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TECHNICAL NOTE

Criterion validity and reliability of an instrumented mouthguard under pendulum impactor conditions

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Abstract

The popularity of instrumented mouthguards (iMGs) use to measure head impact kinematics in contact sports is growing. To accurately compare between systems, mouthguards should be subjected to standardised laboratory validation testing. The study aimed to establish the validity and reliability of a mouthguard system under independently collected pendulum impactor conditions. A NOCSAE anthropometric testing device with attached mouthguard was impacted in four different locations (front, front boss, rear, rear boss) at four target linear accelerations (25, 50, 75 and 100 g) with two different impactor caps (padded and rigid). Peak linear acceleration, peak rotational velocity and peak rotational acceleration values from the mouthguard were compared against the reference data with a battery of statistical tests, namely *R* squared values, Lin's concordance correlation coefficient, intraclass correlation coefficients and Bland Altman analysis. Results indicate the iMG produces valid and reliable data comparable to that of the anthropomorphic testing device reference, with all measured variables reported 'excellent' intraclass correlation coefficients above 0.95; concordance correlation coefficients above 0.95; minimal average bias with Bland Altman analysis and *R* squared values above 0.92 for all measured variables. Results indicate the iMG is appropriately valid and reliable enough to next establish on-field validity.

Keywords Instrumented mouthguards · Impact biomechanics · Validation

1 Introduction

An increased risk of neurodegenerative disease in sports with inherent mild traumatic brain injury risk has been identified [1–4]. Brain injuries are thought to occur from rapid deformations of the brain, most commonly characterised by maximal principle strain of brain tissue [5]. Although strain of brain tissue cannot currently be measured in vivo, a subdomain of instrumented mouthguards (iMGs) with embedded accelerometers and gyroscopes are being increasingly used to characterise head impact biomechanics [6]. iMGs report linear and rotational accelerations of the head, and are favoured over skin patch or helmet based systems due to the rigid coupling with the upper dentitions within the skull [7]. Whilst iMGs offer a step forward in management of head impacts within sport, the usefulness of head impact data is dependent upon the validity and reliability of the systems.

Validation studies with various methodologies have been conducted for iMGs [6–12], but the exponential increase in technical specification and miniaturisation of sensors embedded in mouthguards require re-validation [13]. Whilst establishing the efficacy of individual iMGs is important, the various systems available to researchers necessitate comparison across an independent standardised methodology [9]. For example, four iMGs were recently compared against a reference anthropomorphic testing device (ATD) impact by a pneumatic pendulum impactor [8]. Three out of

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four of the iMGs achieved a Lin's concordance correlation coefficient (CCC)—a measure of agreement between two measurements [14]—of above 0.95. This finding provided preliminary evidence of agreement between iMG and reference measures for linear and rotational acceleration within a laboratory setting. Liu et al. also compared five iMGs against a reference ATD using a pneumatic linear impactor, within impacts representative of American Football [7]. Results showed that all five iMGs were valid compared to the ATD for peak linear acceleration and peak rotational velocity, with all of them reporting intraclass correlation coefficients (ICCs) of above 0.8.

The iMG used in the current study has not been validated under conditions of previous comparisons [8]. Effective comparisons between systems can only be made if they are tested under the same conditions. Whilst impact peak linear and rotational acceleration magnitudes tend to be similar between validation methodologies, impact site, direction and duration can alter impact biomechanics. As such, the current study aims to investigate the laboratory validity of an instrumented mouthguard under pendulum impactor impact conditions identical to those used within previous research [8].

2 Methods

Methodological and procedural information are presented in line with the recent Consensus Head Acceleration Measurement Practices (CHAMP) recommendations, with checklist available within Online Resources [15, 16]. Although the following represented a summary of study methodology, further detail pertaining to testing protocol, data processing and statistical methodology are presented in supplementary materials.

2.1 Testing protocol

Testing was conducted at the Virginia Tech Helmet Laboratory (USA) utilising the Sensor START methodology for un-helmeted impacts. A custom non-biofidelic pendulum impactor [17] with impacting mass 15.5 kg struck a National Operating Committee on Standards for Athletic Equipment (NOCSAE) bareheaded headform [17] in four different locations (front, front boss, rear, and rearboss). Impact velocities were varied by location to achieve four consistent target linear head accelerations (25, 50, 75 and 100 g). The impactor head was fitted with two different caps ('rigid' cap: 25 mm thickness nylon; 'padded' cap: 40 mm thickness CELL-FLEX 740 vinyl-nitrile foam) to elicit different impact durations. Two impacts within each condition were completed, leading a total of 64 impacts. The iMG stayed in place throughout an impact due to an aluminium plate inserted into the space between the iMG and the lower jaw of the headform. Figure 1 shows the pendulum impactor rig, a representation of impact locations, and the custom headform. Full headform characteristics can be found in Online Resources Sect. 2.1. Impact locations, peak linear acceleration magnitudes and durations were chosen to elicit equally spaced variability in direction of force around the head, and to represent a range of impacts expected for injurious and non-injurious impacts within various sports [18–24].

2.2 Measurement and specifications

The NOCSAE headform was instrumented with three linear accelerometers (Endevco 7264b-2000; Meggit Orange County, Irvine, California) and a tri-axial angular rate sensor (DTS ARS3 Pro 18 k; Diversified Technical Systems, Seal Beach, California) at the headform's centre of mass. Linear accelerations and rotational velocity were measured at a sampling rate of 20 kHz and filtered using a CFC 1000 (4th-order low-pass Butterworth filter with 1650 Hz cutoff frequency) and CFC 155 (4th-order low-pass Butterworth filter with 256 Hz cutoff frequency) class filter, respectively [18]. The reference sensors are reported to exhibit high fidelity and were deemed appropriate as a reference measure of head impact kinematics [25].

The iMG (PROTECHT System v2.0, Sport and Wellbeing Analytics) contained a tri-axial accelerometer (H3LIS331DL, STMicroelectronics, Genova, Switzerland) and a tri-axial gyroscope (LSM6DSOX, STMicroelectronics, Genova, Switzerland). The iMG was custom moulded from three-dimensional scans of the standardised artificial teeth mould used by the testing laboratory. The former was sampled at 1 kHz (± 400 g, 12-bit resolution) and the latter at 1 kHz (± 35 rad.s^{-1}, 12-bit resolution). For each impact, the iMG collected 104 ms of data; 10 ms of pre-sample data prior to the impact threshold breach, and 94 ms of data from the point of impact trigger. The trigger-point of the sensors was a raw linear acceleration exceeding 10 g in any one of the three axes. Three iMGs were made available for testing, although which iMGs were used for individual conditions was not noted.

2.3 Data processing

The choice of data processing procedures that bridge the gap between raw iMG outputs and reported variables can influence output kinematics [26]. Online resources Sect. 2.3 detail an extended account of iMG data processing procedures—presented here is a summary of procedural steps. Raw linear acceleration and rotational velocity outputs were downloaded from the proprietary iMG software—a basic Bluetooth app that applies no post-processing procedures—for analysis within custom Matlab script (The Mathworks Inc, Natick, Massachusetts, USA). The orientation of

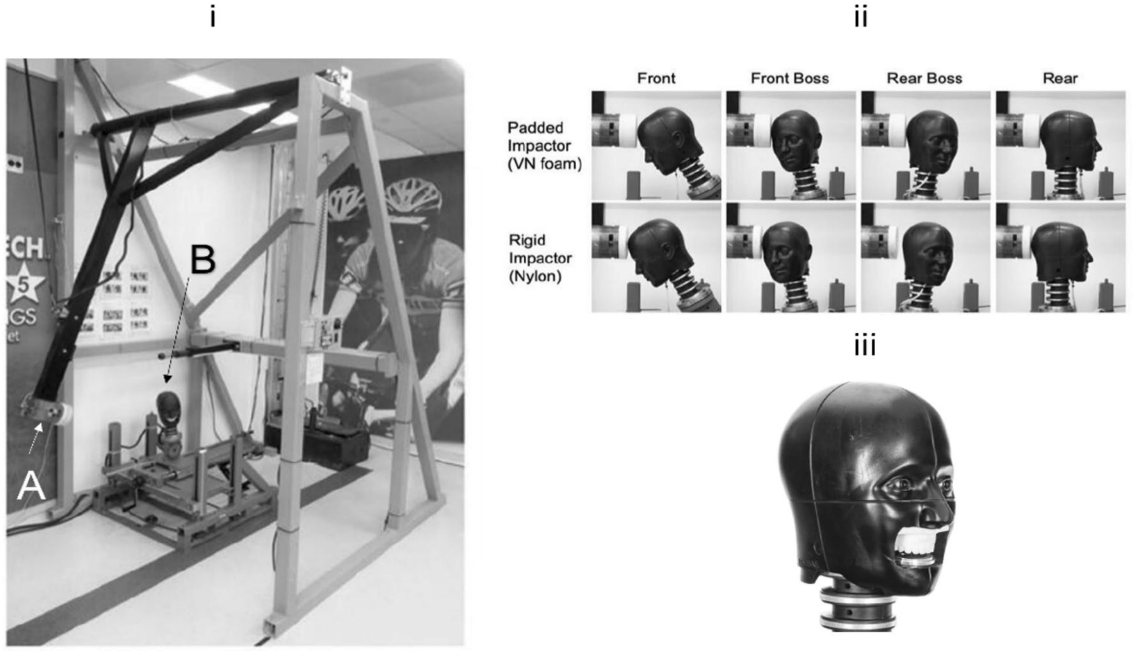

Fig. 1 i shows the pendulum impactor testing set up; **A** pendulum impactor, **B** headform. ii shows the different impact locations and different impactor covers with a standard headform. iii shows the custom headform with mandible modification. Full details of mandible modification and mouthguard coupling can be found in Online Resources Sect. 2.1

Table 1 Low-pass Butterworth cutoff frequencies for linear acceleration data

Impactor condition	Impact location	Filter cutoff frequency at target impact magnitude (Hz)			
		25 g	50 g	75 g	100 g
Padded	Front	200	200	250	300
	Front boss	150	150	150	150
	Rear	150	150	200	200
	Rear boss	150	150	200	300
Rigid	Front	450			
	Front boss	300			
	Rear	450			
	Rear boss	450			

accelerometer and gyroscope axes were then aligned with the SAE-J211 plane utilised by the ATD and time-series outliers removed from raw linear accelerometer data and raw rotational velocity data. Following outlier removal, rotational acceleration was derived from rotational velocity values using a five-point stencil derivative. Time-series outliers were then removed from rotational acceleration data using the aforementioned procedure. Data were then filtered (4th-order low-pass Butterworth) with cutoff frequencies specific to each situational condition (methods for cutoff frequency choice are presented in Online Resources Sect. 2.3). Table 1 presents identified cutoff frequencies for linear acceleration. For rotational velocity, a cutoff frequency of 300 Hz for all impacts was used. For rotational acceleration, a cut off frequency of 300 Hz was used for padded impacts, and 400 Hz for rigid impacts. Filtered linear acceleration data was then translated from the mouthguard origin to the headform's centre of mass, using a displacement vector supplied by the Virginia Tech Helmet Laboratory [27]. Finally, peak values of linear acceleration, rotational velocity and rotational acceleration were calculated for ATD and iMG data. Impact duration was calculated for all trials utilising the ATD resultant linear acceleration, with methods outlined in Online Resources Sect. 2.3.

2.4 Statistical analysis

For ATD and iMG comparisons, dependent variables were peak resultant linear acceleration (PLA) peak resultant rotational velocity (PRV) and peak resultant rotational acceleration (PRA) as measured by the ATD and the iMG. Peak linear and rotational acceleration was defined as the highest numerical sample from the sample time-series data. Headform and iMG data were time aligned such that 10 ms prior to both traces crossing a 10 g threshold was set as timepoint 0. It is acknowledged that relative error between when both system achieve this threshold could influence alignment, and hence visual inspection of traces was performed.

Given the wide array of applications of iMG data, the degree of desired 'agreement' could be variable depending upon the user. As such, the current authors do not advocate for a reliance on inappropriate 'agreement' statistics, such as correlation coefficients, and single statistic outputs in isolation. Whilst single statistics are undeniably useful, a products validity should not be defined by one output, and rather should be evaluated with respect to the intended use of the product and the over the range of measurements collected. As such, the current study assessed agreement using a battery of statistical tests. An extended explanation of agreement statistics, including rationale for use and methods used to calculate, is presented in Online Resources Sect. 3.

Scatterplots and coefficient of determination (*R* squared) were calculated to assess the relationship between the ATD and iMG [29]. Agreement between measures was assessed using intraclass correlation coefficients (ICC), concordance correlation coefficient (CCC) and Bland–Altman 95% limits of agreement (LoA) [14, 28, 29]. Mean relative errors in peaks were defined as the mean percentage difference between the ATD and iMG peak values for all variables. Finally, root mean-square errors were calculated to assess the accuracy of the overall time-series data, following a modified procedure from previous research show in Eq. 1 [19]. The RMS errors were also normalised (nRMS) based on the impact magnitude (Eq. 2):

$$\mathrm{RMS} = \sqrt{\sum_{i}^{n}\left(\frac{\mathrm{iMG}_i - \mathrm{ATD}_i}{n}\right)}^{2} \quad (1)$$

$$\mathrm{NRMS} = \frac{\mathrm{RMS}}{\mathrm{ATD}_{\max} - \mathrm{ATD}_{\min}} \times 100 \quad (2)$$

where *n* is the number of measurements (35 ms), ATDmax and ATDmin are the maximum and minimum values recorded by the ATD during the impact.

3 Results

In total, 64 impacts were collected. Impact duration for the padded impactor condition was 12.01 ± 1.35 ms, and 4.06 ± 0.59 ms for the rigid impactor condition.

Scatterplots of impacts for PLA, PRV and PRA, with different impact locations and impactor conditions and associated *R* squared values are presented in Fig. 2. Intraclass correlation coefficients, Lin's CCC values, RMSE, nRMSE, mean relative error in peaks and Bland Altman statistics are presented in Table 2. All measured variables were found to exceed the 0.8 threshold for CCC as outlined by previous research [9] with a total CCC of 0.983. All measured ICC values were rated as 'excellent', exceeding the 0.9 threshold [30]. Bland Altman plots, comparing the difference between

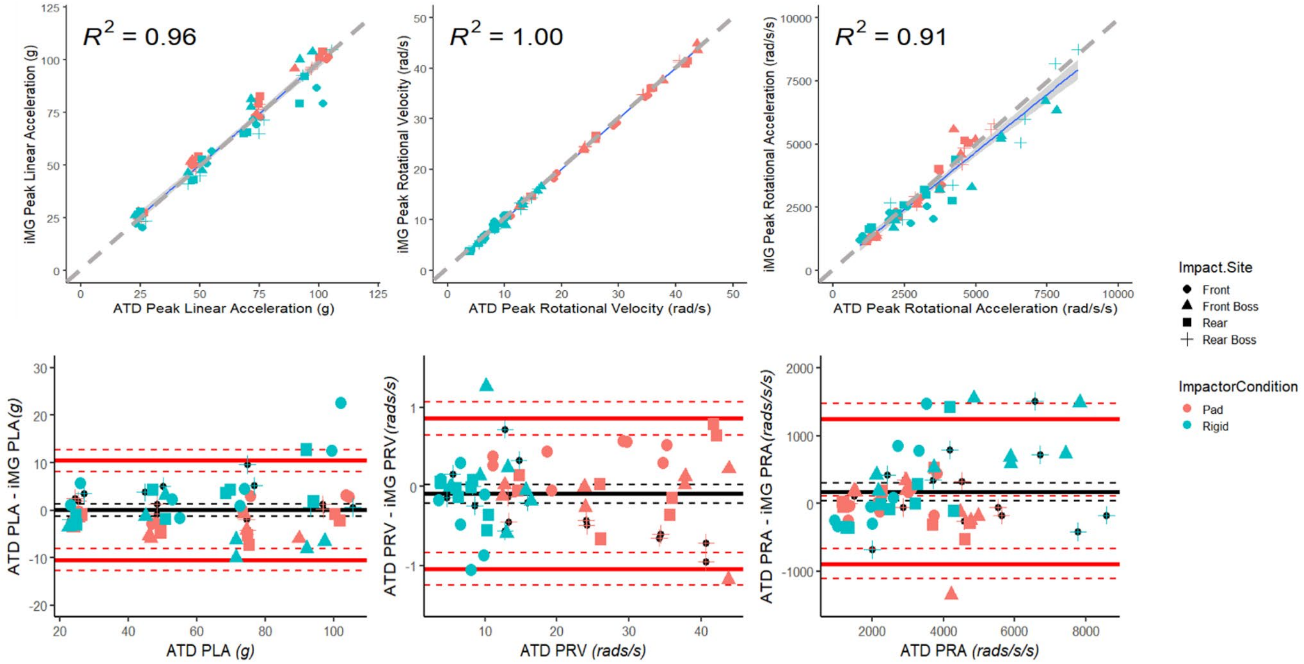

Fig. 2 Top row-scatterplots for PLA, PRV and PRA variables of ATD and iMG data, with impact site and impactor condition, and associated R squared value. Dash line represents line of unity. Bottom row—Bland Altman plots for PLA, PRV and PRA variables of ATD and iMG data

Table 2 Agreement statistics for biomechanical metrics: intraclass correlation coefficients (ICC), concordance correlation coefficients (CCC), RMSE, nRMSE and Bland Altman Statistics for PLA, PRV and PRA in the ATD and iMG

	CCC (95% CI)	ICC (95% CI)	RMSE (± SD)	nRMSE (± SD; %)	Mean relative error in peaks (%; SD)	Bland Altman (% difference)		
						Bias (95% CI)	Lower limit (%)	Upper limit (%)
PLA (g)	0.980 0.968–0.988	0.981 0.969–0.989	6.07 (± 3.70)	11.29 (± 4.45)	6.93 (± 5.22)	− 0.62% (− 4.25 to 3.02%)	− 17.30	16.07
PRV (rad/s)	0.999 0.998–0.999	0.999 0.999–1.00	0.68 (± 0.36)	2.54 (± 3.13)	1.21 (± 3.55)	− 0.79% (− 2.54 to 0.96%)	− 8.82	7.23
PRA (rad/s^2)	0.950 0.919–0.969	0.954 0.926–0.972	409 (± 223)	12.40 (± 11.25)	1.41 (± 15.94)	2.74% (− 3.96 to 9.44%)	− 28.00	33.49

Total CCC = 0.981; Total ICC = 0.979

ATD and iMG measures against the ATD reference, are presented in Fig. 2. Agreement statistics for individual padded and rigid conditions are presented in Table 3. Figure 3 showcases a typical resultant linear and rotational iMG and ATD trace.

4 Discussion

This study established the validity and reliability of an iMG against a reference ATD under pendulum impact conditions. Results indicate that the iMG exceeds (total CCC = 0.981, 95% CI 0.974–0.986) the previously defined minimum combined CCC threshold (0.8) required to proceed to on-field testing outlined by previous research [9]. The iMG also possessed 'excellent' ICC values for PLA, PRV and PRA variables, with minimal average bias reported within Bland Altman Analysis. This discussion shall consider each outcome variable in isolation.

4.1 Linear acceleration

Peak linear acceleration CCC (0.989; 95% CI 0.984–0.992) is comparable to those of previous research who utilised an identical methodology [8], where top performing iMGs achieved CCC values of 0.944 (95% CI 0.906–0.967), 0.980 (95% CI 0.967–0.989) and 0.981 (95% CI 0.967–0.989). The iMG also achieved a marginally greater ICC value than that of a previous version of the same mouthguard (0.985 vs 0.96, respectively), although it is hard to state whether this increase has any applied significance [6]. Bland Altman analysis did identify that, on average, the iMG slightly underestimates the ATD reference by 0.62%, although visual inspection of LoA graphs identified that this bias was not

Table 3 Basic agreement statistics broken down by impactor condition

	CCC (95% CI)	ICC (95% CI)	Bland Altman (% difference)		
			Bias (95% CI)	Lower limit (%)	Upper limit (%)
Padded					
PLA (g)	0.991 0.983–0.996	0.992 0.984–0.996	− 1.43% (− 5.8 to 2.94%)	− 15.32	12.41
PRV (rad/s)	0.999 0.998–0.999	0.999 0.999–1.00	− 0.16% (− 1.23 to 0.9%)	− 3.55	3.23
PRA (rad/s^2)	0.972 0.947–0.985	0.973 0.946–0.987	0.21% (− 5.88 to 6.29%)	− 19.13	19.54
Rigid					
PLA (g)	0.969 0.938–0.984	0.971 0.942–0.986	2.19% (− 3.89 to 8.28%)	− 17.15	21.54
PRV (rad/s)	0.990 0.981–0.996	0.991 0.983–0.996	− 1.41% (− 4.81 to 1.97%)	− 12.20	9.36
PRA (rad/s^2)	0.938 0.883–0.967	0.953 0.906–0.977	5.27% (− 6.89 to 17.44%)	− 33.41	43.96

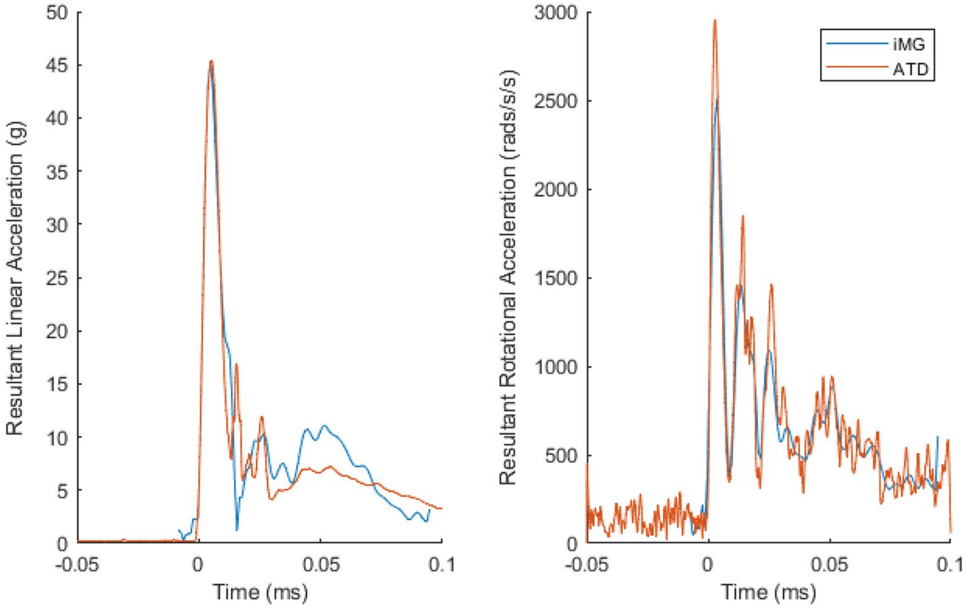

Fig. 3 Example traces of linear and angular accelerations for a front boss impact for iMG and ATD measures

fixed. Mean relative error in peaks (6.93%) were comparable of those of previous research who utilised a pneumatic linear impactor methodology [7], where the minimum mean relative error observed was 2.5%. Although a previous version of the iMG investigated in the current study was also investigated under pneumatic linear impactor conditions, the large mean relative error of 32.4% was not representative of current values due to a lack of signal processing [7, 31].

Agreement with the ATD does differ slightly depending on impact duration. Impact duration for the padded impactor condition was 12.01 ± 1.35 ms, and 4.06 ± 0.59 ms for the rigid impactor condition. For the shorter duration impacts, CCC's were slightly lower (0.969 vs 0.991 for 'rigid' vs 'padded', respectively), ICC's slightly lower (0.971 vs 0.992 for 'rigid' vs 'padded', respectively), and limits of agreement slightly wider (− 15.3 to 12.4% vs − 17.1 to 21.5% for 'rigid' vs 'padded', respectively). However, it is worth noting that impacts of such short duration seldom occur in non-helmet sports. Impact durations of under 7 ms are more often associated with head-to-ground impacts [32] as opposed to soccer ball to head impacts over 15 ms [33, 34] or punch impact durations of 11.4 ms in boxing [35]. Therefore, under conditions that are representative of typical contact-sport impacts, the iMG can be considered valid and reliable for the measurement of PLA.

4.2 Rotational velocity

The measured PRV (*R* squared = 0.99; CCC = 0.999; ICC = 0.999) represents an almost perfect agreement between the iMG and the ATD reference. The current iMG reported lower mean relative errors compared to other systems that were tested under linear pneumatic impact conditions. Other systems have ranged from 4.6 to 7.6% relative error in peak magnitude, and displayed marginally higher *R* squared values, ranging from 0.92 to 0.97 [7]. The current iMG performed almost identically to a previous version of the same iMG, with the same *R* squared, CCC and ICC values, with a marginally lower mean relative error (− 1.2 vs 1.9%, respectively) [6]. Although rotational velocity is the measured rotational variable for most iMG systems, it is seldom reported or interpreted within head impact research, with rotational acceleration being the predominant rotational kinematic variables. Given that angular velocity is an important input variable for estimating the maximal principle strain of brain tissue [36], validations for systems with the potential to be used for brain modelling should also report the validity and reliability of this measure.

Agreement with the reference ATD appeared to only be marginally affected by impact duration, with Bland Altman LoA increasing within the rigid condition (− 12.2 to 9.4% vs 3.6% to 3.2% for 'rigid' vs 'padded', respectively).

4.3 Rotational acceleration

In the current study, the CCC for PRA of 0.95 (95% CI 0.919–0.969), although still well above the 0.8 threshold outlined by previous research [9], is lower than that of the almost perfect agreement of PRV. This also falls below CCCs reported for other iMGs utilising an identical methodology, where values ranging from 0.982 to 0.990 were reported [8]. In the present study, 95% limits of agreement (2.74 ± 30.75%) are also wider than those reported by previous research (− 2.3% ± 14.7%; − 4.2% ± 20.4%; − 6.8% ± 14.8% for three separate iMGs).

Differences between the current iMG and other systems could be due to two reasons. First, as PRA is a derived variable, data processing procedures can influence the output PRA value. Such procedures could include the method of differentiation used, whether rotational acceleration is derived from raw or filtered rotational velocity and the manner in which rotational acceleration data is filtered. Differences could also be influenced by the sampling rate of the system or by error introduced by the variation in impact locations influencing the location-dependent inertial force of the mouthguard [7]. As with PLA values, when the short duration 'rigid' impactor impacts are discounted and the 'padded' impactor impacts—more representative of 'on field' impacts—are considered in isolation, CCC values increased (0.938 vs 0.972 for 'rigid' vs 'padded', respectively), ICC values increased (0.953 vs 0.973 for 'rigid' vs 'padded', respectively) and LoA reduced (− 33.4% to 44% vs − 19.1% to 19.54% for 'rigid' vs 'padded', respectively).

4.4 Limitations

The current study solely reports the laboratory validity and reliability of the sensors utilised within the iMG. Although there are high levels of agreement between the systems, further research is required to establish the on-field efficacy where further biofidelic noise is present within raw signals. The individual manner in which iMG data was filtered could also be considered a limitation within a practical setting. Within the current work, noise characteristics specific to each impact condition, impact magnitude and location where identified, necessitating an individual approach to the choice of cutoff frequency used. Whilst an individual approach to filtering may not be practical on 'on-the-ground' practitioners, the authors feel filtering within respect to impact specific noise should constitute a 'gold standard' approach. Whilst it is acknowledged that filters are reliant on more than just cutoff frequency, future work should address the objective identification of cutoff frequencies for on-field data. The study did also not establish the within device reliability as a result of manufacturer consistency.

4.5 Conclusion

The iMG assessed here was a valid and reliable when compared to a reference ATD in the measured laboratory conditions. The values attained indicate that the iMG would be suitable for the next phase of on-field validation [9].The iMG compared well with previous iMGs subjected to the same testing procedure, with reported combined CCC values of 0.981. Future work could consider the application of individualising filter characteristics to the specific noise characteristics of individual impacts.

Supplementary Information The online version contains supplementary material available at https://doi.org/10.1007/s12283-023-00434-4.

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Data availability Data are available upon request by emailing the corresponding author.

Declarations

Conflict of interest KA, KJN and CJ are employed by Sport and Wellbeing Analytics, who manufacture the PROTECHT mouthguard. ML is a member of the Sport and Wellbeing Analytics executive board.

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