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Normalization and Scaling for the Development of Human Injury Probability Curves: General Approach and Current Recommendation

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Executive Summary

Normalization of human injury probability curve (HIPC) response data is used to reduce its variance and thereby reduce HIPC confidence interval width. Scaling is used to shift the basis of an HIPC from the population used in biomechanical experiments to a target population that is outside the range of the experimental population. In the Warrior Injury Assessment Manikin (WIAMan) HIPC data analysis, scaling could be used to account for the subject population used in experiments being substantially older than the WIAMan target population and thus having lower injury tolerance.

Recommendations for initial WIAMan HIPC development for all body regions are not to normalize or scale the biomechanical data. These recommendations are based on results of analyses showing that different methods of normalization did not meaningfully reduce the HIPC confidence interval width. Likely contributors to this finding include the following:

- WIAMan inclusion criteria may have limited the effects of age on tolerance by limiting the range of allowable specimen bone mineral densities (assessed using dual X-ray absorptiometry) to exclude bones with osteoporosis and osteopenia conditions.
- The sample size of the individual component test series is too small for the expected trends to be observed.

Future work should revisit the decision not to normalize or scale. The use of normalization and scaling based on bone mineral density (BMD) assessed using quantitative computed tomography—a medical technique used to measure BMD using a standard X-ray computed tomography scanner—possibly in combination with other methods, is a particularly promising approach. This approach could be used to account for variance in the specimen injury response not controlled for by the specimen inclusion criteria, and shift the basis of injury metrics to better represent the WIAMan 18- to 35-year-old male target population.

1. INTRODUCTION

1.1 Purpose

This report summarizes the general normalization and scaling recommendations for the development of human injury probability curves (HIPCs) in the Warrior Injury Assessment Manikin (WIAMan) program. The report also discusses future work while highlighting the rationale for differences between these methods and those used for the development of biofidelity response curves (BRCs) in the WIAMan program. Although HIPC data normalization and scaling procedures are not recommended for the current WIAMan program, detailed methods have been developed and reported in separate documents by the HIPC Working Group (WG) and are briefly summarized in this document for contextual awareness.

1.2 Scope

A high-level summary of the normalization and scaling methods for HIPC metrics and associated BRCs is presented for WIAMan body regions. Further details of the specific methods used for BRC normalization and scaling exist in the W0084 guidance document (WIAMan, 2015).

2. GENERAL NORMALIZATION AND SCALING APPROACH FOR HIPC DEVELOPMENT

2.1 Biomechanical Basis for Data Normalization and Scaling

Injury tolerance measured in terms of a biomechanical metric (e.g., force at fracture) can be influenced by PMHS characteristics including size, mass, and age, as well as local geometry of the individual PMHS specimen being tested. Each of these factors has an influence on the levels of biomechanical metrics associated with local failure stress in individual specimens and varies with the population of PMHS used in HIPC tests. Normalization techniques are used to minimize the variance in measured HIPC data associated with the influence of each of these characteristics on local stress to failure, and thereby aim to reduce the width of confidence intervals on the resulting HIPCs. Each normalization method relies on an established relationship between a specimen characteristic (e.g., size, bone mineral density [BMD], bone strength) and the injury-correlating metric governed by biomechanics principles.

Scaling methods are mathematically identical to normalization methods and are employed when the PMHS or PMHS components tested are outside of the range of the target population for which HIPCs are intended to be used in injury risk assessment. The most common reasons for scaling are that specimens have a different physical size or specimens are much older than the target population. Scaling methods also require knowledge of the normative values of subject characteristics being used in scaling the tested injury tolerance to that of the target population. These normative values are often not known when they are specific to individual anatomic components (e.g., femur cross-sectional geometry for a 30-year-old male or calcaneus BMD of a 30-year-old male). Such values are particularly difficult to obtain for the combat population for which injury risk assessment is needed.

Specimen and subject characteristics commonly used in normalization and scaling methods include mass, length, cross-sectional geometry (usually area), and structural/material stiffness, primarily because biomechanical relationships between these parameters and biomechanical quantities correlated to injury tolerance have been established based on mechanics principles. Of these characteristics, mass and length are most commonly used as the basis for scaling as they are the parameters for which normative data for the target populations are most commonly available. BMD is also a normalization and scaling parameter of interest for the WIAMan program because WIAMan HIPCs are primarily based on skeletal fractures, and BMD has been positively correlated to bone failure stress/strain at locations in long bones (e.g., the femoral neck) and in lumbar vertebrae (McBroom, 1985; Ortoft, 1993). This represents the effect of BMD on the local stress to failure in bones and is independent of size effects on stress to failure in materials.

The underlying mechanisms of bony fracture are generally governed by the local bone stress and strain. However, because ATDs do not measure stresses and strains and the measurement of local stress and strains at a point of fracture is difficult in PMHS tests, HIPCs (and therefore injury assessment reference curves) are most commonly expressed in terms of forces or moments. Both are directly measurable in PMHS tests or calculable in posttest data analysis, and can be translated to ATD load cell measurements through match-paired biomechanical tests.

The goal of normalizing HIPC response data is to establish all of the PMHS tests on an equivalent stress/strain basis for geometry/mass (size and inertial effects) or BMD (underlying strength of material effects) to minimize the confidence interval size of the resulting HIPC. As the bone fracture is mostly localized to a specific bone or a small area of a large bone, the normalization value should generally be taken from the fractured bone. For example, calcaneus BMD should be used to normalize the data for calcaneus HIPC. Data normalization is not needed if there is evidence to show that this additional process would not reduce, or could even increase, the confidence interval width. This may occur simply because of uncontrollable variation in specimen covariates such as age or BMD in the small number of samples tested in the WIAMan program. For example, a statistical regression function between a bone strength and age could have a large variance (low R-square value) due to other confounding factors while that variance could be greater than the total age effect on the bone strength within tested PMHS specimens 50–80 years old. This situation would be worse when the data sample size is small, which is common in injury biomechanics studies that use PMHS specimens. Therefore, using age to normalize data to minimize age effect on bone strength may not always improve the normalized confidence interval size in the HIPC development. The number of samples needed for this process to be effective would depend on the size of the variance and the regression line slope (sensitivity of the bone strength to age or any other factors), which are bone-specific.

2.2 Biomechanical Quantities for Use in HIPC Normalization/Scaling

The biomechanical parameters used in normalization/scaling depend on the type of injury metric. For example, size normalization for vertebral body compression fracture force would use the cross-sectional area of the vertebral body. The bending moment for femoral shaft fracture would use the cross-sectional area moment of inertia for data normalization.

2.3 Comparison of Methods between HIPC Data and BRC Data

BRC data normalization and scaling for the WIAMan has two objectives: 1) minimize BRC corridor area due to biological response variance of the specimens within the PMHS group inherent in their size and mass distribution, and 2) scale the response values to the reference size and mass properties of the WIAMan, if they exist. For example, WIAMan has a set of target body segment masses such as a foot, leg, thigh, pelvis (with abdomen), and torso and associated moments of inertia for the design of WIAMan, which could be used as reference values for the

PMHS data scaling to the WIAMan target population. Many of the BRCs for WIAMan included both data normalization and scaling to facilitate better WIAMan biofidelity assessment. However, the scaling step was not carried out for certain components such as cervical and lumbar spines as their normative values for the WIAMan target population for the cross-sectional areas of the spine or individual bones do not exist.

BRC and HIPC sometimes would use different quantities to normalize or scale the PMHS data. For example, BRC would use the leg component mass to normalize or scale the leg-foot response acceleration or force data while HIPC would use the bone cross-sectional area or BMD to normalize/scale the injury response force data. Similarly, BRC would use the intervertebral disc area and height to normalize the cervical or lumbar spine data while HIPC would normalize the vertebral body cross-sectional area to minimize the size effect and scale the BMD to adjust for the bone strength difference due to large age difference between the PMHS population and WIAMan target population.

3. WIAMAN RECOMMENDATIONS ON HIPC NORMALIZATION AND SCALING

Currently, the WIAMan program recommends that normalization and scaling methods not be used on PMHS data in the development of the HIPC products for the following reasons:

1. Scaling requires established relationships between subject characteristics, such as BMD and bone geometry, and injury metrics/tolerance. It also requires normative data for these subject characteristics. Such normative values are not currently available for most WIAMan body regions.
2. Although calculating BMD using quantitative computed tomography (QCT) image data is a promising technique, the processes for standardizing the calculation are still being developed and validated, and are therefore not available at the time HIPC products are due to be delivered.
3. Initial analyses of body-region-specific HIPC datasets showed inconsistent effects or minimal benefit of data normalization on HIPC confidence interval width, likely because the sample size was not sufficiently large for theoretical trends underlying scaling to overcome intra-specimen variability. The amount of additional work in return for inconsistent or inconsequential benefit did not justify a recommendation to normalize for these HIPC products.

The specific normalization and scaling methods and their associated calculation procedures using QCT images acquired from PMHS specimens will be described in separate documents dedicated to the individual component types. Those component types include cervical spine, lumbar spine, pelvis, long bones of the lower extremities (femur and tibia shafts), and foot-ankle. Those documents will be the knowledge products of the WIAMan Biomechanics Scaling WG for consideration of future work.

The following sections outline force HIPC and BRC recommendations for the individual component types. Each section begins with a tabular summary (Tables 1–5) of each force recommendation.

3.1 Cervical Spine

Table 1. Recommendation for Scaling or Normalization of Cervical Spine Force

Force HIPC Recommendation	Force BRC Recommendation
Do not normalize or scale.	Normalize force ratio of the average of the cervical spine intervertebral disc (IVD) area across all specimens in the test series to the average IVD area of an individual specimen.

For BRCs, the recommendation for the cervical spine was to normalize axial compressive force from a specimen using the ratio of the average of the cervical spine intervertebral disc (IVD) area across all specimens in the test series to the average IVD area of an individual specimen. Deformation (compression) BRCs were normalized using a ratio of the across-specimen average cervical column length to the cervical column length of an individual specimen. As moment is force over distance, the recommended approach for determining a normalization ratio for moment was based on the normalization ratio of axial forces and displacements (WIAMan, 2015).

The Biomechanics Scaling WG rationalized that the mid-vertebral-body area was an appropriate parameter to use in normalization as failure is occurring in the vertebral bodies and is associated with stress exceeding a critical value. An analysis of the effect of this normalization using Duke University’s vertebral-body fracture HIPC data (HN-HIPC1) showed marginal improvement on its confidence interval width (CIW) or normalized confidence interval size. Conversely, analyses performed by the Medical College of Wisconsin to develop cervical spine HIPCs using the mid-IVD area as a co-variate suggest that normalization using the IVD area may even increase CIW. Based on these findings, a programmatic decision was made not to normalize HIPC data for cervical spine HIPCs delivered in the current WIAMan program.

3.2 Lumbar Spine

Table 2. Recommendation for Scaling or Normalization of Lumbar Spine Force

Force HIPC Recommendation	Force BRC Recommendation
Do not normalize or scale.	Normalize force ratio of the average of the reference lumbar spine intervertebral disc (IVD) area to the average IVD area of an individual specimen.

For BRCs, the recommendation was to normalize axial compressive force of individual specimens to the group mean and scale to the WIAMan reference population using the ratio of average L2–L4 IVD areas. Because such reference values for the lumbar spine were not available, a PMHS sample mean IVD area of L2–L4 was established by averaging the initial set of specimens tested at Duke University. The scaling process, as is defined in this document, was therefore not carried out for the lumbar spine BRC development. Deformation (compression) BRCs were normalized using a ratio of the initial Duke University average lumbar column length to the column length of an individual specimen using the same set of PMHS lumbar specimens. As moment is force over distance, the recommended approach for determining a normalization ratio for moment was based on the normalization ratio of axial forces and displacements.

The initial MCW lumbar spine HIPCs were developed based on compressive force metrics and data normalization using the BRC normalization procedure based on IVD area as previously

described. However, initial Duke University lumbar spine HIPCs were developed using a force normalization based on average mid-vertebral-body area. Based on discussions by the Biomechanics Scaling WG to rationalize these two approaches, it was decided that the mid-vertebral-body area was a more appropriate parameter to use in HIPC normalization as failure is occurring in the vertebral bodies, rather than the IVD, and is associated with stress exceeding a critical value. However, initial analyses of Duke University lumbar spine HIPC data showed that normalization using the mid-vertebral-body area did not reduce scatter in the HIPC data, likely because of the confounding BMD effect on the bone strength which was not included in their data normalization. Based on this finding, a programmatic decision was made not to normalize HIPC data for lumbar spine HIPCs delivered in the current WIAMan program.

3.3 Pelvis

Table 3. Recommendation for Scaling or Normalization of Pelvis Force

Force HIPC Recommendation	Force BRC Recommendation
Do not normalize or scale.	Equal stress–equal velocity normalization.

Analyses of HIPC data performed by The Johns Hopkins University Applied Physics Laboratory (JHU/APL) showed no clear benefit of normalization on confidence interval size. Therefore, HIPCs are delivered without normalization or scaling. In contrast, BRC normalization recommendations involved equal stress–equal velocity scaling as described in the BRC data normalization method document (WIAMan, 2015). The PMHS BRC response values were normalized within the same PMHS test series and then scaled to the WIAMan target pelvis mass, which were supplied by the WIAMan ATD production team (WIAMan, 2015).

3.4 Femur Shaft and Tibia Shaft (Long Bone Bending)

Table 4. Recommendation for Scaling or Normalization of Long Bone Metrics

Force HIPC Recommendation	Force BRC Recommendation
Do not normalize or scale.	No similar recommendation, as femur and tibia shafts in bending do not have any BRC products.

Based on analyses of femur HIPC data collected by the University of Virginia, which were performed by Wake Forest University and Duke University, normalization of femur HIPC bending-moment and shear-force HIPC data performed using a number of plausible approaches (e.g., based on cross-sectional area moment of inertia) do not reduce the variance in the resulting HIPC data or improve HIPC fit. As a result, a recommendation was made that the femur HIPC data should not be normalized. The same recommendation was made that the tibia shaft HIPC

data should not be normalized, as the bending responses and injury patterns followed the same mechanics principles.

No component femur BRC tests exist, and the only femur BRCs are based on kinematic parameters from whole-body PMHS tests in which femur force and moment were not measured. Therefore, comparable BRC and HIPC metrics do not exist and a direct comparison of scaling methods is not possible. The same can be said for the tibia shaft in bending mode.

3.5 Foot-Ankle

Table 5. Recommendation for Scaling or Normalization of Foot/Ankle Metrics

Force HIPC Recommendation	Force BRC Recommendation
Do not normalize or scale.	Equal stress–equal velocity normalization based on total specimen component mass.

Foot-ankle BRCs were developed using equal stress–equal velocity normalization (Eppinger, 1984). The PMHS BRC response values were normalized within the same PMHS test series and then scaled to the WIAMan target leg and foot masses, which were supplied by the WIAMan ATD PT (WIAMan, 2015). The calcaneus HIPCs were based on the heel contact force, which was not part of the required BRC parameters and therefore did not have a comparable BRC normalization method. Calcaneus HIPC data were not normalized or scaled based on analyses conducted by JHU/APL that showed little effect of specimen mass on heel force responses. Other current WIAMan HIPCs for the foot-ankle anatomy would also follow the same programmatic decision to not normalize or scale.

4. CONCLUSIONS AND NEXT STEPS

A decision was made that the initial WIAMan HIPC deliverables should not be normalized based on the results of preliminary analyses, suggesting that BRC normalization methods did not meaningfully or positively affect HIPC confidence intervals. Further, normative reference values of the WIAMan target population were lacking for proper execution of data scaling processes. Normalization and scaling methods based on QCT-based BMD are under development by the Biomechanics Scaling WG. Such methods should be considered in future normalization and scaling activities to account for differences in age between the WIAMan PMHS specimen population and the WIAMan combat male population, which are not addressed by WIAMan inclusion criteria, as they may reduce variance in HIPCs and, in some cases injury assessment reference curves, when the traditional match-paired method is not used.

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Appendix A – List of Acronyms

ATD	anthropomorphic test device
BMD	bone mineral density
BRC	biofidelity response curve
CIW	confidence interval width
HIPC	human injury probability curve
IARC	injury assessment reference curve
IVD	intervertebral disc
JHU/APL	Johns Hopkins University Applied Physics Laboratory
PMHS	postmortem human surrogate
QCT	quantitative computed tomography
WG	working group
WIAMan	Warrior Injury Assessment Manikin

Appendix B – Glossary

Anthropomorphic Test Device (ATD): A physical device with size, shape, and biomechanical response characteristics representative of a target population of living humans. Embedded sensors within the ATDs enable the measurement of biomechanical responses associated with injury-metrics-based injury assessment reference curves (IARCs). The correlation of these metrics to specific injuries enables ATD to predict the probability of specific injuries in test and evaluation applications.

Biofidelity of ATD: Biofidelity is the degree to which a model represents a biologic system or structure on which it is based. Biofidelity of an ATD signifies the degree to which the ATD, as a human surrogate, represents the living human biomechanically. It is typically assessed in terms of how closely the ATD matches the biomechanical responses of a postmortem human subject (PMHS).

Biofidelity Response Corridor (BRC): BRC is a representative range of time-dependent biomechanical responses from multiple experimental tests of a parameter from multiple biological surrogates (often PMHS). It includes a mean time-dependent curve and two curves that make up the upper and lower bounds (corridors) of the mean using standard deviations of the mean.

Human Injury Probability Curve (HIPC): A statistical relationship between a continuous biomechanical parameter measured in physical tests (or calculated from the results of physical tests) with a postmortem human surrogate and the probability of a particular injury.

Injury Assessment Reference Curve (IARC): A statistical relationship between a continuous biomechanical parameter measured (or calculated from measured data) in physical tests or simulations with an ATD and the probability of a particular injury to a human.

Injury Data Normalization: The process by which biomechanical injury metric values (measured or calculated injury responses) are adjusted to reduce within-group variance (e.g., adjusting injury tolerance values to account for a subject being either weaker or stronger than the mean that is contained within the range of the experimental sample).

Injury Data Scaling: The process by which biomechanical injury metric values (measured or calculated injury responses) are shifted from the subject/specimen population to a reference population that differs from that used in an experiment. An example would be shifting tolerance values from the set of 50- to 80-year-old male specimens used in HIPC testing to a 30-year-old male reference, which is the single reference age selected for the WIAMan program. This shift in reference population was done for scaling based on the proposal submitted by the HIPC WG and confirmed by the WIAMan Engineering Office.

Injury Metric: A biomechanical response quantity measured or derived from PMHS testing that has statistical correlation to injury outcome and severity for a given bone or anatomical component (e.g., force, moment, acceleration, or strain).

Normalization versus Scaling: The following definitions of normalization and scaling for PMHS specimen data illustrate the different utility of the data treatments:

- **Normalization:** Adjusting injury metric values of individual PMHS specimens relative to the group mean to minimize response differences due to biological variation within a group of specimens. This procedure can normalize data from PMHS of varying anthropometry, mass distributions, and various other properties within the PMHS specimen samples of the same data set before they are used to generate a single HIPC.
- **Scaling:** Adjusting the mean injury metric values from one group of PMHS data to a target group of human population. An example of scaling is changing from a 50th male to a 5th female. Another example would be changing from an elderly male population to a young male population. In the context of WIAMan biomechanics products, this scaling would change the values of biomechanical injury metric data from male PMHS of varying ages—mostly the elderly population—to the WIAMan application target population of mostly strong and fit young males.

Postmortem Human Surrogate (PMHS): A term for human cadaveric specimens serving as human surrogates in biomechanical tests that are partially representative of living human subjects of the target population.

Appendix C – Distribution List

ORGANIZATION

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