A Method and Apparatus to Simulate Physiologic Right Side Heart Movement in a Fresh Human Cadaver: Pilot Studies

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In vivo animal models have been and remain the "gold standard" for medical device testing. However, these models sometimes present disadvantages in terms of similarity to human anatomy, associated high cost, and other complexities. This is especially true when considering devices that are to be introduced via the peripheral cardiovascular system and navigated to their destination using catheter-based techniques. Hence, the utilization of fresh human cadavers for such investigations has become an attractive alternative or complement to animal in vivo testing. The main drawbacks to using a cadaver for such testing are the lack of perfusion and heart movement, which can cause difficulties in simulating device placement. To overcome these issues, we constructed a pump system consisting of a centrifugal pump and solenoid valve to generate a pulsatile flow through an intact cadaver heart, causing cardiac movements meant to approximate right heart physiologic conditions. The system was able to generate an approximately sinusoidal right ventricle pressure with a mean of 22 mm Hg and amplitude of 4 mm Hg at 60 beats/min. Heart movements were observable and the physicians testing device delivery methods reported that they could perceive catheter movements during placement. It is planned that in the next iteration the system will be modified to likely include a positive displacement pump and varied cannulation strategies. Overall, the system has provided a solid foundation for future work. Improvements to the system will allow for more realistic heart movement and will aid in subsequent device testing.

Development of a Database for Global Health Medical Devices

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The design, development, and implementation of health-related technologies for resource-limited settings require a detailed consideration of the end user and target community that goes beyond the traditional engineering design needs assessment. In a broader sense, economic, social, and cultural constraints must be considered for successful implementation of technologies. Such constraints are often difficult or impossible to ascertain a priori, necessitating significant fieldwork; there is currently no database where prospective designers for global health can review how others have fared with similar and diverse challenges. Here we present the concept and preliminary results of a medical device case study database developed through research of best practices in low-cost medical devices designed for diagnosis, treatment, and prevention of the World Health Organization top ten causes of death in low-income countries in addition to Millennium Development Goals 4 and 5. Over 170 identified cases were organized based on device type (e.g., diagnostic, treatment, and preventive), development stage (e.g., preclinical, clinical trial, and market) and geographical implementation.