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Procedure to construct injury risk curves for the evaluation of road user protection in crash tests

Procédure de construction des courbes de risques pour l'évaluation de la protection des usagers de la route dans les essais de choc

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Foreword

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The committee responsible for this document is ISO/TC 22, *Road vehicles*, Subcommittee SC 12, *Passive safety crash protection systems*.

Procedure to construct injury risk curves for the evaluation of road user protection in crash tests

1 Scope

The aim of this Technical Specification is to provide a procedure to develop injury risk curves for biomechanical samples. These samples are often heavily censored and limited in size, such that specific steps and checks are required when developing injury risk curves. Moreover, several statistical methods were historically used to build injury risk curves. The curves resulting from the different methods could be rather close or fairly different, depending on the biomechanical samples. It is therefore of major importance to recommend a consensual method to be used. Otherwise, injury thresholds candidates to be included into regulations could be highly influenced by the statistical method used. These different methods were compared in a statistical simulation study[10]. The conclusions of this study were used to recommend the survival analysis.

This Technical Specification identifies steps to be followed to develop injury risk curves. It recommends preliminary checks, statistical method, and recommendation process of the injury risk curve. Guidelines on the type of the samples to be used (cadaver, animal, or dummy), as well as the variables to be used, and the injury severity level are beyond the scope of this Technical Specification.

2 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

2.1
injury risk curve
curve giving the probability, for a defined population and for a given input, to sustain a specified severity of injury

2.2
injury risk function
mathematical function that relates a value of an injury criterion and possible additional factors (variables) to a risk of sustaining an injury of a certain level

2.3
injury criterion
physical parameter which correlates well with a scale of injury severity of the body region under consideration

2.4
injury value
value of an injury criterion

2.5
injury mechanism
mechanical behavior leading to an injury

2.6
abbreviated injury scale
AIS
scale allowing for the classification of injury severity

2.7
variable
parameters which contribute to the prediction of the injury severity

3   Methodology

3.1   General

An injury risk curve corresponds to a statistical modelling of biomechanical data in order to predict the risk of injury. Some general steps are required, as for any statistical model. The modelling includes the choice of the variables to be used in the model. The choice of the model is also of major importance. Once done, the variables of the model are estimated. Essential further steps are to check the assumptions of the model and evaluate the model fit relative to the data used. The prediction is finally made possible when the checks are done.

3.2   Collect the relevant data

The first step is to collect the relevant data, including injury types and severities, and injury values measured during the tests.

There is no specification for the injury severity level (AIS ≥2, AIS ≥3) or the type of injuries evaluated (fracture, soft tissue contusion, etc.).

The data could also include variables such as the Post Mortem Human Subject (PHMS) characteristics (age, bone mineral content, gender, etc.).

The choice of the variables to be included in the construction of the injury risk curves is out of the scope of the guidelines. The researcher's expertise should guide this decision and is expected to vary depending on the body region and injury mechanism considered.

3.3   Assign the censoring status

Once the biomechanical data are available, the censoring status must be assigned (left, right, interval censored, exact).

Data are left-censored or right-censored if the measured injury value is greater than or less than the injury threshold, respectively. The injury threshold is the minimum value that is associated with the occurrence of injury for that subject. Data are interval-censored when the injury threshold is bounded within a known range of injury values.

The censoring status can be provided by a coding which might differ from one statistical software to another and should be checked before the user analyses the data. It can also be provided using a mathematical formulation for censoring without coding, giving the interval (e.g. right-censored data are an interval from the injury value to eternity). The correct censoring according to the used software or function is to be used.

After this step, the data set includes the measured injury values, and possibly, the associated coding for the censoring status indicated.

3.4   Check for single injury mechanism

The complexity of the human body might lead to different injury mechanisms[3]. This could lead to injury risk curves with changes of slope and discontinuities. The next step, before applying a parametric method to build an injury risk curve, is to check that the biomechanical sample only included a single injury mechanism.

This is achieved by building the injury risk curve with the Consistent Threshold Estimate (CTE)[3] for doubly censored data and extended CTE for a mix of actual and censored data[4]. Visually inspect the resulting step function for changes in slope which can be indicative of different injury mechanisms.

If there is evidence of multiple injury mechanisms, separate the biomechanical sample into samples with single injury mechanism before starting again the guidelines given at 3.2. If there is no evidence of

multiple injury mechanisms, use the survival analysis to build the injury risk curve[6][7][8][10] according to the following steps.

3.5 Estimate the coefficients

The coefficients should be estimated with the survival analysis method. Substantially different results can be obtained when extrapolating outside the range of observed data.

Several distributions should be evaluated in order to recommend the one that best predicts the injury risk function. Consider Weibull, log-normal and log-logistic distributions prior to using a more complicated spline formulation in case one of the other distributions is not confirmed in 3.7.

3.6 Identify overly influential observations

Overly influential observations can be identified using the dfbetas statistics. The dfbetas statistic gives an indication of the change of each parameter estimate when deleting one observation of the sample at a time.

The dfbetas corresponds to the difference between the regression coefficient when all the data is included and the regression coefficient calculated with one observation is deleted, scaled by the standard error calculated with the observation deleted. The dfbetas is calculated for each coefficient and for each observation.

Choose a cut-off value close to the cut-off value recommended in Reference [1] given the size of the biomechanical samples [2/sqrt (sample size)]. For the biomechanical sample generally available in the biomechanical field, an absolute value of the dfbetas statistic higher than 0,3 give an indication that the associated observation might be overly influential.

These observations are checked for any specificity. If there is no evidence of difference between these observations and the others included in the sample, keep these observations in the construction of the injury risk curve.

3.7 Check the distribution assumption

Check the assumed distribution. One way is to check graphically using a Q-Q plot ("Q" stands for quantile)[5][11]. The plot of the percentiles of the distribution against the corresponding percentiles of the biomechanical sample is presented in the Q-Q plot. If the plot follows a line through the origin with slope equal to one, then the chosen distribution is appropriate.

Another way to check is to graphically plot the cumulated risk calculated with the survival analysis, with a given distribution against the cumulated risk calculated with the CTE method. If the cumulated risks lie close one to the other, then the chosen distribution is appropriate.

Note that this is not possible if survival analysis is performed with more than one variable.

3.8 Choose the best distribution

Choose the distribution with the best fit based on the Akaike information criterion (AIC).

The AIC criterion assesses the likelihood that the model takes into account the number of variables used in the model (AIC = −2*log likelihood+2*number of variables).

The lowest AIC indicates the best fit of the model with the test data. Of the three distributions, select the one with the lowest AIC.

3.9 Check the validity of the prediction

Check the validity of the injury risk curve predictions against existing results (such as accidentology outcome), if available.

3.10 95 % confidence intervals and its relative size

Calculate the 95 % confidence interval of the injury risk curve with the normal approximation of the error.

The relative size of the confidence interval is defined as the width of the 95 % confidence interval (upper limit minus lower limit of 95 % confidence interval) at a given injury risk, relative to the value of the stimulus at this same injury risk. Perform the calculation at the 5 %, 25 %, and 50 % risks of injury.

3.11 Quality index

Four categories of the quality index are defined, based on the relative size of the 95 % confidence interval ("good" from 0 to 0,5, "fair" from 0,5 to 1, "marginal" from 1 to 1,5, "unacceptable" over 1,5).

The ranges of the quality indices were established to distribute injury risk curves from biomechanical samples into four categories. Provide the quality index along with each injury risk curve.

3.12 Recommendation of the injury risk curves

3.12.1 Principle

It is recommended to select only one injury risk curve per body region, injury type, and injury level.

The injury risk curve recommended should be a function of the more relevant injury measure associated with the single injury mechanism of the sample.

This recommendation is intended to avoid inconsistent injury risk predictions due to contradictory criteria. However, there is no problem to recommend several injury risk curves for a given body region if they address different injury mechanisms (as for example, rib deflection can be the best predictor of thoracic skeletal fractures, while viscous criterion from the ribs can be the best predictor of thoracic soft tissue injuries).

3.12.2 Selection of one injury risk curve

If several injury risk curves can be compared with AIC and if the difference of AIC is greater than two, then the curve with the lowest AIC is selected among the others.

The cut-off values shown in Table 1 were proposed by Burnham and Anderson[2]. The absolute AIC value was not used, but the relative AIC values over a set of injury risk curves were considered to recommend the more appropriate one.

Note that AIC values can only be compared for injury risk curves developed from different injury measures for the same biomechanical samples (the same sample size and the same coding of censoring status).

Table 1 — Difference of one model compared to the model with the lowest AIC

Difference of AIC between a model and the model with the lowest AIC	Difference between the two models
From 0 to 2	Essentially none
From 4 to 7	Slightly more
Higher than 10	Substantial

3.12.3 Non-recommendation based on the quality index

If an injury risk curve had an "unacceptable" quality index (>1,5), it should not be recommended.

3.12.4 Engineering judgment

If after evaluating the AIC differences and the quality indices several injury risk curves are still available for a given injury type and severity level, then engineering judgment should be used to recommend one curve over the others.

3.12.5 Presentation

Finally, the recommended injury risk curves should be provided with their associated quality indices.

If the non-parametric maximum likelihood estimate of the survival analysis shows large steps in some levels of risk, cautions should be considered when using the parametric survival analysis in this area. An estimate of an injury risk below the lowest injury value observed should be used with caution.

4 Related electronic documents

The files providing the R scripts to be used for the construction of the injury risk curves are gathered in related electronic documents posted on the ISO website at the following link:

http://standards.iso.org/iso/18506

— RED1: R scripts to build curves as a function of one variable;

— RED2: R scripts to build curves as a function of one variable and of age.

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