Making Surgery Affordable: Design of a Surgical Drill Cover System for Scale in Low-Resource Settings

*Lawrence L. Buchan M.A.Sc.1,2, Marianne S. Black, M.A.Sc.1,2,3, Michael A. Cancilla, M.Eng.1,2, Elise S. Huisman, M.Sc.1,2, Jeremy J.R. Kooymen, M.A.Sc.1, Scott C. Nelson, M.D.3, Nathan N. O’Hara, M.H.A.1, Peter J. O’Brien, M.D.1, Piotr A. Blachut, M.D.1

1 University of British Columbia  Department of Orthopaedics  3114 - 910 West 10th Ave  Vancouver, BC Canada V5Z 1M9
2 Arbutus Medical  221 - 181 Keefer Place  Vancouver, BC Canada V6B 6C1

3 Stanford University  Department of Mechanical Engineering  450 Serra Mall  Stanford, California 94305
4 Loma Linda University Medical Centre  Pediatric Orthopaedic and Trauma  25455 Barton Road  Loma Linda, California 92354

*Corresponding author: Lawrence L. Buchan
Arbutus Medical
221 - 181 Keefer Place
Vancouver, BC Canada V6B 6C1
Email: lawrence@drillcover.com
Phone: +1(604)250-0320
Fax: +1(604)875-4677

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Funding for this work was provided by a Grand Challenges Canada Stars in Global Health Phase I grant. Grand Challenges Canada is dedicated to supporting bold ideas with big impact® in global health. The grant funds are intended to go directly towards commercialization of the Drill Cover.

Four authors (LLB, MSB, MAC, ESH) are founders, shareholders, and directors of Arbutus Medical (AM), a for-profit social enterprise that develops and delivers surgical technology for low-resource settings. AM is a spin-off from the University of British Columbia focused on commercializing the Drill Cover. Two authors (LLB, MAC) currently receive salary from AM. AM will obtain a non-exclusive licence from the University of British Columbia for this Drill Cover system before publication of this article.
Abstract

Many surgeons in low-resource settings do not have access to safe, affordable, or reliable surgical drilling tools. Surgeons often resort to non-sterile hardware drills because they are affordable, robust, and efficient, however impossible to sterilize. A promising alternative is to use a Drill Cover system (a sterilizable fabric bag plus surgical chuck adapter) so that a non-sterile 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 three main aspects. The first key aspect of our design was a sealed barrier between the surgical field and hardware drill that withstands pressurized fluid. The second feature was the selection of a hardware drill with maximum speed of 1050 RPM, a speed that matches common surgical drills and reduces risk of necrosis. The third key feature was a fabric cover optimized for ease of assembly while maintaining 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. Our Drill Cover design provides a proof-of-concept for a product that can be commercialized and produced at scale. By designing a system that meets the needs of end-users, the Drill Cover has the potential to scale globally.

Key Words

Surgical bone drill, fracture care, global orthopaedic trauma, medical device design, drill cover
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 they 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 non-sterile drill can be used safely in the sterile surgical field. Previous hardware drill solutions (Supplemental Digital Content 1) have improved surgical drill access in some low-resource settings, but none have been successfully commercialized to date, and access to safe surgical drills remains limited globally.

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. Our mission is for every operating room in the world to have access to a safe, affordable surgical drilling device.

Needs Identification

Our redesign of the Drill Cover started as a project within the University of British Columbia’s Engineers in Scrubs program,\(^4\) which brought together a team of graduate biomedical engineering
researchers, orthopaedic surgeons, nurses, reprocessing staff, and administrators from the Uganda Sustainable Trauma Orthopaedic Program (Vancouver, BC, 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 one high-priority problem. Surgical drill availability at Mulago Hospital was limited; in 2013, surgeons had access to a single donated drill with a poorly functioning battery, manual drills, or non-sterile hardware drills. Using the Stanford Biodesign approach, we 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 plus two detachable parts, a “Cover” and “Chuck Adapter”, inspired by early drill cover designs (Figure 1). The Chuck Adapter includes a custom shaft, a three-tooth chuck, a sealed ball bearing, and bearing case. 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).
**Figure 1:** The Drill Cover system. (A) An exploded view. The system is composed of a battery powered power screwdriver drill (DeWalt DCF610S2) plus two detachable parts, the Cover and 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 metal nose piece. (B) An assembled view of the Drill Cover system showing the bearing case connected the cover’s nose piece via 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 1:** Technical features of the Drill Cover system and components that address each feature.

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The Cover includes a fabric sleeve and nose piece. The fabric sleeve is constructed of a double-layered medical fabric (MaximaEX, Burlington Barrier; WA, USA) typically used for surgical drapes and gowns. All seams are sealed using seam tape that survived testing of 100 autoclave cycles (121°F, 30 minutes/cycle; Castle® steam gravity displacement sterilizer; Sybron Corp., Milwaukee, WI). The nose piece clamps the fabric between itself and a nose mating plate via easily removable machine screws. Since the lifetime of the stainless steel adapter will be significantly longer than that of the fabric, technicians can easily replace the fabric without needing to replace the metal components.

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 DCF610S2 unit is 1.0 kg, and dimensions (with battery installed) are 19cm by 15cm by 6cm. 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, R.N) and requires two participants (Supplemental Digital Content 2-3). The first step is for a sterile staff to hold the Cover opening unrolled with their hands tucked under the rolled fabric. The second step is for a non-sterile 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 “Closure Mechanism” can be sealed by screwing together the bearing case and nose piece of the cover together.

**Safety & Efficacy**

Firstly, we aimed to quantify the performance of the Drill Cover system as a sealed barrier to prevent transmission of blood and blood-borne pathogens between the sterile surgical field and the hardware drill. We designed a custom test apparatus (modelled upon 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 (Supplemental Digital Content 4). Fabric swatches resisted fluid penetration up to 1.1 psi; seams resisted penetration up to 0.6 psi, and the closure mechanism resisted 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.

Secondly 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 one 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 DeWalt DCF610S2 maximum unloaded speed of 1050 RPM falls within the range of common orthopaedic surgical drills, this hardware drill choice does not increase the risk of drilling causing necrosis.

Thirdly, the Drill Cover was designed for optimal ease of assembly using sterile technique. During the design process, we assessed improvements in ease of assembly qualitatively using 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 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 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 (Supplemental Digital Content 5).

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; 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 fall short in at least one area (new surgical drills are not affordable; donated surgical drills are not durable; manual drills are not safe; uncovered 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 soon achieve regulatory approval and scale in multiple markets, which will increase access to safe surgical drills in LMICs. We are actively aiming for this Drill Cover system to meet the standards of our home country regulatory body, Health Canada. Meeting such requirements will allow for more efficient approval of the Drill Cover in many low- and middle-income countries (LMICs).

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 any immediate sterilization. A kit of five Drill Covers and a
A single drill provides capacity for an operating theatre to complete five surgeries per day before sterilization is needed. Furthermore, due to its low cost, there is potential to stockpile Drill Covers and reduce dependence on sterilization infrastructure in areas where access to sterilization devices like autoclaves may be limited.

One limitation of the Drill Cover system is that it uses a hardware drill that is not cannulated, which makes 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 such as the DeWalt DCF610S2, are not be as widely available as corded drills in some countries. We aim to partner with hardware drill suppliers 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, meet medical device standards and regulations, and sustain itself via product sales. We aim for the Drill Cover to be supported by product sales, and are using an “Integrated Innovation” approach for the Drill Cover, which demands the combination of scientific, business, and social innovation in order to scale, reach financial sustainability and maximize impact.

Target retail price for the present version of a single Drill Cover is $400 (USD), while target price for a ‘kit’ (one drill, five Drill Covers – enough for a typical day of orthopaedic interventions) is $2000 (USD). Future versions will target a similarly drastic reduction in cost compared with conventional surgical drills. While Drill Cover lifetime testing is currently underway, we aim for the fabric bags to withstand at least 100 repeated uses and sterilization cycles while maintaining the specified barrier performance. After 100 uses, the covers can be replaced by a trained technician and used with the original metal components.
If made widely available, the Drill Cover system can play a contributing role in improving surgical outcomes/efficiency in LMICs. In Uganda, where we have focused our work, long bone fractures account for over 15% of hospital admissions.\(^1\) Nearly all 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 either wait a long time for or surgery or not receive it at all.\(^2\) Long wait times lead to extended periods of disability, reduced income, and a significant socioeconomic trickle-down effect on families and dependents.\(^2\) A widely available Drill Cover system can eventually eliminate surgical inefficiencies due to manual drill use and reduce infections due to non-sterile hardware drill use. Next steps 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.

**Conclusion**

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

**Acknowledgements**

The design of this Drill Cover involved significant contributions from many talented groups/individuals who are passionate about global health and surgery. We thank the members of Uganda Sustainable Trauma Orthopaedic Program, Dr Titus Beyeza and staff at Mulago Hospital, Dr Lewis Zirkle and Joel Gillard of the Surgical Implant Generation Network, Dr Alan Giachino, the Institute for Global Orthopaedics and Traumatology, and surgeons world-wide who contributed design and project feedback. We also thank UBC engineering students Justin Lam, Nicholas Slakov, Giulio Pregolato, the UBC Engineers in Scrubs, Kwantlen Polytechnic University School of Design, the Centre for Hip Health and Mobility, Dr Robin Coope, and Florin Gheorghe of Arbutus Medical for their significant and ongoing contributions to the development of the Drill Cover.
References


## Tables

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Supplemental Digital Content

**Supplemental Digital Content 1:** Early drill cover designs. (A) A homemade solution that used a simple non-waterproof surgical drape tied around the hardware drill. (B) The CURE International drill system, used in Haiti and the Dominican Republic. (C) A version of the drill cover developed by the Surgical Implant Generation Network (SIGN Fracture Care International). (D) The Ottawa Sterile Drill System, developed by Dr Alan Giachino and the University of Ottawa.

**Supplemental Digital Content 2:** A step-by-step video demonstrating the sterile loading procedure of the Drill Cover system.

**Supplemental Digital Content 3:** A poster demonstrating the step-by-step sterile loading procedure of the Drill Cover system.

**Supplemental Digital Content 4:** The test apparatus designed to test the ability of each Drill Cover component to prevent transmission of pressurized fluid, and was modelled on a standard test method, ASTM F1670-08. (A) A schematic showing how the testing interface was pressurized. Each component (closure mechanism, bearing, fabric, seams) was placed at the testing interface for separate trials. (B) An image depicting the actual testing apparatus.

**Supplemental Digital Content 5:** A depiction of two potential loading options: (A) side-load; and (B) bottom load. The bottom-load option has the advantage of moving the roll-over clasp to the base of the drill, eliminating bulk from the surgeon’s hand during drilling. Future work will investigate the optimal loading direction. The bottom-load option was designed by the Kwantlen Polytechnic School of Design (Richmond, BC, Canada).