

Guidelines for the Fabrication, Use and Maintenance of Sports Mouthguards

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Acknowledgments

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Foreword

The purpose of a sports mouthguard is to reduce the stresses and absorb the energy generated by impact to the teeth in order to prevent or minimise consequent injury to the teeth and associated structures while participating in sporting activities. Although most mouthguards are made for sporting activities, they are also useful in other situations, e.g., for people with epilepsy who may fall or fit and damage their teeth; or during intubation for a general anaesthetic.

Attempts to develop a standard for sports mouthguards have been unsuccessful due to a number of factors. Principal among these is that sports mouthguards are custom-made devices, i.e., are made for individual wearers, and consequently the finished product is subject to inherent variations in the fabrication process. In addition, the characteristics required of the raw materials to prevent injury are not well documented.

Therefore, these Guidelines have been developed as an alternative to a standard, and represent a consensus on state-of-the-art procedures for sports mouthguard fabrication, use and maintenance.

Introduction

Several recent systematic reviews^{1,2} have looked at the clinical efficacy of mouthguards in the prevention of sporting injuries. The search strategies revealed over 2,250 citations for mouthguards and head injury. Comparison of published studies is difficult given the variability in research designs, selection bias, definition of injury, mouthguard types, measurements used to assess mouthguard exposure and injury, risk compensation and the variety of sports assessed which have differing head injury risk.

Biomechanical studies have suggested a protective role of mouthguard use in reducing sporting impact-related forces to the head.^{3,4} Two papers have been universally cited in the concussion prevention literature to support mouthguard use as an effective means of preventing concussion, however both of these papers are methodologically limited.^{3,5} Hickey et al.³ revealed a reduction in the amplitude of bone deformation and intracranial pressure by approximately 50 per cent with the use of a mouthguard, whereas Takeda et al.⁴ showed that mouthguard use significantly decreased the distortion of the mandibular bone and the acceleration of the head compared with no mouthguard use. Stenger et al.⁶ also recommended mouthguards based on their anecdotal experience of mouthguard use in US collegiate football. While biologically plausible, particularly with regard to orofacial injury, detailed concussive impact biomechanical studies show that mandibular impact accounts for a small percentage of all concussive injuries and this may be why few prospective studies demonstrate a role for mouthguards in prevention of brain injury.⁷

However, recent laboratory research⁸ showed that mouthguards can reduce distortion to the mandible and the acceleration of the head from the same blow, and therefore may have the potential to prevent mandibular bone fractures and concussion. The proven benefit of a mouthguard is the dissipation of the forces delivered to the maxilla, skull and temporomandibular joint complex when the mandible receives a blow.⁹ There is also stabilisation of the skull through increased neck muscle activity by clenching on the mouthguard, as well as a benefit from the altered position of the condyle in the fossa.¹⁰

Numerous studies on mouthguard efficacy include cross-sectional surveys, case reports, case series and retrospective studies, and these have shown conflicting results. There were five prospective cohort studies that assessed the relation between mouthguard use and concussion rates.

One study provided evidence to suggest a protective effect of mouthguard use on concussion severity as measured by time loss from unrestricted participation, however it did not measure individual mouthguard exposure and therefore could not provide a measure of relative risk.¹¹

Three cohort studies¹²⁻¹⁴ found no significant difference between concussion rates, and one additional study examined concussion rates between football players wearing custom-made versus non-custom mouthguards and thus did not examine risk differences between users and non-users.¹⁵

Only one randomised controlled trial (RCT) has been conducted in this area, which assessed head and orofacial injury rates in Australian Rules football using two study arms (custom laminated mouthguard versus usual mouthguard behaviours).¹⁶ The authors stated that the study was underpowered to determine injury risk for orofacial injury and there was no report of concussion rates for each study arm. Thus, the true association between mouthguard use and concussion risk could not be ascertained. At the same time, there is evidence to support the use of mouthguards for orofacial and dental injury protection.¹⁷ Such findings justify the use of mouthguards and facial protection in collision sports as a means to reduce injuries, but at this time cannot be advocated specifically for concussion risk reduction.

Future studies must not only be methodologically rigorous and statistically powered but must address the different types of mouthguard on the market and their relative efficacy in reducing or preventing injury.^{18,19}

This document provides guidance on the fabrication of sports mouthguards and includes information to be given to users of mouthguards on their use and maintenance. Appendix A gives guidance on the methods of fabrication of custom-made maxillary mouthguards and bimaxillary mouthguards

Types of mouthguards

A mouthguard is a protective device worn in the upper jaw and sometimes the lower jaw, to reduce injuries to the teeth, jaws and associated soft tissues. Types include:

Custom-made mouthguard

Custom-made mouthguards are formed on a cast of the upper jaw, sometimes in conjunction with a cast of the lower jaw, to obtain even occlusal contact and are produced using appropriate materials.

Bimaxillary mouthguards

Worn on the upper and lower jaws with a passage for breathing in the anterior, this type of mouthguard could be considered for players in boxing, martial arts and contact sports who desire a different type of protection. They require a period of adaptation in order to be tolerated.

Laminated mouthguard

These offer flexibility in design and construction. Ethyl vinyl acetate (EVA) blanks of different Shore hardness and thicknesses can be laminated together to provide increased protection.

Mouth-formed mouthguard

Also known as a 'boil and bite' mouthguard, this type is purchased 'over-the-counter' from outlets such as sports shops. It is softened in hot water and then formed in the mouth by finger, tongue and biting pressure.

Such mouthguards fit poorly, are difficult to wear, thin out dramatically, provide poor protection, are difficult to adapt to the mouth's anatomy, may be dislodged during use with a consequential risk of airway obstruction²⁰ and are therefore not recommended.

Mouth-formed "shell-liner" guards, which have a rigid outer layer and a soft thermoplastic inner layer, **are also not recommended as the hard outer layer may amplify impact force and cause injury.**²⁰

Stock mouthguard

Another "off-the-shelf" variety, these mouthguards consist of a curved trough of plastics or rubber and are worn without modification or adaptation. *Such mouthguards fit poorly, are difficult to wear, provide poor protection, may be dislodged during use with a consequential risk of airway obstruction²⁰ and are not recommended.*

Wearing of mouthguards

Custom-made mouthguards (formed on a cast of the wearer's jaws) are the most acceptable. Mouth-formed and stock mouthguards have disadvantages with respect to possible lack of retention, single-tooth contact, inadequate thickness, lack of retention and often rapid material deterioration with a consequent risk of injury. Critical for injury prevention, the mouthguard should have an ideal thickness after fabrication of 3 mm, and provide an occlusal surface balanced to the mandibular teeth.

Provision of professionally fitted, custom-made mouthguards for people involved in contact sports, and recognition of the 'injury-prone dentition' are important in injury prevention.

Consideration should be given to wearing mouthguards in all sporting activities (including training) in which there is risk of trauma to the teeth and associated structures. Such activities include stick and ball sports, all football codes, contact martial arts and where close physical contact could reasonably be expected, e.g., water polo, basketball and netball.

At what age should mouthguard wear commence?

Dental injuries are relatively common in children and their effects can be catastrophic to the developing dentition. Good habits for use of protective equipment are maximised by their early introduction. Wearing custom-made mouthguards should commence as soon as children start participating in organised contact sport.

The mouthguard can be constructed of two layers of EVA, pressure laminated together; the base layer 3 mm thick, and the outer layer 2 mm thick. Custom-made professionally fitted mouthguards should be considered as a part of children's sporting team uniform.

Patients undergoing orthodontic treatment should be provided with custom-made mouthguards.

Biocompatibility

Mouthguard material should not constitute a biological or toxicological hazard with respect to infection or irritation of normal oral mucosa, and should not contain elements or components toxic to oral tissues.

NOTE: Further guidance may be found in ISO 7405, Dentistry—Preclinical evaluation of biocompatibility of medical devices used in dentistry—Test methods for dental materials and ISO 10993-1, Biological evaluation of medical devices, Part 1: Evaluation and testing.

Benefits of mouthguards

The benefits of wearing a sports mouthguard include reducing:

- the risk of injury to the maxillary and mandibular anterior teeth.
- damage to the posterior teeth of either jaw following a traumatic closure of the mandible.
- intraoral and perioral lacerations.
- tongue damage at impact.
- fracture of the body of the mandible and the mandibular condyles.
- damage to the temporomandibular joint.

General design principles

The general design principles for sports mouthguards are:

- For sports where high occlusal loads are to be expected, the mouthguard should enclose the maxillary teeth, preferably to the distal surface of the second molar.
For these design requirements a mandibular model will be necessary to obtain an even occlusal contact.
- For standard club sports, enclosing the maxillary teeth to the distal surface of the first molar is usually sufficient.
- In the mixed dentition, the mouthguard should extend to the distal surface of the maxillary first molar.
- The approximate material thickness should be 2-3 mm on the labial aspect, 3 mm on the occlusal aspect and 2 mm on the palatal aspect.
- The labial flange should extend to within 2 mm of the vestibular reflection.
- The palatal flange should extend about 10 mm above the gingival margin.
- The edge of the labial flange should be rounded in cross-section.
- The edge of the palatal flange should be tapered in cross-section.
- On closing the mouth, there should be even contact between the mouthguard's occlusal surface and the lower teeth.
- For laminated mouthguards, improved impact force dispersion occurs when an airspace is created over the anterior teeth.⁸
- Mouthguards should not be designed and constructed with hard inserts sandwiched between laminations.²²
- Mouthguards should be thoroughly inspected prior to being issued to ensure adequate thickness, resilience and minimum pressure on the soft tissues.

General principles for materials

The general principles for mouthguard materials are:

- Easy to manipulate.
- Resistant to damage from heat
- Sufficient elastic modulus to reduce stress beneath material at point of impact.
- Sufficient rigidity to distribute forces over a large area of the dentition.
- Sufficient toughness to resist cutting by biting.
- Resistant to fracture under sudden impact.
- Resistant to water absorption in order to prevent tainting by mouth fluids.
- Able to withstand normal cleaning compounds.
- Resistant to low pH.
- Tasteless and odourless.

Integrity of materials

Currently, the required mechanical properties of mouthguards are not well defined. The following properties²¹ are recommended:

- Hardness, Shore 'A' at 37 °C
 - » liner 40 to 60
 - » shell 55 to 85
 - » mouthguard specific EVA blanks, 80-95
- Water absorption at 37 °C: < 0.5% w/w
- Impact test at room temperature: ≥ 70% of impact absorbed
- Tear strength at 37 °C: ≥ 200 N/cm.

Advice on use and maintenance

Patients fitted with sports mouthguards should be advised on the use and maintenance of their appliance. This advice should include:

- Wear only a professionally fitted, custom-made mouthguard with an even occlusal contact.
- Wear your mouthguard at training, practice and during the game.
- Rinse your mouthguard before and after use.
- Wash your mouthguard only with soap and in cold or lukewarm water.
- Clean the inner surface after wearing with a soft toothbrush.
- Do not let others use your mouthguard; it is custom-made and so can only be used by you.
- Store your mouthguard in a clean, rigid and ventilated plastic container.
- Keep your mouthguard away from sunlight and heat.
- Examine your mouthguard regularly for signs of deterioration, and replace if it is split or if the resilience, fit or bite have changed.
- Have your mouthguard checked for signs of wear, deterioration or reduction in fit as part of your routine dental review, or at least annually, by your dental practitioner.
- Contact your dental practitioner if your mouthguard becomes loose, too tight or causes you any discomfort.
- Do not expose your mouthguard to petroleum and petroleum products, cleaning agents, paints, adhesives and similar chemicals. It may be damaged and rendered ineffective, without the damage being visible to you.
- Consider regular replacement of mouthguards in children whose mouths are growing, and deciduous teeth are being lost and replaced by permanent teeth.

Appendix A - Fabrication of custom-made mouthguards

Examination and impressions for mouthguards

Mouthguards should be constructed following a thorough clinical examination, including radiographs where appropriate. Mouthguard design should take into consideration previously traumatised teeth and areas where tooth eruption is expected.

The occlusal pattern, soft and hard tissue pathology and the temporomandibular joint should also be assessed.

Impressions should be taken by a suitably trained dental professional and where necessary a registration of the occlusion should be made. For orthodontic patients, wax can be used to block out orthodontic brackets, bands and wires during impression taking, and plaster or light-curing resin can be used on the cast to block out brackets, bands and wires still visible after the initial impressions. It is unlikely that a custom-made mouthguard will interfere with orthodontic tooth movement, however regular review of the mouthguard fit should be undertaken during the treatment period.

A.1. Maxillary mouthguards

Custom-made mouthguards may be fabricated using either pressure-forming or vacuum-forming machines. Each type of machine has advantages and disadvantages. Particular features which are important are infra-red heating of the blank and full forming power (pressure or vacuum) should be achieved at the end of the heating cycle.

Single-Layer Mouthguards

The following procedure is a recommended method for the fabrication of a single-layer custom-made mouthguard:

1. Prepare a gypsum cast of the wearer's upper jaw and preferably also the lower jaw.
2. Outline the periphery of the mouthguard on the upper cast with a marking pencil. (This outline is only useful when using clear or semi-clear EVA blanks. Opaque colours such as black and white will completely mask the pencilled outline).
3. Coat the model with a water-based separator or a polyethylene high-shine foil.
4. Form the mouthguard from either a 3 or 4 mm thick EVA mouthguard blank, using a vacuum or pressure machine.
5. Allow the model and thermoformed EVA blank to cool thoroughly (normally 15 minutes), trim the periphery to the outline with an electric knife or hot scalpel. (A number 11 scalpel in a metal handle produces the best and cleanest outline). Only extend the mouthguard to the distal surface of the upper first molars, unless upper and lower models are needed for even occlusal contact.
6. Shape and smooth the periphery using abrasive wheels.
7. Finish with a soft polishing disk or mounted silicone point.
8. Adjust the mouthguard to provide even contact between its occlusal surface and the lower teeth on closure of the mandible.

NOTE: This adjustment can be made in the mouth after first softening the occlusal surface preferably with a hot air pen or a small flame; or using articulated casts in the laboratory or at the chairside. The laboratory method allows better control of the final thickness of the mouthguard and there is no risk of burning the patient. Only very experienced operators should use the direct heat technique.

Laminated Mouthguard

The following procedure is a recommended method for the fabrication of a laminated custom-made mouthguard:

1. Prepare a gypsum cast of the wearer's upper jaw to the full depth of the sulcus and the hard tissue landmarks of the lower jaw.
2. Outline the periphery of the mouthguard on the upper cast with a marking pencil. (This outline is only useful when using either clear or semi-clear EVA mouthguard blanks. Opaque colours such as black and white completely mask the pencilled outline). (Additional steps are required to add an airspace over the labial surface of the anterior teeth: soak the gypsum cast in water for 5 minutes; dry; add a 1 – 2 mm thick layer of plaster over the anterior teeth [canine to canine]; allow to set).
3. Cover the model with a water-based separator or a polyethylene high-shine foil.
4. Heat a 3 mm EVA mouthguard blank by following the manufacturer's instructions.
5. Thermoform and allow to cool (normally 15 minutes).
6. Trim the periphery to the outline with an electric knife or a hot scalpel. (A number 11 scalpel in a metal handle produces a cleaner more anatomical outline).
7. Degrease the first layer and the bonding surface of the second mouthguard foil with an isopropyl alcohol solution or roughen the bonding surface of the first EVA blank with trimming wheels. Note that this step is critical if using a coloured EVA blank as the second layer.

8. Heat the blank using a machine with infra-red heating that develops full forming power before the end of the heating cycle, follow the manufacturer's instructions for thermoforming the second 3 mm EVA blank.
9. Once the thermoformed EVA blank and model have completely cooled, cut out the second layer following the mouthguard design of the first blank.
10. Shape and trim the periphery with abrasive wheels in a straight handpiece.
11. Finish with a soft polishing disk, mounted silicone point, a hot air pen or commercial polishing solvents designed for this purpose.
12. Adjust the mouthguard either on an articulator or in the mouth to provide even contact between its occlusal surface and the lower teeth on closure of the mandible.
13. The standard custom built pressure thermoformed mouthguard is constructed from two layers of clear 3 mm thick ethyl vinyl acetate mouthguard blanks.

NOTE: This adjustment can be made in the mouth after first softening the occlusal surface preferably with a hot air pen or a small flame. The laboratory method using articulated maxillary and mandibular models allows better control of the final thickness of the mouthguard and there is no risk of burning the patient. Only very experienced operators should use the direct heat technique.

Coloured pressure-laminated mouthguard

Follow steps 1 to 3 for laminated mouthguards.

1. Heat a clear 2 mm thick EVA mouthguard blank following manufacturer's instructions.
2. Allow to cool; cut back following the mouthguard periphery design.
3. Thermoform a coloured 3 mm EVA blank as the second layer.
4. Allow to cool; cut back following the initial outline established by the initial 2 mm clear blank. (This outline is visible even if the second layer is an opaque colour). Using fine abrasive polishers to remove the polished surface of the coloured second layer blank. (A clear second layer EVA blank does not require this step).
5. Thermoform using manufacturer's instructions the third layer using either a 2 or 3 mm thick EVA blank.
6. Allow to cool, cut back the third layer to the already established outline and articulate maxillary and mandibular models to balance the occlusion, as described in point 12 for laminated mouthguards.

A.2. Bimaxillary mouthguards

The following procedure is a recommended method for the fabrication of bimaxillary mouthguards:

1. Take alginate impressions of both arches.
2. Make up a pair of four stacked tongue blades and secure each pair with a piece of sticky tape at both ends.
3. Check the vertical incisal opening by placing each stack along the line of the lower posterior teeth on each side, up to and including the second molars, and ask the patient to close the mouth. This should provide an incisal opening of 10-11 mm. If the opening is more than 12 mm, remove a blade from each stack.
4. Mix up a golf ball sized amount of putty-type silicone impression material, divide into two equal parts and roll each into a finger-like shape. Adapt each piece around one end of each stack, extending about one-third of the length of the top and bottom blades, and flatten out so that the material is not too bulky to fit into the mouth.
5. From closed centric, ask the patient to open wide and curl the tongue backwards. Insert the stacks between the posterior teeth and tell the patient to close into the material until the teeth contact the stacks. Maintain this position until the material hardens. Do not ask the patient to curl the tongue back as far as possible, as this could put the mandible into a retruded position. This step should be practised a few times before mixing the material to ensure that there is no protrusion or lateral deviation when the bite is being taken. To help patients relax and thus avoid an incorrect record, also ask them do this step with their eyes closed.
6. Mark each stack left or right.
7. Pour up the alginate impressions in high-strength gypsum.
8. Form upper and lower mouthguards, extending each to include the second molars in each quadrant.
9. Smooth and trim both mouthguards.
10. Build up the occlusal surfaces of the lower first molars with plaster to cusp height to resemble a small dome. (This is to enhance retention of the lower mouthguard by a suction cup effect). Do not extend the plaster onto other surfaces.

Method for joining using a standard flask

The following procedure is a recommended method for joining using a standard flask:

1. Trim the lower mouthguard to expose one-third of the crown of the six lower anterior teeth on both the labial and lingual aspects.
2. Relieve the silicone on the tongue-blade stack bite record in the region of the lower first molars.
3. Place upper and lower casts into the occlusal silicone impression on the stack, and mount the casts on a plasterless articulator.
4. Paint the inside surface of each mouthguard and both dental arches with separating medium.
5. Place the mouthguards on the casts and wax-up the join on each side with casting wax. (The joins should extend distally from the distal of the canine teeth and should be slightly concave on both inner and outer surfaces).
6. Remove the casts and the waxed-up unit from the articulator and invest in an extra-large flask.
7. When the plaster has set, open the flask and lift out the wax joins with a small wax spatula. (Do not immerse the flask in hot water to soften the wax before opening the flask, and do not use hot water to remove wax remnants from the casts).
8. Remove any remaining wax film by wiping the surfaces of the moulds with a proprietary wax solvent.
9. Heat half a mouthguard blank to a soft, pliable consistency either over a flame, or in a microwave oven at a low power for approximately 4 minutes.
10. Pack the material into the moulds, shut the flask and tighten in a clamp until the flask is approximately 2 mm open. Excess material will be extruded as the clamp is tightened.
11. Immerse the flask in water at 80-85 °C for 15 minutes, then tighten the clamp further. If the flask closes fully, set it aside for cooling. If not, re-immerses the flask in the water for 5 minutes and tighten the clamp again. If the flask now closes fully, set it aside for cooling; if not, re-immerses for another 5 minutes and retighten.
12. Bench-cool the flask for approximately 4 hours before deflasking. (Attempts to accelerate cooling may affect the material).
13. Clean the mouthguard and give a final polish using eucalyptus oil or dipropylene glycol.*

Method for joining without a flask

The following procedure is a recommended method for joining without using a flask:

1. Trim the lower mouthguard to expose one-third of the crown of the six lower anterior teeth on both the labial and lingual aspects.
2. Using the bite record, set up the models on an articulator.
3. Degrease the surfaces to be bonded with an isopropyl alcohol solution.
4. Build up blocks of mouthguard material that extend distally from the distal of the canine teeth on the lower mouthguard. (Use either excess mouthguard material that has been formed into a roll and apply heat from a hot air pen, or apply mouthguard material through a glue gun).
5. Trim the added material.
6. Degrease the surfaces to be bonded with an isopropyl alcohol solution.
7. Heat the surfaces to be bonded of both mouthguards with a hot air pen.
8. Press both heated mouthguards together.
9. Trim the added material and chamfer and trim the peripheries with a fine cross-cut tungsten carbide bur.
10. Finish with a soft polishing disk or mounted silicone point.
11. Scrub the models with water to remove any residual separator; replace the mouthguard on the models and create a high shine with a hot air pen.

Method using mould injection

Mould injection involves a technique using elastomeric acrylic resin and an injection flask.[†] The mouthguard is totally waxed-up for this method and there is minimal final cleaning and polishing required, compared to the methods of joining using a standard flask.

* Examples include 'Zoff' and 'Remove' (Smith & Nephew Pty, North Ryde, NSW www.smith-nephew.com/australia), are available from pharmacies. † Available from Ivoclar Vivadent, Noble Park, Victoria www.ivoclarvivadent.com.au

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