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Kinematic analysis for determination of bioequivalence of a modified Hybrid III test dummy and a wheelchair user

Michael Dvorznak, MS;[1–2] Rory Cooper, PhD;[1–3*] Michael Boninger, MD[1–4]
[1]Human Engineering Research Laboratories/Center of Excellence in Wheelchairs and Related Technologies, Department of Veterans Affairs, Pittsburgh Healthcare System, Pittsburgh, PA; [2]Departments of Bioengineering, [3]Rehabilitation Science and Technology, and [4]Physical Medicine and Rehabilitation, University of Pittsburgh, Pittsburgh, PA

Abstract—We investigated whether a modified 50th-percentile Hybrid III test dummy (HTD) (First Technology Safety Systems, Plymouth, MI) would have motion similar to a wheelchair test pilot (TP) with T8 paraplegia. Test cases were seated in a Quickie P100 electrically powered wheelchair (Sunrise Medical, Inc., Phoenix, AZ) driven at three speeds (0.8, 1.4, and 2.0 m/s). Three braking conditions—joystick release, joystick full reverse, and emergency power-off—were used to stop the wheelchair. The subsequent upper-body motion was recorded for the creation of kinematic exposure profiles of the wheelchair riders. The maximum concentration (Cmax) and area under the trunk angular displacement, velocity, and acceleration curves (AUC_{0-Cmax}) were calculated. Assessments of average, individual, and population bioequivalence were conducted after data were subjected to natural logarithmic transforms. Only the Cmax of the trunk angular acceleration of the HTD and TP was average bioequivalent (0.82–1.04). Both Cmax and AUC_{0-Cmax} measures for all kinematic exposures between the TP and HTD were individual and population bioequivalent (95% upper-confidence bound < 0, linearized bioequivalence criteria). This indicates that the HTD is a suitable surrogate for a wheelchair user in low-speed, low-impact wheelchair studies.

Key words: accident prevention, bioequivalence, electrically powered wheelchairs, Hybrid test dummy, injury assessment, injury biomechanics, kinematics, spinal cord injury, statistical measures, tips and falls, wheelchair safety.

INTRODUCTION

Anthropomorphic test dummies (ATDs) have been used in studies on wheelchair stability and driving accidents [1–5]. The design criteria for ATDs were based on the response and tolerance data acquired from cadaver studies. Such cadavers are typically of advanced age and have

Abbreviations: ABE = average bioequivalence, ATD = anthropomorphic test dummy, AUC = area under the curve, AUC_{0-Cmax} = area under curve from brake initiation to the maximum concentration point, BE = bioequivalence, CI = confidence interval, Cmax = maximum concentration, EPO = emergency power-off, EPW = electrically powered wheelchair, FDA = Food and Drug Administration (U.S.), FR = full reverse, HTD = Hybrid III test dummy, IBE = individual bioequivalence, JR = joystick release, PBE = population bioequivalence, R = reference, SD = standard deviation, T = test, TAA = trunk angular acceleration, TAD = trunk angular displacement, TAV = trunk angular velocity, 3-D = three-dimensional, TP = test pilot, VA = Department of Veterans Affairs.

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*Address all correspondence to Rory Cooper, VA Pittsburgh Healthcare System, Human Engineering Research Laboratories, 7180 Highland Drive, 151R-1, Pittsburgh, PA 15206; 412-365-4850; fax: 412-365-4858. Email: rcooper@pitt.edu or stankovicp@herlpitt.org

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anthropometrics reflecting a healthy, unimpaired population. In addition, vehicle crash testing occurs at higher speeds and accelerations at which muscular activity can be ignored because of reaction time [6]. For these reasons, use of ATDs in relatively low-speed wheelchair studies may underestimate the risk of injury.

This study developed and validated a low-speed, low-impact test dummy for use in the study of the prevention of tips and falls from wheelchairs. We implemented a kinematic analysis comparing the trunk motion of a Hybrid III test dummy (HTD) (First Technology Safety Systems, Plymouth, MI) to the motion of a wheelchair user during various braking trials to determine bioequivalence.

METHODS

Test Cases

A 50th-percentile male HTD simulated the occupant of an electrically powered wheelchair (EPW). The HTD series comes equipped standard with a seated pelvis and curved lumbar spine so the HTD can assume an "automotive seated position" [7]. In an investigation of the nature of EPW accidents, the occupant may not necessarily remain in a seated posture in the occurrence of a fall. To accommodate for this, we used a standing "pedestrian" pelvis with the accompanying straight lumbar spine in place of the seated pelvis with curved lumbar spine. In addition to being the complementary component for the standing pelvis, the straight lumbar spine has a lower stiffness in flexion and extension than the curved lumbar spine (65 vs. 275 N m/°) [8]. We fabricated custom hardware for attaching the lumbar spine to the pelvis on a computer-numerically controlled milling machine so the existing standard instrumentation could be used with the design changes.

We removed vinyl-coated foam "tissue" from the inner thighs of the HTD to allow for a noninterference fit during seated posture. Further modifications were made based on the hypothesis that bending in a forward fall from a wheelchair occurs mostly from flexion in the hip joints, with additional contribution from flexion in the lumbar region of the spine. We removed the foam/rubber buttocks and instead used low-density polyurethane foam to mimic flaccid tissue [9–10] (**Figure 1**). This allowed the HTD's hip joint more freedom. We removed the abdomen to reduce trunk resistance, which has been shown to provide more realistic motion in an HTD [11].

A single wheelchair user with T8 paraplegia due to traumatic spinal cord injury was used for comparison. This study received exemption from the Department of Veterans Affairs (VA) Institutional Review Board and was accepted by the VA Research and Development Committee. **Table 1** details the demographics and anthropometrics of the test cases.

Test Wheelchair

Testing was performed with one EPW as the input: a Quickie P100 (Sunrise Medical, Inc., Phoenix, AZ). We selected the P100 because of its availability at our research center and because it presented minimal risk of causing a fall to the test pilot (TP) as determined in a previous study [1]. Both the HTD and TP were seated on a

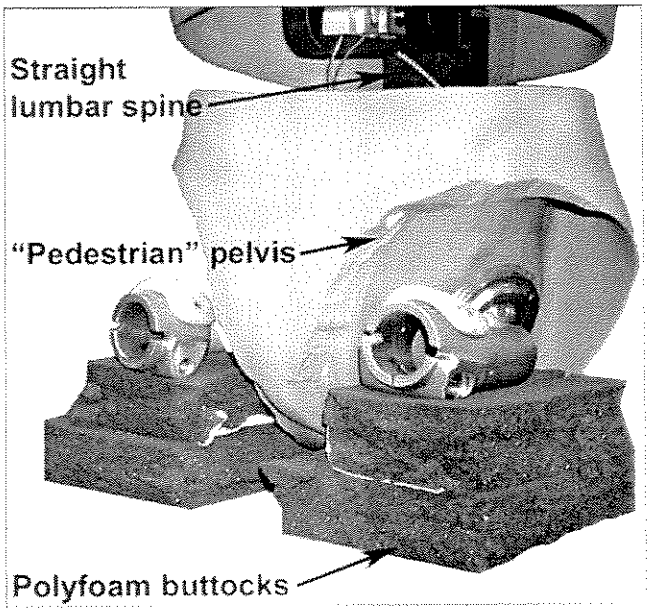

Figure 1.
Hybrid III test dummy modifications, including pedestrian pelvis, straight lumbar spine, and polyfoam buttocks.

Table 1.
Test case characteristics.

Test Case	Sex	Age	Mass (kg)	Height (mm)	Diagnosis
Test Pilot	Male	42	55	177	T8 SCI
HTD	Male	NA	75	171	Modified

HTD = Hybrid III test dummy (First Technology Safety Systems, Plymouth, MI).
NA = not applicable
SCI = spinal cord injury

50 mm polyurethane foam cushion. Markers were placed on the front edge of the seat tube and at the intersection of the seat and back support for determining wheelchair velocity, acceleration, and orientation and on the stem of the joystick to obtain joystick position.

Validation Concept

The HTD was clothed to provide similar friction with the seat as the TP. We used a kinematic analysis of the trunk bending during a braking trial to endorse the modifications to the HTD. We fixed active markers to the shoulder, hip, and knee to capture the trunk motion. The HTD and TP were seated in the wheelchair as depicted in **Figure 2**, with arms abducted and forearms flexed to prevent using them for support during trials. The TP, however, was instructed to stiffen his torso via muscular activation to maintain posture. One should note that this may not be possible for the wheelchair users who would be most at risk for falls, and, while the TP would not represent this particular group, this provides a reference point for the HTD to the wheelchair-user population.

Figure 2.
Hybrid III test dummy showing marker locations (1) ear, (2) shoulder, (3) hip, (4) knee, (5) corner of frame (intersection of seat and backrest), (6) front edge of seat, (7) bottom of joystick stem, and (8) top of joystick stem.

Measurement System

An OPTOTRAK 3020 (Northern Digital, Inc., Waterloo, Canada) motion measurement system collected three-dimensional (3-D) position data. Raw data were sampled at 240 Hz, converted to 3-D marker position data, and filtered before analyses. HTD and TP marker data were conditioned with the use of a fourth-order, zero-lag, low-pass Butterworth digital filter at a 6 Hz cutoff frequency [12]. Wheelchair data were filtered similarly, but with a 12 Hz cutoff frequency, because power spectral density estimates indicated signal power at higher frequencies.

Experimental Protocol

Test protocol included three braking conditions: joystick release (JR), joystick full reverse (FR), and emergency power-off (EPO). In addition, the braking conditions were enacted with three EPW initial velocities: slow (0.8 m/s), medium (1.4 m/s), and fast (2.0 m/s). The slowest speed was obtained by turning of the potentiometer on the joystick to its minimum value. Likewise, the maximum speed was achieved by turning of the potentiometer to its maximum value. We tuned the potentiometer to provide a mid-range speed. One test operator drove the P100 at the selected speed and initiated the braking scenario when the front caster crossed a braking line labeled on the floor. We analyzed position data from the joystick, as well as velocity and acceleration curves of the wheelchair, to determine the start of braking.

Kinematic Variables

We measured the trunk angle by computing the angle between the knee, hip, and shoulder markers (markers 2, 3, and 4 in **Figure 2**) projected onto the sagittal plane of the rider. The angle was referenced relative to the angle of the trunk when braking was initiated. This results in the range of motion of the trunk during the braking scenario. We calculated successive time derivatives of the trunk angular displacement (TAD) numerically with a 5-point centered differencing algorithm to obtain trunk angular velocity (TAV) and trunk angular acceleration (TAA).

Bioequivalence

Inferential statistics commonly test a null hypothesis that two variables are not different against the alternative

that they are different. A lack of significant differences does not imply that the two measures are similar. Sometimes testing the reverse of this hypothesis is desirable; that is, showing that two things are similar. This is common during pharmaceutical testing to show that a generic drug is as effective as the name brand, to show that a drug is as effective after scaling up production from its clinical counterpart, or to validate changes to a drug already approved [13–14]. Proving statistically that one measure is similar to another is known as bioequivalence (BE). BE is defined as "the absence of a significant difference in the rate and extent to which the active ingredient . . . becomes available at the site of drug action . . . [15]." Although BE relates to pharmacological testing, we have extended this definition for use in our study. In general, BE involves a comparison between a test (T) and a reference (R) formulation. In this study, the T formulation is the modified HTD and is compared to the R formulation, the TP.

BE in the pharmaceutical industry is an indirect measure of bioavailability. Since measuring the drug availability at the action site is difficult, the drug concentration in the systemic circulation is investigated. After the drug is introduced to the patient, the concentration in the blood (plasma, serum, etc.) will increase as the drug is absorbed. As the drug reaches the site of action, it is eliminated from the blood and the concentration will decrease [13]. A typical systemic exposure profile may look like **Figure 3**. The U.S. Food and Drug Administration (FDA) recommends that the maximum concentration (Cmax) and the total exposure, or area under the curve (AUC), be used as measures of BE [14]. Rather than investigating exposure measures, we performed analyses on kinematic measures. We determined the maximum point on the TAD, TAV, and TAA curves, as well as the AUC. We had to diverge from typical AUC calculations. In some trials—for example, **Figures 3** and **4**—the kinematic curves did not return to the baseline, leaving an open-ended interval from which to calculate area. To remain consistent and avoid arbitrarily selecting an end point, we calculated the area from brake initiation to the maximum concentration point (AUC_{0-Cmax}) for all trials using trapezoidal rule (step size = 1/240 s).

The FDA also recommends log transformation of exposure measures before statistical analysis because of an interest in the ratio of test and reference treatments, rather than the difference [14]. Differences between two means on the log scale, when transformed back to the natural scale, provide information about the ratio of the two formulation averages.

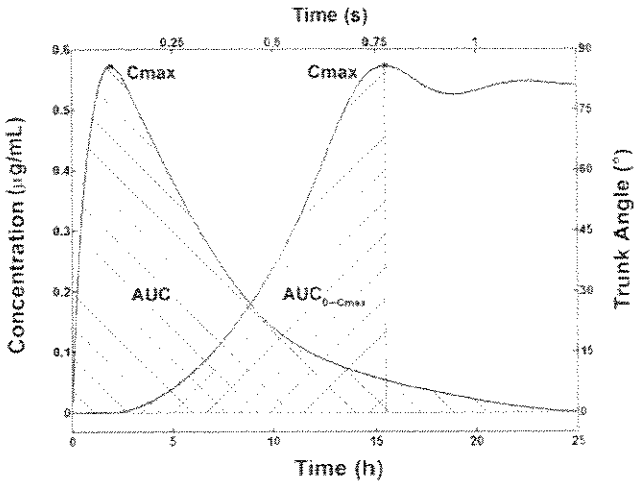

Figure 3.
Example systemic exposure profile. "Kinematic exposure" profile showing trunk angular displacement of test pilot is included for comparison. Maximum concentration (Cmax) on curves denoted with "x." Area under trunk displacement curve (AUC_{0-Cmax}) calculated from brake initiation to Cmax as opposed to closed region used to calculate AUC typical in pharmaceutical studies.

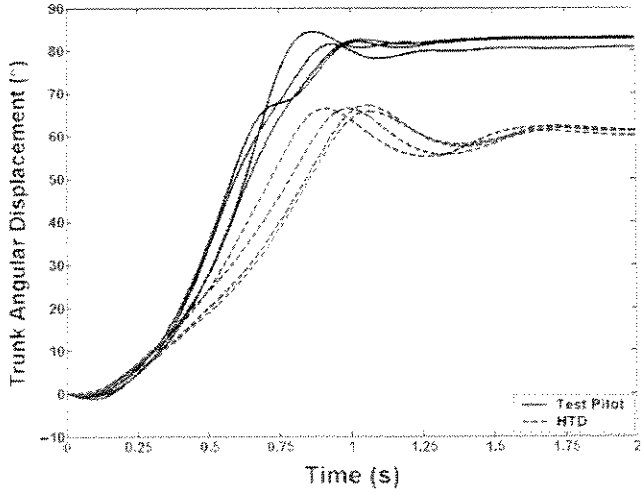

Figure 4.
Trunk angular displacements of test pilot and Hybrid III test dummy (HTD) during 2 m/s emergency power-off braking.

The FDA acknowledges three forms of BE. The most common is average BE (ABE). As the name indicates, ABE is a measure of centrality only and therefore is

insufficient for demonstrating "prescribability" and "switchability" between formulations. For these reasons, population (PBE) and individual BE (IBE) were introduced. In the latter, one must replicate a crossover design to estimate the within-subject variances of T and R measures, as well as the interaction variance component [13–14].

We evaluated ABE using the following criterion:

$$(\mu_T - \mu_R)^2 \le \theta_A^2 , \qquad (1)$$

where μ_T and μ_R are the mean log-transformed values for the T and R exposure measures, respectively. θ_A is a regulatory goalpost, typically equal to the ln(1.25) in the pharmaceutical industry.

Equation (1) is more commonly written as

$$-\theta_A \le (\mu_T - \mu_R) \le \theta_A . \qquad (2)$$

Substituting the value of θ_A and exponentiating **Equation (2)** yields

$$0.8 \le \exp(\mu_T - \mu_R) \le 1.25 . \qquad (3)$$

ABE is demonstrated if the 90 percent two-sided confidence interval (CI) for the ratio of the geometric means is between 0.8 and 1.25. That is, on average, the exposure measures of the T formulation are between 4/5 and 5/4 of the R formulation.

We used the following criterion to evaluate IBE:

$$\frac{(\mu_T - \mu_R)^2 + \sigma_D^2 + (\sigma_{WT}^2 - \sigma_{WR}^2)}{\max(\sigma_{WO}^2, \sigma_{WR}^2)} \le \theta_I . \qquad (4)$$

σ_{WT}^2 and σ_{WR}^2 are the within variances of T and R. $\sigma_D^2 = (\sigma_{BT} - \sigma_{BR})^2 + 2(1-\rho)\sigma_{BT}\sigma_{BR}$ is the subject-by-formulation interaction, where σ_{BT}^2 and σ_{BR}^2 are the between-subject variances for T and R, and ρ is the between-subject correlation of T and R. σ_{WO}^2 is a specified constant within-subject variance, commonly $\sigma_{WO}^2 = 0.04$ [14]. The numerator in **Equation (5)** is scaled by either the within-subject variance of R, σ_{WR}^2 (reference scaled), or by the constant within-subject variance, σ_{WO}^2 (constant scaled), whichever is greater. This is so drug products with a low variability reference will not have to comply with an excessively narrow standard of BE. θ_I is a regulatory limit for IBE. Allowing for a difference of means of ln(1.25), a subject-by-formulation interaction variance of 0.03, and a difference of within-subject variances of 0.02 produces a value of 2.49 for θ_I. Formulations are IBE if the upper bound of the 90 percent CI is <2.49.

We assessed PBE using the following measure:

$$\frac{(\mu_T - \mu_R)^2 + (\sigma_T^2 - \sigma_R^2)}{\max(\sigma_{TO}^2, \sigma_R^2)} \le \theta_P , \qquad (5)$$

where σ_T^2 and σ_R^2 are the total variances of T and R, respectively. σ_{TO}^2 is a specified total variance. In accordance with the FDA, $\sigma_{TO}^2 = 0.04$ [16]. Likewise, PBE can be constant or reference scaled. A similar allowance for the difference of means and variances leads to a PBE limit of 1.74 for θ_P.

We used combinations of wheelchair speed and braking conditions to create nine independent samples. A 2 × 8 replicated crossover design was used in which we randomized the wheelchair speed/braking conditions to either an RRRRTTTT or TTTTRRRR formulation sequence. We performed ABE, PBE, and IBE analyses using SAS version 8 software (SAS Institute, Inc., Cary, NC). A model including sequence, period, and formulation factors was fit with the use of the "proc mixed" function. We used the restricted maximum likelihood method to estimate mean and variance parameters with the "REML" option. An unstructured covariance matrix was estimated with the "type=UN" option. We obtained 90 percent CIs to determine ABE. Formulations were considered ABE if the CIs for both Cmax and AUC measures were within the 0.8 to 1.25 limit standard in pharmaceutical testing. The 95 percent upper-confidence bounds for the linearized constant and referenced scaled PBE and IBE were calculated. Formulations were considered PBE and IBE if their respective upper bounds were negative for both Cmax and AUC measures.

RESULTS

Table 2 displays the speed of the EPW for each speed/braking condition, as well as the trunk kinematics of the test cases before log transformations. **Figures 4** to **6** present curves of the TAD, TAV, and TAA of the test cases during EPO braking and the fast initial wheelchair speed.

AUC was not calculated for the TAA measure. In **Figure 6**, one can see that a portion of the TAA curves extend below the *x*-axis, often resulting in a negative total area. Log transforms of negative areas yield complex numbers that are not compatible with BE analyses. Since there is no basis in literature for transformations in addition to log transforms, these values were considered missing data. Since data were missing in 28 of 72 periods, BE measures for TAA were excluded to avoid bias. The AUC was negative for only 2 of the 72 TAD curves and, consequently, we treated it as missing data.

Table 3 reports the geometric means, ratio, and 90 percent CIs associated with ABE for Cmax and AUC of the TAD, TAV, and TAA curves. The HTD was ABE to the TP only according to the TAA Cmax (0.82–1.04). The ratio of means for the Cmax of TAV (1.21) was within the 0.8 to 1.25 interval; however, the upper bound of the CI was outside the acceptable limit, hence ABE cannot be concluded. Both the ratio of means and the upper bounds were outside the BE interval for both Cmax and AUC measures of TAD.

Table 4 shows the upper bound for both the constant- and reference-scaled IBE and PBE intervals. In accordance with FDA guidance, we used reference scaling since the within variance for the reference, $\hat{\sigma}^2_{WR}$, was >0.04 for IBE and the total variance for the reference, σ^2_R, was >0.04 for PBE. The HTD was PBE to the TP for all kinematic measures since the upper bounds for Cmax and AUC were <0. Testing with reference-scaled IBE showed that the HTD was IBE to the TP since the upper bounds of the 90 percent CIs were <0 for all kinematic measures.

DISCUSSION

The ultimate goal of the development of a low-speed, low-impact test dummy is to reduce wheelchair accident frequency and severity. A first step in this goal is the development of a robust test device that provides accurate and repeatable data relevant to the population being studied.

The modified HTD was ABE to the TP for the Cmax on the TAA curve. In most cases, the upper bound of the 90 percent CI was exceeded. This is, in part, due to the small sample size ($N = 9$). The FDA recommends a minimum of 12 subjects for BE studies [14]. Typically, more than 50 subjects are needed to achieve a power greater than 80 percent. Replicate designs can reduce the number of subjects by up to half while maintaining the same power [13].

While analogies are not perfect between systemic exposure and kinematic measures, subjects and speed/braking combinations, no norm for BE testing exists outside the pharmaceutical industry. One might question the analogy of various speed and braking conditions to independent samples. One could repeat this study using different wheelchairs to provide the deceleration pulses. This would make the samples independent; however, the data spawned from the analysis may not be as rich. We selected samples (speed/braking combinations) to create a large between-subject variance. This increases the signal-to-noise ratio and power, as well as other beneficial

Table 2.
Means ± standard deviations (SDs) of the wheelchair speed at brake initiation, trunk angular displacement (TAD), velocity (TAV), and acceleration (TAA) are compared between Hybrid III test dummy (HTD) and test pilot (TP) for the three braking conditions: joystick release (JR), joystick full reverse (FR), and emergency power-off (EPO). No statistical differences were present between TP and HTD for all measures.

Trial	Speed (m/s)		TAD (°)		TAV (°/s)		TAA (°/s²)	
	HTD	TP	HTD	TP	HTD	TP	HTD	TP
Slow JR	0.76 ± 0.01	0.75 ± 0.01	5.9 ± 0.3	4.0 ± 1.5	29.6 ± 1.5	24.1 ± 4.9	263 ± 24	247 ± 43
Slow FR	0.76 ± 0.01	0.75 ± 0.01	9.2 ± 0.9	8.4 ± 2.9	34.2 ± 2.4	25.3 ± 4.9	287 ± 19	262 ± 34
Slow EPO	0.76 ± 0.01	0.72 ± 0.01	9.2 ± 0.9	13.1 ± 8.0	40.5 ± 3.5	36.1 ± 9.1	348 ± 28	327 ± 45
Medium JR	1.38 ± 0.00	1.54 ± 0.05	5.3 ± 0.7	3.6 ± 2.4	22.9 ± 3.5	13.1 ± 5.7	189 ± 44	155 ± 52
Medium FR	1.38 ± 0.01	1.58 ± 0.02	6.3 ± 0.9	4.1 ± 1.6	24.8 ± 4.9	18.3 ± 6.2	219 ± 35	217 ± 62
Medium EPO	1.38 ± 0.02	1.56 ± 0.01	18.7 ± 6.1	13.6 ± 2.0	40.1 ± 7.5	29.3 ± 3.2	344 ± 39	302 ± 23
Fast JR	1.97 ± 0.01	1.96 ± 0.01	9.6 ± 0.8	2.1 ± 0.7	22.3 ± 1.2	14.8 ± 2.4	148 ± 47	189 ± 29
Fast FR	1.98 ± 0.01	1.97 ± 0.02	52.5 ± 25.2	57.7 ± 37.6	62.2 ± 22.7	90.1 ± 56.5	230 ± 24	350 ± 136
Fast EPO	1.97 ± 0.01	1.95 ± 0.03	66.5 ± 0.6	83.2 ± 1.2	117.7 ± 5.7	185.7 ± 24.9	377 ± 56	619 ± 84

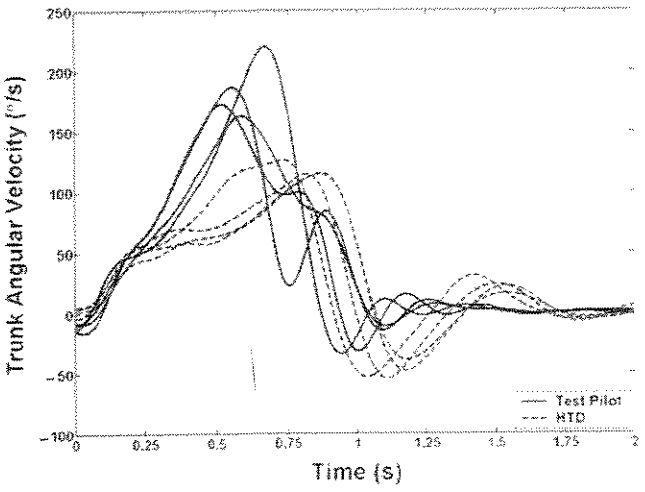

Figure 5.
Trunk angular velocity of test pilot and Hybrid III test dummy (HTD) during 2 m/s emergency power-off braking.

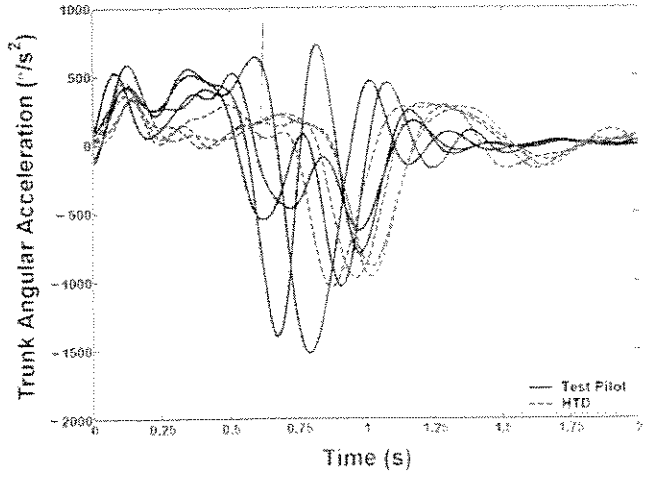

Figure 6.
Trunk angular acceleration of the test pilot and Hybrid III test dummy (HTD) during 2 m/s emergency power-off braking.

effects [17], which prove more valuable than testing many wheelchairs, all at the maximum speed or most severe braking condition.

PBE is used for demonstration of the "prescribability" of a product. This concept is applicable in the terms of this investigation. What is desirable is that testing can be performed with the HTD in place of the TP, or human subjects for that matter. PBE indicates that either may be prescribed (or used).

Table 3.
Geometric means, ratios, and 90% confidence intervals (CIs) associated with determining average bioequivalence of Cmax and AUC of trunk angular displacement (TAD), trunk angular velocity (TAV), and trunk angular acceleration (TAA) curves.

Parameter	Geometric Means			Two One-Sided 90% CIs	
	HTD (T)	TP (R)	T/R	Lower Limit	Upper Limit
TAD					
Cmax	12.9	8.9	1.45	1.03	2.05
AUC	890.9	683.7	1.30	0.99	1.71
TAV					
Cmax	37.5	30.9	1.21	0.97	1.52
AUC	3092.4	2143.3	1.44	1.05	1.99
TAA					
Cmax	253.8	274.0	0.93	0.82	1.04

HTD = Hybrid III test dummy (First Technology Safety Systems, Plymouth, MI)
TP = test pilot
T/R = test/reference
Cmax = maximum concentration
AUC = area under the curve

Table 4.
Upper bound of 90% confidence interval (CI) for constant (con)- and reference (ref)-scaled individual bioequivalence (IBE) and population bioequivalence (PBE) intervals. Variances of reference measures (σ_{WR} and σ_R) indicate that reference-scaled IBE and PBE should be used.

Parameter	Upper Bound, 90% CIs				Reference Variance	
	PBE Ref	PBE Con	IBE Ref	IBE Con	σ_{WR}	σ_R
TAD						
Cmax	−0.87	−0.05	−0.09	0.37	0.33	2.07
AUC	−20.06	−0.36	−10.48	−0.35	0.91	2.96
TAV						
Cmax	−0.51	−0.18	−0.13	0.04	0.17	0.95
AUC	−0.81	−0.04	−0.10	0.31	0.31	1.97
TAA						
Cmax	−0.09	−0.03	−0.05	−0.06	0.06	0.19

TAD = trunk angular acceleration
TAV = trunk angular velocity
TAA = trunk angular acceleration
Cmax = maximum concentration
AUC = area under the curve

IBE was developed because two formulations can possibly have the same mean and variance but produce a different effect when the patient is changed from one to the other. In the context of this study, testing to determine "switchability" would seem unnecessary. After all, why should the HTD behave differently just because the TP

was seated first? No carryover effects between formulations would be expected. For this reason, an unbalanced design was selected (T or R precedes itself three times, but the alternative formulation only once). A carryover effect may be present for sequential doses of the same formulation. For example, the TP, after nearly losing stability on the first trial, may prepare for the remaining three trials, thus reducing the severity of the motion. While this is not possible with the HTD, a tester influence may be aliased within the formulation carryover effect. For example, after a near tip of the HTD, the tester may subconsciously position the HTD differently or enact the braking condition with a slight difference to produce more motion. For these reasons, a carryover effect was included in the model, and IBE testing can detect these aliased effects. The HTD and TP were IBE when reference scaling was used, indicating that the HTD is an ethical and viable alternative to testing with wheelchair users.

Repeatability is an important feature of a test device. The motion curves in **Figures 4** to **6** are similar in magnitude, shape, and phase. This is reflected in the small standard deviations (SDs) of the peak values in **Table 2**. The larger SDs noticeable during the fast-speed, joystick FR braking condition are due to the number of trials in which the test cases fell forward: three of the four trials. In the remaining trial, the test case displaced forward but did not fall over and returned to rest on the seat back. This occurred for both the TP and HTD and may be further qualitative evidence that the HTD is a suitable surrogate for wheelchair testing. **Table 5** summarizes qualitatively the level of trunk stability of the test cases. Since no falls occurred during the study, the occurrence of loss of controls was reported. A loss of control was defined as the event during which the wheelchair rider falls forward but remains in the EPW in a position that would make operating the wheelchair difficult. Also note that the averages of the kinematic parameters of the HTD exceeded that of the TP in most cases but underestimated the motion at the fast driving speed and FR and EPO conditions. This occurred because of a truncation problem. Interference between the pelvis and thighs limited trunk flexion to around 60°. The remaining flexion occurred at the lumbar spine.

Table 5.
"Loss of controls" experienced by test cases during braking trials.

Speed (m/s)	Braking Condition	Test Pilot	HTD
0.8	JR	0/4	0/4
	FR	0/4	0/4
	EPO	0/4	0/4
1.4	JR	0/4	0/4
	FR	0/4	0/4
	EPO	0/4	0/4
2.0	JR	0/4	0/4
	FR	3/4	3/4
	EPO	4/4	4/4

HTD = Hybrid III test dummy (First Technology Safety Systems, Plymouth, MI)
JR = joystick release
FR = full release
EPO = emergency power-off

CONCLUSIONS

The conclusions of this study are mixed, depending on the BE criterion used. ABE methods would tend to indicate that further modifications would be necessary to the HTD for accurate assessment of wheelchair user kinematics during tips and falls. PBE, IBE, and qualitative data would suggest that the HTD is a suitable surrogate. Because this is a novel application of BE, further investigation is required to evaluate BE methods for parameters with large within-subject variability. Another method not approved by the FDA, such as the Kullback-Liebler divergence, is worthy of consideration because it imposes the restriction that IBE constitutes PBE, which implies ABE [18].

REFERENCES

1. Cooper R, Dvorznak M, O'Connor T, Boninger M, Jones D. Braking electric-powered wheelchairs: effect of braking method, seatbelt, and legrests. Arch Phys Med Rehabil. 1998;79:244–49.
2. Kirby R, DiPersio M, MacLeod D. Wheelchair safety: effect of locking or grasping the rear wheels during a rear tip. Arch Phys Med Rehabil. 1996;77:1266–70.
3. Sosner J, Fast A, Begeman P, Sheu R, Kahan B. Forces, moments, and accelerations acting on an unrestrained dummy during simulations of three wheelchair accidents. Am J Phys Med Rehabil.1997;76:304–10.
4. Fast A, Sosner J, Begeman P, Thomas M, Durkman D. Forces, moments, and accelerations acting on a restrained dummy during simulation of three possible accidents involving a wheelchair negotiating a curb. Am J Phys Med Rehabil. 1997;7:370–77.

5. Corfman TA, Cooper RA, Fitzgerald SG, Cooper R. Tips and falls during electric-powered wheelchair driving: effects of seatbelt use, legrests, and driving speed. Arch Phys Med Rehabil. 2003;84:1797–802.
6. Viano DC, King AI, Melvin JW, Weber K. Injury biomechanics research: an essential element in the prevention of trauma. J Biomech. 1989;22(5):403–17.
7. Tennant JA, Jensen RJ, Potter RA. GM-ATD 502 anthropomorphic dummy—development and evaluation. Proceedings of the 3rd International Conference of Occupant Protection; 4–7 June 1974; Society of Automotive Engineers (SAE), SAE 740590; Troy (MI). Washington (DC); The Administration; 1974. p. 394–420.
8. Kaleps I, Whitestone J. Hybrid III geometrical and inertial properties, Society of Automotive Engineers (SAE), SAE 880638, 1988.
9. Development of a flesh-like material [fact sheet]. Simula Government Products, Inc.; 1995 August 18.
10. VanIngen-Dunn C, Hurley TR, Yaniv G. Development of a humanlike flesh material for prosthetic limbs. Available from: http://ieeexplore.ieee.org/iel5/7705/21095/00979152.pdf?arnumber=979152/
11. Dvorznak MJ, Cooper RA, O'Connor TJ, Boninger ML, Fitzgerald SG. Kinematic comparison of Hybrid II test dummy to wheelchair user. Med Eng Phys. 2001;23(4):239–47.
12. Cooper RA, DiGiovine CP, Boninger ML, Shimada SD, Koontz AM, Baldwin MA. Filter frequency selection for manual wheelchair biomechanics. J Rehabil Res Dev. 2002;39(3):323–36.
13. Jones B, Kenward M. Design and analysis of cross-over trials. Boca Raton (FL): Chapman & Hall; 2003. p. 13–14, 323–49, 355–58.
14. U.S. Food and Drug Administration (FDA) guidance for industry: Statistical approaches to establishing bioequivalence. Washington (DC): FDA; January 2001. Available from: URL: http://www.fda.gov/cder/guidance/3616fnl.htm/
15. U.S. Food and Drug Administration (FDA) 21CFR320.1(e): Title 21, Food and drugs; Part CFR320, Bioavailability and bioequivalence requirements; Section .1, Definitions; Paragraph (e), Bioequivalence. Washington (DC): FDA; December 19, 2002 (updated).
16. U.S. Food and Drug Administration (FDA) guidance for industry: Average, population, and individual approaches to establishing bioequivalence. Washington (DC): FDA; August 1999. Available from: URL: http://www.fda.gov/cder/guidance/index.htm/
17. Carrasco J, Jover L. Assessing individual bioequivalence using the structural equation model. Stat Med. 2003;22:901–12.
18. Dragalin V, Fedorov V, Patterson S, Jones B. Kullback-Leibler divergence for evaluating bioequivalence. Stat Med. 2003;22:913–30.

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