Making Safe Surgery Affordable: Design of a Surgical Drill Cover System for Scale

Lawrence L. Buchan, MASc,† Marianne S. Black, MASc,*†‡ Michael A. Cancilla, MEng,*† Elise S. Huisman, MSc,*† Jeremy J. R. Kooyman, MASc,* Scott C. Nelson, MD,§ Nathan N. O'Hara, MHA,* Peter J. O'Brien, MD,* and Piotr A. Blachut, MD**

Summary: Many surgeons in low-resource settings do not have access to safe, affordable, or reliable surgical drilling tools. Surgeons often resort to nonsterile hardware drills because they are affordable, robust, and efficient, but they are impossible to sterilize using steam. A promising alternative is to use a Drill Cover system (a sterilizable fabric bag plus surgical chuck adapter) so that a nonsterile hardware drill can be used safely for surgical bone drilling. Our objective was to design a safe, effective, affordable Drill Cover system for scale in low-resource settings. We designed our device based on feedback from users at Mulago Hospital (Kampala, Uganda) and focused on 3 main aspects. First, the design included a sealed barrier between the surgical field and hardware drill that withstands pressurized fluid. Second, the selected hardware drill had a maximum speed of 1050 rpm to match common surgical drills and reduce risk of necrosis. Third, the fabric cover was optimized for ease of assembly while maintaining a sterile technique. Furthermore, with the Drill Cover approach, multiple Drill Covers can be provided with a single battery-powered drill in a "kit," so that the drill can be used in back-to-back surgeries without requiring immediate sterilization. The Drill Cover design presented here provides a proof-of-concept for a product that can be commercialized, produced at scale, and used in low-resource settings globally to improve access to safe surgery.

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From the *Department of Orthopaedics, University of British Columbia, Vancouver, British Columbia, Canada; †Arbutus Medical, Vancouver, British Columbia, Canada; ‡Department of Mechanical Engineering, Stanford University, Stanford, CA; and §Department of Pediatric Orthopaedics and Trauma, Loma Linda University Medical Centre, Loma Linda, CA.
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Reprints: Lawrence L. Buchan, MASc, Arbutus Medical, Unit 221-181 Keefer Place, Vancouver, British Columbia V6B 6C1, Canada (e-mail: lawrence.buchan@arbutusmedical.ca).

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INTRODUCTION

In many hospitals in low-resource settings, the available surgical drilling tools are unsafe, unaffordable, or unreliable, often forcing surgeons to make compromises when treating orthopaedic trauma injuries. Purchasing new surgical drills is not feasible for most resource-constrained hospitals. Donated surgical drills often arrive at their new hospital in poor condition, or fail over time because the required replacement parts are not readily available.[1,2] Surgeons usually have access to manual hand drills, but manual drills can be dangerous and inefficient. Surgeons commonly resort to using hardware drills because they are affordable, efficient, and robust,[3] but hardware drills cannot be sterilized in an autoclave and may increase the patient's risk of infection.

One promising solution for surgical drilling is to use a sterilizable fabric bag and surgical chuck adapter (a "Drill Cover" system), in combination with a hardware drill, so that the nonsterile drill can be used safely in the sterile surgical field. Previous hardware drill solutions (see **Figs. 1A–D, Supplemental Digital Content 1**, http://links.lww.com/BOT/A462; http://links.lww.com/BOT/A463; http://links.lww.com/BOT/A464; http://links.lww.com/BOT/A465) have improved surgical drill access in some low-resource settings, but none have been successfully commercialized to date, and limited access to safe surgical drills remains a challenge throughout the world.

Our objective was to design a safe, effective Drill Cover system for scale in low-resource settings. Designing for "scale" meant that we aimed to: (1) meet the specific needs of end users in low-resource settings, (2) address international medical device standards of safety, and (3) develop a proof-of-concept Drill Cover that can be commercialized and made available at low cost worldwide. The overall project mission was to develop a device that could provide every operating room in the world with access to a safe, affordable surgical drilling device.

NEEDS IDENTIFICATION

The Drill Cover redesign started as a project within the University of British Columbia's Engineers in Scrubs program,[4] which brought together a team of biomedical engineering researchers, orthopaedic surgeons, registered nurses, reprocessing staff, and health administrators from the Uganda Sustainable Trauma Orthopaedic Program (Vancouver, British Columbia, Canada). After a round-table discussion based on the observation of pressing clinical problems at Mulago Hospital (Kampala, Uganda), we identified the lack of appropriate surgical drills as a high-priority problem. At Mulago Hospital in 2013, surgeons only had access to a single donated drill with a poorly functioning battery, manual drills, or nonsterile hardware drills. We applied the Biodesign process for medical device innovation[5] and collaborated with surgeons, nurses, and medical device reprocessing staff at Mulago Hospital to identify specific unmet surgical drilling needs, to generate concepts to meet the current needs, and to prototype selected concepts for further feedback.

Overall, user feedback suggested that we: (1) design a Drill Cover system with a sealed barrier between the sterile surgical field and the hardware drill; (2) select a hardware drill that is safe for bone drilling; and (3) improve the process of loading the drill into the Drill Cover.

DESIGN

We designed a Drill Cover system that includes a battery-powered hardware drill, a "Cover," and a "Chuck Adapter," inspired by early drill cover designs (Fig. 1). The Chuck Adapter includes a custom shaft, a 3-tooth chuck, and a custom rotating interface. The design of the overall system focused specifically on addressing the user requests for a sealed barrier, a drill that is safe for bone drilling, and improved ease of loading (Table 1).

The Cover includes a fabric sleeve and nose piece. The fabric sleeve is constructed of a double-layered medical fabric (Maxima EX; Burlington Barrier, Greensboro, NC, USA) typically used for surgical drapes and gowns. All seams are sealed using seam tape that survived testing of 100 autoclave cycles (121°C, 30 minutes per cycle; Castle steam gravity displacement sterilizer; Sybron Corp, Milwaukee, WI).

Based on the previous CURE International drill system, we selected a power screwdriver (DeWalt DCF610S2) with a maximum drilling speed of 1050 rpm. The weight of the DeWalt DCF610S2 unit is 1.0 kg, and the dimensions (with battery installed) are 19 × 15 × 6 cm. Surgeons indicated a preference for this size and weight because it closely resembles surgical drills. Qualitatively, surgeons noted that some larger hardware drills are bulky and too heavy for delicate bone drilling.

The sterile loading technique of the cover was designed with an experienced operating-room nurse (Alicia Green, RN) and requires 2 participants (see **Video**, **Supplemental Digital Content 2**, http://links.lww.com/BOT/A465; see **Fig.**, **Supplemental Digital Content 3**, http://links.lww.com/BOT/A466). The first step is for a sterile staff to hold the unrolled Cover opening with their hands tucked under the rolled fabric. The second step is for a nonsterile hand to carefully place the drill into the fabric bag without touching the exterior of the Cover. The third step is for the sterile staff person to close the bag using a dry-bag–rolling technique. Once the drill is inside the bag, the Chuck Adapter easily inserts into the hexagonal drive chuck, and the custom closure mechanism can be sealed by screwing together the rotating interface on the Chuck Adapter and nose piece of the Cover.

SAFETY AND EFFICACY

First, we aimed to quantify the barrier performance of the Drill Cover system to evaluate its ability to resist transmission of blood between the sterile surgical field and nonsterile hardware drill. We designed a custom test apparatus (modeled on a standard test method, ASTM F1670-08) to determine the ability of each component of the Drill Cover system (fabric, seams, closure mechanism) to resist penetration by pressurized synthetic blood (See **Figs. 4A, B**, **Supplemental Digital Content 4**, http://links.lww.com/BOT/A467; http://links.lww.com/BOT/A468). Fabric swatches resisted a fluid penetration of up to 1.1 psi; seams resisted a penetration of up to 0.6 psi, and the closure mechanism resisted a penetration up to 0.3 psi. Current testing suggests that the Drill Cover can achieve "Level 2" liquid barrier performance, as specified by the Association for the Advancement of Medical Instrumentation (AAMI) voluntary standard AAMI/ANSI PB70:2012, pending further testing to address barrier performance after repeated use. Future work will include design refinements with the goal of achieving AAMI "Level 4" liquid barrier performance.

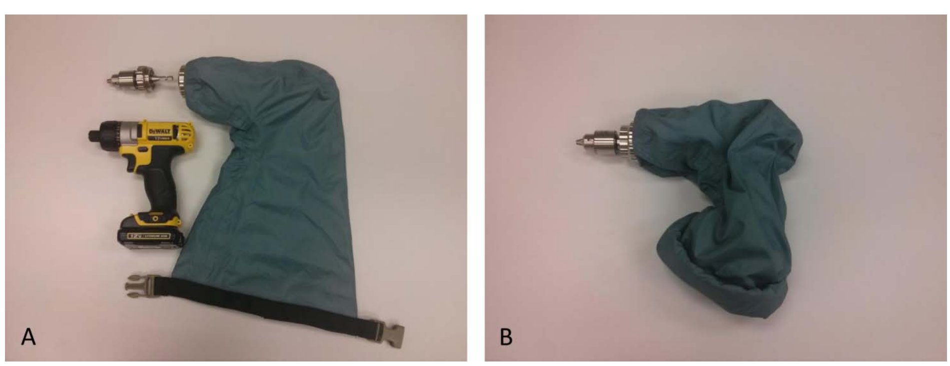

FIGURE 1. The drill cover system. A, An exploded view. The system is composed of a battery-powered power screwdriver drill (DeWalt DCF610S2) and 2 detachable parts, the cover and the chuck adapter. The chuck adapter includes a shaft, chuck, bearing, and bearing case constructed primarily from stainless steel. The cover is composed of a medical-grade fabric bag and a metal nose piece. B, An assembled view of the Drill Cover system showing the bearing case connected the cover's nose piece through a sealed closure mechanism. The closure mechanism was designed for ease of assembly and to maintain a sealed barrier between the hardware drill and sterile surgical field.

TABLE. Technical Features of the Drill Cover System and Components That Address Each Feature

Technical Feature	Components That Address Feature
Sealed barrier between surgical field and drill	Fluid resistant fabric used commonly in drapes and gowns
	Seams sealed using seam tape
	Custom closure mechanism and sealed rotating interface create waterproof barrier
Hardware drill safe for bone drilling	Drill selected with maximum speed of 1050 rpm to match drilling speeds of common surgical drills
Easy to assemble with sterile technique	Size of cover optimized for ease of assembly of the Drill Cover system while maintaining sterile technique

Second, we aimed to substantiate claims that our Drill Cover system uses a hardware drill that is safe for bone drilling. Drilling speed must be carefully considered when selecting a hardware drill for use in bone. High drilling speed can cause high temperatures that increase the risk of osteonecrosis, and necrosis prevents bone from properly healing and integrating with implants. Necrosis begins when bone reaches a temperature of 47°C for more than 1 minute.[6] When drilling without irrigation, speeds above 1140 rpm have been shown to cause temperatures above 47°C.[7] The Surgical Implant Generation Network recommends drilling at speeds lower than 1100 rpm, and that pushing harder (17 lbs) is better than softer (7 lbs) to control bone temperature.[8] Given that the maximum unloaded speed of DeWalt DCF610S2 is 1050 rpm, it falls within the range of common orthopaedic surgical drills; this hardware drill choice does not increase the risk of drilling causing necrosis.

Third, the Drill Cover was designed for optimal ease of assembly using a sterile technique. During the design process, we assessed ease of assembly using qualitative surveys at Mulago Hospital. The first design iteration was small and form-fitting to the drill, which made the drill difficult to fit into the cover while maintaining the sterile technique. After evaluation by users at Mulago Hospital, the mode user rating for ease of the loading process was 2/5 ("difficult") on scale from 1/5 ("very difficult") to 5/5 ("very easy") for the first prototype. A later, larger version was evaluated and the mode user rating was 4/5 ("easy"), which indicated that a larger bag allowed for simpler loading while maintaining the sterile technique. The current version of the fabric cover is a product of more than 90 bench-top iterations (9 of which have been user tested) and now features a bottom-load entry (see **Figs. 5A, B**, **Supplemental Digital Content 5**, http://links.lww.com/BOT/A469).

Other important design factors that we have considered, but have not addressed here, include: durability of each component after repeated use and sterilization, the effect of tool choice on drilling performance,[9] sterile reprocessing considerations, material biocompatibility, and hardware drill electrical safety.

DISCUSSION

We designed a surgical drill for scale by designing specifically for end users in low-resource settings. The Drill Cover system provides surgeons a device that is durable, affordable, and safe, whereas current alternatives are inadequate for users in low-resource settings in at least one of these criteria area (new surgical drills are not affordable; donated surgical drills are not durable; manual drills or nonsterile hardware drills are not safe). The current Drill Cover has been well received by surgeons and nurses because it creates an improved sterile barrier between the operating room and drill, uses a hardware drill carefully selected for safe bone-drilling speeds, and is sized for easy loading of the drill into the bag. Each of these features represent significant improvements over previous drill cover designs.

This Drill Cover system provides a proof-of-concept for a product that can scale globally which will increase access to safe surgical drills in low- and middle-income countries (LMICs). Development of this Drill Cover system can now progress towards meeting the standards of Health Canada (our group's home country regulatory agency).

A key strength of the Drill Cover approach is that multiple covers can be provided with a single drill in a "kit", meaning that a hardware drill can be used in back-to-back surgeries by changing drill covers, eliminating the need for immediate sterilization. A kit of 5 Drill Covers and a single drill provides capacity for an operating theater to complete 5 surgeries per day, before sterilization is needed. Furthermore, because of its low cost, hospitals with limited access to sterilization devices can stockpile Drill Covers in order to reduce dependence on same-day sterilization.

One limitation of the Drill Cover system is that it uses a drill that is not cannulated, making it difficult to use some reaming attachments, and challenging to grip Kirschner wires using a collet in the same manner as a modern surgical drill. To overcome these limitations, future Drill Cover designs will pursue compatibility with reaming attachments and an affordable cannulated drill. Another limitation is that battery-powered drills are not be as widely available as corded drills in some countries. One potential solution is to form partnerships with hardware drill suppliers so that battery-powered hardware drills (safe for bone drilling) are widely accessible in LMICs at affordable prices.

To maximize the positive impact of this Drill Cover system, the design must be optimized for safety and efficacy in order to meet medical device standards and regulations, and production growth must be sustained by product sales. Development of a sustainable model requires the use of "Integrated Innovation"[10]: the combination of scientific, business, and social innovation to scale using a sustainable business model and maximize impact by improving access to safe surgery for patients throughout LMICs.

If made widely available, the Drill Cover system can play a contributing role in improving surgical outcomes and efficiency in LMICs. For example, in Uganda (where we have focused our work), long bone fractures account for over 15% of hospital admissions.[11] Nearly all patients should receive surgical care in a timely fashion, but in reality, a lack of resources—occasionally specific to the lack of a powered surgical drill—means that patients will long wait times or not receive surgery at all.[12] Long wait times lead to extended periods of disability, reduced income, and a significant socioeconomic trickle-down effect on families and dependents.[12] A widely available Drill Cover system can eventually eliminate surgical inefficiencies because of manual drill use and reduce infections because of the nonsterile hardware drill use. Next steps in the development of this Drill Cover system include a clinical study at Mulago Hospital that will track surgical site infections and surgical drilling time using both currently available tools and the Drill Cover system.

CONCLUSIONS

By designing for the needs of end users, we have developed a Drill Cover system that is suitable for use in low-resource settings. The Drill Cover has the potential to scale globally and improve access to safe orthopaedic trauma surgery worldwide.

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