

Characterization of mouth-formed mouthguards: Thermal performance

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This study examined whether the thermo-modeling process suits the thermal properties of the material constituting mouth-formed mouthguards (MGs). Five mouth-formed MGs were compared: four commercially available MGs (SDITM, Gel NanoTM, Opro Shield GoldTM, and Kipsta R300TM) and one prototype. Differential scanning calorimetry was used to determine melting (T_m) and crystallization (T_c) temperatures and specific fusion and crystallization enthalpies (ΔH_f and ΔH_c (J/g)). MGs were modeled with recording of vestibular flange and occlusal cushion temperatures (T_{occl}). T_m ranged from 45.3°C to 53.0°C and T_c ranged from 40.9°C to 48.2°C. Specific heat of fusion ranged from 40.2 J/g to 62.0 J/g. T_{occl} was higher than T_m for all MGs except Kipsta R300TM. Guidelines provided by manufacturers may not be adapted to thermal properties of the MG material. To ensure proper thermo-modeling, heating and biting durations should be adjusted.

Keywords: Differential scanning calorimetry, Polyvinyl acetate-polyethylene copolymers, Mouthguard materials, Polymer structure, Standardization

INTRODUCTION

Whatever the type or method of manufacture, mouthguards (MGs) are considered as Personal Protective Equipment¹. As a result, they have to provide the highest level of protection for a reasonably foreseeable risk and without discomfort during use. Using a MG is an efficient way to avoid oral injuries². At the beginning of the last century, some “Prize Fighters” tried to protect themselves from lip injuries by inserting a piece of cotton under their lips^{3,4}, but the true predecessor of the MG seems to be a strip of Gutta Percha, as recommended by the London dentist, Woolf Krause⁵. At present, most studies agree on the role and properties of MGs^{2,6,7}.

An MG must decrease the risk of soft tissue injuries (lips and cheeks), decrease the risk of dental trauma, avoid violent knocks between the mandibular and maxillary teeth after an impact on the mandible, decrease the risk of concussion, dampen impact forces thanks to their thickness^{8,9}, stay in place during play and not interfere with breathing. However, Knapik *et al.* reported the need for high-quality studies to prove that concussion is prevented by MGs⁶.

Custom-made MGs (CM-MG) are the most able to meet these criteria. They are made on a dental cast after an impression of the maxillary dental arch or both dental arches taken by a dentist^{10,11}.

However, almost 90% of the MGs worn by athletes are mouth-formed MGs (MF-MGs), known as the “boil and bite” model¹². According to the manufacturers’ recommendations, adjustment is obtained by putting the device in boiling water to reach the temperature

necessary to soften it¹⁰ and allow for thermo-modeling. This can lead to two different effects. On the one hand, if the temperature is too high, there is a risk of burning the surrounding soft tissues⁷. On the other, if the temperature of the MG is too low, its shape is inadequate and it behaves like a stock MG¹³, with the risk of becoming wedged in the airway during sports activity¹⁴.

To adjust an MF-MG properly, its thermal properties have to be known. Even though there is a consensus in the literature that polyvinyl acetate-ethylene copolymer (PVAc-PE) is the most suitable material for MGs¹⁵, the percentage of VA changes from one MG to another, thus modifying the thermal properties of the material¹⁶. Differential Scanning Calorimetry (DSC) is commonly used to characterize the thermal properties of polymers^{16,17} and provides information on melting and crystallization temperatures. Above these temperatures, the MF-MG may be fitted to a support. So when the athlete positions the hot MG in his mouth, it has to be above the melting temperature of the material. When he removes it, it has to be under the crystallization temperature to be sure that the geometry of the MG is properly established.

So far, it is not clear whether the manufacturers’ guidelines, involving characteristic times and temperatures, are adapted to the thermal properties of the material from which MF-MGs are made.

The formatting protocol is directly related to the thermal properties of the material of MF-MGs, which vary depending on the variation in temperature to which the material is subjected. This study sought to determine

these properties such as the melting and crystallization temperatures of four commercially available MGs and a prototype, and to check whether the processes of shaping MF-MGs are adapted to the material used. Given the disparity of the protocols proposed by suppliers, the assumption was that they are not all adapted to the material properties.

MATERIALS AND METHODS

Mouthguard and DSC analysis

Four commercially available MF-MGs were selected for this study: SDI™ (Techniques Actuelles France, Le Meux, France), Gel Nano™ (Shock Doctor, North America, Minnetonka, USA), Opro Shield Gold™ (Opro, Hertfordshire, UK) and Kipsta R300™ (Oxylane, Villeneuve d'Ascq, France), respectively named SDI, GN, OSG and KR300 in the study. A fifth PVAc-PE (32% PVAc, Hardness Shore A 73) type thermoplastic MF-MG (hereafter termed 'prototype') was also studied¹⁸⁾. Commercial (boil-and-bite) MF-MGs were purchased locally (Bordeaux, France). Five models were used for

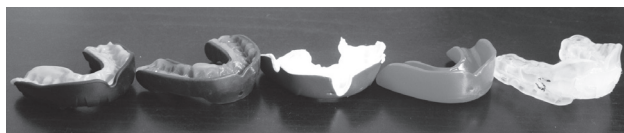


Fig. 1 Five MF-MGs in the study (from left to right): SDI, GN, OSG, KR300 and Prototype.

each selected MG (Fig. 1).

Even though the exact composition of the commercially available devices remains unknown, differential scanning calorimetry (Netzsch Phox DSC 200PC, Selb, Bavaria, Germany) was performed on one sample of the five sorts of MF-MG to determine their melting and crystallization temperatures (T_m and T_c respectively). The weight of the samples was 20.0 ± 0.2 mg and they were taken from the MGs at the occlusal cushion of the distal border of the second molar.

DSC scans were conducted over the temperature range from 20°C to 200°C using 10°C/min heating and cooling rates. All samples were equilibrated at 200°C for 2 min before cooling. Thermograms were plotted from heating and cooling. Melting temperature was extracted for each sample from DSC heating scan and corresponded to the endothermic peak value of the heat flow. Crystallization temperature was also determined from the DSC cooling thermogram and corresponded to the exothermic peak value of the heat flow on cooling. Enthalpy of fusion ΔH_f (respectively of crystallization ΔH_c) of the EVA samples was also evaluated from the area of melting peak (respectively of cooling peak).

Thermo-modeling

Thermo-modeling procedures recommended by manufacturers (Table 1) were used to fit the commercially tested MF-MGs and the prototype. All the MF-MGs were thermo-modeled on the same day. Before thermo-modeling, a small hole (0.5 mm diameter) was drilled in each MG in the vestibular flange and in the occlusive pad (thinnest and thickest layers of the MG

Table 1 Thermo-modeling characteristic times for commercially available MF-MGs and prototype

	SDI	GN	OSG	KR300	Prototype
Water cooling time after boiling [t_0-t_1]	30 s	30 s	none	none	30 s
Mouthguard Heating [t_1-t_2]	90 s	90 s	20 s	5 s	90 s
First cooling [t_2-t_3]	1 s	1–2 s	Not mentioned: dry the Mouthguard	Not mentioned	1 s
Thermoform in mouth [t_3-t_4]	Not defined: Time to thermoform the Mouthguard on teeth	20 s	30 s	10 s	180 s
Last cooling $t > t_4$	30 s	30 s	Drinking a glass of water with the Mouthguard in mouth*	20 s	30 s

* This recommended step couldn't be achieved in Laboratory environment; the same cooling procedure as used in the other MGs was adopted, *i.e.*, cooling down under tap water.

respectively) to allow for the insertion of thermocouples. These locations were chosen in order to compare core and surface temperatures during the process.

Instrumentation during thermoforming

We used the same procedure for all devices. However, the geometric variations of the MF-MGs and the presence of composite structures led to unusable results for some models because the thermocouple in the PVAc-PE material moved because the latter was too viscous. Four temperatures were measured using K thermocouples with refractory steel sheath AISI 310 at a sensitivity of $41 \mu\text{V}/^\circ\text{C}$ connected to a TC08 USB (PICO, Dimelco, France). Temperatures were recorded during the whole fitting process using a 1 Hz sampling frequency. Two thermocouples were set up on the MGs (vestibular flange and occlusal cushion) (Fig. 2) and the two others were placed in two water trays (used to heat and cool the mouthguards). A protocol made with a steel cast of jaws^{19,20} was used to thermo-model the MG into a specific device^{19,20}. Before thermo-modeling, steel jaws were conditioned at 37°C for 1 h in a thermal vessel (Zwick Roell, Ulm, Germany) with a 0.05°C sensitivity. During thermo-modeling, the manufacturers' recommendations were followed under the supervision of a dentist and with the jaws in a closed position. At the end of the process, core and surface temperatures were plotted as a function of time and corresponding modeling step. The duration between t3 (time when MG was inserted into mouth, see Table 1) and the time when core and surface temperatures reached the crystallization temperature of the specimen was taken to be the thermo-modeling time.

Statistical analysis

The data collected was analyzed to describe the distribution of quantitative variables as mean and standard deviation.

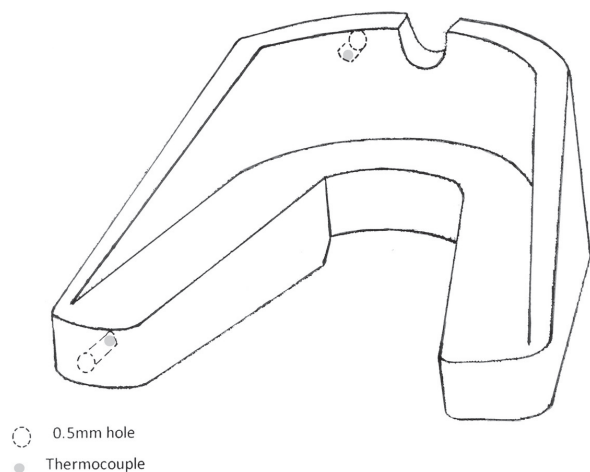


Fig. 2 Location of the thermocouples on vestibular flange and occlusal cushion of the MGs.

RESULTS

Differential scanning calorimetry

Figures 3 and 4 show DSC heating and cooling curves for the five models. All thermograms had a similar shape with two endothermic peaks for the heating curves and one exothermic peak for the cooling curves. On the heating curves, the melting temperature was recorded for the most endothermic peak. Values ranged from 45.3°C for the SDI to 53.0°C for the prototype. On the cooling curve, an exothermic peak was visible for each specimen on the cooling flow, which corresponds to the crystallization temperature of each sample. The

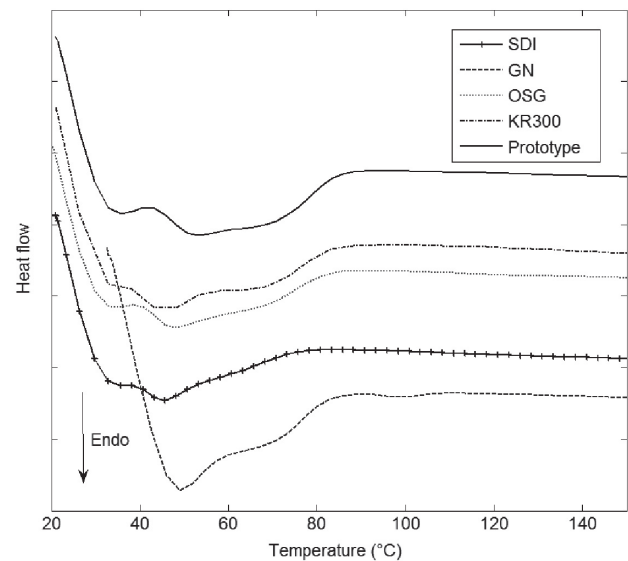


Fig. 3 DSC heating curves of commercial and prototype MGs at heating rate of $10^\circ\text{C}/\text{min}$.

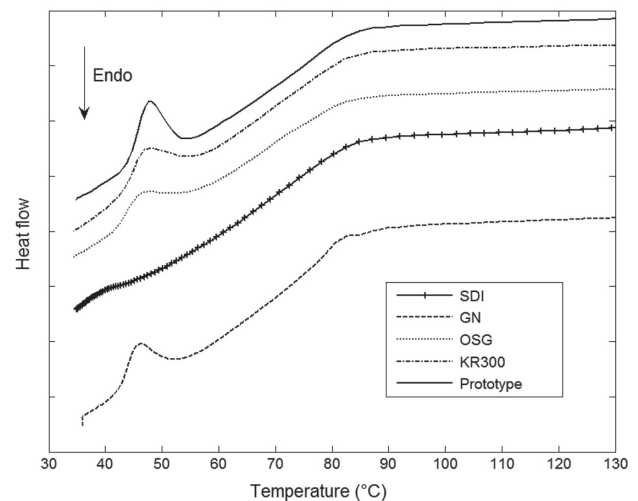


Fig. 4 DSC cooling curves of commercial and prototype MGs at cooling rate of $10^\circ\text{C}/\text{min}$.

crystallization temperature range was from 40.9°C for the SDI to 48.2°C for the KR300 and the prototype.

Enthalpies of fusion ΔH_f and crystallization ΔH_c were also extracted from the DSC heating and cooling curves respectively. All numerical values of melting and cooling temperatures and enthalpy of fusion and crystallization are shown in Table 2. Note that the lowest enthalpy of fusion (and crystallization) was with SDI MG and the highest with the prototype.

Thermo-modeling

Owing to various experimental problems such as thermocouple sliding within the specimen when the MG material became too viscous, only three samples

of SDI, GN and the prototype and four samples of OSG could be analyzed. Figure 5 shows the evolution of the four recorded temperatures as a function of time during the thermo-modeling process. All the curves had the same shape and the five characteristic times of the thermoforming process are highlighted:

—From t_0 to t_1 , the boiling water is cooling down and the MG is at room temperature.

—From t_1 to t_2 , the MG is immersed in hot water and both MG recorded temperatures are increasing. The vestibular flange temperature, *i.e.* the surface temperature, increases faster than the occlusive pad temperature, *i.e.* the core temperature. At t_2 , both MG temperatures are above the melting

Table 2 DSC results: melting and crystallization temperatures and specific fusion and crystallization enthalpies ΔH_f and ΔH_c (J/g) (obtained from one sample of each type of MG)

	Weight (mg)	T_{Melting} (°C)	$T_{\text{Crystallization}}$ (°C)	ΔH_f (J/g)	ΔH_c (J/g)
SDI	20.1	45.3	40.9	40.2	0.26
GN	20.2	49.2	46.0	49.9	2.57
OSG	19.8	48.1	47.3	41.5	2.35
KR300	20.0	45.4	48.2	54.6	3.24
Prototype	20.1	53.0	48.2	62.0	3.72

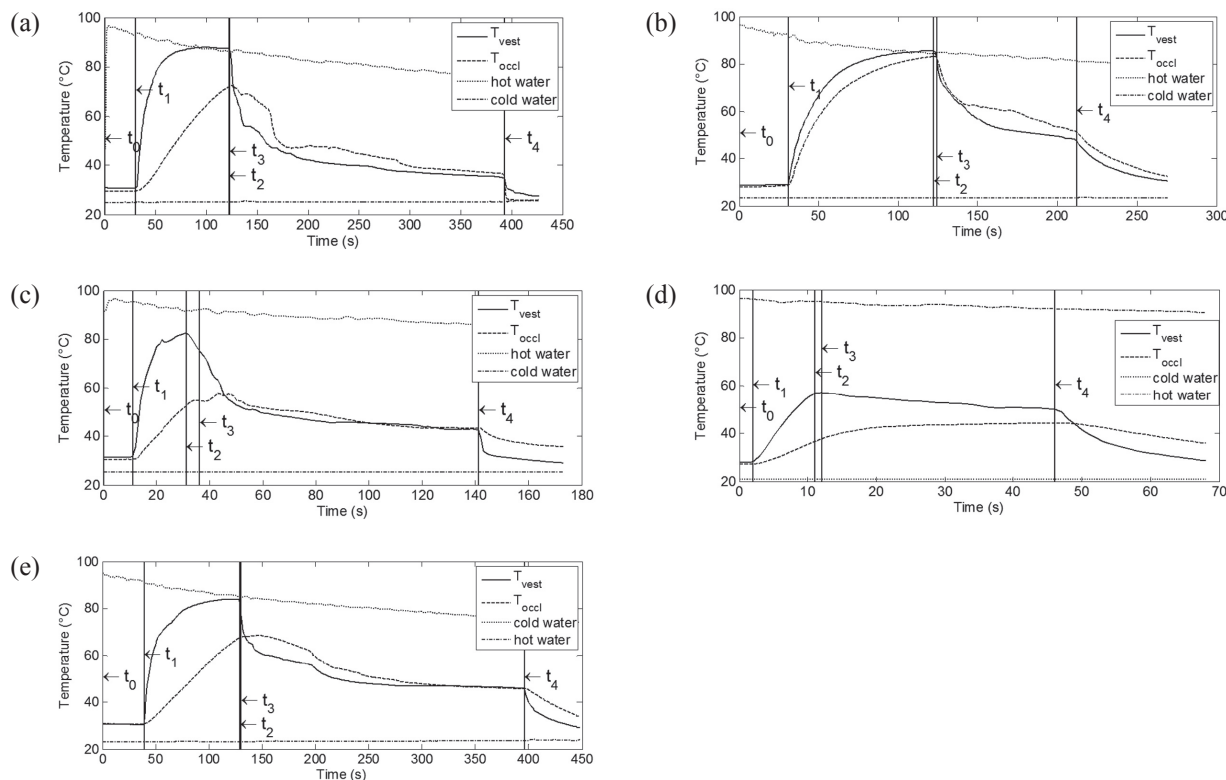


Fig. 5 Evolution of temperatures during thermo-modeling for one of each of the five mouthguard types: (a) SDI, (b) GN, (c) OSG, (d) KR300, (e) Prototype. t_0 to t_4 corresponds to the stages of the process.

Table 3 Mean maximum temperatures (Standard Deviation) for each mouthguard type during thermo-modeling stage (between t_3 and t_4) and modeling durations

	T_{vest} (max) (°C)	T_{occl} (max) (°C)	$T_{\text{occl}} > T_m$	Modeling duration (s)	
				Vest.	Occ.
SDI ($n=3$)	80.0 (0.3)	76.1 (5.0)	Yes	90.0 (7.7)	95.3 (2.0)
GN ($n=3$)	81.1 (0.8)	79.9 (0.8)	Yes	60.6 (2.0)	124.3 (2.3)
OSG ($n=4$)	74.7 (5.9)	62.4 (5.8)	Yes	42.5 (1.5)	66.5 (2.4)
KR300 ($n=5$)	59.6 (5.8)	36.0 (1.5)	No	23.5 (1.1)	—
Prototype ($n=3$)	75.8 (1.3)	70.1 (1.4)	Yes	67.3 (3.6)	141.0 (10.0)

temperature.

—From t_2 to t_3 , the MG is immersed in cold water. Cooling influences only the vestibular flange temperature and both core and skin temperatures are still above the melting temperature at t_3 .

—From t_3 to t_4 , the MG is maintained on the jaws for thermoforming. The cooling down of the vestibular flange occurs faster than that of the occlusive pad. During this step, both temperatures drop to below the crystallization temperature.

—At t_4 , the MG is immersed in the same cold-water tray until the end of the thermoforming process.

Table 3 presents MG temperatures recorded when the devices were in the mouth (t_3). There was little variation between occlusive pad and vestibular flange temperatures. The core temperature of all the MGs except the KR300 was above the melting temperature, *i.e.* thermo-modeling could take place. The duration of thermo-modeling is also shown in Table 3. This duration was very dependent on the MG type and was longer in the occlusive pad than in the vestibular flange (as the first one is a core temperature, the decrease is slower and the corresponding duration where T_{occl} is above T_c is longer).

DISCUSSION

This study investigated the thermal characteristics of five different types of mouth-formed MGs. Thermal properties and modeling times were closely linked to the ability of the devices to be thermo-modeled. However, the manufacturers' guidelines give specific boil-and-bite times that may not suit the devices.

Five models were thermo-modeled according to their manufacturers' guidelines for using the same specific device. The boil-and-bite method has been previously described^{19,20}.

DSC analysis

To characterize the ability of MF-MGs to be thermo-formed, a DSC analysis was performed. While there is agreement that EVA is the best material for making MGs, the percentage of PVAc used is variable, which modifies the thermal properties of the devices: Softening

temperature decreases as PVAc content increases²¹.

DSC analysis of the five devices showed that the T_m melting temperature ranged from 45.3°C (for SDI) to 53.0°C (for the Prototype) and that the crystallization temperature ranged from 40.9°C (for SDI) to 48.2°C (for KR300 and Prototype). Below these temperatures, modeling of the MG could not occur. The ability of a MG to be mouth-formed can also be assessed by measuring the specific heat of fusion of the material from which the device is made. Enthalpy of fusion characterizes the energy that must be supplied to the specimen in order to melt it. For the MGs tested here, a high heat of fusion was associated with a high degree of crystallization. Much energy was therefore required to thermo-model the specimens, so the greater the heat of fusion, the longer the duration above T_m .

Our DSC data can also be compared to the manufacturers' guidelines. After heating in boiling water, the MF-MG is placed in the mouth to allow for modeling. At that moment, the occlusal temperature must be higher than T_m . Table 3 shows that the occlusal temperature of the KR300 did not reach the required temperature, and that the SDI MG did not need a long period in boiling water as it has a low specific heat of fusion. On the contrary, the KR300 and the prototype needed more time above T_m to allow for good thermo-modeling. The temperature of the prototype was above T_m for 67.3 s and 141 s in the vestibular and occlusal regions, respectively. The temperature in the vestibular region of the KR300 was above T_m for 23.5 s, but the occlusal temperature (which is a core temperature) never reached T_m . Thermo-modeling of the KR300 is therefore superficial and only the outer part of the mouth-guard can be slightly modeled.

Thermo-modeling

While most thermal studies on MGs have focused on CM-MGs^{16,17,21,22}, we investigated whether the manufacturers' guidelines for modeling are adapted to the thermal properties of the material from which their devices are made.

First, if the boiling time is too short, the occlusal temperature does not reach the melting temperature. During the thermo-modeling process, the core

temperature has to be above the T_m melting temperature to allow the material to adopt its correct shape, but the surface temperature has to be sufficiently low to ensure that the surrounding soft tissues and dental material are not scalded. To our knowledge, scalding temperature in the mouth has not yet been documented. Turner *et al.* and Scheer hypothesize that dental and oral injuries may be due to hot water or to the burning material of the mouthguard but do not give precise temperatures at which this occurs^{7,23}.

Second, if the biting time is too short (*i.e.* occlusal temperature above the crystallization temperature), the shape of the device will not be set when the MG is removed. At the end of thermo-modeling when the MG is removed, the core temperature must be below the crystallization temperature so that the shape of the MF-MG is definitive. The duration of intra-oral fitting with bite force (400 N) has to be long enough to reach T_c whilst avoiding shape modification during the final handling when the MG is immersed in cold water. In our study, all the MGs models remained sufficiently long in the mouth for intra-oral fitting to reach T_c .

Despite the lack of statistical analysis, it appears that only the KR300 has a setting protocol that is not suited to the thermal properties of the material (Insufficient occlusal temperature).

Table 3 shows that when the specimens were removed, both vestibular and occlusal temperatures were under the crystallization temperature. Although recommended in the manufacturers' guidelines, the final cooling step in cold water did not have any effect on the final shape of the devices since the internal structure of the MF-MG was already established.

CONCLUSION

MF-MGs are formed by a boil-and-bite process whose guidelines are provided by their manufacturers. Even though EVA is the most suitable material for MF-MGs to date, the modeling ability of MGs also depends on the specific time to boil and bite the MF-MG, so some basic rules have to be followed to ensure proper modeling: a) sufficient boiling time for mouthguard material to reach the melting temperature; b) sufficient biting time for the mouthguard material temperature to drop below the crystallization temperature. According to the thermal characteristics and geometry of the material from which the device is made, modeling times have to be adapted.

ACKNOWLEDGMENTS

The authors thank Aquitaine Science Transfert and Nicolas Crebessegues for their assistance. They also thank Ray Cooke for linguistic assistance. This study was funded by the Department of Education and Research and by the Aquitaine Regional Government.

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