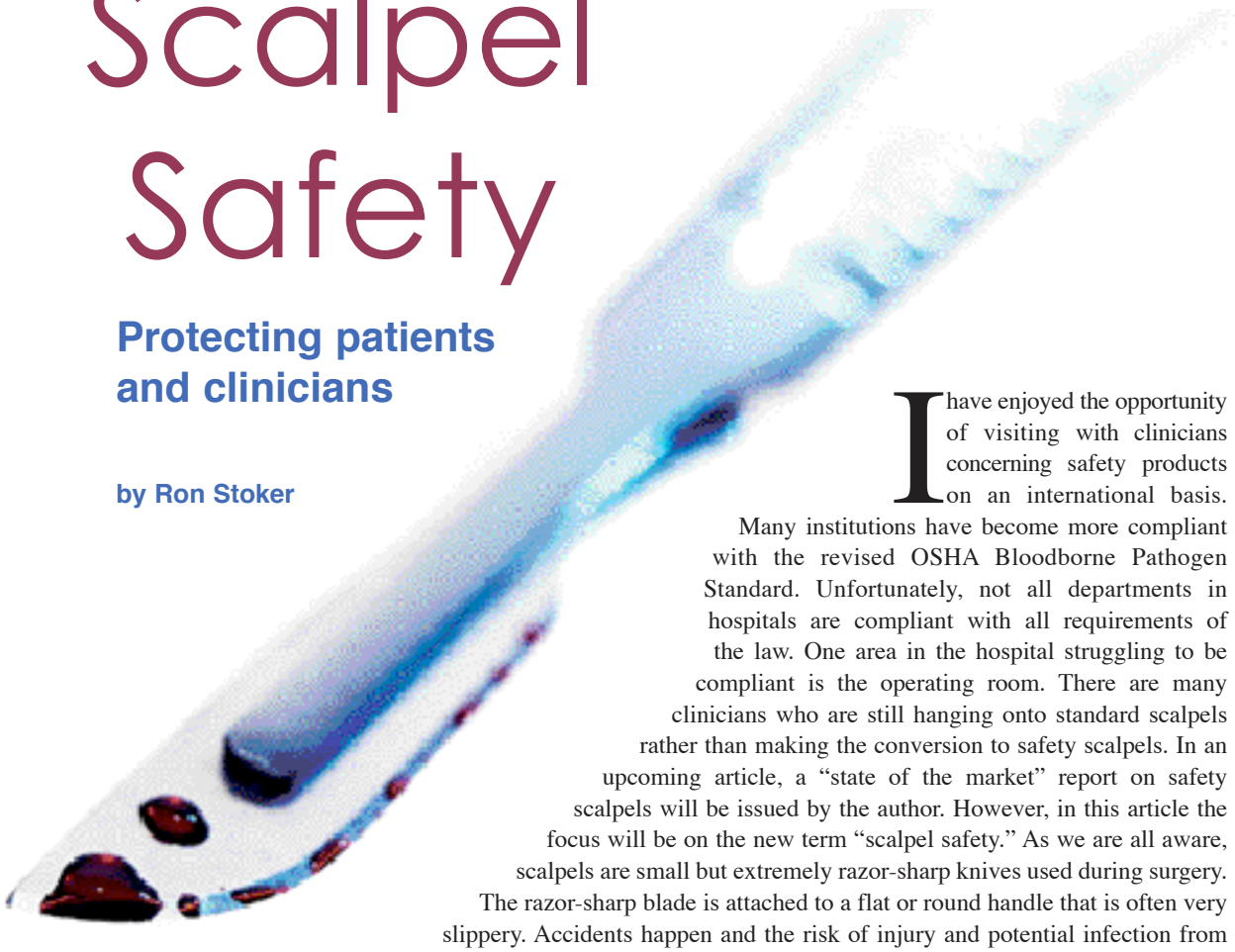
Scalpel Safety

Protecting patients and clinicians

by Ron Stoker



I have enjoyed the opportunity of visiting with clinicians concerning safety products on an international basis. Many institutions have become more compliant with the revised OSHA Bloodborne Pathogen Standard. Unfortunately, not all departments in hospitals are compliant with all requirements of the law. One area in the hospital struggling to be compliant is the operating room. There are many clinicians who are still hanging onto standard scalpels rather than making the conversion to safety scalpels. In an upcoming article, a "state of the market" report on safety scalpels will be issued by the author. However, in this article the focus will be on the new term "scalpel safety." As we are all aware, scalpels are small but extremely razor-sharp knives used during surgery. The razor-sharp blade is attached to a flat or round handle that is often very slippery. Accidents happen and the risk of injury and potential infection from bloodborne pathogens is very high.

Scalpel blade injuries are among the most frequent sharps injuries, second only to the ubiquitous needlestick. Scalpel injuries make up 7 percent to 8 percent of all sharps injuries.[1] One of the challenges of scalpel blade injuries is their severity. Typically these scalpel blade injuries are deeper and more dramatic than needlestick injuries. It was estimated in 2005 that less than 5 percent of the acute care market for reusable scalpels had converted to the use of safety devices. For disposable scalpels in acute care the conversion was about 59 percent.

Why Don't More Surgeons Use Safety Scalpels?

According to the literature there are a variety of reasons why many surgeons are are reluctant[2] to adopt the use of safety scalpels. Some surgeons have indicated that they saw a patient safety issue because the safety scalpels were not rigid enough in their hand during deep tissue incisions. Another surgeon indicated that he found the sheet covering the blade awkward to use. He felt that it did not retract or slide back over the blade easily. Other reasons include: concerns for patient safety, felt too clumsy in their hand, obstructs vision of incision, etc.

One additional reason could be the current generation of safety scalpels are "active" safety devices, meaning the safety feature of the product has to be activated by the clinician. This is different than the passive blood collection devices that are on the market. These passive

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devices simply require the insertion of the needle into the patient to activate the safety feature. With a safety scalpel, the safety feature has to be activated by retracting the blade or by shielding it following use.

In one study,[3] sponsored by the Centers of Disease Control and Prevention (CDC), the authors discovered the safety features of "active" safety devices (where the safety mechanism needs to be activated by the user, in contrast to "passive" safety devices where the safety mechanism is activated automatically) were not always activated. In fact, the activation rates in their study ranged from a low of 17 percent to 90 percent. This was quite a range—the activation rates recorded in this study were 17 percent, 27 percent, 67 percent and 90 percent.

In yet another study,[4] it was reported that 4.1 percent of the scalpel injuries inflected during the study were due to injuries suffered from safety scalpels. An additional 4.1 percent were injuries suffered from reusable scalpels. At first the authors thought that there were an equal number of injuries from safety scalpels as from reusable scalpels. However, this figure was misleading because there are not equal amounts of safety scalpels used as compared to reusable scalpels. Using the assumption that only 20 percent of scalpel usage has been converted to safety scalpels, this study indicates that there were **actually four times more injuries with safety scalpels than reusable scalpels**.

How does OSHA handle these surgeon complaints? OSHA requires that the facility document an exemption stating that

the surgeons are not able to use the safety product for patient safety reasons. There has to be a specific reason why the physician is unwilling to use a safety product. OSHA requires the medical facility adopt safety work practices to protect all employees. In an interpretation letter posted on the OSHA Web site, OSHA indicated that "in some surgical procedures, the 'feel' of a device in the hands of the surgeon may be crucial to properly execute a surgical technique. OSHA recognizes there might be unique circumstances where the safety of the patient or the integrity of the procedure might be best served with the use of a device that is not a safety device … In those circumstances, it is important that good work practice controls, such as the prevention of hand to hand instrument passing in the operating room be implemented to provide protection to employees who are at risk of getting injured by an unprotected device."[5]

Scalpel Safety vs. Safety Scalpels

In a soon-to-be published research paper,[6] the authors indicated that using a single-handed scalpel blade remover, combined with a passing tray or a neutral zone, was as safe as a safety scalpel and up to FIVE times safer. In the study by Fuentes et al., "Scalpel Safety: A comparison of safety devices to reduce scalpel blade injuries," the authors looked at scalpel injuries over a 15-year period from 1987 to 2003 in a 700-bed tertiary referral hospital. The studies show that 137 of the 141 scalpel injuries were reported.

When Do These Injuries Occur?

Three scalpel injuries happened when the scalpel blade was loaded. Almost 50 percent of injuries were sustained while the scalpel was in use and these were assumed to be not preventable. Twenty-four scalpel injuries occurred during the passing of the scalpels. Seven injuries occurred during cleaning and six occurred during handling by downstream workers.

How to Avoid These Injuries?

Fuentes et al. looked at several strategies to prevent these types of scalpel injuries. One strategy required combining the use of a single-handed scalpel blade remover with a passing tray or a neutral zone. This strategy was compared with the use of safety scalpels. Fuentes and the other researchers found that the two processes were comparable. However, despite the use of safety scalpels potentially preventing three more injuries during one critical time—when the scalpel was being loaded—when **taking into account activation rates, the combination was as safe and up to FIVE times safer than a safety scalpel**.

Fuentes' study demonstrated that both of these safety strategies have the potential to prevent a large proportion of scalpel blade injuries in the hospital setting. It indicates that the use of passive safety devices, such as passing trays and scalpel blade removers, could potentially represent more effective interventions than those that require user activation, such as current safety scalpels.

Passing Trays

As you look at the variety of neutral zone products that are now available in the marketplace, it is easy to see that passing trays are growing in popularity in the United States. Many surgical suites have designated areas as "no passing zones" or "neutral zones." Others have mandated the use of passing trays and have found them to be as effective. What is important here, is that there is no "hand-to-hand" passing of scalpels or with other sharps. One study indicated that the use of passing trays in the operating room can reduce sharps injuries by as much as 65 percent.[7] A no-hands-passing procedure, such as the use of a passing tray, is a frequently used work practice control for the prevention of sharps injuries in operating rooms across the United States. The neutral zone[8] concept is supported by OSHA, Association of periOperative Registered Nurses (AORN), American College of Surgeons (ACS)[9] and International Sharps Injury Prevention Society (ISIPS). It is believed that using a neutral zone can reduce the risk of sharps injury to healthcare workers during surgery.

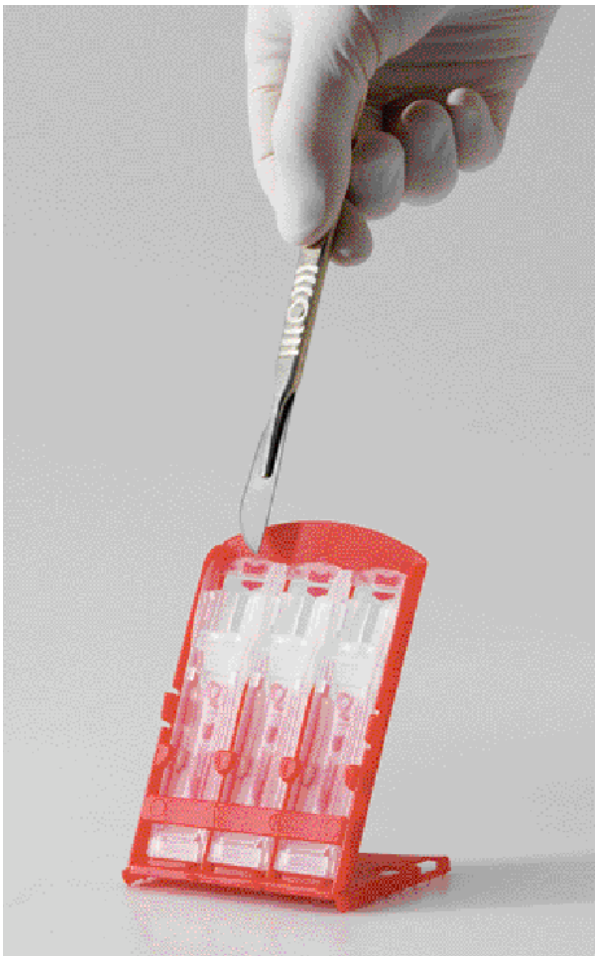
Single-use Scalpel Blade Removers

Scalpel blade removal by hand or even with forceps is antiquated and dangerous. Many scalpel injuries occur during blade removal. OSHA[10] has indicated that in situations where an employer has demonstrated that the use of a scalpel with reusable handle is required that blade removal must be accomplished through the use of a mechanical device or a one-handed technique. The use of a single-handed scalpel blade remover meets these criteria.

Fuentes further discusses this as he indicates the use of a single-handed scalpel blade remover is also an effective method of reducing a large proportion of scalpel blade injuries, which could reliably prevent injuries if incorporated into a hospital's sharp handling protocols. He recommended the use of a single-handed scalpel blade remover compliant with the appropriate standard, in combination with a passing tray to reduce scalpel blade injuries in the hospital setting.

So, has OSHA indicated a preference for one type of safety device or another? According to an interpretation letter from OSHA,[11] it indicated that "… not one medical device is appropriate for use in all circumstances and that 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 medical procedures."

There are numerous scalpel blade removers that are currently available on the market. These scalpel blade removers operate differently. The most common method is to hold the scalpel blade remover in one hand and place the scalpel into the remover. The top half of the scalpel blade remover is clicked into place and the handle is withdrawn. Many of these scalpel blade removers require the use of two hands. There are several scalpel blade removers that require only a single hand to use.



The Qlicksmart Cassette 3in1 Single-hand Sterile Scalpel Blade Remover keeps hand away from the sharp end of the scalpel.

One such product is the Qlicksmart Cassette 3in1 Single-hand Sterile Scalpel Blade Remover. The scalpel blade remover is easy to use. After opening the sterile package the sides of the cassette are squeezed together to open the cover. The cover is folded underneath the device and locks into place and becomes the base. It is then ready to use. The nodules on the base of the cassette grip onto the drape during use. The tip of the scalpel blade is rested upon the landing pad. The blade is then fully inserted into the jaws of the device. The scalpel is pushed fully into the holder until a click is heard and felt. Holding the cassette down with the other hand the empty handle is then removed. This procedure can be repeated three times. The blades are counted and the cover is closed. The cassette is then dropped into a sharps container for proper disposal.

Conclusion

It would appear that additional research is needed to compare different safety strategies; namely, safety scalpels vs. scalpel safety. Scalpel safety products include those involved in the passing of scalpels as well as in the removal of contaminated blades. Clinicians will need to know what options are available for their use and will need to make a choice that only they are qualified to make. OSHA requires that frontline workers participate in the identification, evaluation and implementation of safety products that will best meet the needs of both patients and staff. ✛

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Ron Stoker is the founder and executive director of the International Sharps Injury Prevention Society (ISIPS). Mr. Stoker has a graduate degree in Bioengineering from the University of Utah with an undergraduate degree from Brigham Young University, Utah. He has been involved in the medical device industry for more than 27 years in a variety of settings, including research and development, business development, marketing and public relations, and has six patents issued in his name. He writes frequently about sharps safety and infection control issues and speaks internationally on the issues. Mr. Stoker is co-author of the Compendium of Infection Control Technology that is available at www.medicalsafetybook.com.

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