Online Supplementary Materials

Online Resources 1 – CHAMP Checklist

Table 1 details the checklist items from the consensus head acceleration measurement practices (CHAMP) consensus [1].

TABLE 1. CHAMP 2022 checklist of information to include when reporting laboratory validation studies of head acceleration measurement devices.

Checklist Item	Explanation	Example(s)	Reported on Page No
1. Sensor Technology and Speci			
(1a) Device model name	The name or model of device used to collect data	PMID: 33051745, ''The Cue, GForceTracker, and Shockbox sensors were mounted directly inside the helmet.''	____5____
(1b) Sensor type	The type of sensor (e.g., triaxial linear accelerometer, triaxial ARS)	PMID: 26268586, ''The X2 system has a 3-axis linear accelerometer and a 3-axis angular rate sensor…''	__5___
(1d) Sensor sample rate	The sampling rate of the sensor	PMID: 32975553, ''The sensor records 62 ms of data at 1000 Hz….''	_____5___
(1e) Sensor magnitude range	The range of magnitudes the sensor can record	PMID: 23604848, ''Mouthguard sensing is accomplished via a triaxial accelerometer (ADXL377, Analog Devices, Inc., Norwood, MA, USA) with 200 g maximum per axis and a tri-axial angular rate gyroscope (L3G4200D, ST Microelectronics, Geneva, Switzerland) with 40 rad/s maximum per axis.''	____5____
(1f) If applicable, device hardware/firmware version number	The version number related to the hardware/firmware for the device	PMID: 29613824, ''Hardware and firmware were fully up to date according to the manufacturers at the time of testing [xPatch: Hardware updated Oct 2014, Software and firmware updated Aug 2017; SIM-G: Hardware updated Jun 2014, Software and firmware updated Aug 2017]''	_____5___
(1g) Recording trigger threshold	The sensing threshold (e.g., 10 g) for an event to be recorded on the head acceleration measurement device and how the trigger threshold is evaluated	PMID: 23891566, ''The helmet recorded …if the impact exceeded 10 g.''	____5____
(1h) Pre-trigger duration	Duration of pre-trigger data recorded	PMID: 32975553, ''…10 ms before and 52 ms after linear acceleration exceeds the threshold.''	__5______
(1i) Post-trigger duration	Duration of post-trigger data recorded	PMID: 32975553, ''…10 ms before and 52 ms after linear acceleration exceeds the threshold.''	____5____
(1j) Device form factor and attachment	The type of device/how the device is mounted (e.g., mouthguard)	PMID: 30802147, ''MV1 (MVTrak) is a sensor system designed for custom-molded placement in the left external ear canal to optimize coupling to the head.''	___5_____
2. Surrogate Selection			___4/5_____
(2a) Surrogate used	The surrogate used (e.g., non-biofidelic [by intent] test device, anthropometric test device (ATD), post-mortem human subjects (PMHS), human volunteers)	PMID: 23846161, ''A Hybrid III (HIII) 50th percentile male ATD head and neck with the 3-22-2 accelerometer array was rigidly mounted at T1.''	

(2b) Inertial properties of surrogate	Geometry and mass—including what reference population is intended to be represented by this surrogate	PMID: 27155744, ''This ATD had the inertial properties of a 50th percentile male head.''	_____4/Online Materials___
(2c) If applicable, modifications made to standard surrogates	Any modifications made to standard surrogates for this study	PMID: 34263384, ''Modifications to the NOCSAE headform include a mouth cut-out for mounting dentitions and a Hybrid-III neck adapter to replace the standard rigid neck and allow 6DOF head motion.''	____4/5/ Online Materials ____
(2d) If applicable, corresponding neckform and/ or other body segments used	The neckform used to simulate head-neck response (e.g., Hybrid III neck, THOR neck) and/or other body segments (e.g., torso) used to simulate the system mass	PMID: 21994068, ''… mounted to a standard HIII neck was used to replicate the response of a football player's head. Per manufacturer's specification, the cable in the HIII neck was tensioned to 1.1 Nm (10 inÆlb.).''	__4/ Online Materials ______
(2e) Modifications made to standard neckforms, if applicable	Any modifications made to standard neckforms for this particular study	PMID: 33000448, ''…the lower neck mount of the Hybrid III dummy was modified to incorporate a spherical ball joint that allowed for lateral flexion and twist of the neck.''	___NA_____

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Checklist Item	Explanation	Example(s)	Reported on Page No
(2f) Validation of the surrogate	Evidence that the surrogate has been shown to produce a validated response for the chosen application	PMID: 29613824, ''These reference sensors have been found to exhibit high fidelity (ref) and were considered to quantify the true head kinematics of the headform during impact.''	___5_____
(2g) Mounting of the device on the surrogate	Details on how the device is mounted on the surrogate and the biofidelity of that mounting	PMID: 29383374, ''The dental model was rigidly attached to the ATD headform in the place of the upper dentition, and the instrumented mouthpiece was mounted on the dental model, with the lower jaw firmly clamped to the mouthguard simulating jaw clenching…''	____4/ Online Materials ____
(2h) Factors related to coupling of the device to the surrogate	Specific parameters that could influence coupling of the device to the surrogate (e.g., helmet fit, skin/hair surrogate, use of nylon skull cap, sweat, jaw mechanics)	PMID: 23891566, ''The helmet was fit by inflating the Z-pad bladders until they contacted the head.''	____4/ Online Materials ____
3. Test Conditions			
(3a) Test device	The device used in testing (linear impactor, pendulum, drop tower)	PMID: 21451177, ''The helmet was impacted using a pneumatic linear impactor.''	_4/5_______
(3b) Impactor surface and mass	The type and material of the impact interface (elastomer padding, use of anvils, etc.). Provide the mass and its relevance to desired test conditions	PMID: 24920257, ''The impactor mass was 14 kg and was padded with a 36 mm thick, 127 mm diameter vinyl nitrile pad (Impax VN 600, DerTex Corp, Saco, ME) without the standard hard plastic cap. This configuration generated an impact amplitude and duration similar to that observed during helmet-to-helmet impacts.''	___4_____
(3c) Surrogate orientation and mounting, if applicable	How the surrogate was placed in the test device	PMID: 24920257, ''Both headforms were mounted on a 50th percentile male Hybrid III neck mounted to a table free to slide horizontally parallel to the impactor's axis.''	___4/ Online Materials _____
(3d) Impact velocity	The velocities used in testing and their relevance to desired test conditions	PMID: 32989591, ''Regarding the impact velocities used for the testing, three of the used velocities (5.5, 7.4, and 9.3 m/s) are based on the National Football League (NFL) helmet test protocol, and an additional lower velocity (3.6 m/s) was added to analyze impacts of lower intensity as well.''	___4_____
(3e) Impact duration	The duration(s) used in testing and their relevance to desired test conditions	PMID: 29613824, ''The helmeted tests yielded average impact durations of 10.7 (1.3) milliseconds. The padded impactor to bare head condition was performed with a vinyl-nitrile foam impactor face measuring 127 mm in diameter and 40 mm thick. These tests yielded average impact durations of 12.5 (1.3) milliseconds and were chosen to provide similar impacts to the helmeted condition without the effect of the helmet. The rigid impactor to bare head condition was performed with the same flat, rigid, nylon impactor face from the helmeted tests to be representative of impact magnitudes and durations seen in unhelmeted impacts. These impacts yielded average durations of 3.6 (0.25) milliseconds.''	____4/5/9/ Online Materials ____

(3f) Impact location	The impact location(s) used in testing and their relevance to desired test conditions	PMID: 29613824, ''Impacts were performed to the front, front boss, rear boss, and rear locations of the headform at targeted linear acceleration magnitudes of 25, 50, 75, and 100 g. Impact locations were equally spaced around the head and chosen because of their variability in direction of force.''	___4/5_____

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Checklist Item	Explanation	Example(s)	Reported on Page No
(3g) Impact direction	The direction(s) of impact used in testing and their relevance to desired test conditions	PMID: 26268586, ''Ten impacts were nominally centroidal, i.e., the impactor's axis passed near a vertical axis through the headform's COG.'' PMID: 26268586, ''The front-oblique test condition was intended to represent a centric impact (head CG path eccentricity = 65 mm) and the rear eccentric test condition was intended as a more eccentric impact (head CG path eccentricity = 101 mm).''	________
(3h) Number of trials	The number of trials performed for each of the test conditions	PMID: 17597937, ''Three drops were performed at each location.''	____4____
(3i) If applicable, helmet manufacturer/model name	The name of the manufacturer/model of the helmet used in impact testing	PMID: 29613824, A large Riddell Speed (Riddell, Elyria, OH) football helmet without the facemask was worn by the headform throughout helmeted tests	_____N/A___
(3j) Repeatability and reproducibility of test conditions	Methods used to evaluate the repeatability and reproducibility of the test conditions and surrogate	PMID: 24920257, ''Repeatability was assessed using the COV, which equals the ratio of the standard deviation (SD) to the mean, expressed as a percentage. Repeatability was categorized as excellent (COV £ 3%), acceptable (3 < COV £ 7%), marginal (7 < COV £ 10%) and poor (COV > 10%). The COVs for PLA and PAA were calculated for each series of five repeated tests for all eight impact conditions in each lab.''	____Not Tested____
4. Reference Sensor Mea	surement		____5____
(4a) Reference sensor type and model	The type of sensor or measurement device used as a reference (triaxial accelerometer, nineaccelerometer package, high-speed video), including the sensor part number	PMID: 26268586, ''…a 3-2-2-2 array of linear accelerometers (Endevco 7264B-2000 g, San Juan Capistrano, CA)''	
(4b) Reference sensor mounting	The method and location for reference sensor mounting	PMID: 26268586, ''…a 3-2-2-2 array of linear accelerometers (Endevco 7264B-2000 g, San Juan Capistrano, CA) installed in a compact cluster (rx = ry = 34 mm, rz = 27 mm) in a modified load-sensing headform (MLSH) based on the 50th percentile male Hybrid III headform.''	___5_____
(4c) Reference sensor sampling rate	The sampling rate of the reference sensor	PMID: 26268586, ''…modified load-sensing headform (MLSH) based on the 50th percentile male Hybrid III headform. Accelerometer data were acquired at 10 kHz with hardware anti-aliasing filters prior to digitization (SAE Channel Class 1000).''	_____5___
(4d) Reference sensor magnitude range	The range of magnitudes the reference sensor can record		_____5___

(4e) Reference sensor filtering	Filtering methods used for the reference measurements	PMID: 29613824, ''The reference data were filtered at CFC 1000 for linear acceleration and CFC 155 for rotational velocity.''	___5_____
(4f) Time synching of reference sensor to head kinematic device	Method for synching reference data to wearable device data	PMID: 31297724, ''Mouthpiece and reference traces were time-aligned such that the first data point that crossed the 5 g trigger threshold was set to time t = 0.''	____10____

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Checklist Item	Explanation	Example(s)	Reported on Page No
5. Advanced Post-pr (5a) Data transformation	Methods used to transform recorded data to analyzable data (e.g., numerical integration from angular velocity to angular acceleration, transformation from the location of the sensor to the center of gravity of the head, if transformation used, specify measurements defining the location to which data is transformed, must disclose if a ''black box'' algorithm was used)	PMID: 31122140, ''The acceleration data are transformed to calculate linear acceleration at the centre of gravity of the head. Rotational acceleration is calculated from rotational velocity using five-point differentiation. Both the transformation and differentiation were carried using the software supplied by X2Biosystems.'' PMID: 34263384, ''Kinematics measured by the mouthpiece were transformed to a local head coordinate system using a rigid body transformation based on the geometry of each headform. Detailed 3D surface scans of both headforms with the IM affixed to the upper dentition were obtained to determine the location and orientation of the sensing elements in relation to the head CG (Artec Eva, Artec 3D, Santa Clara, CA). Reference measurements at the maxilla and device measurements from the electronics board inside the head of the MLSH were transformed to the head CG based on detailed computer drawings''	____5/6/ Online Materials ____
(5b) Kinematic data filtering	Any filtering used for processing data collected from a wearable device; must disclose if manufacturer ''black box'' post-processing was used. Include offset removal	PMID: 29383374, ''Raw signals were low-pass filtered according to Society of Automotive Engineers protocols. The mouthpiece data used threshold frequencies of 300 Hz and 110 Hz for linear acceleration and angular velocity, respectively, with 110 Hz being the bandwidth limit for the gyroscope.'' PMID: 30802147, ''Raw data are uploaded to the MVTrak server before being processed by the producer's algorithm.''	____5/6/ Online Materials ____
(5c) Other post-processing techniques	Any software or hardware used for processing data collected from a wearable device (e.g., impact detection filtering, infrared system); must disclose if manufacturer ''black box'' post-processing was used. Provide details on validation of post-processing techniques (e.g., training data set used)	https://doi.org/10.1177/1754337117739458, ''…data were processed using proprietary algorithms from which the resultant peak linear acceleration (PLA) and peak angular acceleration (PAA) impact magnitude measures were output.''	_____5/6/ Online Materials ___
(5d) Event removal	Clear, objective methods for sensor event removal, if any sensor events are removed from analysis	PMID: 32975553, ''A positive single axis maximum of 28.9 rad/s and negative single axis absolute maximum of 29.1 rad/s were determined. One trial was removed from analysis because this maximum angular velocity measurement was sustained for more than five consecutive data points.''	___NA_____

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Checklist Item	Explanation	Example(s)	Reported on Page No
6. Analytical Methods and Data Description of each primary and secondary validation (6a) Validation metrics, including equations used to derive metrics, if applicable	metric (e.g., impact counts, peak linear acceleration, change in angular velocity)	PMID: 32975553, ‘‘Key event characteristics include peak angular velocity (i.e., maximum velocity during event), rise time (i.e., time for angular velocity to reach peak velocity from event start at velocity surpassing 5% of peak), fall time (i.e., time from peak velocity to 5% of the peak), and a proxy for average angular acceleration (i.e., approximated by taking the ratio of peak angular velocity and the rise time).’’	___6/7/ Online Materials _____
(6b) Statistical and analytical methods for comparison	The statistical and analytical methods used to compare the wearable device data to the reference measures (e.g., recall, RMS error, general linear mixed models)	PMID: 31297724, ‘‘Average resultant peak percent error was used to determine agreement between reference data and the mouthpiece data. Normalized root-meansquare error (NRMS) was used to determine agreement over the entire impact duration recorded by the mouthpiece (60 ms).’’	______6/7/ Online Materials __

Online Resources 2 – Expanded Methodology

Section 2. 1 Headform Characteristics

A National Operating Committee on Standards for Athletic Equipment (NOCSAE) bareheaded headform, [2] was impacted. The headform was modified with a Hybrid III neck adapter to allow for 6 degrees of freedom head movement, and a mouth cut out to fit a detachable three-dimensional printed mould. To accommodate the mouth cut off, a portion of the rubber from the nose to the middle of the chin was removed and replaced with a 3D printed mandible based on the size and shape of the class 1 Ideal Arch used in Hybrid III mandible modification [2]. The mandible was oriented at an 8-degree occlusal plan angle and placed in an anatomically correction position within the headform. The hybrid III neck was mounted per manufacturers specifications. To ensure the iMG stayed in place throughout an impact, and to mimic teeth clamping used by on field players, an aluminium plate was inserted into the space between the iMG and the lower jaw of the headform. This palte was then screwed upwards to ensure there was no gap between the plate and the mouthguard.

Section 2.2 Mouthguard Characteristics

The mouthguard utilised 1.5 mm Erkoflex material and 2 mm of ethylene vinyl acetate (EVA). Sensors are placed on the back left (relative to the athlete) of the mouthguard, situated on the outside gum. The mouthguard is CE and UKCA safety certified [3].

Section 2.3 Mouthguard Data Processing

Raw linear acceleration and rotational velocity data were downloaded from proprietary software and exported to Matlab script (The Mathworks Inc, Natick, Massachusetts, USA) for analysis. The orientation of accelerometer and gyroscope axes were then aligned with the SAE-J211 plane utilised by the ATD. As the iMG coordinate system originates at the sensor, axes required a further rotation using the rotation matrices:

$$R_1 = \begin{bmatrix} 1 & 0 & 0 \\ 0 & \cos\alpha & -\sin\alpha \\ 0 & \sin\alpha & \cos\alpha \end{bmatrix}$$

$$R_2 = \begin{bmatrix} \cos\beta & 0 & \sin\beta \\ 0 & 1 & 0 \\ -\sin\beta & 0 & \cos\beta \end{bmatrix}$$

$$R_3 = \begin{bmatrix} \cos\theta & -\sin\theta & 0 \\ \sin\theta & \cos\theta & 0 \\ 0 & 0 & 1 \end{bmatrix}$$

$$R_4 = \begin{bmatrix} \cos\mu & -\sin\mu & 0 \\ \sin\mu & \cos\mu & 0 \\ 0 & 0 & 1 \end{bmatrix}$$

The gyroscope was rotated using R_1*, *R_2*, and *R_3*,* where R_1 refers to rotation about the x axis (α = -10), R_2 refers to rotation about the y axis (β = -10), and R_3 refers to rotation about the z axis (θ = 15). The linear accelerometer was rotated using R_4, where R_4 refers to rotation about the z axis (μ = 20). Rotation angles were estimated via image analysis of sensor placement within the mouthguard and headform, and an iterative process to ascertain visual alignment of *x, y* and *z* linear acceleration and rotational velocity waveforms.

Impact duration was calculated for all trials utilising the ATD resultant linear acceleration. Impacts were assumed to be linearly elastic, with impact duration calculated as the time difference between peak impact acceleration and impact start, multiplied by 2. Impact start was determined as the first instance of the resultant linear acceleration time-series exceeding a threshold of the mean of pre-impact quiet acceleration period plus or minus five times the standard deviation of pre-impact quiet acceleration period [4].

Regarding PRV, whilst previous literature has advocated for the use of peak change in rotational velocity to offset for any initial velocity present[5], the current study assumes a starting rotational velocity of zero due to a static headform, and hence utilised raw rotational velocity outputs.

To establish situation specific cut off frequencies for iMG data, Fast Fourier transform (FFT) analysis was completed within Matlab R2022a (Signal Processing Toolbox; The Mathworks Inc, Natick, Massachusetts, USA) assessing the *x, y, z* and resultant components of linear acceleration, rotational velocity and rotational acceleration time-series data. Frequency data was observed only over the first 35 *ms* of impact to increase time resolution. Optimal cut off frequencies for condition and each impact magnitude were visually identified. To provide further time-resolution to the frequency analysis of signals, continuous wavelet transformations (CWT) were also completed within Matlab (Signal Processing Toolbox; The

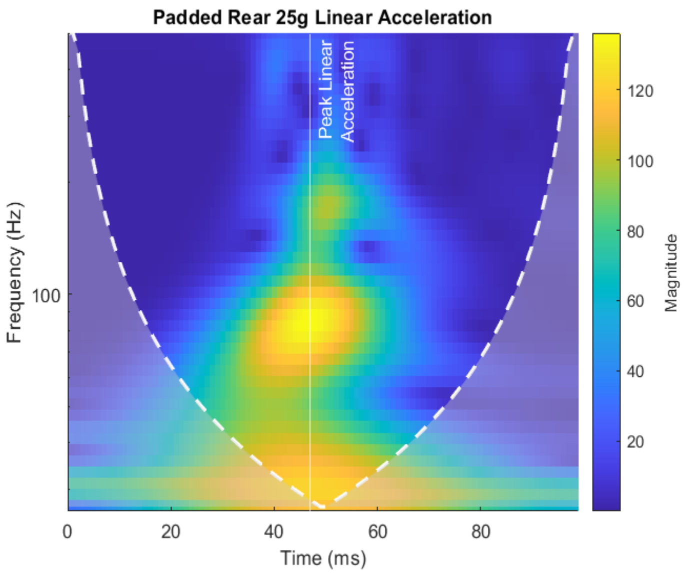

Figure 2. Example CWT output detailing signal frequency content and magnitude around point of impact.

Mathworks Inc, Natick, Massachusetts, USA), utilizing an analytic Morlet wavelet ('amor') to elicit equal variance in both the time and frequency features. For CWT analysis, time-series data were zero padded to ensure the impact point lay within the cone of influence and was not subject to boundary effects. High magnitude frequency components around the time of impact were interpreted as true signal, with noise elements either interpreted as time-frequency clusters away from the assumed true-signal cluster, or not time aligned with the point of impacts. An example trace is presented within Figure 2.

The authors acknowledge that individual analysis of impact frequency characteristics may not be suitable for on field impacts, but due to the short time duration of 'rigid' impactor impacts (which are not representative of on field impacts in sports such as rugby, boxing or football), a singular cut off frequency is inappropriate to apply to all impacts. Previous versions of the current mouthguard have utilised a cut off frequency of 160 Hz [6]. When this filter was applied to the impacts in the current study, there was good agreement for all impacts within the padded condition (all CCC's above 0.976; Table 2), however there was insufficient agreement for PLA and PRA within the rigid condition, where the short duration of impacts make such a low cut off frequency inappropriate (Table 2). As such, the current authors advocate that the specific characteristics of impacts are accounted for when defining filter characteristics.

Table 2. Agreement statistics for padded (mean ± SD impact duration 12.01 ± 1.35 ms) and rigid (mean ± SD impact duration 4.06 ± 0.59 ms) impacts when a singular cut off frequency (160Hz) used for all impacts.

		CCC (95% CI)	ICC (95% CI)	Bland Altman (% Difference)		
				Bias (95% CI)	Lower Limit	Upper Limit
Padded	**PLA (*g*)**	0.987 0.975-0.994	0.988 0.976-0.994	0.3% (-4.93% - 4.33%)	-15.01%	14.42%
	PRV (*rad/s*)	0.998 0.997-0.999	0.999 0.998-0.999	0.35% (-0.67% - 1.36%)	-2.88%	3.57%
	PRA (*rad/s²*)	0.976 0.955-0.987	0.991 0.981-0.995	8.48% (4.87% - 12.09%)	-2.98%	19.94%
Rigid	**PLA (*g*)**	0.651 0.515-0.756	0.874 0.758-0.936	28.68% (23.13% - 34.24%)	11.02%	46.34%
	PRV (*rad/s*)	0.994 0.989-0.997	0.995 0.989-0.997	0.05% (-2.70% - 2.81%)	-8.70%	8.81%
	PRA (*rad/s²*)	0.596 0.461-0.704	0.850 0.715-0.924	41.60% (36.77% - 46.43%)	26.26%	59.94%

<u>Online Resources 3 – Statistical Analysis Expansion</u>

Agreement between measures was calculated using a battery of tests.

R-squared values indicates the proportionate amount of variation in the response variable y explained by the independent variables X in the linear regression model [7]. Although a commonly used method within iMG validation methodology [8, 9], correlation and linear regression model R squared value (interpreted in isolation) do not assess statistical agreement between measures and should not be utilised as a sole statistical test within such methodologies.

Intraclass correlation coefficients measure the reliability and validity of measurements for data that has been collected as groups [7]. For all variables, ICC's were calculated using the (3,1) convention[10], and were interpreted using the thresholds of >0.5 as poor, between 0.5 and 0.75 as moderate, between 0.75 and 0.9 as good, and above 0.9 as excellent[11]. The CCC evaluates the degree to which pairs of observations fall on the 45° line through the origin [12]; values for linear and rotational kinematic measures were calculated. The combined CCC value that accounts for peak linear and the highest rotational (velocity or acceleration) CCC value represented the overall iMG in-laboratory validity [13]. The minimum validity threshold value for both CCC and ICC values is considered 0.80 [13, 14].

Bland-Altman 95% limits of agreement analysis is a simple method to evaluate the mean difference between measurement systems, and to estimate an agreement interval within which 95% of the differences between methods falls [15]. Bland-Altman analysis was conducted using the "blandr" package [16] on RStudio (RStudio, Vienna, Austria). Differences were calculated weighing towards the ATD system, meaning positive bias indicated an underestimation in the iMG. Analyses were expressed using percentage difference, and plotted using custom RStudio script with absolute differences expressed in relation to the ATD reference. Although *a priori* 95% limits of agreement are usually required for Bland-Altman analysis [17], there is a lack of clinically informed criteria regarding what constitutes 'agreement' within head impact sensors.

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