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Customized mandibular orthotics in the prevention of concussion/mild traumatic brain injury in football players: a preliminary study

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Abstract – *Background/Aim*: It is accepted that sports mouthguards decrease the incidence of dental injuries in athletes, but the value of oral orthotics in the prevention of concussion/mild traumatic brain injuries in footballers remains contentious. However, previous investigations have primarily studied non-customized mouthguards without dental/temporo-mandibular joint examinations of the subjects. Therefore, the aim of this study is to determine whether the use of a customized mandibular orthotic after temporo-mandibular joint assessment reduces the incidence of concussion/mild traumatic brain injuries in high-school football players. *Materials and methods*: Using a longitudinal, retrospective design, data were collected from a cohort of football players ($n = 28$) over three seasons using a questionnaire. The mean age of the sample prior to the use of the customized mandibular orthotic was 17.3 years ± 1.9. Prior to deployment, dental records and temporo-mandibular joint evaluations were undertaken, as well as neurocognitive assessment, including history of concussion/mild traumatic brain injuries. After establishing optimal jaw position, a customized mandibular orthotic was fabricated to the new spatial relations. *Results*: The mean age of the sample after three seasons was 19.7 years ± 2.0. Prior to the use of the customized mandibular orthotic, the mean self-reported incidence of concussion/mild traumatic brain injuries was 2.1 ± 1.4 concussive events. After the deployment of the customized mandibular orthotic the number of concussive events fell to 0.11 ± 0.3 with an odds ratio of 38.33 (95% CI 8.2–178.6), $P < 0.05$. *Conclusion*: The preliminary results of this study suggest that a customized mandibular orthotic may decrease the incidence of concussion/mild traumatic brain injuries in high-school football athletes, but a comprehensive study is required to confirm these initial findings. Furthermore, additional research is necessary to indicate the possible mode(s) of action of a customized mandibular orthotic in the prevention of concussion/mild traumatic brain injuries.

Concussion or mild traumatic brain injury (MTBI) may be caused by a direct blow to the head, face, neck or elsewhere on the body (1). Typically, this trauma results in the rapid onset of a short-lived impairment of neurological function that resolves spontaneously. However, concussion/MTBI can also result in a graded set of clinical symptoms that may or may not involve loss of consciousness. Commonly-described neurologic alterations associated with concussion/MTBI include: anterograde and/or retrograde amnesia; loss of orientation with respect to time, place and person; gait or postural instability; vertigo, and dysarthria. But, the occurrence of concussion/MTBI during participation in sporting events may lead to more than temporary alterations in mental status. For example, it is thought that concussion/MTBI is associated with: increased recurrence rates for subsequent concussion (“second impact syndrome” or post-concussion syndrome) (2); an associated loss of time from participation in contact sports activities, as well as an increased risk of cognitive impairment in later life. In a two-year prospective study involving high-school football players (3), it was reported that the relative risk of concussion/MTBI is approximately six times greater for individuals with a prior history of concussion as compared to those with no prior history.

In contrast, when acute recovery from concussion/MTBI was assessed in professional footballers and high-school football players, the professional athletes demonstrated a rapid neuropsychological recovery (2–7 days) after injury, while the high-school athletes demonstrated a slower recovery with more prolonged neuropsychological effects of concussion/MTBI (4). These results suggest that other factors such as age and weight *inter alia* may influence the outcome of head injuries. Indeed, simulation studies suggest that a stronger neck musculature reduces head acceleration and displacement, which might explain the increased concussion risk in youths and women when compared to male football players (5). Interestingly, other research indicates that skeletal muscle strength might be enhanced while wearing a customized mouthguard (6–8).

Powell and Barber-Foss (9) report that approx. 4–7% of high-school and college athletes sustain a concussion/MTBI each year. Many of these athletes will continue to play despite these increased risks, and feel protected by such appliances. But, a study of the incidence of concussions in college basketball players showed no statistical difference between mouthguard-wearers and non-wearers (10). Wisniewski et al. (11) also found no positive affect for a custom-made mouthguard compared to a ''boil and bite'' type appliance for the prevention of orofacial injuries or concussions in a study on football players. Similarly, a dual-arch appliance recommended by the American Boxing Association to prevent concussion/MTBI, was found to provide no greater protection when compared to a non-custom mouthpiece in a randomized trial (12). These studies perhaps explain why many experts in Sports Medicine discount the potential effects of blows to the jaw in the aetiology of concussion/MTBI. In contrast, an investigation of hockey players wearing full vs. half face-shields suggested that forces directed against the mandible may act as contributing factors to the incidence of concussions (13). Moreover, it was found that the increased potential for concussion/MTBI in those players wearing half face-shields could be reduced significantly if they wore a mouthguard. Furthermore, in a laboratory study using lateral blows to the jaw on a skull model (14), it was found that wearing a mouthguard decreased distortion of the mandibular bone and acceleration of the head significantly compared with not wearing a mouthguard. Therefore, the 'mouthguard' issue remains unresolved.

In studies of incidence during athletic participation, concussion/MTBI occurred most frequently in association with football (15). Based on these initial reports, this preliminary study was undertaken on a group of high-school football players. The aim of this study is to determine whether the use of a custom-made mandibular orthotic (CMO) reduces the incidence of concussion/MTBI in high-school football players after correction for TMJ/jaw relations. Note that the use of CMOs for the prevention of dental injuries is not considered as part of this particular investigation. Indeed, studies describing the efficacy of custom-made mouthguards in the reduction of dental and maxillofacial trauma are numerous (16–19) and will not be reported in the present study. The null hypothesis to be tested in this study is that there is no difference in the incidence of concussion/MTBI in footballers even after wearing the CMO. Rejection of the null hypothesis could lead to translational research that would focus on the provision of CMOs to football players and other sports athletes at increased risk of concussion/MTBI during contact sports.

Subjects and methods

All potential subjects for this study presented independently following the recommendation of their team coach to get a protective mouthguard. Potential study subjects recruited for this study were from different high schools, and were provided with a letter of informed consent for review and signing by their parents or legal guardian. After receiving informed consent, 40 subjects received a questionnaire regarding their previous symptoms, and an examination of their dentition, occlusion and TMJ, which was carried out by one clinician (GJM). For this study, 28 consecutive high-school football players with a mean age of 17.3 years ± 1.9 prior to deployment of the CMO were identified. Eleven of these subjects were from the same high-school team, but the remainder were not. All of the subjects had been cleared to play by their family physicians. The athletes were followed over 3 seasons. During this time, the diagnosis and treatment of those who suffered a concussion/MTBI was recorded. However, information about the incidence of dental trauma was not recorded. Athletes fitted with the CMO while they were in high-school were sent a second questionnaire after the period of study. Non-respondents were excluded from the study.

Clinical protocol

Clinical examination started with history-taking; specifically, any prior history of concussions/MTBI or orthodontic treatments. If an affirmative response was elicited, then the subject's class of occlusion prior to and after orthodontic treatment was determined. As well, a cervical spine evaluation was undertaken to assess the cranio-cervical relationship prior to a cranio-mandibular examination.

Next, a thorough temporo-mandibular joint (TMJ) evaluation was undertaken. The TMJ was palpated bilaterally to determine the degree of asymmetry, any tenderness and any reciprocal disc clicking. In addition, the clinician (GJM) looked for acceleration of the condyle on closure, and whether the slope of the articular eminence was steep or shallow. The position of the condyles was assessed to determine if they were located posteriorly on closure, as well as any lateral movement. Other signs of TMJ dysfunction, such as eccentric movements on opening or closure were assessed, as well as listening for joint sounds (crepitus) using a stethoscope. For the intra-articular disc, evidence of dislocation was assessed to determine any anterior disc displacement with or without reduction.

A dental evaluation was undertaken to determine what occlusal (Angle) class presented in the cuspid and molar regions bilaterally. Specific features noted included: anterior or posterior crossbites; wear facets; increased or decreased overbite (vertical overlap), including anterior open bite; third molar development (degree of eruption); missing teeth (congenital or early loss), and any retained deciduous teeth.

After patient examination, upper and lower alginate impressions were taken. The impressions included details of all frenae and the mucobuccal fold, ensuring that the

Fig. 1. The customized mandibular orthotic (CMO) viewed from above.

impression extended deeply into lingual flange region. Critically, the bite registration was finished to an occlusal vertical dimension that recaptured the intra-articular disc, if it was found to be displaced on initial examination. This spatial relation was verified by digital palpation, auscultation, or visual confirmation.

Dental casts were made and the customized mandibular orthotic (CMO) was fabricated (Fig. 1). Once received, the CMO was checked for goodness-of-fit, tightness and smoothness. It was adjusted according to patient feedback. The occlusion was checked with horseshoe, dual-coloured articulating paper (Ardent, Whip Mix Corp., Louisville, KY, USA) to determine whether it was even and whether any 'slides' occurred. (A slide is an occlusal line instead of a specific spot of occlusion.) If good occlusion was close to being achieved, spot grinding was carried out and all slides were eliminated. If good occlusion was found only on one side (6–8 contacts, Fig. 2), the opposite side was relined

Fig. 2. The customized mandibular orthotic (CMO) showing the marks made by articulating paper on occlusion. Good occlusion (7 contacts) is seen only on the left side.

Fig. 3. The customized mandibular orthotic (CMO) showing the marks made by articulating paper on occlusion. Poor occlusion (4 contacts) is seen with contact only on the second molars.

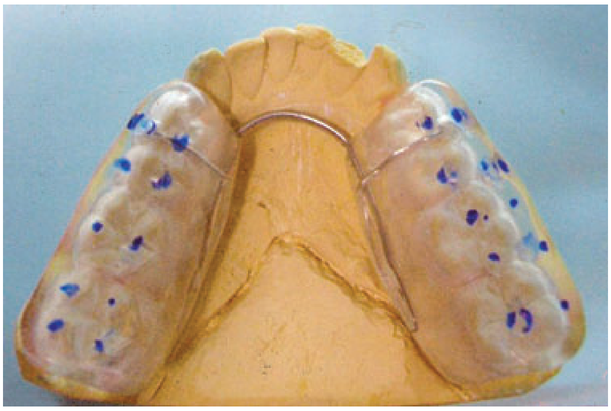

Fig. 4. The customized mandibular orthotic (CMO) showing the marks made by articulating paper on occlusion. Equilibration has been reached with even contact on both sides, with no occlusal interferences and no premature contacts.

with self-cure acrylic. If an anterior open bite was found with contact only on the second molars, both sides were relined (Fig. 3). If the CMO was found to rock, its fitting surface was relined with self-cure acrylic, and burnished to eliminate locking into undercuts. Thus, equilibration was carried out until even contact was achieved with no occlusal interference and no premature contacts (Fig. 4).

Next, the subject's condyles were palpated and observed on opening and closing to ensure the subject was still on the intra-articular disc. The positioning of the mandibular condyles during occlusion is critical to prevent the subject from being overclosed. All subjects were instructed in the proper use and cleaning of the CMO, and were reviewed within a week. Once properly habituated all subjects were instructed to utilize the CMO during all football-related activities. The investigators did not interact with the subjects during the subjects' sports involvement, and there was no verbal or written correspondence between the investigators and the study subjects. No individual subject identifiers, including the subject's name were used in the analysis.

Results

Of the subjects recruited for this present study, 28 of the initial 40 subjects successfully completed the questionnaires. Of this study sample: 71% (20) had a history of orthodontic treatment; 89% (25) had a Class I occlusion; 57% (16) had a good bite (cuspal interdigitation) while 18% (5) had a poor bite (deficient cuspal contacts); and about one-third of the sample had good (32%), fair (36%) or poor (32%) TMJ health, respectively. Figure 5 shows 3-D reconstructions from cone-beam CT scans with and without the CMO *in situ*. In this study, the athletes played 10 games per season (30 games/athlete). The incidents of concussions/MTBI were initially diagnosed by coaches and trainers on the sidelines. The concussions/MTBI were reported in actual games and the concussed athlete was removed from the game. The diagnosis and treatment of the concussed athletes was verified after the athlete was hospitalized by the parents. Following the completion of three competitive seasons (27 months) the mean age of the sample was 19.4 years ± 1.8. Prior to the use of the CMO, the mean self-reported incidence of concussion/MTBI was 2.1 ± 1.4 concussive events. Between them, they had suffered a total of 59 grade I or II concussions in the preceding two seasons (Table 1). However, there were only three reported concussions/MTBI in the study subjects after three seasons (Table 1). Thus, after the deployment of the CMO the number of concussive events fell to 0.11 ± 0.31 with an odds ratio of 38.33 (95% CI 8.2–178.6), $P < 0.05$. These results are summarized in Table 1.

Table 1. Summary of concussive events

Subject	Initial age (years)	Final age (years)	Number of concussions without CMO	Number of concussions with CMO
1	19	21	3	0
2	16	20	4	0
3	19	21	3	0
4	16	20	3	1
5	16	18	3	1
6	17	19	4	0
7	20	22	2	0
8	15	18	2	0
9	16	19	1	0
10	15	17	0	0
11	20	22	0	0
12	17	20	1	1
13	15	17	2	0
14	15	17.5	1	0
15	20	22	2	0
16	15	17.5	1	0
17	17.5	19.5	5	0
18	17.5	19.5	0	0
19	16	18	0	0
20	19	24	3	0
21	21	24	3	0
22	17	19	0	0
23	17	18	4	0
24	20	21	2	0
25	17	19	1	0
26	20	22	2	0
27	15	17	4	0
28	17	19	3	0
			59	
Mean	17.3	19.7	2.1	0.11
SD	1.9	2.0	1.4	0.3

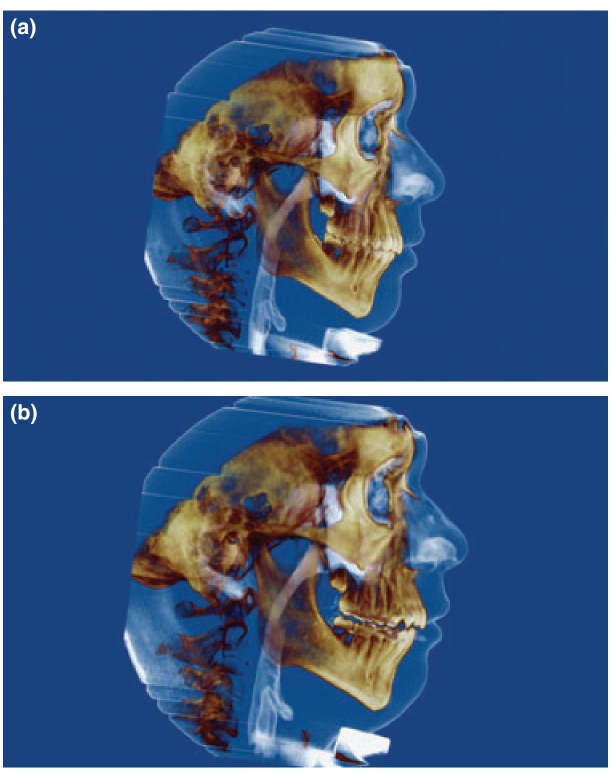

Fig. 5. (a) 3D reconstruction of hard and soft tissues of a subject at rest from a cone-beam CT scan. Note the relationship of the upper airway to the mandible, and the occlusion, without the CMO in place. (b) 3-D reconstruction of hard and soft tissues with the CMO *in situ* from a cone-beam CT scan of the subject in Fig. 5a. Note the change in spatial relations, with separation of the occlusion and the widening of the upper airway with the CMO *in situ*.

Discussion

There appears to be a growing consensus that mouthguards are important in the prevention of sports-related injuries to the dentition and oral soft tissues, as reflected by the policy on prevention of sports-related orofacial injuries of the American Academy of Pediatric Dentistry (2006) (20). However, the usefulness of a customized mandibular orthotic (CMO) in the prevention of MTBI/concussion has not been tested. Indeed, McCrory (21) suggests that one of the most commonly-held myths in sports medicine is the premise that wearing a mouthguard will prevent concussion/MTBI. Therefore, the role of the CMO investigated in this study was to gauge its effect on the incidence of concussion/MTBI – and not its efficacy in protecting the dentition. However, none of the athletes studied in this particular investigation experienced dental trauma, presumably because they wore a facecage along with the CMO under investigation. In addition, clear distinctions need to be made on the classification of oral appliances, which have variously been described as: mouthpieces; mouthguards; oral splints and oral orthotics. In this study, we consider: a mouthpiece to be a commercial, over-the-counter, product that is available without prescription; a mouthguard to be a customized, laboratory-fabricated appliance, specifically designed for the prevention of oro-dental trauma; and an oral splint to be a laboratory-fabricated appliances for the treatment of temporo-mandibular dysfunction (TMD), following the prescription of a dental professional. Finally, we define an oral orthotic to be a customized, laboratory-fabricated appliance for alignment of the upper and lower jaws, prescribed by a dental professional. A customized mandibular orthotic CMO (Fig. 1) that provided spatial correction of the TMJ was the device under investigation in this study.

An odds ratio of 38.33 was found in the sample studied in this investigation. This means that in the sample of 28 footballers, 23 had a concussion/MTBI when not wearing the CMO, while in the same sample only 3 experienced a concussion/MTBI when wearing the CMO during the same period. Thus, the odds of a footballer having a concussion/MTBI while not wearing the CMO are 23 to 5, or 4.6:1, while the odds of a footballer having a concussion/MTBI while wearing the CMO are only 3 to 25, or 1:8.33 = 0.12:1. The odds ratio is thus 4.6/0.12, or 38.33, showing that concussion/MTBI is much more likely in footballers that are not wearing the CMO. Therefore, in this sample, footballers are 23/3 = 7.67 times more likely to have a concussion/MTBI while not wearing the CMO, but have 38 times the odds. Nevertheless, the main limitation of this study is that dental injury as well as any preventive effect of the CMO on dental trauma was not assessed. The epidemiology of dental trauma (mainly to maxillary incisors) as well as the fact that current policies and regulations mandate the use of custom-made mouthguards (and not a CMO for some sports) cannot be ignored. So to address the question of how to reconcile two different approaches to prevent dental and neurological trauma, it is important to note that the jaw position obtained with the CMO can be reproduced using a maxillary ethylene vinyl acetate (EVA) extension for tooth protection. In many cases, when over the counter stock or boil and bite mouthguards are used, they are not comfortable, are mutilated by chewing when not participating in the sport, and usually have the posterior aspect removed for comfort by the athlete. We do not see this discomfort when properly fabricated pressure laminated mouthguards are used in sports such as basketball, rugby, soccer, and in other contact sports where protective helmets and faceguards are not worn. In football, however, the facecage worn by the athlete protects the vulnerable maxillary incisors from fracture. Nevertheless, if additional protection for the maxillary incisors is required, a maxillary EVA pressure laminated mouthguard would be added to the CMO, maintaining the same jaw position and TMJ relationships.

Stenger et al. (22) first reported a dramatic decrease in injuries to the head and neck, including concussion-associated neurological symptoms, in a group of football players who used a particular type of mouthguard. In a more recent study, Wisniewski et al. (11) report that there is no advantage in wearing a mouthguard to reduce the incidence of cerebral concussions in collegiate football players. Nevertheless, while mouthguards are custom-made to fit the dentition, customization in terms jaw relations has never been documented. Thus, we suspect that there may be an association between derangements of the TMJ and susceptibility to concussive injury in contact sports, such as the infamous 'glass jaw' in boxing. While the designs of protective helmets and facemasks provide measurable safeguards against a number of injuries to the dentition, face and head, the transmission of forces to the brain from blows either directly or indirectly through the mandible is still an area of major concern. Previous studies have demonstrated the association of biomechanical forces on the brain and clinical symptoms of concussion/MTBI (23). Consequently, concussion/MTBI in professional footballers is thought to be primarily related to translational acceleration with considerable head velocity changes (24). Furthermore, it is asserted that concussion/MTBI in professional football involves four typical collision conditions (25), which do not include blows to the chin. For example, about 70% of concussions involve impacts by another player's helmet, but the remaining 30% involve impacts by other body regions or the ground. Nevertheless, when concussive impacts were simulated by finite element analysis (26), the early strain occurred in one temporal lobe and migrated to the other temporal lobe after head acceleration in 40% of concussive simulations. These early strains in the orbito-frontal cortex and temporal lobe correlated with symptoms of dizziness. Therefore, the prevention of MTBI/concussions may, at least in part, be dependent on full protection of the temporal lobes.

Blows to the chin are dangerous as there is no protection from such a blow to prevent direct transmission of the force to the brain, while forces from other directions can be controlled by the player's helmet and facemask. Various studies have examined the benefit of mouthguards to prevent force transmission through the mandible from blows under the chin (27–32). These data indicate that the anatomical and physiologic association of the mandible to the temporal bone during a blow to the jaw may permit the transmission of forces to the brain, resulting in injuries consistent with a concussion/MTBI. It has been reported that up to 60% or more of the general population has at least one sign of a TMJ disorder, yet only a very small percentage ever seek medical or dental treatment (33). One common TMJ disorder is internal derangement, where the articular disc no longer localizes to its proper position in the joint. Typically, the disc becomes displaced anteriorly, limiting its functional benefit in relation to the movement of the mandibular condyle. Moreover, in this position it can also no longer serve as an intermediary of force absorption if a blow is directed through the mandible. The absence of this cushioning component would make it more likely that a force to the mandible would transfer more of its energy directly through the glenoid fossae to the temporal bone of the cranial base, and to the temporal lobe of the brain. On the other hand, the design of the CMO is such that when it is worn, it causes a repositioning of the mandible so that the condylar elements are moved from resting directly against the articular disc or, in the case of patients with internal derangements, the glenoid fossae, onto the articular eminence. This re-positioning changes the contact area and, therefore, might limit the direct transmission of force through the TMJ to the temporal bone and temporal lobe of the brain, by dissipating the forces through the thickest part of the articular eminence *inter alia*.

Gusenbauer (34) proposes three explanations for the prevention of concussions with dental appliances i.e. dissipation of forces directed to the jaw; stabilization of neck muscles, and distraction of the condyle from the glenoid fossa. Our preliminary results suggest that the CMO re-positions or aligns the mandible to better absorb, dissipate or reduce potentially-concussive forces. Indeed, interdigitation of the teeth may be critical in dissipating forces before they reach the brain. With interdigitation the upper and lower jaws work in concert as a functional block, which is the strongest position of the dental arches and the jaw-joint complex. In addition, a hard material should be used to fabricate a mouthguard or orthotic so that it will not lose the bracing of interdigitation. In view of the above contention, a poorly or incorrectly designed mouthguard could contribute significantly to a concussion/MTBI mediated via jaw-joint trauma, and this notion might explain why some previous studies have not found benefits associated with mouthguards in the prevention of concussion/MTBI. But, it is also possible that the benefits of a CMO are limited to a subset of athletes such as those with: TMJ disk displacement; forward head posture; non-adult subjects; females, or athletes with a prior history of MTBI. Conceivably, it is possible that, in conjunction with a change in head posture, which involves the muscles of the neck, there may be enhancement of craniofacial homeostasis. Thus, further structural (anatomical) and physiologic analyses need to be undertaken to compare the 2D and 3D craniofacial characteristics of players with and without a CMO *in situ*. Clearly further study with a randomized clinical trial to answer these questions is indicated. In addition, the benefits of a CMO made of hard acrylic need to be compared to one that is made of a more force-absorbing material.

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