Evaluating the "Threshold Theory": Can Head Impact Indicators Help?

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[1]Department of Exercise and Sport Science, Matthew Gfeller Sport-Related Traumatic Brain Injury Research Center, The University of North Carolina, Chapel Hill, NC; [2]Curriculum in Human Movement Science, Department of Allied Health Sciences, School of Medicine, The University of North Carolina, Chapel Hill, NC; [3]Injury Prevention Research Center, The University of North Carolina, Chapel Hill, NC; [4]Department of Kinesiology, The University of Georgia, Athens, GA; [5]Datalys Center, Indianapolis, IN; and [6]Department of Epidemiology, The University of North Carolina, Chapel Hill, NC

ABSTRACT

MIHALIK, J. P., R. C. LYNALL, E. B. WASSERMAN, K. M. GUSKIEWICZ, and S. W. MARSHALL. Evaluating the "Threshold Theory": Can Head Impact Indicators Help? *Med. Sci. Sports Exerc.*, Vol. 49, No. 2, pp. 247–253, 2017. **Purpose**: This study aimed to determine the clinical utility of biomechanical head impact indicators by measuring the sensitivity, specificity, positive predictive value (PV+), and negative predictive value (PV−) of multiple thresholds. **Methods**: Head impact biomechanics ($n = 283,348$) from 185 football players in one Division I program were collected. A multidisciplinary clinical team independently made concussion diagnoses ($n = 24$). We dichotomized each impact using diagnosis (yes = 24, no = 283,324) and across a range of plausible impact indicator thresholds (10g increments beginning with a resultant linear head acceleration of 50g and ending with 120g). **Results**: Some thresholds had adequate sensitivity, specificity, and PV−. All thresholds had low PV+, with the best recorded PV+ less than 0.4% when accounting for all head impacts sustained by our sample. Even when conservatively adjusting the frequency of diagnosed concussions by a factor of 5 to account for unreported/undiagnosed injuries, the PV+ of head impact indicators at any threshold was no greater than 1.94%. **Conclusions**: Although specificity and PV− appear high, the low PV+ would generate many unnecessary evaluations if these indicators were the sole diagnostic criteria. The clinical diagnostic value of head impact indicators is considerably questioned by these data. Notwithstanding, valid sensor technologies continue to offer objective data that have been used to improve player safety and reduce injury risk. **Key Words**: BIOMECHANICS, BRAIN INJURY, CONCUSSION, SPORT INJURY

Proper detection and management of sport-related concussion continues to challenge clinicians working with athletes. Various methods are advocated to evaluate athletes with suspected concussions. The most commonly used is the Sport Concussion Assessment Tool Version 3 (18), which includes the Standardized Assessment of Concussion (17) and the Balance Error Scoring System (28). These acute injury screening tools are typically administered only after the clinician has sufficient evidence to suspect a concussion diagnosis. In the absence of obvious concussion signs (e.g., loss of consciousness and staggered gait), clinicians must rely solely on subjective symptoms reported by athletes. Research has documented a large portion of athletes either underreport concussion symptoms or fail to report them entirely (16,19). This suggests that clinicians must explore alternative methods of identifying concussions.

Technological advances have resulted in the emergence of commercially available head impact measurement devices. These devices typically serve two broad functions: 1) to collect data for research-based inquiry and 2) to signal to clinical staff the occurrence of high-level impacts in near real time during sports participation. Head impact indicators—the latter function—seek to identify athletes who have sustained pronounced head impacts so that they can be evaluated for symptomatology. These products are worn directly on the head or affixed to a helmet and are designed to indicate to medical personnel, players, coaches, and parents when a head impact magnitude has exceeded a preprogrammed threshold. The thresholds used by head impact indicators have been based, in part, on previous laboratory work reconstructing professional football concussions from video footage (26). In addition, Zhang et al. (31) used finite brain models to recreate injurious collisions sustained by professional football players and reported that head impacts exceeding 66g, 82g, and 106g were associated with a 25%, 50%, and 80% probability of sustaining concussion, respectively.

Head impact indicators are believed to identify athletes who otherwise would elect not to report symptoms to the clinical staff. If an "alert" is triggered, some of the manufacturers

recommend the athlete be removed from activity and evaluated for a head injury, regardless of whether the athlete is exhibiting signs or reporting symptoms consistent with concussion. In light of evidence that injury thresholds remain elusive (10,11,20,26), these products may have permeated the marketplace before their clinical utility has been fully evaluated.

Sensitivity, specificity, negative predictive value (PV−), and positive predictive value (PV+) are common measures used to assess the clinical utility of any diagnostic or screening assessment. In particular, any head impact indicator must demonstrate that it has predictive value; that is, it is an efficient use of time and resources and that it yields a practical frequency of identified concussions to be clinically useful (27). This is particularly hard to achieve because 1) the incidence of concussion is low relative to the large number of head impacts in contact sports and 2) there is substantial heterogeneity in the range of biomechanical values associated with diagnosed concussions. For example, a study of injured college football players wearing in-helmet accelerometers with concussive head impacts reported values of linear acceleration ranging from $60.51g$ to $168.71g$ (12). In this same study, less than 0.5% of impacts exceeding $80g$ resulted in diagnosed concussion.

The purpose of this study was to investigate the clinical utility of head impact magnitude thresholds used by various commercially available head impact indicators to positively predict concussion among American football players. We hypothesized that these tools, by themselves, would be limited in helping clinicians make informed decisions regarding head injury during athletics because of the inherent variability of biomechanical values observed in concussed individuals and the low incidence of concussion even at very high measured impact levels. Many of the head impact indicators are marketed specifically for nonclinical end users. Thus, exploring the diagnostic value of these devices is critically important to understanding the true role of head impact indicators.

METHODS

Study design and participants. We enrolled 185 Division I Football Bowl Subdivision college football players (Table 1) from one school over the course of eight full academic years. Our convenience sample was representative of collegiate football playing positions (Table 1). A detailed explanation of the study was provided for all potential participants in group settings. Those interested in participating provided full informed consent by signing informed consent documents approved by the university's institutional review board. Because the investigators did not have individual contact with every player on the roster, it was not possible to determine whether key demographic variables influencing concussion risk differed between those participating in the study and those who did not.

Instrumentation. The Head Impact Telemetry (HIT) System (Riddell Corp., Chicago, IL) was used to collect head

TABLE 1. Participant characteristics.

Characteristic	Mean ± SD
Age at enrollment	19.2 ± 1.4 yr
Height	188.6 ± 6.2 cm
Mass	108.2 ± 19.4 kg
Position[a]	***n* (%)**
Offensive lineman	50 (27.0)
Defensive lineman	32 (17.3)
Defensive back (i.e., cornerback and safety)	37 (20.0)
Linebacker	29 (15.7)
Offensive back (i.e., fullback, running back, and tailback)	28 (15.1)
Wide receiver	19 (10.3)
Quarterback	9 (4.9)
Other (e.g., special teams, kicker, and long snapper)	13 (7.0)
Concussions[b]	***n* (%)**
None	164 (88.6)
One	18 (9.7)
Two or more	3 (1.6)

[a]Position frequencies and percentages sum to more than 185% and 100%, respectively, because 28 participants played two positions and 2 participants played three positions.
[b]Concussion percentages add up to 99.9% because of rounding.

impact biomechanics, including linear acceleration, rotational acceleration, HIT severity profile (HITsp), head injury criterion (HIC), and Gadd severity index. The HIT System consists of six spring-mounted single axis accelerometers, the RedZone software, and the Riddell Sideline Response System. The accelerometer units equipped with a battery pack, a telemetry unit, and an onboard data collection device (hereafter called MxEncoders) were embedded within Riddell VSR4, Revolution, and Speed Revolution football helmets. The MxEncoders were designed to collect head impact data and transmit them in real time to the Sideline Response System, which consists of a sideline controller (antenna) attached via USB connectivity to a laptop computer. Each impact was uniquely linked to a participant using a study identifier assigned to each participant's MxEncoder. In the event the accelerometer unit was unable to communicate directly with the sideline data collection system, the onboard systems were capable of storing up to 100 impacts in nonvolatile memory, ensuring that any data not transmitted in real time could be retrieved at a later time. The HIT System has been previously validated by laboratory testing (8).

Procedures. At the start of each season, professional equipment managers fit each participant with a study-eligible Riddell football helmet. We subsequently installed the MxEncoders in these helmets and verified helmet fit. Helmets were regularly maintained thereafter. Data were collected throughout the preseason, regular season, postseason (bowl season), and spring season. During the 8-yr period, we collected data from 121 games and scrimmages, 365 full-pad practices, and 266 partial-pad or helmets-only practices.

Data analysis. Head impact biomechanics (linear acceleration, rotational acceleration, and HITsp) were computed by the HIT System. Data for all years were simultaneously exported from the Sideline Response System into custom Matlab 7 code (The Mathworks, Inc., Natick, MA). This ensured computational algorithms used by the HIT System were applied consistently to all our data. Matlab was used to reduce data to include only those impacts sustained during

practices and games/scrimmages. Impacts occurring outside of team-sanctioned events (e.g., impacts imparted to the helmet during handling of equipment or travel, while players walked to the practice facility) were excluded from analyses. Only impacts exceeding $10g$ of peak linear acceleration were included in our analyses. For impacts below this $10g$ threshold, it is difficult to distinguish between head impacts and voluntary head movements (8,10,12,20,23). While the HIT System is capable of recording and computing several variables associated with head impact biomechanics, our study focused primarily on resultant linear acceleration to align with the preponderance of linear acceleration thresholds used by head impact indicators in the marketplace. To our knowledge, none of the available head impact indicators use rotational acceleration in defining their concussion threshold.

Our clinical sports medicine staff define concussion broadly as a direct or indirect insult to the brain, with transient impairments of mental functions such as memory, balance or equilibrium, and/or vision, which may or may not result in loss of consciousness. An athlete suspected of having a concussion is evaluated by the team physician, and more serious injuries such as cervical spine injury, skull fracture, and/or intracranial bleed are ruled out. The initial evaluation includes a symptom assessment and physical examination with emphasis on the neurological examination. The team physician or team's athletic trainer evaluates cognition and balance using the Standardized Assessment of Concussion, the Balance Error Scoring System, and a graded symptom checklist. All clinical diagnoses are made without any knowledge of the head impact data we collect. Once we are informed of each physician-diagnosed concussion (typically within 24–48 h of the event), event videos are reviewed, and the corresponding impacts are matched via time stamp and coded as "injury" in the data set. All other impacts are coded as "noninjury."

We computed the impact frequency, sensitivity, specificity, negative predictive value (PV−), and positive predictive value (PV+) for a range of plausible impact indicator thresholds ($10g$ increments beginning with $50g$ and ending with $120g$). Table 2 defines sensitivity, specificity, PV+, and PV− and offers example computations. Many devices use customizable indicator thresholds. Therefore, we chose to provide data across a distribution of thresholds that may be used by the end user.

We performed additional sensitivity analyses because of reports that as many as 80% of concussions may go unreported or undiagnosed (3). We also acknowledge that PV+ and PV− are largely driven by concussion incidence. As such, we scaled our injury frequency by a factor of 5 to provide an estimate of clinical utility for all possible events that may have been sustained—but not reported—by athletes in our sample. This larger sample of suspected undiagnosed concussions was then used in our formulae to compute adjusted PV+ and PV− values (reported in the far right column of Table 3). Documented concussive events captured by on-field biomechanical head impact monitoring systems have all exceeded $40g$ (12), suggesting that concussion from head impacts lower than $40g$ may be biologically implausible from a pathogenesis standpoint. In combination, we also performed our sensitivity analyses excluding all impacts lower than $40g$.

RESULTS

During the 8-yr period (2004–2012 seasons), a total of 283,348 impacts were collected during all practices (219,426 impacts) and competitions (63,922 impacts). Of these impacts, 24 resulted in a diagnosed concussion (Table 1), a rate of 0.08 diagnosed concussions for every 1000 impacts. Of the diagnosed concussions, 15 (62.5%) occurred during practices (0.07/1000 impacts) and 9 (37.5%) occurred during competitions (0.14/1000 impacts). Diagnosed concussion impacts ranged from $40.3g$ to $173.22g$ in linear acceleration and from 163.35 to 15397.07 rad·s^{-2} in rotational acceleration. Noninjury impacts ranged from $10.00g$ to $350.00g$ in linear acceleration and from 0.15 to 30,601.02 rad·s^{-2} of rotational acceleration.

Regardless of the indicator threshold used in the analyses—$50g$, $60g$, $70g$, $80g$, $90g$, $100g$, $110g$, or $120g$—PV+ was very low (the highest was 0.39% for a $100g$ threshold). Similarly, PV− was very high (99.9%) regardless of the indicator threshold used. Sensitivity ranged from 95.8% ($50g$ threshold) to as low as 16.7% ($120g$ threshold). Specificity remained high regardless of indicator threshold (>90%). Sensitivity and specificity remained unchanged after scaling the concussion frequency by a factor of 5 to conservatively accommodate as many as 80% of concussive events going unreported/undiagnosed in our sample. The PV+ still remained very low (no greater than 1.94% for any threshold used), and PV− remained unchanged. Increasing the measurement threshold to retain only impacts exceeding $40g$ allowed for a small increase in indicator sensitivity to injury. Table 3 provides the sensitivity, specificity, PV+, and PV− for all plausible thresholds and concussion frequencies.

TABLE 2. Variables, definitions, and computational formulae.

Variable	Definition	Example
Sensitivity	Among true concussions, the proportion for which the head impact indicator shows a positive test (i.e., threshold exceeded)	100 concussions are diagnosed; 80 of these exceed an indicator's programmed threshold; sensitivity is 80/100 = 80%
Specificity	Among true nonconcussions, the proportion for which the head impact indicator shows a negative test (i.e., threshold not exceeded)	100 impacts are sustained that do not cause concussion; 97 of these do not exceed an indicator's programmed threshold; specificity is 97/100 = 97%
Positive predictive value (PV+)	Likelihood that a person who tests positive (i.e., exceeds indicator threshold) actually has a concussion	1000 impacts exceed an indicator's threshold. Only 8 are ultimately diagnosed as concussions. PV+ is 8/1000 = 0.8%
Negative predictive value (PV−)	Likelihood that a person who tests negative (i.e., fails to exceed indicator threshold) actually does not have a concussion	1000 impacts do not exceed an indicator's threshold; 995 are impacts that do not result in a diagnosed concussion (5 are injurious); PV− is 995/1000 = 99.5%

TABLE 3. Sensitivity, specificity, positive predictive value (PV+), and negative predictive value (PV−) across a range of plausible resultant linear head acceleration impact thresholds.

Indicator Threshold	Recorded Injuries (n = 24)				Estimated Injury Frequency (n = 120)[a]	
	Sensitivity (95% CI)	Specificity (95% CI)	PV+ (%)	PV− (%)	PV+ (%)	PV− (%)
Including all recorded impacts ≥10g (n = 283,348)						
50g	95.8% (79.8–99.3)	90.4% (90.3–90.5)	0.08	99.9	0.42	99.9
60g	75.0% (55.1–88.0)	97.0% (96.9–97.0)	0.21	99.9	1.00	99.9
70g	75.0% (55.1–88.0)	96.2% (96.1–96.3)	0.17	99.9	0.83	99.9
80g	70.8% (50.8–85.1)	97.6% (97.5–97.6)	0.25	99.9	1.24	99.9
90g	54.2% (35.1–72.1)	98.5% (98.4–98.5)	0.30	99.9	1.48	99.9
100g	45.8% (27.9–64.9)	99.0% (99.0–99.1)	0.39	99.9	1.94	99.9
110g	25.0% (12.0–44.9)	99.4% (99.3–99.4)	0.33	99.9	1.63	99.9
120g	16.7% (6.7–35.9)	99.6% (99.6–99.6)	0.33	99.9	1.65	99.9
Including all recorded impacts ≥40g (n = 43,981)						
50g	95.8% (79.8–99.3)	38.3% (37.8–38.8)	0.08	99.9	0.42	99.9
60g	91.7% (74.2–97.7)	61.2% (60.7–61.6)	0.13	99.9	0.64	99.9
70g	75.0% (55.1–88.0)	75.5% (75.1–75.9)	0.17	99.9	0.83	99.9
80g	70.8% (50.8–85.1)	84.4% (84.1–84.7)	0.25	99.9	1.24	99.9
90g	54.2% (35.1–72.1)	90.1% (89.8–90.3)	0.30	99.9	1.48	99.9
100g	45.8% (27.9–64.9)	93.6% (93.4–93.8)	0.39	99.9	1.94	99.8
110g	25.0% (12.0–44.9)	95.8% (95.6–96.0)	0.33	99.9	1.63	99.8
120g	16.7% (6.7–35.6)	97.3% (97.1–97.4)	0.33	99.9	1.65	99.8

[a]Diagnosed concussion frequency conservatively adjusted (i.e., increased) by a factor of 5 to account for 80% of injuries being unreported/undiagnosed. Since sensitivity and specificity are unaffected by an adjustment to incidence, they are not included in the presentation of test diagnostics using the estimated injury frequencies to the far right of the table.

Examining the data from the final season of this study (48 players wearing sensors), we identified the total number of impacts occurring during games or practices that exceeded various thresholds. When a 50g impact threshold was used, 739 impacts exceeding this threshold were recorded during games and 1353 were recorded during practices. At a 120g impact threshold, 26 impacts exceeding this threshold were recorded during games and 36 were recorded during practice. However, only one diagnosed concussion was recorded during the season (58.8g).

DISCUSSION

The most important finding of our study was that commercially available head impact indicators lack clinical utility, characterized by the extremely low positive predictive values. This finding holds true even when we conservatively accounted for as many as 80% of all concussions being unreported or undiagnosed. Although specificity remained high regardless of the threshold used, positive predictive values were less than 2% in every condition examined. High specificity should be complemented with high sensitivity for a product to meet some level of clinical utility. The variable sensitivity values we observed, in combination with the very low PV+, suggest that head impact indicators should not be used as diagnostic indicators of concussion. Thus, the ability of a head impact indicator—used in isolation—to detect a concussive injury is minimal, even if it is able to accurately measure and report biomechanical outcomes. Simply put, there is no population-average concussion threshold. Rather, there is substantial between-player variability in the observed biomechanical values associated with diagnosed concussion.

We acknowledge up front that all our data were collected using the HIT System, and not directly with the devices identified in Table 4. However, these head impact indicators have permeated the commercial marketplace and are becoming pervasive in athletic settings. Many of these devices lack validation and function mostly on the premise they will indicate to an end user (e.g., medical professional, coach, and parent) if a threshold event has been sustained. We used our data as a means to evaluate the "threshold theory" and, indirectly, question the clinical utility of head impact indicators functioning on that premise alone. We test a plausible range of impact thresholds and present these overall results to the reader. While the data are collected by the HIT System, our data are rooted in our clinical information and can be translated to any device that is threshold driven.

Several previous attempts have been made to explore the relationship of head impact biomechanical variables and concussive outcomes. Pellman et al. (26) conducted one of the first studies to attempt to define the concussion threshold. Using video footage of actual concussion-causing impacts recorded during professional football games, the authors were able to recreate the collisions in the laboratory. They suggested that a linear acceleration value of 70g to 75g was sufficient to cause concussion in professional football players. Another study using similar methods reported concussion-causing impacts ranged in linear acceleration from 61g to 144g and non–injury-causing impacts ranged from 32g to 102g (31). Head injury criterion (HIC) averaged 441 ± 224 in injury-causing impacts, whereas non–injury-causing impacts averaged 137 ± 124. The authors reported that a blow to the head of 82g or higher would result in a 50% probability of being the player who sustained the concussion among helmet-to-helmet impacts recreated to simulate those that resulted in a concussion. In terms of HIC, an impact registering 240 HIC would result in a 50% probability of being the player with the concussion.

As the volume of head impacts recorded *in vivo* has grown, the population-average injury threshold values have proven to be elusive. Guskiewicz et al. (12) reported on 13 concussions (of the 24 reported in this paper) sustained by

TABLE 4. Summary of current commercially available head impact indicators.

Manufacturer	Product Name	Cost/Unit[a]	Attachment	Indicator Type	Indicator/Monitoring[b]	Threshold
X2 Biosystems, Inc.	xPatch	$150	Adhesive patch over mastoid process	Wireless device	Monitoring	Programmable threshold
Reebok	CHECKLIGHT	$99	Skullcap	Light	Indicator	Unspecified
Riddell	InSite	$150	Select Riddell helmets	Wireless device	Indicator	3 factors: 1) position 2) skill level, and 3) single impact in top 1% (HITsp) or multiple impacts in the 5-d period in top 5%
Riddell	HIT System	$1870	Football helmet (limited to Riddell brand helmets)	Pager	Monitoring	Programmable threshold
gForce Tracker, Inc.	gForce Tracker™	$150	Helmet	Alarm and light	Monitoring	Programmable threshold
Triax Technologies LLC	Sim-G and Sim-P	$189	Headband or skullcap	Wireless device	Monitoring	Programmable threshold
i1 Biometrics	Vector Mouthguard	$199	Mouthguard	Wireless device	Monitoring	Programmable threshold
i1 Biometrics	Shockbox Helmet Sensors	$179	Helmet	Wireless device	Unclear	Unspecified
Common Sensor, LLC[c]	Common Sensors GC 1.0	$79	Helmet	Light	No[c]	80g
Jolt Athletics, Inc.	Jolt Sensor	$99	Clip to any type of headgear	Vibration, wireless device	Unclear	Unspecified
Head Case	Head Case Impact Sensor	$99	Helmet	Not real time; e-mail alert sent after data are uploaded to the cloud manually	Monitoring	Programmable threshold
BlackBox Biometrics, Inc.	Linx IAS	N/A[d]	Headband or skullcap	Light, wireless device	Unclear	Unspecified
Force Impact Technologies	FITGuard	$99	Mouthguard	Light, wireless device	Monitoring	Programmable threshold
Archetype	PlayerMD	$180	Headband or skullcap	Wireless device	Monitoring	Programmable threshold

The information contained herein are derived from publicly available sources or obtained through inquiry with the device manufacturer.

[a] The prices indicated do not cover the cost of any base station, software, other user costs, subscription fees, or any volume order discounts established by the manufacturer.

[b] A monitoring device records information about each impact, and these details can be downloaded and viewed by the user. An indicator does not record information about each impact. Some indicators may alert the user to the impact frequency in a period but do not allow the user to download information related to each impact.

[c] All products listed are considered reusable. The Common Sensor device is good for 1 yr. A subscription service is offered.

[d] BlackBox Biometrics' Linx IAS is not commercially available and is scheduled to release in 2016.

collegiate football players. They found the range at which the concussions occurred was between 61g and 169g of linear acceleration. In a study investigating 13 high school concussions, the authors reported that linear acceleration ranged from 74g to 146g (5). Individually, linear acceleration, rotational acceleration, and impact location are poor predictors for concussion. Combining these metrics into a predictive model (linear acceleration >96.1g, rotational acceleration >5582.3 rad·s^{-2}, and impact location) was associated with a 13.4% chance of injury for impacts exceeding these criteria.

Because of the high number of unreported concussion symptoms in high school football players (16,19), researchers have speculated that neurocognitive and balance deficits may exist in athletes who sustain high magnitude impacts during play and who are believed to have suffered an undiagnosed concussion. McCaffrey et al. (15) sought to investigate this possibility by testing athletes who suffered an impact of more than 90g in a single session of activity on both neurocognitive and balance measures in the absence of reported symptoms. The authors reported that high magnitude impacts did not result in measurable neurocognitive or balance deficits and even saw improvements in some neurocognitive domains as compared with baseline scores.

Although no single universal (i.e., "population-average") impact concussion threshold has been identified, several investigators have explored the possibility that concussions may more likely result from an accumulation of subconcussive blows (9). After examining the impact history of 19 high school athletes who sustained concussion, no significant difference was observed between those who were injured and control subjects who were matched to them (9). More recently, Beckwith et al. (4) compiled the largest known data set of biomechanically recorded concussions. After analyzing the impact history in 105 cases of diagnosed concussion, the authors reported that players sustain more frequent and higher magnitude impacts on days of diagnosed concussion than they do on days without injury. Although outside the scope of this investigation, more research is needed to attempt to identify any injury threshold that may be present when multiple biomechanical variables are studied along with the impact history of a given athlete.

Several problems may arise from use of head impact indicators. Because of the high number of false positives (in data we collected with the HIT System, >99% of all positive alerts, regardless of the threshold), it is possible that these indicators may lead to complacency regarding concussions. Athletes who choose to use these indicators are likely doing so out of a concern regarding concussion. If the impact indicator alerts the athlete on multiple occasions that he or she has sustained a high magnitude impact but the athlete feels no concussion symptoms, that athlete may become desensitized to the indicator over time. Perhaps a critical aspect worthy of discussion is that scientists have published validation data for only some of the devices listed in Table 4, particularly the HIT System (1,14,30), the X2 mouth guard technology used

in the xPatch (30), and the gForceTracker (2,6), and that these studies address whether the device is valid from a measurement standpoint. No studies have explored any of the devices in Table 4 with respect to clinical validity.

Another potential downside to using head impact indicators to initiate injury evaluations may be the high frequency of unnecessary evaluations that would ensue. Examining impacts among 48 players in one season, we observed that as many as 2092 evaluations would be needed, depending on the threshold employed. Only one diagnosed concussion occurred during this time frame in this 48-player sample. As most clinicians are responsible for a large numbers of athletes, adding evaluations for uninjured individuals may reduce the time required to provide adequate care for the remaining athletes they are supervising. Time spent evaluating athletes for concussion will take away from time spent scanning the field for all injuries (including concussion) and talking to players on the sideline who appear to be injured during a play. Considering a thorough concussion evaluation consists of at least a symptom checklist, balance assessment, and brief neurocognitive examination along with a clinical examination of motor and sensory deficits and cranial nerve function, the team athletic trainer will devote a considerable amount of time evaluating injuries that are not present.

Head impact indicators capable of measuring head impact biomechanics and providing meaningful data export capabilities have had a positive influence on player safety and reducing injury risk. They have been used to influence rule changes surrounding kickoff locations in professional and college football (25), have identified the effects of head impact forces sustained during mechanisms that contravene playing rules (22), and have provided some insights into the potential injury prevention role anticipatory training may have on mitigating head injury risk (21,24). In addition, they may be useful for tracking repetitive head impacts and helping to identify practice and game situations predisposing athletes to higher head impact frequency.

We acknowledge several limitations to our research. First, we did not investigate the validity or reliability of head impact indicators. Further investigation is warranted to ensure these devices actually work as they are advertised. Second, not all indicator thresholds are published, and many are customizable. For this reason, we chose to include multiple potential thresholds in our analysis whether or not they were known to us. We used the HIT System to collect head impact biomechanics and discussed the clinical utility of head impact indicators derived from the indicator thresholds they use, rather than actually using the alerts from the devices.

Also, our sample size of concussive impacts was fairly small. It is possible we may have missed some concussions (or they were not reported to our clinical providers), and thus these impacts were labeled as "noninjury" instead of "injury." However, of the 185 observed players, 21 (11%) sustained injuries (three athletes suffered two concussions), which is similar to previously reported concussion risks (7,13). With only 24 recorded impacts that led to concussion out of almost 285,000 total impacts, any threshold or test is likely to have low PV+. The PV+ is largely dependent on the injury prevalence in the population; the lower the prevalence, the lower the PV+ (29). Therefore, any threshold used in this setting will yield many false positives.

Future research should continue to investigate head impact biomechanics and explore any relationship that multiple biomechanical variables and cumulative load of impacts may have to head injury. Although a universal or population-average threshold for injury has proven elusive (11), databases with large numbers of injuries and richly characterized genomic, neurological, and biological covariates may possibly determine subject-specific ("individual") thresholds. These technologies present a unique opportunity to identify athletes who participate in at-risk behaviors.

In conclusion, it is clear that injury thresholds used by existing head impact indicators do a poor job of predicting concussion when used in isolation. This has important consequences. First, using these thresholds in isolation may lead to a large number of unnecessary evaluations by medical professionals, stretching already thin resources and diverting these resources away from more important uses. Second, if coaches, parents, and medical professionals remove athletes from play unnecessarily, this may lead to complacency over time, such that impacts (both below and above the threshold) accompanied by important signs and symptoms of injury may be disregarded. The failure to remove and manage true concussions can be very dangerous. Until injury thresholds from head impact data can be better researched and refined, it is irresponsible to use injury thresholds for diagnosis and management of concussion.

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