SurgiBox: An Ultraportable System to Improve Surgical Safety for Patients and Providers in Austere Settings

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***Abstract*— Over 25% of the global disease burden requires surgical therapy, which could prevent over 18 million deaths per year. Yet two billion people have no meaningful access to safe surgical care, and two to three billion more have access only to unsterile surgeries, leading to disproportionate rates of surgical infections. At the same time, over 85,000 medical providers are infected by patient bodily fluids annually, with 90% of infected providers worldwide having been exposed while working in austere settings. We have designed SurgiBox to address both patient and provider safety in surgeries by providing protection of the surgical field microenvironment and by functioning as more effective personal protective equipment for provider teams. The SurgiBox platform integrates into standard surgical workflow as a clear, sterile enclosure sealed to the patient then accessed via arm ports and material ports. An integrated environmental system controls field conditions to produce 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 and can be set up rapidly using draping methods familiar to surgical teams. This combined barrier and active protection system embodies a paradigm shift away from the operating "room" with all its infrastructural limitations and toward protecting the critical surgical site and personnel.**

Keywords—safe surgery, surgical site infections, occupational exposures, surgical capability, global surgery, disaster relief, low and middle income countries

I. Introduction

A. Background: Safe Surgery as a Double Challenge

Surgery is necessary for saving lives in a broad range of situations, from traumatic hemorrhage and obstructed labor to gallbladder infection, lung cancer, and beyond. It is gaining recognition as a critical part of the global health armamentarium, with recent estimates of 116 million DALYs per year lost globally due to conditions addressable by surgery [1]. This avoidable burden of morbidity and mortality is caused by gross disparities in access to safe surgical care, with the individuals with wealth in the bottom two-thirds experiencing sporadic or no access [2] to the facilities needed for sterile surgical care. The Lancet Commission on Global Surgery suggested a global target of 5,000 procedures per 100,000 people [3]. This target represents the volume of surgeries needed to address the global burden of disease, and would cost an estimated 420 billion dollars in 2030. Although this financial cost of surgical expansion is significant, the cost of inaction on national incomes is far greater. The deaths and disabilities caused by lack of access to surgery will cost global economies 12.3 trillion dollars (2010, US$, PPP) from 2015-2030 and slow annual income growth by as much as 2% in some countries [4].

In addition to this chronic deficiency in surgical access, field surgical zones in disaster-affected areas are often exposed to dust particulate and insect contamination. Patients in austere surgical environments - a term comprising both low-resource settings and areas involved in disasters - are at disproportionate risk of surgical site infections (SSIs), particularly severe visceral infections characteristic of intraoperative contamination, which affected as much as 46.5% of patients [5] according to one large meta-analysis.

Patients are not the only people who can get infected during surgeries. Some 85,000 medical providers worldwide are infected annually [6] by patient bodily fluids. Despite the lower volume of invasive procedures occurring in austere settings, 90% of providers infected were working in such settings [7]. Such chronic risks were thrust into sharp relief during the Ebola epidemic, when Sierra Leone's surgeons encountered 100-fold infection rate increases compared with the general population, resulting in the death of 25% of the surgeons in the main teaching hospital of the capital [8, 9].

B. Operating Rooms and Theatres

The current gold standard for intraoperative protection of patients from infection has been the modern operating room, which is best described as shorthand for an expansive infrastructure encompassing not only a physical room in which surgeries occur but also meticulously-designed and maintained heating/ventilation/air conditioning (HVAC) systems for circulating sterile air, regular disinfection protocols, critical equipment, patient skin sterilization and draping techniques, and personal protective equipment (PPE) clothing (e.g. scrub gowns, caps, footwear, etc), as well as behavioral norms.

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Because of contaminants such as skin continuously produced and shed from both patient and provider bodies, state-of-the-art operating rooms typically utilize continuous, laminar airflow from over the patient as well as lesser airflow horizontally, in total supplying 20-40 full air changes per hour depending on level of sterility needed [10]. HVAC design has marked impact on patient infection risk, with systems that more consistently and rapidly moves particles away from incision sites corresponding to lower rates of wound contamination and infection than systems with issues such as turbulence or external particle ingress [11].

Most efforts to date to improve patient safety in austere settings have focused on bringing "operating rooms" to patients in somewhat more portable formats, such as tents, trucks, and trailers; these have variable levels of HVAC performance. There have been efforts to render airflow systems more portable as well, independent of facility. These operating room-focused solutions have been helpful for extending surgical capability, but they tend to share a number of key limitations: high upfront and maintenance costs, limited portability, and various external dependencies such as truck-accessible roads or flat ground for setup.

C. Personal Protective Equipment

Personal protective equipment serves the dual functions of protecting patients from providers and providers from patients. Exact items vary by procedure, item availability, institutional policy, and provider preference. Typical items include surgical caps, hoods, goggles, masks of various filtration capabilities, gowns of various levels of impermeability, scrub tops and bottoms, 1-2 layers of gloves, and either shoe covers or longer booties of various heights. In general, achieving better protection from patients' bodily fluids and potentially infectious aerosols generated during procedures comes with increased per-case costs and decreased provider convenience.

D. Solution Concept

We studied the two challenges of patient safety and provider safety, and noted that both stem from a common source: the actual surgical site at the level of the incision both receives and produces potentially infectious contaminants. When considered at this core level, it becomes manifest that the problem is not inevitably a multi-million-USD one of protecting entire operating rooms and every single person therein. We literally shrink the problem down to the level of the incision, isolating the immediate surgical field with a clear plastic barrier accessible through arm and materials ports.

II. IMPLEMENTATION

SurgiBox consists of a transparent enclosure which is attached to the patient with an antimicrobial adhesive incise drape, which has been gaining popularity among surgeons for reducing skin sources of infection. Such an interface also allows the system to be "one size fits all" for patient torsos, heads, or extremities. The enclosure itself is supplied in a drape-like format for easy incorporation into existing workflows, but instead of keeping contaminants out of the sterile field as traditional drapes do, SurgiBox seals the surgical field in.

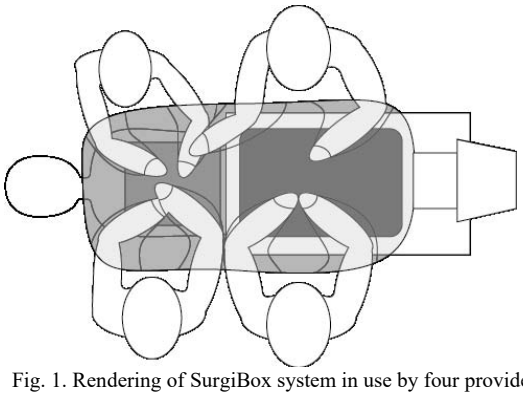

Fig. 1. Rendering of SurgiBox system in use by four providers for torso-based procedure; instrument tray is resting atop Mayo stand over legs. Environmental control system is running from feet.

TABLE 1: Key Design Features from Stakeholder Interviews

Reduces intraoperative skin and airborne contamination
Reduces risk of provider exposure to body fluids and aerosols
Fits well into existing surgical workflows: • Familiar setup procedure • Standard intraoperative maneuvers within sterile field • Objects can be transferred into and off of sterile field
Ergonomic for wide range of user and patient sizes
Compatible with wide range of high-frequency clean procedures in low-resource settings which pose high infection risks for patients/providers: • Exploratory thoracotomy • Exploratory laparotomy • Herniaplasty/herniorraphy • Appendectomy • Cesarean section • Cholecystectomy • Tumor resection • Splenectomy • Splenic/hepatic laceration repair • Kidney stone extraction • Bladder stone extraction • Hysterectomy • Postpartum hemorrhage control
Excellent visual clarity of field in varying lighting conditions
Laminar airflow at rates adequate to prevent condensation and maintain positive pressure (at least 0.01 in H_2O relative to outside) while avoiding wound desiccation
Maintain <5 colony forming units per cubic meter within system
Ready to use/fully self-contained
Ultraportable
Low marginal cost per case (relative to existing precautions)
Reasonable total initial cost of system

Figure 1 illustrates setup for a torso-focused procedure, with the surgical field portion over the torso and instrument tray portion extending over the legs. Modifications are possible based on procedural demands. A surgical tray with tools is passed through a port into the enclosure, then set on standard Mayo tray stand over the patient's legs.

The enclosure is then inflated with HEPA-filtered air, with low maintenance flow as in traditional operating rooms even though major sources of contamination - both patient bodies and providers - are outside of the system. Laminar airflow is primarily supplied downward over and outward from midline. The positive pressure in the enclosure provides the primary source of structural stability and additional protection against

ingress of external contaminants.

The system uses battery power, which makes it a versatile, ultraportable system which can be used out-of-the-box with no external dependencies. Up to four providers can work through the SurgiBox at a time via the four sets of arm ports. Based on our own (DLT, SM, and RJS) surgical experiences and interviews with other providers, typically 2-3 providers require access to the sterile field during the procedure (1-2 surgeons and 1 scrub tech). The enclosure can also work with 1 (generally temporary circumstances) or 4 providers (e.g. with trainees). Neonates, specimens, instruments, etc. can be brought in and out of the corresponding four material ports. An optional external rigid frame can be attached for further stability, e.g. in procedures requiring frequent use of ports.

At the end of the procedure, with instruments and other reusable items removed, the enclosure is disposed of in typical fashion for drapes after a case. The environmental system and frame can be reused for the next case. Table 1 details design features, first obtained from interviewing dozens of surgical providers who have or currently work in austere settings and field hospitals, before and during prototyping.

III. TESTING METHODS

Because of the intensive surgeon input in our physician co-designed system, we pursued parallel, iterative prototyping and testing. Overall testing objectives included testing of human factors issues and environmental control efficacy.

A. Human Factors Testing

For human factors testing, the following standardized battery of testing was administered, with semi-quantitative results obtained from users testing on dedicated ergonomics rig with functional rigs but without the optional frame or incise drape.

- Setup time over patient (mannequin and pregnant volunteer subject)
- Getting arms in and out of system
- Passing instruments among providers
- Making incisions
- Using retractors
- Using materials ports to pass items in
- Using materials ports to pass items out
- Suturing incisions

B. Environmental Testing

Environmental control system testing methodology has been adapted from the method we previously published [12] which validated SurgiBox's ability to achieve sterile enclosure as well as tolerance to potential airflow aberrations related to arm port use. We evaluated efficacy of passive barrier to baseline external conditions in the mixed-use machine shop used for testing. The variable of interest was particle count by PTrak TSI Model 8525 particle counter, a system used in both operating room and developing setting air particulate testing. We further used Aerotrak TSI Model 9303 to study the concentration of different sizes of particles over the course of setup and at rest, post-setup. For our analysis of this nonsterile test rig, we pre-set cutoff values for each particle size based on findings from Wagner et al 2014 [reported in 13 and 14] who set up full procedural simulations using different operating room ventilation systems, then correlated particle counts with fungal and bacterial counts. We utilized the parameters found for their SLD-1 30 FPM, which corresponded to ISO 7 level of cleanroom sterility. We selected 0.3 microns (maximum expected penetration for HEPA filter), 0.5 microns (diameter of some typical aerosolized particles produced during surgery), and 1 microns (per Wagner; and given microbes/vectors of interest.) If the system fails triplicate testing based on the cutoff values, then we would plan to test with sterilized rigs.

We also evaluated inflation timing; effective air changes per hour (validated with Proster TL017 anemometer); net pressure generated against outside at rest and with movement (using Dwyer Mark II manometer); and particle movement by following gross movement of vapor (polyethylene glycol, glycerol, and water mixture) introduced via smoke machine, and also by tracking particle counts at expected patient xiphoid (junction between thorax and abdomen), umbilicus, pubis, left and right flanks, and at each of the four bottom corners of the system.

IV. RESULTS

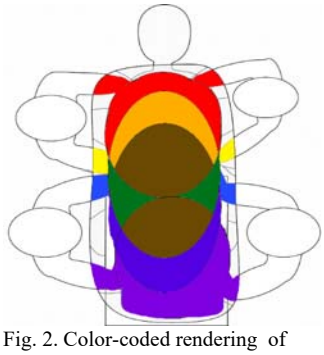

Fig. 2. Color-coded rendering of arm reach zone for each provider. Orange is overlap of red and yellow; brown is overlap of red, yellow, and blue(top) or yellow,blue, and purple (bottom); green is overlap of yellow and blue; indigo is overlap of blue and purple.

Fig. 3. Setup of ergonomic-testing rig over pregnant volunteer subject.

A. Human Factors Testing

The entire SurgiBox system weighs 2.7 kg and fits in a 40-liter hiking backpack.

Setup time benchmarking encompassed time from opening package containing SurgiBox to time of readiness for environmental system engagement. This included tray placement into enclosure over patient. Of the six volunteers who tested this parameter with no previous familiarity with the device, the results were consistently less than 30 seconds.

Based on ultimate sleeve/cuff configuration, providers' resting reach at the level of the patient was confirmed as exhibited in figure 2. It was further observed that with leaning inward and pushing, user extremities in the purple and red

zones could overlap as well. In practical terms, this meant it was ergonomic to pass things among subjects working immediately across the surgical field, hand things to the proximal arm of the person either next to or transverse from the tester, receive and remove items with either hand from the tester's most proximal material port, and receive and remove items with at leàst one hand from all other ports.

Further human factors testing was conducted in the rig as shown in figure 3. Testers (four medical personnel and four engineers) were able to get arms into, out, and into the system repeatedly without contaminating hands on sleeves or introducing contaminants into the enclosure. Cutting, retracting, and suturing activities were reported by medical users as "same as usual" from ergonomic and convenience standpoint. Visual clarity under both overhead lighting and portable lighting (headlamp and phone light) was noted to be "good". Feedback for changes included stabilization of patient-system contact to prevent incise drape dehiscence and backup structural support in case of prolonged multiple material port opening. We incorporated these changes into the prototype shown in figure 4 and opted to use this for the particle size bin assessment in the next section.

Fig. 4. Prototype incorporating human factors testing feedback, looking from patient's head to patient's legs and partially stabilized by frame to balance ergonomics (favoring more support) and consistency of enclosure environment with port openings as well as workflow (both favoring less support). Instrument tray is over leg. Incise drape is covered by paper adhesive backing. User puts gloved hands through sleeve port. Materials ports run longitudinally.

B. Environmental Testing

Inflation time was consistently 55 seconds, with auto-sealing of arm ports signaling completion, at which point airflow was manually switched to maintenance mode. Anemometer testing with air velocities and inflow areas corroborated this value (5,182 cubic centimeters per second), supporting no significant flow losses via the inlet. Internal pressure relative to outside was noted to range 0.05-0.08 inches water column depending on arm port use.

Outside particle count was noted to be 3,980 particles per cubic centimeter. After single initial inflation and environmental control system stoppage, spot measurements at each critical point had a mean of 86.2 (SD 11.1) particles per cubic centimeter, representing a 97.8% decrease relative to outside. This was in a nonsterile internal enclosure set up in machine shop.

To improve sensitivity of detecting stagnant pockets of air within the enclosure, particles were introduced into the airstream and enclosure directly to produce 342,000 particles per cubic centimeter initial value. The maximum difference in particle count at different measurement sites was 8.3% (maximum under first inflow point introducing particles and minimum evenly spread over patient level).

Figures 5A and 5B show the particle count at 0.3 microns or above and 0.5 microns or above in diameter, respectively; at baseline, during enclosure inflation, and at maintenance flow. We additionally noted that particles 1 micron or above consistently started below preset values of at least 83,200 particles per cubic meter even at baseline, so excluded it from full analysis. We did note that it started in the 3,000-5,000 particles per cubic meter range on three runs, but consistently dropped to 0 particles per cubic meter before completion of inflation.

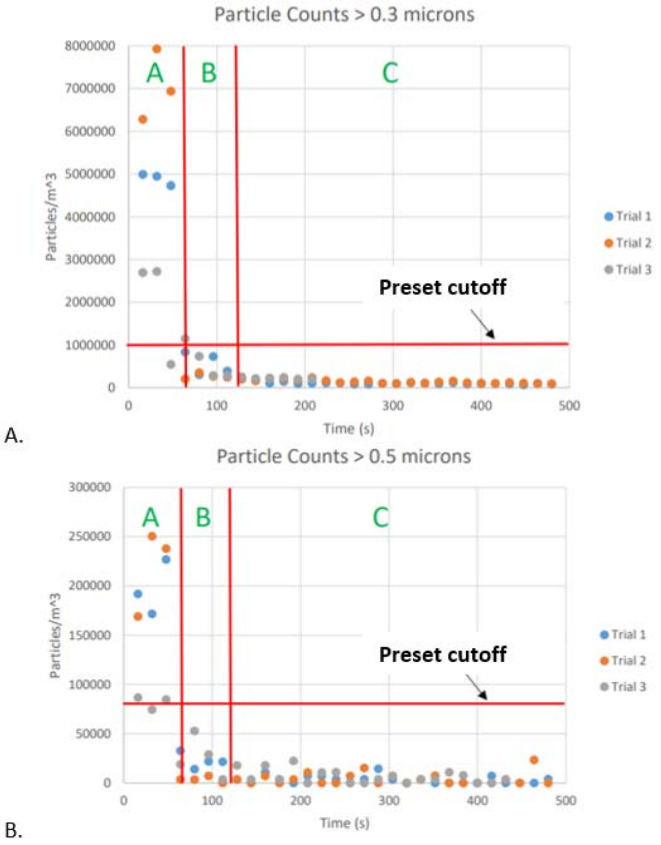

Fig. 5A. Particle counts for all particles 0.3 microns or greater in diameter over time. Zone A delineates baseline resting values of pre-inflated, nonsterile system. Zone B delineates inflation time, with the left red line depicting when environmental system was engaged. Zone C delineates time spent with maintenance flow, with the right red line depicting when environmental system flow was switched over. Sampling was every 16 seconds. Fig. 5B. The same as for Fig. 5A, for all particles 0.5 microns or greater in diameter.

V. DISCUSSION

The human factors testing suggests that SurgiBox presents acceptable ergonomic and optical performance for surgical providers in austere and field settings. Workflow was well-preserved, with the enclosure portion disposable in the same way as disposable PPE is and the remainder portions (environmental control system and frame) requiring no special processing prior to reuse. The expected costs, while not yet finalized, are currently projected to be effectively cost-neutral on a per-procedure basis given reductions in PPE and draping needed.

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While the adhesive drape and instrument tray both provided structural stabilization, movement of the single arm ports closest to the patient head on each side did result in movement of the enclosure and drape, though not to a significant enough degree to affect the visual field. Although opening the ports singly and to approximately halfway (12 inches) resulted in little to no appreciable change in system structural integrity, opening fully for more than 10 seconds did result in visual field rippling. These results suggested that depending on use scenario, particularly with respect to degree of arm movement expected and material port use expected, modifications such as automatic flow augmentation, drape reinforcement, and/or external rigid frame could be helpful.

We noted as well that automating the switch to maintenance mode would further reduce risks of enclosure overpressurization which increases the likelihood of ports opening unintentionally, or excess cost of maintaining the environmental system.

The environmental testing was conducted with a known nonsterile prototype in a high-contaminant testing environment. The system's relative positive pressure to the outside was observed to be higher than planned (based on operating room standards of 0.01 inches of water column), but it had the dual function of providing structural support and of reducing inflow of particles with port opening.

Further environmental testing with analysis of binned particles demonstrated rapid reduction of particle counts for all three particle diameters of interest, and effective preservation of particle count below accepted thresholds with maintenance flow alone.

The environmental testing supports SurgiBox having both passive (via its enclosure walls) and active environmental control. Although the test rig is not sterile, the system for clinical use would start with a sterile enclosure on removal from packaging, only becoming (minimally) contaminated with port opening to add instrument tray. It is reassuring that even in that circumstance, environmental controls would be expected to flush out particulate matter by 97.8% by the time of system inflation, with subsequent air changes further reducing contaminant burden prior to incision. Our previously published work suggests that by 95 seconds after system start, the surgical field within the enclosure should be fully sterile [12].

VI. ONGOING IMPROVEMENTS AND WORK

In addition to structural improvements as above, ongoing efforts on this project focus on further improving ease of use, reducing cost of system operation, and advanced testing. We are evaluating ways to automate switching airflow modes, signal filter life, and improve energy efficiency. Although particulate count testing is validated within the operating room literature, the gold standard is settle plate testing with incubated cultures, so we are conducting this testing. We are also coordinating with our physician co-developers to conduct full-length simulations of their highest-frequency procedures to evaluate such usage scenarios.

VII. CONCLUSIONS

We have demonstrated the preliminary acceptability of the SurgiBox system to surgical users from a human factors and workflow integration standpoint. Existing specifications exceed state-of-the-art operating room standards for air exchange at a miniscule fraction of the cost relative to standard operating rooms, and demonstrate efficient system inflation, enclosure maintenance, and air volume distribution. This work demonstrates a critical step toward implementing an ultraportable system that will improve both patient and provider safety during surgeries anytime and anywhere they are needed.

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