

REQUEST TO VACATE FTC/BRAIN PAD CONSENT AGREEMENT

Concussions are a serious problem for participants in many athletic events. The Journal of the American Medical Association (JAMA) estimated in 1999 that there are over 250,000 concussions sustained in contact sports every year. The Associated Press estimates 100,000 football concussions occur each year. The National Athletic Trainer's Association estimates between 43,000 and 67,000 concussions per year in high school football alone. The US Center for Disease Control and Prevention claims 1.6 to 3.8 million cases of concussion a year in the United States. The National Institute of Health explains the diversity in prevalence numbers as athletes not understanding what constitutes a concussion and athletes' macho predilection, that by reporting the possible concussion they may lose starting status or look like a sissy if they remove themselves from the game.

Over the last five to seven years numerous studies on the long term effects of repeated concussion have linked it to increased rates of Alzheimer's Disease, Parkinson's disease, dementia, and Chronic Traumatic Encephalopathy (CTE) and suicides. CTE is marked on autopsy by neurofibrillary tangles, neutrophil threads and dead nerve cells in the brain tissue. The symptoms of CTE are deteriorated cognitive function, paranoia, panic attacks, depression and inappropriate violent behavior.

Everyone is aware of the danger from concussion. The full extent of the danger is not well known. After one concussion, the risk for a second concussion is three times greater, and the risk for a third injury is eight times greater. Repeated concussions hugely magnify the morbidity of the consequences. Diagnosis is important so treatment can be instituted. The best treatment is rest. Protection becomes the paramount concern as a safety measure.

Concussion is an injury to the brain caused by trauma to the head that results in the rapid onset of impaired brain function. Concussion may or may not involve loss of consciousness. The acute clinical symptoms were previously thought to merely reflect loss of normal function but as the knowledge base grew, the list now encompasses over 25 symptoms including dizziness, headache, blurring or other visual disturbances, amnesia, impaired balance and speech, wobbly gait, reduced cognition of surroundings and understanding of verbal instruction. Recent studies have

shown that long term permanent neuropathological damage can result from repeated concussions. Recent research has demonstrated the brain is not an organ capable of withstanding repeated traumatic injury. Cases of a second concussion before complete recovery from the first one have been shown to be fatal. Rest is the only known concussion treatment and *prevention is still the best medicine*. Recently thought to be minor temporary injuries, concussions have now been convincingly shown to pose serious, dangerous and morbid, life-threatening consequences.

There are **two distinct types of concussion** injuries that can occur as a result of head trauma in sporting activity - direct and indirect. Direct **head** impact bangs the brain into the skull. Alternatively an impulsive force specifically to the **chin** or mandible indirectly concusses by intruding the jaws into the brain.

I. Head Impact Concussion (HIC) The brain floats in cerebrospinal fluid inside a sac of dura mater situated inside the human skull. When the head is hit traumatically the brain bangs against the inside of the skull, usually on the side opposite to the trauma. The predominance of football concussions occur at the frontal lobe of the brain but can occur at any lobe of the cerebrum. The fragile brain tissue can become bruised or even tear if at that impact site it proximates the sharp bony ridges inside the skull. Bleeding, inflammation and swelling ensue that can result in damage to the brain tissue.

Helmets would appear to be the obvious solution. Helmets arose at the dawn of the game of football and the goal of the original leather helmet was to eliminate such deadly injuries as skull fractures and subdural hematomas. In that task they have succeeded. A study by the Cleveland Clinic reported that pre-World War II leather helmets performed as well as some current helmets at HIC protection. This demonstrates that the level of protection by helmets against concussions is still too low. Face masks and shields have all but eliminated most, if not all, facial injuries in football. Awareness of the danger of HIC however, generates the need for a new generation of protective devices.

There is little scientific evidence that mouthguards or mouthpieces, as they are more correctly called, offer any protection from HIC. Lack of evidence however, must not be taken to imply evidence of absence. Scientific

research needs to be done comparing the effects of head trauma in athletics with and without mouthpieces, as well as chin and jaw trauma in athletes wearing a mouthpiece in a position of biofacilitation versus those not wearing a mouth piece in biofacilitated position.

II. Chin Impact Concussion (CIC)

Traumatic blows to the chin or jaw have been shown to force the head of the mandibular condyle to perforate the thin superior surface of the GLENOID fossa (see *Figures 1. and 2. radiographic images*). Rupture of the temporomandibular disc and/or the mandibular condyle into the skull, causes bruising and direct damage to the temporal lobe of the brain. The symptoms of this type of concussion are frequently expressed as "getting my bell rung" or "seeing stars". Other signs occurring as a result of temporal lobe concussion are diminished visual pattern-recognition, and processing of spoken instructions, amnesia, seizures, tinnitus and reduced hearing.



Figure 1. The 3D tomographic images above depict a perforated glenoid fossa, hard evidence that CIC has occurred on the person's left side. The images above of the right side depict a healthy glenoid fossa. A new

technology, 3D tomographic imaging, allows computerized reconstruction of TMJ concussion not previously available.

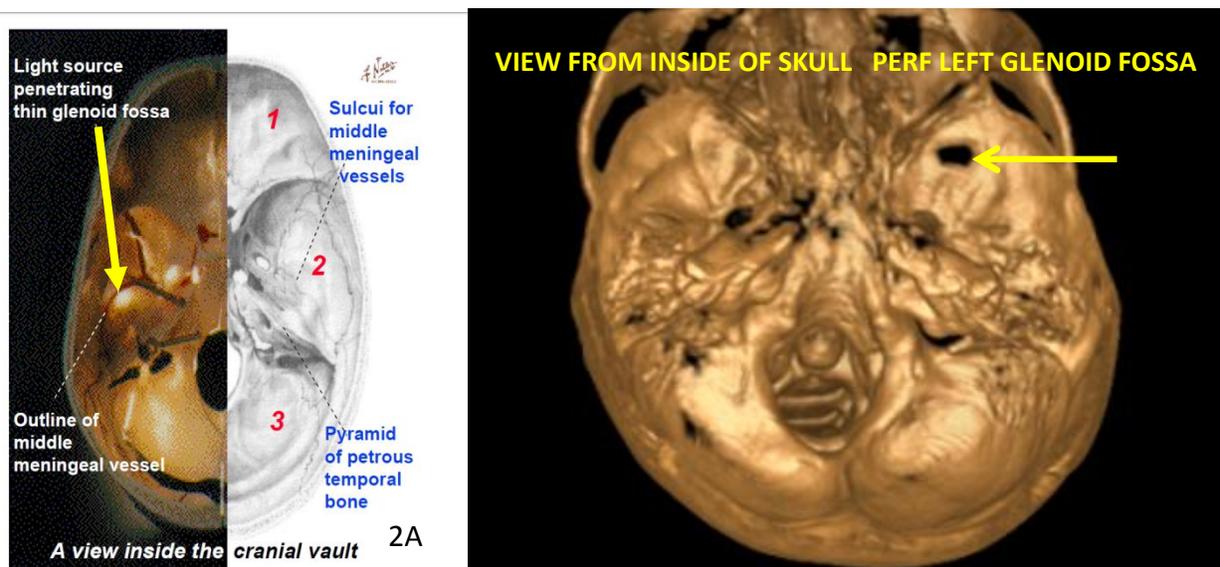


Figure 2A. A basal view of the skull illuminated from beneath to emphasize the thinness of the roof of the glenoid fossa and how vulnerable the temporal lobe of the brain is to perforation by chin impact impulsive forces

Figure 2B. The 3D tomographic image above depicts the view from inside the skull of the person in Figure 1. The arrow points to an area of the skull that was perforated by a traumatic impulse, an example of hard evidence for CIC. The area of the skull perforation cradles the temporal lobe of the brain.

It is certainly not logical to claim that a properly fitted mouthpiece would have prevented the traumatic injury shown above. It is very logical however, to assume that a resilient mouthpiece that separated the dental arches 4-5 mm. would have absorbed and redistributed some of the impulsive force from the chin to the mandibular condyle that ruptured the roof of the glenoid fossa. It is very reasonable to assume that a properly fitted mouthpiece would have reduced the risk of damage from CIC. It is unreasonable to contend that a mouthpiece would not reduce the risk of damage, or that no mouthpiece offers the same security against CIC.

It is the contention of this author that concussion protection reduces to two distinct and separate issues - 1. HIC Protection and 2. CIC Protection. Make a better mouthpiece to protect the athlete from CIC and invent a better

helmet to protect athletes from HIC. Well-fitted, well-designed, dual arch sports mouthpieces properly distract and stabilize the mandibular condyles relative to the glenoid fossae, thus furnishing excellent protection from temporal lobe concussion(CIC) caused by trauma to the mandible and jaws.

The radiographs in Figs. 1 and 2 are evidence that glenoid fossa perforation does occur. There is no logical explanation of causation other than trauma to the mandible. The radiographic views presented are excellent evidence of a CIC. It has not been previously possible to assess the extent or as accurately diagnose temporal lobe concussion. Newer technology seriously questions validity the FTC assertion that mouthpieces do not reduce the risk of concussion, specifically CIC.

It is not logical to deny that a concussion occurred. It is still not logical to claim that a properly fitted mouthpiece would have *prevented* the concussion. The most logical conclusion that a dental clinician or anatomist can offer based on Figures 1 & 2 is that a resilient mouthpiece, securely supporting the dental arches 4 - 5mm. apart, would have redistributed the force transmitted from the chin to the mandibular condyle ultimately rupturing the glenoid fossa in such a way that the risk of damage would be reduced.

This consent agreement that prohibits a manufacturer of mouthpieces from saying that mouthpieces reduce the risk of jaw concussion is misguided, because it runs the risk of implying that there is no greater risk to a football, soccer, hockey or lacrosse player, from chin impact concussion not wearing a mouthpiece, or that the risk of jaw impact concussion is insignificant. The greater risk of suffering CIC is certainly to not wear a protective mouthpiece rather than to wear one.

The FTC consent agreement signed by Brain Pad that would prevent a mouthpiece manufacturer from saying that a mouthpiece reduces the risk of chin impact concussion has no merit. I believe the Brain Pad packaging makes a reasonable and true statement. I believe I have presented a reasonable case for vacating the BrainPad/FTC consent agreement.

The issue of concussion prevention is a newly emerging problem of grave seriousness. Virtually everyone *and their mother* understands that there are explicit dangers from participation in football or hockey. The act of

participation implies that the player and/or their parent accept some of that risk. The job of the FTC must be refocused more positively on education rather than emphasizing improperly informed prosecution. Prosecution does not mean protection.

The greater good is served by vacating the Brain Pad/FTC Consent Agreement.

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