Developing a Low-Cost, Portable Device to Improve Access to Safe Surgery

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Background & Device Objective

Conditions requiring surgical and anesthesia services account for 30% of the global disease burden, yet over 70% of the world's population lack access to safe and timely care. In low-to-middle-income countries, around three billion people have access only to surgeries performed in unsterile settings. Field surgical zones in austere environments are often exposed to frank particulate and insect contamination. Provider protection due to lack of sterile equipment is also a limitation in these settings, particularly in the COVID-19 era. Previous solutions have often failed due to cost and logistical barriers. Here we expand on benchtop proof-of-concept of a low-cost, ultraportable device (SurgiBox), provide early needs assessment data, and evaluate the device's feasibility via human factor (HF) testing.

Device Description & Method of Use

SurgiBox is an ultraportable system designed to provide sterile intra-operative environments directly over surgical sites (Figure 1a and 1b). Integrated glove-sealed arm ports are used for access while a High-Efficiency Particulate Air (HEPA)-filtered laminar airflow system produces state-of-the-art levels of sterility within two minutes. The fully self-contained device can collapse to fit in a backpack for rapid deployment.

To assure successful development and deployment, rigorous and iterative biodesign principles (e.g. robustness and ergonomics) were applied throughout multiple cycles of product development. First, a needs assessment was conducted with Special Operations Force (SOF) members aimed at identifying unmet military surgical needs. Second, human factors testing was performed for six generations of SurgiBox using a semi-structured 30-min simulation exercises wherein users were observed setting up the system and conducting surgical tasks on a manikin within the system. For each critical step, opportunities to improve either the design/user interface were identified. Qualitative feedback from each round of exercises was used to guide the next steps in the development of SurgiBox.

Preliminary Results & Product Design

Figure 1a



Figure 1b

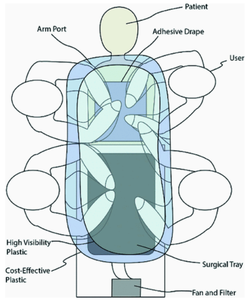


Figure 2
Simulated field deployment



Initial needs assessment emphasized the importance of being ease of transport, low-cost, and providing sterile environment to protect surgical wounds. Participants foresaw the most utility for Surgibox in Level 2 and 3 of the military evacuation chain as well as humanitarian and disaster-relief missions.

HF testing with surgeons demonstrated ease of repeat usage of the system without contamination of the provider's hands or sleeves. Cutting, retracting, and suturing were reported as "same as usual" from an ergonomic and convenience. Visual clarity under both overhead lighting and portable lighting was noted to be "good" and participants perceived SurgiBox to be appropriately safe as well as functional in terms of user interface and model interpretability. Qualitative feedback for changes included improvements in labelling and usage instructions, enlargements of the extremity ports, and minor changes to improve provider range of motion.

Conclusion

SurgiBox provides a safe, intuitive, and portable sterile field for surgical providers in austere settings. This work represents a critical step toward conducting preclinical and clinical trials to test the safety and efficacy of SurgiBox in preventing surgical site infection. Next steps include optimizing potential supply and distribution channels as well as pre-clinical trials in animals.