Fabricating a better mouthguard. Part II: The effect of color on adaptation and fit

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Correspondence to: Gianluca Del Rossi, PhD, Athletic Training Education Program, Department of Orthopaedics and Sports Medicine, University of South Florida, College of Medicine 3500 E, Fletcher Avenue, Suite 511, Tampa, FL 33612, USA Tel.: 813 974 7320 Fax: 813 396 9195 e-mail: gdelross@health.usf.edu Accepted 30 August, 2006 Abstract – The thermoforming process involves the heating of plastic sheets to a critical temperature followed by the shaping of the heated material into a threedimensional structure. Given that custom-fabricated mouthguards are produced using the thermoforming process, the adaptation of plastic sheets to a stone model of the dentition is likely to be affected by the ability of the mouthguard material to be heated. The purpose of this study was to establish if material color affected the adaptation and fit of custom-made mouthguards. Twelve stone models were used in this investigation. Five mouthguards were produced using each model. These mouthguards were made using clear-, white-, black-, blueand green-colored ethyl vinyl acetate. The force required to remove the various colored mouthguards from the corresponding stone models was determined using a strain gauge housed within a specially designed apparatus. Each of the mouthguards were tested three times at two different angles of pull -45° and 90°. Statistical tests performed using the average amount of force required for mouthguard removal revealed an angle by color interaction. Post hoc analyses revealed that the mean force required to remove the clear-colored mouthguards from their respective stone models was significantly less than the force required to pull away blue-, black- and green-colored mouthguards. This difference between clear- and dark-colored mouthguards was observed at both angles tested with the exception of the black mouthguard which differed from the clear-colored mouthguard only when removed at an angle of 90°. The results of the present study indicate that by using dark-colored mouthguard material, one can achieve superior adaptation and thus produce a more firmly fitting mouthguard.

Custom-made mouthguards are composed of thermoplastic polymers (plastics) and generally fabricated over molds of the maxillary dentition. Custom mouthguards can be either vacuum-formed or pressure-formed. Although there are certain notable differences between vacuum-formed and pressure-formed mouthguards, they are essentially constructed in a similar manner, that is, both rely on radiant heat transfer to allow for the thermoforming of the plastic material used to fabricate the mouthguards. The thermoforming process consists of placing a sheet of plastic, usually the co-polymer ethylene vinyl acetate (EVA), beneath an infrared heater. The absorption of the infrared radiation and conversion to heat energy results in an increase in the temperature of the plastic. Once the plastic material has been heated to its forming temperature, and thus been rendered soft and pliable, it is stretched over the dental model by applying either pressure or suction. The formed plastic is then trimmed and processed to create the final product.

Of the two types of custom-fabricated mouthguards, pressure-formed protectors are preferred, because they offer the best adaptation, superior fit, and maximum comfort (1). These enhanced physical characteristics are attributed in part to the heating temperature used during fabrication (1). Vacuum-formed mouthguards are shaped using low to moderate heat, whereas pressureformed mouthguards are fashioned using high heat (1). This difference in heat could mean the difference between achieving proper forming temperature or not. Another factor that may determine whether or not the critical temperature is reached is color. Given that different colors absorb radiant heat at different levels (2), this effect may influence the final temperature attained by the plastic material, which in turn, may impact the level of adaptation that is achieved during the fabrication process. Therefore, the purpose of this investigation was to determine how color affects the fit of customfabricated, pressure-formed mouthguards.

Materials and methods

In order to test the level of adaptation or relative fit of our test mouthguards, we fabricated a manually driven, vertically oriented strain gauge apparatus. This device was used to measure the amount of force required to remove mouthguards from their corresponding models. The strain gauge used to measure tension force was incorporated within the upright stand. A manual winch was secured on top of the stand and a bench vise at the bottom. Suspended from the winch was the strain gauge,



Fig. 1. Device for measuring force needed for mouthguard removal.

which was linked via a hook and fine wire to the mouthguard/model assembly. The bench vise was used to clasp the dental models and was secured to detachable and interchangeable blocks of wood, which were in turn secured to the base of the stand. These blocks of wood were either flat (0°) or sloped (45°) to allow us to change the angle of pull exerted on the mouthguards (Fig. 1).

Test mouthguards were fabricated using stone models produced from impressions of the maxillary arches of 12 individuals. All stone models had an overall height of 2.5 cm. Mouthguards were manufactured using a Biostar pressure-thermoforming unit (Great Lakes Orthodontics, Ltd., Tonawanda, NY, USA) and were produced using one 3 mm standard EVA sheet. Five different colors were tested in this experiment: black, blue, green, white and clear. All the mouthguards were constructed following established manufacturer/distributor guidelines. Initially, the EVA was placed on the gasket of the pressure chamber and locked into place using a clamping frame. The heating element was than positioned over the EVA material. Once in place, a code was entered into the computer interface which began a preset heating session. The total heating time for all material colors (as determined by the distributor) was 90 s. The pre-established heating temperature was 233°C. When the heating time was completed, the heating element was swung away from its location over the EVA sheet and placed in its resting position. The pressure chamber containing the EVA material was then flipped onto the platform containing the stone model. Once over the model, the pressure chamber was locked, allowing air pressure to enter the chamber. The air pressure was set at approximately 5×10^5 Pa. As the chamber pressurized, the mouthguard material adapted to the shape of the mold. After pressurizing, the EVA was allowed to cool for 120 s. When the cooling was completed, the air was released from the pressure chamber. The chamber was then opened and the EVA-enveloped model was removed. The EVA was then allowed to cool and set further. After the mouthguards had set (a minimum of 30 min), they were trimmed and labeled. All mouth-guards were produced with similar specifications, with the palatal flange approximately 10 mm above the gingival margin and the labial flange within 2 mm of the vestibular reflection (3). Additionally, after formation, a fixed length of fine metal wire was pierced through the palatal flange of each mouthpiece and twisted to form a loop.

To be able to test the mouthguards, a 2 cm^2 wood block was glued to the underside of the base of each of the dental models. This wood block was inserted into the clamping arms of the bench vise to lock the dental stone models into a fixed position. The aforementioned metal wire loop projecting from each of the mouthguards was used to hook the mouthguard to the strain gauge. The strain gauge was driven by a Grass RPS 107E DC amplifier (Grass-Telefactor; Astro-Med, Inc., West Warwick, RI, USA). The output from the amplifier was then fed to our laboratory computer through a Metrobyte Dash-16G analog-to-digital conversion board using a collection program written for this purpose. Data were collected at 200 samples per second and electronically scanned to detect the maximal force recorded during each trial.

Each mouthguard was tested three times at two different angles. The order of testing was randomized by angle and then by color to reduce the possibility of any order effect. The average value of the three trials was used for statistical analysis. The angles tested in this protocol were 90° (or a pull in a perpendicular direction) and 135° (or 45° from the transverse plane in a downward direction). This latter angle was chosen as it was believed to mimic the angle of pull generally used by athletes to remove their mouthguards.

Before collecting any data, we assessed both the validity and reliability of the test apparatus. Validity of the device was established by comparing force values obtained by our device with values generated from known weights. We used 10 weights ranging from 100 g to 2.1 kg. These weights were hooked to the strain gauge and the value reported by the strain gauge was compared with the actual value of the weight. Pearson product moment correlation coefficients were then calculated to assess the accuracy of force measurements. Additionally, each of the weights was tested two more times, in random order, so that the reliability of device could be determined. To assess the reliability of our device, intraclass correlation coefficients (ICC) were calculated from the repeated measurements that were obtained. Tests revealed our device to be very accurate with a strong correlation coefficient (r = 1.00). Furthermore, tests of reliability revealed our device to be consistent in the ability to measure tension forces. The ICC values calculated from out data ranged between 0.99 and 1.0.

An analysis of variance (ANOVA) with repeated measures across angles and colors was used to evaluate changes in the average force required for mouthguard removal. *Post hoc* pairwise *t*-tests with Sidak adjustments



Fig. 2. Average force (in kg) required to remove mouthguards from dental model. All bars bracketed with the same line are not significantly different from each other. Solid lines are used to compare forces generated when the pull was exerted at 90°; dashed lines are used to compare forces generated when the pull was exerted at 135°. *Significantly different between angles (P < 0.05).

(P < 0.002) were calculated when necessary. All statistical analyses were performed using SPSS statistical software (SPSS Inc., version 11.5, Chicago, IL, USA) with the level of significance for all statistical tests set, *a priori*, at $\alpha \le 0.05$.

Results

A significant angle \times color interaction was detected for repeated measure analysis $(F_{(3,33)} = 4.77,$ the P = 0.007). Figure 2 presents the average force required to remove the different colored mouthguards from their respective models. Post hoc tests revealed significant differences between clear- and dark-colored mouthguards. Specifically, the force required to remove clear mouthguards differed significantly from the force required to pull away the blue (at 90° and 135°), green (at 90° and 135°) and black (at 135° only) mouthguards. Also, once the Sidak correction was applied, post hoc tests did not reveal any statistical difference between similar-colored mouthguards when compared between the two test angles.

Discussion

In order to avoid becoming dislodged on impact, which is when protection is most needed, mouthguards must fit properly and firmly (1). Custom-fabricated mouthguards offer excellent fit compared with over-the-counter products because the fabrication process allows for the plastic material from which the mouthguards are constructed to adapt closely to a model of the dentition (1). The ability of EVA to adapt to the model is a function of the pliability of the material at the time of shaping, which in turn is related to the content temperature of the material. As light-colored materials are likely to reflect a significant amount of energy striking its surface, a much lesser build up of heat would be expected within the substance (2). Conversely, dark-colored materials would be expected to provide the best adaptation as they absorb the greatest amount of infrared energy (2). This was precisely our finding, as we noted that dark-colored mouthguard required the greatest amount of force to remove the mouth protectors from their position on the dental models.

In our study, the transparent or clear mouthguards offered the least suitable fit of all those tested. This result was somewhat predictable as it has been reported that transparent sheets allow radiant energy to be transmitted through their structure with minimal heat absorption (4). With less heat absorption, the transparent material would not be expected to attain the same level of pliability as a colored material, especially if the heating times were kept constant, as was the case in our investigation.

Presumably, with normal wear and tear, mouthguards undergo a loss in shape or retention. If a mouthguard does not achieve the best possible adaptation when it is formed, this loss of retention and fit is likely to occur sooner rather than later. With a loss of fit, mouthguards will need to be replaced sooner and more frequently than those offering superior adaptation. It is for this reason that we urge dentists or other dental practitioners to take the findings of this investigation into consideration when manufacturing mouthguards for athletes. If a lightcolored or transparent material is used to fabricate mouthguards, the users of these products should be informed that the shape of the mouthguards might not be maintained for an extended period of time, and therefore, the characteristic fit and retention afforded by these devices might be short lived. Fortunately, the National Collegiate Athletic Association has a rule in place that does not allow the use of clear- or whitecolored mouthguards in the game of American football; therefore, this issue might not be as much of a concern to those athletes (5).

The results of this investigation may also be of interest to those involved in the fabrication of multicolored mouthguards, in particular, if co-extruded sheets of material are used in the process. Obviously, the problem with using different colored materials is that each of the different colors would obtain a distinctive temperature and consequently will not yield equal levels of adaptation along the various sections of the finished product.

It has been reported that an athlete's attitude toward wearing a mouthguard and usage pattern (compliance) is influenced at least in part by comfort (proper fit) and the ability to speak and breathe (6–8). Naturally, a loosely fitting mouthguard may require the clenching of the teeth to keep it in position, and this may interfere with the ability to speak and breathe. Thus, to avoid developing resistance to mouthguard use, it may be beneficial to fabricate a mouthguard that offers the best fit and prolonged retention. Using a dark-colored material certainly would make it easier to obtain a product that offers the favorable aforementioned qualities.

As a part of our investigation, we examined how the pulling angle impacts the ability to remove mouthguards from the teeth. We found that extracting the maxillary mouthguards obliquely in both a downward and outward direction (simultaneously) decreased the amount of force required to remove the mouthguards from their usual position on the maxillary teeth. This reduction in force requirement is perhaps related to how the mouthguard drapes over the bony alveolar arch of the maxillary bone. Obviously, pulling the mouthguard in the described manner would make it easier to disengage the mouthguard from the alveolar arch and thus facilitate the removal of the mouthpiece.

As with most experimental research, there are limits to the generalizability of our results. The EVA sheets used in this investigation were all from the same distributor. The material content or the constituents of the EVA samples used in this study were presumably similar for all colored sheets. However, if the various components of the EVA co-polymer were to change, so too would its properties. This would imply that the results of this study might not be reproducible if the EVA used in the fabrication process were from other unrelated manufacturers or distributors, or if the content of the co-polymer were to change from color to color. Furthermore, in this investigation, we did not test all the possible colors in which EVA is produced and therefore we cannot comment on how well the various other colors would have adapted to the dental models. Finally, we are uncertain if increasing the temperature or increasing the heating time during the fabrication process would have improved the degree of adaptation of light-colored EVA. Certainly further research using additional colors and various combinations of temperature and heating times is warranted.

In summary, the findings of the present study indicate that, all else being equal, dark-colored sheets of EVA achieve superior adaptation during the fabrication process compared with light-colored or transparent material. This being the case, a mouthguard made from darker-colored material is likely to fit more firmly and remain retentive for a longer period of time. This may increase user compliance and decrease the chances of displacing the mouthguard with contact.

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