Selected Aspects of the Experimental Methods of Impact Biomechanics

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Abstract

Owing to the specificity of the experimental tests conducted in impact biomechanics, whose subjects are volunteers, cadavers or animals, ethical and legal aspects are just as formidable as the restrictions of 'technical nature'. The first part of the paper presents fundamental ethical principles, universally accepted by the international community, which must be followed in the course of conducting biomedical experimental tests (including those that fall under the category of impact biomechanics). The second part is a presentation of the preparation (e.g. to install a great number of measurement sensors, necessary for collection of as much data as possible regarding the behaviour of individual body parts under impact load) and course of experimental tests in which human cadavers were subjected to different loading scenarios of the thorax. The purpose of these tests was to identify the parameters and to validate an advanced simulation model of the human thorax developed within the THOMO project.

Keywords: impact biomechanics, ethical and legal aspects, human cadavers, experimental works

1. Introduction

Impact biomechanics is a field of research dedicated to the examination of phenomena that occur in the bodies of humans (or animals), especially in their musculoskeletal and circulatory systems, as well as in their internal organs, under conditions of loading characterized by short time of duration (usually of few/few tens of milliseconds) and very high amplitudes (such as acceleration reaching few tens/few hundred times the gravitational acceleration).

Experimental tests constitute an important element of the cognitive process in science. This applies also to biomechanics of the human body, including impact biomechanics. However, the specificity of the issues that are investigated by impact biomechanics places certain limitations on the options of experimental tests. This especially concerns tests with the participation of volunteers. In this case, tests conducted under conditions closely imitating real-life incidents could potentially lead to severe injuries or even death.

For this reason, experimental tests in impact biomechanics resemble puzzle pieces – tests avail themselves of both volunteers, animals and post-mortem human subjects (PMHS) that complement each other.

Computer modelling methods, whose rapid advancement is observed in parallel with the increasing computing power of computers and development of specialized software, play an important role as regards correct interpretation and generalization of results obtained from such experimental testing.

Owing to the specificity of these tests, whose subjects are volunteers, cadavers or animals, ethical and legal aspects are just as formidable as the restrictions of 'technical nature'.

2. Ethical and legal aspects of conducting experimental research with the participation of volunteers and with the use of cadavers/biological material

The use of human cadavers or segments/tissues extracted from them in experimental tests raises particularly heated controversies. For moral, ethical and religious reasons, some parts of the public opinion (these parts vary in size depending on the country/cultural circle/religion/...) are convinced that the use of human cadavers (PMHS – Post-mortem Human Subjects) in biomechanics research, including for the purpose of enhancing traffic safety, should not be taking place.

This belief is often supported by the message sent out by the mass media, which tend to purport that dummies and computer models are sufficient to conduct research on systems designed to improve vehicle safety. This is not true – both dummies and computer models (despite the very rapid advancements in the field of modelling over the recent years) are still far from perfect.

Of pivotal significance is the improvement of *biofidelity* of dummies and computer models. This requires tests with the use of PMHS in order to collect data regarding properties of tissues, of the mechanisms of their injuries, as well as the global responses of human bodies, indispensable for their validation.

The use of human cadavers is not only one of the methods of researching crash impact on the injuries of accident victims, but also one of the most important ones. In 1995, King and Viano [1] estimated the number of survivors attributable to the development of safety engineering and they compared this number with the number of PMHS used in biomechanics testing. They have calculated that each PMHS employed in research on the improvement of safety has saved the lives of over 60 people.

Two documents contain a collection of fundamental ethical principles, universally accepted by the international community, which must be followed in the course of conducting biomedical experimental tests (including those that fall under the category of impact biomechanics): *The Nuremberg Code* (1946) [2]and the *Declaration of Helsinki* (1946, as subsequently amended) [3].

The provisions laid down in these documents have been introduced, directly or following relevant adaptations, to the national legislation all over the world.

The above-mentioned documents do not deal directly with the use of cadavers in scientific research, but they do not contain prohibition of such research, either. Given the absence of other legal regulations, it is assumed that they may be expanded to include research with the use of human corps.

The first of the foregoing document, released in 1946 as a result of the Nuremberg Trials in response to information about the criminal medical experiments conducted on prisoners of Nazi concentration camps, sets out what may be referred to as the decalogue (formulated in 10 points) establishing the fundamental principles of conducting (generally speaking) medical experiments on human subjects.

Particular focus, in the form of an extensive commentary, has been placed on its first point: "The voluntary consent of the human subject is absolutely essential".

This provision – of pivotal significance in 1946, that is shortly following the plight of prisoners of WWII concentration camps – still holds as the central tenet.

The second of these documents (*Declaration of Helsinki*), repeatedly amended by experts connected to the Council for International Organizations of Medical Sciences (CIOMS), in collaboration with the World Health Organization (WHO), upholds all the vital principles set out in the *Nuremberg Code*, expanding its scope to cover purely medical research associated with the introduction of new medications and medical procedures. It also offers interpretations and clarifications of the Nuremberg principles. An important new element, formulated in Guideline 2: *Ethical Review Committees*, is the requirement to conduct all research whose subjects are human beings under the close supervision of an appropriate ethical committee/commission.

Human cadavers are only used for biomechanics research in a small number of countries. This is owing to a number of reasons. In some countries, such research is prohibited by law or by religious principles; in others, they are not conducted due to the pressure exerted by the public opinion.

Everywhere where such research is allowed, it is subject to tight supervision and conducted with observance of established rules [4, 5].

In France, the Bioethics Law no. 94-654 of 29 July 1994 concerns the extraction of organs for diagnostics, transplantation or other scientific purposes. It is presumed that, unless otherwise stated, organs may be used for transplantation.

On the other hand, if a body or its individual organs are to be used for purposes other than transplantation or establishment of the causes of death, a relevant consent must be signed and pre-registered (body donation programme).

If the deceased had previously signed consent for the donation of his body for research, his family may not object to this. If the will of the deceased is not known, the decision is made by the family.

In Germany, use of bodies is subject to the law on organ transplantation, even though this piece of legislation does not make any explicit stipulations about whole-body donations.

A part of the PMHS comes from people who had signed a relevant agreement, establishing the scope of purposes for which their bodies may be used after their death. However, in the majority of cases, members of the closest family of the deceased are asked for consent to donate bodies for biomechanics research (this consent must be expressed in writing). Prior to signing, they are informed of the type of load that will impact the body, the expected type and gravity of injury, the type of autopsy which will be carried out, and of the collection and keeping of samples for further testing.

As for the United States, there exists the obstacle of mutually exclusive acts of law, as well as of differences between states.

The violation of bodily integrity (profanation) is prohibited.

In some states, body donation for scientific purposes is allowed, yet under various conditions. In some cases, consent to such donation must be registered prior to death, while the family may still object to it.

In other states, such consent may not be expressed prior to death. It is only after a person has passed away that their family may agree to the use of the body for scientific purposes.

Scientific activities in the area of impact biomechanics is regulated by detailed provisions of law (such as NHTSA Orders 700-3 and 700-4).

In the United States, there are a few places where PMHS research is conducted. Each of these places has their own, strict protocol to be followed. Below are the basic principles in place at one of the Laboratories in the USA.

This particular state has a body donation programme – interested parties sign consent for their bodies to be used for scientific purposes following their death.

Additional consent is necessary for civil-purposes crash tests.

Another consent must be expressed for military-purposes crash tests.

After death, and upon verification of the scope of consent granted by the given person, the coroner/another authorized institution, forwards the information to the Laboratory, and enquires whether they are interested in such particular body.

If so, the Laboratory contacts the closest family members (if possible) and asks whether they agree to the use of the body in the planned tests. The family receives general information only, no specific descriptions of the tests are provided.

If the family's answer is NO (regardless of the consent given by the deceased), the Laboratory withdraws from taking over the body.

If the answer is YES, the body undergoes medical tests (carriage of determined viruses, CT scans, etc.) and, based on the results, it either qualifies to be used in given tests (recorded in the database and placed in a freezer), or is returned.

Prior to the test, a protocol outlining in detail how the body is to be handled, as well as a thorough description of tests to be conducted, is presented to a specially committee.

During these tests, each of the Laboratory employees must follow the internal protocol regarding tests involving biological material (special outfits, covering the face of the deceased, etc.).

In each test, great emphasis is placed on the proper collection, recording and storing of the greatest amount of data possible, both for ongoing and future research, so as to ensure that each test with the use of PMHS renders as much information as possible.

Following the tests, the whole body or its individual segments/tissues may be re-used.

If the body/segments can no longer be used, they are returned to the family (if the family wishes to have it returned), or cremated. Once a year, the Laboratory organizes a scattering ashes ceremony, of which families are also notified.

<u>To sum up:</u>

- Tests with the use of PMHS are an important source of data indispensable for getting to know the mechanisms of how human bodies are injured when subjected to impact loads, which is the necessary condition for further progress in preventing injuries that result from, among others, traffic accidents.

- In order to minimize the critical attitude of some portions of the public opinion toward such research, it must be conducted with observance of ethical principles and in strict conformity with the provisions of law in the each country.
- Ethical Committees, responsible for adopting the test scopes and protocols, as well as for the oversight of these tests, have an important role to fulfil in this respect.
- It is necessary to improve the collection of test results and make them available to all interested science centers in order to avoid repetitions, and to ensure the fulfilment of the principle that guides those willing to donate their body after death to science: donation for science = donation for the humanity.

3. An example of experimental tests with the purpose of identification of parameters and validation of an advanced model of human thorax

What follows is a presentation of the preparation and course of experimental tests in which human cadavers were subjected to impact loads. The purpose of these tests was to identify the parameters and to validate an advanced simulation model developed within the THOMO project [7, 8].

THOMO project (*Development of a Finite Element Model of the Human Thorax and Upper Extremities*), was carried out under FP7 of the European Community (contract number: SCP7-GA-2008-218643), in the period from 2009.01.01 to 2012.10.30, by an international consortium which included 4 research teams: CEESAR – Centre Européend'Etudes de Sécurité et d'Analyse des Risques (Nanterre, France), UVHC – Université de Valenciennes et du Hainaut Cambrésis (Valenciennes, France), UWB – University of West Bohemia (Plzen, Czech Republic) and the Institute of Aeronautics and Applied Mechanics of the Warsaw University of Technology– Virtual Safety Engineering and Biomechanics Laboratory (ViSEB). CEESAR was the project coordinator.

THOMO aimed to develop new, greatly improved models of the human thorax with upper extremities, both 'standard' (5th, 50th and 95th percentile) and 'personalized' (for any type of body build).

The developed models should ensure appropriate (stable, resilient to changes of parameters, natural for biological systems and with proper *biofidelity* properties) behaviour of solutions during simulation tests with their use (the problem of *3-R: Rating, Reliability, Robustness* [6]).

The complicated structure of the thorax model was described with ca. 400 thousand elements, which allowed for a detailed modelling of the thorax anatomy, accounting for many different muscle groups, bones, main blood vessels, etc., as well as for the interactions between them and the varied material properties.

The method used was the Finite Element Method (FEM), implemented in the LS-DYNA package.

Already at the initial stage of drafting the project application, cooperation was initiated with the Global Human Body Model Consortium (GHBMC). This was facilitated by a research group from University of Virginia (USA), which acts as the centre of expertise of GHBMC for the thorax and upper extremities. This cooperation made it possible to exchange data and information about test results and updates introduced based on them, as well as about the research methods used/developed. Results of the THOMO project were implemented in the final human body model developed by GHBMC. The employment of such an advanced model by the automotive industry and by research centres which work for it, including academic centres, should facilitate the design of increasingly safe vehicles, thus reducing the number of traffic accident injuries, especially serious ones, and deaths.

Two basic research directions were pursued under the THOMO project – experimental tests and computer modelling works.

The experimental tests were carried out by French teams: CEESAR (primarily crash tests with the use of whole-body cadavers) and UVHC (research over selected anatomical structures).

This latter research direction focused on the development of simulation computer models (reference 50th percentile model and scaled 5th and 95th percentile models, as well as 'personalized' models). A research group from the ViSEB Laboratory at the Warsaw University of Technology participated in these works (among others, they have developed an effective method of scaling and personalization), as well as groups from UWB and CEESAR. Proper scaling is a particularly important issue in the case of building models of children's bodies. Owing to the virtually complete absence of experimental tests with the use of paediatric PMHS, such models are usually developed based on scaling adult body models (usually of the 5th percentile).

The experimental stage comprised 18 crash tests conducted with the use of both male and female bodies. The tests were designed specifically for the needs of this project. Different loading scenarios of the thorax were tested.

Figure 1. Cadaver ready for the test – side impact onto thorax

Particular attention has been paid to preparing the cadavers for the tests (Figure 1). One important element was to install a great number of measurement sensors/instruments, necessary for collection of as much data as possible regarding the behaviour of individual body parts under impact load.

In order to obtain proper rib strain profiles, over 100 strain gauges (Figure 2) were attached to the ribs and sternum. Accelerometers were also fixed onto the vertebrae T1, T4, T12 and onto the sternum. Pressure transducers were installed in the aorta, pleurae, inferior vena cava, trachea, and stomach in order to analyze the pressure wave transmission through the different organs.

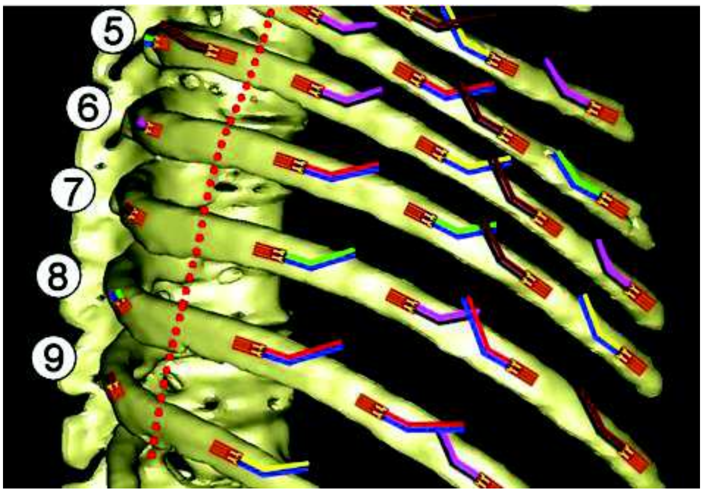

Figure 2. Visualization of the thorax bones, with location of the strain gauges to register strain during crash

Besides the crash tests, also tests regarding ribcage shape and material properties played an important role. In order to obtain correct geometrical data, important from the point of view of durability of the ribcage which protects internal organs, a multistep procedure of scanning thoracic skeleton (Figure 3) was used, with particular focus on the ribs. This has allowed for identification of both differences between individual ribs, as well as of the change of shape (including the change of the cortical bone cross-section area, particularly significant for evaluating the durability) along individual ribs.

The first task was to image the entire thorax with the use of typical computer tomography. Next, external surfaces of individual bones were scanned with the use of a laser 3D scanner. The next step was to cut the examined ribs into segments with a length of 3.5 cm and to scan each segment with the use of micro-CT scanning (μCT), which provides much higher resolution of the obtained images. Based on the micro-CT scanning data, detailed geometrical models were developed, which included both internal and external surfaces and the boundary of the cortical bone, which allowed for, among others, finding characteristics that describe the changing cortical bone cross-section area along individual ribs.

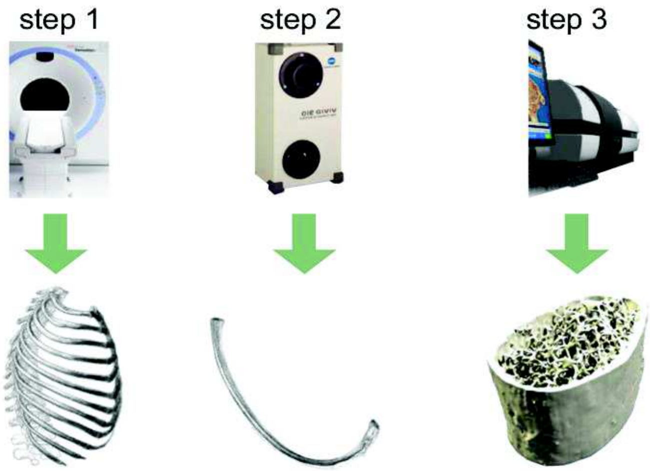

Figure 3. The three-step process of collecting geometrical data of the thorax bones

Information on the external geometry of individual ribs, previously collected with the use of a laser scanner, as well as CT images of the whole thorax, rendered it possible to put together accurate geometrical data for specific segments into a single model of the thoracic skeleton.

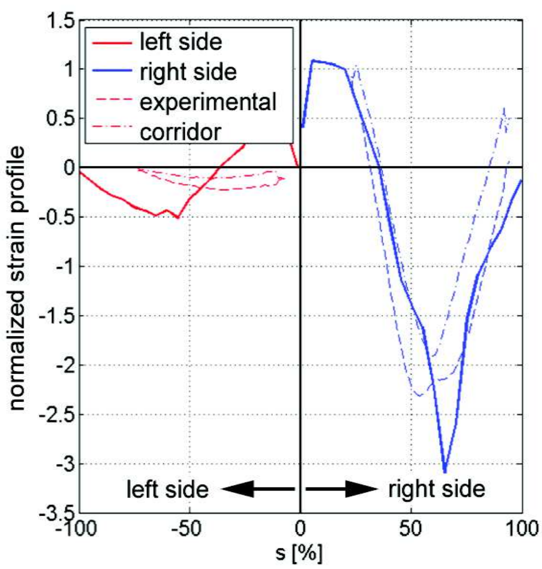

Figure 4. An example of a fifth rib strain profile for the reference model, developed as a result of simulation with the use of the reference model, with side impact, at the moment of maximum ribcage deflection

In order to verify the correctness of computer modelling of the consequences of injuries caused by impact with the amplitude and character typical of traffic accidents, it was important to conduct comparative analyses of the strain profiles and fields in ribs. They were identified in experimental tests with cadavers. Strain gauges had been fixed onto their ribs (Figure 2) and individual experiments were simulated on the computer. The conformity levels have been found satisfactory (Figure 4). The broken lines show the corridor built on the basis of experimental tests conducted under the THOMO project.

4. Conclusions

Based on many years of experience, I can state that:

- The future of research on impact biomechanics and its practical applications rest mainly on virtual methods (based on computer models of the human body).
- Owing to significant limitations, the role of experimental tests will increasingly boil down to identification of parameters and validation of virtual models. However, for many years to come, these tests will continue to serve as a very important source of information.
- Owing to the number and complex nature of the problems (medical, ethical, legal, biomechanical, numerical, equipment-related, etc.), which must be solved in order to develop improved virtual models representing the behaviour of human body under load impact, at a degree enabling reliable assessment of injury risk, works conducted by large interdisciplinary teams are much more likely to succeed, as they combine the necessary experience, computing, experimental, human and financial resources. This is the case of the GHBMC project, for example.

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