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Tackling sport-related concussion: effectiveness of lowering the maximum legal height of the tackle in amateur male rugby – a cross-sectional analytical study

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ABSTRACT

Objective Rugby union ('rugby') is popular globally, with most of its participants being amateur. Concern regarding sport-related concussion (SRC) sustained during rugby is increasing. SRC occurs most frequently in the tackle, yet few interventions have aimed to mitigate this risk factor. This study investigated the influence of a lowered legal tackle height on SRC incidence in amateur rugby.

Design Cross-sectional analytical study: 2018 (control—standard tackle height) and 2019 (intervention—lowered legal tackle height) seasons.

Setting South African collegiate student rugby competition.

Participants Between 800 and 900 male amateur student players (age: 20±1.6 years) in each year.

Intervention Maximum legal tackle height lowered from line of the shoulder on the ball carrier to the line of the armpit.

Outcome measures Number of overall (medical attention) and time-loss (≥1 day lost) injuries, head injuries and SRCs in 2018 and 2019 (dependent variables); events associated with injury incidents (independent variables).

Results There was no statistically significant difference in incidences of time-loss injuries (IRR: 0.79; 95% CI: 0.6 to 1.1; p=0.13), head injuries (IRR: 0.83; 95% CI: 0.5 to 1.3; p=0.42) and SRC (IRR: 0.69; 95% CI: 0.4 to 1.2; p=0.20). In 2018 and 2019, most time-loss head injuries (57%, n=43) and SRCs (55%, n=26) occurred during the tackle.

Conclusions Despite a trend towards reducing injuries, head injuries and SRC, lowering maximum legal tackle height to armpit level did not change SRC incidence in this amateur male rugby cohort. Most time-loss head injuries and SRCs occurred during the tackle. Further tackle-related interventions to reduce SRC incidence require investigation.

INTRODUCTION

Background

Rugby union (rugby) is a popular team-based sport played by 9.1 million registered players in 121 countries around the world.[1] In South Africa, rugby is played by over 600 000 players.[1] Data derived primarily from the UK, New Zealand, South Africa and other countries (Japan, Hong Kong) indicate that injury incidence in rugby is high (47 and 81–91 injuries per 1000 player hours in amateur and professional rugby, respectively) but comparable to other collision sports.[2–5] The tackle is responsible for the majority of injuries sustained during rugby[4 6–8] and mostly involve the head and neck, lower limb, shoulder/upper limb and mid-torso.

Sport-related concussion (SRC) in rugby: current research focus

SRC is defined as a traumatic sporting-related brain injury induced by biomechanical forces caused either by a direct blow to the head, face, neck or elsewhere on the body, with an impulsive force transmitted to the head.[9] Symptomatology develops predictably but can vary in number, type, severity and time course and is not due to any other cause.[9] SRC has long been regarded as a purely functional disorder; yet, recent studies report structural brain changes following SRC.[10–12] Furthermore, a growing body of evidence points to a possible association between concussion and repetitive subconcussive head impacts, and structural and other long-term neurological consequences.[10–18]

The tackle is the phase of play that most frequently causes head injuries[19] and has the highest head injury assessment (HIA) propensity.[20] During the tackle, the defender attempts to impede the attacker's (the ball carrier) progression towards the try (goal) line and regain possession of the ball. World Rugby's Laws of the Game define the tackle as 'the method of holding a ball carrier and bringing that player to ground'. Law 9.13 states that 'a player must not tackle an opponent early, late or dangerously' and that 'dangerous tackling includes, but is not limited to, tackling or attempting to tackle an opponent above the line of the shoulders even if the tackle starts below the line of the shoulders'.

In addition, the tackler's body position during the tackle has been shown to influence HIA propensity.[19] Head injuries sustained during the tackle were found to be 4.5 times more likely when the tackle height is above the armpit (the tackler makes contact with the ball carrier above the line of the armpit), 40% more likely for an upright tackler and 72% more frequent in the tackler than in the

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tackled player.[21] Other risk factors with a high propensity to cause SRC are an accelerating tackler, high tackler speed, head contact type and tackle type.[22] Therefore, the tackle has been targeted for intervention to reduce concussion incidence.

A recent study by Stokes *et al*[23] reported on a legal tackle height law variation trial conducted in English professional rugby and found that a lowered legal tackle height did not influence SRC incidence rates. However, positive player behaviour changes were observed. Most rugby players across the world are non-professional; yet few studies have been conducted in this population.[3]

Thus, the aim of this study was to investigate the effect of a tackle law variation that reduces the maximum legal tackle height from the line of the shoulder of the ball barrier, to the line of the armpit, on injury, head injury and SRC incidence in amateur community rugby union.

METHODS

Study design

The study used a cross-sectional analytical design[24] over the period 2018 (control) and 2019 (intervention).

Preliminary data, using the standard maximum legal tackle height (line of the shoulder), was obtained from an injury surveillance study,[25] performed during 2018. These data were limited due to the condensed format of the rugby competition on which data collection was performed, due to a severe regional drought. The university banned the use of all sports fields for most of the season during this period. This resulted in fewer matches played in a shorter than usual time frame.

The law variation was implemented by the university rugby club in 2019. The law variation was introduced to relevant stakeholders in the period immediately preceding the start of the competition. The COVID-19 pandemic led to the cancellation of all sports in 2020, which prevented the planned continuance of the study—and an additional season's data collection—in 2020. Therefore, the 2018 and 2019 datasets were compared with evaluate the effect of the tackle law variation on injury, head injury and SRC incidence rates.

Setting and study population

The residence rugby competition is the university rugby club's unofficial intrauniversity competition between teams from the various university residences, divided into four leagues, with ~42 teams participating in the competition.[26] The competition is played over 14 weeks (usually April–October, as in 2019; from end July to early October in 2018). Matches are scheduled on a weekly basis, that is, one match per week. On consecutive weeknights, teams from a single league compete on six adjacent rugby fields in matches lasting 60 (1st–3rd leagues) or 50 min (4th league). First league teams generally adopt a serious approach to the competition and will have 1–2 training sessions per week. The lower leagues train infrequently or not at all.

The university's official healthcare service provider, Campus Health Service (CHS), a multidisciplinary healthcare team comprising sports physicians, nurse practitioners and physiotherapists, delivers medical care on every night of the competition.

In addition, six World Rugby trained first aid providers with specially adapted first aid carts are assigned to each of the six fields. These first aid providers are trained in the recognition and management of suspected SRC cases and can transport any player to the medical room for urgent medical attention.

Players are required to present to the first aid providers or medical room voluntarily to seek medical care, except in cases of suspected SRC, where the first aid providers will transport players with suspected SRC to the medical room immediately for an assessment by a sports physician.

Participants

All players participating in any form of rugby sanctioned by the university, including players in the residence competition, are required to register with the rugby club. The study proposed that all registered, consenting players taking part in the residence competition shall be eligible for the study. Players are registered university students aged 18 years and older.

Measures

From 2018 onwards, a standardised injury collection form based on a consensus statement for injury recording in rugby union[27 28] was used by CHS. All medical attention-seeking injuries were recorded. These encounters included players presenting to the medical room at the rugby fields and players who presented subsequently to the medical offices of CHS. It is possible that players who chose to consult with their own private medical practitioner may not have been captured by the injury surveillance system. In addition, the observing first aid providers have the ability and responsibility to remove a player from play for any suspected head injury. Owing to this being a non-professional tournament that functions under World Rugby's 'recognise and remove' regulations, all players removed for suspected SRC were seen in the medical room immediately and were unable to return to that match.

Recorded injuries were categorised into the following domains: (1) all injuries, (2) head injuries (any soft tissue or bony injury to the head; includes SRC) and (3) SRC (only). Injuries were further subdivided into medical attention (ie, all injuries; return to play (RTP)≥0 day) and time-loss (RTP≥1 day) injuries.

RTP in 2018 is based on the physician's estimation at the time of assessment (ie, no follow-up of a player's actual RTP), whereas RTP for 2019 is based on actual time lost.

Data management

Data collection was performed by a consistent team of medical professionals from CHS, with the assistance of pitch side first aid providers.

An automated report was generated daily of all injuries captured the previous day. This automated list was verified for accuracy (players, injury type, position played, etc) with the sports physician who was on duty the previous day. This information was also used to collect RTP data.

In addition, weekly player sheets were collated to identify any player who may have been absent from matches. These players were then contacted via SMS,[29] telephone or through that player's residence management committee, to confirm whether their absence from a match was due to injury. Injured players may have been treated outside of the university's official healthcare

Table 1 Club-registered player anthropometric data: 2018 and 2019

	2018 (n=807)		2019 (n=906)	
	Mean±SD	Median (IQR)	Mean±SD	Median (IQR)
Age (year)	20±1.5	20 (19–21)	20±1.6	19 (18–20)
Height (m)	1.82±0.07	1.82 (1.78–1.86)	1.81±0.07	1.81 (1.76–1.86)
Weight (kg)	88±14	86 (80–95)	86±13	85 (78–94)
Body mass index (kg/m²)	26.7±3.6	26.1 (24.5–28.1)	26.2±3.3	25.7 (24.1–27.8)

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Table 2 Match exposure for 2018 and 2019

League	Minutes/ match	2018 Matches (n)	2018 Total exposure (h)	2019 Matches (n)	2019 Total exposure (h)
1st	60	40	1200	59	1770
2nd	60	20	600	21	630
3rd	60	17	510	23	690
4th	50	24	600	13	325
Total		101	2910	116	3415

service. Therefore, this follow-up system was implemented to minimise the number of injuries not identified through the injury surveillance system.

The dependent variables are the number of injuries, head injuries and SRCs in 2019 and 2018, whereas the independent variables are the player match hours from 2018 and 2019 and events associated with injury incidents.

A real-time list of completed matches by league, based on the official fixtures list and information provided by the SRFC, was maintained to ensure accurate calculation of match exposure. Match exposure was calculated as the number of matches per league multiplied by the number of players exposed (30), multiplied by the time exposed (leagues 1–3: 1 hour, 60 min; league 4: 0.83 hour, 50 min). Metrics calculated include incidence proportion (number of injuries divided by total number of players), incidence rate (number of injuries per 1000 match hours) and incidence rate ratio (2019 incidence rate divided by 2018 incidence rate). SRC incidence rate comparison between years using Poisson regression analysis was performed and the data presented as incidence rate ratios with corresponding 95% CIs and the level of significance set at $p<0.050$.[30] Injury severity was compared between 2018 and 2019 by performing a Pearson's χ^2 test, after grouping severity categories (0–7 days vs 8 days or more).

Patient and public involvement

It was not appropriate or possible to involve patients or the public in the design, or conduct, or reporting, or dissemination plans of our research.

RESULTS

Player anthropometric (table 1) and match exposure (table 2) data for 2018 and 2019 are summarised below. Despite the condensed format in 2018, overall exposure was similar to that of 2019.

Overall, there were no statistically significant differences in the incidence rates of medical attention and time-loss injuries, head injuries and SRCs from 2018 to 2019 (table 3). By definition, all SRCs were time-loss injuries.

Head injuries accounted for 42% (n=38) and 49% (n=47) of all medical attention injuries in 2018 and 2019, respectively. SRC accounted for 68% (n=26) and 45% (n=21) of medical attention and 70% (n=26 of 37) and 58% (n=21 of 36) of time-loss head injuries in 2018 and 2019, respectively.

The SRC incidence rate ratio was 0.69 (95% CI: 0.4 to 1.2; p=0.2). Importantly, the SRC incidence rate did not increase in 2019 following the implementation of the legal tackle height law variation.

Time-loss injury incidence rates by leagues are shown in table 4. All leagues, except for second league, showed no significant change in incidence in 2019 compared with 2018.

Estimated (2018) and actual (2019) injury time-loss, as an indicator of injury severity (table 5), was recorded for all injured players. In 2019, 2655 days were lost to injury overall. The mean (±SD) and median (IQR) days lost per injury was 31 (±48) and 14 (21). In 2019, a total of 360 days, 19 (±13) mean and 21 (12) median days were lost due to SRC, in addition to two season-ending SRCs. There was no difference in injury severity between 2018 and 2019.

Phases of play and associated time-loss injuries are shown in table 6. The majority of time-loss head injuries in 2018 (51%, n=19) and 2019 (67%, n=24) occurred during the tackle event (tackling, or being tackled), and it was the phase of play most commonly associated with SRC, accounting for 46% (n=12) and 67% (n=14) of SRCs in 2018 and 2019, respectively. The tackle-related SRC incidence rate ratio was 0.99 (95% CI: 0.53 to 1.87; p=0.99).

DISCUSSION

Our aim in this study was to investigate the effect of a tackle law variation that lowered the maximum legal tackle height from the line of the shoulder to the armpit of the ball carrier, on the incidence rates of head injuries and specifically SRC, in amateur community rugby.

We found that the incidence rates for medical attention and time-loss injuries, head injuries and SRC did not differ statistically between 2018 and 2019. The tackle event was found to be the injury incident most associated with time-loss head injuries and SRC.

The statistically non-significant reduction in SRC incidence of 31% during the lower legal tackle height condition in the present study could be postulated to be clinically relevant, but without another season of data under the tackle law variation, this remains speculative. Furthermore, the incidence rate ratio for tackle-related SRC was 0.99. Additionally, the condensed 2018 schedule gives the 'control' or comparison year reduced utility.

Table 3 Overall medical attention and time-loss injury incidence rates in 2018 (estimated) and 2019 (actual)

		2018 (807 players)				2019 (906 players)						
		n	IP%	I	95% CI	n	IP%	I	95% CI	IR	95% CI	P value
All injuries	ma	90	11.2	30.9	24.5–37.3	97	10.7	28.4	22.8–34.1	0.92	0.7 to 1.2	0.56
	t-l	89	11.0	30.6	24.2–36.9	83	9.2	24.3	19.1–29.5	0.79	0.6 to 1.1	0.13
Head injuries	ma	38	4.7	13.1	8.9–17.2	47	5.2	13.8	9.8–17.7	1.05	0.7 to 1.6	0.81
	t-l	37	4.6	12.7	8.6–16.8	36	4.3	10.5	7.1–14	0.83	0.5 to 1.3	0.42
SRC		26	3.2	8.9	5.5–12.4	21	2.3	6.1	3.5–8.8	0.69	0.4 to 1.2	0.20

I, incidence rate per 1000 hours; IP%, n/total registered players; IR, incidence rate ratio; ma, medical attention; SRC, sport-related concussion; t-l, time-loss.

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Table 4 Overall time-loss injury incidence rates by league in 2018 (estimated) and 2019 (actual)

	2018 (807 players)				2019 (906 players)						
	n	IP%	I	95% CI	n	IP%	I	95% CI	IR	95% CI	P value
First	35	4.3	29.2	19.5 to 38.8	44	4.9	24.9	17.5 to 32.2	0.85	0.5 to 1.4	0.49
Second	30	3.7	50.0	32.1 to 67.9	9	1.0	14.3	5.0 to 23.6	0.29	0.1 to 0.6	<0.001
Third	9	1.1	17.6	6.1 to 29.2	23	2.5	33.3	19.7 to 47.0	1.89	0.8 to 4.6	0.11
Fourth	15	1.9	25.0	12.3 to 37.7	7	0.8	21.5	5.6 to 37.5	0.86	0.3 to 2.2	0.83
Second-Fourth	54	6.7	31.6	23.2 to 40.0	39	4.3	23.8	16.3 to 31.1	0.75	0.5 to 1.2	0.18

I, incidence rate per 1000 hours; IP%, n, total registered players; IR, incidence rate ratio; SRC, sport-related concussion.

The only other tackle height law variation trial reported in the literature, where the legal tackle height was lowered from shoulder to armpit in the Rugby Football Union's (RFU) second and third tier professional competitions,[23] found no difference in overall SRC incidence rate. The SRC incidence rate ratio reported was 1.31 (95% CI: 0.9 to 2.0), which suggests a non-significant upward trend between the control and intervention conditions. In comparison, the present study's SRC incidence rate ratio was 0.69 (95% CI: 0.4 to 1.2), which suggests a non-significant downward trend between the control and intervention conditions. The RFU study was conducted using a very different design where the study investigated the tackle law variation using the same professional player cohort in two different competitions within the same season. Our study compared amateur collegiate players participating in two successive seasons as control and intervention conditions. It may be possible that match intensity differences exist between the professional and amateur cohorts. Furthermore, according to the authors of the RFU study, the stakeholders (players, coaches and referees) were not engaged successfully and effectively prior to the initiation of the study, in addition to possible changes in SRC reporting behaviour due to heightened SRC-related awareness created by the study. In the present study, the rugby club actively engaged with all relevant stakeholders (referees, coaches and players) through various presentations, question and answer sessions, video review sessions and a general awareness campaign in the university residences, prior to the implementation of the law variation in 2019. Despite observing positive player behaviour changes, the RFU study authors felt that poor stakeholder engagement may have impacted on the outcome of the study and state that 'law changes have great potential in preventing injuries, but working with stakeholders on adoption and implementation might improve outcomes', in addition to proposing that the scientific understanding of the interaction between tackler and ball carrier be further investigated in future law variation trials involving larger cohorts and especially where SRC reporting is 'mature', so as not to be influenced by heightened awareness created by any ongoing studies.

Table 5 Overall medical attention injury severity: 2018 (estimated) and 2019 (actual)

	All injuries		Head injuries		SRC	
	2018	2019	2018	2019	2018	2019
Severity	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
0–1 days (slight)	1 (1)	14 (15)	1 (3)	11 (23)	–	–
2–3 days (minimal)	4 (4)	–	1 (3)	–	–	–
4–7 days (mild)	34 (38)	19 (20)	13 (34)	11 (23)	6 (23)	5 (24)
8–28 days (moderate)	39 (43)	33 (34)	22 (58)	19 (40)	20 (77)	11 (52)
>28 days (severe)*	7 (8)	29 (30)	1 (3)	6 (13)	–	5 (24)
Missing	5 (6)	2 (1)	–	–	–	–
Total	90	97	38	47	26	21

*10 season-ending injuries included in severe category in 2019.
SRC, sport-related concussion.

In the present study, overall injury and SRC incidence rates ranged from 24.3 to 30.9/1000 player match hours and 6.1–8.9/1000 player match hours, respectively. The overall injury incidence rates are lower than that reported in a meta-analysis[3] of only six studies, that found an overall injury incidence in senior amateur rugby of 46.8 injuries/1000 player hours (95% CI: 34.4 to 59.2). The RFU's six-season study (2009–2015) in English community rugby[31] reported an overall time-loss (eight or more missed days) injury incidence of 22.3 injuries/1000 player match hours (95% CI: 20.5 to 24.1). By comparison, a meta-analysis[5] of studies conducted in senior professional rugby reported an overall injury incidence of 91 injuries/1000 player hours. Furthermore, the England Professional Rugby Injury Surveillance Project (PRISP),[4] the most comprehensive and longest running injury surveillance project in professional rugby union, reported an overall injury incidence rate of 87 injuries/1000 player hours.

PRISP report an SRC incidence of 20.9/1000 player hours. SRC was the most diagnosed injury, accounting for 22% of all match injuries, had the highest match injury burden of all injuries and 68% of SRCs were sustained during the tackle. SRC has been the most common injury since 2011.[4] The SRC incidence rate in the RFU community rugby study was 3 injuries/1000 player match hours (95% CIs: 2.3 to 3.6),[6] a rate that is similar to that (2.16/1000 player match hours) found in a 2008 study of American collegiate rugby players.[32] Therefore, the SRC incidence rate in the present study is lower than the rate reported for professional rugby but 2–3 times higher than that found in comparable study cohorts in the RFU community study[6] and the American collegiate cohort.[32] A study in a Japanese collegiate cohort conducted over eight season found an SRC incidence rate of 11.7/1000 player hours (95% CI: 9.4 to 14.5).[33]

It is likely that increased awareness, greater knowledge, improved recognition tools, and therefore greater SRC reporting due to scientific advances in the last decade may explain the higher SRC incidence rate found in the present study. The consistency and standardisation of medical care rendered by CHS should be seen as a major positive factor in the gathering of injury data during this study. The clinical personnel involved in the management of injured players and data capturing are all experienced sport and exercise medicine physicians with many years' experience in rugby at the highest elite level in South Africa, assisted by pitch-side trained first aiders. Therefore, we believe that SRC reporting in our research setting is mature. Although we see this as an important, positive factor, it should be noted that the medical staff, as key role players, could not be blinded in the study design.

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Table 6 Mechanism of injury according to phases of play associated with estimated (2018) and actual (2019) time-loss injuries

	2018 (807 players)												2019 (906 players)											
	All injuries				Head injuries				SRC				All injuries				Head injuries				SRC			
	n	%	I	95% CI	n	%	I	95% CI	n	%	I	95% CI	n	%	I	95% CI	n	%	I	95% CI	n	%	I	95% CI
Tackling	26	29	8.9	5.8 to 13.1	14	38	4.8	2.6 to 8.1	9	35	3.1	1.4 to 5.9	32	39	9.4	6.4 to 13.2	19	53	5.6	3.3 to 8.7	9	43	2.6	1.2 to 5.0
Tackled	20	22	6.9	4.2 to 10.6	5	14	1.7	0.6 to 4.0	3	12	1.0	0.2 to 3.0	20	24	5.9	3.6 to 9.0	5	14	1.5	0.5 to 3.4	5	24	1.5	0.5 to 3.4
Accidental collision	16	18	5.5	3.1 to 8.9	10	27	3.4	1.6 to 6.3	8	31	2.7	1.2 to 5.4	9	11	2.6	1.2 to 5.0	3	8	0.9	0.2 to 2.6	–	–	–	–
Ruck	7	8	2.4	1.0 to 5.0	2	5	0.7	0.1 to 2.5	1	4	0.3	0.0 to 1.9	14	17	4.1	22 to 6.9	9	25	2.6	1.2 to 5.0	7	33	2	0.8 to 4.2
Other*	20	22	6.9	4.2 to 10.6	6	16	2.1	0.8 to 4.5	5	19	1.7	0.6 to 4.0	8	10	2.3	1.0 to 4.6	–	–	–	–	–	–	–	–
Total	89				37				26				83				36				21			

*Includes: changing direction/side stepping, foul play (punched/stamped/kicked), jumped, maul, running (including acceleration/deceleration), slipped/fell and unspecified.
I, incidence rate per 1000 hours; %, n, column total; SRC, sport-related concussion.

Major environmental events limited this study. The severe drought in 2018 in the region reduced the planned number of matches and the COVID-19 pandemic and its associated lockdowns and government-imposed restrictions in South Africa led to the cancellation of the entire 2020 rugby season. Therefore, the only data available for comparison were obtained during the 2018 and 2019 rugby seasons. Furthermore, methodological differences in player RTP follow-up between 2018 (estimated) and 2019 (actual) creates the possibility that captured RTP data in 2019 is more accurate than that of 2018, in addition to statistical assumptions that had to be made to allow for calculation of the various statistical measures.[25] While it is unlikely that incidence data were affected, it is likely that RTP estimation may impact on severity data in 2018. Furthermore, despite the implementation of a follow-up system to minimise the number of injuries not identified through the injury surveillance system, it remains possible that not all injuries were captured. Injured players may have sought care outside of the official university healthcare system, experienced delayed presentation of health-related symptoms and signs or failed to seek medical care. Additional limitations were introduced by the absence of recorded baseline data and inaccurate completion of player match sheets. Therefore, no clustering effects, effect modification or covariate confounding could be explored. Despite these limitations and introduced change in 2019, we believe that this study is a good representation of a competitive amateur population, as the medical infrastructure and personnel are well established, consistent and specifically trained to observe and remove suspected concussion cases.

In conclusion, this study found that reducing the legal tackle height from the line of the shoulder to the armpit of the ball carrier in community amateur rugby did not influence SRC incidence rate, similarly to the only previous study investigating the same law variation in a professional rugby setting. Previous research has identified the tackle event as a target for intervention with the potential to reduce injury risk to players. Thus, the effect of reduced maximum legal tackle height law variations on SRC incidence in community and professional rugby requires further, ongoing investigation to determine its real-life clinical benefit.

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WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Concussion sustained in rugby union—particularly during the tackle event—is a growing concern, requiring the study of tackle-related preventive strategies to reduce concussion incidence.

WHAT THIS STUDY ADDS

⇒ This study suggests that maximum tackle height law variation did not influence concussion incidence.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ Tackle-related law changes have the potential to reduce concussion incidence. Further study in amateur and professional settings is required to provide scientific weight regarding the clinical utility of tackle height law changes.

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Patient consent for publication Not applicable.

Ethics approval This study involves human participants and was approved by Stellenbosch University Health Research Ethics Committee—N20/02/017. Participants gave informed consent to participate in the study before taking part.

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Data availability statement No data are available.

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