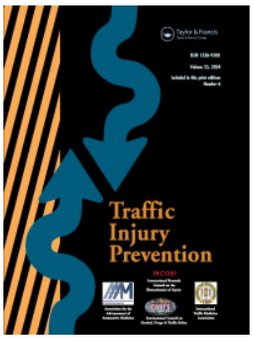

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The ethics, applications, and contributions of cadaver testing in injury prevention research

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ABSTRACT

Objective: This study aims to establish best practices and guidelines to ensure that experimental research utilizing Postmortem Human Subjects (PMHS) for injury prevention adheres to relevant ethical principles, which are also commonly accepted in research involving human tissues and living subjects. Furthermore, it reviews existing literature to underscore the pivotal role of PMHS testing in evaluating the efficacy of safety systems, with a particular focus on airbag performance.

Methods: This paper conducts an examination of the primary ethical principles governing human subject research as outlined in the Declaration of Helsinki (1965) and traces their evolution up to the latest framework proposed by the Council for International Organizations of Medical Sciences (CIOMS) in 2002. Input was solicited from international experts and laboratories experienced in PMHS testing to understand how these ethical principles are implemented in practice. This is complemented by a comprehensive review of literature that assesses the contribution of PMHS testing to airbag performance enhancements in frontal impacts.

Results: The findings underscore the importance of informed consent from donors or their next-of-kin, as highlighted in CIOMS declarations, to ensure the ethical integrity of the donation process in line with international standards. The study also finds it customary for an independent review board to evaluate the research methodology and the necessity of employing PMHS tissue over alternative methods, such as computational models or crash test dummies. Despite various national regulations on human subject participation and living tissue research, no specific legal framework governing PMHS tissue use was identified. The systematic literature review revealed that PMHS testing has been crucial in identifying potential injury mechanisms not detected by Anthropomorphic Test Devices (ATD), significantly contributing to the enhancement of computer human body models and the biofidelity of crash test dummies.

Conclusion: The International Council on the Biomechanics of Injury (IRCOBI) recognizes the need to provide guidance for research involving human cadaveric tissue to be conducted with the highest ethical standards. This study proposes five recommendations to ensure adherence to these ethical principles in PMHS testing, highlighting the paramount importance of obtaining informed consent and securing independent committee approval. Moreover, IRCOBI emphasizes that until a thorough understanding of tissue damage tolerance levels is achieved and human surrogates, such as ATDs or Human Body Models (HBM), reach full biofidelity, the use of human cadavers remains indispensable for developing effective injury prevention strategies and measures.

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Introduction

Despite significant advancements, motor vehicle (MV)-related incidents are the 12th leading cause of death globally, causing 1.19 million fatalities annually. Vulnerable road users (VRUs), such as pedestrians, cyclists, and motorcyclists—predominantly in low- and middle-income countries (LMICs)—constitute over half of these deaths. The impact is profound, with MV deaths being the primary cause of mortality for individuals aged 5-29 worldwide (WHO, 2023). Technical regulations, as endorsed by the World Health Organization, have shown potential in decreasing road fatalities. For example, assessments by the National Highway Traffic Safety Administration (NHTSA) in the US reveal that safety technologies, including seat belts, air-bags and electronic stability control, saved approximately

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613,501 lives from 1960 to 2012 (Kahane et al. 2015). Frontal airbags alone have reduced driver fatalities in frontal crashes by 29% across all age groups.

The use of post mortem human subjects in injury biomechanics

Human cadavers, also known as Post Mortem Human Subjects (PMHS), have been used in anatomical studies since the fourth century BC (Britannica 2023), but their use for research on injury tolerance did not begin in earnest until the second half of the nineteenth century (Weber 1859; Messerer 1880). Since then, other human surrogates, each with their own advantages and disadvantages (Crandall et al. 2011), have been used (e.g., human volunteers, anthropomorphic test devices (ATDs), animals and computer models). Despite a lack of physiologic functions, human cadavers remain the only surrogates that allow the most accurate description of the human anatomy (excluding living humans) and the best approach to understanding human tolerance to injury.

PMHS tests have been essential in the development of many vehicle safety systems, such as seatbelts, airbags, instrument panel padding, and collapsible steering columns. The biomechanical and injury data acquired from experimental cadaver tests is unique and cannot be obtained using any of the other surrogates. King et al. (1995) estimated that for each cadaver utilized in the development and validation of vehicle safety technologies, more than 60 lives were saved, and countless injuries were prevented, or their severities reduced. Despite these clear benefits, concerns remain about the societal acceptance of using human cadavers for research and may depend on regional cultures, habits, traditions, and religious views. These concerns are relevant and therefore it is necessary to discuss the ethics of using human cadavers in automotive and injury prevention research. A purely utilitarian analysis of the number of lives saved does not address these concerns. Further guidance is needed to ensure that research involving human cadavers is performed with the utmost respect for the donors, their families, and for the concerns expressed by different portions of society. These concerns parallel, in many instances, those regarding research involving living human subjects over the last century. The ethical principles and guidelines applicable to the research performed on living humans, such as the Declaration of Helsinki, provide a reasonable starting point for how research using human cadavers can and should be performed in accordance with existing regulations and the ethical considerations respected worldwide.

On the ethics of using human tissue, pre- or postmortem, in research

The two World Wars are examples of much scientific progress in the service of developing weapons and improving our knowledge about how to injure and heal people. Unfortunately, during these times, several studies that threatened and/or disregarded human dignity were carried out. The Nuremberg trials in 1947 were perhaps the first time that such experiments were disclosed openly to the public. As a reaction to the atrocities exposed during the trials and the absence of a proper legal framework for experiments involving human beings, the Nuremberg Code was created to define what constitutes legitimate medical research involving human subjects. The Code consisted of 10 principles including informed consent, properly formulated scientific experimentation and beneficence toward experiment participants among others. Voluntary informed consent was the first of these principles and was considered to be:

> "absolutely essential. (…) This latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration and purpose of the experiment; the methods and means by which it is conducted; all the inconveniencies and hazards reasonably expected; and the effects upon his health or person which may probably come from his participation" (Nuremberg Code, Principle 1, 1949)

The Declaration of Helsinki (1964) was developed upon the Nuremberg Code and reinforced the need for free and informed consent. It is a set of ethical principles regarding human experimentation that was proposed to the medical community by the World Medical Association. Since its adoption, the Declaration of Helsinki has undergone several revisions by the World Medical Association, including the most recent one in 2013. It is considered to be the most fundamental international document in the field of ethics in biomedical research, influencing international, national and regional legislation and codes of conduct.

In 2002; the Council for International Organizations of Medical Sciences (CIOMS) in collaboration with the World Health Organization (WHO) published a series of guidelines to direct the application of the three basic ethical principles for research involving human subjects (CIOMS 2002, 2016). The three ethical principles that should be respected at all times in biomedical research are:

1. Respect for persons: this principle requires respect of the autonomy of the person to make personal choices and the protection of vulnerable persons that are unable to provide for themselves.
2. Beneficence: this principle refers to the ethical obligation to maximize benefit while minimizing harm. It also requires that researchers avoid maleficence or the deliberate infliction of harm on persons.
3. Justice: this principle demands that each person is treated according to what is morally right and proper. Particularly, distributive justice is essential in research involving human subjects as it requires that burdens and benefits must be equally shared by subjects participating in the study and the population that will benefit from it.

These principles establish that the ethical justification of biomedical research involving human subjects is the prospect of discovering new knowledge or ways of benefiting people's health. Some might argue that this approach is utilitarian in the sense that one person or group benefits while others are harmed (O'Neill 1996; Jones and McOullough, 2011). To address this argument, CIOMS requires that the research must be carried out in ways that respect and protect the subjects, are fair to the subjects, and are morally acceptable by the community.

However, the focus of this paper is not to examine the general principles that are required in experimentation involving human subjects (living), but how these principles may apply to the specific case of using human cadavers in studies focusing on injury prevention and, in particular, injury biomechanics to ensure that this research is thoughtfully performed according to regulations and ethical principles proposed for research involving human subjects.

There have been substantial efforts made recently to address ethical practices of body donation in the U.S. (e.g., Champney et al. 2019; Johnson et al. 2023) and numerous professional organizations have published best practices (AAA 2019; AACA 2017; IFAA 2012). These guidelines include many recommendations similar to those considered for human subjects in research studies, most notably related to informed consent, and are a critical foundation for the specific research applications discussed here. This study aims to extend beyond the existing literature, proposing a set of recommendations that encompass not only the donation process but also broader aspects of the research on injury biomechanics utilizing cadaveric human tissue. This approach intends to ensure comprehensive adherence to pertinent ethical principles.

Objectives

Injury biomechanics applies mechanical principles to human tissue under injurious loading conditions, with special focus on establishing a tissue's tolerance to injury (Viano et al. 1989; Crandall et al. 2011). The International Research Council on Biomechanics of Injury (IRCOBI) started its activities in the early 1970s when a small group of researchers from several countries collaborated to organize an international conference on the biomechanics of vehicle crashes and on the human tolerance to impact. Since then, IRCOBI has devoted itself to encouraging research on impact biomechanics and injury mechanisms, providing a forum for the presentation and dissemination of these research findings. Given the recent advancements in the field of injury biomechanics, which include the introduction of new dummies with varied anthropometries and sexes, as well as a proliferation of computational human body models, IRCOBI recognizes the importance of reevaluating the necessity and proper use of cadavers within this evolving context. IRCOBI advocates for a thoughtful consideration of these issues, aiming to provide clear guidance and ethical clarifications regarding the use of human cadavers in biomechanical testing that can address current perceptions and sensibilities within the society. The organization supports the continuation of these experiments, emphasizing that the unique insights derived from them are essential for further reducing injuries and fatalities related to mechanical loading.

In this study, we focus specifically on the role and contributions of cadaver testing in the development of airbags. Since their inception, airbags have played a significant role in preventing or mitigating injuries and fatalities associated with automobile accidents (Viano 2024). Although the National Highway Traffic Safety Administration (NHTSA) estimates that airbags saved 28,244 lives up to 2009; they have also been implicated in 320 reported fatalities. This paper will later discuss how tests using Postmortem Human Subjects (PMHS) have identified potentially injurious scenarios that preliminary assessments with dummies or computational models failed to detect. Therefore, airbags are one recent example in a long line of safety developments that require detailed biomechanical knowledge for their successful development.

Therefore, the objectives of this paper are twofold:

- To provide a review of existing testing practices involving the use of whole-body cadavers within the context of the ethical principles required in all research involving tissue derived from humans.
- To discuss the impact that whole-body cadaver testing has had in the field of automotive safety by focusing on the use of cadaver tests in the development and optimization of airbags.

Methods

Review of existing PMHS testing practices worldwide

The review of the existing practices and protocols observed in public and private laboratories worldwide was done by interviewing researchers from institutions that had been involved in either PMHS or volunteer testing programs within the last 10 years. These researchers were approached thanks to the professional network created around the annual conference organized by IRCOBI. To standardize the information requested, the contacted researchers were asked to fill in a survey including questions about how the testing program involving the use of human tissue was carried out at each institution.

Systematic review to assess the impact of PMHS testing in the development and optimization of airbags

SCOPUS was used to search for scientific publications in journals and conferences reporting the use of PMHS in the investigation of airbag performance. The search was performed with the command: *((TITLE-ABS-KEY (airbag) OR TITLE-ABS-KEY (air AND bag)) AND (TITLE-ABS-KEY (pmhs) OR TITLE-ABS-KEY (cadaver)))*, that returned all documents in SCOPUS that contained either in the abstract or in the title or in the keywords the terms "airbag" or "air bag" and "cadaver" or "PMHS".

The documents were initially categorized according to a predefined template, the contents of which were agreed upon by the authors. This template included fields such as the number of subjects tested, general characteristics of the subjects, type of airbag, and type of collision, among others. This template is provided as Supplementary Material. The intent was for these fields to be filled in using information found in the abstracts of the publications. The primary aim of this initial review was to determine in which studies the

use of Postmortem Human Subjects (PMHS) testing was crucial, either to supplement or alter the conclusions drawn from Anthropomorphic Test Device (ATD) testing or computer simulations, or to provide unique insights only obtainable through cadaveric experiments. After this initial classification, a meeting of the expert group was organized to examine the results of the classification process. This meeting served to narrow the scope of the review down to a subset of the papers retrieved in the initial search (i.e., focus on frontal impacts). These papers were then distributed among the members of the expert group for a thorough read in which more detailed information about the methods and the relevance of the results to the goal of this study were identified. After this second filter, the expert group drafted a summary of the contribution of PMHS testing for the advancement of airbag development (Figure 1).

Results

PMHS testing worldwide

Table 1 summarizes the information received from the several researchers within the IRCOBI network. It should be noted that, on some occasions, more than one institution from each country participated in the survey. In these cases, the information in the table combines all the responses received from each country. It should further be noted that these examples are supposed to demonstrate the differences and variety of corresponding regulations rather than providing a complete picture for reference. National legislation is subjected to change such that the specifics of these guiding principles should be checked before planning a research project.

France

The "Ordonnance n° 2016-800 du 16 juin 2016 relative aux recherches impliquant la personne humaine", approved in 2016; regulates any research involving human beings, regardless of the focus of the investigation (behavioral sciences, epidemiology, biomechanics, etc.). This regulation is applied also to both volunteer and PMHS tests.

Focusing on injury biomechanics, the regulation establishes that the research protocol must be approved by national authorities and an independent committee depending on the Ministry of Health and under the supervision of the Director General of the National Agency for the Safety of Medicines and Health Products. Securing the approval of the independent committee is mandatory before starting the research program. There are several committees in the country with the capacity of granting this approval (they are called Committee for the Protection of the Person, or CPP) and it is the responsibility of the research group to secure this permission. It is also required that the research facilities are inspected annually to ensure that they are fit to carry out this type of research.

Institutions may have their own internal review board to assist researchers in the preparation of the materials that need to be submitted to the CPP. For instance, at the University Gustave Eiffel (formerly known as IFSTTAR) the committee is composed of two researchers in the field and two external members (a lawyer and a medical doctor).

Regarding tests performed with cadaveric tissue, there is a distinction between using just some tissue or the whole body of the donors. If the tissue is obtained during surgery, the process is the same as the one aforementioned, requiring the involvement of the CPP and the consent of the donor. But in the case that the full body is donated to science, there is not a particular regulation that needs to be followed as the donation is considered the will of the donor. These donations go directly to universities that can decide the research program to what the body is allocated. Bodies are not returned to families after the research is finished and children are not allowed to participate in this program (as it is assumed that they do not have the necessary independence to choose). Each institution has its own policies to ensure that these donations are treated respectfully and following Ethical requirements, but there is not a particular law regulating the process. Results from the research involving human cadavers need to be published as a way of giving back to society, but there are no efforts to communicate to society at large the benefits in health obtained through these donations.

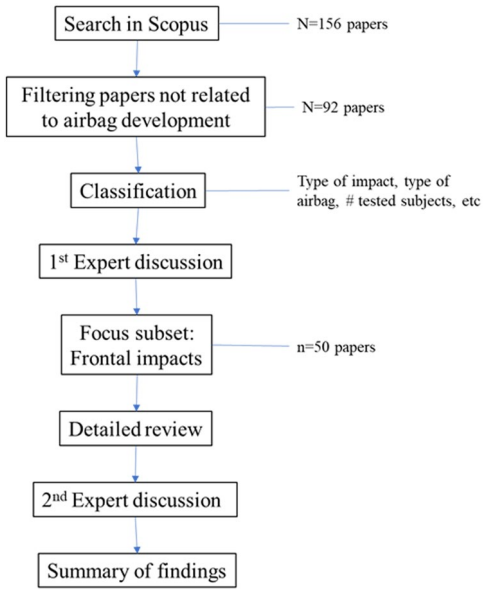

Figure 1. Flow chart showing the process followed to perform the review.

Japan

Research involving human volunteers is allowed in Japan. This research needs to follow a set of guidelines published by the Ministry of Health, Labor and Welfare but there is not a particular law regulating the procedure. Different institutions may have their own bioethics committee that specifies how research must be carried out according to the aforementioned guidelines, and therefore the procedures may change between different institutions. From the information obtained for this publication, research involving human volunteers must seek approval from an internal

Table 1. Characteristics of the existing testing programs for injury prevention involving the use of human tissue worldwide.

	Testing involving post mortem human subjecTS					
	France	Japan	Spain	Switzerland	USA	Canada
Are tests involving human subjects allowed in your country?	Yes	Yes	Yes	Yes	Yes	Yes
Is there a particular law that regulates how these tests are to be carried out in your country?	Yes, but it is applicable only to volunteers. Ordonnance n° 2016-800 du 16 juin 2016 relative aux recherches impliquant la personne humaine	No. There are only guidelines published by the Ministry of Health, Labor and Welfare	Yes, applicable to research projects involving living human beings. Law 14/2007 of Biomedical Research (updated on 2 June 2011)	Yes, the Federal Human Research Act	Yes, but only for research involving human subjects conducted, supported, or otherwise subject to regulation by any Federal department or agency. Current version is known as the 2018 Common rule (45 CFR 46 Protection of Human Subjects)	No law, but research funded by the 3 federal research agencies must conform with the Tri-Council Policy Statement – Ethical Conduct for Research Involving Human Subject (TCPS2 2018)
If yes, is it needed to undergo an external approval process so that a public body/ authority grants permission to carry out the tests? Which is this external organization granting approval? It is a national or a regional/ municipality level institution?	Yes, but only in the case of volunteers. Submission to a CPP is mandatory. CPP depend on the Ministry of Health, and it is valid for the whole country.	--	Yes, it is needed the approval of one of the Ethics Committees for Clinical Research, existing in each Autonomous Community (regions) in Spain	Approval is granted only for the location of the study. If it is a multi-center study, all regional ethics committees are contacted by a leading one.	Approval can be granted either by an internal or an external IRB. There also exists a commercial IRB. It is valid for the conditions described in the approval request.	Most approvals are granted by REBs internal to the institution (typically a university REB). Private REBs are permitted.
What kind of information are required by the internal and/or external groups to assess how Ethics are dealt with in the project?	Objectives and methodology, informed consent obtained in an interview, economic compensation (if any), information about the right of withdrawing from the research program.	Objective, methodology (including location and timing), procedures, data to be collected, data analyses, recruitment methodology, protection of personal data (including storage of data), publication restrictions, potential risks to participants, honorarium, consent form	Objective, Methodology, Justification of the need of involving human subjects, Budget, Confirmation of abiding by the Helsinki declaration	For the clarification of responsibility: summary of research using an official form. For a full proposal under the Human Research Act: a detailed proposal including objective, methods, consent forms, data management plan, etc.	Volunteer tests: Objective, Methodology, potential risk to participants, informed consent forms. PMHS tests: Objective, Methodology, Sponsor, Tissue source and use of the data.	Objectives, methods, participant safety, informed consent form (including risks and benefits), recruitment plan, data security and access plan

review board or committee. The application to obtain approval must include detailed information about the research objectives, methodology and schedule, data to be obtained and how the information is going to be stored and protected (access and anonymization), publication, funding sources for the research, protection of participants during the research, etc. It is strongly mandatory to provide insurance to the participants. Volunteers need to provide informed consent to participate in the research program.

Tests involving the use of human cadavers are not allowed in Japan. Post mortem bodies can be used only in anatomy classes in medical schools. However, Japanese institutions are entitled to subcontract research using PMHS with overseas third parties, provided they obtain prior approval of their respective bioethics committees.

Spain

Experimentation with human subjects is allowed in Spain and it is regulated under the Law 14/2007 of Biomedical Research (updated on 2 June 2011). This Law protects the dignity of all human beings and establishes the necessary informed consent and the opt out possibility so that

volunteers can participate in clinical trials. To ensure that biomedical research is performed under the required Ethical conditions, the Law establishes the need for approval by officially appointed Ethics Committees for Clinical Trials (CEIC). These official Ethics Committees are frequently hosted by either hospitals or Universities, although any institution can also have its internal review board that assists the researchers in the preparation of the application to get the approval from the relevant CEIC. The content of these applications may vary between the different regions but they have to include the objective of the research, why it is needed to be performed on human beings, the methods, a copy of the informed consent, the experience of the group in previous research involving human beings and the budget of the project.

Post Mortem Human Subject tests can be also performed in Spain. There is not a particular law regulating these experiments. Cadaver bodies can be donated to research and teaching programs at universities. Even if it is not required by the law, it is good practice to submit the research project to be assessed by one of the CEIC in the country, always after obtaining the internal approval of the institution review board.

Switzerland

Since 2014 research involving human beings is regulated by a specific national law, the Federal Human Research Act. The Act applies to various research related to human diseases and concerning the structure and function of the human body. This includes research that involves persons, deceased persons, embryos and fetuses, biological material as well as health-related personal data. All research within the scope of the law needs approval by an official ethics committee. If in doubt whether a study falls under the Human Research Act, researchers can also file a so-called clarification of responsibility. The ethics committee then decides whether approval is required or not. To ensure best practice also for research that does not require approval under the Human Research Act, research institutions have installed institutional review boards that address ethical implications as well as other aspects of research.

United States of America

In the case of tests involving volunteers, the US department of Health and Human Services (HHS) developed (and the US government adopted) the Common Rule in 1991 (45 CFR 46 Protection of Human Subjects). This was updated in 2018 to reflect changes in the research landscape since 1991. The Common Rule generally requires that researchers get informed consent from volunteers who participate in research. However, specific laws pertaining to how PMHS tests are to be carried out do not exist. In general, regulations in the US allow for the decedent's next-of-kin to have legal authority over how the decedent's remains are treated and handled. From there, the specifics on the use of PMHS in such testing is not governed by regulations but by ethical standards practiced by the institutions themselves or by guidelines adopted by individual states.

As part of the Common Rule, all human volunteer research must be approved by an Institutional Review Board (IRB). Large research institutions usually have their own IRB. It is also possible for researchers to have their research approved by a commercial IRB or an IRB at another institution. IRBs must have at least five members with various backgrounds to provide different perspectives on the research, including at least one member who is not connected to the institution performing research and one member who is not a scientist. Further, it must have members who know the community where the research will take place.

In the case of PMHS tests, institutional review is not generally required by law. However, institutions may have in place procedures similar to those described above for volunteer research. For instance, the University of Virginia (UVA) has an institutional review board for Human Surrogate Use (IRB-HSU). This process is implemented at UVA to ensure that UVA only engages in research that will use the donated tissue to benefit society, and so that the work adheres to the ethical guidelines of the NHTSA and the US DOD, who both publish ethical guidelines for PMHS testing.

Canada

Canada does not have a law or statute governing human subject testing except for research involving experimental drugs or devices. Instead, the three main federal research agencies have a shared policy statement on the ethical conduct of research involving humans (TCPS. 2018). All research they fund involving living human subjects or human biological materials (including cadavers) must comply with the provisions set out in these guidelines. The guidelines describe how to constitute a research ethics board (REB) and highlight the importance of free and informed consent, fairness and equity in research participation, and privacy and confidentiality. REBs are typically constituted at the institutional level (e.g., universities), although private companies can also have their own REB. Human subject research is permitted without REB approval, but researchers expose themselves to potential professional, civil, and criminal liability if the research does not meet an appropriate standard of care or if the researchers failed to obtain free and informed consent from the participants (Tremayne-Lloyd and Srebrolow 2007). With respect to cadaver research, REB review is required to conduct research involving cadavers or cadaveric material at a Canadian University but can usually be rapidly reviewed as a "low risk" experiment (with respect to the danger to human subjects). Some universities place restrictions on their researchers to prohibit them from obtaining cadavers or cadaveric tissue from third party "tissue banks" and instead insist that tissue and cadavers come from a local willed body program. The procurement and use of cadaveric tissue for research within a province is controlled by provincial law that typically identifies an "anatomical inspector" who can certify universities and other institutions to receive and use cadaveric tissue. In some provinces the legislation

governing the procurement and use of cadaveric tissue dates from the 1800s which complicates the procurement and use of cadaveric tissue for injury biomechanics and other research or training uses.

Other countries

While the countries listed above are traditionally represented at the IRCOBI Conference, the IRCOBI network has also enabled engagement with researchers from additional global regions (Middle East and Latin-American countries). Furthermore, a comprehensive search was conducted in SCOPUS using the keywords TITLE-ABS-KEY ((pmhs OR cadaver OR cadavers OR (post AND mortem AND human)) AND (injury OR injuries)). This search yielded 17,450 papers spanning from 1946 to 2024. Predominantly, these publications originate from the United States, with Germany and the United Kingdom ranking second and third, respectively. This finding is notable considering that many foundational studies in vehicle-related injuries using human cadavers were conducted in Germany from the 1970s until the late 1990s. Presently, Germany does not engage in PMHS testing for vehicle injuries; however, cadaver testing remains prevalent in other areas such as military applications, legal medicine, bioengineering, and orthopedics, with over 1,400 articles published in these fields according to SCOPUS.

In the Middle East, SCOPUS documents a total of 733 publications, with 669 categorized under Medicine and only 18 under Engineering. Turkey leads the region in this research, followed by Iran, where direct PMHS testing related to vehicle collision injuries does not occur, though the use of human cadavers for injury prevention research is permitted. Extensive cadaver testing also continues in orthopedics.

In Latin America, SCOPUS lists 453 papers, with Brazil accounting for 289 of these. Chile, Mexico, Argentina, and Colombia each have approximately 40 publications, whereas other countries in the region show minimal contributions to the field. Discussions with researchers from this area confirm the limited research into injury prevention using human cadavers.

In Asia, substantial research involving human cadavers is evident, with China and India leading in publication numbers, recording 926 and 555 papers respectively. While the majority of these publications are medical (1237 papers), there are also significant contributions in Engineering, totaling approximately 170 publications.

Contribution of PMHS testing to the development of effective injury prevention systems: the case of the airbag

The initial search in SCOPUS returned 156 papers fulfilling the search criteria. These papers expanded from 1972 to 2020. The initial screening reduced the number of papers to 92, as several of the studies included airbags in the testing setup but the goal of the study was not directly related to the development of the airbag and therefore were excluded from this work. The remaining papers were classified according to different criteria (body region protected by the airbag, type of airbag, and type of impact). The distribution of the papers included in each category is shown in Table 2.

After this initial classification, the expert group decided to focus on the papers that discussed frontal impacts as this was the most frequent category ($n = 43$). They were published between 1972 and 2020. Nine of these papers had been cited more than 20 times according to Scopus. Fourteen studies reported matched PMHS and ATD (crash test dummies) tests for comparison, while the remaining focused only on PMHS tests. The number of PMHS used in each study varies largely, as several of them will include data from previously performed PMHS tests incorporating new subjects in the study. This finding indicates that it is frequent that PMHS data are revisited in multiple occasions in later research as new cadaveric data continues to be developed. For instance, tests from studies performed in 1982 were still referenced in 2020. Age of the PMHS ranged from 20 years old to 89 years old and both male and female PMHS were tested. For the purpose of this publication, these papers were classified, depending on their objectives, as follows:

- Papers assessing the performance of the airbag.
- Papers investigating new injury criteria.
- Papers investigating the biofidelity of crash test dummies.
- Papers investigating the biofidelity of human body models.

The remaining papers were considered out of the scope of this work and were not further analyzed. Table 3 provides additional information about the studies that were finally considered and summarizes why the study was considered important for this research.

Table 2. Distribution of airbag papers per each category.

	Number of papers
Body region protected by airbag	
Chest	38
Cervical spine	7
Chest and cervical spine	15
Upper extremities	16
Lower extremities	3
Other	13
Type of airbag	
Frontal	38
Lateral	26
In belt	6
Knee airbag	2
Airbag jacket	2
Other	18
Impact direction	
Frontal	43
Near side	5
Far side	7
Oblique	2
Near side and oblique	3
Far side and oblique	2
Near and far side	7
Frontal and other	1
Motorcycle airbag	2
Other	20

Table 3. List of studies reviewed in detail in chronological order of publication.

Paper	Cited by	Publication year of last paper citing the study	Comments
Cheng et al. (1982)	4	2020	Cadaver cervical spine behaves differently than the Hybrid III neck
Yoganandan et al. (1993)	10	2019	The combination of seat belt and airbag provides the optimal restraint condition for occupants
Morgan et al. (1994)	28	2019	A multipoint injury criterion is needed to discriminate between airbag and seatbelt loading. It can be related to the origins of the THOR dummy
Crandall et al. (1995)	23	2018	Importance of the combined used of airbag and seatbelt to avoid impacts of the head against the windscreen and bending of the steering wheel.
Crandall et al. (1997)	35	2020	The combination of force limiting seatbelts and frontal airbags produced an optimal restraint of front occupants.
Duma et al. (1997)	6	2023	Airbag deployment was not the cause of retina or any other eye injury in the PMHS tested.
Hardy et al. (1998)	2	2020	Proposed kinematic injury criteria to identify forearm fractures during airbag deployment
Hardy et al. (2001)	7	2023	PMHS data used to support the development of a new dummy abdomen presented in Rouhana et al. (2001)
Kent et al. (2001)	4	2023	Chest compression is the best predictor of rib fractures, and chest acceleration is not.
Prasad et al. (2008)	6	2018	Differences observed in chest and neck injury predictions between ATD and PMHS
Song et al. (2009)	24	2021	PMHS tests used to validate the human body model HUMOS 2
Forman et al. (2010)	14	2022	The Hybrid III dummy failed to predict the injuries observed with PMHS in the same test conditions
Hallman et al. (2012)	1	2012	Combination of FE models and experimental PMHS data to predict strain in internal organs. Aim was to identify optimal transducer location in ATD capable of detecting internal injuries.
Lopez-Valdes et al. (2018)	15	2023	THOR and FE HBM did not correctly predict the risk of PMHS injuries, but they were sensitive to changes in restraint conditions like what was observed in PMHS tests

Papers assessing the performance of the airbag

In the United States, airbags were made mandatory in all new vehicles starting in 1998. This new regulation prompted the investigation of the effects of airbag deployment with and without wearing a seatbelt on the potential occupant injuries. Crandall et al. (1995) investigated the effect of a frontal airbag and a knee bolster without a seatbelt restraint system in 4 PMHS tests compared to Hybrid III tests performed in matching impact conditions. The Injury Severity Scores (ISS) for all the PMHS were severe to critical. This study showed the need for a combination of airbag and seat belt to avoid large forward displacements of the occupant, impacts of the head against the windscreen and bending of the steering wheel.

Slightly later, Crandall et al. (1997) carried out nine PMHS (8 males, 1 female) and six dummy sled tests at 56 km/h in a driver position to investigate the effect of combining an airbag either with a conventional non-force-limited seatbelt or with a force-limited seatbelt. PMHS subjects were lighter and shorter than the 50th percentile (Average weight: 67.6 kg; average height: 153 cm). Although the study concluded that the combination of a force limiting seatbelt and a frontal airbag provided an optimal restraint for both the PMHS and the Hybrid III, it should be noted that the dummy tests showed somewhat different spinal acceleration responses than those found in the PMHS especially at the T1 vertebral level. These differences are relevant since, at the time, dummy spinal acceleration was one of the injury thresholds used to assess thoracic injury in several regulations.

Around the date of the mandatory inclusion of airbags in the vehicle fleet, there were concerns in the public about the potential for ocular damage caused by the deployment of airbags. Duma et al. (1997) addressed the potential for eye injuries in a PMHS study with 13 subjects. Ten different airbags (different materials, coatings, tethers and folding patterns) were deployed into the face/eyes of isolated heads. It has to be noted that 12 out of the 13 subjects had detached retinas before the tests, but none of them received any additional eye injury in the deployment. The study looked specifically for surface/corneal abrasions.

Papers investigating new injury criteria

Morgan et al. (1994) analyzed data from 63 PMHS tests in frontal impact using several restraint conditions and measuring both chest acceleration and deformation. The study proved that the human chest under pure seatbelt loading, pure airbag loading or a combination of both, exhibited different responses and that the injury criteria to assess the injuries caused by each restraint condition should be, therefore, different. The study concluded that a "suitable dummy that has both the needed biofidelity and instrumentation capability" was needed to identify the type of chest loading prior to applying the relevant injury criteria. Based on the authors' research, the proposed discrimination method involved the need of multipoint chest deformation measurements, which is probably related to the origins of the THOR dummy that started to be developed as the Advanced ATD (AATD) Thorax system in 1992 (Schneider et al. 1992) and was eventually presented as the THOR dummy (Haffner et al. 1994). The AATD measured 3D chest deflection using doble-gimballed string potentiometers that were eventually replaced with the current IR_TRACCs.

Kent et al. (2001) exposed 10 PMHS to frontal sled tests at 48 km/h restrained by either a depowered airbag paired with a seat belt or a standalone non depowered airbag. Accelerations at different spinal levels, intra-aortic pressure

and chest deflection at two locations were measured in the tests. This study identified that chest compression was the best predictor of rib fracture, which was not dependent on chest acceleration nor even improved when combined with chest acceleration (as frequently used both in the American and European automotive safety regulations up to the 1990s).

Hardy et al. (1998) investigated forearm injuries caused by airbag deployment as function of airbag power. Based also on previous dummy and PMHS studies, the authors proposed to use two kinematic injury criteria (Peak and Average Distal Forearm Speed, PDFS and ADFS). These criteria were preferred over injury criteria based on bending moments, which were being developed using surrogate arms (the Research Arm Injury Device, RAID, or the instrumented-Hybrid III forearm by Johnston et al. (1997)). These two surrogate arms had exhibited dramatically different kinematics but had ranked correctly different airbag systems according to their relative aggressivity based on field data. Hardy et al. (1998) in addition to finding that either PDFS or ADFS could be used as a reasonable predictor of forearm fractures, found that internal pressure of the airbag did not have a direct relationship with the likelihood of forearm fractures.

Papers investigating the biofidelity of crash test dummies

Hardy et al. (2001) exposed 16 PMHS to different abdominal loading: seat belt loading, airbag loading and abdominal impact loading with a rigid bar. The study developed force vs. displacement corridors that were used to support the development of a new more biofidelic abdomen for the Hybrid III ATD proposed in Rouhana et al. (2001), that would account for deformation rate effects seen in the human abdomen. A second contribution of the study was the development of a surrogate airbag that was repeatable (avoiding the variability introduced by airbag folding and fabric) and representative of the first stages of abdominal loading in the PMHS tests. This airbag was proposed to be used with ATDs too to increase the robustness of the ATD response to abdominal loading.

Yoganandan et al. (1993) investigated thoracic injuries caused by different restraint conditions that included an airbag and one additional restraint system (knee bolster, lap belt or a three-point seat belt). This study is one of the earliest ones comparing the response of the Hybrid III 50th percentile and of 14 PMHS. The test subjects were exposed to sled frontal impacts at two different speeds. The study showed that the degree and location of the maximum chest compression varied with the seat belt condition despite the presence of the airbag. The research identified similar deformation patterns in the upper and lower torso when the restraint system consisted of the airbag and the knee bolster or lap belt (with the fractures occurring in the middle/lower rib cage due to the contact with the steering wheel), which were different from the injury patterns observed when the airbag and three-point seatbelt were used (fractures occurring along the rib cage region that was loaded by the diagonal shoulder belt).

In 1982; Cheng et al. (1982) performed frontal impacts at 48 km/h in the WHAM III sled. The study reports on matching tests with 6 PMHS and the Hybrid III 50th percentile. The test setup included a rigid seat cushion angled at 10 deg and a vertical seatback. A pre-inflated non-vented airbag (8.6 kPa) was initially in contact with the chest. Occupants were unbelted. The focus of the paper was on neck injuries: four of the six PMHS sustained neck injuries, three of these ranked as AIS6 injuries. In the comparison with the Hybrid III, the authors concluded that the response of the dummy neck was different from the cadaver neck in the tested configuration. The PMHS neck was more flexible and resulted in greater injury severity despite the fact that the Hybrid III neck measured neck loads that were considered reasonable according to previous studies. The authors pointed out that the kinematics of the unbelted PMHS were substantially different from those of the unbelted Hybrid III, which was the cause of the different neck loading mechanisms observed in the matching tests. This study is the earliest one encountered comparing the outcomes of PMHS and ATD restrained with airbags in matching conditions and establishes the ground for the need of adding a three-point seatbelt to the airbag to cause a more favorable kinematics of the human occupant avoiding critical AIS cervical injuries.

The use of PMHS has been also used to understand potential injuries in out-of-position (OOP) conditions. Prasad et al. (2008) compared the outcome of five unbelted female cadavers exposed to static airbag deployment in three OOP conditions (nose on steering wheel, chest on steering wheel, forehead on steering wheel) with similar positions when possible of the Hybrid III 5th percentile dummy. As in other studies, the dummy predicted a low risk (always under 15% of AIS3+ chest injuries), while all the PMHS received multiple rib fractures and sustained AIS3+ thoracic injuries. As in the study by Cheng et al. differences were also identified in neck injuries, although the conclusions were somehow contradictory. In this study, tests with the dummies suggested the possibility of AIS2 injuries but no neck damage was found in the PMHS in this case. Note that since these deployments were static the kinematics of the occupant would be completely different from those observed in the Cheng et al. study. Regardless of the increased/reduced neck injury, what is more important for the goal of our study is the fact that PMHS and ATD were observed to behave differently and to predict different risks of chest and cervical injuries.

Forman et al. (2010) discussed the results observed with an inflatable shoulder belt designed for the rear seat that incorporated also a pre-tensioned lap belt. In these tests, the occupants were exposed to a 48 km/h frontal impact in the rear seat of a representative American sedan car. Despite the deformation of the chest of the three tested PMHS was more benign than the one observed in previous PMHS tests with other contemporary restraints, PMHS still exhibited AIS3 and AIS4 chest injuries, something that was unexpected from the predictions obtained with the Hybrid III dummy tested in matching conditions, which resulted in substantially lower chest injury risk.

Lopez-Valdes et al. (2018) performed frontal sled tests at 35 km/h on 6 older PMHS and the THOR dummy. Occupants were restrained by a non-retractor force-limited three-point seat belt and a pre-inflated vented airbag. Both the Cmax and the PC-score thoracic injury criteria (based on the maximum deformation of the chest and on a multi-point measurement of chest deformation as presented in Poplin et al. (2017)) were used to estimate the risk of thoracic injuries. The tests were performed in two slightly different conditions (modifying the geometry of the seat belt, changing the friction of the seat and optimizing the initial position of the occupant to minimize the risk of injury). Regardless of the test conditions, the THOR dummy always estimated extremely low thoracic injury risk compared with the number of rib fractures observed in the PMHS. The decreased number of rib fractures obtained in the PMHS tests in the optimized restraint condition was captured correctly by the THOR dummy, although the dummy again overestimated the risk reduction in comparison with the injuries observed in the PMHS.

Papers investigating the biofidelity of human body models (HBM)

Hallman et al. (2012) analyzed the mechanical visceral response to multi-directional loading using a simple FE model of human viscera in combination with PMHS deformation data of the thorax and abdomen obtained with chestbands. The motivation of the study was the lack of correlation between some internal viscera injuries caused by localized airbag deployment and the surface deformation measurements carried out in PMHS. The authors pointed out the need to identify the strain/strain density magnitudes causing the injuries to the viscera to optimize the development and position of ATD sensors that could pick up relevant predictors for internal organs injuries.

One of the advantages of incorporating PMHS tests in the development of human FE models is the possibility of benchmarking the models at the strain level. Song et al. (2009) used previously published PMHS tests to compare the global response of the chest of the HUMOS 2 in matching test conditions, and included the measured strain in the ribs of the PMHS tests in the comparison. This is particularly relevant as injury criteria being developed for HBM can be developed based on strain predictions, which requires a previous validation of the strain levels given by the HBM. The authors suggested that a validated HBM can serve as a tool to assess the effectiveness of restraint systems in a human occupant, without the uncertainty associated with cadaver scattering, measurement and autopsy. Whether this is the right approach to develop effective restraint systems is out of the scope of our work, but what is important is to point out that the authors could claim that the HBM had been validated by comparing the outcome of the model to eight studies including results from impact tests performed on cadaveric human subjects.

Discussion

Within the overall context of safety and injury prevention, engineers use a multi-step process that consists of following general steps: i) learn how a particular injury is caused (the injury mechanics), ii) measure the level of force or some other mechanical parameter needed to cause the injury (the injury tolerance), iii) develop a method or laboratory tool for measuring these forces in a vehicle crash (e.g., a crash test dummy or computer model), iv) use cadaver data or human volunteer data to validate these models, and v) generate guidelines or a regulatory safety standard that vehicle designers and manufacturers need to meet so that their products reduce the potential for these injuries in real-world crashes involving the general public. This fundamental workflow has been used many times over the years to develop safety interventions like seatbelts, head restraints, helmets, and more recently airbags to prevent or mitigate head, neck, chest, pelvis and lower extremity injuries in automobile crashes. Where possible, prior cadaver and human volunteer data are re-used, but new and better safety interventions occasionally require new mechanism, tolerance and validation data that necessitate additional cadaver or human volunteer testing. Similarly, the existing mechanisms, tissue tolerances and validation data are often biased toward specific populations (50th percentile men, 5th percentile women) and expanding this knowledge to include all the variability in the population also necessitates additional cadaver testing. And while computer models are increasingly used to develop and design new safety interventions, they too need to be validated against actual human responses before they can be relied on to develop interventions that will be deployed into the vehicle fleet.

Indeed, this workflow has been also followed in the case of airbag prototypes and research systems development. Early studies showed the potential for mild concussions and abrasions in volunteers (Smith et al. 1972) and animal and human cadavers testing has shown the risk of severe neck and thoracic trauma (Patrick & Nyquist, 1972; Prasad and Daniel, 1984) in out-of-position deployments. Kent et al. (2005) reviews the available literature about field performance of frontal airbags and describes how PMHS studies have also helped to understand the mechanisms causing some of the most frequent injuries found in the field. This was the case, for instance, of face and head injuries of unbelted, airbag-restrained front occupants occurring in the 90's in the US that would hit the front header or windshield of the vehicle. Until the results included in Crandall et al. 1995; there was no sensible explanation of the injury mechanism associated with these field injuries. Although PMHS studies alone can provide only a partial explanation of real-world injuries, they are an essential part of a complex puzzle that enlightens essential aspects of the development of effective safety systems from knowing injury thresholds and mechanisms to understanding how the outcome of the same mechanical insult varies across different groups of the population.

It is relevant to notice that, in addition to the individual contributions to advance either airbag technology or the design of more biofidelic surrogates for airbag loading conditions, the studies discussed in this paper have had a tremendous influence in the field. This effect can be quantified by the citations received by these papers in later studies.

Indeed, PMHS experimental data that were generated for a specific purpose at a moment in time can be used for other purposes different from the original one as time passes. A detailed look at Table 3 shows studies that presented experimental data in 1994 or 1996 and were still referenced in publications in 2020. This contribution of PMHS data to contemporary research is difficult to assess but provides insight into how valuable a set of new PMHS experiments can be for the field: its contribution to develop more effective restraint systems remains over a long time.

It should not be forgotten that despite all the experimental work done with PMHS in the past, new crash circumstances may require new PMHS tests. This is the case of the different studies that are being carried out currently to understand the kinematics and dynamics as well as the potentially new injury patterns that may be observed in reclined postures, new seating arrangements and the rear seat (Jorlöv et al. 2017; Koppel et al. 2019; Rawska et al. 2020; Richardson et al. 2020a; Richardson et al. 2020b; Östling et al. 2022; Kang et al. 2022, 2023; Shin et al. 2023), which are frequently associated to future automated vehicles. The PMHS tests addressing this occupant's position are being used to assess the performance of current and new designs of restraint systems, more biofidelic crash test dummies, such as the THOR Reclined, and HBM. Indeed, every time that there is a significant shift in how the users interact with the safety systems of the vehicle, it is necessary to assess whether the non-human surrogates (ATD and HBM) are still biofidelic. Another relevant consideration at the time of performing tests with PMHS is the necessity of adopting a sound scientific methodology that allows to draw as much information as possible from the experiments to maximize the benefit to society of the donation. In this regard, we strongly advocate for making as accessible as possible the information gathered from the tests which, usually, will be published in the scientific literature and therefore available to relevant stakeholders.

Unfortunately, the task of estimating how many lives have been saved by performing PMHS tests is extremely challenging. Some decades ago, King et al. (1995) provided a straightforward calculation to illustrate the contribution of PMHS testing to the American society using data from NHTSA. They estimated that per each cadaver test, 60 lives were saved in the USA. This number can only increase with time as more and more road users are benefiting from safety devices that were developed using PMHS data. King's paper has continued to be pertinent, garnering 42 citations in Scopus from 1997 to 2024. The research citing this paper originates from institutions in the United States as well as internationally from France, Germany, Canada, the United Kingdom, New Zealand, Belgium, Brazil, China, Poland, Portugal, Spain, and Switzerland. Notably, the citations of King et al.'s work span beyond the field of injury biomechanics, with a significant number originating from medicine, and others from as varied fields as social sciences, dentistry, and computer science. This diversity underscores the ongoing relevance of using human cadavers in multidisciplinary research to further scientific advancements. While most of these studies are within medical fields, a substantial portion also pertains to Engineering, Neuroscience, Materials Science, Physics, Immunology, and Nursing, among others. It would be mistaken to assume that most of this cadaveric research occurred in the past, before the development of alternative methodologies like computer simulations or synthetic surrogates. In fact, nearly 80% of these publications have been issued since the year 2000; indicating a robust reliance on cadaver studies in contemporary research.

However, to extend King et al.´s estimate to all research in which PMHS experimental data have been used up to date, to all safety systems existing in the current fleet and to all countries that currently perform PMHS tests or use the data arising from them is simply not possible. Thus, a more descriptive approach is taken to the question, justifying why PMHS data are essential to design both biofidelic tools and effective restraint systems.

This paper reflects about the past, present and future of using human cadavers for research purposes. In these days, in which improving computational models might induce the false idea that volunteer and/or cadaver testing is no longer necessary, it is important to emphasize that the field still needs experimental data from experiments with humans to validate and benchmark human body models.

Conclusion

The International Research Council of Biomechanics of Injury (IRCOBI) is dedicated to promoting research in the field of impact biomechanics and injury mechanisms. Given that such research frequently involves the utilization of post-mortem human subject (PMHS) cadaveric tissue, a subset of IRCOBI Council members has undertaken the task of providing recommendations regarding ethical guidelines for the conduct of this type of research.

This publication aims to consolidate global best practices in this regard, aligning them with the ethical principles established by international organizations governing research involving human subjects. Thus, the following recommendations are proposed to ensure that PMHS testing is conducted with the utmost adherence to ethical principles, in conjunction with strict compliance with applicable local and national regulations:

1. Informed Consent: Prior informed consent should have been obtained from the donor before their death. In cases where obtaining direct consent is not feasible due to the donor's lack of autonomy or post-mortem donation, proxy consent must be sought from their next-of-kin.
2. Independent Review: An independent review board should evaluate the relevance and appropriateness of the research goals and methodology, the PMHS sourcing and handling practices (including consent, preservation of anonymity and processes to ensure that the PMHS are treated with the due respect). To ensure an adequate knowledge of the field, this review board should include or seek advice from at least one expert in injury biomechanics.

3. Subject Selection: The selection of research subjects should prioritize the least vulnerable individuals to safeguard the rights of vulnerable populations. Vulnerable individuals, in this context, refer to those who cannot provide fully autonomous consent.
4. Scientific Justification: The necessity of conducting experiments with human cadavers should be well-founded based on the current state of knowledge. Prior to planning research involving human cadavers, alternative surrogates, such as Anthropomorphic Test Devices (ATD) or computer models, should be explored. While recognizing the intrinsic value of body donation, the findings resulting from cadaveric investigations should be disseminated within the research community to maximize the societal benefits of such research.
5. Ethical Oversight: The principal investigator must be prepared to terminate the experiment if there is reasonable cause to believe that it is unlikely to yield the requisite information to achieve the study's objectives.

Furthermore, IRCOBI asserts that, until a comprehensive understanding of tissue damage tolerance levels is achieved (including considerations of mechanical energy, energy delivery, sex, age effects, as detailed in Forman et al. 2012), and until human surrogates like ATD or Human Body Models (HBM) attain complete biofidelity, experimentation involving human cadavers remains indispensable for the development of effective injury prevention policies and countermeasures.

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In the interest of full transparency and ethical integrity, it is relevant to report that several authors of this paper actively engage in experimental research involving human cadavers.

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