Chapter 9
Developing a Low-Cost, Ultraportable, Modular Device Platform to Improve Access to Safe Surgery

Debbie L. Teodorescu, Dennis Nagle, Sashidhar Jonnalagedda, Sally Miller, Robert Smalley and David R. King

9.1 Introduction

9.1.1 Surgical Care as Part of the Global Health Armamentarium

Over 30% of the global disease burden requires surgical therapy, which could prevent over 18 million deaths and save USD $200 billion annually. The conditions amenable to surgical therapy range broadly, from traumatic to obstetrical to infectious to oncological and beyond. Yet, in low–middle-income countries (LMICs), an estimated two billion people have effectively no access to surgical care, and another

D. L. Teodorescu (✉) · D. Nagle
MIT D-Lab, Cambridge, USA
e-mail: DLTeodor@surgibox.org; debbiepl@mit.edu

D. Nagle
e-mail: dennisnagle8@gmail.com

S. Jonnalagedda
Program Essential Tech Cooperation and Development Center EPFL, Lausanne, Switzerland
e-mail: sashidhar.jonnalagedda@alumni.epfl.ch

S. Miller
MIT Department of Mechanical Engineering, Cambridge, USA
e-mail: millersa@mit.edu

R. Smalley · D. R. King
Harvard Medical School, Boston, USA
e-mail: rob@surgibox.org

D. R. King
e-mail: dking3@mgh.harvard.edu

D. R. King
Massachusetts General Hospital Department of Surgery, Boston, USA

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two to three billion have access only to surgeries performed in unsterile settings such as general-use buildings or even outdoors ("Global Surgery 2030", 2015; Disease Control Priorities Project 2008). In addition to this chronic deficiency in surgical access, field surgical zones in disaster-affected areas are often exposed to frank particulate and insect contamination.

9.1.2 Patient Safety in Surgery: Infrastructural Challenges to Sterility

In LMICs, surgical patients develop disproportionate rates of surgical site infections (SSIs), particularly the deep infections characteristic of intraoperative contamination. Meta-analyses (Allegranzi et al. 2011) have found that 0.4–30.9 per 100 surgical patients in LMICs develop SSIs. In particular, even in clean and clean-contaminated wounds, which had not previously been contaminated by traumatic skin breaks, uncontrolled gut flora spillage, etc., the median cumulative incidences were still, respectively, 7.6% (range 1.3–79.0%) and 13.7% (1.5–81.0%), all several times higher than in higher income countries (Ortega et al. 2011). Most alarmingly, these figures represent early postoperative infections of deep visceral spaces and organs, not superficial tissues, a finding underscored by Nejad et al. (2011) meta-analysis that showed 6.8–46.5% incidence of deep infections in postoperative patients, and 10.4–20.5% of infections in organ spaces. Bjorklund et al. (2005) analysis showed a particularly unfortunate interaction between immunosuppression—all too common in the developing world due to poor nutrition, untreated illness, and HIV—and unsterile surgical conditions in producing very high rates of severe infection following c-sections. These infections translate into longer stays at already-overcrowded hospitals: eight additional days on average in Tanzanian and Ethiopian studies, 10 days in a Burkina Faso study comparing surgical patients with and without SSIs (Eriksen et al. 2003; Taye 2005; Sanou et al. 1999). In nascent healthcare systems with limited infrastructures, SSIs that effectively double or triple patient stay lengths fetter institutions' ability to cope and reduce the volume of new patients that could be accommodated. Taye (2005) noted that SSIs were associated with 2.8-fold increased mortality (10.8% vs. 3.9%).

Numerous factors impact surgical site infection rates. These have been most authoritatively summarized by the Lancet Commission on Global Surgery (2015) and range from preoperative antibiotic administration to drape selection to handwashing and beyond. A particularly pernicious and challenging one to address has been that of the contaminated environment. Whyte et al. (1982) and Edmiston et al. (2005) have described the general link between airborne contamination and SSIs, with an estimated 30–98% of wound bacteria attributable to airborne contaminants, depending on the ventilation system in an operating room. In higher income countries, invasive procedures are typically performed by scrub-attired personnel striving to reduce contamination in operating rooms with meticulously filtered air. In LMICs, such facil-

ities and infrastructure are frequently unavailable. Procedures instead often occur wherever dedicated space could be found, whether general-use rooms, outdoors, or other suboptimal settings. Pathogen-carrying insects, dust particles, provider skin squames, and numerous other dangers frequently breach the sterile field. Even in state-of-the-art operating rooms, relatively modest breaches due to events such as door openings have been associated with increased SSI rates. Indeed, decreasing the number of times doors was opened decreased SSI rates by 36% in one study and 51% in another (Van der Slegt et al. 2013; Crolla et al. 2012). The absence of any door at all, or of effective surgical suite ventilation, in the LMIC operating space is therefore quite a concern.

The need to provide safe surgical care outside of traditional surgical facilities is certainly not a new problem. However, solutions to the challenge have typically started from the assumption that the core problem is to provide a sterile operating room outside of a standard facility. This mindset informs solutions such as surgical tents, operating rooms mounted on trailers or trucks, semi-portable laminar airflow systems, and most other solutions to date. These devices unfortunately tend to share several significant limitations in practice. They are challenging to transport to remote or disaster-affected areas, requiring both time and logistical capability. Once at the desired site, they require significant setup time. For example, surgical tents can take a full team of technicians working around the clock for 72 h to fully set up. Several of these systems have at least one external dependency, particularly availability of electricity or requirement of flat terrain. They require significant resources not only for sunk cost but also for marginal cost of each procedure. Personnel, a particularly scarce resource, is also required to set up and maintain these complex systems. These systems are not always robust to the high levels of external contamination, with sand particulate ingress into the tents a particularly notorious phenomenon in the field (e.g., as described by Stevenson and Cather 2008). Finally, any contamination in these systems, including that generated by providers through squame shedding, can still contaminate the surgical site.

9.1.3 Provider Safety in Surgery: Protecting Surgical Teams

Patients are not the only ones who can get infected during surgeries. Some 85,000 medical providers worldwide are infected every single year by patient bodily fluids, with the vast majority of surgeons and obstetrician/gynecologists having experienced at least one exposure in the past year (Butsashvili et al. 2012). Despite the lower volume of invasive procedures occurring in austere settings, 90% of providers infected were working in such settings (World Health Organization 2011). Such chronic risks were thrust into sharp relief during the Ebola epidemic, when, for instance, 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 (Yasmin and Sathya 2015; Bundu et al. 2016). Unfortunately, personal protective equipment (PPE) is costly and cumbersome to wear during surg-

eries, leading to both poor availability and poor provider adherence. Thus, surgical teams are vulnerable to infections from patient bodily fluids.

9.1.4 SurgiBox: Solution Concept for the Double Challenge in Safe Surgery

The SurgiBox platform moves away from the assumption that the surgical space of interest is the operating room. Fundamentally, the space that matters is the incision and immediate surgical field over the patient. This recognition literally shrinks the challenge down from over thousands of cubic feet of space to well under 10 cubic feet to be kept sterile. The nature of protection actually changes, as contamination can come from patients themselves, providers, and the external environment. Creating a physical barrier from contamination completely from the latter two, and significantly from the patients themselves, theoretically permits more robust protection than would the classic, costly combination of sterile room, sterile scrub suit, and sterile drapes. A system that can effectively maintain a sterile field in this limited space, as presented here, provides a low-cost, ultraportable platform for regulating intraoperative conditions at the surgical site, making safe surgery more accessible. At the same time, isolating the surgical field blocks potentially infectious particles and fluids from reaching providers at all. This is a more efficient system than capturing with individual PPE after they have already left the surgical field.

This paper is organized as follows. Section 9.2 describes SurgiBox's iterative prototyping and evaluation methods. Section 9.3 presents the design and our results to date. Section 9.4 discusses ongoing as well as future efforts in device development and deployment. Section 9.5 discusses SurgiBox's broader implications.

9.2 Methods

9.2.1 Patient- and Stakeholder-Centered Development

The objective of SurgiBox overall is to provide a low-cost, ultraportable system to maintain sterile conditions during invasive procedures, even when performed in contaminated settings. However, as with any medical device, particularly one intended for developing settings, other complex requirements are critical to stakeholder acceptance (Caldwell et al. 2011). A key risk was the rejection of the device by the end user despite technical success, so extensive measures were taken to mitigate this. Extensive preliminary interviews as well as ongoing stakeholder interviews were conducted, and input was received from physicians who work in the developing world, surgical researchers, biomedical and device engineers, global health and development researchers as well as other workers, members of the medical device industry,

Table 9.1 Stakeholder-generated device specifications

Ultraportable	Entire system should fit into a backpack or duffel bag
Quick setup	Setup time should not interfere with surgical prep
Ergonomic	Should fit well into existing surgical workflow
One size fits all	Can be used for all sizes of patients by all types of users
Low cost	Cost should not exceed the cost of surgical drapes
Self-contained	Battery-powered
Sterile	Meets or exceeds operating room standards
Good visibility	User's view of surgery must be unobstructed
Protective	Prevents bodily fluid splashes and aerosols from reaching users

and innovation strategists. These discussions generated the objectives and specifications as shown in Table 9.1. We used existing data from anthropometric tables (with the aim to accommodate the 5th through 95th percentiles of providers and of patients), surgical ergonomics research, and operating room design guidelines to populate design specifications for the prototypes.

Throughout the design process, the prototype has been split into modules to improve team efficiency. The overall design concept was split into enclosure design, ports design, and environmental control system design.

9.2.2 Proof of Concept Testing

In addition to evaluating ergonomic and workflow acceptability, we focused on whether the system actually provides a level of sterility consistently equivalent to or exceeding that available in state-of-the-art operating rooms.

We actually proved this for two separate setups of SurgiBox, both set up in a mixed-use machine shop at MIT D-Lab. In an earlier iteration, as reported in Teodorescu et al. (J Med Dev 2016), the prototype utilized a rigid external frame and therefore started with a full internal volume of contaminated air. The environmental system was based on an off-the-shelf powered air purifying respirator system calculated to supply 110 air changes per hour from a simple hole-in-side inlet. Measurements were then taken at the xiphoid as the approximate center point of a large surgery combining laparotomy and thoracotomy as may occur to address trauma or hemorrhage, as well as at the flanks to assess particle pooling. These were repeated with armports and material ports open. In the more recent iteration, as detailed in Teodorescu et al. (in press, IEEE Xplore), the enclosure is inflated from flat packaging, but intentionally not sterile as it would be in real life, to mimic contamination that could occur during introduction of the instrument tray during setup. Air was supplied at 66 air changes per hour by a HEPA-motor-power setup that we built ourselves. The system then used a special manifold setup to distribute airflow in laminar fashion through the

enclosure. Material ports were kept closed; armports were kept in neutral position. Particle counts were then benchmarked against Wagner et al. (2014) data correlating particle counts and colony-forming units in operating rooms.

9.3 Results

9.3.1 Device Design

SurgiBox is an ultraportable, modular system to provide sterile intraoperative environments over surgical sites. This product went through extensive evolution. Initially, the design comprised a reusable box-like system with hinged clear panels of polycarbonate that could be collapsed into a flat package. Based on stakeholder feedback regarding sterilization capabilities, bulk, ergonomics, and modularity potential, the design was iterated upon and became a disposable, patient-contacting plastic enclosure with a minimal frame, and reusable environmental controls. The arm ports were redesigned several times to ensure that the system was ergonomic for the users and minimized the chances of contamination. By contrast, whereas we had originally planned for material ports to be hermetic airlock-inspired systems, feedback on impact to workflow prompted redesign to quick-opening ports with a single layer of sealing, and this design was shown to not compromise sterility through environmental testing. Throughout the design process, each iteration was tested with local surgeons, ensuring that each new design improved upon the previous.

The final design comprises a low-density polyethylene enclosure with a high-visibility vinyl window. The enclosure adheres to the patient's surgical site with an adhesive iodine-infused antimicrobial drape and is inflated with HEPA-filtered air. There is an optional minimal frame that can be used with the enclosure, but the enclosure can also be used alone and the positive pressure within provides its structure. In the case that a port needs to be opened to move materials in or out, the airflow can simply be increased to accommodate the extra outflow. The inflow system is designed such that the filtered air enters the enclosure directly over the surgical site, in the same way that air is introduced to state-of-the-art hospital operating rooms.

There are four sets of arm ports to accommodate up to four users at any given time. The arm ports were designed so the users can perform the same motions that they would use in a standard operation, and can pass tools back and forth easily. There are also four material ports so materials (such as tools or even an infant in the case of a cesarean section) can quickly be passed in or out of the surgical field.

Based on serial testing of workflow, it was found that the time of patient being positioned on the operating table to time of first incision was consistently less than 85 s for users naïve to the system. Per qualitative report from the medical members of the team, this timing compares favorably to that of existing patient and provider preparation. We note that system does not preclude users from donning additional

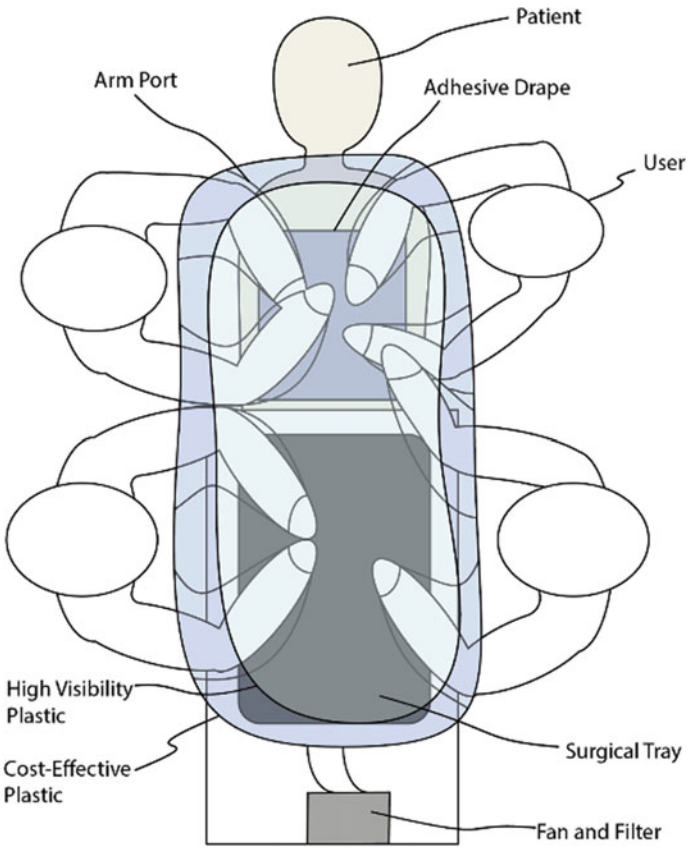

Fig. 9.1 Schematic of surgeons and nurses performing a surgical procedure with SurgiBox

personal protective equipment or further draping the patient but reduces the burden of both (Fig. 9.1).

A rechargeable battery powers a microcontroller and fan so the system can be used off-grid. The airflow is high initially for rapid system inflation but is subsequently turned down to a maintenance flow to maintain the pressure inside the enclosure (Fig. 9.2).

9.3.2 Particle Testing

The rigid frame system consistently achieved 0 particle count at all test sites within 90 s, or after 2.75 air changes. The minimal frame system consistently achieved target thresholds even before completion of insufflation. Importantly, both systems maintained acceptable thresholds with open ports.

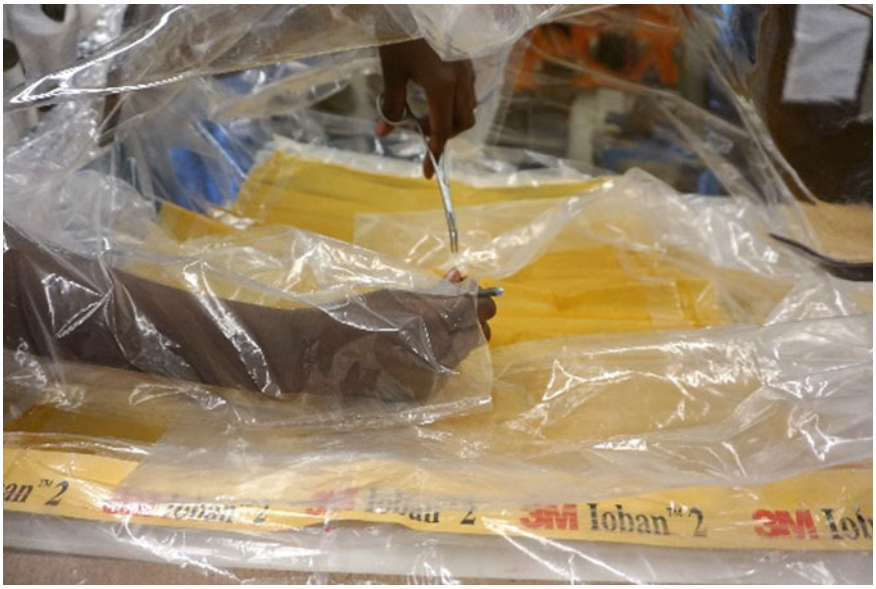

Fig. 9.2 Range of motion demonstrated as shown from inside SurgiBox

9.4 Discussion

9.4.1 Ongoing and Future Research

Our efforts to further optimize SurgiBox with our existing iterative prototyping workflow are ongoing. At the time of submission, we are completing two major prototyping tasks in parallel. First, we are preparing advanced human factors testing with full-length simulated procedures. Second, we are optimizing for manufacturability. To date, the latter efforts have yielded over 12-fold decrease in system cost. The cost-determining portions are fully reusable between patients for an estimated 10,000 cases depending on airflow requirement, based on the life expectancies of the battery and the filter cartridge, both of which are replaceable to permit continued use of the system.

The patient-contact components are ideally disposable because in many cases setting up reliable reprocessing can in fact be more logistically challenging than stockpiling disposable components, especially ones of minimal bulk. In any case, once the design has been optimized, it will be important to continue work with medical logisticians and hospital administrators to estimate the setup and recurring costs that constitute the total cost of ownership needed to meet each institution's needs, based on procedures and personnel.

In addition, the current experimental setup has two main limitations. First, although particle testing is a well-validated way to obtain dynamic measurements

of the system's barrier function, we also plan to correlate with settle plate testing to assess colony-forming unit counts. The second limitation is that the tests are conducted in static conditions. Ongoing work is using standardized rigs to simulate use conditions.

While we do strive to simulate field conditions in the lab and to assess ease of use of the prototypes by stakeholders with experience in LMIC settings, we are planning to work with LMIC community partners abroad to supply SurgiBox kits to the field. By performing ex vivo setups in truly field conditions, we can collect further data and feedback to identify any additional issues requiring optimization as well as impacts on workflow. These will most likely occur in India and Uganda. By supplying SurgiBox kits with a variety of frame and port components, we hope to encourage community partners to tinker with the prototypes to suit their needs.

While we have striven at every step to make SurgiBox as user-friendly as possible, we recognize that there will likely be resistance if it were presented on the basis of in vitro sterility data only. After all, there are many determinants of safe surgery. Therefore, even though SurgiBox would qualify as a CE Mark IIA device that does not require efficacy studies, we still plan to voluntarily conduct trial surgeries on animals in simulated field conditions to assess impact on clinical outcomes such as wound contamination rates and SSI rates.

9.4.2 Road to the Market

The key to deploy SurgiBox worldwide is to understand the existing market, the needs, and how the device can fill the void. Our major considerations fall into three main categories: market segmentation, production, and distribution.

9.4.2.1 Market Segmentation

The first step is to segment the market into different categories. There are two main segments that SurgiBox strives to target: on one hand, it can be used to reinforce protections available in existing medical infrastructures. On the other hand, it can be used as part of an ultraportable kit that gives access to surgery in places where there is no medical care, such as war zones, natural disaster areas, and even remote villages only accessible by foot.

Through different interviews with surgeons from LMICs, we discovered that many existing infrastructures such as district hospitals are austere: due to their very high cost, ventilation systems are often absent from operating rooms, which also often have doors open throughout surgeries, sometimes even directly showing to the main road. All these highly increase the probability for the patients to develop SSIs. SurgiBox is therefore expected to reduce healthcare costs by permitting surgical procedures to be performed in less-expensive procedure rooms, and reduce SSIs if used in tandem with existing facilities. In tertiary care centers, it can conceivably offer improved

outcomes in lengthy, complex procedures by providing more intensive control of the intraoperative environment. LMICs will be interested in this device because of its affordable price for creating a sterile environment for surgery that meets or exceeds US and European standards, leading to a general improvement in surgical outcomes.

Within the second market segment, this device addresses a distinctive problem, the unsafe and unsterile ad hoc operative location. Some stakeholders from NGOs shared that they sometimes had to operate in open air. We expect the early adopters to be surgeons from higher income countries working in disaster zones and in low resource settings. While in disaster zones our device is a direct fit as there is no infrastructure at all, in low resource settings it addresses the main concern of their current inability to provide the standard of hygiene and infection mitigation to which they are accustomed. In addition, it also enhances provider safety by offering them a reduction of exposure to the patient's bodily fluids and aerosols. During the Ebola outbreak, physicians and organizations promulgated and implemented standards for appropriate drapes and protective equipment for operating on possibly infected patients. SurgiBox is in line with such protective efforts.

9.4.2.2 Production

To support advanced development of SurgiBox and pilot deployment, our collaboration is able to leverage our position at the intersection of academia and nongovernmental organization to seek both competitive grant funding and mutually beneficial partnerships with other nongovernmental or governmental organizations. As a social venture, we further benefit from the robust small business and social entrepreneurship resource infrastructure available in the United States in general and in the Boston area in particular, including funding initiatives.

SurgiBox's design and prototyping process have emphasized minimizing not only the cost of raw materials but also of manufacturing and packaging. By finding alternatives to complex, high-variance, high-cost components, we expect that the device should be able to be manufactured to consistently high quality to comply with United States Federal Drug Administration General Controls and similar regulations. Indeed, it is conceivable that we can eventually engage with regional or local manufacturing entities during scale-up stage, recognizing the importance of maintaining quality controls compatible with a medical device. With the "cost of goods sold" for benchtop prototypes stabilizing, we are now conducting this analysis in the real world setting.

9.4.2.3 Distribution

SurgiBox itself will be distributed as ultraportable, fully self-contained, ready-to-use kits suitable for hand luggage, backpacks, drones, and other limited spaces. These kits will contain the reusable component, one or more of the patient-contacting components all individually wrapped, and batteries: all the items needed for full use

of the system. Users can therefore continue to utilize their preferred skin disinfectant, lighting source, instrument trays, gloves on top of the universal-sized thinner gloves in place, and other things to best preserve workflow.

At this stage, we are working on finalizing strategic partnerships critical to pilot deployment and eventually distribution success in the future. Supply and demand bottleneck analyses of the expected uptake challenges along the value chain are ongoing, as highlighted above. In the market segment we are first targeting, procurement is primarily by each mission-sponsoring entity—most commonly militaries, surgical relief organizations, hospitals, and device companies—or by individual providers. Upstream, many of the former have relationships with procurement superstructures such as the World Health Organization, which in 2015 reported allocating the plurality ($333 million) of its procurement budget to strategic category products, which cover most key surgical devices, tools, and kits. For the second market segment, we plan to contact Ministries of Health and Defense in LMICs. Certainly, engaging with all of these diverse stakeholders is critical to success.

9.5 Conclusion

Taken together, the growing interest in surgery as an inalienable part of global health, as well as the ethical as well as practical need to provide this surgical care in a safe manner, provides a rich opportunity for innovative solutions to the complex challenges entailed.

In this paper, we described one such innovation in the form of a co-designed, ultraportable sterile field platform. By shifting the site of regulation from the operating theater to the incision itself, we introduced a novel paradigm more amenable to flexible, cost-effective solutions.

To reduce this paradigm to practice, we closely engaged user–stakeholders by starting with a systematic needs analysis, then using feedback to drive the evolution and refinement of SurgiBox. We presented the device design and results from benchtop testing that showed how SurgiBox can rapidly create a particle-free environment. Ultimately, deploying SurgiBox to LMICs and beyond requires continued close stakeholder engagement in the form of robust relationships along the production and supply chains.

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