



The Economic Argument for Using Safety Scalpels

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Hospital risk managers, infection prevention specialists, surgeons, surgical technologists and other members of the surgical staff are acutely aware of scalpel injuries in both OR and non-OR settings. Scalpel injuries are occurring too frequently and cost too much money; however, they can be prevented. This report examines the benefits and economics of using safety scalpels, which may enable purchasing personnel to better evaluate the cost of scalpels, as they become aware that conventional scalpels cost more than just the price tag.

INCIDENCE OF SCALPEL INJURIES

It has been estimated that more than 75 million scalpel blades are used annually in the United States. The frequent use of conventional scalpels creates a never-ending supply of opportunities for scalpel-related injuries. Nearly every OR staff member has seen or heard about a scalpel-related injury. Almost half of the respondents of a recent survey witnessed a scalpel-related injury, with more than 80% of them reporting the incidents. And while less than 10% of the respondents indicated that someone else had injured them with a scalpel, only 2% admitted to injuring someone with a scalpel.

It has been 14 years since the landmark 2000 Needlestick Safety and Prevention Act was signed into law by President Bill Clinton. Revision of the OSHA Bloodborne Pathogen Standard soon followed. Since that time, many hospital departments have embraced the standard and have almost entirely converted to safety products. The operating room, however, is one area that has struggled to comply with the OSHA standard. Most operating room workers continue to use

LEARNING OBJECTIVES

- ▲ Examine the economic burden of scalpel injuries
- ▲ Identify the incidence rate of scalpel injuries within the OR
- ▲ Review OSHA's stance on the use of safety scalpels
- ▲ Learn the reasons some surgeons choose not to use safety scalpels
- ▲ Summarize why it's beneficial for healthcare institutions to use safety scalpels

standard conventional scalpels rather than adopting the use of safety scalpels. A 2005 estimate indicated that fewer than 5% of reusable scalpels were safety scalpels. A 2010 estimate indicated that fewer than 15% of the acute-care market had converted to the use of safety devices.¹ In a survey conducted in 2011, 60% of respondents reported that safety scalpels were not being used at their facility.¹ Scalpel injuries, although less common than needlestick injuries, present a serious risk to surgical technologists, surgical assistants, nurses and surgeons in the OR and in other departments in the hospital.² The OR department is one of close collaboration where individuals work under intense pressure, continually in the presence of sharp instruments and potentially infectious blood and bodily fluids.

Scalpel injuries are typically more severe than a needlestick injury. In both cases, there is the concern about seroconversion to HIV, hepatitis B or hepatitis C, but with scalpel injuries, concerns about damage to workers' connective tissue, including tendons, rises. Most scalpel injuries occur during either assembly or disassembly, transfer between personnel, use of the scalpel or disposal of the

sharps injury for every 100,000 scalpels used. Therefore, the dangers of using conventional scalpels is more than 200 times that of conventional needles.²

The 2003 EPINet analysis indicates that scalpel blades were more likely than needles to be involved in deep or otherwise severe injuries.⁵ A breakdown of scalpel and needle injuries revealed that 58% of scalpel injuries were classified as moderate (ie, surface cut, some bleeding) and 11% as severe (ie, deep cut, profuse bleeding), compared with 39% and 2%, respectively, for suture needles. Wound severity also correlates directly with a higher risk of mutual infectious fluid transmission between the healthcare worker and the patient because deep wounds produce a larger quantity of blood and exposed tissues than shallow ones.

In most cases, surgeons and surgical residents were the original users of devices causing their injuries (81.9% and 67.3% of injuries, respectively). Conversely, nurses and surgical technologists were most often injured by devices originally used by others (77.2% and 85.1% of injuries, respectively). Most injuries to surgeons (71%) and surgical residents (66%) occurred during the use of the device.

By contrast, injuries to nurses (75.3%) and surgical technologists (73.4%) occurred when passing or dissembling devices, either during or after their disposal. Regardless the origin of the injury, scalpels are a major threat to healthcare workers.⁶

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ECONOMIC BURDEN OF SCALPEL INJURIES

scalpel.³ The largest proportion of scalpel injuries occurred “between steps of a multi-step procedure.” Most often this occurs during the passing of the scalpel between steps. The hectic pace in the operating room puts everyone at risk for needlestick injuries and scalpel injuries due to the prolonged exposure to open surgical sites and the frequent handling of sharp instruments.⁴

Scalpel injuries represent an estimated 7% to 8% of all sharps injuries. They are different and more dramatic, however, than needlestick injuries, and can cause lifechanging and life-threatening injuries. The rate of incidence of sharps injuries for scalpels is much higher than for needlesticks. Eisenstein and Smith reported that 3.2 syringe and needle injuries occurred for every 100,000 devices used. However, there were 662 incidences of

In one study, Hatcher describes that a single sharps injury without infection costs healthcare facilities anywhere from \$2,234 to \$3,832.^{7,8} In the case of a transferred blood-borne disease after a sharps injury, the overall long-term financial cost is calculated to be as high as \$1.1 million.⁹

In another study, it was estimated that the cost of non-infecting sharps exposure to a staff member runs between \$500 (low risk) to \$3000 (high risk)¹⁰ to pay for reporting, medical testing, precautionary antiviral drug treatment and lost work hours. In yet another study, the direct cost of managing a sharps injury (estimated in 2003) had increased to \$4,800 per injury.¹¹ The average direct costs, including laboratory costs for tests of both patients and exposed employees, labor costs associated with testing and counseling and the costs of post-exposure prophylaxis, were estimated to be

\$3,042 (ranging from \$1,663 to \$4,838).^{11,12}

If the injury requires microsurgery, for example a tendon injury, it might cost as much as \$100,000 plus as long as three months rehabilitation, along with the loss of salary. Costs that are harder to quantify include the social, psychological and emotional costs associated with fear and anxiety worry-

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ing about the possible consequences of an exposure, direct and indirect costs associated with antiviral drug toxicities, lost time from work and the societal cost associated with an HIV or HCV seroconversion. The seroconversion following a sharps injury could include the possible loss of a worker's services in patient care, the economic burden of medical care, the cost of any associated litigation and even family death benefits.

Management of occupational exposures to blood and body fluids is expensive, even if the patient is not infected. To avoid these costs, healthcare facilities should identify cost-effective interventions that can prevent or reduce exposures to avoid the physical, emotional and fiscal toll of exposure management. The objective should be cost avoidance rather than measuring the cost of the injury. The cost of investing in safety products is much less than the potential of spending tens of thousands of dollars or more on injuries. By complying with the bloodborne pathogen standard requirement to adopt safer surgical technologies and promote policies and practices, hospitals would substantially reduce blood exposures its OR teams and patients.

ARE SAFETY SCALPELS OSHA MANDATED?

Does OSHA require that healthcare facilities use reengineered safety scalpels to be in compliance with the bloodborne pathogens regulations, or can they simply evaluate safety scalpels? According to an OSHA Interpretation Letter,¹³ the revised OSHA bloodborne pathogen standard requires employers to evaluate safer medical devices to eliminate or minimize employee exposure to blood or other potentially infectious materials (OPIM). Employers must solicit input from non-managerial employees in the selection process; it cannot just be a purchasing department decision. After having frontline workers participate in the identification and evaluation of the safety products, including safety scalpels, they must participate in the implementation and training in their use wherever use is feasible.

Some healthcare institutions, under certain circumstances, may choose not to employ safety scalpels. This is allowed under the OSHA blood-borne pathogen standard because OSHA recognizes that no single medical device is appropriate for use in all circumstances and it is important to safeguard both patients and employees during medical and surgical procedures. If the use of a particular engineering control – in this case a safety scalpel – compromises patient safety, its use would not be considered feasible. The employer, therefore, must determine what engineering and work practice controls effectively minimize hazards without unduly interfering with the safe conduct of medical procedures. The standard also recognizes that market availability is another limiting factor in implementing the use of engineering controls and must be considered in both the choice of an engineering control and the enforcement of their use. However, the fact that a safety-engineered device may be inappropriate for a subset of procedures should not categorically exclude it from use in all procedures. Where exposures have been documented and where engineering controls are both commercially available and feasible, they should and must be used.¹⁴

WHY DON'T SURGEONS USE SAFETY SCALPELS?

There are many different types of safety scalpels. Some safety scalpels require the sliding of the shield to go toward the scalpel blade, while others require that the blade be slid back toward the hand. Many users report that these activation features are not intuitive and require the clinician to reposition the scalpel in his/her hand, creating a situation where slipping and injury may occur. An ideal

safety scalpel feature should be intuitive and not require the repositioning of the scalpel within the surgeon's hand.¹⁵ In addition, the surgeon should be able to easily activate the safety feature without looking at the scalpel. The rapid and safe activation of the safety feature during passing in the neutral zone would make many of the injuries during surgical steps most likely preventable.

There are a number of entrenched objections to the use of safety scalpels. Some clinicians argue that safety scalpels feel too light (even though light electrocautery pens are commonly used), don't fit in their hands well and feel clumsy to use. Others note that retractable shields and other safety mechanisms often obstruct the view of the blade during use and make the safety scalpel unsuitable for deeper incisions.¹⁶ Other surgeons have indicated that some safety

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scalpel blades cut poorly or wear out quickly. The first-generation safety scalpels were of poorer designs and resulted in many objections, whereas some of the newer ones incorporate some of the features that make them more desirable – or less objectionable – to surgeons.

Another frequent objection is the fact that safety scalpels are active devices, meaning that a clinician has to consciously activate the products' safety features. Unlike some passive blood collection devices, whose spring-loaded mechanisms simply require needle insertion to automatically activate the retracting feature, safety scalpels require the proactive retracting or shielding of the blade between uses. This adds steps to a surgical procedure, and some surgeons even fear injuries may accidentally occur while these steps are being taken. Some surgeons have complained that some safety scalpels require both hands to activate the safety

feature, which places the hands in jeopardy of being cut by the scalpel during the activation process.¹⁷ Despite these objections, a small but definite minority of surgeons seems to have no problem using the more user-friendly versions of safety scalpels.

REAL COSTS OF USING SAFETY SCALPELS AND CONVENTIONAL SCALPELS

One of the most common objections concerning why an institution or surgeon does not use a safety scalpel is the cost of the safety scalpel. OSHA answers this question in an interpretation letter dated November 21, 2002, stating that “selecting a safer device based solely on the lowest cost is not appropriate. Selection must be based on employee feedback and device effectiveness. OSHA compliance officers have issued citations to employers that have facilities that were not using effective engineering controls because of the product availability limits of their purchasing contracts.”¹⁸ If during an OSHA inspection it is determined that an employer did not evaluate and select appropriate and effective devices, the employer may be cited.

Since many health institutions are using costs to determine whether they use safety scalpels, it may be instructive to take an in-depth look at the costs of scalpel injuries:

- Costs of baseline and follow-up laboratory testing of healthcare worker and testing of the source patient
- Cost of diagnostic testing
- Cost of post-exposure prophylaxis and other treatment that might need to be provided
- Cost of treatment (stitches, microsurgery, etc)
- Cost of lost time in a procedure
- Cost of reprocessing scalpel handles
- Cost of replacement staff
- Workers' compensation claims
- Time spent investigating and reporting
- Increase in a facility's insurance premium
- Increase in liability reserves
- Attorney's fees
- Cost of a settlement
- Cost of unreported injuries (51%-90%)

In certain circumstances, other direct costs may need to be considered. For example, if occupational exposures are managed through a contract with another provider, there may be a fee for each patient visit.

To come up with a true economic cost for the non-use of safety scalpels, we used data cited in the previous portion of this paper in the following calculations:

HEALTH ECONOMICS DATA FOR SCALPEL INJURIES

Available Data	Assumption/Calculation	Source/Methodology
The average hospital cost for a sharps injury reported in 2007	\$3,042	O'Malley et al, Costs of Management of Occupational Exposures to Blood and Body Fluids, Infection Control and Hospital Epidemiology, July 2007, vol. 28, no. 7 Massachusetts Sharps Injury Surveillance System (2010). Sharps Injuries Among Hospital Workers in Massachusetts.
Number of sharps injuries per year in the US	385,000	Decades-old number that has not been adjusted for the number of healthcare workers, number of procedures, number of patients, etc. In addition, this number has not adjusted for the non-reporting of sharps injuries.
Percentage of sharps injuries that are left unreported in the United States each year	51% (51%-90%)	Makary, MA; Al-Attar, A; Holzmueller, CG; Sexton, JB; Syin, D; Gilson, MM; Pronovost, PJ. (2007). Needlestick injuries among surgeons in training. <i>N Engl J of Med</i> , 356(26), 2693-2699. Jagger, J; Berguer, R; Phillips, EK; Parker, G; Gooma, AE. (2011). Increase in sharps injuries in surgical settings versus nonsurgical settings after passage of national needlestick legislation. <i>AORN</i> , 93(3), 322-330. A range of 51-90% of non-reporting is given. This article references the most conservative number.
Percent of sharps injuries due to scalpels	7% (7.0% - 17%) In addition, there is a percentage of scalpel injuries that are left unreported.	Jagger, J; Berguer, R; Phillips, EK; Parker, G; Gooma, AE. (2011). Increase in sharps injuries in surgical settings versus nonsurgical settings after passage of national needlestick legislation. <i>AORN</i> , 93(3), 322-330. Perry, J; Parker, G; Jagger, J. (2003). Scalpel blades: reducing injury risk. <i>Advances in Exposure Prevention</i> , 6(4), 37-48. A range of 7 to 17.1% injuries due to scalpels is given. The authors have used the 17% figure for scalpel injuries in the OR and 7% figure for injuries across all healthcare settings.
Total number of injuries due to scalpels per year in the US	Surgical 43,633 Non-Surgical 8,982 <hr/> 52,615 scalpel injuries	Assuming that 2/3 of scalpels are used in surgery and 1/3 are used in non-surgery settings $2/3 * 385,000 * 17\% = 43,633$ surgical injuries $1/3 * 385,000 * 7\% = 8,982$ non-surgical injuries
Total economic burden per year on US hospitals due to scalpel injuries	\$160,054,830	Average cost of sharps injuries multiplied by total number of injuries due to scalpels $\$3,042 * 52,615$ injuries = \$160,054,830
Total estimated scalpel blades used per year (This includes disposable scalpels plus blades used on reusable scalpels.)	75,000,000	ISIPS calculations and data from vendors
Risk premium* per scalpel blade across all blades used per year in the US	\$2.13	Total economic burden per year on US hospitals due to scalpel injuries / total estimated number of scalpels used. (This excludes medical costs and unreported injury costs.) This total economic burden per year due to scalpel injuries/total estimated scalpel blades per year is the calculated risk premium per scalpel blade. $\$160,054,830 / 75,000,000$ blades = \$2.13 risk premium per blade

*Risk premium per scalpel blade is the added cost of the use of a conventional scalpel that must be considered in addition to the purchase price of the blade.

The cost of using a conventional scalpel breaks down to this:

Cost	Explanation
\$0.25	Average cost of conventional scalpel blades
\$2.13	Risk premium per conventional scalpel blades as described above
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\$2.38	Total estimated cost for using conventional scalpel blades

SUMMARY

The risk premium per blade is the real cost of using conventional scalpels that must be added to the purchase price of the blade. These costs warrant the following observations concerning the costs of using conventional scalpels.

- Operating room scalpel injuries indirectly increase the cost of purchased blades by at least \$2 per blade.
- Health economics argues that safety products that have the potential to reduce injuries garner a premium over the cost of conventional blades. One may assess a device's ability to reduce the risk premium by considering how a device might reduce risk in each stage of use (before use – how blade attachment is eliminated; during use – when cutting tissue and other materials; when passing – the likelihood of the blade being unexposed between steps; and after use – the likelihood of finishing the procedure with the blade unexposed).
- The purchasing cost of a conventional scalpel blade should NOT be considered the actual cost of the blade.
- Risk managers and purchasing agents should re-examine how they assess the costs of using safety scalpels.

When evaluating a potential safety-engineered device, it is important to consider the percentage of risk premium (added cost) that it will eliminate. The use of an appropriate safety scalpel that reduces blade exposures (and therefore risk of injury) can bring the cost of using safety scalpels below the cost of using conventional scalpel blades.

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