

“Scalpel safety”: Modeling the effectiveness of different safety devices’ ability to reduce scalpel blade injuries

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Abstract. *Background:* The objective of this study was to analyse and compare the potential effectiveness of two safety strategies in reducing scalpel blade injuries. The two strategies examined were safety scalpel vs. a single-handed scalpel blade remover combined with a hands free passing technique (HFPT) (e.g. passing tray or neutral zone).

Methods: This was a retrospective study involving review of a 550-bed adult metropolitan tertiary referral hospital’s sharps injuries database, chart review, and hypothetical modelling of the data to determine potential preventable injuries. The modelling was done twice, firstly assuming 100% effectiveness of each safety device and secondly using previously published activation rates for “active” safety devices which were considered to be a more accurate reflection of real-life work practices.

Results: A total of 141 scalpel injuries were reported between 1987 and 2003. Clinical charts were reviewed for 137 of these injuries. Just under 50% of injuries were sustained while the scalpel was in use and these were assumed to be not preventable. Assuming 100% effectiveness for each safety device resulted in 72 injuries being prevented by safety scalpels and 69 injuries being prevented by a combination of a single-handed scalpel blade remover and an HFPT. When injury prevention was calculated using published data on activation rates for “active” safety devices, the number fell to as low as 12 for safety scalpel and to 61 for the combination of a single-handed scalpel blade remover and an HFPT.

Conclusion: Both safety strategies are potentially effective in reducing scalpel blade injuries. However the safety scalpels are active devices and as such are subject to widely variable activation rates. We recommend use of a single-handed scalpel blade remover in combination with an HFPT as this can potentially prevent 5 times as many injuries as safety scalpels.

Keywords: Scalpel safety, safety scalpels, scalpel blade remover, prevention, hands free passing technique

1. Introduction

Sharp medical devices are a common source of injury amongst health care workers. In the US, approximately 600,000 sharp related injuries occur in hospitals each year [7]. Scalpel blade injuries make up a small (7–8%) but important proportion of these injuries [8].

Injuries from scalpel blades pose a risk of infection and of structural damage to the body, generally the hand. The risk of acquiring a potentially fatal infection from deep injury with a hollow-bore needle

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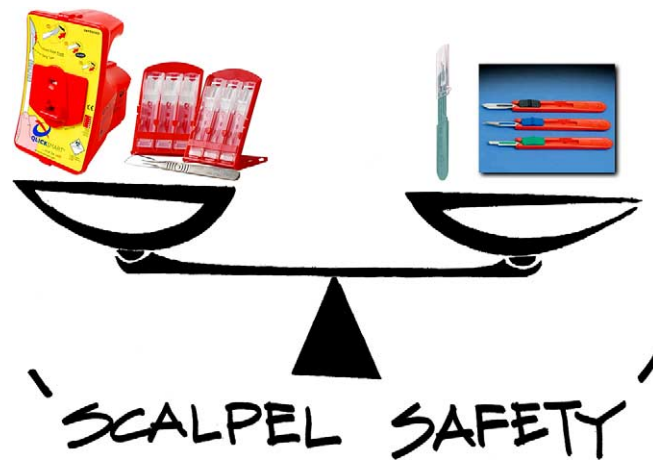


Fig. 1. Scalpel safety. Left side: single-handed scalpel blade removers: non-sterile and sterile. Right side: safety scalpels – sheath type and retracting type.

involving a patient infected with a blood-borne virus is 0.2–0.5% for HIV, 2–40% for Hepatitis B and 3–10% for Hepatitis C [3]. The risk of infection from an injury with a contaminated scalpel is not known. Repair of damage to a digital nerve, artery or tendon may involve general anaesthesia and potentially several months of rehabilitation.

Knowledge of, and compliance with, Australian/New Zealand Standard (AS/NZS 3825:1998), “Procedures and devices for the removal and disposal of scalpel blades from scalpel handles” has been previously shown to be poor [2,10]. Manufacturers have developed two broad strategies to improve safety with respect to scalpel blades. The author’s have coined the term, “Scalpel safety” (see Fig. 1) to highlight the available choices. The first strategy, the safety scalpels, provide protection for the user via one of two methods; either allowing the withdrawal of the blade into the handle after use, or alternatively in other designs, via a sheath which can be advanced over the blade after use. For the safety scalpel to be effective the safety mechanism has to be employed each time during the course of its intermittent use in a procedure. The second strategy, the scalpel blade removers, also falls into two categories. They are devices that allow the safe removal and containment of the scalpel blade from the handle at the completion of use with either a single-handed or two-handed operation. This strategy is combined with the adoption of a “hands free passing technique” (HFPT) (i.e. by using a neutral zone or a kidney dish or similar passing tray to pass the scalpel, rather than passing it hand to hand) throughout a procedure. There has been no published comparative study of the effectiveness of these two design strategies to improve scalpel blade safety.

Safety devices in general can be classified as either “active” whereby the safety action is performed by the user, or “passive” in which the safety action is performed automatically. This means that a “passive device” offers far superior protection for the user, as it is considered to be effective 100% of the time it is used. Safety scalpels are active safety devices, whereas the single handed scalpel blade removers are passive devices.

The aim of this study is to compare hypothetically the effectiveness of the safety scalpel and the single-handed scalpel blade remover combined with a hand free passing technique in reducing scalpel related sharp injuries within a hospital setting.

2. Methods

2.1. Study design

This was a retrospective study involving review of a hospital's sharps injuries database, chart review, and hypothetical modelling of the data to determine potential preventable injuries.

2.2. Setting

The study was conducted at the Princess Alexandra Hospital (PAH), a 550-bed adult metropolitan tertiary referral hospital in Brisbane, Australia.

2.3. Data collection and analysis

The hospital's Infection Management Services' database of reported sharps injury data from 1987 to 2003 was reviewed for scalpel blade injuries, occupational data regarding the staff member involved and the circumstances in which the injuries occurred. Only those incidents that had an associated clinical chart to review to confirm the details of the incident were included in the study.

2.4. Hypothetical modelling

The scalpel blade injuries identified within the database were subjected to modelling by hypothetically applying to each incident the use of the two scalpel safety design strategies currently available (the safety scalpel and the scalpel blade remover) to determine whether the injury would have occurred had either of the strategies been in use. The hypothetical modelling was performed in two ways. Firstly, it was performed on the assumption of 100% effectiveness for the devices whilst taking into consideration that the devices will not prevent injuries while the scalpel is in use. The safety scalpel will prevent injuries associated with loading and unloading of the scalpel, during passing, disposal, cleaning and to downstream worker. The single-handed scalpel blade remover, combined with an HFPT, will prevent injuries while unloading but not loading the scalpel as well as during passing, disposal cleaning and to downstream workers. Secondly, the modelling was performed utilising the results of a literature review on the actual reported effectiveness of the two design strategies. The literature review was performed using Medline (1966–2004). Searches were performed using keywords of sharps, needlestick, scalpel, safety and injury. Subject headings of equipment design, occupational health, protective devices, needlestick injury and prevention and control were used. Occupational health and safety resource materials at our institution were also utilized, including occupational health and safety manuals, and copies of relevant Australian Standards and local reports.

3. Results

There were 141 scalpel blade injuries reported during the study period. Of these, 137 incidents had associated clinical charts to review. The charts associated with the other 4 incidents had been lost in medical records.

The incidences of scalpel blade injuries amongst occupational groups are shown in Fig. 2.

The circumstances surrounding the injury are shown in Fig. 3. The greatest proportion of injuries occurred while the scalpel was being used.

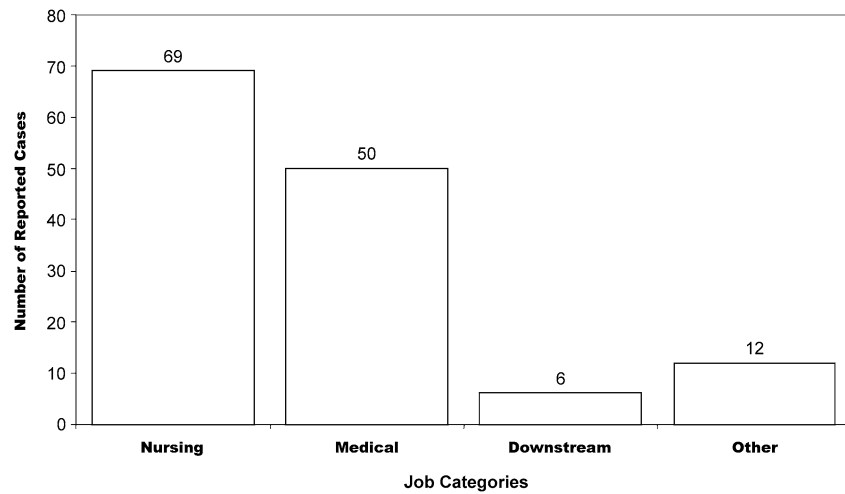


Fig. 2. Job categories and reported scalpel blade injuries.

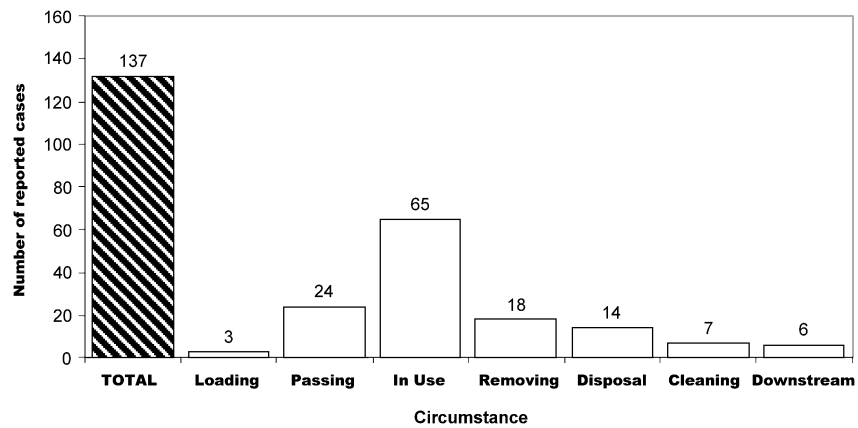


Fig. 3. Circumstances associated with scalpel blade injuries.

The literature review identified articles that referred to rates of effectiveness for the design strategies. Active safety devices, such as the safety scalpel, have widely variable and unpredictable activation rates, in one large series varying between 17% and 90% [1]. The single-handed scalpel blade remover, being a passive device is assumed to be effective 100% of the time it is used; depending of course on the device actually being used, though this can be formalized by incorporating its use into relevant sharps handling policies and procedures. The use of an HFPT (such as a neutral zone or passing tray), which both designs are reliant upon in practice, has been reported to reduce sharps injuries by 65% [9].

Theoretically preventable injuries were determined firstly assuming 100% activation rate and effectiveness of the safety devices. This showed that safety scalpels could have prevented a maximum of 72 injuries out of 137, whereas the combination of a scalpel blade remover and an HFPT could have prevented a maximum of 69 injuries (Table 1). Potentially preventable injuries were then also calculated utilising the range of rates of activation (17, 27, 67 and 90%) for the safety scalpel. This resulted in 12, 19, 48 or 65 prevented injuries respectively (Table 2). Using a 65% anticipated reduction with the use of the HFPT meant 16 injuries could be prevented. The single handed scalpel blade remover,

Table 1
Theoretical *maximum* potential injury prevention by category of safety device

	Safety scalpel (%)	Maximum # injuries prevented	HFPT (%)	Maximum # injuries prevented	Scalpel blade remover (%)	Maximum # injuries prevented
Loading scalpel	100	3	Nil	0	Nil	0
In-use	Nil	0	Nil	0	Nil	0
Passing	100	24	100	24	Nil	0
Removing	100	18	Nil	0	100	18
Disposal	100	14	Nil	0	100	14
Cleaning	100	7	Nil	0	100	7
Downstream	100	6	Nil	0	100	6
Total		72/137 (52.5%)		24/137 (17.5%)		45/137 (32.8%)

HFPT = hands free passing technique.

Table 2
Probable injury prevention using a safety scalpel – an 'active device'

Safety scalpel →	17% activated	27% activated	67% activated	90% activated
Loading	0.5	0.8	2	2.7
In-use	0	0	0	0
Passing	4	6.5	16.1	21.6
Removing	3.1	4.9	12.1	16.2
Disposal	2.4	3.8	9.4	12.6
Cleaning	1.2	1.9	4.7	6.3
Downstream	1	1.6	4	5.4
Total # injuries prevented	12/137 (8.9%)	19/137 (14.2%)	48/137 (35.3%)	65/137 (47.3%)

being a passive device, was considered to be 100% effective in this calculation (Table 3). The combination of a single handed scalpel blade remover with an HFPT could have theoretically prevented at least 61 injuries. This is potentially up to five times as many (61 vs. 12) injuries as using a safety scalpel.

4. Discussion

This study found that a majority of the preventable scalpel blade injuries reported at the Princess Alexandra Hospital were potentially avoidable if either of the scalpel blade safety design strategies had been utilised.

The two safety design strategies, the safety scalpel and the single-handed scalpel blade remover combined with an HFPT, could have theoretically prevented a similar number of injuries to health care professionals within the hospital setting if both were utilised correctly 100% of the time. Due to the potential inconsistency in activating a safety scalpel in practice, the number of preventable injuries could be quite variable in comparison to the more predictable reductions potentially achievable with a single-handed scalpel blade remover.

Table 3
Probable injury prevention using an HFPT and scalpel blade remover

	HFPT (%)	# Injuries prevented	Blade remover (%)	# Injuries prevented	Combined
Loading	Nil	0	Nil	0	0
In-use	Nil	0	Nil	0	0
Passing	65	16	Nil	0	16
Removing	Nil	0	100	18	18
Disposal	Nil	0	100	14	14
Cleaning	Nil	0	100	7	7
Downstream	Nil	0	100	6	6
Total # injuries prevented		16/137 (11.7%)		45/137 (32.8%)	61/137 (44.5%)

HFPT = hands free passing technique.

Scalpel blade injuries not only cause physical injury and psychological distress to the health care worker, but also represent a cost-burden for the health care industry. The costs of medical follow up alone for a high-risk exposure is estimated to be almost US \$30,000 per sharps injury [4]. Since the introduction of new legislation in the United States, health organisations must now be aware of the different preventative strategies, their efficacy and their cost, as the use of safety devices can decrease sharps injuries by 51% [5,6].

Safety scalpels have an advantage in being the only device that prevents injuries during the loading phase (2.2% of injuries). Though structural damage may occur, these injuries do not carry a risk of infection for the staff member, as the scalpel blade is sterile at this stage. As this study determined, when utilised consistently, the safety scalpel is theoretically as effective as a single handed scalpel blade remover combined with an HFPT in preventing scalpel blade injuries. However, the main disadvantage of safety scalpels is that they are active devices, which require the user to activate/deactivate the safety mechanism multiple times. Whilst there is no published data on the rate of activation of the safety scalpel, the hypothetical modelling in this study revealed that varying rates of activation can lead to a wide range of effectiveness in reducing injuries. The limitations of other active safety devices are well documented. EPINET (Exposure Prevention Information Network) 2001 data showed that the safety mechanism was fully activated in only 12.1% of cases of sharps injuries reported, was partially activated in a further 16.8% of cases, and that 26.3% of injuries occurred during activation of the safety feature [8]. Alvarado-Ramy et al. found activation rates for three "active" safety devices ranged from 17% to 90%, depending on the ease of activation, personal preference of the user, and amount of training [1]. These activation rates relate to single-activation devices only, whereas safety scalpels require activation multiple times, which could result in lower and less consistent rates of activation.

The single-handed scalpel blade remover is also potentially able to prevent a large number of injuries. It has the advantages of being a passive device, simple to use and offers a single point of access; thereby being easily incorporated into the operating theatre sharps disposal/instrument-handling protocols.

4.1. Limitations of the study

This study has several limitations. With respect to the database and chart review, four charts were not found, therefore were not included in the analysis. This was unlikely to have influenced the outcomes. There was no published data on the specific activation rates of safety scalpels, so the activation rates

of other active safety devices were used for the hypothetical modelling. These rates may either under-represent or over-represent the actual activation rates of the safety scalpel as unlike the devices in other studies which only had to be activated once; a safety scalpel must be activated and released on multiple occasions during a surgical procedure.

5. Conclusion

In conclusion, this study has demonstrated that both scalpel safety strategies have the potential to prevent a large proportion of scalpel blade injuries in the hospital setting. The ongoing development of engineered active safety devices, such as safety scalpels, is important. However, these devices are currently disadvantaged by a variable rate of activation, and therefore an unreliable and uncertain rate of protection. Similarly, the 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. We recommend the use of a single-handed scalpel blade remover compliant with the appropriate standard, in combination with an HFPT (such as a neutral zone or passing tray) to reduce scalpel blade injuries in the hospital setting.

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