

The association between Guardian Cap use during practices and sport-related concussion risk in high school American football players

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ABSTRACT

Objective Guardian Caps (GCs) have been widely implemented at all levels of American football participation based on laboratory evidence that they may reduce head impact forces. The purpose of this study was to determine if GC use during practice was associated with a lower risk of sport-related concussion (SRC) during practices and games among high school football players.

Methods Data were collected on 2610 athletes from 41 Wisconsin schools that self-selected into GC or Non-GC cohorts. Athletic trainers recorded practice and game exposures and SRCs through the 2023 season. Generalised linear mixed models were built to determine the effect of GC utilisation on SRC rates, accounting for school and player exposures.

Results In the total cohort (Non-GC n=1188 (45.5%); GC n=1422 (54.5%)), 180 athletes (6.9%) sustained SRCs. 64 SRCs occurred during practice (GC n=33 (51.6%); Non-GC n=31 (48.4%)). GC use was not associated with a decreased risk of SRC during practice in the univariable analysis (relative risk (RR)=1.04, 95% CI 0.58 to 1.86, p=0.90) or after accounting for previous SRC within the last year (RR 1.01, 95% CI 0.57 to 1.79, p=0.97). No players of either cohort wore GCs during games. There were 116 SRCs sustained during games (GC n=68 (58.6%); Non-GC n=48 (41.4%)). GC use during practice was not associated with the risk of SRC during games in the univariable analysis (RR 1.13, 95% CI 0.72 to 1.78, p=0.60) or after accounting for previous SRC within the last year (RR 1.13, 95% CI 0.71 to 1.78, p=0.61).

Conclusion GC use during practice in high school American football players was not associated with a decreased risk of sustaining SRC in practice or games.

BACKGROUND

American football (henceforth referred to as 'football') is one of the most popular high school sports in the USA with over 1 million participants.¹ Unfortunately, football players experience a high rate of sport-related concussion (SRC) and head impacts compared with other high school athletes.^{2,3} SRCs are a major concern due to short-term and long-term symptoms, disablement and cost of the injury.⁴⁻⁸ Preventing SRC injuries remains a priority for athletes, parents, medical providers and sport governing organisations. Additionally, the Concussion in Sport Group shares this objective and has identified primary prevention as a focus area for SRC research.^{9,10}

WHAT IS ALREADY KNOWN ON THIS TOPIC?

⇒ Helmet add-on devices like the Guardian Cap have been shown to reduce impact forces in laboratory settings.

WHAT ARE THE FINDINGS?

⇒ Guardian Cap use in high school American footballers during practice was not associated with a decreased risk of sustaining a sport-related concussion during practice or games.

HOW MIGHT IT IMPACT CLINICAL PRACTICE IN THE FUTURE?

⇒ The effectiveness of Guardian Caps and similar helmet covers should be established in real-world environments to more accurately inform use.

To that end, progress has been made in reducing the risk of SRCs in high school football. When policies aimed at limiting contact in football practices were implemented, practice-related SRC rates were reduced by 64%.¹⁰ Coach participation in a comprehensive football safety standards training programme also reduced the rate of SRCs in practices and games by 50%.¹¹ Modifications of helmets to increase padding over the zygoma/mandible were associated with a 31% lower rate of SRC (figure 1).¹² Interest in further improving the effectiveness of football helmets has continued.



Figure 1 Football helmet with increased padding around the zygoma/mandible indicated by arrow.



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Figure 2 Football Guardian Caps NTX installed on a football helmet.

Aftermarket add-on shell devices for football helmets, such as the Guardian Cap (GC), have been developed to reduce head impact forces (figure 2). The use of these devices was mandated during the preseason in certain position groups by the NFL in 2022 on the premise of reducing the cumulative impact forces to the head.¹³ Subsequently, the NFL attributed a significant reduction in concussion rates during the preseason to GCs.¹⁴ Laboratory studies investigating the efficacy of GCs to reduce impact forces have had mixed results, and no studies have investigated the real-world effectiveness of GCs to prevent SRC in high school football players.^{15–17} The objective of this study was to determine if GC use during practice was associated with a lower risk of SRC during practices or games among high school football players.

METHODS

Study design, setting and participants

A convenience sample of 2610 football players from 41 high schools in Wisconsin participated in this prospective cohort study during the 2023 football season. One additional high school was recruited but ultimately excluded from the data analysis because team GC use changed midway through the season (figure 3). Study team members travelled to participating schools to present the study to the players and their parents at preseason team meetings. To be eligible to take part in the study, players had to be (1) a member of an interscholastic football team, (2) enrolled in grades 9 to 12 (ages 14 to 18 years) and (3) able to fully participate in preseason practice on the day of study recruitment. Prior to the start of the season, players reported their demographic data (sex, age, grade in school, height, weight), history of SRC, and previous football playing experience. Players also completed a head injury Symptom and Severity score from the Sports Concussion Assessment Tool V.5 (SCAT5).¹⁸

Data collection

Licensed athletic trainers (ATs) employed at each school reported the football helmet model, GC use, football exposures and injuries for all players from the first practice through to the last game. An exposure was defined as one player participating in one practice or game. Athletes were classified as ‘GC’ if they wore a helmet and GC during practice and ‘Non-GC’ if they only wore a helmet. GC versus Non-GC designation was captured per each exposure. Injury data were collected by the ATs and included injury characteristics (mechanism, football activity and playing surface), SCAT5 Symptom and Severity score, and confirmation of whether a GC was in use at the time of injury.

Sport-related concussion

A player was determined to have sustained an SRC using the definition provided by Amsterdam International Consensus Statement on Concussion in Sport.⁹ The school ATs administered the SCAT5 within 72 hours of the onset of the injury to any player suspected of having an SRC. This included the Symptom Evaluation which measures the severity of 22 SRC symptoms on a 6-point scale. When appropriate, injured players were referred

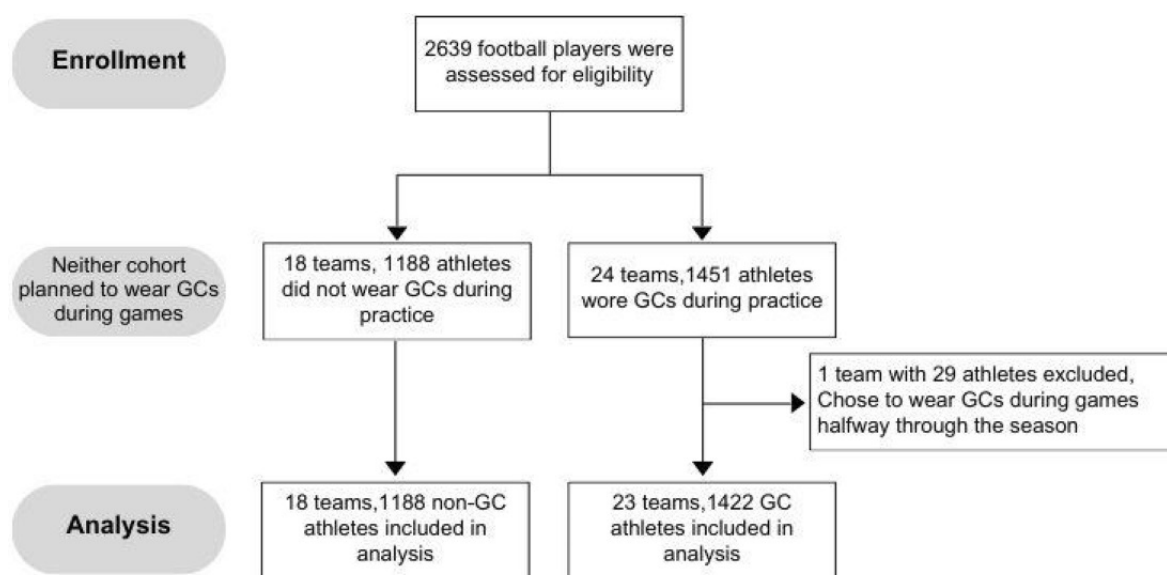


Figure 3 Flow diagram of participants in the study.

to their primary care provider for further evaluation and treatment. Only the first SRC for each player was included in the analysis.

Players recovering from an SRC were permitted to gradually return to full unrestricted sport participation in accordance with consensus-based guidelines.⁹ ATs monitored all participants who sustained an SRC from the date of the onset of the injury, and recorded all missed practices and games and documented days from the time of injury to full recovery.

Statistical analysis

A power analysis was completed to determine the minimum number of players needed to test for 40% change in the proportion of athletes who sustained an SRC this season. This was based on previous work using similar methods in the same population where 5.8% of athletes sustained an SRC over the course of one season.⁶ It was determined that to achieve 80% power a minimum of 2630 players would be needed to find a small to medium effect size significant (Cohen's $d=0.31$). Statistical analyses were conducted using SAS V.9.4. Data were summarised via mean (SD) or frequency (%) for the GC and Non-GC cohorts. Player and SRC exposure characteristics were compared between groups of interest (SRC vs Non-SRC and GC vs Non-GC) using χ^2 tests of association and unpaired t-tests. Univariable and multivariable (controlling for previous SRC within the last year) generalised linear mixed effects models using a Poisson regression were built to model SRC rates, with school as a random effect to account for school-level traits. Player exposures were included as an offset to account for differences in number of exposures between athletes. Relative risks (RR) and 95% confidence intervals (CI) are reported.

Patient and public involvement statement

No patients were involved in the design or interpretation of this study. Letters of support were elicited from the Wisconsin Intercollegiate Athletic Association who expressed interest in the objectives of the study. All participation was voluntary. Players were not asked to assess the burden of their participation. Study results will be shared with stakeholders after peer review and publication.

Equity, diversity, and inclusion statement

We intentionally recruited athletes from urban, suburban and rural schools around the state of Wisconsin. The investigator team consists of three women and four men from different disciplines (medicine, biostatistics, athletic training, physical therapy and biomechanics). It included two junior researchers (ET and AC). There were very few female athletes included in the study, an issue we have expanded on in the discussion.

RESULTS

There were 2610 high school football players (mean age 15.9, 99.1% male) included in the study, of which 1422 (54.5%) wore GCs (table 1). No differences in baseline player characteristics were identified (p values ≥ 0.06). Players participated in 131048 practice exposures and 25538 game exposures. 23 teams required all of their players ($n=22$) to wear GCs during practices. One school required 14 offensive or defensive lineman to wear GCs while the other 61 athletes did not. Another school required athletes whose helmets were compatible with GCs ($n=72$) to wear them while 13 wide receivers, punters and kickers did not because their helmets were not compatible. All athletes who wore GCs used the Football Guardian Caps XT

Table 1 High school football player characteristics

	Non-GC (n=1188, 45.5%)	GC (n=1422, 54.5%)	P value*
Age (years)	15.9 (1.2)	15.9 (1.2)	0.10
Sex			
Male	1174 (98.8%)	1413 (99.4%)	0.33
Female	14 (1.2%)	9 (0.6%)	
Weight (kg)	87.7 (18.7)	88.3 (18.6)	0.32
Height (cm)	178.3 (8.1)	178.8 (7.9)	0.06
Grade			
9	378 (31.8%)	417 (29.3%)	0.15
10	314 (26.4%)	349 (24.5%)	
11	268 (22.6%)	364 (25.6%)	
12	228 (19.2%)	292 (20.5%)	
Previous SRC within the last year			
No	1140 (96.0%)	1342 (94.4%)	0.06
Yes	48 (4.0%)	80 (5.6%)	
Any history of SRC			
No	1093 (92.0%)	1290 (90.7%)	0.25
Yes	95 (8.0%)	132 (9.3%)	
Total years of tackling experience	4.05 (2.6)	4.06 (2.4)	0.90
Helmet brand			
NR	16 (1.3%)	7 (0.5)	<0.0001
Riddell	951 (80.0%)	1054 (74.1%)	
Schutt	182 (15.3%)	195 (13.7%)	
Vicis	2 (0.2%)	20 (1.4%)	
Xenith	37 (3.1%)	146 (10.3%)	

Data are reported as mean (SD) or N (%).

*Comparison between Non-GC and GC, t-test or χ^2 test.

GC, wore Guardian Gaps; Non-GC, did not wear Guardian Caps; NR, not reported; SRC, sport-related concussion.

model, which is available to high school athletes. Our study included 18 teams with players who did not wear GCs at any time.

Sport-related concussion

A total of 180 athletes (6.9%) sustained SRCs during the 2023 football season. 64 (36%) SRCs occurred during practices and 116 (64%) SRCs occurred during games.

SRCs sustained in practice

There were 64 SRCs sustained during practice between the GC and Non-GC cohorts (table 2). A greater proportion of female football players ($n=3$, 18.75%) sustained an SRC during practice compared with males ($n=61$, 2.4%, $p=0.001$). Other than sex, there were no significant differences in demographic characteristics, history of SRC, helmet brand or total years of tackling experience between athletes who sustained an SRC and those who did not. Of the 64 SRCs sustained during practice, 33 (51.6%) occurred in GC athletes and 31 (48.4%) in Non-GC athletes (table 3). The rate of SRC was 0.49 and 0.54 SRCs/1000 practice exposures in the GC and Non-GC cohorts, respectively. All SRCs were sustained as a result of contact during practice and there was no difference in history of SRC or grass/turf surface between the GC and Non-GC groups. GC use was not associated with decreased risk of SRC during practice in the univariable analysis ($RR=1.04$ (95% CI 0.58 to 1.86), $p=0.90$) or after accounting for previous SRC within the last year ($RR=1.01$ (95% CI 0.57 to 1.79), $p=0.97$). There was no difference in initial SRC symptom

Table 2 Demographic characteristics of high school football players who did and did not sustain an SRC during practice

	No SRC (n=2546)	SRC (n=64)*	P value†
Previous SRC within the last year			
No	2423 (95.2%)	59 (92.2%)	0.2
Yes	123 (4.8%)	5 (7.8%)	
Helmet brand			
NR	23 (0.9%)	0 (0.0%)	0.80
Riddell	1956 (76.8%)	49 (76.6%)	
Schutt	368 (14.5%)	9 (14.1%)	
Vicis	22 (0.9%)	0 (0.0%)	
Xenith	177 (7.0%)	6 (9.4%)	
Age (years)	15.9 (1.2)	15.7 (1.1)	0.12
Sex			
Male	2526 (99.2%)	61 (95.3%)	0.001
Female	20 (0.8%)	3 (4.7%)	
Height (kg)	178.6 (8.1)	178.6 (8.1)	0.97
Weight (cm)	88.0 (18.6)	88.1 (17.7)	0.89
Grade	10 (9, 11)	10 (9, 11)	0.33
Total years of tackling experience	4.1 (2.5)	3.5 (2.5)	0.07

Data are reported as mean (SD), median (IQR) or N (%).

*One GC player sustained 2 SRCs.

†Comparison between Non-GC and GC, t-test, Fisher's exact test or χ^2 test.

NR, not reported; SRC, sport-related concussion.

evaluation severity scores between the GC and Non-GC athletes who sustained SRCs in practices (table 3). Similarly, there was no difference in time to return to sport between the GC and Non-GC cohorts.

SRCs sustained in games

There were 116 SRCs sustained during games across both the GC and Non-GC cohorts, neither of whom wore GCs during games (table 4). There was no difference in demographic characteristics, history of SRC, helmet brand or total years of tackling experience between athletes who sustained an SRC and those who did not. Of the 116 SRCs sustained during games, 68 (58.6%) occurred in GC athletes and 48 (41.4%) in Non-GC athletes (table 5). The rate of SRC was 4.80 and 4.22 SRCs/1000 game exposures in the GC and Non-GC cohorts, respectively. Most SRCs during games were sustained due to contact with another

Table 3 Exposure and SRC characteristics of high school football players who did and did not wear Guardian Caps during practice

	Non-GC (n=31)	GC (n=33)*	P value†
Surface			
Grass	23 (74.2%)	23 (69.7%)	0.69
Turf	8 (25.8%)	10 (30.3%)	
Previous SRC within last year			
No	29 (93.5%)	30 (90.9%)	1.00
Yes	2 (6.5%)	3 (9.1%)	
Initial SCAT5 symptom score	30.3±18.7	33.5±21.7	0.54
Days to RTS	16.4±7.1	14.5±8.1	0.31

Data are reported as N (%).

*One GC player sustained 2 SRCs.

†Comparison between Non-GC and GC, t-test, Fisher's exact test or χ^2 test.

GC, wore Guardian Caps; Non-GC, did not wear Guardian Caps; RTS, return to sport; SCAT5, Sport Concussion Assessment Tool 5; SRC, sport-related concussion.

Table 4 Demographic characteristics of high school football players who did and did not sustain an SRC during games

	No SRC (n=2494)	SRC (n=116)*	P value†
Previous SRC within the last year			
No	2371 (95.1)	111 (95.7)	0.76
Yes	123 (4.9)	5 (4.3)	
Helmet brand			
NR	23 (0.9%)	0 (0.0%)	0.88
Riddell	1915 (76.8%)	90 (77.6%)	
Schutt	361 (14.5%)	16 (13.8%)	
Vicis	21 (0.8%)	1 (0.9%)	
Xenith	174 (7.0%)	9 (7.8%)	
Age (years)	15.9 (1.2)	15.9 (1.1)	0.73
Sex			
Male	2471 (99.1%)	116 (100.0%)	1.00
Female	23 (0.9%)	0 (0.0%)	
Height (kg)	178.6 (7.9)	178.3 (8.9)	0.71
Weight (cm)	88.0 (18.6)	88.9 (20.0)	0.58
Grade	10 (9, 11)	10 (9, 11)	0.80
Total years of tackling experience	4.0 (2.4)	4.3 (2.5)	0.20

Data are reported as mean (standard deviation), median (IQR) or N (%).

*One Non-GC player sustained 2 SRCs.

†Comparison between Non-GC and GC, t-test, Fisher's exact test or χ^2 test.

NR, not reported; SRC, sport-related concussion.

athlete. One SRC was due to contact with the ground and one SRC occurred via an unknown mechanism. The proportion of SRCs sustained on turf versus grass during games was greater in the GC cohort than in the Non-GC cohort ($p=0.02$). GC use during practice was not associated with risk of SRC during games in the univariable analysis ($RR=1.13$ (95% CI 0.72 to 1.78), $p=0.60$) or after accounting for previous SRC within the last year ($RR=1.13$ (95% CI 0.71 to 1.78), $p=0.60$). There was no difference in initial SRC symptom evaluation severity scores between the GC and Non-GC athletes who sustained SRCs in games (table 5). Similarly, there was no difference in time to return to sport between the GC and Non-GC cohorts.

Table 5 Exposure and SRC characteristics of high school football players who did and did not wear Guardian Caps during games

	Non-GC (n=48)	GC (n=68)*	P value†
Contact mechanism			
No	1 (2.1%)	1 (1.5%)	1.00
Yes	47 (97.9%)	67 (98.5%)	
Surface			
Grass	21 (43.7%)	16 (23.5%)	0.02
Turf	27 (56.3%)	52 (76.5%)	
Previous SRC within last year			
No	47 (97.9%)	64 (94.1%)	0.40
Yes	1 (2.1%)	4 (5.9%)	
Initial SCAT5 symptom score	26.7±17.4	30.5±16.3	0.23
Days to RTS	14.5±9.5	13.8±8.6	0.70

Data are reported as N (%).

*One Non-GC player sustained 2 SRCs.

†Comparison between Non-GC and GC, t-test, Fisher's exact test or χ^2 test.

GC, wore Guardian Caps; Non-GC, did not wear Guardian Caps; RTS, return to sport; SCAT5, Sport Concussion Assessment Tool 5; SRC, sport-related concussion.

DISCUSSION

In this large sample of high school football players, GC use during practice was not associated with lower risk of SRC during practice or games. We considered whether there were characteristics of the athletes, schools or environments that could confound our findings by contributing to SRC risk, but none of our analyses revealed any significant associations. Our analysis accounted for school as a random effect given that there are likely differences in practice styles between schools that might contribute to SRC risk. Player exposures were also accounted for in our models. The multivariable analysis included prior SRC in the past year, as previous studies have consistently demonstrated that a history of SRC is associated with increased risk for future SRC.¹⁹ Despite this, neither the univariable nor multivariable analysis detected an association between GC use and SRC.

There is some laboratory evidence that GCs may augment energy attenuation characteristics of American football helmets by absorbing forces to the head with a variety of simulated head impact mechanisms, though these results are mixed.^{15–17} One study found that GCs reduced rotational and translational measures of head motion in laboratory simulated helmet-to-helmet impacts by 9%, which correlates to a large effect size.¹⁷ Another failed to demonstrate that GCs could reduce peak acceleration forces.¹⁶ Furthermore, reduced rotational and translational forces may not correlate with a reduced incidence of SRC. In any case, previous work has shown symptomatic SRCs are not clearly associated with biomechanical accelerometer measurements.¹⁹ While laboratory-based studies have found GCs can reduce impact forces, GCs have not been shown to reduce impact forces sustained by players in practices as measured by instrumented mouthguards,¹⁵ and no studies have demonstrated an association between GC use and a lower risk of SRC.

The NFL has drawn attention to the use of GC to prevent cumulative head impact forces by their progressive adoption of GC first in the preseason and now by some athletes during games. Indeed, the report that GCs reduced preseason SRC incidence in the NFL by 50%¹⁴ garnered immense interest among stakeholders in football at all levels though it was not accompanied by a peer-reviewed publication. Of note, the GC used in the NFL is a different model than that used at the high school level so the results of our study cannot be generalised to the NFL or collegiate football. The Football Guardian Caps XT (high school model) weighs approximately 220 grams and the foam is approximately 1.5 cm thick. In comparison, the Football Guardian Caps NTX model (NFL and collegiate) weighs approximately 357 grams and is approximately 2.5 cm thick.

Sex differences

A greater proportion of girls sustained an SRC compared with boys in practice. However, we would caution against overinterpretation of this finding as only 0.8% of the athletes included in the study were girls. Interestingly, no girls sustained an SRC in games, though this may be because their playing time was less than their male teammates.

Playing surface

We collected data on characteristics of the setting in which SRCs were sustained such as mechanism of injury and playing surface. Nearly all SRCs in practices and games resulted from contact with another athlete. There were no differences in the proportion of SRCs that occurred on grass or turf during practice, but significantly more SRCs occurred on turf than on grass during games where GCs were not used by a large majority of athletes.

This finding does not signify that athletes are more likely to sustain SRCs on turf compared with grass; instead, we suspect that games are more likely to be played on turf than on grass.

Clinical implications and potential harms

Given the toll of SRCs in American football, there is enormous pressure to prevent them. But athletic departments and other stakeholders should be cautious of promoting devices with uncertain on-field effectiveness. Furnishing a football team with equipment with unproven benefits may provide false reassurance to parents that their children are protected from SRCs. Similarly, athletes may play more aggressively because they feel protected by wearing a GC.²⁰ It also might divert resources away from evidence-based measures that can reduce SRC incidence and improve health outcomes such as employing ATs²¹ or considering rule changes.²² Although it is tempting to bypass rigorous real-world testing and expedite distribution of safety equipment, it is imperative that decisions are informed by evidence.

Limitations

We acknowledge several limitations for this study. First, we used a prospective cohort design for this study instead of a randomised controlled trial (RCT). Each school that participated in the study decided to use or not use GCs independent of their participation in the study. As a result, it is possible that factors beyond the scope of this study could have affected the analyses and results. Our decision to use a prospective cohort design rather than an RCT was in part due to a statement from the National Operating Committee on Safety in Athletic Equipment (NOCSAE) that “Add-on accessories can change a helmet and interfere with performance in ways unintended by the manufacturer. The helmet’s original padding, fit and components were tested for compliance with the NOCSAE standards, and altering these components may result in a helmet that does not perform as designed, and could increase the risk of injury”.²³ Conversely, Guardian Sports disputes the concerns laid out by NOCSAE, specifically that helmet manufacturers cannot decertify a helmet after the helmet is sold, use of a GC does not void the helmet’s warranty, and use of a GC is not illegal.²⁴ Given this ambiguity, we did not feel it was ethical to assign athletes to use GCs if it could affect their helmet NOCSAE certification. However, despite recruiting a convenience sample of schools and players, the baseline characteristics of the GC and Non-GC cohorts were well balanced, and we accounted for school-level confounding factors by including school as an offset in the analysis. Additionally, there might have been other unidentified factors that could have interacted with GC status, thus confounding SRC risk due to the lack of randomisation. Comparing the risk of SRC in practice and games between the GC and Non-GC cohorts suggests that this was not the case. Neither cohort wore GCs during games and there were no differences in SRC rates/1000 game exposures or risk of SRC during games between the cohorts, indicating that baseline SRC risks were similar between the cohorts. Finally, exposures were binary, and ATs did not collect more detailed data on playing time which could have affected the results.

SRC research is always limited by imperfect diagnostic accuracy given the lack of reliable objective tests, in part due to reliance on athletes to self-report symptoms. However, all schools in our study, regardless of GC status, employed ATs which likely boosted the proportion of SRCs that were

identified and included in the analysis.²¹ Additionally, the SRC rates/1000 exposures reported in our study are comparable to those in prior epidemiological studies,^{2 25} which suggests that our findings are valid. However, our results may not be generalisable to schools who do not have ATs on staff to assess SRC status and monitor injured athletes' recovery from their injury.

We recruited an almost identical number of subjects prescribed by an a priori power calculation to provide a buffer to protect against an underpowered analysis. If GCs provided a substantial risk reduction to prevent SRC, a large study like ours should have detected a difference between the cohorts.

CONCLUSIONS

Preventing SRC in American football remains an elusive goal. Given the importance of athlete safety, a prioritisation of risk reduction, and the cost associated with add-on shell devices, effectiveness of GCs and similar helmet covers should be established in real-world environments prior to widespread advocacy and adoption. Investing in devices with unproven on-field effectiveness should not divert resources away from measures that can reduce SRC incidence and improve health outcomes. High school athletic departments and sport organisations should continue to prioritise evidence-based strategies such as employing ATs²¹ or considering rule changes²² while further real-world research is conducted on protective equipment.

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Contributors EH, TM, MAB, SM and MRJ participated in the design and conception of the study. EH obtained funding. TM, MRJ and ET were responsible for data collection. SM performed the data analysis and table designs. EH, SM and TM drafted the manuscript and all authors revised it critically and gave their approval of the final version. EH is the study guarantor.

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Competing interests Dr. Hammer is principal investigator and team physician for the University of Wisconsin football team. Dr. Brooks is the District VI representative on the AAP National Nominating Committee and a member of the AAP Council on Sports Medicine & Fitness and former Chair of its Executive Committee. No other disclosures were reported.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Not applicable.

Ethics approval This study involves human participants and was approved University of Wisconsin-Madison, ID 2023-0109. Participants gave informed consent to participate in the study before taking part.

Provenance and peer review Not commissioned; externally peer reviewed.

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