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Reuse of Orthopaedic Equipment

Barriers and Opportunities

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Abstract

» Reuse of orthopaedic equipment is one of many potential ways to minimize the negative impact of used equipment on the environment, rising healthcare costs and disparities in access to surgical care.

» Barriers to widespread adoption of reuse include concerns for patient safety, exposure to unknown liability risks, negative public perceptions, and logistical barriers such as limited availability of infrastructure and quality control metrics.

» Some low- and middle-income countries have existing models of equipment reuse that can be adapted through reverse innovation to high-income countries such as the United States.

» Further research should be conducted to examine the safety and efficacy of reusing various orthopaedic equipment, so that standardized guidelines for reuse can be established.

This article explores the practice of reusing orthopaedic surgery equipment. We explore the potential benefits, barriers, and solutions to successfully implement such reuse in a safe and effective manner. For this review, we use the term "orthopaedic equipment" loosely to include items that are commonly used in the operative care of the orthopaedic patient. These could include protective barriers (e.g., drapes and gowns), patient-worn devices (e.g., blood pressure cuffs, pulse oximeters, sequential compression devices, and tourniquets), instruments (e.g., drill bits and shavers), and external hardware (e.g., external fixator bars, clamps, and rings). Implants that violate the skin envelope (such as half-pins, plates, screws, and prostheses) are excluded from this discussion.

First, a few definitions: "repurpose" refers to the act of using a device for a purpose other than originally intended. "Reuse" refers to the act of using an equipment or device for more than 1 deployment of its intended function. "Refurbish" refers to processing a previously used device for reuse after confirming appropriate fitness to use based on specific standards[1]. Refurbishing can be performed by the original manufacturer or a third party, who decides whether the device is fit for release back into the market and takes a piece of the profit[1,2]. Refurbishing provides inherent quality control, at a cost. Not all reused devices are refurbished, but all refurbished devices are intended to be reused. This article will focus on reuse and refurbishing of equipment pertinent to the practicing orthopaedic surgeon.

Why Reuse Equipment?

A compelling case for reusing orthopaedic equipment can be made by examining its impact through an environmental, economic, and ethical lens.

Environmental Reasons

Climate change is a major threat to global health: The 2009 Lancet Climate Change Commission declared it as "the biggest

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global health threat of the 21st century."[3-5] The United States is one of the top 3 contributors of greenhouse gases[6], and the healthcare industry is one of the largest culprits, producing 10% of all greenhouse gases[7] and more than 4 billion pounds of medical waste annually[8-10]. Operating rooms produce 50% to 70% of hospital waste[8,11]. Therefore, surgical specialties are an ideal area to focus efforts to combat climate change.

The environmental benefits of reusing surgical equipment are well documented[8,12-16]. A systematic review studying the contributors to the carbon footprint of surgical procedures found that single-use devices (SUDs) were often the largest offenders, and that switching to reusable items could reduce carbon footprint by more than 50%[12]. Indeed, surgeons at University of Washington hospitals eliminated 5.8 tons of waste in 1 year by reusing SUDs, and a 163-hospital corporation saved 298 tons of waste 1 year by reprocessing certain medical devices[13]. A life cycle analysis (LCA) found that sterilizing and reusing surgical gowns 60 times reduced water use by 83% and landfill waste by 84%[17]. LCAs found that reusable sharps containers in the United States and United Kingdom reduced global warming potential by more than 3000 tons of carbon dioxide (CO_2) equivalents annually[18,19]. In other reports, reusable laryngoscope plastic handles used 16 to 18 times less CO_2 equivalents than single-use handles[20], and reusable laryngeal mask airways (LMAs) had 5% the carcinogenic effect of single-use handles, mainly from eliminating harmful waste byproducts such as those generated from the burning of polyvinyl chloride plastic[21].

The environmental impact of reprocessing equipment for reuse must also be considered. In the aforementioned study, the majority of such impact from reusable LMAs stemmed from the energy required to heat water into steam for the autoclave[21]. In another LCA, the environmental impact of reusable surgical instrument sets, which stemmed mainly from washing and steam sterilization, was 75% larger than that of disposable sets, which stemmed mainly from the production process[22].

The increasing number of reports on waste audits and LCAs of various orthopaedic procedures[23-35] reflects a growing interest in "greening" the orthopaedic operating room. Orthopaedic surgery is a contributor to climate change, and practitioners are uniquely positioned to appropriately modify their practice to minimize negative impacts on the environment[16,36].

Economic Reasons

In many low- and middle-income countries (LMICs), high costs render healthcare unaffordable and inaccessible to a large segment of their population[37]. Patients often buy and bring certain equipment and medications for their surgical care to hospitals before their procedure. The issue of unaffordable healthcare applies to high-income countries (HICs) as well, where substantial price markups for surgical equipment and devices often result in poor cost-utility[38,39]. According to one report on price variability, inguinal hernia mesh costs $108 in the United States and 0.004% the amount in Burkina Faso; intraocular lenses cost $100 in the United States and $3.50 in Nepal; a hydrocephalus drain sold by a American manufacturer costs $650 and $35 when sold by an Indian manufacturer—and this is despite each of these device pairs having equivalent safety and efficacy when tested by researchers[39]. The United States stands out when it comes to healthcare spending. In 2021, 18% of the country's gross domestic product was spent toward healthcare, nearly twice as much as other HICs[40]. In 2022, nearly half of American adults delayed or went without medical care because of unaffordable costs[41], with minorities, low-income, and uninsured individuals (of which there were more than 23 million in 2023) disproportionately affected[40,41]. Therefore, lowering healthcare costs is a priority for LMICs and HICs alike.

Reusing medical equipment can generate enormous cost savings. Practice Greenhealth, a sustainable healthcare organization, published a summary containing multiple successful examples of such cost-saving healthcare initiatives[13]. One of their members, the Hospital Corporation of America, realized a net annual savings of $17.6 million across their 163 hospitals by reprocessing various medical devices. Another member, MetroWest Medical Center, saved $29,843 in 1 year by transitioning 66% of their instrument packaging from disposable wrap to reusable containers[13]. In a separate study, Chen et al. held weekly focus groups with orthopaedic surgery residents to brainstorm cost-containment interventions at a level 1 trauma center[42]. Among the highest impact interventions were reusing undamaged drill bits (projected to save $1.78 million per year) and tourniquets (projected to save $201,068 per year)[42].

External fixators have garnered particular attention for their substantial cost-saving potential[37,43]. Researchers implemented an external fixator reuse program in which components were inspected by a trained nurse, and if no obvious signs of wear were found, sterilized and reused up to 3 times; this resulted in a 32% decrease in mean unit cost, from $4,067 to $2,791[44]. Pulate et al. sought to make external fixators more affordable for patients in India and found that 3 or more reuses resulted in a 97% cost reduction from $400 to $13.6[37]. Padhi and Padhi used locally manufactured external fixators at a hospital in rural India and found that reusing components reduced cost further by 76%, from $50 to $12[45]. Rods and clamps were reused more than 10 times[45]. Based on an randomized controlled trial at a US level 1 trauma center comparing new with refurbished external fixators, 46 patients randomized to receive refurbished external fixators accounted for a savings of $65,452 over 30 months[2].

Ethical Reasons

From an ethical perspective, reusing surgical and perioperative equipment

fulfills principles of justice and beneficence that are foundations of medicine. Patients in LMICs frequently face severe shortages including inadequate hospital infrastructure and oftentimes the burden of purchasing their own surgical equipment—barriers that limit their access to quality surgical care[37]. From this perspective, discarding potentially reusable equipment after a single use could be considered wasteful, when instead they could be reused to address unmet needs of other patients, either locally or overseas. Such reuse can reduce disparities in access to care (justice)[37,46], as well as generate financial savings that can be directed toward expanding care to more patients (beneficence).

HICs are not immune to healthcare disparities. Within the United States, there are large healthcare disparities by socioeconomic status, geographic region, race/ethnicity, disability status, and sexuality/gender identification[47]. In 2023, 94 billion Americans were enrolled in low-income public insurance programs (Medicaid, Children's Health Insurance Program), and 23 million were uninsured. It is well documented that this population experiences care barriers and worse outcomes across all orthopaedic subspecialties: They have difficulty obtaining initial appointments, experience longer wait times and delays in care, travel further for appointments, and have lower utilization rates of surgical interventions such as total knee arthroplasty[48-58]. Furthermore, uninsured adults are more likely to avoid recommended tests and treatment because of excessive cost[41]. Given this relation between cost and access, the practice of reusing orthopaedic equipment and its associated cost savings could potentially expand access to care, distribute resources, and address inequities in health in LMICs and HICs alike.

Barriers to Reusing Equipment

Despite its potential benefits, the practice of reusing equipment remains limited, particularly in HICs. It is important to identify and critically appraise the perceived barriers to implementation.

Safety Concerns

There are understandable concerns with reusing equipment such as increased risk of infection and mechanical failure[59]. Does this bear out in the clinical practice? A critical review of some common equipment used in orthopaedic procedures is presented below.

Drapes and Gowns

Before the 1980s, reusable surgical drapes were often composed of the same fabric as hospital linen[60]. Advanced barrier protection was introduced in the 1980s and basic quality standards for drapes in the 1990s[60]. Over the decades, many studies have compared reusable and disposable drapes[16,60-65], but no definitive conclusions can be drawn because of wide variation in study design, and a number of studies were conducted before the 1980s[66]. Neither the 1999 nor 2017 Centers for Disease Control and Prevention Guidelines for Prevention of Surgical Site Infection made recommendations regarding reusable vs. disposable gown and drape systems[67,68].

Tourniquets

Although tourniquets are easily contaminated, they are also readily sterilized. In a study comparing sterile with nonsterile tourniquets, Thompson et al. found that none of the 34 sterile tourniquets were colonized with microorganisms, whereas 68% (23/34) of the nonsterile tourniquets were colonized with various organisms, most commonly *Staphylococcus* spp[69]. Mufarrih et al. found that a weekly cleaning protocol consisting of soaking tourniquets for 30 minutes in sodium hypochlorite eliminated growth of all organisms. Similarly, Sahu et al. showed that a cleaning protocol using either alcohol or chlorhexidine wipes led to a 92% to 95% reduction in colony counts on all 16 tourniquets[70]. These studies suggest that tourniquets can be safely reused if appropriate cleaning protocols are implemented.

Surgical Instruments

Various researchers have studied the mechanical integrity of reprocessed surgical instruments. In a human cadaver study comparing new vs. refurbished drill bits, both performed similarly with regards to force required, heat generated, and usable passes[71]. On the other hand, several studies of arthroscopic shaver blades found visible wear after a single use[72,73]. Sheep menisci cut by refurbished shavers had rougher edges than those cut by new shavers[73].

In addition, multiple researchers have reported the presence of residual biofilm, microscopic soilage, or even active endotoxin on various instruments (forceps, drill bits, and intramedullary reamers) after washing and autoclaving[74-77]. In studies of refurbished arthroscopic shaver blades, King et al. detected residual protein on spectrophotometry, although did not identify what type of protein[73]. Kobayashi et al. detected protein, collagen, hydroxyapatite, and salts on scanning electron microscopy and XR spectroscopy, but reported no adverse patient outcomes after anterior cruciate ligament reconstruction using the refurbished shavers[72]. It is unclear whether these contaminants can transmit disease, nor what degree of contamination would cause infection[72].

Although these findings of residual contaminants and microscopic wear on refurbished surgical instruments are concerning, more research is needed to determine whether these findings have clinical significance and whether additional sterilization procedures should be adopted before reuse.

External Fixator Components

Multiple studies comparing new and reused external fixators, conducted at academic medical centers in the United States and abroad, found no statistically significant differences in the incidence of pin tract infections, loss of fixation, nor component loosening[2,44,78]. On the other hand, one study of 42 open tibial fractures treated with reused external fixators in rural India reported high rates of pin track infections (52%) and deep infections or wound breakdowns (14%)[45]. However, all injuries in this study were open fractures, and an unspecified number of patients also received nailing or plating

along with external fixation, which could have contributed to infection risk; furthermore, there was no control group for comparison. Hardware-related infection can have devastating consequences, leading to major morbidity, financial cost, and psychosocial burden to patients[79,80]. Until further safety data are published, the reuse of implanted hardware (such as external fixator half-pins) should be approached with caution.

With regards to mechanical integrity, Beck and Seligson found that in circular external fixators, the initial "break-in" period alone can leave visible deformation and scoring, and 1 of the 3 tested systems was unable to maintain wire tension after multiple uses[81,82]. On the other hand, an op-ed based on available animal and biomechanical studies suggested that external fixators are strong enough to withstand multiple uses[83]. However, durability is not the only factor under consideration. An external fixator must operate at a stiffness that is sufficient to withstand biomechanical loads yet not so excessive that it prevents micromotion needed for secondary healing. Furthermore, an external fixator has multiple functions: as temporary or definitive fixation, for limb lengthening, or as an intraoperative reduction aid—each requiring slightly different mechanical properties and duration of intended use. The properties of reused external fixators performing in their various functions need further study in vivo.

Challenges with Safety Data

In 2008, the US Government Accountability Office analyzed the 434 adverse events reported from 2003 to 2005 and concluded that, because of similar adverse events rates between new and reprocessed devices, the evidence "does not indicate that reprocessed SUDs currently in use pose an increased safety threat."[84]

However, several factors make accurate evaluation of the safety of reused equipment challenging. First, there is a paucity of safety data—existing data are based on a combination of adverse event reports that often lack comprehensive information[84] and ex vivo studies, many of which are industry-funded, from which limited conclusions can be drawn regarding clinical outcomes[85]. Second, adverse events are likely underreported. In a systematic review, authors noted that the number of publications regarding unsuccessful decontamination of surgical instruments (21) in the context of the annual number surgical procedures (51 million) was disproportionately low, compared with flexible endoscopy (147 publications regarding failed decontamination of flexible endoscopes, with 1.6 million flexible endoscopies performed annually)[86]. There are no standard adverse event reporting mechanisms, and those that do exist are often voluntary[85].

Litigation and Liability Concerns

Fear of litigation is another major barrier to reusing surgical equipment: In a 2007 survey of Canadian acute-care hospitals, such a concern was the top reason why 72% of 287 hospitals did not reuse SUDs[59,87]. A detailed understanding of this topic warrants historical perspective. In 2000, the U.S. Food and Drug Administration (FDA) began regulating the reuse of SUDs, stating that reused SUDs must comply with the same regulatory requirements as those established for the original device[88,89]. Those using reprocessed SUDs must submit a premarket notification report, or 510(k), to the FDA that contained validation data demonstrating that the reprocessed device is safe, effective for its intended use, and "substantially equivalent" to the original[89]. This policy was enforced on medical devices prioritized by their FDA category, with certain class I and II devices eligible for exemptions (Table I)[90]. The majority of reused SUDs (65%-75%) fall into the class II category[14].

Two years later, the Medical Device User Fee and Modernization Act was published. This act added several notable regulatory requirements: (1) that the FDA identify any reused SUDs that required additional validation data, (2) that the FDA publish a list of exempt reprocessed SUDs, and (3) that reprocessors clearly label reused SUDs as such, along with the reprocessor's name[91]. Under this act, reused devices are considered the product of the reprocessor, not the original manufacturer.

Violations result in serious consequences. In 2022, the United States sued Prometheus, Ltd. for encouraging providers to reuse rectal pressure sensors and anorectal manometry catheters on multiple patients as a strategy to cut costs, despite the fact that they were FDA-cleared as single-user and SUDs, respectively[92]. Several preceding cases were filed against individual practitioners over this same issue: In May

**TABLE I Description of FDA Medical Device Classes[90]*

FDA Class	Description	Examples
I	Low risk	Anesthesia breathing circuits, manual instruments (e.g., rongeur, wrench, awl, and depth gauge)
II	Medium risk	Sterilization wrap, surgical gowns, surgical drapes, surgical masks, wound vacuum, pulse oximeters, power instruments (e.g., saw bladers, and burr tips), and orthopaedic implants
III	High risk	Implanted pacemakers, implanted defibrillators, and ventilators

*FDA = US Food and Drug Administration.

2020, an urologist was sentenced to 57 months in prison and agreed to pay part of a $1.26 million civil settlement for conspiracy to healthcare fraud and adulteration of medical devices[93]. In 2014, another urologist who reused prostate biopsy needle guides that were FDA-approved for single-use only was sentenced to 4 years in prison for adulterating a medical device[94,95]. And, in 2017, the Indian state of Maharashtra prosecuted 7 hospitals for reusing angioplasty catheters that were not approved for reuse and without patients' consent[96]. Such examples, although egregious, not only underscore the importance of following regulations on the reuse of equipment but also validate hospitals' and surgeons' concerns over litigation and liability. It also touches on the issue of informed consent. According to the principle of autonomy, patients should be informed when reused equipment is used in their surgical care. However, if reusing a specific piece of equipment is the standard of care, there may not be a moral imperative to disclose to patients and rather it would be treated similarly to other standard practices, such as the use of intraoperative fluoroscopy[97].

Public Perceptions

Negative public perceptions are another barrier to reusing certain surgical equipment. In a study that randomized patients to receive either new or refurbished external fixator clamps, 65% of eligible participants refused to participate, despite reassurance that the refurbished clamps would be sterilized and undergo FDA-approved testing[2]. In a similar study in India, 17% of the eligible patients refused to participate, despite reassurance that reused parts would be properly sterilized[78]. Public mistrust in reused equipment is in part fueled by media coverage of malpractice suits such as those aforementioned cases. Another reason for patients' refusal could be the perception that new equipment is superior and reused equipment is secondhand and a marker of social inferiority[97]. Alternatively, patients may perceive orthopaedic equipment as a Giffen good, where low cost is interpreted not as a benefit but rather as signaling inferior quality[97]. Finally, the discrepancy in proportions of refusing patients between the 2 studies suggests attitudes toward reused equipment may be mediated by socioeconomic, educational, and cultural factors[2,78].

Logistical Barriers

A recent review found that the greatest barriers to sustainable change for environmentally friendly practices in orthopaedics were "lack of appropriate infrastructure" and "lack of knowledge or training."[16] Indeed, there are no universal protocols for evaluating whether equipment is suitable for reuse, nor evidence suggesting the number of times specific items can be safely reused[43,59,98,99]. In addition, there is limited equipment and trained personnel for reprocessing orthopaedic equipment, particularly in LMICs[74,87,100,101]. Finally, the setup and equipment used by original manufacturers for premarket testing, as well as design-specific knowledge for each device, are often proprietary[102]. These unknowns further contribute to ongoing concerns over safety and litigation, which disincentivize healthcare systems and surgeons from reusing certain orthopaedic equipment[59,87].

Potential Solutions

How can the United States and other HICs overcome safety and liability concerns as well as cultural and logistical barriers to realize the environmental, economic, and ethical benefits of reusing orthopaedic equipment? Several strategies and concepts are proposed below.

Reverse Innovation

"Reverse innovation" refers to the flow of ideas from lower- to higher-income settings (Fig. 1). This is a well-established concept in the business world[103] and is a successful strategy because (1) conditions in lower-income countries provide powerful incentives and gaps that drive change, and (2) decreased regulatory and cultural resistance facilitates a more rapid adoption of

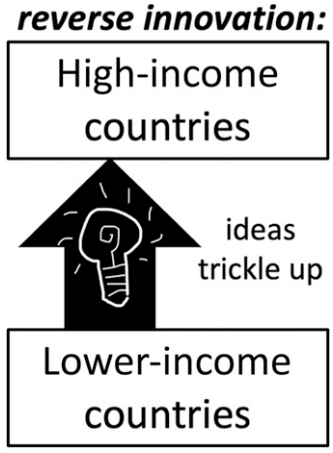

Fig. 1

A graphic depiction of the concept of reverse innovation. Reverse innovation refers to the upward trickle of ideas from lower- to higher-income settings.

new systems and technology. Indeed, many LMICs have already successfully piloted models of reusing orthopaedic equipment. For instance, in a report from India, external fixators were reused at least 3 times, reducing cost from $40 to $13.60 and making it affordable for more patients[37]. At the start of the COVID-19 pandemic, orthopaedic surgeons at another overseas hospital addressed personal protective equipment shortages by manufacturing a reusable faceshield that was well received and worn during orthopaedic splinting, wound care, and surgeries[104]. In Colombia, a multidisciplinary team implemented a reuse program at one hospital to allow it to remain financially viable on a limited budget[105]. Following FDA guidelines, they developed a reuse manual that, for each item, specified important details including the number of allowable reuses and steps for proper inspection[105]. By looking to resource-limited environments for certain frugal innovations, stakeholders in HICs can invest in some of these creative ideas and safely adopt relevant practices for reusing surgical equipment.

Researching and Publicizing Safety Data

Data on the safety of reused orthopaedic equipment are limited and only available inconsistently. Gaps in knowledge

remain regarding the number of times certain items can be reused, how their mechanical properties and infection risk profiles change over time, and how these are mediated by host factors and injury phenotypes. Further research and reporting should be performed in these areas, and the resultant safety data publicized to all stakeholders including hospitals, surgeons, and patients. Although our current review does not discuss orthopaedic implants such as plates, screws, intramedullary nails, and prostheses, more research is needed to evaluate the viability of selectively reusing some of these implants safely.

Establishing Standards

In light of recent cases prosecuting unlawful reuse of SUDs and evolving regulations governing equipment reuse[92-96], surgeons may find navigating the legal arena to be challenging. Medical-legal teams should be well informed on current regulations and closely advise surgeons and hospital administrators on issues of liability. Clear guidelines published by professional associations and regulatory bodies can also alleviate uncertainty and worry surrounding litigation. Guidelines should contain standardized criteria and workflows for screening, evaluating, and preparing equipment for reuse, which will allow for safe and uniform reuse practices across multiple settings[98,100,102]. Hospitals should keep a log of reused items, which includes information on recommended lifespan and number of previous uses. Finally, appropriate organizations and licensing entities with oversight should establish mandatory adverse event reporting systems that incorporate automated data collection as much as possible to eliminate reporting biases. This will allow equipment to be appropriately tracked, retired at the end of their lifespan, and contribute to data used for ongoing research into equipment efficacy and safety[98].

Conclusion

Reusing orthopaedic equipment has the potential to generate environmental and economic benefits, improve access to surgical care in resource-limited environments, and address healthcare disparities. However, for widespread adoption of this practice to occur in the United States, further research must be conducted to examine the safety of reusing various orthopaedic equipment, and standardized guidelines for reuse must be established.

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