



Australian Safety and Efficacy Register of New Interventional Procedures — Surgical  
Royal Australasian College of Surgeons



## Scalpel safety in the operative setting

ASERNIP-S Report no. 59

### Objective

To identify and assess the efficacy and effectiveness of devices and procedures designed to lower the incidence of scalpel injuries in the operative setting, through a systematic review of the literature.

### Methods

**Search strategy:** Studies were identified by searching MEDLINE, EMBASE, CINAHL, The Cochrane Library, Current Contents, PubMed and AMI from inception to December 2006. The Clinical Trials Database (US), NHS CRD Database (UK), The National Research Register (UK) and the Meta Register of Controlled Trials were also searched in January 2007.

**Study selection:** Included for review were randomised controlled trials (clinic and laboratory based), randomised comparative studies, non-randomised comparative studies, observational studies, surveys and modelled data. Outcomes examined included rates of glove perforation, injuries and user satisfaction.

**Data collection and analysis:** Data from the included studies were extracted by an ASERNIP-S researcher using standardised extraction tables developed a priori and checked by a second researcher. Studies that were sufficiently homogeneous were examined by meta-analysis. Heterogeneous studies that did not meet the criteria for meta-analysis were reported qualitatively.

### Results

A total of 19 studies were included in this review: 13 examining cut-resistant gloves and glove liners; three assessing the hands-free passing technique; one reporting on protective footwear; one investigating the feasibility of sharpless surgery and one evaluating a single-handed scalpel blade remover. Seven of these studies were randomised trials (NHMRC Level II), three were non-randomised comparative studies (Level III-2), two were comparative studies with historical controls (Level III-3), one was a Level IV study and seven were experimental studies to which the NHMRC Hierarchy of Evidence could not be applied.

In both clinical and experimental (laboratory) conditions, the use of a cut-resistant glove or glove liner reduced the number of inner latex glove perforations in comparison to double latex. While statistical pooling of the data pertaining to cloth gloves confirmed a significant protective effect resulting from the use of cloth gloves, there were not enough studies reporting outcomes on each glove material to be able to

determine which material was the most effective in lowering the rate of inner latex glove perforation overall. Furthermore, given the aggregate outcomes reported, it was not possible to determine precisely how many injuries were directly attributable to scalpels, and how many were as a result of other sharp instruments.

Cut-resistant gloves and glove liners were found to lessen the wearer's dexterity and tactile sensation and resulted in minor impairment when tested against a number of comparators.

Based on the evidence reported in three studies, benefit derived from the use of the hands-free passing technique appeared equivocal, but its implementation may provide greater potential benefits in operations involving more than 100mL of blood loss. While the procedure did not appear to impact adversely on injury rates, it must also be acknowledged that there will remain the need for occasional hand-to-hand passing between members of the operative team, particularly in complex or emergent situations.

One study indicated that sharpless surgery provided a feasible alternative to the use of traditional sharps in surgery.

Theoretical modelling data presented in one study indicated that the use of a passive single-handed scalpel blade remover in conjunction with a passing tray had the potential to prevent approximately as many injuries as an active safety scalpel with a 100% activation rate, and up to five times as many injuries as a safety scalpel with a lower activation rate.

Evidence from one study indicated that materials such as non-pliable leather, rubber with leather lining and new rubber provided superior foot protection from dropped scalpel blades under experimental conditions.

### Classification and recommendations

On the basis of the evidence presented in this systematic review, the ASERNIP-S Review Group agreed on the following classifications and recommendations concerning scalpel safety in the operative setting:

#### Classifications

##### Evidence rating

The evidence base in this review is rated as poor, limited by the quantity and quality of the available evidence. Specific limitations of the evidence included the diversity of interventions and outcomes considered, the lack of a standard comparator and the differences in clinical settings

and experimental environments in which the interventions were employed.

### Effectiveness

Effectiveness outcomes were considered for those interventions that were undertaken in clinical settings:

#### Cut-resistant gloves & glove liners

Based on the published literature, the effectiveness of cut-resistant gloves and glove liners in the clinical setting cannot be determined.

#### Hands-free passing technique

Based on the published literature, the effectiveness of the hands-free passing technique in the clinical setting cannot be determined.

#### Sharpless surgery

Based on the published literature, the effectiveness of sharpless surgery in the clinical setting cannot be determined.

#### Pass tray & single-handed scalpel blade remover

Based on the published literature, the effectiveness of a pass tray used in conjunction with a single-handed scalpel blade remover in the clinical setting cannot be determined.

### Efficacy

Efficacy outcomes were considered for those interventions that were undertaken in laboratory experimental settings:

#### Cut-resistant gloves & glove liners

Based on the published literature, the efficacy of cut-resistant gloves and glove liners in experimental settings cannot be determined.

#### Protective footwear

Based on the published literature, the efficacy of protective footwear in experimental settings cannot be determined.

### Clinical and research recommendations

There are few studies published that systematically assess the effectiveness of safety devices in reducing percutaneous injuries, despite the proliferation of such devices. As noted in this review, available reports show substantial variation in study methodology and measurement of outcomes. Standardisation of these features needs to be considered by trial designers in order to compile a clinically relevant and statistically valid body of evidence by which to assess new safety procedures and devices; however, the undertaking of randomised controlled trials (particularly of cut-resistant gloves and glove liners) is both feasible and desirable.

Additionally, the undertaking of a suitably detailed audit of scalpel injuries would assist in contextualising the incidence, prevalence and epidemiology of these injuries within the Australian healthcare setting, allowing targeted interventions



to specific areas of the operative process where large numbers of injuries are occurring.

However, it should be emphasised that a large part of preventing sharps injuries involves creating a culture of safety within an institution and its operative personnel. The concept of 'scalpel safety' must be reinforced through practice and education in order to achieve lowered rates of scalpel injury in the operative setting in the long-term.

### Review Group membership

Protocol Surgeon: Mr Michael Parkin; Advisory Surgeons: Dr Michael Sinnott, Mr Robert Black; ASERNIP-S Surgical Director: Professor Guy Maddern; ASERNIP-S Researcher: Ms Amber Watt

For the full review and executive summary, please visit the publications page of our website at <http://www.surgeons.org/asernip-s/publications.htm>.

# ASERNIP/S



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and Efficacy  
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## Systematic Review

# Scalpel Safety in the Operative Setting

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**The Royal Australasian College of Surgeons**

Makary *et al.* (2006) undertook a hospital-based feasibility study to preoperatively identify candidate surgeries in which sharpless techniques could be utilised and to evaluate the technical success of these procedures. The primary outcome variable was the ability to complete a candidate operation without the use of a sharp device, defined as a needle, scalpel or any other sharp instrument that could incise the skin. The methods employed in the study were well described by the authors, however the identification of candidate procedures was on a subjective basis.

A retrospective review of hospital injuries coupled with hypothetical modelling was performed by Fuentes *et al.* (2006) in order to establish the potential efficacy of a pass tray and single-handed scalpel blade remover in comparison to a safety scalpel. The modelling was undertaken twice, once assuming 100% effectiveness of each safety device and secondly using previously published activation rates for active safety devices. The authors acknowledged the potential limitations of their study, including the need for extrapolation of activation rates from other devices to safety scalpels, but described their modelling conditions and resultant conclusions thoroughly.

One laboratory study (Barr & Siegel, 2004) examined the effectiveness of different shoe materials in preventing penetrating foot injuries from dropped scalpels. The experimental apparatus was well described, and each experiment replicated three times, with results compared to those obtained from a standard control.

### **Procedures/devices for which no studies were identified**

The following devices and procedures were identified, but no evidence pertaining to their safety, efficacy or effectiveness was found in the literature: safety scalpels (disposable or reusable); scalpels with round-tipped blades and innovative blade disposal systems. The authors acknowledge that this is most likely not an exhaustive list and that additional interventions not identified may currently be in clinical use.

The design of passing trays may also play a role in their effectiveness. Passing trays with an indentable surface, or two channels (on either side of the scalpel handle and clear of the blade), would allow for ease of transfer by providing adequate friction to allow the scalpel to be tightly gripped, unlike hard, flat trays which prevent easy grasping of flat scalpel handles (M. Patkin: personal communication, 2007).

It must also be acknowledged that there will remain the need for occasional hand-to-hand passing between members of the operative team, particularly in complex or emergent situations. Extensive training and experience may assist in lowering the need for this, however other techniques need to be developed among operative teams to maintain a safe operative environment during such occurrences. This may be as simple as verbalised passing announcements while the scalpel is in transit, to ensure that all team members are aware of the passage of the instrument.

### ***Sharpless surgery***

Evidence from one study indicated that sharpless surgery provided a viable alternative to the use of traditional sharps in surgery. Clearly, there remains a need for the option to revert to sharps should this arise during the procedure.

Additionally, more in-depth examination of the potential impacts on cosmesis, altered operative and recovery times and the potential to exacerbate certain conditions (e.g. tumour seeding in cases of malignancy) must be undertaken before these techniques can become established in routine clinical practice.

### ***Single-hand scalpel blade remover & passing tray***

Theoretical modelling data presented in one study indicated that the use of a single-handed scalpel blade remover in conjunction with a passing tray had the potential to prevent approximately as many injuries as a safety scalpel with a 100% activation rate. However, the ultimate effectiveness of a device where the user must activate the safety mechanism is dependent on the activation rate. Reported rates of activation for these devices are notoriously low, which may strengthen the evidence that passive safety devices such as passing trays and scalpel blade removers represent more effective interventions than those that require user activation, such as safety scalpels

### ***Protective footwear***

Evidence from one study indicated that materials such as non-pliable leather, rubber with leather lining and new rubber provided superior foot protection from dropped scalpel blades under experimental conditions.