European Review for Medical and Pharmacological Sciences 2014; 18: 3420-3424

Scalpel blade changer

A.R. MONADI SEFIDAN, B. HAJIPOUR[1]

Department of Laboratory Sciences, Tehran University of Medical Sciences,Tehran, Iran
[1]Department of Surgery, Urmia University of Medical Sciences,Urmia, Iran

Abstract. – Surgical knife has been extensively used in surgery for a number of years and is the most widely used surgical instrument in the world at present. Manual removal of the blade can be difficult, particularly when the scalpel is wet. Percutaneous injuries during changing the scalpel blade may lead to serious and potentially fatal infections from blood borne pathogens such as hepatitis B virus (HBV), hepatitis C (HCV), or human immunodeficiency virus (HIV) and others including cytomegalovirus, herpes simplex virus and parvovirus B19. In addition to the risk of illness and death after an exposure, psychological trauma and long-term disability are of great concern.

Many devices have been developed in an effort to facilitate the removal of the blade from the scalpel, and to render the removal procedure less dangerous. But there is no device to both remove and install the blade at the same time. In particular, the present invention relates to a scalpel blade changer that enables a blade to be removed from a scalpel and retained in the remover and at the same time to install the blade on to the scalpel handle.

Key Words:
Surgical knife, Infections, Scalpel blade.

Exposure to blood borne pathogens via percutaneous sharp injuries or mucosal exposure has long been considered to be an accepted occupational hazard for the surgeons and operating room (OR) personne[1]. Health care workers (HCWs) are among those at highest risk of occupational infection from biological factors, as they are exposed to human body fluids daily. Every year, hundreds of thousands of HCWs are at risk of occupationally acquired blood borne diseases as the result of needle stick and sharps injuries (NSSIs)[1,2]. NSSIs have been one of the major issues in the protection of HCWs, and vigorous preventive action has been practiced worldwide in recent decades. NSSIs may lead to serious and potentially fatal infections from blood borne pathogens such as hepatitis B virus (HBV), hepatitis C (HCV), or human immunodeficiency virus (HIV)[3] and other blood borne pathogens including cytomegalovirus, herpes simplex virus and parvovirus B19[4].

In addition to the risk of illness and death after an exposure, psychological trauma and long-term disability are of great concern. Historically, the operating room has been second only to patient rooms in the frequency of reported injuries[5]. The surgical environment is unique among health care settings in that it is blood-intensive, requires extensive manipulation of sharp instruments, often with compromised visual cues, and involves highly orchestrated interactions among members of the surgical team. These special circumstances place surgical personnel at higher risk of percutaneous injury and blood exposure than most other health care professionals[6-10]. Also, the prevalence of blood borne pathogen infection among surgical patients in some settings is disturbingly high. In a recent study in an urban hospital, as many as 38% of surgical procedures involved a patient infected with at least 1 blood borne pathogen[11].

The number of occupationally infected surgical personnel in the United States is not known, but Centers for Disease Control and Prevention reported 10 possible or documented cases of occupationally transmitted HIV among surgical personnel before 1999[12]. Although both HBV and HCV have higher exposure and transmission rates than HIV, surveillance of occupational exposures to HBV and HCV is not systematically carried out or reported in the United States.

Percutaneous injuries to surgical staff carry a reciprocal risk for patients, with potential for infection transmission from provider to patient. The operating room is the highest-risk setting for this mode of transmission because open wounds are susceptible to contamination, and injury to the hands of surgical staff resulting in bleeding is not uncommon. Since 1991 there have been 132 documented cases of health care worker-to-patient

Corresponding Author: Babak Hajipour, MD; e-mail: Hajipourb@yahoo.com

transmission of HIV, HBV, and HCV worldwide; 131 cases were transmitted during deeply invasive surgery[13] The potential for reciprocal exposures is not rare; as many as 25% of injuries in surgery occur while the operator's hands are in contact with the surgical site[10]. Reducing percutaneous injuries in surgery would also reduce patients' risk of exposure to surgeons' blood.

The close working conditions and interaction among surgical team members lead to a "shared risk" of sharps injuries. Decisions regarding the selection of surgical tools and injury-mitigating techniques by one member (often the attending surgeon) have direct bearing on injury risk to nurses, technicians, and residents[5].

Sharps injuries occur more frequently in surgical settings. That is according to a recent report[14] published in the *Journal of the American College of Surgeons (JACS)* that found that percutaneous sharps injuries from needles and other pointed and edged sharps occurred more frequently in surgical settings, as compared to nonsurgical settings between 1993 and 2006. These injuries occurred in spite of the requirement to provide safety-engineered devices as mandated by the Needlestick Safety and Prevention Act of 2000. Of the 31,324 total sharps injuries analyzed in the study, 7,186 were to surgical personnel. After the Needlestick Safety and Prevention Act passed in 2000, injury rates in nonsurgical settings dropped 31.6%, but increased 6.5% in surgical settings. The study also found that most injuries were caused by suture needles (43.4%), scalpel blades (17%), and syringes (12%), and three-quarters of injuries occurred during use or passing of devices. Surgeons and residents were most often original users of the injury-causing devices, while nurses and surgical technicians were typically injured by devices originally used by others.

The skin or mucous membranes of OR personnel may enter in contact with patient blood in as many as 50% of operations (reported range 6.4% to 50%) (5,6). Cuts or needle sticks may occur in as many as 15% of operations (reported range 1.7% to 15%) (5,6). Risk increases with longer, more invasive, higher blood loss procedures[15-19]. Surgeons and first assistants are at highest risk for injury[10]. They suffer as many as 59.1% of injuries in the operation room[10]. Scrub nurses and scrub technicians sustain the second highest frequency of injuries in the OR (19.1%), followed by anesthesiologists (6.2%) and circulating nurses (6%)[10]. The remainder of injuries are sustained by various other groups, including medical students. Although risk of injury and exposure is different for various personnel, risk in the OR is never zero[20].

Scalpel injury occurred in 12.2% of surgeons, 12.5% of surgical residents, 17.2% of nurses, 21.1% of technicians and 17.1% of all injuries. Attaching and removing blades from reusable handles caused a somewhat larger fraction of scalpel-related injuries (12.0%). A similar fraction of suture needle and scalpel blade injuries occurred after use, during or after disposal (11.3% and 14.4%, respectively)[13,14,21].

New Procedures and Devices

Several procedures: devices to prevent scalpel injuries were identified, some of which decrease the duration, frequency, or severity of exposure to the hazard, whereas others change the design of equipment to eliminate hazards at the identified source.

Cut-resistant gloves/glove liners: Made from protective materials, such as Kevlar, cotton, and thick ''orthopedic'' latex, these products generally are worn over or ''sandwiched'' between standard latex gloves.

Hands-free passing technique: This technique involves passing trays, magnetized mats, or designated ''neutral zones'' to ensure that only 1 operator touches the scalpel at any time (ie, after an incision, the scalpel is returned by the surgeon to the neutral zone and retrieved from there by the assistant rather than passed directly from surgeon to assistant).

Sharpless surgery: Nonsharp devices and techniques replace the use of conventional sharps by surgeons in ''sharpless surgery.'' For example, scalpels are replaced by electrocautery and suture needles by skin staplers, glues, and tapes. Innovative scalpels: This category of devices may include safety/protective scalpels (reusable or disposable) that include features such as retractable blades, disposable scalpels that negate the need for blade removal, and scalpels with round-tipped blades. Scalpel blade removal devices: Removal devices are designed to protect the user and downstream staff from accidental injury when removing a scalpel blade from a reusable handle[22].

Summary of the Invention

The traditional scalpel (surgical knife) has been extensively used in surgery for a number of years and would be the most widely used surgi-

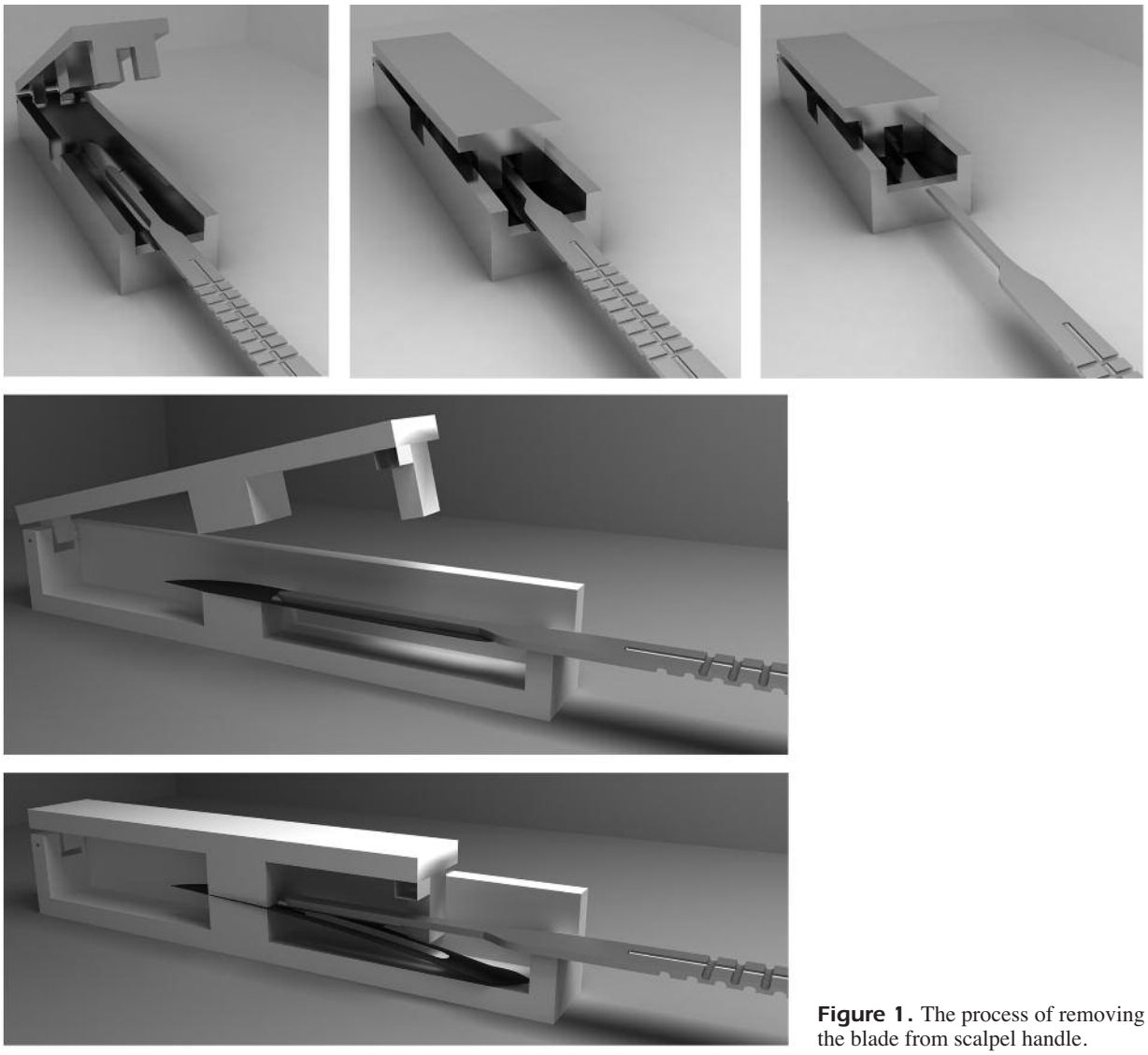

Figure 1. The process of removing the blade from scalpel handle.

cal instrument in the world at present. Manual removal of the blade can be difficult, particularly when the scalpel is wet. Many devices have been developed in an effort to facilitate the removal of the blade from the scalpel, and to render the removal procedure less dangerous. But there is no device to both remove and install the blade. The present invention relates to a scalpel blade changer. In particular, the present invention relates to a scalpel blade changer that enables a blade to be removed from a scalpel and retained in the remover and also install the blade on to the scalpel handle. A conventional surgical scalpel typically comprises a reusable, sterilizable elongated handle or shaft on to which a replaceable slotted blade is mounted. At the distal end of the handle is a tang that normally includes opposed grooves or channels to receive the blade. Generally the tang is a narrow extension of the handle. The blade has a slot extending longitudinally, which slot has a portion of sufficient width to be received over the tang, and a narrower portion at its distal end whereby the edges of the slot are closely received in the opposed grooves. The blade may have a heel that is received in a recess in the handle. The term heel is intended to refer to the proximal portion of the blade, i.e. the end portion near the user's hand. The handle is intended to be used repeatedly, but the blade is normally discarded after single use, or if the blade becomes dull or contaminated, or if a different style of blade is required. In many operations

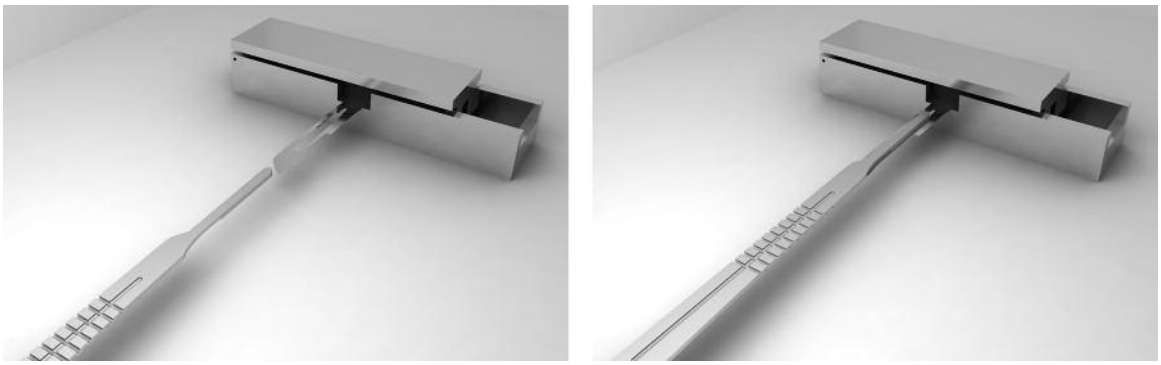

Figure 2. The process of installing the blade on scalpel handle.

several blades, are required and are typically used successively on the same handle. In order to remove the blade from the handle, the heel portion of the slotted blade must be bent out of its plane (i.e. separated or lifted off the handle), and then the blade may be moved axially along the tang thereby releasing the tang from the slot Manual removal of the blade can be hazardous. During the manipulation of the blade the operator is put at risk of being cut on the sharp blade. With the ever –increasing spread of blood transmitted diseases such as AIDS and hepatitis, any accidental injury from the blade can result in infection or contamination. So this device is designed to decrease injury both in installing and removing the blade from scalpel handle.

The device consisted of two parts that are connected to each other with a hinge. At the anterior edge of the upper plate there is an axial surface in which have a clefts. There is a protuberances in lower plate in which have its complementary on the upper plate. For using the device the scalpel blade is placed on the lower plate, and then the upper plate will locate on the lower plate, in this situation the blade is fixed between the to protuberances of the upper and lower plates that are complementary, in this position proximal part of the blade is located in the cleft of the axial surface of upper plate and pushed down, in this condition the handle will pulled out and the blade will be released safely with one motion (Figure 1). This device may be a good option for reducing the scalpel blade related injuries. The device has a part for installing the blade on to the scalpel handle (Figures 2). On the right side of the device there is a place for fixing the blade to enable the blade to be installed on the scalpel handle. This ability reduces the possible injury during installing the blade on to the scalpel handle. This is the first approved invention by national medical equipment center in this issue in Iran, and some time is needed to study the real safety of the device but during its use for evaluating efficacy and safety there was no report of injury through using this device.

Conflict of Interest

The Authors declare that there are no conflicts of interest.

References

1) Nagao Y, Baba H, Torii K, Nagao M, Hatakeyama K, Iinuma Y, Ichiyama S, Shimokata K, Ohta M. A long-term study of sharps injuries among health care workers in Japan. Am J Infect Control 2007; 35: 407-411.
2) Stein AD, Makarawo TP, Ahmad MF. A survey of doctors' and nurses' knowledge, attitudes and compliance with infection control guidelines in Birmingham teaching hospitals. J Hosp Infect 2003; 54: 68-73.
3) Koh A. Management of needlestick injuries for healthcare workers in hospitals. Masui 2010; 59: 31-35.
4) Wicker S, Cinatl J, Berger A, Doerr HW, Gottschalk R, Rabenau HF. Determination of risk of infection with blood-borne pathogens following a needlestick injury in hospital workers. Ann Occup Hyg 2008; 52: 615-622.
5) Jagger J, De Carli G, Perry J, et al. Occupational exposure to bloodborne pathogens: epidemiology and prevention. In: Wenzel R, ed. Prevention and control of nosocomial infections. 4th ed. Philadelphia, PA: Lippincott, Williams and Wilkins 2003; pp. 430-466.
6) Panlilio AL, Foy DR, Edwards JR, Bell DM, Welch BA, Parrish CM, Culver DH, Lowry PW, Jarvis WR, Perlino CA. Blood contacts during surgical procedures. JAMA 1991; 265: 1533-1537.

7) Tokars JI, Bell DM, Culver DH, Marcus R, Mendelson MH, Sloan EP, Farber BF, Fligner D, Chamberland ME, McKibben PS, Percutaneous injuries during surgical procedures. JAMA 1992; 267: 2899-2904.

8) Jagger J, Detmer DE, Blackwell B, et al. Comparative injury risk among operating room, emergency department and clinical laboratory personnel. Infect Control Hosp Epidemiol 1994; 15: 345.

9) White MC, Lynch P. Blood contact and exposures among operating room personnel: a multicenter study. Am J Infect Control 1993; 21: 243-248.

10) Jagger J, Bentley M, Tereskerz PM. A study of patterns and prevention of blood exposures in OR personnel. AORN J 1998; 67: 979-981, 983-984, 986-987.

11) Weiss ES, Makary MA, Wang T, Syin D, Pronovost PJ, Chang D, Cornwell EE. Prevalence of bloodborne pathogens in an urban, university-based general surgical practice. Ann Surg 2005; 241: 803-809.

12) Centers for Disease Control and Prevention. Surveillance of healthcare personnel with HIV/AIDS, as of December 2002. Table: Healthcare personnel with documented and possible occupationally acquired AIDS/HIV infection, by occupation, as of December 2002. Available at: http://www.cdc.gov/ncidod/dhqp/bp_hiv_hp_with.html. Accessed March 30, 2009.

13) Perry JL, Pearson RD, Jagger J. Infected healthcare workers and patient safety: a double standard. Am J Infect Control 2006; 34: 313-319.

14) Jagger J, Berguer R, Kornblatt P, Parker G, Gomaa A. Increase in sharps injuries in surgical settings versus nonsurgical settings after passage of national needlestick legislation. J Am Coll Surg 2010; 210: 496-502.

15) Gerberding JL, Littell C, Tarkington A, Brown A, Schecter WP. Risk of exposure of surgical personnel to patients' blood during surgery at San Francisco General Hospital. N Engl J Med 1990; 322: 1788-1793.

16) EJ Quebbeman, GL Telford, S Hubbard, K Wadsworth, B Hardman, H Goodman, MS Gottlieb. Risk of blood contamination and injury to operating room personnel. Ann Surg 1991; 214: 614-620.

17) Panlilio AL, Foy DR, Edwards JR, Bell DM, Welch BA, Parrish CM, Culver DH, Lowry PW, Jarvis WR, Perlino CA. Blood contacts during surgical procedures. JAMA 1991; 265: 1533-1537.

18) Popejoy SL, Fry DE. Blood contact and exposure in the operating room. Surg Gynecol Obstet 1991; 172: 480-483.

19) White MC, Lynch P. Blood contact and exposures among operating room personnel: a multicenter study. Am J Infect Control 1993; 21: 243¬248.

20) Berguer R, Heller PJ. Preventing sharps injuries in the operating room. J Am Coll Surg 2004; 199: 462-467.

21) Naghavi SH, Sanati KA. Accidental blood and body fluid exposure among doctors. Occup Med 2009; 59: 101-106.

22) Watt AM, Patkin M, Sinnott MJ, Black RJ, Maddern GJ. Scalpel safety in the operative setting: a systematic review. Surgery 2010; 147: 98-106.