Application of a standard test to the in vitro performance of mouthguards

A Greasley, G Imlach, B Karet

Abstract

Objective—To use a simulated upper jaw made from a rubber arch containing replaceable ceramic teeth and a renewable composite ceramic jawbone to compare the effectiveness of seven custom made mouthguard designs and a “boil and bite” mouthguard.

Methods—Following an earlier development of a standard impact test using a selection of projectile shapes and energies, the most sensitive conditions were selected. These were then applied to a series of six guards constructed in ethylene vinyl acetate and styrene butadiene. The guards were constructed to reflect possible variations in both design and materials.

Results—Significant differences between the mouthguard performances were observed in response to the impact conditions selected. All the custom made designs gave better performance than the “boil and bite” mouthguard.

Conclusions—The differences observed indicated that the standard test should be sensitive enough to be used as an assessment procedure for the approval of the manufacture of these safety devices. A sequence of tests on eight identical mouthguards selected from a batch of 12, based on the best design, gave remarkably consistent results, indicating that both the manufacturing technique and the test method are reliable. The features of the best design should be incorporated into the current “best practice” for the construction of these devices.

Keywords: mouthguards; mouth; teeth; jaw

Previous work has indicated that a standard test could be used to assess the performance of mouthguards. A standard rubber arch, containing replaceable ceramic teeth of fracture toughness 0.5 MN/m$^{3/2}$ and a composite jawbone of fracture toughness 3.0 MN/m$^{3/2}$, is fitted with the mouthguard under test and impacted with a conical ended projectile which has an impact velocity of 6.25 m/s (10 J energy). The jaw, with its fitted guard, is located in spring loaded tubes and the complete assembly is then preheated for 30 minutes at 37°C in the test chamber. Figure 1 shows the experimental set up. Figure 2 shows a close up of the impact area for a custom made mouthguard being impacted by the conical ended projectile recommended in the previous work.

At present clinicians provide a standard impression mould of the upper and lower jaw for the manufacturing laboratory. Mouthguards are designed and constructed using the preferences of the laboratory with respect to design and materials. Current recommended design practice in the literature comes from Scott et al and is described as follows.

1. It should enclose the maxillary teeth to the distal surface of the second molars.
2. Thickness should be 3 mm on the labial aspects, 2 mm on the occlusal aspect, and 1 mm on the palatal aspect.
3. The labial flange should extend to within 2 mm of the vestibular reflection.
4. The palatal flange should extend about 10 mm above the gingival margin.
5. The edge of the labial flange should be rounded in cross section whereas the palatal edge is tapered.
6. Even when a single maxillary guard is constructed it should be articulated against the matching mandibular model to give optimum comfort.

Manufacturing practices in current use deviate from each of these recommendations. Some-
timesthisisformedphysiologicalreasonsproduced
byparticularoralconfigurationsoftheclient.
However,itisalsoduestoperceivedoptimisa-
tionsbythemanufacturinglaboratory.
Forinstance,manylaboratoriesfinishtheguard
atthefirstmolar improve speech during use.
Thicknesses and edge finishes vary, as does the
overall extent of the guard on the palatal and
labial flanges. Moreover guards can be manu-
factured from a small range of materials. This
also means that different materials can be used
in different layers within the overall construc-
tion of the guard. Hence there is considerable
scope for different laboratories to provide
considerably different mouthguards against the
same request. The most common material is
ethylen vinylacetate (EVA) which is available
inblank sheet form for vacuum moulding.
Also available is the stiffer and harder material,
sty-
rene butadiene sheet, both on its own and
prebonded to EVA. The intrinsic shock absorb-
ing properties of such materials have attracted
theinterestsoftertaintestingauthorities.1
However,itisconsideredthatafulltesting
standard should not divorce materials from
design and manufacturing variables.

Methods
Batches of 12 guards were each produced on
the standard jaw to six different designs. “Boil
and bite” guards were also fitted to the
standard jaw following the instructions sup-
plied by the manufacturers. All the custom
made guards were translucent and uncoloured.
TheEVA “boil and bite” guards were opaque
and coloured black (A) and pink (B) (see table
1).

From these batches two samples were
selected at random and tested using the conical
projectile with the 10 J impact energy which
has been identified in previous work to offer
themostscopeintermsofsensitivityandbest
comparison with clinical observation.1

The mouthguard used in the previous study
and an unguarded standard jaw were used as
controls.

Figure 3 shows the six guards along with the
control guard and a “boil and bite” guard.
Thelevel of variation between different sam-
ples within each batch was investigated by test-
ing a further six samples from the best
performing design.

Results
Table 1 gives the manufacturing and design
details of the different guards and the amount
of damage caused in terms of tooth and
jawbone fracture. Softtissue damage is also of
clinical concern but beyond the scope of this in
vitroinvestigation.

Table 2 gives the damage recorded when
eight samples of the best performing guards
(type 2) were tested under identical conditions.

Discussion
The test has proved sensitive enough to detect
differences in performance between the
mouthguards even when only minor changes
are made to design, manufacture, and material.
It is assumed that this in vitro investigation
contains direct comparisons with in vivo
performance.

All custom made guards performed better
than the “boil and bite” guards. With such
deVICES, only marginal improvements are made
over the unguarded condition. The average
number of broken teeth fell from 6 to 4.5 when
these guards were used compared with 0.5
when the best performing custom made guard
was fitted.

The incorporation of the stiff and hard styrene
butadiene material into the guard had no
observable beneficia
teffects. It madethemouth-
guards difficult to fit and susceptible to crack
damage in the impact zone. The benefit of large
labial and palatal flanges was not obvious from
this work. A possible important factor is to
extend the reach of the guard to at least the rear
of the first molar. This is in agreement with the

Figure 3 Finished mouthguards: A, control sample; B, “boil and bite”; C, type 1; D, type
2; E, type 3; F, type 4; G, type 5; H, type 6.
performance of mouthguards

Table 1 Manufacturing and design details of the mouthguards tested and the amount of damage caused

<table>
<thead>
<tr>
<th>Mouthguard Material used</th>
<th>No of layers and thickness</th>
<th>Design details</th>
<th>Damage in test 1 (No of broken teeth, jawbone intact)</th>
<th>Damage in test 2 (No of broken teeth, jawbone intact)</th>
<th>Average damage</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control EVA</td>
<td>2 layers, 2 mm and 3 mm thick</td>
<td>Finished at distal surface of 1st molar, 11 mm labial flange and 7 mm palatal flange</td>
<td>4, zero</td>
<td>6, zero</td>
<td>6 broken teeth, jawbone 100% intact</td>
<td>Comparable to previous work</td>
</tr>
<tr>
<td>Type 1 EVA/styrene butadiene/EVA sandwich EVA</td>
<td>2 layers, 3 mm EVA/styrene and 2 mm EVA</td>
<td>Finished at rear of 1st molar, 7 mm labial flange, no palatal flange</td>
<td>5, zero</td>
<td>3, zero</td>
<td>4 broken teeth, jawbone 100% intact</td>
<td>Crack in impact zone. Full detachment during impact</td>
</tr>
<tr>
<td>Type 2 EVA</td>
<td>2 layers, 2 mm thick and 3 mm thick</td>
<td>Finished at rear of 1st molar, 9 mm labial flange, 1 mm palatal flange</td>
<td>1, zero</td>
<td>Zero, zero</td>
<td>0.5 broken teeth, jawbone 100% intact</td>
<td>Slight detachment during impact</td>
</tr>
<tr>
<td>Type 3 EVA/styrene butadiene bilayer EVA</td>
<td>1 layer, (EVA exterior) 3 mm thick</td>
<td>Finished at rear of first molar, 5 mm labial flange, no palatal flange</td>
<td>4, zero</td>
<td>4, zero</td>
<td>4 broken teeth, jawbone 100% intact</td>
<td>Total detachment. Cracks in impact zone. Difficult to fit.</td>
</tr>
<tr>
<td>Type 4 EVA</td>
<td>2 layers, EVA 2 mm and 3 mm thick plus 3 mm air gap behind front 6 teeth</td>
<td>Finished at rear of 1st molar, 9 mm labial flange, 1 mm palatal flange</td>
<td>3, zero</td>
<td>4, zero</td>
<td>3.5 broken teeth, jawbone 100% intact</td>
<td>Guard detached during impact. Spits in impact zone</td>
</tr>
<tr>
<td>Type 5 EVA/styrene butadiene bilayer EVA</td>
<td>1 layer, (EVA exterior) 3 mm thick</td>
<td>Finished at rear of 2nd molar, no labial flange, no palatal flange</td>
<td>3, zero</td>
<td>2, one</td>
<td>2.5 broken teeth, 50% failure rate in jawbone</td>
<td>Very difficult to fit. Partial detachment. Single crack in impact zone.</td>
</tr>
<tr>
<td>Type 6 EVA</td>
<td>2 layers, 2 mm thick and 3 mm thick</td>
<td>Finished at distal surface of 1st molar, 14-10 mm labial flange, 11 mm palatal flange</td>
<td>4, zero</td>
<td>4, zero</td>
<td>4 broken teeth, jawbone 100% intact</td>
<td>Partial detachment. Some splitting to inner surface at impact zone</td>
</tr>
<tr>
<td>“Boil and bite” A Pink EVA</td>
<td>3 mm thick</td>
<td>Finished at rear of 1st molar, 15 mm labial flange, 10 mm palatal flange</td>
<td>4, zero</td>
<td>5, zero</td>
<td>4.5 broken teeth, jawbone 100% intact</td>
<td>Easily detached during impact</td>
</tr>
<tr>
<td>“Boil and bite” B Black EVA</td>
<td>3 mm thick</td>
<td>Finished at rear of 1st molar, 15 mm labial flange, 10 mm palatal flange</td>
<td>5, zero</td>
<td>4, zero</td>
<td>4.5 broken teeth, jawbone 100% intact</td>
<td>Easily detached during impact</td>
</tr>
</tbody>
</table>

NA, not applicable; EVA, ethylene vinyl acetate.

Table 2 Damage recorded when eight of the best performing mouthguards were tested

<table>
<thead>
<tr>
<th>Test no</th>
<th>Broken teeth (No of broken teeth, jawbone intact)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>1 (Yes, Yes)</td>
</tr>
<tr>
<td>2</td>
<td>0 (Yes, Yes)</td>
</tr>
<tr>
<td>3</td>
<td>0 (Yes, Yes)</td>
</tr>
<tr>
<td>4</td>
<td>2 (Yes, Yes)</td>
</tr>
<tr>
<td>5</td>
<td>0 (Yes, Yes)</td>
</tr>
<tr>
<td>6</td>
<td>1 (Yes, Yes)</td>
</tr>
<tr>
<td>7</td>
<td>0 (Yes, Yes)</td>
</tr>
<tr>
<td>8</td>
<td>0 (Yes, Yes)</td>
</tr>
</tbody>
</table>

published “best practice” and contrary to certain laboratory practice. Type 2 guard had this feature incorporated along with a modest labial flange and gave the best results. The incorporation of an air gap “cushion” at the impact zone was not beneficial as can be seen by comparing the data of type 2 and type 4 guards.

The high reproducibility observed in both manufacture and testing is displayed by the results in table 2 which is the data on eight different type 2 guards tested under identical conditions. The very small spread in the number of broken teeth gives confidence in the output data and suggests that the test may be of use as a quality approval procedure.

Overall the data indicate that the test is capable of distinguishing between the performance of mouthguards containing only minor variations in design and materials.

The observations indicate that the following guidelines should be added to the current “best practice”:

1. Utilise multiple layers of EVA to build up a 5 mm thick layer in the thickest parts of a custom made guard.

2. Incorporate a 9 mm labial flange where feasible.

3. Extend the guard to at least behind the first molar or as far along the second molar to provide wearer comfort.

4. Design the palatal flange to provide wearer comfort.

5. Air pockets or cushioning devices should not be incorporated as no beneficial effects can be expected from them.

6. Incorporation of stiff and hard layers should not be used as no benefits accrue in terms of broken teeth.

It should be emphasised that these trials have been conducted on an “idealised” standard jaw. The adoption of this type of test by product safety authorities would allow the mass production of the standard jaw arch by injection moulding. This would allow precise dimensions and configurations to be brought even closer to the average in vivo situation.

The six custom made mouthguards were made under the supervision of Andrew Simmons at Sheffield Orthodontic Laboratories.

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