

## Original articles

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

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Figure 1 Drop weight impact test chamber.

## 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.

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Keywords: mouthguards; mouth; teeth; jaw

Previous work has indicated that a standard test could be used to assess the performance of mouthguards.<sup>1</sup> A standard rubber arch, containing replaceable ceramic teeth of fracture toughness 0.5 MN/m<sup>3/2</sup> and a composite jawbone of fracture toughness 3.0 MN/m<sup>3/2</sup>, is fitted with the mouthguard under test and impacted with a conical ended 0.51 kg 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

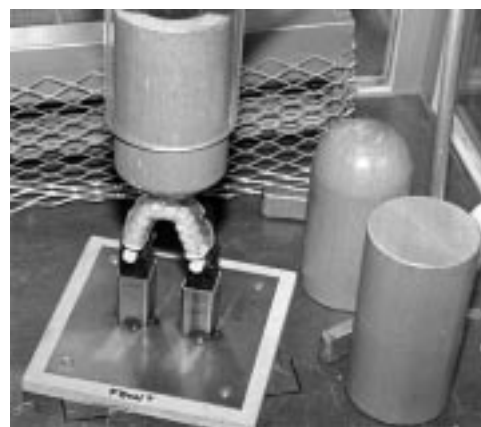


Figure 2 A conical ended impactor in contact with the test mouthguard and standard jaw located in the spring loaded support.

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.<sup>1</sup>

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*<sup>2</sup> 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-

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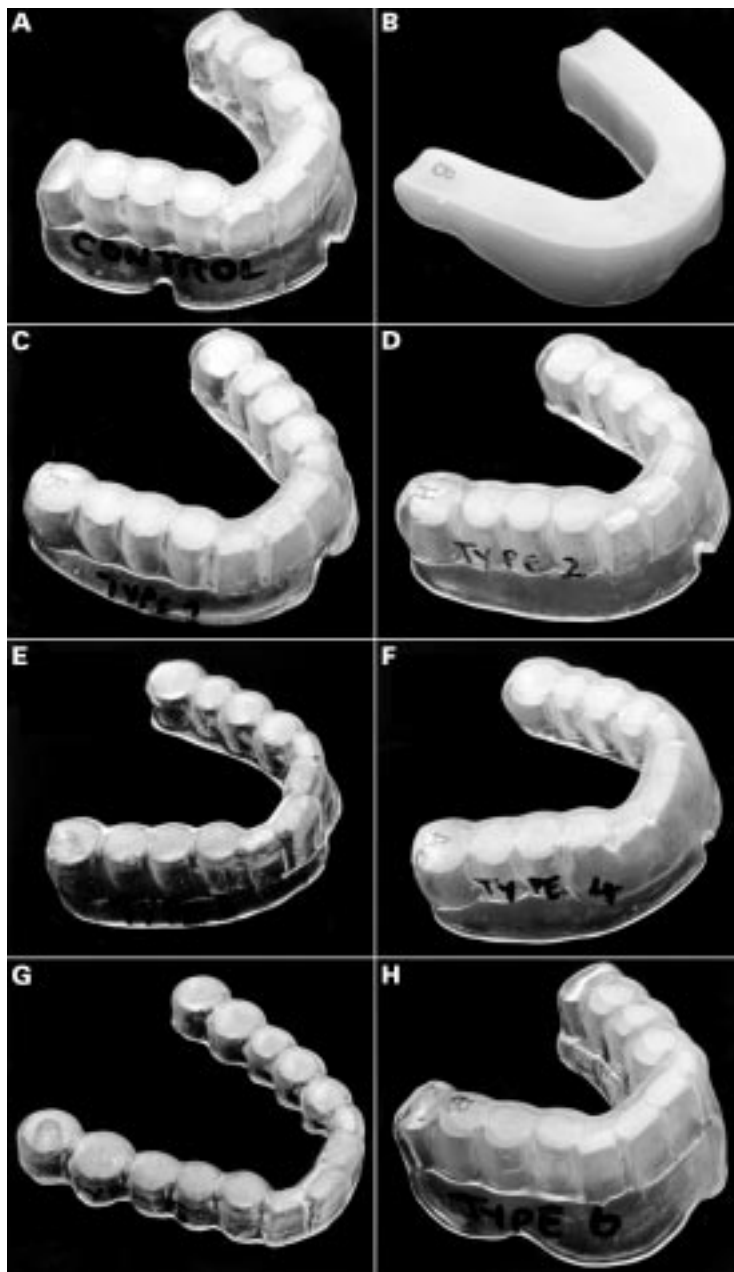


Figure 3 Finished mouthguards: A, control sample; B, “boil and bite”; C, type 1; D, type 2; E, type 3; F, type 4; G, type 5; H, type 6.

times this is for physiological reasons produced by particular oral configurations of the client. However, it is also due to perceived optimisation by the manufacturing laboratory. For instance many laboratories finish the guard at the first molar to 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 manufactured from a small range of materials. This also means that different materials can be used in different layers within the overall construction 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 ethylene vinyl acetate (EVA) which is available in blank 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 absorbing properties of such materials have attracted the interests of certain testing authorities.<sup>3</sup> However, it is considered that a full testing 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 supplied by the manufacturers. All the custom made guards were translucent and uncoloured. The EVA “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 the most scope in terms of sensitivity and best comparison with clinical observation.<sup>1</sup>

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.

The level of variation between different samples within each batch was investigated by testing 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. Soft tissue damage is also of clinical concern but beyond the scope of this in vitro investigation.

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 beneficial effects. It made the mouthguards 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

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

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

NA, not applicable; EVA, ethylene vinyl acetate.

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

Test no	Broken teeth	Jawbone intact
1	1	Yes
2	0	Yes
3	0	Yes
4	2	Yes
5	0	Yes
6	1	Yes
7	0	Yes
8	0	Yes

published "best practice"<sup>2</sup> 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.

- 1 Greasley A, Karet B. Towards the development of a standard test procedure for mouthguard assessment. *Br J Sports Med* 1997;31:31-5.
- 2 Scott J, Burke FJT, Watts DC. A review of dental injuries and the use of mouthguards in contact team sports. *Br Dent J* 1994;176:110-14.
- 3 SATRA. *Shock absorption of gum shields: falling mass/transmitted force method*. SATRA draft test method MG1 February 1997. SATRA, Rockingham Road, Kettering, Northants NN16 9JH, UK.