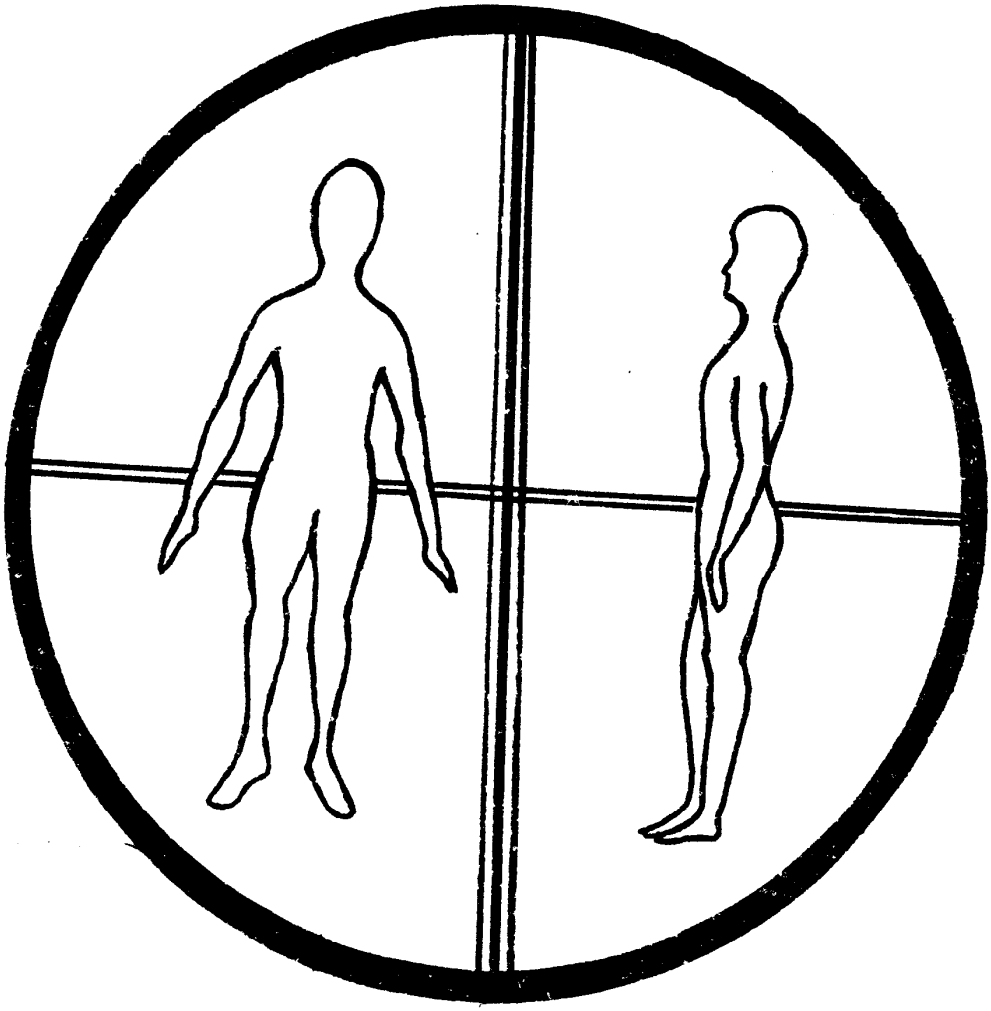
HUMAN SUBJECTS FOR BIOMECHANICAL RESEARCH

SIXTH ANNUAL
INTERNATIONAL
WORKSHOP



ANN ARBOR
MICHIGAN
OCTOBER 23, 1978

INTERNATIONAL WORKSHOP ON

HUMAN SUBJECT FOR BIOMECHANICAL RESEARCH

SIXTH ANNUAL MEETING
October 23, 1978
Ann Arbor, Michigan

FOREWORD

The sixth annual meeting of the workshop on "Human Subjects for Biomechanical Research" was held at the Rackham Building Assembly Hall of the University of Michigan. The past year has been a difficult one with respect to the use of human cadavers in biomechanical research. Congressional hearings were held on August 4, 1978 to probe the scientific value of the use of cadavers in biomechanical research. Evidence presented by the witnesses was overwhelmingly in favor of cadaver testing but it failed to convince Congressman Moss. However, the Subcommittee on Oversight and Investigations did not take action to stop cadaver testing but will monitor the guidelines that NHTSA will establish for future use of cadavers.

At this meeting we also discussed the guidelines that are being drawn up by the Association of Anatomy Chairmen as they control the source of cadavers for use in research.

A series of reports from various working groups were presented followed by technical presentations on the collection of biomechanical data and injury assessment. During the afternoon a panel discussion was held to talk over the guidelines being proposed. The reports of the working groups and other presentations are compiled in this volume. I would like to thank the participants for the timely submission of the manuscripts and Ms. Shirley Lawson who designed the cover and put together the reports and papers.

Albert I. King, Chairman
International Workshop on
"Human Subjects for
Biomechanical Research"

SIXTH ANNUAL INTERNATIONAL WORKSHOP ON

HUMAN SUBJECTS FOR BIOMECHANICAL RESEARCH

MINUTES OF WORKSHOP - OCTOBER 23, 1978

The Sixth Annual International Workshop on Human Subjects for Biomechanical Research was convened by Dr. Albert I. King of Wayne State University at 9:00 a.m. in the Rackham Building of the University of Michigan. Approximately 70 people attended this workshop.

Dr. King opened the workshop by noting that a Congressional Subcommittee chaired by Representative Moss from California had held hearings on August 4, 1978. The Subcommittee had dealt with the issue of using government funding for automotive safety research in which human cadavers were the test subjects. The Subcommittee took no direct action at the hearings, but rather decided to monitor guidelines for cadaver testing being developed by NHTSA. The Association of Anatomy Chairmen was drawing up the guidelines.

SESSION #1 - REPORTS FROM WORKING GROUPS

1. Head Injury Workshop - Arthur E. Hirsch and Dr. Carley Ward.

Mr. Hirsch introduced the report by noting that a head injury workshop had been held earlier in the year. An international group of forensic pathologists, neuropathologists, and engineers had gathered to discuss detailed autopsy procedures for head and neck injury research and methods by which the results could be put into a readily available computerized format.

The workshop produced an internationally - agreed - upon set of head and neck autopsy procedures. These procedures are considered tentative and preliminary until laboratories have had the opportunity to work with them and evaluate them. Mr. Hirsch noted that modifications to the procedures were to be expected and also noted that he anticipated the NHTSA would require these procedures, once finalized, for its research contracts.

Dr. Ward discussed the concept and some details of the reporting format adopted by the Head Injury Workship. The procedures aim at uniform methods of lesion identification, reporting and computer input. Requirements were that the reporting procedures be applicable to living and dead humans and experimental animals and to pressurized cadavers. The methods also require quantified measures of injury, rather than subjective opinions.

The computerized format calls for each lesion to be described by a thirteen-digit number, compiled as follows:

Digits 1-7 Two "locators" - general and specific
8-9 Injury name, or type of injury (differs for different parts of the head)
10-11 Grade, or degree, of injury (based on work by Dr. Hume Adams at University of Glasgow)
12-13 A measurement.

The forms will eventually include photographs to demonstrate the various ratings.

Dr. Ward distributed draft copies of the coding format to attendees, and noted that more copies are available from Mr. Hirsch's office at NHTSA.

In answers to questions, it was noted that Department of Transportation autopsy protocol could be reported using this format and may in fact be specified for DOT contracts. It is also possible to code existing data and some laboratories are doing that.

Future plans call for using test data and this format to assess disability in living head-injured humans. It is also intended to use the procedures for applications other than autopsy. Mr. Hirsch noted that Dr. T. A. Gennarelli is conducting a study at the University of Pennsylvania Hospital in Philadelphia to input a large group of serial CAT scans (from admission, hospital course, and discharge) using the computerized format adopted at the Head Injury Workshop. It is hoped that CAT scan results can be related to autopsy results.

2. Ad-hoc Committee on Orthopedic Injuries - Dr. Robert S. Levine and Dr. John States, Co-chairman

Dr. Levine gave the committee report. This committee has been dealing with scaling methods for lower extremity injury. The problem in using AIS is that lower extremity injuries are seldom a threat to life, but are often a threat to the quality of life. Disruptions of the knee and ankle, fractures of the acetabulum, and fractures of the tibial plateau all are scaled AIS 3, but almost always result in great impairment of the injured individual. The questions then arises if there should be some method adopted to account in the injury rating scales for a post-injury reduction in quality of life.

Drs. States and Levine advocate a workshop of interested physicians and other researchers to establish a method of evaluating lower extremity injuries during cadaver tests. Knee damage should be given major emphasis since ligament strains and tears in cadavers often go undetected, but in living humans they can lead to knee instability and much functional impairment.

As to protocol for cadaver tests, Dr. Levine suggested checks of the knee for function before and after the test. Post-test, detailed identification of ligamental damage is suggested prior to examination for damage to the interior of the knee. Protocols for ankle and hip injuries also need to be developed.

Responding to a question, Dr. Levine described the following etiology for post-traumatic arthritis in joints: Either irregular surfaces which remain after healing of a fracture, or stretched ligaments which allow excessive motion, create localized increased wear patterns. These conditions lead to localized synovial hypertrophy and the formation of osteocytes, then to degenerative joint disease. He noted that removal of menisci of the knee can result in arthritis as much as 10-15 years later.

3. Feasibility of a National Data Bank - Dr. Albert I. King and Dr. Murray H. Loew.

Dr. King reported that the NRC's CHABA Committee had met three times during the year and were preparing a final report containing recommendations for the various types of data banks which might be available from testing with cadavers.

Dr. Loew, who is with George Washington University, reported that he has been working with NHTSA to set up a biomechanics data bank. Currently, thoracic injury data are being addressed under contract to Adaptronics, who have just published an interim report "Thoracic Injury Data Base and Modeling System." The Adaptronics work will construct a data management system for thoracic injury which can be used for mathematical modeling. The data management features involve consolidation of data from various sources, pre-processing signals for data base consistency, storage and retrieval methods, and selection of data subsets. The model features would allow the use of subsets to either develop new models or evaluate existing ones, and to predict injury based on objective features of the data (such as acceleration waveforms). Adaptronics has reached three conclusions to date: the data base management system is feasible (although it is currently used mostly for retrieval); it is a useful research tool; and some data base management components may be useful in a national biomechanics data bank.

Dr. Loew also requested that representatives of laboratories which conduct experiments with cadavers complete a questionnaire during the Workshop.

SESSION #2 - TECHNICAL PRESENTATIONS

1. Intracranial Pressure and Brain Injury in Frontal Impacts- Dr. Carley Ward, U.S. Naval Civil Engineering Laboratory.

Dr. Ward presented a second interim report which included progress during the previous year in her use of a finite element model of the brain to predict intracranial pressures from various types of impacts. Dr. Alan Nahum of the University of California at San Diego has been measuring intracranial pressures in cadaver tests, and Dr. Ward is using those data to refine her model.

Dr. Ward is modeling three pressure phenomena - spike patterns resulting from hard-surface impacts, longer-duration pressure pulses from padded-impactor blows, and delayed-peak pulses which occur when padding becomes fully compressed. She has been comparing predictions from the finite element model with actual test results and iterating model features until good correlation is achieved. To date, the model predicts experimental waveforms very well for frontal impact; parietal, occipital, and posterior fossa impacts are fitted well except for minor curve variations.

During the year, it was discovered that "effective compressibility of the brain" had to be considered. Three models, each with different Poisson's ratio, were developed to account for different brain compressibility effects.

She has compared intracranial pressures with injury and has studied intracranial pressures in terms of HIC and Severity Index, and has concluded that the model could be useful for designing helmets and padding.

Although the model needs additional experimental verification, four conclusions have been reached: 1) the model does predict intracranial pressures; 2) a pressure/injury relationship does exist; 3) intracranial pressure can be used to predict injury; and 4) adequate padding can reduce brain injury.

In answers to questions, Dr. Ward indicated the pressure transducer was located in brain tissue, just below the dura; that frontal lobe injury was a function of frontal lobe peak positive pressure; that although padding "smooths" the pressure peak, the entire pulse shape is important; that 30-40 tests with the head tilted 45° forward had been used as the basis for the three padding models; and that the test specimens had not been examined for neck injury.

2. Differences in Mechanical Response between Live and Dead Skeletal Muscle - Dr. Roger Haut, General Motors Research Laboratories.

Dr. Haut has been interested in post-mortem changes in mechanical properties of cadavers and the possible modeling of those changes.

Recently, experiments have been conducted with skeletal muscle tissue (New Zealand white rabbit gastrocnemius muscle) under five conditions - in vivo relaxed, in vivo tensed, fresh cadaver, fresh cadaver with rigor mortis, and embalmed cadaver. Repeated tensile tests were conducted under non-damaging conditions using a Haversine stretch of the muscle at 10 Hz frequency.

Test results revealed that living tissue exhibited elastic characteristics, post mortem tissue had fluid characteristics and both exhibited hysteresis. Tissue in rigor mortis was as stiff as pretensed in vivo tissue, but the effects of rigor are destroyed by manipulation before the test. Fixation by formaldehyde made the muscles very stiff and the stiffness was dependent on the formaldehyde concentration.

Dr. Haut now has four phenomenological models: in vivo response may be represented by a passive element Kelvin model in parallel with a contractile element and a series element Maxwell model; rigor mortis is modeled by replacing the force-generating contractile element with a plastic element; post mortem fresh tissue is modeled by modifying the rigor model to replace the Kelvin model with another Maxwell model; embalmed tissue may be modeled with a single stiff elastic element.

Dr. Haut answered a number of questions. Maximum rigor mortis was determined by isometric tests and was found to be a function of storage temperature. The contractile element is needed when modeling an anesthetized animal because electrical stimulation of muscle can produce partial tetanus. The largest rate dependency was observed in the post mortem state, but the experiments did not vary strain rates except within the spectrum of the applied Haversine pulse. Muscle tissue qualities begin deteriorating very shortly after death, although passive properties did not change substantially until just before rigor mortis. The "global hysteresis" effects noted between human volunteers and cadavers reflect the influence of joints and ligaments.

3. Limitations of the Chest Injury Assessment Based on Cadaver Tests - Dr. David C. Viano, General Motors Research Laboratories.

Dr. Viano discussed the implications for thoracic injury assessment of recent analyses of cadaver test data. He noted that laboratory testing techniques now permit measurement of spinal and sternal accelerations in addition to chest deformation. Also, lung and vascular pressurization techniques have been adopted to better simulate reactions of the living human.

Dr. Viano analyzed the results of torso impact tests with 46 cadavers (35 from UC San Diego and 11 from Highway Safety Research Institute). These tests varied widely in impactor mass and impact velocity, spanning an order of magnitude in available energy applied to the chest. He found reasonable correlation between impact force and chest injury for impactor mass greater than 20 kg. For lighter impactor mass, force and injury did not correlate at all.

Noting that published test results suggested that chest compression correlates with injury in cadaver tests, Dr. Viano reviewed the available data, assigning Abbreviated Injury Scale (1976 Revision) values to overall injury, skeletal injury and nonskeletal injury. He was successful in using linear regression of force/deflection data to predict skeletal injury, and he also noted the data had a threshold appearance. He then examined the data for nonskeletal injury and found an injury threshold above approximately 0.4 P/D, where P= maximum penetration, D= initial thickness, and P/D is the percentage compression of original chest thickness. When P/D is plotted vs AIS, a linear positive slope is obtained through rib fracture stages of injury, then the slope becomes vertical in the internal injury phases. Also, there is an aging effect, with older cadavers sustaining greater damage from similar impacts. Statistical analysis led to the conclusion that, in order to be 95% confident that 95% of the population would not suffer internal injury, either chest compression must be limited to less than 0.32 P/D, or rib fractures must be limited to four or fewer.

Based on his analysis of volunteer and cadaver tests, Dr. Viano postulated that, when "too many" rib fractures occur, the structural integrity of the thoracic cage is lost and it undergoes a dynamic collapse. He cited data showing that volunteers can accept static chest compressions of 0.2 P/D without difficulty, and that cadaver injuries are reported when chest compressions reach .32 - .40 P/D. The lack of injury data below 0.3 P/D led to the dynamic collapse hypothesis.

A questioner, noting that his own experiments with cadavers in automotive restraints revealed no link between rib fractures and internal injuries, inquired as to the appropriateness of the chest-impactor type of tests. Dr. Viano replied that further analysis is needed to determine the utility of data obtained in the laboratory setting, but that he thinks the cadaver results are realistic for severe chest compressions. In response to a comment that aortic injury has been found with only one or two rib fractures, Dr. Viano noted that impactor tests do not simulate all types of injury mechanisms.

4. Filtering Requirements for Biomechanical Data - Dr. Nabih Alem, Highway Safety Research Institute.

Dr. Alem discussed analog and digital filtering procedures for tests involving the head. He noted that signal filtering guidelines are well established for analog data,but that digital filtering guidelines have not been established for biomechanics tests. He also noted that acceleration data are being used widely to define model parameters, but data measuring techniques (such as filtering) can alter the reported peak values. Dr. Alem feels that uniform digital, as well as

analog, filtering standards must be adopted if researchers are to successfully adopt a uniform format in a data bank.

Dr. Alem's research into digital filtering revealed that too much "noise" is passed through if SAE J211b analog values of 1000 Hz are adopted for digitial filtering. Using power spectral analysis, he found that little useful data are contained in frequencies above 600 Hz.

Citing the need for uniform guidelines for digital filtering which would be compatible with various types of data analysis (gross motion, brain wave propagation, etc.), Dr. Alem offered the following "proposal".

1) For direct impact of a cadaver head, set filter cutoff at 400 hz;
2) For non-impact of a cadaver head, set filter cutoff at 200 hz;
3) For analog-to-digital sampling rates and pre-sample analog data, filters should be such that attenuation is 24 dB at the Nyquist rate;
4) Linear phase digital filters should be used. Of the two types available, the finite impulse response, or linear phase, type is phaseless in digital theory. Infinite impulse response, or non-linear phase, type filters approximate analog filters but are phase-distorting.

Dr. Alem emphasized that his proposals were not yet finalized, and that response from other researchers was welcome.

Asked about the effect on HIC of filtering at different levels, Dr. Alem commented that he had not explored the question in depth but he has observed that peak accelerations are damped differently by different filter levels.

5. Some Comments on the Correlation of Impact Injury Data - Arnold Johnson, NHTSA

Mr. Johnson discussed a statistical method to correlate impact severity with injury. The method was developed for predicting rib fractures of cadavers resulting from lap-shoulder belt restraint tests. The presentation is included with the proceedings and will be summarized only briefly in these minutes.

Mr. Johnson contrasted the least squares regression technique of curve fitting to predict injury based on "indicator" parameters to that of a probability distribution method. Shortcomings of the least squares method include "miscorrelation" and curve biasing because non-injury data must be separated out, and the need to assume normal distribution of the data. The probability distribution method has the advantage of being able to "predict" from no injury through maximum likelihood of injury. However Poisson's distribution may be more appropriate for the situation of "mild" injury.

Mr. Johnson answered several questions. He noted that age, weight and impact force must be included in rib fracture criteria if fractures were to be predicted from chest compression. This may lead to a chi-square distribution. He has not yet observed the dynamic collapse effect hypothesized by Dr. Viano, but will be looking for it. His definitions of mild and severe injury are arbitrary so far. His method has some bias because he forced predictions of "negative injury" to zero injury. The fact that a Poisson distribution assumes that the occurrence of one rib fracture is independent of another rib fracture is a problem, but it may be able to be accounted for when the technique is applied to the maximum likelihood of occurrence. Finally, since a given rib may be only either

unfractured or fractured, the proposed method is one in which parametric statistics are being applied to non-parametric events.

6. Anatomical Geometry and Mass Distribution Data Base - Dr. H. K. Huang, Georgetown University Medical School.

Dr. Huang described a method using the CATscan to obtain anatomical location and mass distribution data. The objectives of the program are to:

1) Use a computerized tomography technique to obtain a representative number of cross-sectional body scans;
2) extract anatomical geometry and density distributions from the CATscan;
3) form an optimal data base for various subjects; and
4) develop computerized retrieval programs.

Dr. Huang noted that the CATscan has the advantages of being non-invasive and nondestructive (it utilizes very low levels of radiation). It produces a digitized cross-section which can be correlated to changes in density, and each scan takes only 20 seconds.

Currently, six cadavers are being scanned at one-centimeter intervals, and the scans are being sotred on magnetic tape. In addition, CATscans have been obtained from several animals and one volunteer. Scanning of a 180-cm adult takes four hours and produces 180 scans. Each scan can be analyzed for densities and anatomical coordinates to produce a three-dimensional map of bones, muscles and other organs within a definable outline of the body. Dr. Huang anticipates applications of the data to three-dimensional crash victim models and for pre-vs-post-injury comparisons.

A questioner observed that the supine position of the cadaver during scanning would have measurable effects on mass distributions and asked if a seated cadaver could be scanned. Dr. Huang replied that a cadaver which had been frozen in the seated position had been successfully scanned. A workshop attendee also voiced a strong objection to any unnecessary exposure to "ionizing radiation" for volunteers, even the 1.5 rads of exposure for a complete body scan.

SESSION # 3 - PANEL DISCUSSION

The afternoon session of the Sixth Annual Workshop was devoted to a panel discussion on guidelines for use of human cadavers in safety research. The panel moderator was Dr. R. S. Levine of Wayne State University. The panelists included: Mr. A. E. Hirsch, NHTSA; Dr. R. Eppinger, NHTSA; Dr. J. W. Melvin, HSRI: Dr. J. J. Vostal, General Motors Research Laboratories; and Mr. M. J. Walsh, Calspan Corporation.

Dr. Levine read an opening statement outlining the effects of restrictions placed on cadaver testing and seeking panel response to the questions of ethics and standards for cadaver use and handling. The complete text of the statement is included in the proceedings. Each of the panelists presented some opening remarks, followed by discussion among the panelists, questions from the audience and closing remarks.

Initial Comments by the Panelists:

1) M. J. Walsh, Calspan Corporation. Mr. Walsh first noted the need for testing with cadavers as part of the total approach to understanding the biomechanics of impact. It is Calspan's opinion that no single available system is adequate for complete evaluation of human impact tolerance. However, taken together, cadavers, human volunteers and anthropomorphic test dummies (ATD's) can cover the spectrum. The great advantage of the ATD lies in its being a repeatable device which can demonstrate conformance to performance evaluation criteria. Cadavers are not repeatable and therefore cadaver performance criteria could not be written into a standard. However, data from cadaver tests can be used to make ATD's more humanlike in response. Cadavers are oversensitive to concentrated loading, even though stress concentration effects are important and should be considered.

Mr. Walsh then discussed a test protocol which has been developed by Calspan during the past two years. All of Calspan's cadaver donations come from the same medical school and are returned to that medical school after testing. To avoid misunderstandings about the use of the cadaver, the next of kin is asked to sign a special informed consent for Calspan. For each whole-body test involving a cadaver, the medical team includes a pathologist, a radiologist, a neurologist and an anatomist. A licensed physician is always present when a test is conducted, and New York law also requires a mortician to be present. A copy of the current Calspan protocol is included in the proceedings.

2) Dr. J. J. Vostal, General Motors Research Laboratories.

Dr. Vostal noted the difficulty in obtaining injury evaluation criteria from cadaver tests since a cadaver cannot simulate underlying physiological effects.

As to guidelines and restrictions governing the use of cadavers in biomechanical research, General Motors prefers a positive approach along the lines of the Department of Health, Education and Welfare's Institutional Guidelines. General Motors has appointed a committee composed of a lawyer, an ethicist and a physician, none of whom are GM employes, to provide guidance and recommendations for proposed testing with cadavers. Starting with the Uniform Anatomical Gift Act, the committee has developed guidelines. Responding to committee recommendations that similar approaches be used for both cadaver and human volunteer studies, GM now reviews both types of studies in the same light. GM has adopted five principles governing studies with cadavers. They concern methods of acquisition, ethics for conduct of tests, specific needs for cadaver testing, and the requirement that the study demonstrate substantial potential benefit to humans generally. Certain types of automotive safety research with cadavers are permitted within these principles.

3) Dr. J. W. Melvin, Highway Safety Research Institute.

Dr. Melvin noted that this Annual Workshop strives to establish standards and protocol for biomechanical testing with cadavers and to improve the overall quality and applicability of the data that are collected in cadaver tests. He cautioned that researchers must always insure that the cadaver test is really needed and that an anthropomorphic test device is not appropriate for the proposed study. He also urged researchers to scrutinize their test techniques and procedures so that the best method is brought to bear on a particular problem and that the most lifelike state (appropriate to the test) is attained.

Dr. Melvin then briefly discussed HSRI's methods of cadaver acquisition and handling For consent, HSRI follows University of Michigan policy and uses the DHEW guidelines for testing with cadavers. As to protocol for tests involving cadavers, HSRI has active involvement of physicians in test planning and development. After a test, bioengineers investigate for gross trauma, and physicians advise when autopsy-related questions arise.

Dr. Melvin then expressed his opinions that the benefits accruing from testing with cadavers continue to make those tests very worthwhile and that efforts must continue to optimize data-taking and reporting techniques to achieve maximum benefit from each cadaver test.

4) Mr. A. E. Hirsch, National Highway Traffic Safety Administration.

Mr. Hirsch first complemented GM on the rapid adoption of their policy on cadaver use - it was effective in May 1978. He also indicated that, from the auto safety research standpoint, he would prefer having the standard anatomical donation research and education authorization serve as the only necessary informed consent. He believes it unnecessary to single out crash research as being different or more catastrophic than other types of research with cadavers.

Mr. Hirsch mentioned that NHTSA has approached the Association of Anatomy Chairmen (AAC) to draw up a statement of ethics for crash research with cadavers. Currently, he believes that statement will categorize crash research as different from ordinary research. NHTSA will adopt whatever statement is developed by the AAC, although it would be preferable to avoid "specialty" categories. He noted that this Workshop adopted a statement of ethics, endorsed by the National Academy of Science , in 1975.

Mr, Hirsch then reviewed the approach that will be used by NHTSA prior to resuming any testing with cadavers, if and when the current "hold" is removed. All existing studies and any new research will be reviewed by a Human Use Advisory Committee consisting of seven members, three from DOT and four from outside DOT. The four non-DOT members will represent medical, legal and theological disciplines. Each study will also be reviewed by a local steering committee and both committees will evaluate programs according to new guidelines now being developed by NHTSA.

Mr. Hirsch felt that the ethical questions resulting from cadaver research would be addressed by first having the project manager scrutinize the proposal and justify the use of cadavers from both the technical and the real-world sense. Second, adherence to certain ethical practices must be assured. Mr. Hirsch believed that regular medical school procedures governing handling, privacy, and disposal should be adequate.

5) Dr. R. Eppinger, NHTSA. Dr. Eppinger addressed the technical objectives involved in crash research with cadavers and discussed the need for detailed working procedures. While acknowledging the danger that specificity may limit ingenuity, he pointed out the need to be specific because of the number of institutions involved.

Dr. Eppinger observed that current research must try to anticipate future data needs and therefore accumulate as much information as possible from each test. He then listed technical approaches that should be adopted:

a) Uniform anatomical definitions to characterize the test subject;

b) Preselection techniques for proper utilization of available cadavers and to avoid subjects inappropriate for research;

c) Standardization of test procedure to enhance understanding of subject variability.

d) Detailed autopsy protocol spelling out procedures and who should perform them (may be project-dependent);

e) Post-test classification of subjects when optimum preselection is not possible;

f) Analysis of tests being performed to be sure they really address the point of the research.

Following the opening statements, a general discussion was held among the panelists.

Dr. Vostal pointed out that GM had moved quickly to adopt guidelines because the committee was formed first and was charged with developing general guidelines before detailed aspects of cadaver testing were addressed. Guidelines are much more justifiable and defensible if developed outside of the agency doing the research. He also prefers building arguments for the use of cadavers on the specific tests to be performed and the fact that the particular item to be measured can be measured only in a cadaver test. This method is preferable to general arguments tying cadaver testing to the reduction of highway fatalities.

In response to a comment from another panelist concerning the relative "morality" of testing with cadavers versus testing with animals and human volunteers, Dr. Vostal pointed out that differences in education lead to different viewpoints. Being an MD, he feels the Hippocratic oath takes precedence and he is reluctant to empirically test humans in any form. He also noted that the same ethics ought to apply to testing with both animals and humans.

Another panelist pointed out that some surrogate - animal, cadaver, or volunteer - must be used or no progress can be made in understanding injury tolerance and mechanisms. He thought that animal use would become very limited in the not-too-distant future and that, so long as cadavers are used wisely and to best advantage, there will be no widespread public outcry against cadaver testing.

It was noted that researchers are often asked if they would use a family member's remains in their test program. Most would not test a family member themselves, but would not have ethical objections to another researcher conducting the test. This is analogous to a medical doctor's reluctance to perform a serious operation on a close relative while allowing a respected colleague to do so.

Dr. Melvin closed the panel discussion by expressing his opinion that the cadaver is the best model in many applications - those involving skeletal response, for example. Certain phenomena can only be understood from tests with living tissue, but then the problem exists of extrapolation to man. He has found that vocal opposition to animal testing persists even when sound test objectives exist and are understood. However, his experience has been that there is very little opposition to research with cadavers.

At this point, the audience was invited to participate in the discussion. A participant observed that the trend in HEW is to treat cadavers as human subject with residual rights, thus requiring consent from next of kin. He anticipated HEW will soon require an informed consent. This will cause time delays, especially when fresh cadavers are needed for test objectives. Another observer lamented that severe consent restrictions would effectively prohibit essential research.

Mr. Walsh briefly reviewed Calspan's experience with informed consent from the next-of-kin of willed body donors. He interviews the donor's relative or executor and has had good success in obtaining releases. He believed this is partly because Calspan does no testing of unrestrained cadavers. He also observed that what works under New York's unique laws may not be workable in other states.

After a short break, the subject of the meeting of the Association of Anatomy Chairman was brought up. The AAC was to meet on October 25, 1978, in New Orleans and proposed guidelines for "unusual" research with cadavers were to be discussed. Among the guidelines to be discussed is required consent from next-of-kin for testing other than that considered to be educational.

A proposed resolution was presented to the Workshop. The proposed resolution would have urged the AAC to have any next-of-kin consent for "unusual" research be made optional for the anatomical boards of the individual states.

The Workshop engaged in much discussion over the proposed resolution. The word "unusual" was characterized as being detrimental and also potentially so restrictive as to require consent for any use of cadavers beyond the gross anatomy lab. It was pointed out that the AAC had initiated the use of "unusual" to describe crash research and the Workshop would likely not be able to change the terminology. It was also pointed out that NHTSA was committed to including AAC guidelines into NHTSA contracts.

An alternate approach was then suggested by Dr. D. F. Huelke of the University of Michigan Medical School. He proposed that the Workshop adopt the idea that state, rather than federal, requirements govern anatomical donations. Under this approach, permission for human trauma testing with cadavers would be subject to the following rules:

a) Anatomical acts of the state must be followed;

b) The Human Use Committee of the institution must review the proposal and approve it; and

c) If neither of the above is applicable, then consent must be obtained from next-of-kin. In the alternative, the Human Use Committee can require informed consent.

The consensus of the Workshop was that this approach would be much more workable than inflexible requirements for informed consent. The Workshop voted to adopt wording similar to the above three points as the Workshop's position on informed consent. The statement was to be presented to the AAC during their October 25 meeting.

Closing remarks for this Workshop were delivered by Dr. John P. Stapp. Colonel Stapp observed that there is ample justification for conducting research with cadavers. However, he said, researchers should not retreat to a position of doing only cadaver research when there are opportunities, in his opinion, to take advantage of violent sports as a means of conducting impact research with volunteers. He recommended instrumenting football players and boxers as long ago as 1975, when subminiature instrumentation began to be developed. He believes these potentially valuable sources of human volunteer data should be tapped when non-interfering instrumentation becomes available.

The Sixth Annual International Workshop on Human Subjects for Biomechanical Research was adjourned at 4:40 p.m. The Seventh Annual Workshop is to meet on October 16, 1979, at the Del Coronado Hotel in San Diego, California.

David R. Foust
Secretariat

TABLE OF CONTENTS