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Matched-pair hybrid test paradigm for behind armor blunt trauma using an experimental animal model

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ABSTRACT

Background The current behind armor blunt trauma (BABT) injury criterion uses a single penetration limit of 44 mm in Roma Plastilina clay and is not specific to thoracoabdominal regions. However, different regions in the human body have different injury tolerances. This manuscript presents a matched-pair hybrid test paradigm with different experimental models and candidate metrics to develop regional human injury criteria.

Methods Live and cadaver swine were used as matched pair experimental models. An impactor simulating backface deformation profiles produced by body armor from military-relevant ballistics was used to deliver BABT loading to liver and lung regions in cadaver and live swine. Impact loading was characterized using peak accelerations and energy. For live swine, physiological parameters were monitored for 6 hours, animals were euthanized, and a detailed necropsy was done to identify injuries to skeletal structures, organs and soft tissues. A similar process was used to identify injuries to the cadaver swine for targeted thoracoabdominal regions.

Results Two cadavers and one live swine were subjected to BABT impacts to the liver. One cadaver and one live swine were subjected to BABT impacts to the left lung. Injuries to both regions were similar at similar energies between the cadaver and live models.

Conclusions Swine is an established animal for thoracoabdominal impact studies in automotive standards, although at lower insult levels. Similarities in BABT responses between cadaver and live swine allow for extending testing protocols to human cadavers and for the development of scaling relationships between animal and human cadavers, acting as a hybrid protocol between species and live and cadaver models. Injury tolerances and injury risk curves from live animals can be converted to human tolerances via structural scaling using these outcomes. The present experimental paradigm can be used to develop region-based BABT injury criteria, which are not currently available.

INTRODUCTION

Need for a new experimental design

The responses of the human thoracoabdominal regions depend on the impact to the body armor that applies the dynamic loading via its backface deformations to a specific region of the human anatomy (eg, lungs, liver, heart). The surrounding ribcage deforms, as it is the first structural component to sustain the impact from the backface deformation. Injury tolerance is not the same for all regions of the thorax, its organs and skeletal structures, and consequences or severity of injuries or injury risks at a particular threshold are not identical to all regions. These considerations lead to the need for a new experimental design that can delineate injuries and injury mechanisms and determine human injury criteria for different thoracoabdominal regions from Behind Armor Blunt Trauma (BABT) impacts.

Animal model

Clay, gelatin and foam were used by Clare *et al*, Goldfrab *et al*, Metker *et al*, and Parther *et al*, to develop standardized test procedures for BABT applications, including soft body armor.[1–5] The original studies conducted by Clare *et al* used 74 goats.[2] In previous studies using a goat model, Clare *et al* developed a binary regression injury risk model .[2] Lethality was defined using the 24-hour survival criterion, after which autopsies were conducted to document injuries.

Alternate materials and 44 mm limit

Metker *et al* reported that 20% gelatin is an accepted surrogate simulant for ballistic trauma standardization tests.[4] However, gelatin needs high-speed imaging for deflection measurements, and it is cumbersome to prepare. Thus, there was a need to explore alternate materials, and the responses of foam and different types of clay surrogates were compared with the responses from the 20% gelatin tests. The Roma Plastilina (RP1) clay was chosen as the best alternative to the 20% gelatin, as had a plastic response characteristic, which eliminated the high-speed imaging for deformation measures, and it was also easier to prepare. The legacy 44 mm clay deflection criterion was suggested as the BABT safety standard for soft body armor and Carton *et al*, Lehowicz *et al*, and Rafales *et al*, have mentioned in their studies.[5–8] Despite national and international research efforts to improve the standard, the 44 mm limit continues to be applied to soft and hard types of body armor for design, development and injury assessment. The limit is also applied equally to all thoracoabdominal regions covered by the body armor, despite regions having different injury tolerances.

While the historical work using BABT tests with the goat and simulant models resulted in the 44 mm clay standard, regional tolerances for different thoracoabdominal regions are not available. Therefore, the study's objectives are to develop a new approach for assessing these injuries for improving human safety, developing injury assessment standards, and designing and validating newer type of body armor for protection against current and potential emerging threats. Specifically, the focus of this study is to demonstrate the feasibility of using a matched pair test protocol with the swine and gather biomechanical candidate metrics to describe regional human injury criteria. The matched pair test protocol was defined similar testing and analysis procedures with cadaver and live swine.

METHODS

Rationale for using the swine

Swine was selected for experiments, although goat was used in original studies conducted by Clare *et al*.[2] Physiological responses such as coagulation and blood loss in goats are different from humans, and goat is not the optimum model to predict human responses following BABT impacts. The respiratory system, circulatory system, and skeletal anatomical structures of the swine are analogous to the human, in addition to similarities in blood chemistry and perfusion characteristics.[9 10] To determine biomechanical metrics such as peak thoracic compression and develop injury risk curves for standardization tests, automotive crashworthiness studies reported by Cavanaugh and Yoganandan, Prasad, Kroell *et al*, Viano *et al*, and Viano and Warner have used physiological responses from impacts to thoracoabdominal regions of live and cadaver swine.[11–15] Animal Research: Reporting of In Vivo Experiments (ARRIVE) reporting guidelines were followed in this study.[16]

Animal preparation

Experiments were conducted at the VA Medical Center, Milwaukee, WI, with live and cadaver swine after obtaining approvals from the local Institutional Animal Care and Use Committee and the agency sponsoring the research study. The protocol was prepared and approved by the two institutions before the study. For whole-body live experiments, swine was obtained from a local vendor, acclimatized in the veterinary unit for 48 hours and prepared to receive the BABT-simulated insult. The trauma surgeon author of this study placed trachea tubes and intravenous lines following the induction of anesthesia using Telazol and Xylazine. Pressure transducers were placed in both lungs and aorta. One transducer was guided into each lung through the trachea tube. To place the aorta transducer, a small incision in the neck was made to isolate a blood vessel routing to the aorta. The blood vessel was clamped on one end to allow for a small incision to be made to insert the transducer. The transducer was sutured and secured to prevent movement and blood loss. Radiographic imaging confirmed transducer lung and heart placements. The swine was connected to isoflurane ventilation for continuous anesthesia delivery for 6 hours following the impact. For whole-body cadaver experiments, swine was prepared analogously with no longitudinal physiological response measurements. Data are available at the VA Medical Center. The lead biomedical engineer was aware of the entire testing and analysis protocol. The schematic of the experimental design is shown in figure 1.

BABT loading and data acquisition

We adopted an impactor (~214 g)-simulating backface deformation profiles produced by body armor from military-relevant ballistic rounds reported by Bass *et al* was used to deliver impact.[17] The impactor was launched to impact a targeted region on the live and cadaver swine using a custom gas-driven launching system. A triaxial accelerometer (Endevco 7284–20K (Endevco, Depew, New York)) was mounted within the impactor and hardwired to an external data acquisition system. Signals from the accelerometer inside the impactor and pressure transducers (Millar SPR-350 and Millar MPR-500 (Millar, Houston, Texas)) were recorded at 500 kHz and filtered at 2 kHz.

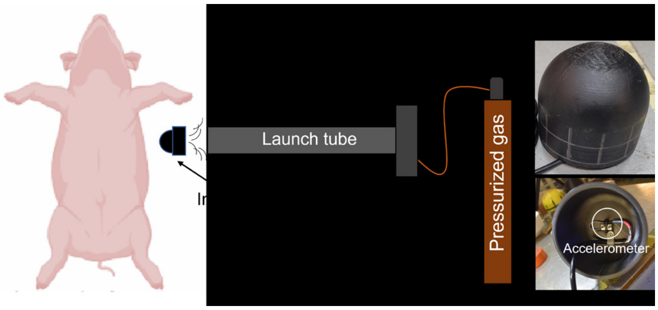

Figure 1 Schematic of the schematic of the experimental design.

Impact and locations

One single impact was delivered to each live swine. The animals were positioned supine on the laboratory table, and the impact sites were aligned along the exit axis of the impactor launching system. The liver and left lung were the two targeted thoracoabdominal regions. The targeted lung impact was to the left thoracic wall between the third and fourth ribs. The targeted liver impact was to the unprotected (not covered by skeletal anatomy) part. The animals were kept in a continuous state of anesthesia, and vitals (ie, ECG, pulse rate, SpO2, respiratory rate, temperature, and blood pressure) were monitored for 6 hours postimpact. The animals were then euthanized, necropsies were performed, and injuries to the skeletal and soft tissues and organs were documented. Injuries were assessed by the trauma surgeon for both live and cadaver animals. A similar procedure was used for the cadaver swine. Injuries and biomechanical metrics were evaluated for consistency between the cadaver and live swine for each region, except for physiological data obtained from live animals.

Test Matrix: the experimental unit was a single animal in each case. No isolated organs were tested. All were whole-body impact tests. Two animals were used for lung tests, one as a cadaver and the other as a live model. Impacts to the liver were conducted on one live and two cadaver swine. The animals were approximately 12–17 weeks in age, o weights ranged from 42 kg to 52 kg, length (defined as the dimension from the base of the ear to the base of the tail) ranged from 83 cm to 97 cm, height (defined as the dimension from the plantar surface of the feet (ground) to the rump of the animal) ranged from 46 cm to 55 cm, and circumference at the abdomen, chest, and waist ranged from 78 to 100 cm, 74 to 84 cm, and 75 to 87 cm, respectively. Two additional animals serving as control group did not undergo any impact loading to the liver or lung; however, the same protocol was followed with euthanasia followed by autopsy. No injuries were observed in the control group of animals.

RESULTS

Results from lung experiments

For the live animal test, the impactor peak acceleration was 3844 G, and impact was energy of 349 J. The animal survived the 6-hour survival window. While cardiovascular activity increased immediately following the insult, vitals stabilized during the survival window period. Injuries included a contusion at the impact site with the skin remaining intact, fractures to ribs 5

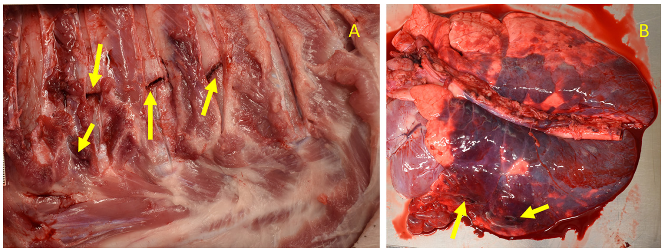

Figure 2 (A) Arrows show fractures of ribs 5–8 from left to right for the live swine lung test (349 J). (B) Left lung hemorrhages and lacerations adjacent to fractures of fifth and sixth ribs (arrows).

through 8 (figure 2A), pleural lacerations with hemorrhages in the left lung, and lung lacerations adjacent to fractures of ribs 5 and 7 (figure 2B). Blood aspiration was found in the right lung. The heart rate increased from 75 bpm to 180 bpm and respiration rate from 15 min to 29 min, approximately 20 min postimpact. The injury was associated with blood aspiration and large pulmonary lung contusion. There were no injuries to the heart, stomach, spleen, or kidneys. For the cadaver swine test to the lung, the impactor peak acceleration was 2400 G and energy was 200 J. Other data (peak deflection, viscous criterion, impulse, and force) are included in online supplemental table 1 for each test. Injuries include contusion at the impact site and non-displaced fractures at ribs 5 and 6 (figure 3). Lower insult levels (energy and acceleration) produced less severe injuries and in both cases injuries were similar. Online supplemental figures A1–A4 in the appendix show the acceleration, deflection, force, and viscous criterion data.

Results from liver experiments

Online supplemental table 1 shows data for each test. The peak impactor accelerations for swine cadaver tests were 2224 G and 2400 G, with impact energies of 172 J and 197 J. The peak acceleration for the live swine test was 1735 G, with an impact energy of 122 J. Other data are included in online supplemental table 1. Like in the lung test, the animal survived the 6-hour survival window after the impact loading. All impacts resulted in contusion at the impact site. The 197 J impact had two liver lacerations: 2×9 cm on the dorsal aspect and 5×5 cm on the ventral aspect, and the 172 J impact had a single laceration, 5×8 cm (figure 4), while 122 J impact resulted in a single linear laceration of liver measuring approximately 4.5 cm. Only the 197 J cadaver test sustained fractures of ribs 5–9. Both cadaver and live tests had similar expected injuries with insult levels, that is, the greatest insult was associated with the higher severity of trauma. A comparison of injuries from the lung and liver tests for both cadaver and live animals is shown in figures 1–3.

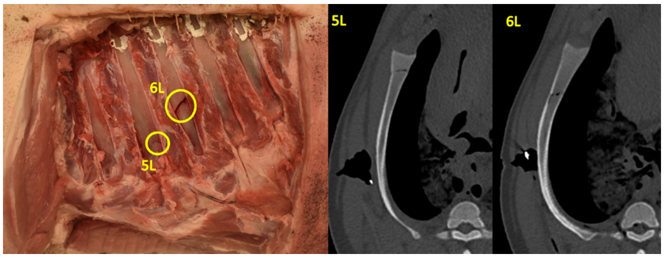

Figure 3 Non-displaced fractures of the fifth and sixth ribs (200 J impact to left lung on a swine cadaver, shown as circles) in the left is necropsy. The two right CT images show rib fractures.

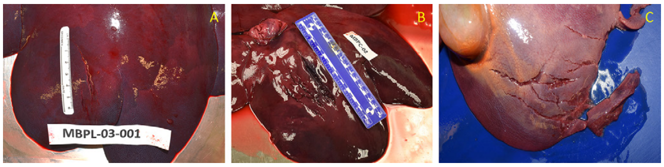

Figure 4 (A) shows the liver lacerations in the live swine at 122 J. (B,C) show the 5×8 cm laceration (172 J), and 2×9 cm and 5×5 cm lacerations (197 J) in two cadaver swine.

DISCUSSION

As the current clay-based 44 mm deformation criterion is not region specific and the need exists to develop regional human injury criteria for standardized tests, this study aimed to develop a matched pair hybrid test paradigm and demonstrate its feasibility to record injuries and gather biomechanical metrics. The impactor shape simulated body armor induced backface deformations, as reported by Bass *et al*.[17] The protocol used live and cadaver swine as matched-pair experimental surrogates and obtained measures such as acceleration, energy, and injuries to skeletal structures and organs were identifed for similar assessments.[5 18]

For the development of injury tolerance, an essential criterion to meet the matched pair design constraint is that the responses should be similar between the two or more surrogate models. In other words, at the same impact levels (eg, energy), both models should produce comparable outcomes. In the present context, both live and cadaver swine experiments produced similar injuries in the lung and liver. For the liver series of experiments, three animals were tested, two as cadaver models with energy inputs of 172 J and 197 J, and the live swine test at 122 J (lower energy) resulted in less severe injuries than those at the two higher levels of energies (figure 2). For the lung experiments, a similar analysis applied with greater insults produced expected greater severity injuries in the matched pair model tests. These results showing similarities between the injury outcomes of two distinctly different types of organs with similar energy inputs demonstrate that the present matched pair model is feasible for conducting additional studies targeting these two and other thoracoabdominal organs/regions to develop animal-based region-specific injury criteria via injury probability curves.

Injury mechanisms differ between solid organs because of differences in structural compositions. The presence of air in the lung alveoli alters the transmission of the energy from the backface deformations. The rib cage encasing the lung acts as an initial line of defense as its deformation decreases the energy transferred to the lung, while rib cage deformations may not always result in fracture. Pulmonary contusion with alveolar hemorrhage can occur without rib fracture or pleural rupture/laceration. Contusions can occur due to rib fracture and/or tearing of pleura. The speed of sound through the lung parenchyma (25–70 m/sec) is approximately 80% of the speed in air. In contrast, the speed of sound in a normal liver is approximately 1500 m/sec. Lungs may be more susceptible to shock waves than the liver due to this difference. The anatomic location of the liver in the human adds to the importance of the energy transfer: BABT impacts directly to the unprotected liver transfer more energy to the liver than impacts directed initially at the ribcage, absorbing some energy due to deformation.

A similar loading paradigm can be extended to subject intact human cadavers to BABT impacts and develop structural relationships between the two models, which can be used to translate injuries from the animal to humans. Use of human cadaver model, together with swine cadaver and live animal models, acts as matched pair hybrid protocol for BABT. The authors of this study from academic institutions are using the matched pair protocol to develop animal and human injury criteria and standardization tests for improved assessment of hard and soft body armor to protect military personnel from successful defeat of known and emerging ballistic threats.

Contributors NY contributed to the conception of the experimental design, data acquisition and analysis, interpretation of data, preparing the manuscript, responding to review comments, and final approval of the submitted article. NY is acting as guarantor. AS conducted the experiments and gathered biomedical data. BS was involved in mechanical data analysis. JB, MO, and LS were involved in experimentation and with live animals and monitoring and interpreting clinical data and autopsy findings. CB and RS reviewed the manuscript and were involved in discussions with the team and NY. JM was involved in data analysis and discussions with AS following experiments. VC reviewed the manuscript and participated in technical discussions before the preparation of the article. BM provided administrative support, was the scientific office, involved in all discussions during experiments, reviewed the manuscript for technical content and obtained approval from the U.S. Department of Defense.

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