricated from a 35 predetermined thickness of material typically ranging between 3-6 mm. Currently, there 36 is very little published information that is accessible to the public to make an informed 37 decision as to the correct thickness of mouthguard that should be worn for each type of 38 The mouthguard is formed using a thermoforming process, where the sport. 39 mouthguard material is heated between 80-120°C (1). This causes the ethylene vinyl 40 acetate (EVA) material to pass its glass transition temperature (Tg) of 84±3°C (2), allowing the material to sag by 15 to 25 mm (3, 4). After this phase it is then either 41 42 pulled down (in the case of vacuum forming) or forced down (in the case of the pressure 43 forming technique) over the dental model.

44 However, during the fabrication process there is an inherent further thinning of the 45 mouthguard material on heating and during the forming of the mouthguard (5). A 46 mouthguard's performance (i.e. energy absorbency) has been linked to the finished postproduction thickness (6, 7). Therefore the greater the thickness of the finished 47 48 mouthguard the greater the ability to dissipate any impact force it may potentially 49 encounter. There are many production factors that could influence the degree of 50 thinning. For example, height and orientation of the model, duration of heating, degree 51 of material sag prior to forming, operator's level of experience, model size, palatal 52 depth, model position on platform, and model temperature (4, 8). Del Rossi and Leyte-53 Vidal (5), examined the correlation between dental model height and the thinning of 54 mouthguard material at the anterior, canine, and molar sites. Their study found that 55 when using a 3 mm blank with a model height of 20 mm the material thinned to 1.6

56 mm; thus equating to the material thinning by approximately 47%. Similarly, at a model 57 height of 25 mm, the material thinned to 1.4 mm (i.e. thinning by 53%), and a model height of 30 mm gave rise to material thinning to 1.2 mm (i.e. thinning by 60%). 58 59 Interestingly, during all test conditions the molar cusp (occlusal) region thickness 60 remained constant at 1.6 mm (5). Geary and Kinirons (4) also investigated model height 61 in relation to material thinning. They found that by increasing the model height by 62 10mm (from 25 to 35 mm) this had a corresponding additional thinning of the EVA 63 material of 21% (from 1.53 to 1.21 mm) when using a 3 mm blank. This gives an 64 overall thinning of the material from, in the case of the 25 mm model, a mouthguard material thinning to 1.53 mm or by 49%, and with the model at 35 mm a material 65 66 thinning of 1.21 mm or by 60% (4). Both Geary et al. (4) and Del Rossi et al. (5) 67 concluded that by keeping the dental model height low, the degree of material stretching 68 observed during the thermoforming process is minimized.

69 Geary et al. (4) investigated how prolonging the heating interval of the EVA material 70 prior to forming affected the finished mouthguard thickness. They found increasing the 71 duration of heating by 30 seconds actually decreased the amount of thinning in the 72 material. Initially this seems counter-intuitive, however, they postulated an explanation relating to the proximity of the sagging EVA material with the dental model, whereby 73 74 the sagging EVA material contacts the model, transforming from its elastic plasticised 75 state to its plastic state, prior to the pressure being introduced (4). They also altered the 76 model position on the platform from the centre (1.53 mm), to the distal edge of the 77 model placed at the edge of the platform, finding that this significantly (p < 0.01) 78 increased the stretching of the material (1.31 mm) (4).

79

80 Mizuhashi et al (9) examined the thickness and fit of a 3.8mm blank during two 81 different thermoforming conditions. The conditions being (i) sheet lowered over the 82 model when vacuum applied and (ii) sheet lowered over the model prior to vacuum 83 applied. They measured anatomical points at both the incisal and first molar region and 84 found that there were differences in thickness between anatomical points. However, there were no significant differences between thickness and condition. The thinning 85 86 patterns observed within these conditions were 40-42% (incisal region), 32% (molar 87 region) and 23-24% occlusal region. They also found that the fit differed between the 88 two conditions. Mizuhashi et al. (10) also examined four heating conditions in relation 89 to thickness and fit, they found again that there was a difference in fit, which was 90 dependant on the heating method, but no difference was reported between method and 91 thickness between conditions. Thinning reported within this study ranged from 26-45% 92 and was dependent upon the anatomical site. A study by Takahashi et al. (11) examined 93 the effects of six conditions, which varied in relation to height of the model and heating 94 procedures they reported that within conditions there was up to a 26% variation in 95 thickness difference. Holding conditions of the mouthguard blank during the heating 96 process has also been investigated, and this has been demonstrated to have an increase 97 within thickness (not sure I understand within thickness) of the processed material 98 especially when the mouthguard material is held at four points during heating (12). 99 Thus, from the mentioned literature it shows that technique plays an important crucial 100 factor within the fabrication process.

Previous studies have used callipers to record measurements. For instance, Geary et al.
(4) sectioned their mouthguard samples and measured at 12 points using a digital
micrometer (resolution 0.001 mm). Del Rossi et al. (5) used a spring-loaded calliper
gauge (resolution 0.01 mm) and measured the mouthguard thickness occlusally at each

105 cusp of the first molars and labial from the central incisors and both right and left 106 canines, with an average mouthguard thickness value assigned to each region. In the 107 present study, measurement reference points were selected in the anterior sulcus, 108 posterior lingual section and occlusal measurements as shown in Table 1. Hence, to 109 develop our understanding of the factors that influence the finished mouthguard and 110 render these more reliable, the primary focus of this study was to examine the 111 reproducibility of the thermoforming task, describing the degree of both intra and inter-112 individuals variability from a large cohort of commercial operators under normal 113 laboratory conditions (i.e. no experimental control of usual practice). Our objective was 114 to highlight how the reproducibility of the thermoforming task fared in relation to 115 mouthguard thickness and production consistency.

116

117 MATERIALS & METHODS.118

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

122

123 Fabrication of Mouthguards.

124 A total of 22 boxes were distributed to dental technicians, each containing 5 identical 125 duplicated dental models (n=100 models in total) and 5 \times 4 mm, EVA, 120 mm Ø 126 (diameter), clear mouthguard blanks (Bracon Dental Laboratory Products, East Sussex, 127 UK). The rationale for the selection of the mouthguard material for the study was 128 linked to the fact that: EVA has been recorded as the most commonly used mouthguard 129 material (8, 13, 14). Personal communications with material suppliers and internet 130 resources, indicated that 4-6mm mouthguard blanks were the most common thickness 131 used in the construction of mouthguards for the majority of sports within the UK.

132 Each technician received a Participant Information Sheet that explained the blind study, 133 and they then completed the mouthguard production process in their usual manner and 134 returned the box if they were willing to partake. They were also asked to complete a 135 short questionnaire, which encompassed their level of experience (i.e. years in this 136 career), the type and age of their laboratory's mouthguard formation machine, the size 137 of blanks used, and any further details on the technique they routinely employed in 138 manufacturing mouthguards. All the questionnaires and mouthguards were analysed 139 and measured blindly.

140

141 Measurements of the processed mouthguards.

142 Following the return of the mouthguards, each box was assigned a code and each model 143 in the assigned box was also given a numerical number for reference purposes. 144 Anatomical plot points were marked on the master model, which indicated where all the 145 subsequent mouthguards were to be measured. These plot points were then transposed 146 onto the mouthguard using a permanent medium tipped marker pen, to ensure 147 consistency in the testing methodology. Three anatomical measurement points were 148 selected and marked on the finished mouthguards (Table 1 & Figure 1), allowing for 149 precise comparisons to be made both within and between technicians. 150 < INSERT TABLE 1 HERE > 151 152 < INSERT FIGURE 1 HERE > 153 154 155 An electronic calliper gauge (External Digital Calliper 442-01DC Series, Moore & 156 Wright, UK) was used to measure the thickness of the finished mouthguards. This type 157 of gauge, was chosen for ease and level of range of action, giving viable access to the 158 occlusal cusp areas of the mouthguard. The callipers had a range resolution of 159 ± 0.01 mm. Each mouthguard anatomical point was measured three times and a mean 160 value obtained, after each measurement the gauge was zeroed. It should be noted that 161 the callipers were calibrated using a 4mm steel calibration block, grade 1, ISO-DIN-BS 162 (Cen Dev µm +0.02, Max Dev +0.02, Min Dev -0.11, Variation 0.13; Alan Browne 163 Gauges Ltd, Learnington Spa, UK) and were frequently used to check the accuracy of the gauges between the measurements sessions. 164 165 166 CT scanned comparison of two surfaces for model accuracy and the thickness of the

167 *finished mouthguards.*

168 Five master models and five randomly selected duplicate models were taken from the 169 110 models prepared in the course of this study. These were then analysed using a 170 Computed tomography (CT) scanner (Scanner: GE Medical Systems) with the 171 following settings: - Light Speed 16, Mode of Capture – Helical, Gantry Tilt – 0 Voxel Size $-0.7031 \times 0.7031 \times 0.5$, Matrix Size -256×256 , KV -120, Ma -90, 172 173 Reconstructed in 0.625 mm axial slices. These scans would help to systematically 174 determine any degree of error between the models that could have occurred during the 175 replication process (Figure 2).

The computer software programme, Robin's 3D - 3D Editor software (V3.1.0.0) 176 177 (www.robins3d.co.uk), used an established algorithm technique to calculate the least square fit 178 points between the two images surfaces (15). Essentially, the programme fits the two images as 179 closely as possible to an average number of points (200) with the difference between the two 180 surfaces viewed as a colour that was assigned a numerical value that was set at 0.001 mm. A 181 cursor was also placed on the surface to further confirm the difference between the surfaces. 182 There was a slight distortion as expected in the production of the duplicate models used for this 183 study; a +/-0.2mm discrepancy between the duplicated models was observed in the anatomical 184 region from where the thickness measurements were taken (Figure 2) which is deemed to be 185 within acceptable tolerances within dentistry (16). The five thickest and thinnest mouthguards 186 were also subjected to further analyses using a CT scanner using the scanning procedures 187 described above.

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- 189

< INSERT FIGURE 2 HERE >

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192 Statistical Analysis

Statistical analyses were performed using PASW® Statistics 18 (SPSS Inc., Chicago, IL, 193 194 USA). Parametricity checks were carried out using the Kolmogorov-Smirnov (for 195 normal distribution) and Levene's (for equal variance) tests. The statistical analyses to 196 identify the variability in mouthguard characteristics within technician groups were 197 tested through computing the Coefficients of Variation and Intraclass Correlation 198 Coefficients (2-way random model, absolute agreement). Between technicians/groups 199 differences were tested using factorial ANOVA (with appropriate post-hoc Independent 200 Bonferonni corrected 2-tailed t-tests). Where data did not obey the parametric 201 assumption, Kruskal Wallis analyses (with appropriate post-hoc Mann Whitney pairwise 202 comparisons) were run. The degree of association between dependent and independent 203 pairs of variables was investigated using correlations (Pearson or Spearman's-204 depending on whether the data set was parametric or not). Data are presented as Mean \pm 205 STDEV, with the alpha set at ≤ 0.05 .

206 **RESULTS**

207 Questionnaire Results.

208 The questionnaire-based survey from the cohort of technicians showed that 70% of the 209 participants generally used 4mm blanks for their mouthguards, 25% used 3 mm, and 210 only 5% used 5 mm blanks (which they may have used for either single or dual 211 laminate). However, the vast majority (i.e. 75%) of the participants did not laminate 212 mouthguard material to increase the finished thickness of the mouthguard. In total 90% 213 used pressure forming machines to make their mouthguards. Furthermore, 70% of the 214 respondents had 20 years or more experience as technicians. The age of the 215 thermoforming machines ranged from 1- to 20 years with a mean age of 6.6 years.

Research Question: How consistent were the technicians at the task of forming
mouthguards within and between groups at three anatomical measurement points?

A total of 20 of the 22 boxes were returned completed, which equates to a response rateof 91%.

- 220 < INSERT FIGURE 3 HERE >
- 221

222 When setting a threshold of 5% for maximal acceptable coefficients of variation in 223 repeated mouthguard manufacture thicknesses, (see data in Figure 3), it was observed 224 that at Site A, all the technicians (to a lesser extent technicians 8, 10 & 13) showed a 225 significant degree of inconsistency, with CV's reaching up to 34%. At site B, Figure 3, 226 technicians 4, 6, 9-11, 13-17, 19-20; and Site C, Figure 3, technicians 1-3, 6, 9, 10, 14, 227 16-20; also showed significant inconsistencies in manufacturing thicknesses, though 228 inconsistencies here were less pronounced than those seen at Site A, reaching 12.2% in 229 Site B and 9.8% in site C respectively.

A Kruskal Wallis test was used to compare the mean mouthguard thickness difference observed between technicians; this showed that there was a significant technician effect (p < 0.001) at all three sites.

Research Question: Did any of the following variables i.e. type and age of
thermoforming machine or level of experience of the operator/technician have a
significant influence on the finished thickness of the mouthguards?

236 It was shown that the make/model of the moulding machine and the average mouthguard thickness were not significantly associated, regardless of the anatomical 237 238 site (A-C) under consideration (p > 0.05). Similarly, there was no significant 239 correlation between the approximate age of the forming machine and the finished thickness of the mouthguard (p > 0.05). Also, there was no significant correlation 240 241 between the number of years' experience and the finished thickness of the mouthguard. 242 There was a statistically significant difference in mouthguard thickness within, and 243 between, sub samples/groups of participating technicians at the assigned measurement 244 points as shown in Figures 4-6. This is observed to a greater extent in the anterior 245 region (Figure 4) where the greatest degree of material stretching/thinning was noted.

246

< INSERT FIGURES 4-6 HERE >

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Some showed greater consistency within their group than others, (e.g. respondents 3 and 10), when measuring the finished mouthguards at the anterior region point (Figures 3 & 4). At the other end of the consistency spectrum, there were technicians with high variability in mouthguard manufacturing whilst using the same model, material and machine. A case in point was respondent 11 who showed a 63% thickness variation, Figure 4. The mean thickness of the mouthguards, from all samples, in the anterior region was 1.62 ± 0.38 mm with a range of 0.77-2.80 mm at the chosen specific single point on the anterior region. The reduction in thickness on forming from 4 to 0.77 mm,
in the most extreme case, represents a total of 81% thinning of the material. From this
cohort of technicians, 52% had a greater material thinning than 1.62mm at the anterior
region measurement point, with the mean thickness equating to an overall thinning of
59.5% in a single 4mm laminate blank.

260

261 CT scanned comparison of two surfaces of the finished mouthguards

The scanned images act as a visual assessment tool for the thickness patterns observed over the whole of the finished mouthguard, not just at the single pre-selected measurement points. The blue/green colour denotes 1 mm+/- and the orange/red colour denotes 3-4 mm as shown on the measurement range bar at the bottom of each image (Figure 7).

267 In Figure 7 the first set of images show an example of the thinnest anterior labial flange 268 of the mouthguard which is shown in green, denoting the material has thinned to less 269 than 2 mm, which concurs with the previous gauge measurements. The section labial to 270 the anterior teeth in most of the anterior view is shown as yellow, indicating the material 271 is 2 mm or above. Below this set of images is an example of the thickest mouthguard, 272 there was a marked colour change towards the vellow to red spectrum in the anterior 273 region, showing the mouthguard thickness increasing towards 3 mm around the anterior 274 teeth. The occlusal surface of this second set of images has a greater proliferation of red 275 and darker (Black) sections, where it forms into the deeper fissures of the posterior 276 teeth, indicating the mouthguard is thicker in this section also.

- 277
- 278 < INSERT FIGURE 7>
- 279

280 DISCUSSION

281 The main focus of the current study was to investigate consistency in the thermoforming 282 procedure in relation to dimensional characteristics. We also aimed to ascertain which 283 parameters would be associated with decreased reproducibility in the thermoforming procedures 284 be they machine- or human-related. Thinning appears to be a consequence of the stretching of 285 the material into the extremities and undercuts areas of the model i.e. anterior sulcus and palatal 286 section. The current study showed 52% of the 100 mouthguards had a greater material thinning 287 of 1.62mm within the anterior region point, with the mean thickness equating to an overall 288 thinning of 59.5% in a single 4mm laminate blank. Excessive thinning may be addressed by the 289 use of a lamination technique, whereby two or more layers of mouthguard materials are bonded 290 together to create a thicker finished blank, with the aim of absorbing greater energy (8, 17). Our 291 study showed that the majority (i.e. 75%) of the participant technicians do not laminate the 292 mouthguard material to increase the finished thickness. Westerman, Stringfellow, Eccleston (8) 293 found that a 1 & 2 mm thickness of EVA offered lower protection in relation to energy 294 absorption when tested in the laboratory. Indeed, they reported that with 2 mm, transmitting 295 15.70 kN, this was more than three times less effective as the 4 mm material, that transmitted 296 only 4.38 kN. The same study observed that there was only a marginal increase in material 297 performance, i.e. force transmission, through increasing the material thickness beyond 4 mm, 298 with 5 and 6 mm blanks reducing transmission forces to 4.03 kN and 3.91 kN respectively (8). 299 Reductions in material thickness could increase injury risk if sports-induced impacts occurred 300 above the values stated by Westerman et al. (8). However, as they stated comfort is also an 301 issue within thicker guards thus a guard that is comfortable is better than not wearing one. Our 302 results showed notable inconsistencies/variations in the fabrication which agrees with previous 303 studies in terms of thinning, in particular with respect to thickness, in the anterior sulcus region 304 measurement point, both within and between individuals as shown in Figures 3 & 4. The 305 greatest degree of material thinning and thickness inconsistency was observed in the anterior 306 sulcus region point of the finished mouthguard as shown in Figure 7. The occlusal and posterior

307 lingual regions were much less of a problem. This study found there was an 81% thinning of the 308 processed mouthguard material in the most extreme case, from 4 to 0.77 mm. This degree of 309 thinning is marginally higher than that described in the study by Geary et al. (4) in which a 310 thinning of 72% when using a 3mm mouthguard blank was reported. The mean thickness of the 311 mouthguards, from all samples, in the anterior region, was 1.62 ± 0.38 mm with a range of 0.77-312 2.8 mm. At 1.62 ± 0.38 mm the mean degree of thinning would be 59.5% of the original blank 313 thickness of 4 mm, which is similar to studies by Del Rossi et al. (5) who reported thinning as 314 high as 60% in the labial surface of the incisal and canine dentition, when using 3 mm mouthguard blanks. Geary et al. (4) reported thinning in the anterior labial sub gingival region 315 316 of 49%, which is a comparable measurement point to the anterior site as used in this study. 317 They also recorded thinning as high as 72% in the incisal region, also using 3 mm blanks (4). 318 However, within our study, 4 mm blanks were used showing that even the thicker blanks still have significant variations in thinning. This study showed that 70% use 4 mm blanks for their 319 320 mouthguards (which may be used for single/dual laminate use), this is in accord with the earlier 321 personal communication with dental material suppliers. Conversely, studies by Geary et al. (4) 322 and Del Rossi et al. (5) used 3mm blanks, Mizuhashi et al. (9,10,12) 3.8mm blanks and 323 Takahashi et al. (11) 4mm blanks.

324

325 Factors that may affect mouthguard material thinning.

326 Another key novel aspect in the present study was the large sample size not only in 327 terms of individuals, but also the total number of formed mouthguards; with most 328 earlier studies only using one investigator to form the mouthguards (4, 5). In our study, 329 with participation from twenty dental technicians, our data is arguably representative of 330 dimensional changes during fabrication in a commercial environment rather than 331 laboratory research (hence controlled) environment. To add to which, the technicians 332 were requested to complete an accompanying questionnaire, which collected data on the 333 technician's own material thickness preference, the age/make/type of forming machine

used, the technician's level of experience (in numbers of years in practice), which mayhave had a bearing on the finished thickness of the mouthguards.

336 The age of the thermoforming machines ranged from 1-20 years. This is relevant as in 337 most cases the thermoforming machine uses a halogen heater to heat the blank and over 338 time, the heaters may become less efficient and may not heat the blank evenly. The 339 effects of heating is an important factor as it has been shown as a potential key element 340 in terms of fit of the mouthguard (10,11). Pressure forming machines are shown to be 341 the most widely used to make mouthguards even though they are the most expensive to 342 purchase. Only two of the twenty-strong cohort used vacuum forming machines making 343 a true statistical comparison unfeasible with regard to a comparison between vacuum 344 and pressure forming machines. It would have been ideal to make comparisons between 345 the vacuum forming types of machines. However, due to the study being blind we 346 cannot address which type was more favourable. To add to which, the human factor (i.e. 347 an individual's own technique) may have also been present during fabrication, and thus 348 difficut to separate from the true merits of the equipment. Nonetheless, we propose that 349 a direct comparison of makes of equipment could be a useful follow-up study to the 350 present research work. Statistically there were no correlations between the thickness of 351 the finished mouthguard and either the years of experience of the technician or the age, 352 make or type of machine used. Accepting this, other possible reasons for the observed 353 discrepancies within groups could be: different positioning of the models i.e. 354 orientation, as discussed previously in a study by Geary et al. (4), and/or distance from 355 the heat source, fluctuations in environmental temperature i.e. open window cooling the 356 blank or not following the manufacturer's instructions.

357 The level of experience of technicians ranged from 6-10 to 30+ years; arguably it might358 have been assumed that with greater experience one would have seen less variation, in

359 terms both of thickness and consistency. Interestingly, statistically there was no 360 significant difference (p > 0.05) between the levels of experience of the groups of 361 technicians in this task. We therefore propose that the reason for this lack of influence of 362 number of year's-experience on the technician's results may be that different technicians 363 will allow the material to heat for indeterminate amounts of time. Consequently, since 364 the amount of time heating correlates to the degree of sag (amount the heated blank is 365 allowed to slump), ultimately this will have impacted on the degree of thinning of the 366 material prior to forming. The present study showed 70% of respondents used 4 mm 367 mouthguard blanks for construction of their custom-made mouthguards. Following the 368 inherent thinning observed in the processing of the given cohort 52% had a greater 369 material thinning of 1.62mm within the anterior region point and an overall thinning of 370 59.5% in a single 4mm laminate blank. All in all the present study shows the 371 differences in consistency within, and between, groups of technicians in the fabrication 372 of this custom made mouthguard (Figures 3 & 4).

373 CONCLUSION

374 The current production methods showed 52% of produced mouthguards had a material 375 thinning greater than 1.62mm within the anterior region point, and an overall thinning 376 of 59.5% for a single laminate 4 mm mouthguard blank, at the chosen point at the 377 anterior sulcus, irrespective of the technicians level of experience or type/age of the 378 thermo-forming machine. It is recommended that prior to any mouthguard being sent to 379 the dentist, it should be measured in the thinnest section of key anatomical points, i.e. 380 anterior sulcus. The dental technology community also needs to be aware of these 381 issues in relation to the thermoforming technique, and not take it at face value that the 382 mouthguard's thickness would be consistent throughout the manufacturing process. This 383 recommendation applies regardless of the initial thickness of the blank as there are 384 variations within the degree of thinning. Differences in thickness may affect the 385 performance of the guard, particularly if a large impact was to occur during sports 386 activity (8, 13, 18). However, it must be emphasised here that any form of custom made 387 mouthguard protection regardless of thickness is better than wearing none at all even with the lower levels of thickness reported in this study (7, 19, 20). 388 Also, as 389 previously suggested by Patrick, van Noort, Found (18), a grading, based in part on the 390 thickness of the finished mouthguard whether by lamination, design or blank selection, 391 could be awarded to the mouthguard as to the level of protection the mouthguard affords 392 to an individual's chosen sport. This study highlights, the need for a definitive and 393 readily available guide for both the dentists and members of the public, to show the 394 correct thickness of mouthguard, so that an informed decision as to the adequacy of the 395 mouthguard to perform the expected function in relation to the selected sport.

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