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Review Article

The Ethical Implications of Reusing External Fixation Systems: A Used Car or A Plastic Water Bottle?

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The reuse of external fixation systems raise several important ethical considerations. Reusing external fixators can decrease costs, but questions emerge about who owns the implant, who will benefit from the savings, and the need to disclose the use of reprocessed parts. In addition, there are concerns relating to infection, as well as humanitarian and environmental considerations that must be weighed when deciding whether to implement a reprocessing program for external fixators.

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Conflicts of Interest Statement for This Author

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Selected to lead the Department of Orthopaedic Surgery in 2012, Dr. Suk became one of the youngest people in the U.S. to head an academic orthopaedic department. Since then, he has overseen tremendous growth — from 2 main hospital centers and 22 orthopaedic surgeons to 13 hospital platforms, including 1 Level I and 3 Level II trauma centers, representing more than 100 employed and non-employed surgeons.

As the clinical driving force behind the Geisinger ProvenCare® acute orthopaedic programs in total hip, total knee, hip fracture and lumbar spine, Dr. Suk is sought for his expertise in new models for healthcare payment and delivery, physician engagement and leadership. In 2018, he disrupted the dialogue on value-based care by offering the world's first "lifetime warranty" agreement for total hip replacement, which now includes primary and revision total knee replacements.

Dr. Suk helped transform Geisinger's care delivery approach from compartmentalized service lines to an "institute" model centered around patient convenience and meeting the highest expectations. In 2015, he was named chief physician officer of Geisinger System Services, providing clinical leadership over supply chain, facilities management and care support services.

Dr. Suk is an accomplished leader on organized medicine and in promoting patient safety and quality, achieving distinction as the first medical student and Asian American elected to the Board of Trustees of the American Medical Association (AMA) in 1994.

In 2016, he was appointed to the American Medical Political Action Committee Board of Directors, initiating advocacy for the medical profession, and was named a Baldrige Executive Fellow for performance excellence. In 2019, he was again elected to the AMA Board of Trustees and to the board of The Joint Commission.

Before joining Geisinger, Dr. Suk was associate professor of orthopaedic surgery at the University of Florida–Shands Medical Center, where he was division chief of Orthopaedic Trauma and associate director of its Regional Trauma System and its Orthopaedic Residency Program. There, he established a specialized orthopaedic trauma division focused on efficiency and patient outcomes.

He serves on the editorial board for several orthopaedic journals and has authored numerous articles and a landmark orthopaedic textbook. His work on the link between patient expectations and clinical outcomes in orthopaedic trauma surgery has gained worldwide attention. He speaks internationally on orthopaedic fracture management; healthcare literacy; access and delivery; and the interface between law and medicine.

Dr. Suk simultaneously earned his Doctor of Medicine from the University of Illinois College of Medicine and his Juris Doctor and Master of Public Health with special certification in healthcare law from Boston University School of Law and School of Public Health. He completed an orthopaedic surgery residency at Montefiore Medical Center, Albert Einstein College of Medicine, and an orthopaedic trauma fellowship at the Hospital for Special Surgery, Weill College of Medicine at Cornell University. He earned his Master of Business Administration from The University of Scranton.

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INTRODUCTION

There are many situations in orthopaedic trauma in which a temporizing procedure may first be employed, and a longer definitive procedure may be delayed as a secondary surgery. In these cases, a patient may be too sick to undergo a lengthy surgery, or the surgical conditions, such as the soft tissues surrounding their injury, may not be ideal for a more involved surgery. In these scenarios, often an external fixator device or a frame that holds the broken bones in place is utilized to stabilize a fracture until the definitive surgery can be performed.

External fixators are unique among orthopaedic implants in that the pins that are drilled into the bone to stabilize the fracture are the only part that penetrate the skin and are within the body. Most of the device is external to the body. As a result, these frames should be considered for reuse, particularly as healthcare costs continue to rise.

EXTERNAL FIXATION AND RISING COSTS

Implants are often the most expensive costs of any operative orthopaedic procedure (Robinson et al. 2012). While this is often unavoidable as solid fixation represents a critical part of a successful outcome, implant costs represent a potential area for lowering overall healthcare costs. Indeed, implant wastage occurs in approximately one quarter of orthopaedic trauma procedures, accounting primarily of wasted screws (Jayakumar et al. 2020). There is a large variation in cost for surgical implants; for example, high technology implants add a great deal of costs with unclear benefit compared to less expensive options (Wetzel et al. 2016). In addition, the knowledge of the cost of orthopaedic implants by surgeons at every level of training is poor (Rohman, Hadi, and Whitwell 2014; Chan, Foo, and Kwek 2018; Egol et al. 2014), indicating that the high costs associated with implants may not stem from a surgeon taking a thoughtful approach to provide high value care, but rather not knowing the costs of the implant he or she chooses.

An external fixator is an expensive piece of equipment that costs on average $5993 (Hayek et al. 2019; Chaus et al. 2014). Considering it is not meant to be used long-term, external fixation in particular is an ideal target area for cost reduction, given that it costs more than definitive internal fixation of a tibial plateau fracture (valued at $3,219) (Wetzel et al. 2016). One way to reduce costs is to reprocesses external fixators and re-use them. Healthcare costs are increasing and purchasing a new temporary external fixator device for each patient to use permanently represents a waste in the system. Reprocessing programs represent savings of 25-34% across the system (Sung et al. 2008; Dirschl and Smith 1998; Horwitz, Schabel, and Higgins 2007). However, doing so introduces several ethical considerations.

WHO OWNS THE IMPLANT?

While it is current practice in orthopaedic surgery to reuse many of the tools in an orthopaedic procedure, the implants themselves are not. Typically, the cost of a surgical implant is charged to a patient's insurance. Insurance will cover that product for the patient with the intention the implant will permanently belong to the patient. While implants, such as plates and screws, are not infrequently removed if the hardware becomes symptomatic or if there is an infection, often the patient can request to keep "their hardware" after it has been sterilized, underscoring the concept that patients believe they have purchased this surgical equipment. This is a similar concept of ownership as when purchasing a vehicle, whether used or new, in which ownership is clearly indicated by the transferring of a title. Currently, the vast majority of patients have an understanding that the orthoapedic implants purchased at the time of surgery are new devices and that surgical implants belong to the patients.

However, as a temporary piece of equipment that is mostly external to the body, an external fixator functions well as a reusable device, with the potential to save the healthcare system a great deal of money. Reusing surgical equipment is not uncommon. Reprocessing single-use surgical supplies became a recognized practice by the federal government in the United States in 2000, with safety practices and regulatory practices improving since that time (Ubaldi 2019). In 2005, approximately 25% of hospitals utilized reprocessed single-use devices (Sikka, Fischer, and Swiontkowski 2005). In fact, most of the expensive, precise technical equipment used in the operating room, from scalpel handles to tibial reamers, is re-sterilized and reused for multiple cases on multiple patients. According to a 2007 study, Dr. Daniel Horwitz and colleagues performed a recertification program using temporizing Hoffmann-II external fixation systems. They set a predetermined limit of 3 recertification cycles, with the recyclable components sold back to the hospital at 50% of the original price. The average number of uses of a recyclable component was 2.7 with a total savings of 27% on the whole external fixation system, without any complication due to the recertification process. (Horwitz, Schabel, and Higgins 2007). Likewise, Dirschl and Smith found that reprocessing external fixators could reduce costs by 34% without negative complications (Dirschl and Smith 1998). Sung and colleagues performed a randomized controlled recertification trial utilizing the Stryker Hoffmann external fixator. The cost savings between the new and refurbished program was substantial, at $65,452 across 96 fractures with a refurbished frame costing 55% less. There were no statistical differences in complications, such as pin tract infections, loss of fixation, or loosening of components (Sung et al. 2008).

However, in order to reprocess external fixators, the device needs to be made available for multiple patients. This challenges the current concept of who owns the implant. If patients own their implants, then they are under no obligation to give them back to the hospital for reuse, just as a car owner is not under obligation to give back his or her vehicle. After all, they have paid for them. If the hospital owns the implant so that it can be used and reused multiple times, then the purchasing of implants by surgical patients connotes something other than an ownership rela-

tionship. Instead, in this example, the hospital functions more like a car rental agency, giving out the external fixator for a period of time as the patient needs it. This consists of a renting arrangement without transferring actual ownership. While this change in ownership of implants is necessary for a reprocessing program to be feasible, it nevertheless fundamentally changes healthcare business relationships in the United States.

TRANSPARENCY

The bioethical principle of autonomy calls for the surgeon to educate the patient about his condition, including informing him about the risks and benefits of any proposed procedure. In so doing, the surgeon and patient can engage in shared decision making about the best course of action when faced with a particular problem. Thus, while reusing an external fixator would save the health system substantial cost, the principle of autonomy suggests an obligation to disclose the use of reprocessed equipment. This is the current system when purchasing a vehicle. The dealer has certain legal and ethical obligations to disclose information about the car for sale, including whether the car is used and if there are any known problems with the car.

However, the argument can be made that if utilizing reprocessed external fixators becomes the standard of care, there is no longer an ethical imperative to disclose the fact these devices are used to the patient. This is the current case with water bottles, which are commonly made with reusable plastics. The standard practice is to make plastic bottles with a non-specified amount of recycled polyethylene terephthalate, the amount of which is not disclosed, nor is the price adjusted to reflect the previous use of the product. While the water bottle might be made of 100% recycled materials, the product is still marketed and sold as a new product.

Often the patient cannot dictate specific details of their care, such as who is on call in the hospital during an emergency or what company manufactures the implants that are utilized in a surgical case. In addition, savings to the healthcare system as a whole have positive ramifications for equity, justice, and healthcare access that may outweigh individual concerns about autonomy. Reusing materials currently plays an important role in patient care and will continue to do so. While informed consent is a crucial component of a surgical procedure, it is unclear what the disclosure obligation is until it is decided whether external fixators are more akin to used cars or recycled water bottles.

WHERE DO THE SAVINGS GO?

In the above referenced study by Sung and colleagues, 65% patients refused to participate as they were unwilling to be randomized and not have a say as to whether they would receive a reprocessed or a new external fixation system (Sung et al. 2008). The reluctance of the American public to accept reprocessed external fixation systems warrants further investigation. One possible explanation is that American healthcare functions as a Giffen good, with the higher cost associated with the new external fixation system signaling to the consumer a better product. More likely, because the cost savings are being shared between the hospital and the insurance company, the patient is not economically incentivized to choose the reprocessed external fixator over the new model.

Indeed, if a reprocessed external fixator is used, many questions arise about billing. In the used car model, the patient should not be charged the full price for a new system. After all, many people choose a used car over a new car because it is more affordable. However, even if a patient is not charged full price for a reprocessed external fixator, patients may not realize any financial benefit depending on the specifics of the cost-sharing arrangement of their insurance plans. If reprocessing external fixators become the standard of care, such as water bottles made of recycled materials, it is likely that third payors will not reimburse the full cost for a new system in the future. This may make new external fixator systems obsolete because, when they are not reimbursed, they represent a financial risk to the hospital system. Because water bottles do not typically disclose the exact amount of recycled material they contain, their price is not adjusted to account for previous use. This may happen to external fixators as completely new systems become increasingly financially unfeasible.

CONCERNS ABOUT INFECTION

Reusing surgical equipment and implants comes with a very small, though not zero, risk of increased infection. Costa and colleagues studied flexible medullary reamers, depth gauges, and screws used for intramedullary femoral nailing from loaner kits in use over 1 year in Brazil. While the implants became significantly cleaner with processing, there was still ATP, protein, and biofilm present after cleaning and sterilization (Costa et al. 2018). In addition, reprocessing reusable implants increases the complexity of safety protocols to ensure only properly processed implants are utilized. In other words, there are more opportunities for processes to go wrong when utilizing reprocessed implants than when using only new, single-used implants (Seavey 2010; Winthrop, Sion, and Gaines 2007).

Infection can be a devastating complication, potentially leading to repeat surgery, prolonged antibiotic usage, chronic pain, amputation, and even loss of life. While these results are not the most common outcome, their seriousness imparts a certain liability, particularly when using reprocessed components. While sterilization protocols can be put in place that can safely reprocess single-use external fixators, liability is still a significant concern. Third-party re-processors are a growing market, and with limited access to the original manufacturer's inspection and testing information, there may be a reluctance on the part of the third party to mix reprocessed and original products together and certify them (Horwitz, Schabel, and Higgins 2007; Sikka, Fischer, and Swiontkowski 2005). However, when reprocessing external fixators, only the external frame, without the implanted pins, is reused, which decreases many of the risks associated with infections.

ENVIRONMENTAL CONCERNS

Utilizing new equipment for every case, particularly for a short-term, temporizing procedure, generates an enormous amount of waste. Using a new external fixator, which would be used for a few days or a week and then discarded, is wasteful and harmful to the environment. According to Denmark and colleagues, the health care facilities in the United States produces 4 billion pounds of medical waste per year, with approximately 70% of this waste produced in operating rooms. This has increased by 15% per year since 1992, likely due to increased reliance on disposable products (Van Demark, Smith, and Fiegen 2018). Environmental stewardship is an ethical issue as it speaks to the responsibility to future generations to inherit a livable world, and reprocessing external fixators is a feasible way to reduce overall medical waste.

HUMANITARIAN CONCERNS

On a global scale, there is an ethical concern regarding justice in the wasteful practice of single-use external fixators. There is not enough access to orthopaedic implants in the developing world due to the high costs of implants, poverty, and lack of government-funded health insurance (Magetsari et al. 2004). Numerous networks and non-profits have been developed to try to address the unaffordability of implants in developing nations to treat orthopaedic injuries (Zirkle 2008; Agarwal-Harding et al. 2016). Even if the American public were uncomfortable with using reprocessed external fixators, these devices could be put to better use than merely discarded as medical waste. For the vast majority of devices, external fixators retain their metallurgic properties after one use, which makes them safe for re-use. As such, it is question of justice to reuse these external fixators where they will be of the biggest benefit, including in the developing world where patients often do not have access to implants and where traumatic injuries are common, instead of allowing them to be discarded as medical waste.

CONCLUSION

The use of single-use temporary external fixators represents a clash between the principles of autonomy and justice. While at first glance, it appears that a single-use external fixator represents a better deal for the patient in terms of getting what one has paid for, a lack of clarity in terms of cost transparency and perceived concerns over safety makes it challenging to have an informed opinion about the relative risks and benefits of single use versus reprocessed external fixators. In reality, reprocessing external fixators represents a substantial savings to the system that could increase access to care for more patients.

The question of reprocessing and reusing supplies goes far beyond the external fixator and can transform the delivery of healthcare and the field of orthopaedic surgery to bring down costs and make healthcare more accessible and affordable. It is not uncommon in medicine for expensive patient devices, such as continuous passive motion machines, bone growth stimulators, post-operative ice machines, and hospital beds that are intended to be used for a limited amount of time, to be made available to patients as rentals. The path forward in terms of reusing external fixators involves redefining the concept of ownership of orthopaedic implants. Whether an external fixator acts like a used car or a reusable water bottle has important implications for lowering costs, decreasing medical waste, and transforming the way Americans think about surgical implants.

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