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ABSTRACT.

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.

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

Conclusion: This study highlights variability in the finished thickness of the mouthguards especially in the anterior region specific point, both within and between 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 single 4mm laminate blank.

INTRODUCTION.

Mouthguards are used as an intervention against trauma from violent impact between the upper and lower dentition, transferring forces to the surrounding structures. A mouthguard blank, when used for a sports mouthguard, is fabricated from a predetermined thickness of material typically ranging between 3-6 mm. Currently, there is very little published information that is accessible to the public to make an informed decision as to the correct thickness of mouthguard that should be worn for each type of sport. The mouthguard is formed using a thermoforming process, where the mouthguard material is heated between 80-120°C (1). This causes the ethylene vinyl 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 pulled down (in the case of vacuum forming) or forced down (in the case of the pressure forming technique) over the dental model.

However, during the fabrication process there is an inherent further thinning of the mouthguard material on heating and during the forming of the mouthguard (5). A 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 mouthguard the greater the ability to dissipate any impact force it may potentially encounter. There are many production factors that could influence the degree of thinning. For example, height and orientation of the model, duration of heating, degree of material sag prior to forming, operator's level of experience, model size, palatal depth, model position on platform, and model temperature (4, 8). Del Rossi and Leyte-Vidal (5), examined the correlation between dental model height and the thinning of mouthguard material at the anterior, canine, and molar sites. Their study found that when using a 3 mm blank with a model height of 20 mm the material thinned to 1.6

mm; thus equating to the material thinning by approximately 47%. Similarly, at a model 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%). Interestingly, during all test conditions the molar cusp (occlusal) region thickness remained constant at 1.6 mm (5). Geary and Kinirons (4) also investigated model height in relation to material thinning. They found that by increasing the model height by 10mm (from 25 to 35 mm) this had a corresponding additional thinning of the EVA material of 21% (from 1.53 to 1.21 mm) when using a 3 mm blank. This gives an 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 thinning of 1.21 mm or by 60% (4). Both Geary et al. (4) and Del Rossi et al. (5) concluded that by keeping the dental model height low, the degree of material stretching observed during the thermoforming process is minimized.

Geary et al. (4) investigated how prolonging the heating interval of the EVA material prior to forming affected the finished mouthguard thickness. They found increasing the duration of heating by 30 seconds actually decreased the amount of thinning in the 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 the sagging EVA material contacts the model, transforming from its elastic plasticised state to its plastic state, prior to the pressure being introduced (4). They also altered the model position on the platform from the centre (1.53 mm), to the distal edge of the model placed at the edge of the platform, finding that this significantly ($p < 0.01$) increased the stretching of the material (1.31 mm) (4).

Mizuhashi et al (9) examined the thickness and fit of a 3.8mm blank during two different thermoforming conditions. The conditions being (i) sheet lowered over the model when vacuum applied and (ii) sheet lowered over the model prior to vacuum applied. They measured anatomical points at both the incisal and first molar region and found that there were differences in thickness between anatomical points. However, there were no significant differences between thickness and condition. The thinning patterns observed within these conditions were 40-42% (incisal region), 32% (molar region) and 23-24% occlusal region. They also found that the fit differed between the two conditions. Mizuhashi et al. (10) also examined four heating conditions in relation to thickness and fit, they found again that there was a difference in fit, which was dependant on the heating method, but no difference was reported between method and thickness between conditions. Thinning reported within this study ranged from 26-45% and was dependent upon the anatomical site. A study by Takahashi et al. (11) examined the effects of six conditions, which varied in relation to height of the model and heating procedures they reported that within conditions there was up to a 26% variation in thickness difference. Holding conditions of the mouthguard blank during the heating process has also been investigated, and this has been demonstrated to have an increase within thickness (not sure I understand within thickness) of the processed material especially when the mouthguard material is held at four points during heating (12). Thus, from the mentioned literature it shows that technique plays an important crucial 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 cusp of the first molars and labial from the central incisors and both right and left canines, with an average mouthguard thickness value assigned to each region. In the present study, measurement reference points were selected in the anterior sulcus, posterior lingual section and occlusal measurements as shown in Table 1. Hence, to develop our understanding of the factors that influence the finished mouthguard and render these more reliable, the primary focus of this study was to examine the reproducibility of the thermoforming task, describing the degree of both intra and inter-individuals variability from a large cohort of commercial operators under normal laboratory conditions (i.e. no experimental control of usual practice). Our objective was to highlight how the reproducibility of the thermoforming task fared in relation to mouthguard thickness and production consistency.

MATERIALS & METHODS.

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.

Fabrication of Mouthguards.

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

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

Measurements of the processed mouthguards.

Following the return of the mouthguards, each box was assigned a code and each model in the assigned box was also given a numerical number for reference purposes. Anatomical plot points were marked on the master model, which indicated where all the subsequent mouthguards were to be measured. These plot points were then transposed onto the mouthguard using a permanent medium tipped marker pen, to ensure consistency in the testing methodology. Three anatomical measurement points were selected and marked on the finished mouthguards (Table 1 & Figure 1), allowing for precise comparisons to be made both within and between technicians.

< INSERT TABLE 1 HERE >

< INSERT FIGURE 1 HERE >

An electronic calliper gauge (External Digital Calliper 442-01DC Series, Moore & Wright, UK) was used to measure the thickness of the finished mouthguards. This type of gauge, was chosen for ease and level of range of action, giving viable access to the occlusal cusp areas of the mouthguard. The callipers had a range resolution of ±0.01mm. Each mouthguard anatomical point was measured three times and a mean value obtained, after each measurement the gauge was zeroed. It should be noted that the callipers were calibrated using a 4mm steel calibration block, grade 1, ISO-DIN-BS (Cen Dev µm +0.02, Max Dev +0.02, Min Dev -0.11, Variation 0.13; Alan Browne Gauges Ltd, Leamington Spa, UK) and were frequently used to check the accuracy of the gauges between the measurements sessions.

CT scanned comparison of two surfaces for model accuracy and the thickness of the finished mouthguards.

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

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

< INSERT FIGURE 2 HERE >

Statistical Analysis

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

RESULTS

Questionnaire Results.

The questionnaire-based survey from the cohort of technicians showed that 70% of the participants generally used 4mm blanks for their mouthguards, 25% used 3 mm, and only 5% used 5 mm blanks (which they may have used for either single or dual laminate) . However, the vast majority (i.e. 75%) of the participants did not laminate mouthguard material to increase the finished thickness of the mouthguard. In total 90% used pressure forming machines to make their mouthguards. Furthermore, 70% of the respondents had 20 years or more experience as technicians. The age of the 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 rate of 91%.

< INSERT FIGURE 3 HERE >

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

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

< INSERT FIGURES 4-6 HERE >

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.

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).

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

< INSERT FIGURE 7>

DISCUSSION

The main focus of the current study was to investigate consistency in the thermoforming procedure in relation to dimensional characteristics. We also aimed to ascertain which parameters would be associated with decreased reproducibility in the thermoforming procedures be they machine- or human-related. Thinning appears to be a consequence of the stretching of the material into the extremities and undercuts areas of the model i.e. anterior sulcus and palatal section. The current study showed 52% of the 100 mouthguards had a greater material thinning of 1.62mm within the anterior region point, with the mean thickness equating to an overall thinning of 59.5% in a single 4mm laminate blank. Excessive thinning may be addressed by the use of a lamination technique, whereby two or more layers of mouthguard materials are bonded together to create a thicker finished blank, with the aim of absorbing greater energy (8, 17). Our study showed that the majority (i.e. 75%) of the participant technicians do not laminate the mouthguard material to increase the finished thickness. Westerman, Stringfellow, Eccleston (8) found that a 1 & 2 mm thickness of EVA offered lower protection in relation to energy absorption when tested in the laboratory. Indeed, they reported that with 2 mm, transmitting 15.70 kN, this was more than three times less effective as the 4 mm material, that transmitted only 4.38 kN. The same study observed that there was only a marginal increase in material performance, i.e. force transmission, through increasing the material thickness beyond 4 mm, with 5 and 6 mm blanks reducing transmission forces to 4.03 kN and 3.91 kN respectively (8). Reductions in material thickness could increase injury risk if sports-induced impacts occurred above the values stated by Westerman et al. (8). However, as they stated comfort is also an issue within thicker guards thus a guard that is comfortable is better than not wearing one. Our results showed notable inconsistencies/variations in the fabrication which agrees with previous studies in terms of thinning, in particular with respect to thickness, in the anterior sulcus region measurement point, both within and between individuals as shown in Figures 3 & 4. The greatest degree of material thinning and thickness inconsistency was observed in the anterior sulcus region point of the finished mouthguard as shown in Figure 7. The occlusal and posterior lingual regions were much less of a problem. This study found there was an 81% thinning of the processed mouthguard material in the most extreme case, from 4 to 0.77 mm. This degree of thinning is marginally higher than that described in the study by Geary et al. (4) in which a thinning of 72% when using a 3mm mouthguard blank was reported. The mean thickness of the mouthguards, from all samples, in the anterior region, was 1.62 ±0.38 mm with a range of 0.77-2.8 mm. At 1.62 ± 0.38 mm the mean degree of thinning would be 59.5% of the original blank thickness of 4 mm, which is similar to studies by Del Rossi et al. (5) who reported thinning as 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 of 49%, which is a comparable measurement point to the anterior site as used in this study. They also recorded thinning as high as 72% in the incisal region, also using 3 mm blanks (4). 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 mouthguards (which may be used for single/dual laminate use), this is in accord with the earlier personal communication with dental material suppliers. Conversely, studies by Geary et al. (4) and Del Rossi et al. (5) used 3mm blanks, Mizuhashi et al. (9,10,12) 3.8mm blanks and Takahashi et al. (11) 4mm blanks.

Factors that may affect mouthguard material thinning.

Another key novel aspect in the present study was the large sample size not only in terms of individuals, but also the total number of formed mouthguards; with most earlier studies only using one investigator to form the mouthguards (4, 5). In our study, with participation from twenty dental technicians, our data is arguably representative of dimensional changes during fabrication in a commercial environment rather than laboratory research (hence controlled) environment. To add to which, the technicians were requested to complete an accompanying questionnaire, which collected data on the 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 may have had a bearing on the finished thickness of the mouthguards.

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

The level of experience of technicians ranged from 6-10 to 30+ years; arguably it might have been assumed that with greater experience one would have seen less variation, in terms both of thickness and consistency. Interestingly, statistically there was no significant difference ($p > 0.05$) between the levels of experience of the groups of technicians in this task. We therefore propose that the reason for this lack of influence of number of year's-experience on the technician's results may be that different technicians will allow the material to heat for indeterminate amounts of time. Consequently, since the amount of time heating correlates to the degree of sag (amount the heated blank is allowed to slump), ultimately this will have impacted on the degree of thinning of the material prior to forming. The present study showed 70% of respondents used 4 mm mouthguard blanks for construction of their custom-made mouthguards. Following the inherent thinning observed in the processing of the given cohort 52% had a greater material thinning of 1.62mm within the anterior region point and an overall thinning of 59.5% in a single 4mm laminate blank. All in all the present study shows the differences in consistency within, and between, groups of technicians in the fabrication of this custom made mouthguard (Figures 3 & 4).

CONCLUSION

The current production methods showed 52% of produced mouthguards had a material thinning greater than 1.62mm within the anterior region point, and an overall thinning of 59.5% for a single laminate 4 mm mouthguard blank, at the chosen point at the anterior sulcus, irrespective of the technicians level of experience or type/age of the thermo-forming machine. It is recommended that prior to any mouthguard being sent to the dentist, it should be measured in the thinnest section of key anatomical points, i.e. anterior sulcus. The dental technology community also needs to be aware of these issues in relation to the thermoforming technique, and not take it at face value that the mouthguard's thickness would be consistent throughout the manufacturing process. This recommendation applies regardless of the initial thickness of the blank as there are variations within the degree of thinning. Differences in thickness may affect the performance of the guard, particularly if a large impact was to occur during sports activity (8, 13, 18). However, it must be emphasised here that any form of custom made 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). Also, as previously suggested by Patrick, van Noort, Found (18), a grading, based in part on the thickness of the finished mouthguard whether by lamination, design or blank selection, could be awarded to the mouthguard as to the level of protection the mouthguard affords to an individual's chosen sport. This study highlights, the need for a definitive and readily available guide for both the dentists and members of the public, to show the correct thickness of mouthguard, so that an informed decision as to the adequacy of the mouthguard to perform the expected function in relation to the selected sport.

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