Human Impact Exposure Onboard High-Speed Boats

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STUDY DESCRIPTION

Brief Summary
Operating high-speed boats is dangerous. The purpose of this study is to establish what levels and what characteristics of impact exposure cause injuries. Impact-induced injuries are sometimes severe and cause permanent disabilities. The slamming-impact exposure causes more injuries per workday than seen in most other peacetime work. It is however NOT known which levels or kinds of impacts are dangerous and which are safe or sustainable. To prevent injuries and to reduce fatigue onboard high-speed boats, this knowledge is crucial. Current standards and regulations lack relevance. They are based on mean values of vibrations, and the stated exposure limit values are impossible to comply with even in normal maritime operations. The purpose of this study is to establish what levels and what characteristics of impact exposure cause injuries. This prospective observation study will measure human impact exposure and correlate this to the occurrence and development of pain, used to indicate the risk of injury.

Condition or Disease:

Intervention/treatment:

Phase: N/A

DETAILED DESCRIPTION
INTRODUCTION The ultimate purpose of the study is to protect professionals operating high-speed boats from severe impact-induced injuries. This requires establishing what kinds of impacts are dangerous and defining relevant limits for sustainable human impact exposure. It is also important to understand how impact exposure onboard high-speed boats can cause severe, permanent, and debilitating injuries. Increasing speeds and increasing numbers of high-speed boats used in professional operations seem to increase these problems both in numbers and severity worldwide. A lack of knowledge about the actual exposure and understanding of the causes of injuries, and the implementation of counterproductive regulations, test methods, specifications may have contributed to the increasing number of injuries. To determine what impact exposure is dangerous, it is necessary to conduct a prospective longitudinal study on humans being subjected to the relevant actual real-life exposure at sea and correlate this exposure in real-time to a physiologic parameter indicating the risk of acute injury. Based on the new knowledge, relevant exposure limits can be proposed to protect operators from injury and allow full operational capability underway and at target or mission. Furthermore, the research will lay the basis for a new quantitative measurement unit representing the impact-induced forces challenging the anatomical structures and based on the magnitude and characteristics of the impacts.

2. BACKGROUND A recent retrospective web survey of self-reported injuries on retired US SOF (Special Operations Forces) HS boat operators, the SWCC2020 survey, indicates a significant increase in injuries compared to a similar survey done on active duty personnel 20 years earlier, Ensign 2000. The SWCC2020 survey showed that 1.1 injury per person per year served; 50% of injuries affecting the spine, 33% of respondents having been unconscious onboard due to whole-body impacts, 40% of respondents have a VA Disability rating of 70 to 100%. This is an extreme work environment, and relatively few individuals in each country are exposed. Hence, there are still significant knowledge gaps that must be filled to solve the problems.

What is the actual exposure? When does it get dangerous? Which impact characteristics do affect the risk of injury? How should these characteristics be weighed against each other? As the impact exposure is unpredictable and stochastic, it is impossible to simulate in an artificial environment. The human body is a highly intricate ‘apparatus’ designed to protect itself from noxious exposure in several ways: It is also extremely difficult to predict the physiological response from an unlimited variety of impacts. The body has 360 joints, 206 bones, and 600 muscles reacting to sudden external forces. Many physiological factors influence how impacts affect the human body: bodyweight, stature, central gravity, posture, muscular strength, physical shape, training status of the reflex response, etc.

3. METHOD The purpose of the study is to correlate impact exposure on boat hulls and humans to a physiologic parameter possible to use as an indicator of developing an injury. The only such parameter possible to monitor daily in a cohort of hundreds is pain.

3.1 MULTI-AGENCY STUDY DESIGN The collaborative effort aims to gather sufficient volumes of data to reach statistical power. This requires all agencies to use the same study protocols, hardware, and software and eventually share the relevant results in a shared database. Agencies in 16 nations have already expressed their interest in participating. All subject data will be anonymous and boat data stripped of potentially sensitive operational information before being submitted to the shared database.

Crucial synergies can also be achieved by sharing costs, data, and results. To achieve statistically significant results, a sufficient number of boats, subjects, and wave-slam events can be gathered.

3.2 MEASURING IMPACTS ON HUMAN AND HULLS Whole-body impact will be monitored on two people on board each boat at all times. Each boat will have a data logger installed for the entire study period. This will be connected to a 3-axis accelerometer attached to the hull, close to its CG. Two crew, preferably the coxswain and navigator, will wear 3-axis accelerometers mounted to their heads and connected to the hulls data logger. Recorded data will indicate the actual real-life impact exposure on the hulls and humans. This data will show the real exposure and the relation between hull impacts and human impacts for each boat type. The data logger and accelerometer can be used to monitor the impact exposure on hulls and humans onboard operating in real sea conditions. Accelerations will be recorded as unfiltered, raw data. This will allow for analysis of all the characteristics of impacts, potentially relevant for physiological effects and risks of injury. This shall make it possible to assess the signification of not only peak acceleration values but also of rise-times (time from 0 g to peak g), impact duration, energy content, slam period (time between slams), and force vector (direction of impact, etc.). This will also make the results transparent and possible to scrutinize.

3.3 DATA LOGGER AND SENSORS A bespoke data logger device has been developed for this study. MAREC (Marine Acceleration Recorder) is optimized for ease of use and installation. Installed onboard and connected to 12 or 24 V DC, it will automatically start recording as soon as the boat makes a speed of more than 3 kts. MAREC has 10 analog channels, of which 9 are used for the three 3-axis accelerometers with a ± 25 g range. The sampling rate will be 600Hz. It also has a built-in GPS receiver logging satellite time, position, heading, and speed. The 16 Gb internal USB memory can store the data for the entire period of the study. Afterward or even during the study, the data can be uploaded to a PC for analysis.

3.4 PAIN INDICATES RISK OF INJURY Pain is used to indicate if exposure causes a risk of injury. All personnel serving onboard the boats will log events and development of pain during the entire trial period.

3.5 DATA ANALYSIS AND MANAGEMENT Participating agencies and organizations will upload the collected exposure data to their local computers. The binary files will be converted and presented in a graphic format legible even by laypersons. The data analysis software will then select the relevant non-sensitive part for sharing and, on command, be uploaded to a common big-data database. A data analysis engine DAE, built for the purpose, will analyze the correlation of the various characteristics of the impacts to the physiological response, reported as experience and perception of pain.

4. RESULTS AND APPLICATIONS Based on the expected results of the study, it will be possible to calibrate instruments with dashboard-mounted indicators, telling operators when hull impacts exceed safe levels by green, yellow, or red signals, where red should indicate out of boundaries. The results should also indicate the significance of the various analyzed impact characteristics. Ultimately, the results can lay a base for relevant recommendations for allowable various levels of exposure to whole-body impact. Participating agencies will gather information about how their various boats perform, producing slamming impacts in actual use. They will also be able to see how various levels of operator skills affect exposure. 5. CONCLUSION Current standards and regulations cannot quantify or help control human impact exposure at sea. In many fields of medical science, it is only possible to get relevant answers by studying the human itself. In this case, the new knowledge needed to solve the problem can only be established by studying what happens in real life. Scientists and medical professionals have a duty to implement State-of-the-Art knowledge to find the facts needed to solve these severe occupational health problems. Hence, the investigators have chosen an empirical approach, investigating what happens to humans in real-life at sea.
STUDY DESIGN

Study Type: Observational
Estimated Enrollment: 250 participants
Intervention Model: N/A
Masking: N/A
Primary Purpose: N/A
Observational Model: Cohort
Time Perspective: Prospective
Official Title: Human Impact Exposure Onboard High-Speed Boats

Actual Study Start Date: February 2022
Estimated Primary Completion Date: April 2023
Estimated Study Completion Date: May 2024

OUTCOME MEASURES

Criteria

CONTACTS AND LOCATIONS

Contacts

Locations

Sponsors and Collaborators

Investigator

MORE INFORMATION

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Individual Participant Data (IPD) Sharing Statement:
Plan to Share IPD: No

Studies a U.S. FDA-regulated Drug Product:
No

Studies a U.S. FDA-regulated Device Product:
No