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CONSENSUS DOCUMENT

Closed surgical incision management: Understanding the role of NPWT

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FOREWORD

Substantial numbers of patients develop surgical site infections and other incisional complications worldwide each year. The social, healthcare and wider economic implications are considerable. As the average age of the population increases and multi-morbidity becomes more common, the number and complexity of surgical procedures performed is rising. As a result, reducing the risk and burden of incisional complications continues to be a major challenge.

Negative pressure wound therapy (NPWT) used on the closed incision is a new and emerging approach to managing closed incisions, which shows early promise in being able to reduce the incidence of incisional complications. In January 2016, an international group of surgical care experts met to discuss the challenges involved in closed surgical incision management and the interventions that can be used to reduce the risk of surgical site complications. Optimising wound outcomes is a complex, multifactorial challenge and the discussions included why, when and how to use NPWT on closed surgical incisions as part of a 'bundled' approach. The core expert working group and a wider review panel produced the final consensus following extensive review of the initial draft. It is hoped that this document will raise the profile of surgical site complications and, ultimately, help surgeons and other clinicians to improve outcomes for patients.

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NPWT IN THE MANAGEMENT OF CLOSED SURGICAL INCISIONS

Box 1 | Negative pressure wound therapy (NPWT)

- NPWT involves the application of controlled suction (negative pressure) over a wound and perilesional tissues. Usually, a wound filler, such as foam or gauze, and sometimes a liner, is placed in the wound and an adhesive film is used to cover the wound and filler to form a seal
- The seal delivers suction generated by an electrically powered vacuum pump that contains batteries or is plugged into a mains electricity source, or by a mechanically powered pump
- Traditional NPWT systems include a canister for the collection of fluids removed from the wound.

CLOSED SURGICAL INCISIONS — CHALLENGES AND OPPORTUNITIES

Negative pressure wound therapy (NPWT) (Box 1) has been in use for more than 20 years for the management of a wide range of different wound types in adults, including traumatic, hard-to-heal and chronic wounds, and wounds covered with flaps and/or skin grafts^[1,2]. It has also been used for the management of complex wounds, e.g. congenital open abdomens, in paediatric patients for more than 10 years^[3-7]. More recently, NPWT systems have been used to manage closed surgical incisions in patients at high risk of surgical site complications^[8-10].

NPWT systems continue to evolve in response to clinical experience and patients' needs. Models have been developed for open wounds that incorporate topical delivery (instillation) of solutions such as normal saline, wound cleansers or antiseptics^[11]. In addition, smaller, lighter and more portable single-use models are now available that are suitable for ambulatory or homecare^[12,13].

Some simplified systems no longer employ a fluid-collection canister but allow any exudate produced by the wound to evaporate through a high moisture vapour transmission rate (MVTR) dressing^[14,15].

The ultraportable, discreet versions of NPWT are ideally suited for use on closed surgical incisions that are not expected to produce large volumes of exudate, and on patients who will benefit from the potential for earlier discharge from hospital and the ability to mobilise sooner^[14,16].

NPWT has been used on closed surgical incisions following a variety of different types of surgery, including abdominal, cardiothoracic, colorectal, obstetric, orthopaedic, paediatric, plastic/breast, trauma and vascular surgery.

'NPWT use over closed surgical incisions has been shown in a substantial number of studies to be beneficial in reducing rates of surgical site infection, seroma/haematoma and dehiscence, and improving scar quality'^[10] (see pages 19-22)

Closed surgical incisions (Box 2, page 5) are common: about 250 million major surgical procedures are performed worldwide each year^[17]. In many countries, caesarean section is either the most common, or one of the most common, major surgical procedures^[18,19].

Challenges

Unfortunately, even if surgery is successful and primary closure achieved, the incision required to perform the procedure may itself be associated with post-operative complications. Surgical site complications include infection, seroma, haematoma, local skin ischaemia and necrosis, dehiscence and delayed healing^[20] (see pages 5-8). Poor quality or abnormal scarring may also be later unwanted outcomes of surgical incisions (see pages 8-9). Surgical site infection (SSI) tends to be the focus of surveillance programmes and prevention initiatives worldwide (see pages 9-10).

A wide range of factors influence reported surgical site complication rates in adult and paediatric populations including patient characteristics, surgical procedure and reporting methods^[21-24].

'Surgical site complications may delay healing and result in considerable morbidity, mortality and socioeconomic costs'^[25]

Opportunities

Improving outcomes for patients with closed surgical incisions by reducing rates of surgical site complications could have a significant impact on patients' lives, and societal and

Box 2 | Closed surgical incision — a definition

A surgical incision made through skin and underlying tissues in which the edges of the incision have been brought together (closed) to aid healing by primary intention. A variety of materials may be used to hold the incision edges together including sutures, staples/clips, tapes, skin adhesives or skin closure devices.

healthcare costs. Prompt, uncomplicated healing is particularly important in certain subgroups of patients, such as those about to embark on adjuvant chemotherapy or radiotherapy, to avoid delays in further treatment.

In the US, it has been estimated that the use of evidence-based practices in just colorectal surgery could prevent >30,000 SSIs and save up to US\$834m per year^[26]. It has also been calculated that the additional costs to European health services due to increased length of stay experienced by patients suffering from SSI are about €19bn per year^[27].

Furthermore, a large study of data from 346 hospitals in the US identified SSI as the most common reason for readmission to hospital, accounting for 19.5% of overall readmissions^[28]. As a result, the study panel concluded that SSI research should be a priority. The panel also suggested that readmissions in general might be reduced by ensuring better coordination of care with outpatient care teams, minimising fragmentation of post-discharge care, developing high-quality homecare programmes, and improving the quality of education and discharge instructions given to patients.

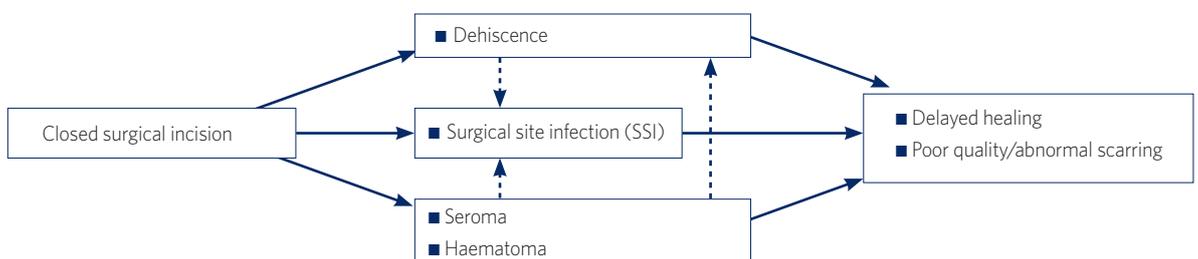
Avoidance of surgical site complications may:

- Reduce morbidity (including systemic complications, long-term sequelae, pain, patient/carer anxiety) and mortality
- Reduce length of hospital stay and unplanned readmissions
- Improve hospital efficiency, e.g. by preventing delays in follow-on treatment (such as chemotherapy) and allowing greater patient throughput
- Reduce indirect and direct healthcare costs
- Reduce social and psychological costs for patients, their families and caregivers
- Enhance oncological survival
- Enhance patient satisfaction and departmental/institutional standing.

SURGICAL SITE COMPLICATIONS

Complications that may affect closed surgical incisions include SSI, dehiscence, seroma, haematoma, delayed healing and poor quality or abnormal scar (Figure 1).

Figure 1 | Relationships between surgical site complications



Surgical site infection

In the US, SSIs affect about 500,000 surgical patients each year and lead to about 8,000 deaths annually^[29]. A patient with an SSI has a 2-11-fold increase in mortality compared with a post-surgical patient without an SSI^[30]. An association between wound complications, e.g. SSI, and increased mortality may exist beyond the initial post-operative period. Recent studies found that surgical site complications were associated with decreased long-term survival in patients who underwent surgery for colorectal or breast cancer^[31,32].

Table 1 Centers for Disease Control and Prevention (CDC) definitions of SSI ^[35]	
Type of SSI	Definition
Superficial incisional SSI*	Infection occurs within 30 days after any operative procedure (where day 1 = the procedure date) AND involves only the skin and subcutaneous tissue of the incision AND the patient has at least one of the following: <ol style="list-style-type: none"> purulent drainage from the superficial incision organisms identified from an aseptically obtained specimen from the superficial incision or subcutaneous tissue by culture- or non-culture-based microbiologic testing method that is performed for purposes of clinical diagnosis or treatment superficial incision that is deliberately opened by a surgeon, attending physician or other designee and culture- or non-culture-based testing is not performed AND The patient has at least one of the following signs or symptoms: pain or tenderness; localised swelling; erythema; or heat. A culture- or non-culture-based test that has a negative finding does not meet this criterion <ol style="list-style-type: none"> diagnosis of a superficial incisional SSI by the surgeon or attending physician or other designee
Deep incisional SSI*	Infection occurs within 30 or 90 days** after the procedure (where day 1 = the procedure date) AND involves deep soft tissues of the incision (e.g. fascial and muscle layers) AND the patient has at least one of the following: <ol style="list-style-type: none"> purulent drainage from the deep incision a deep incision that spontaneously dehisces, or is deliberately opened or aspirated by a surgeon, attending physician or other designee and an organism is identified by a culture- or non-culture-based microbiologic testing method that is performed for purposes of clinical diagnosis or treatment or culture or non-culture-based microbiologic testing method performed AND The patient has at least one of the following signs or symptoms: fever (>38°C); localised pain or tenderness. A culture- or non-culture-based test that has a negative finding does not meet this criterion <ol style="list-style-type: none"> an abscess or other evidence of infection involving the deep incision that is detected on gross anatomical or histopathologic examination, or imaging test
Organ/space SSI***	Infection occurs within 30 or 90 days** after the procedure (where day 1 = the procedure date) AND infection involves any part of the body deeper than the fascial/muscle layers, that is opened or manipulated during the operative procedure AND the patient has at least one of the following: <ol style="list-style-type: none"> purulent drainage from a drain that is placed into the organ/space (e.g. closed suction drainage system, open drain, T-tube drain, CT guided drainage) organisms are identified from an aseptically obtained fluid or tissue in the organ/space by a culture- or non-culture-based microbiologic testing method which is performed for purposes of clinical diagnosis or treatment an abscess or other evidence of infection involving the organ/space that is detected on gross anatomical or histopathologic examination, or imaging test

*Superficial incisional SSI and deep incisional SSI may both be further categorised as primary or secondary according to whether the incision in question is the primary incision or is the secondary incision in an operation with more than one incision

** Some SSI classifications specify 30 days if no implant is in place, or within one year if an implant is in place^[36]

***Some SSI classifications based on the CDC classification include diagnosis of organ/space SSI by a surgeon or physician^[36]. However, the expert working group has recommended that diagnosis of organ/space SSI is made by a surgeon only

SSIs are financially costly, resulting in around \$7bn in excess costs in the US each year, with individual infections estimated to cost from US\$400 to >US\$30,000 to treat, depending on severity^[29,33]. In the UK, in 2008, the annual cost of treating SSIs was estimated at £758m^[34]. SSIs affect large numbers of patients worldwide (Appendix 1, page 23) and considerably increase mortality, however, up to 60% are thought to be preventable^[30]. Reported SSI rates vary considerably according to the type of surgery involved (Appendix 2, page 23).

Defining and identifying SSI

The Centers for Disease Control and Prevention (CDC) definitions of SSIs are used widely for surveillance purposes. They classify SSIs as superficial incisional, deep incisional or organ/space infections (Table 1), and are applicable to all types of surgery^[35].

'Although the CDC definitions provide clear distinctions between classes of SSI, it should be noted that in a small subgroup of patients SSI may progress, e.g. superficial SSI may progress to deep incisional or organ/space infections and affect grafts or prostheses'

Box 3 | Definition of seroma

N.B. In reports of complications following surgery, haematoma and seroma are sometimes grouped together

Seromas usually occur as a complication of surgery, but may also occur after procedures such as inguinal cannulation or following trauma. A seroma is a collection of serous fluid that forms in a cavity or potential space, e.g. under a skin flap, and is distinct from an abscess. Lymphatic fluid/leak from tissue disruption may contribute to the fluid collection. Seromas generally contain few red blood cells.



Seroma following breast implantation (photo courtesy of Michael Sugrue)



Seroma following repair of incisional hernia (photo courtesy of Michael Sugrue)

The ASEPSIS system is a quantitative scoring system used to identify and classify SSI^[37]. Points are assigned according to the extent of signs and symptoms of infection and the presence of additional factors. The total score is then used to indicate whether infection is present (Appendix 3, page 23). The system was originally designed for use in cardiothoracic surgery, but is also now more widely used for other types of surgery^[38].

A study of four commonly used definitions of wound infection, including the CDC definition, National Nosocomial Infection Surveillance (NNIS) system (Table 4, page 12), ASEPSIS score, and the presence of pus alone, found poor agreement and highlighted the difficulties of comparing outcomes from clinical studies using different criteria for SSI^[39].

Seroma

Seromas (Box 3) are thought to result from fluid extravasation due to an inflammatory response resulting from surgical trauma and/or foreign material^[40]. They can occur after minimally invasive procedures, but are more likely after procedures that involve significant tissue disruption and where there is a large dead space, e.g. plastic surgery or abdominoplasty^[41], and where there has been transection of numerous lymphatic channels, e.g. mastectomy, groin operations^[42].

Recent research in patients undergoing mastectomy with sentinel lymph node biopsy indicates that injection of methylprednisolone into the wound cavity may reduce seroma formation^[43].

The reported incidence of seroma varies considerably, and is thought to be increasing. Incidences of 3%–85% have been reported following breast or axillary surgery^[44], and 4%–15% following repair of abdominal incisional hernia^[45].

Contributors to the rate variations include surgical technique, extent of dissection, surgical devices used, and inconsistencies in definitions, e.g. differences in diagnostic criteria (clinical or ultrasound diagnosis, duration of seroma), and whether the seroma required percutaneous aspiration or drainage^[44,46]. A widely agreed and accepted definition of seroma that is suitable for consistent reporting of study outcomes is needed. Seromas may resorb spontaneously. However, depending on site and size, some require (multiple) aspiration or insertion of a drain. Following breast implant insertion, aspiration of seroma poses a challenge due to the risk of implant rupture and procedure-related infection.

Excessive and/or recurrent seroma formation may produce significant morbidity, e.g. increased risk of SSI, wound dehiscence, incisional hernia formation, discomfort and prolonged recovery, and may also delay adjuvant therapy in patients receiving treatment for breast cancer^[47]. Research is required to determine the role and clinical significance of detection of seroma by ultrasound scanning.

Haematoma

Haematoma (Box 4, page 8) is a common surgical wound complication that is increasing in incidence as the use of thromboprophylaxis and anticoagulation becomes more widespread^[48]. Haematomas provide a nutrient-rich environment for bacterial replication and increase the risk of SSI, wound dehiscence and delayed healing^[42,49].

Imperfect haemostasis is the usual cause of haematomas. This may be due to the use of antiplatelet medication, low-dose heparin, oral anticoagulants, pre-existing

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Box 4 | Definition of haematoma

N.B. In reports of complications following surgery, haematoma and seroma are sometimes grouped together

Haematoma may occur following surgery or trauma. It is a collection of blood that may be found in an organ, such as a liver or kidney, in muscle or beneath the skin. A haematoma may form beneath the skin in a closed incision. Ecchymosis (bruising) should be distinguished from a haematoma, and may occur separately or in conjunction with a haematoma.



Haematoma after mastectomy with flap reconstruction (photo courtesy of Risal Djohan)

coagulopathies, or poor surgical technique^[42]. In some types of cardiac surgery, e.g. revascularisation for acute coronary syndrome, attaining haemostasis may be particularly challenging because most patients are receiving dual antiplatelet therapy.

Haematomas may be dangerous if they occur at anatomical sites where they could compress important structures, e.g. in the neck. They may also damage adjacent tissues or organs through pressure and increase the risk of wound dehiscence. Small haematomas may resolve spontaneously. However, further surgery may be required for evacuation of the blood and to ensure haemostasis.

Dehiscence

Wound dehiscence (Box 5) is possible after any incisional surgical procedure that is followed by closure of the wound, and is probably under-reported. Dehiscence following orthopaedic, abdominal, cardiothoracic and vascular surgery is the most fully documented^[50].

The incidence of surgical wound dehiscence has been reported as 1.3%–9.3%^[50]. Dehiscence following oncological breast surgery may have serious implications by delaying initiation of adjuvant therapy. Abdominal wound dehiscence has a mortality rate of up to 45%^[50]. The mortality rate of sternal dehiscence has been reported as 0.3%–9.7%^[51]. In the presence of mediastinitis, however, this increases to 14%–47%^[52].

Dehiscence increases morbidity and mortality rates, and extends hospital stays^[50]. It may occur within a few days following surgery, or up to months or even years afterwards. It has numerous possible causes and may be related to closure technique, mechanical stresses and/or factors that interfere with wound healing^[53].

Closed incisions under tension, e.g. closed abdominal incisions and breast reconstruction flaps, are at particular risk^[54,55]. At flap donor sites, risk of dehiscence is dependent on flap size. Larger flaps result in bigger tissue defects and increased tension on the suture line at the donor site^[55].

Obese patients are at increased risk of dehiscence^[56,57]. This is possibly because incisional healing may be impaired due to increased tension on suture lines and poor perfusion of adipose tissue^[56]. Haematoma and seroma may also increase tension and risk of dehiscence at closed surgical incisions^[53].

Other risk factors include conditions that may impair wound healing, e.g. wound infection, increased age, diabetes, oedema, poor nutrition and immunosuppression^[50,53].

Dehiscence is significantly more frequent following emergency abdominal surgery than elective^[54,58]. In children, major risk factors for dehiscence after abdominal surgery are age <1 year, wound infection, median incision and emergency surgery^[59].

The potential role and economics of using ultrasound scanning to screen for dehiscence are under debate.

Abnormal and poor quality scarring

Mechanical stress applied to an incision may aid increase in tensile strength during healing, it may also have a negative effect on scar formation and increase abnormal scarring^[60].

Box 5 | Definition of surgical wound dehiscence

Dehiscence (wound separation) is the splitting apart or rupturing of the margins of a previously closed wound along some or all of its length.

Dehiscence may be:

- Superficial — i.e. involve only separation at skin level
- Deep — i.e. involve separation of tissues below the skin; may or may not include skin separation.



Superficial dehiscence following caesarean section (photo courtesy of Baha Sibai)



Deep dehiscence following surgery to correct scoliosis (photo courtesy of Guido Ciprandi)

Hypertrophic and keloid scars (Box 6, page 11) are the result of abnormal wound healing and may cause considerable distress due to poor cosmetic appearance, pruritus, pain and contractures^[61,62]. Hypertrophic and keloid scars tend to occur in wounds under high tension^[63]. Hypertrophic scarring occurs in 34%–64% of patients undergoing standard surgical procedures^[64]. Keloid scars occur mainly on the ear lobe, shoulders and over the sternum^[61]. They can occur in patients of all races, but the incidence is higher in dark-skinned people. Up to 6%–16% of African populations may have keloid scarring^[62].

'Surgical scar quality should be monitored, ideally for 12 months after surgery, and the Expert Working Group recommend inclusion of scar quality in patient-reported outcomes'

A number of assessment tools have been developed as methods of monitoring scar quality. These generally contain some degree of subjective evaluation that may affect reliability^[65]. Tools used for assessment of post-surgical scars include Patient and Observer Scar Assessment Scale (POSAS) and Visual Analog Scale (VAS)^[66,67].

Surveillance of surgical site complications

Surveillance and reporting of surgical site complications is integral to efforts to reduce their occurrence. However, the use and interpretation of particular definitions/diagnostic criteria, follow-up processes (including for readmission), reporting systems and timelines can have a significant impact on the rates reported^[22,24]. The variability in such factors can make it difficult to draw meaningful comparisons between surgical site complication rates from different studies.

For the same reasons, caution should be applied when interpreting the results of local surveillance for surgical site complications in the context of other local, national or international rates, e.g. for the purposes of benchmarking or producing hospital performance league tables.

In addition, it is likely that hospital-based surveillance systems underestimate surgical complication rates because some complications may not become apparent until after discharge from hospital^[68-70]. This problem is likely to be exacerbated by the trend for earlier patient discharge.

'Because of the difficulties of determining rates of SSI and other surgical site complications, it is important that individual institutions/departments implement their own surveillance programmes to determine and track local complication rates'

Several initiatives have been developed for, or include, the prevention of SSIs, e.g. CDC Guideline for Prevention of Surgical Site Infection, World Health Organization (WHO) Surgical Safety Checklist, Association for Professionals in Infection Control and Epidemiology (APIC) 'working towards zero' initiative, American College of Surgeons National Quality Improvement Program (ACS NSQIP), National Institute for Health and Care Excellence (NICE) guidance^[68,71-75].

When compliance with validated protocols is high, reductions in SSI rates have been observed^[76-78]. However, compliance with the use of checklists and intervention bundles is variable (e.g. 20%–60% in the UK and US)^[24].

Existing SSI surveillance programmes have shown a range of changes in SSI rates. Some indicate that SSI rates have fallen overall for some categories of surgery in recent years,

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but remain unchanged or increased in others^[79-81]. However, there are doubts about the extent to which reported rates reflect reality and whether it is valid to compare rates over extended periods, e.g. 10 years or more.

Reasons for this include that SSI rates based on inpatient data alone are likely to be underestimated, and that over time the population is at greater risk of surgical site complications due to increasing average age and higher rates of multi-morbidity. These concerns are also likely to apply to other types of surgical site complications.

Surveillance programmes use a range of data collection methods for surgical site complications. The most robust approach is to collect data prospectively, from every patient, using direct patient contact (telephone survey or questionnaire) at 30 days^[22].

'An internationally agreed, robust, validated surveillance system that uses uniform definitions for SSI and other surgical site complications needs to be developed'

IDENTIFYING PATIENTS AT RISK OF SURGICAL SITE COMPLICATIONS

Recognition of which patients are at risk of surgical site complications, and to what extent, is essential in managing that risk, and for surveillance and benchmarking. It may also aid in ensuring a tailored approach to care and appropriate use of interventions.

Risk factors

Risk for surgical site complications is dependent on a large number of factors: some are patient-related and others are dependent on surgical procedures. Table 2 lists risk factors for surgical site complications, such as SSI, seroma, haematoma, dehiscence and abnormal scarring, that are general to all types of surgery. Table 3 lists additional risk factors that are specific to a selection of different types of surgery.

Table 2 | General risk factors for surgical site complications (adapted from^[41,50,63,68,82,95])

Category	Patient-related risk factors	Procedure-related risk factors
Major risk factors Presence of 1 = high risk of surgical site complication	<ul style="list-style-type: none"> ■ BMI $\geq 40\text{kg/m}^2$ or $\leq 18\text{kg/m}^2$ ■ Uncontrolled insulin dependent diabetes mellitus ■ Renal dialysis 	<ul style="list-style-type: none"> ■ Extended duration of surgery* ■ Emergency surgery ■ Hypothermia
Moderate risk factors Presence of ≥ 2 = high risk of surgical site complication	<ul style="list-style-type: none"> ■ ASA Physical Status $\geq \text{II}$ ■ Age < 1 year or > 75 years ■ BMI $30\text{-}39.9\text{kg/m}^2$ ■ Diabetes mellitus ■ Chronic obstructive pulmonary disease $\geq \text{GOLD class 2}$ ■ Renal insufficiency/chronic kidney disease ■ Immunosuppression ■ Steroids for a chronic condition ■ Chemotherapy ■ Pre-existing infection at a body site remote from operative site ■ Serum albumin $< 2.5\text{g/dl}$ ■ Smoking (current) 	<ul style="list-style-type: none"> ■ Anaemia/blood transfusion ■ High wound tension after closure ■ Dual antiplatelet treatment ■ Suboptimal timing or omission of prophylactic antibiotics ■ Tissue trauma/large area of dissection/large area of undermining
Minor risk factors Presence of any = increased risk of surgical site complications	<ul style="list-style-type: none"> ■ African or African-American race ■ BMI $25\text{-}29.9\text{kg/m}^2$ ■ Extended pre-operative hospitalisation or residency in a nursing home ■ Peripheral vascular disease ■ Congestive cardiac failure with left ventricular ejection fraction $< 30\%$ 	<ul style="list-style-type: none"> ■ Failure to obliterate dead space ■ Location of incision ■ Previous surgery ■ Surgical drains

*Defined as $> T$ (hours) which is dependent on the type of surgical procedure, and is the 75th centile of duration of surgery for a particular procedure, e.g. coronary artery bypass graft has a T of 5 hours and caesarean section has a T of 1 hour^[81]

Box 6 | Definitions of hypertrophic and keloid scarring

Hypertrophic scar

Raised scar, characterised by deposits of excessive amounts of collagen, arising soon after surgery; does not exceed the margins of the original wound; occurs when scars cross joints or skin creases at a right angle; may be itchy and painful; usually subsides with time.



Hypertrophic scar after bilateral mastectomy with radiation skin changes and flap reconstruction on the right (photo courtesy of Risal Djohan)

Keloid scar

Raised scar, the result of overgrowth of dense fibrous tissue, which may develop months after trauma; spreads outside the boundaries of the initial incision; rarely regresses; rarely develops across joints; may be itchy and painful; associated with dark skin colour.



Keloid scarring post-laparotomy (photo courtesy of Guido Ciprandi)

'Major patient-related risk factors for surgical site complications are extremes of BMI ($\leq 18 \text{ kg/m}^2$ or $\geq 40 \text{ kg/m}^2$), uncontrolled insulin dependent diabetes, renal dialysis, extended duration of surgery, emergency surgery and hypothermia (Table 2)'

A number of classification schemes have been devised to indicate a patient's level of risk of SSI, e.g. surgical wound classification (SWC)^[113] and the NNIS Risk Index^[82]. In general, these are used for surveillance purposes, omit or include few patient-related risk factors, and are not used to guide clinical decision-making.

Surgical wound classification

Surgical wound classification was devised to identify and describe the degree of bacterial contamination of a surgical wound at the time of surgery^[114]. It categorises wounds into one of four classes: clean, clean-contaminated, contaminated, and dirty or infected (Appendix 4, page 24).

Table 3 | Examples of the main additional risk factors for surgical site complications by selected surgery type (adapted from^[88,91,96,111])

Type of surgery	Additional risk factors
Abdominal	<ul style="list-style-type: none"> ■ Perforated viscus ■ Ostomy formation/closure ■ Previous radiotherapy to surgical site ■ Multiple incisions
Breast/plastic	<ul style="list-style-type: none"> ■ Coronary artery disease ■ Bleeding risk ■ Breast Reconstruction Risk Assessment (BRA) score*
Cardiothoracic	<ul style="list-style-type: none"> ■ Bilateral internal mammary artery harvesting ■ Chest wall radiotherapy ■ Left ventricular assist device (LVAD) ■ Transplant ■ Cardiopulmonary bypass time extended ■ Delayed closure
Paediatric	<ul style="list-style-type: none"> ■ Very low birthweight** (<1kg) } ■ Bone marrow aplasia } major risk factors ■ Inflammatory bowel disease } ■ Concomitant morbidity or illness, e.g. cerebral impairment, immobility (complete or partial), skin condition such as ichthyosis or inherited skin condition (genodermatosis) other than epidermolysis bullosa ■ Mechanical ventilation ■ Neonatal/paediatric intensive care unit (NICU/PICU) ■ Organ transplant ■ Implantable device, e.g. pacemaker
Obstetric	<ul style="list-style-type: none"> ■ Multiple (>3) caesarean sections ■ Anticoagulants ■ Operative blood loss >1.5l ■ Pre-eclampsia ■ Chorioamnionitis
Orthopaedic	<ul style="list-style-type: none"> ■ Implant/prosthesis ■ Rheumatoid arthritis ■ Nasal carriage of <i>Staphylococcus aureus</i>
Vascular surgery	<ul style="list-style-type: none"> ■ Groin incision

*The BRA Score calculates risk (as %) of a range of complications, e.g. SSI, seroma, dehiscence, flap loss, explantation and reoperation, based on factors including reconstructive modality, BMI, age, ASA Physical Status class, bleeding disorder, history of percutaneous cardiac intervention or cardiac surgery (www.brascore.org)

** However, prematurity does not appear to be a risk factor for SSI or for a resulting mortality-related event^[112]

The incidence of SSI increases with level of contamination^[113]. Consequently, surgical wound classification is used to stratify patients according to risk of SSI for reporting outcomes in studies and for surveillance and benchmarking purposes.

Limitations of surgical wound classification include that the system does not take into account intrinsic characteristics of the patient that may increase risk of SSI^[115], and that the classification is inconsistently applied^[114,116]. Suggested causes of inconsistent application include misinterpretation of definitions and inconsistencies in processes for determining class.

NNIS Risk Index

Surgical wound classification has been incorporated into a system adopted by the CDC known as the National Nosocomial Infection Surveillance (NNIS) Risk Index^[82].

Patients are scored either 0 or 1 for each of three categories that are based on the results of pre-operative assessment, surgical wound classification (Table 4) and duration of operation. Patients can therefore receive a score for NNIS Risk Index in the range 0 (low risk of SSI) to 3 (highest risk of SSI). Patients can receive a total NNIS Risk Index score between 0 and 3.

A limitation of the NNIS Risk Index score is that it does not take into account detail of the operative procedure, e.g. the placement of an implant that may affect the risk of SSI^[88].

Surgical risk calculators

Risk calculators use information about the procedure and the patient to calculate the risk of surgical complications for individual patients, e.g. mortality, pneumonia, renal failure and SSI. The calculators are usually accessed via the internet.

Several risk calculators specific to particular types of surgery have been devised, e.g. Society of Thoracic Surgeons (STS) risk calculator for valve replacement or coronary artery bypass surgery (www.riskcalc.sts.org), and the Breast Reconstruction Risk Assessment (BRA) Score (www.brascore.org).

'A risk calculator needs to be developed that is specific for a range of surgical specialities and surgical site complications and can be used for pre-operative patient education and counselling, and to indicate the need for interventions to reduce risk'

The American College of Surgeons has used data collected through the National Surgical Quality Improvement Program (NSQIP) to develop a general online calculator to estimate risks from a range of different types of surgery^[118] (www.riskcalculator.facs.org). Clinicians enter information about the surgical procedure to be performed and patient details,

Table 4 | National Nosocomial Infection Surveillance (NNIS) Risk Index^[68,82,117]

Category	Score one for each category if criteria present
American Society of Anesthesiologists (ASA) preoperative physical status*	In ASA PS class III, IV or V
Surgical wound classification (Appendix 4)	Contaminated or dirty-infected
Operation duration**	Duration >T (hours)

*ASA PS (physical status) classification: ASA PS I — A normal healthy patient; ASA PS II — A patient with mild systemic disease; ASA PS III — A patient with severe systemic disease; ASA PS IV — A patient with severe systemic disease that is a constant threat to life; ASA PS V — A moribund patient who is not expected to survive without the operation; ASA PS VI — A declared brain-dead patient whose organs are being removed for donor purposes

**See footnote in Table 2, page 10

e.g. age, sex, height, weight and comorbidities. The calculator produces estimated probabilities for death, 'any complication' and a range of individual complications. However, the only surgical site complication reported is SSI.

RISKS AND CONSEQUENCES OF SURGICAL SITE COMPLICATIONS

At present, there are no calculators available to calculate risk of surgical complications for paediatric patients. A study using data collected through NSQIP on paediatric patients has identified a flexible logistic regression model as the best predictor of 30-day surgical morbidity in paediatric patients. It is hoped that after further validation the model could be used to assist clinical decision-making^[119].

In addition to variations in incidence, the severity of the consequences of surgical site complications varies depending on the type of surgical procedures. Understanding which patients are at highest risk of severe consequences from surgical site complications will aid resource allocation by indicating which groups of patients may benefit most from additional interventions. Where possible, modifiable risk factors should be corrected prior to surgery, e.g. smoking cessation and weight reduction^[68].

Examples of procedures that have high rates of surgical site complications with potentially serious outcomes include heart–lung transplants and complex surgery (Table 5). Even for other procedures where the risk of surgical site complications is relatively low, the consequences of a complication may also be more severe because it might affect the underlying structures and/or implant material, e.g. an infection in a total hip arthroplasty may necessitate further surgery to replace the prosthesis.

However, individual patients undergoing the same procedure may be more or less likely to experience surgical site complications as a result of variation in the presence of other risk factors. For example, in Table 5, a patient with an inguinal hernia who has uncontrolled insulin-dependent diabetes mellitus may be in the higher incidence category for SSI/surgical site complications.

Table 5 | Risks and consequences of surgical site complications of closed incisions

Severity of consequence(s) of surgical site complications		Higher severity	Lower severity
		<ul style="list-style-type: none"> Primary arthroplasty Implant surgery — e.g. replacement heart valve, breast augmentation, implant reconstruction following mastectomy Coronary artery bypass graft Vascular surgery with aortic and limb graft insertion Abdominal wall repair for congenital open abdomen (gastroschisis, omphalocele) Maxillofacial and craniofacial paediatric plastic surgery Complex multi-staged urethroplastic procedures 	<p>Higher consequence severity/higher incidence</p> <ul style="list-style-type: none"> Complex surgery — e.g. major colorectal surgery, oesophagogastrectomy, extensive combined procedures which include a long skin-to-skin time especially in redo or multiple redo procedures Heart, lung or heart–lung transplant Arthroplasty revision Liver transplant in children Major oncological procedures in children After radiotherapy
		<p>Lower consequence severity/lower incidence</p> <ul style="list-style-type: none"> Inguinal hernia Thyroidectomy Carpal tunnel surgery Mole/elective lesion surgery Elective breast augmentation Liposuction/other elective cosmetic surgery 	<ul style="list-style-type: none"> Caesarean section in a patient with chorioamnionitis Planned caesarean section (high BMI) Colorectal surgery Pilonidal sinus Peripheral vascular surgery Paediatrics — site of implanted pacemaker/defibrillator Reduction mammoplasty
		Lower incidence	Higher incidence

Incidence of SSI/ surgical site complications

N.B. The classification of procedures in this figure are highly generalised, and the procedures given here are examples and do not comprise a complete list. In reality, level of severity and incidence exist as continuous scales. In addition, individual patients undergoing the same procedure may experience different levels of risk and severity of consequences of surgical site complications as a result of variation in the presence of other risk factors. Higher severity consequences include failure of surgery, life-changing implications for the patient, and death

PREVENTING SURGICAL SITE COMPLICATIONS

Prevention of surgical site complications is complex because of the wide range and convoluted interactions of patient-related, environmental and surgical factors that may be involved. Risk factors may occur at multiple points during the pre-operative, operative and post-operative phases of surgery.

Since 2009, the WHO Surgical Safety Checklist (Appendix 5, page 24) has been used and adapted in many countries worldwide with the aim of improving surgical outcomes and reducing surgical mortality^[71].

A prospective international multicentre cohort study found that introduction of the checklist was associated with significant reductions in mortality, and rates of any complication and SSI^[120]. However, difficulties in replicating these results, and research showing that the checklists are not always used properly, have highlighted the complexity of the operating room environment and the importance of carefully planned implementation that includes gaining acceptance and support^[24,121-123].

Interventions to reduce the risk of surgical site complications

A wide range of interventions may help to reduce the risk of surgical site complications. Published recommendations about which interventions should be used tend to focus on those intended to reduce the incidence of SSI^[30,68,72,73,124].

Efforts to reduce SSI, whether at local or national level, often include a limited number of selected interventions that are grouped together in a 'care bundle' to aid implementation^[125] (Box 7). Compliance to the care bundle is often a feature of audit to monitor the impact of a bundle on SSI rates.

The challenges of constructing a care bundle include ensuring that the interventions selected are evidence based and feasible within the healthcare organisation^[127], and that using the bundle does not distract from established good practice^[128].

However, at present, risk stratification for surgical site complications and the impact of interventions in different patient groups are not sufficiently understood for a tailored, patient-centred approach. As a result, bundles are often used for all patients regardless of level of risk for surgical site complications. Ideally, interventions to reduce the risk of surgical site complications should be tailored and used according to an individual patient's level of risk.

General pre-, intra- and post-operative interventions identified by the Expert Working Group as important for reduction of surgical site complications are summarised in Appendices 6-8 (pages 25-27). When constructing a bundle for a particular type of surgery or procedure, interventions specific to that surgery or procedure that reduce rates of surgical site complications effectively should also be considered. The strategy for implementation of an intervention or bundle is as important as the intervention or bundle itself.

Post-operative care of closed surgical incisions

The aim of post-operative care of closed surgical incisions is to allow the wound to heal rapidly, without complications, and with the best functional and aesthetic results. Despite lack of definitive evidence that applying a dressing to a closed incision reduces the evidence of SSI^[129], it is common practice and is advocated in SSI prevention guidelines^[72].

Box 7 | Definition of a care bundle^[126]

A care bundle is a structured way of improving the processes of care and patient outcomes: a small, straightforward set of evidence-based practices — generally three to five — that, when performed collectively and reliably, have been proven to improve patient outcomes.

ROLE OF NPWT IN CLOSED SURGICAL INCISION MANAGEMENT

Functions of a dressing applied to a closed surgical incision include acting as a barrier to external contamination, absorption of excessive leakage and providing a moist environment to aid healing^[130]. Dressings containing antiseptic agents, such as silver, are being investigated for potential to prevent SSI^[131].

Alternatives to conventional dressings

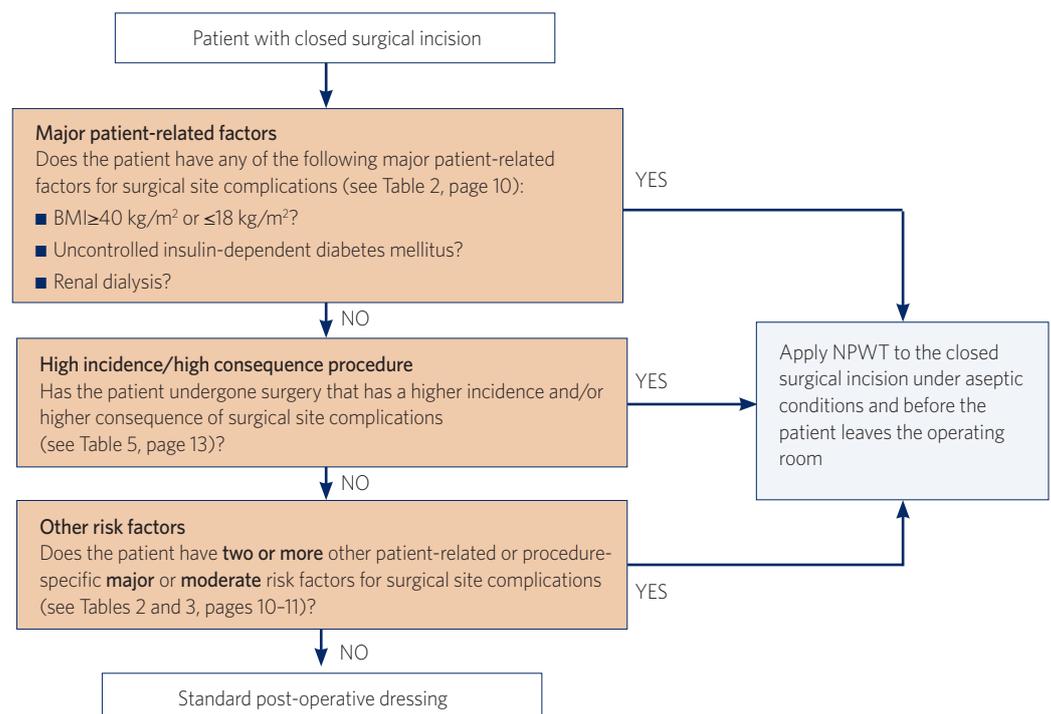
Cyanoacrylate surgical wound adhesives perform the roles of surgical closure and wound sealant. However, a systematic review concluded that sutures are significantly better than adhesives at preventing dehiscence, and that there was no difference in SSI rate between incisions that had been sutured or glued^[132].

NPWT is indicated for use on closed surgical incisions to aid healing in patients who are at increased risk of surgical site complications such as SSI, seroma, haematoma and dehiscence. There is a substantial body of evidence that incisional NPWT following a wide range of surgery types reduces the rates of surgical site complications^[10,20,92,133-136] (Appendix 9, pages 28-32).

As shown in Figure 2, the Expert Working Group proposes that NPWT is used in patients with closed surgical incisions who have intrinsic risk factors for surgical site complications or who have had a surgical procedure associated with higher incidence and/or higher consequence of surgical site complications. As research continues, new Level I evidence may become available that demonstrates beneficial effects of NPWT on surgical site complication rates in particular patient populations. If so, these patients should also be considered for incisional NPWT.

It may be clear pre-operatively that incisional NPWT is indicated for a patient. However, where this is not the case, a review following surgery and prior to application of a dressing

Figure 2 | Proposed role of NPWT in closed surgical incision management for the prevention of incisional complications



may reveal factors that have arisen during surgery that indicate incisional NPWT should be reconsidered.

Use of NPWT in combination with antimicrobial dressings

Although not all of the data are from randomised trials, there is some evidence that application of antimicrobial dressings can reduce rates of SSI following colorectal surgery^[137], cardiothoracic surgery^[138] and arthroplasty^[139]. However, in a study on closed incisions following vascular surgery, only a subgroup of incisions treated with antimicrobial dressings showed a reduction in SSI. The subgroup comprised patients with incisions classified as clean-contaminated or worse^[140]. This suggests that a potential synergy might be obtainable by combining antimicrobial dressings and NPWT in the management of closed surgical incisions.

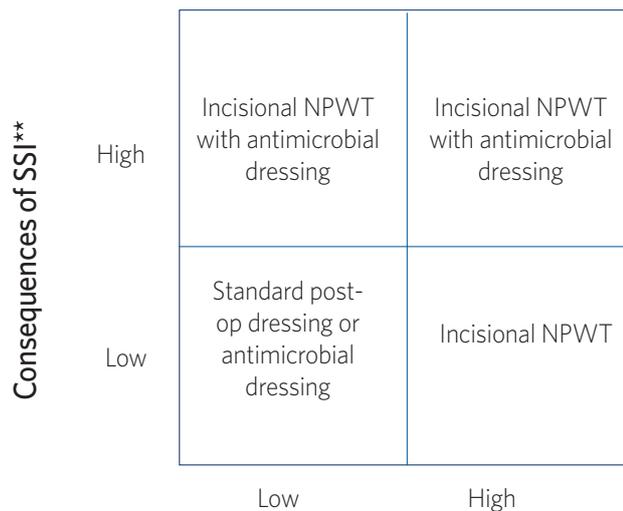
At present, however, there is insufficient evidence to support or disprove any such decision-making. Instead clinicians may tend towards an instinctive approach where an anticipated synergy might be applied to those closed incisions with the highest potential for serious consequences for the patient if an SSI occurs (Figure 3).

Using NPWT on closed surgical incisions for prevention of complications

Box 8 lists tips for the use of NPWT on closed surgical incisions, and Box 9 (page 18) lists properties as identified by the Expert Working Group of an ideal NPWT system for use on closed surgical incisions.

NPWT is well established in the management of chronic wounds and surgical wounds healing by secondary intention^[141]. There is also growing evidence that the use of NPWT

Figure 3 | Instinctive approach to a potentially synergistic use of antimicrobial dressings and NPWT in the management of closed surgical incisions



Patient risk factors for SSI*

*e.g. BMI, diabetes, length of surgery

** e.g. low consequence = breast reduction dehiscence

high consequence = mediastinitis or peri-prosthetic joint infection

over closed surgical incisions (i.e. those healing by primary intention) reduces the incidence of surgical site complications^[10,20,92,133-136] (see pages 19-21).

MODE OF ACTION OF NPWT ON CLOSED SURGICAL INCISIONS

The mode of action of NPWT has been investigated mainly with respect to open wounds, and largely in animal and laboratory studies. This research has found that in open wounds, NPWT aids healing in a number of ways, including:

- Contracting wound edges to reduce wound size
- Stimulating angiogenesis
- Increasing the rate of granulation tissue formation
- Reducing oedema^[8,11,14].

For closed surgical incisions that have closely approximated wound edges and should heal by primary intention, increased rate of granulation tissue formation and a contracting wound edge seem less relevant.

In addition to providing a physical barrier to external contamination, animal studies, *in vitro* studies and computer models have suggested that NPWT, when used over closed surgical incisions, has effects beyond the incision itself and reduces lateral tension, improves lymphatic drainage, and reduces seroma and haematoma^[142-144].

Reduced lateral tension

Computer modelling of the effects of NPWT over a closed surgical incision indicated that lateral stresses were decreased by about 45%–70%^[142,145]. In a physical model of a closed incision, about 50% more force was required to disrupt an incision that had NPWT

Box 8 | General tips for the use of NPWT on closed surgical incisions for the prevention of incisional complications

Before surgery

- Describe, show and discuss NPWT with the patient/carer and/or for paediatric patients, parents.

During surgery

- Consider placement of the incision, surgical drains and colostomies to accommodate the NPWT dressing
- Consider placement of the port and tubing to avoid pressure damage if relevant for the NPWT device in use
- Ensure drains are placed in a lower position. (N.B. NPWT over closed incisions does not replace the need for surgical drains where indicated.)
- Ensure the patient's skin is hair free and dry before application of the dressing to ensure good dressing adhesion and formation of a seal. Gel strips may be useful to aid adhesion in areas that are difficult to seal
- Apply the dressing under aseptic conditions and according to the manufacturer's instructions
- The dressing should not be placed over drains or wires
- If applied over a joint, e.g. a knee, ensure the dressing is applied with no tension to minimise the risk of blistering
- Consider the zone of tissue injury on either side of the incision and select a wide NPWT dressing
- Inspect the dressing, canister (if present), and power unit regularly.

After surgery

- If the dressing needs to be changed, use aseptic technique
- Leave the dressing in place for up to 5–7 days, according to manufacturer's instructions and availability of outpatient clinic access for removal, unless there are concerns about the incision or dressing change is required
- If the incision is closed and dry when the dressing is removed, there is no need to reapply NPWT or a conventional dressing
- Provide patients who are discharged from hospital with written information about how to care for the NPWT system, and when and how to contact a healthcare professional
- If signs of SSI occur, follow local protocol for management of SSI. Consider whether continuation of NPWT is appropriate.

applied than an incision closed with sutures or staples^[142,145]. Three animal studies have also found that the breaking strength of wounds is increased when NPWT is applied to closed incisions to reduce lateral tension^[138,146,147].

Improved lymphatic drainage

An animal study that involved comparing a film dressing with a canister-containing NPWT system on sutured incisions with dead spaces underneath, used isotope-labelled nanospheres introduced into the dead spaces to monitor lymphatic drainage^[143]. More nanospheres were found in lymph nodes from NPWT-treated sites ($p \leq 0.05$) and in the lungs, spleen and liver ($p < 0.05$). Furthermore, haematoma/seroma volume was 63% less ($p = 0.002$) in the incisions treated with NPWT, but no fluid was collected in the canister.

This indicates that fluid dispersion was achieved through increased lymphatic drainage and not by fluid being drawn out through the incision. Although not demonstrated experimentally, enhanced lymphatic drainage by NPWT may also reduce oedema in open wounds^[148].

Reduced seroma and haematoma

In addition to the study mentioned above, a further animal study showed reductions in haematoma cross-section under closed incisions subject to NPWT ($p < 0.05$)^[144]. Clinical studies have also replicated this effect^[49,149].

Effects on microcirculation

When applied to open wounds in animal models, NPWT caused relative hypoperfusion close to the wound edge (0.5cm) but an increase in perfusion 2.5cm away from the edge, effects that may both be beneficial to healing^[8]. However, the effects of NPWT when applied to closed surgical incisions on the local microcirculation are currently unclear. NPWT applied to intact skin of healthy volunteers increased oxygen saturation and blood flow^[150]. However, an animal study of closed incisions found a slight decrease in blood flow in superficial tissues beneath NPWT^[14].

Box 9 | Ideal properties of an NPWT system for use on closed surgical incisions for the prevention of incisional complications identified by the Expert Working Group

N.B. Some of these properties are aspirational and not yet available

- Device is discreet and does not interfere with daily activities
- Dressing component:
 - Adheres well
 - Removes easily without damage to skin
 - Hypoallergenic
 - Flexible/pliable
 - Range of sizes and shapes
- Single use/disposable
- Incorporates an imperfect seal or leak detector
- For paediatrics — pump unit does not contain components that could come loose and that may be ingested, e.g. does not use coin-shaped batteries
- Low battery indicator
- Can be left in place for up to 5-7 days
- Supported by clinical evidence of reductions in surgical site complications
- Safe
- Affordable and cost-effective
- Wish list:
 - Contains a warning system for undesirable levels or types of bacteria
 - Monitors tension across the wound
 - Patient can adjust alarm volume and character (e.g. change to vibration)
 - Allows inspection of the closed incision
 - Size and shape can be modified according to need.

Perhaps the major beneficial effect of closed incision NPWT on perfusion is through the reduction of post-operative oedema and restoration of occluded blood flow. An experiment performed on random pattern flaps sized so that they would suffer necrosis from their distal tips found that when NPWT was applied for 4 days a greater percentage area of the flaps remained viable^[151].

Clinical support for the mechanism of this effect can be found in experiments on the application of NPWT to free tissue transfer flaps^[152]. NPWT statistically significantly reduced oedema and inflammatory markers induced by ischaemia during flap placement. This suggests that if the two sides of a closed incision are considered as potentially partially ischaemic, perhaps due to extensive tissue undermining or trauma, then application of NPWT across a wider surface area — ‘the zone of injury’ — rather than simply to the closed incision, may be a better clinical strategy^[8].

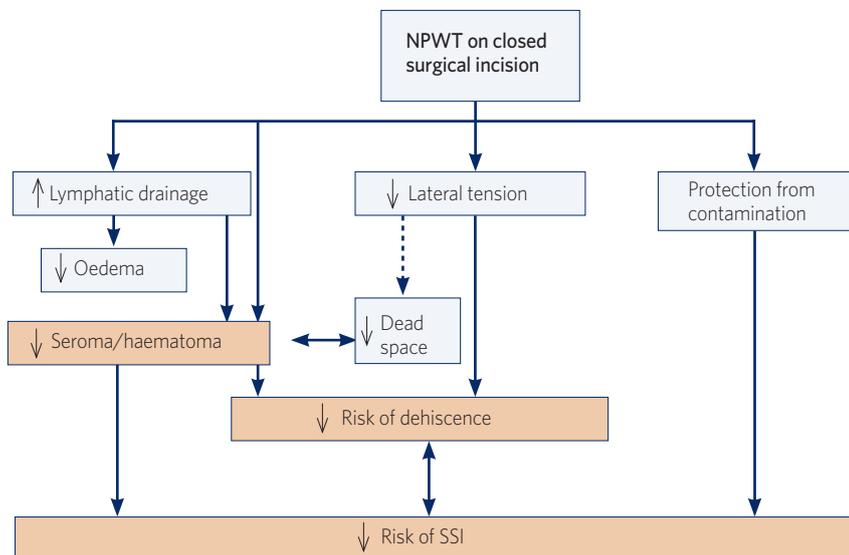
‘The combined effects of reduced lateral tension, improved lymphatic drainage and reduction in haematoma and seroma found in studies of NPWT on closed surgical incisions are likely to contribute to faster and stronger healing, and reduced risk of infection and dehiscence (Figure 4)^[8]’

Clinical evidence of the effect of NPWT on closed surgical incisions

The use of NPWT on closed surgical incisions for the prevention of incisional complications has been evaluated in a range of different types of surgery (Appendix 9, pages 28–32). A number of systematic reviews and meta-analyses have been conducted on incisional NPWT and have produced a range of conclusions on effect on clinical outcomes. The variations in results are probably due to differences in inclusion criteria: each analysis uses a different set of studies. The most recent review and meta-analysis focuses solely on RCTs comparing incisional NPWT with standard post-operative care^[10].

SSI rates are the most commonly reported outcome. Several systematic reviews and meta-analyses that included studies from a range of surgery types have reported that NPWT on

Figure 4 | Effects of NPWT on closed surgical incisions (adapted from^[8])



A discussion by the authors of the findings of the most recent systematic review of NPWT on closed surgical incisions^[10] can be viewed at: <https://www.youtube.com/watch?v=L-fZGpHzubo>

closed surgical incisions is associated with reductions in SSI incidence when compared to standard care^[10,20,136,153-155].

In general, the rate of SSI is halved by incisional NPWT^[10]. Individual studies (RCTs and comparative) found a significant reduction in SSI with NPWT on orthopaedic, cardiothoracic and vascular surgical incisions^[16,156-159] (Table 6).

Some systematic reviews and meta-analyses also report reductions in seroma or sero-haematoma formation when compared with standard care^[10,20], while others found the evidence inconclusive^[136,154]. In general, the incidence of seroma formation is halved by incisional NPWT^[10]. Individual studies (RCTs) found a significant reduction in seroma with NPWT on orthopaedic surgery^[49,149,160] (Table 7).

‘The body of evidence on incisional NPWT is growing: a number of randomised clinical trials are underway, including several with published protocols^[162-167]’

Individual studies in orthopaedic and breast surgery have found significant reductions in dehiscence with NPWT^[134,156,159] (Table 8). However, published systematic reviews and meta-analyses have found that study heterogeneity prevented analysis or that the evidence for reductions in dehiscence is inconclusive^[10,20,136,153,161,168].

Scar quality has been assessed in a randomised trial of NPWT when compared with standard care in closed incisions following breast reduction surgery^[134]. VAS and POSAS were used at 42 days and 90 days post-operatively. At both assessments the breast treated with NPWT was found to have significantly better scar quality than the breast treated with standard care at both early assessments ($p < 0.001$).

Cost-effectiveness

Surgical site complications are very costly to treat. Interventions that reduce the risk of complications occurring have the potential to avoid costs, enabling patients to return to their home, social and work lives quickly following surgery.

NPWT on closed surgical incisions has been shown to reduce length of hospital stay and readmission rate. In a cohort study of NPWT in high-risk cardiothoracic surgery patients,

Table 6 | Reductions in SSI rates in studies of NPWT on closed surgical incisions

Author	Type of surgery	Details	
Stannard et al, 2012 ^[156] (RCT)	Orthopaedic (lower limb)	249 patients; 263 fractures	n=141 NPWT*; n=122 control SSI incidence: 10% vs 19% ($p < 0.05$)
Grauhan et al, 2013 ^[157] (RCT)	Sternotomy	150 patients	n=75 NPWT** (6-7 days); n=75 control SSI incidence: 4% vs 16% ($p < 0.05$)
Witt-Majchrzak et al, 2015 ^[158] (RCT)	Sternotomy	80 patients	n=40 NPWT***; n=40 control SSI incidence: 2.5% vs 17.5% ($p < 0.05$) (only superficial SSI seen)
Adogwa et al, 2014 ^[159]	Orthopaedic (spine)	160 patients	n=46 NPWT***; n=114 control SSI incidence: 10.6% vs 14.9% ($p < 0.05$)
Matatov et al, 2013 ^[16]	Vascular (groin)	90 patients; 115 incisions	SSI incidence: 10.6% vs 14.9% ($p < 0.05$)

*V.A.C. (KCI); **Prevena™ Incision Management System (KCI); ***PICO™ Single Use Negative Pressure Wound Therapy (Smith & Nephew)

Table 7 | Reductions in incidence and volume of seroma in studies of NPWT on closed orthopaedic incisions

Author	Details
Pachowsky et al, 2012 ^[149] (RCT)	19 patients, n=9 NPWT* (5 days), n=10 control Seroma incidence: 44% vs 90% Seroma volume: <ul style="list-style-type: none"> day 5: 0.6ml vs 2.0ml (p=not significant) day 10: 2.0 ml vs 5.1ml (p<0.05)
Pauser et al, 2014 ^[160] (RCT)	21 patients: n=11 NPWT* (5 days); n=10 control Seroma incidence: 36% vs 80% Seroma volume at day 5: 0.26cm ³ vs 4.00cm ³ (p<0.05)
Nordmeyer et al, 2015 ^[49] (RCT)	20 patients: n=10 NPWT** (5 days); n=10 control Seroma volume: <ul style="list-style-type: none"> day 5: 0.0ml vs 1.9ml (p<0.05) day 10: 0.5ml vs 1.6ml (p<0.05)

*Prevena Incision Management System (KCI); **PICO Single Use Negative Pressure Wound Therapy (Smith & Nephew)

those treated with NPWT had an average length of stay of 5 days. The length of stay of the historical controls who were treated with film dressings was 10.2 days^[169]. Another study examined the effect of introducing NPWT for caesarean section incisions in high-risk women: the return to theatre rate fell from 3% to 0.5% and the readmission rate fell from 3% to 0.54%^[170].

In a pilot study of patients who had undergone bowel surgery as a result of Crohn's disease, NPWT was associated with fewer wound complications, and significantly shorter hospital stay than with standard care^[171]. Length of stay for patients treated with NPWT was 7.5±1.8 days and for standard care was 10.3±1.6 days (p=0.0007).

Few formal cost-effectiveness analyses of NPWT in closed surgical incision management have been conducted. An Australian group evaluated the cost-effectiveness of NPWT compared to standard dressings from the healthcare provider's perspective in the prevention of SSI in obese women undergoing elective caesarean section^[172]. The study used a decision model and previously published data, and concluded that NPWT is cost-effective when compared with standard care. The incremental net monetary benefit of NPWT was A\$70, and the probability of NPWT being cost-effective was 65%.

Another cost analysis from the payer's perspective assessed NPWT when compared with a standard post-operative dressing in patients undergoing caesarean delivery^[173]. This concluded that NPWT would be cost beneficial if it costs less than US\$192 (2014 prices) per unit and is used on patients at high risk of SSI.

Table 8 | Reductions in dehiscence in studies of NPWT on closed surgical incisions

Author	Type of surgery	Details	
Stannard et al, 2012 ^[156] (RCT)	Orthopaedic (lower limb)	249 patients; 263 fractures	n=141 NPWT*; n=122 control Dehiscence incidence: 8.6% vs 16.5% (p<0.05)
Galiano et al, 2014 ^[134] (RCT)	Breast	200 patients; 400 incisions	n=200 NPWT**; n=200 control Dehiscence at 21 days: 16.2% vs 26.4% (p<0.05)
Adogwa et al, 2014 ^[159]	Orthopaedic (spine)	160 patients	n=46 NPWT**; n=114 control Dehiscence incidence: 6.38% vs 12.28% (p<0.05)

*V.A.C. (KCI); **PICO Single Use Negative Pressure Wound Therapy (Smith & Nephew)

Box 10 | Areas for future research

- Mechanism of healing in closed surgical incisions, e.g. what is happening within the incision beneath the skin at a cellular, molecular and biochemical level?
- Characterisation of the mode of action of NPWT on closed surgical incisions, including effects on tissue perfusion and microcirculation, oedema and exudate production, the lymphatic system, penetration of antibiotics into tissues, growth factor production, cell replication, and measurement of pressure in different areas of the wound and surrounding tissues
- Comparison of the mechanism of action and effects of continuous and intermittent NPWT and different levels of negative pressure on closed surgical incisions
- Further clinical studies examining the effect of NPWT on closed surgical incision complications in different:
 - Patient risk groups
 - Types of surgery
 - Incision locations
- Effect of NPWT use in closed surgical incisions on patient-reported outcomes, including scar quality and pain
- Determination of factors which affect patient compliance with NPWT
- Analyses of the costs of treatment and prevention of different closed surgical incision complications, including cost-effectiveness of NPWT
- Combination studies of NPWT with antimicrobial for high SSI risk surgery in contaminated or wounds.

'Further studies of cost-effectiveness of incisional NPWT are required. However, by reducing surgical site complications, NPWT has the potential to bring wide cost benefits through improved healing and reduced healthcare costs (e.g. lower costs of treating SSI, shortened hospital stays and fewer readmissions)^{[174,175]'}

FUTURE RESEARCH NEEDS

A number of randomised trials to assess the effect of NPWT on closed surgical incisions are ongoing, planned or due to report in 2016/17 (see: clinical trials.gov). Box 10 lists some aspects of closed surgical incision management and NPWT that require further investigation.

Appendix 1 | Examples of reported SSI rates

N.B. Rates of SSI by country are highly variable, in part, at least, this is because of geographical differences in reporting criteria and systems. The Expert Working Group believe that the rates reported in this table are likely to be underestimates

Country	Overall SSI rate (%)	SSI rate by surgery type* (lowest-highest) (%)
China ^[176]	4.5	1.0 (orthopaedic) — 8.3 (abdominal)
England ^[81]	1.4	0.6 (knee prosthesis) — 10.4 (large bowel)
Germany ^[177,178]	2.0	0.1 (carotid artery reconstruction) — 9.4 (colon surgery)
Italy ^[179]	5.2	2.6 (caesarean section) — 18.9 (colon)
India ^[180]	4.2	1.7 (knee prosthesis) — 8.3 (breast surgery)
Japan ^[181,182]	6.0	0.5 (mastectomy) — 19.4 (oesophagectomy)
Mexico ^[183]	5.5	5.1 (hip prosthesis) — 18.4 (ventricular shunt)
USA ^[35,184]	1.9	0.26 (thyroid/parathyroid) — 13.7 (liver transplant)

*Reported surgical types and categorisations varied

Appendix 2 | Example SSI rates according surgery type^[185]

Type of surgery	INICC (%)	CDC-NHSN (%)
Abdominal — exploratory	4.1	2.0
Appendix	2.9	1.4
Bile duct, liver or pancreas	9.2	9.9
Breast surgery	1.7	2.3
Caesarean section	0.7	1.8
Cardiac	5.6	1.3
Colon surgery	9.4	5.6
Coronary bypass with chest and donor incision	4.5	2.9
Gall bladder	2.5	0.6
Hip prosthesis	2.6	1.3
Open reduction of fracture	4.2	1.7
Peripheral vascular bypass surgery	2.5	6.7
Rectal surgery	2.3	7.4
Thoracic surgery	6.1	1.1
Thyroid and/or parathyroid	0.3	0.3

INICC: International Nosocomial Infection Control Consortium (30 countries from 4 continents; 2005–2010); CDC-NHSN: Centers for Disease Control and Prevention National Health Safety Network (US; 2006–2008)

Appendix 3 | ASEPSIS grading system^[37,186]

	Criterion	Points
A	Additional treatment:	
	- Antibiotics	10
	- Drainage of pus under local anaesthetic	5
	- Debridement of wound (general anaesthetic)	10
S	Serous discharge*	Daily 0-5
E	Erythema*	Daily 0-5
P	Purulent exudate*	Daily 0-10
S	Separation of deep tissue*	Daily 0-10
I	Isolation of bacteria	10
S	Stay as inpatient prolonged over 14 days	5

*Scoring is according to proportion (%) of wound affected:

	0	<20	20-39	40-59	60-79	≥ 80
Serous exudate	0	1	2	3	4	5
Erythema	0	1	2	3	4	5
Purulent exudate	0	2	4	6	8	10
Separation of deep tissues	0	2	4	6	8	10

Category of infection

ASEPSIS score	Category
0-20	Satisfactory healing
10-20	Disturbance of healing
>20	Minor infection
>30	Moderate-to-severe infection
>40	Severe infection

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Appendix 4 Surgical wound classification ^[35,113,187]			
Category/class	Definition	Examples of surgery type	Risk of infection
Clean	An uninfected operative wound in which no inflammation is encountered and the respiratory, alimentary, genital or uninfected urinary tracts are not entered. In addition, clean wounds are primarily closed and, if necessary, drained with closed drainage. Operative incisional wounds that follow nonpenetrating (blunt) trauma should be included in this category if they meet the criteria*	Hernia, varicose veins, breast, cardiac, vascular and orthopaedic implants	1-5%
Clean-Contaminated	Operative wounds in which the respiratory, alimentary, genital or urinary tracts are entered under controlled conditions and without unusual contamination. Specifically, operations involving the biliary tract, appendix, vagina and oropharynx are included in this category, provided no evidence of infection or major break in technique is encountered	Elective cholecystectomy	3-11%
Contaminated	Open, fresh, accidental wounds. In addition, operations with major breaks in sterile technique (e.g. open cardiac massage) or gross spillage from the gastrointestinal tract, and incisions in which acute, nonpurulent inflammation is encountered including necrotic tissue without evidence of purulent drainage (e.g. dry gangrene) are included in this category	Elective colorectal	10-17%
Dirty or Infected	Includes old traumatic wounds with retained devitalised tissue and those that involve existing clinical infection or perforated viscera. This definition suggests that the organisms causing post-operative infection were present in the operative field before the operation	Drainage of abscess, faecal peritonitis	>27%

*CDC guidance for SSI surveillance advises that the following types of surgery should not be classified as clean: appendix surgery, bile duct, liver or pancreatic surgery, gall bladder surgery, colon surgery, rectal surgery, small bowel surgery and vaginal hysterectomy

Appendix 5 Elements of the WHO Surgical Safety Checklist ^[71]		
<p>Sign in (before induction of anaesthesia)</p> <ul style="list-style-type: none"> ■ Patient has confirmed identity, site, procedure, consent ■ Site marked/not applicable ■ Anaesthesia safety check completed ■ Pulse oximeter on patient and functioning ■ Does patient have a: <ul style="list-style-type: none"> - Known allergy: no/yes? - Difficult airway/aspiration risk: no/yes — and equipment/assistance available? - Risk of >500ml blood loss (7ml/kg in children): no/yes — and adequate intravenous access and fluids planned? 	<p>Time out (before skin incision)</p> <ul style="list-style-type: none"> ■ Confirm all team members have introduced themselves by name and role ■ Surgeon, anaesthesia professional and nurse verbally confirm patient, site, procedure ■ Anticipated critical events: <ul style="list-style-type: none"> - Surgeon reviews: what are the critical or unexpected steps, operative duration, anticipated blood loss? - Anaesthesia team reviews: are there any patient-specific concerns? - Nursing team reviews: has sterility (including indicator results) been confirmed? Are there equipment issues or concerns? ■ Has antibiotic prophylaxis been given within the last 60 minutes? <ul style="list-style-type: none"> - Yes/not applicable ■ Is essential imaging displayed? <ul style="list-style-type: none"> - Yes/not applicable 	<p>Sign out (before the patient leaves the operating room)</p> <ul style="list-style-type: none"> ■ Nurse verbally confirms with the team: <ul style="list-style-type: none"> - The name of the procedure recorded - That instrument, sponge and needle counts are correct (or not applicable) - How the specimen is labelled (including patient name) - Whether there are any equipment problems to be addressed ■ Surgeon, anaesthesia professional and nurse review key concerns for recovery and management of this patient

Appendix 6 | Pre-operative interventions for reduction of surgical site complications

Intervention	
All patients/procedures	
Education of patient/family/carer	<ul style="list-style-type: none"> ■ Explain and provide information on risk of surgical site complications and the actions taken to reduce risk
Assessment for and management of pre-operative malnutrition	<ul style="list-style-type: none"> ■ Pre-operative malnutrition is associated with increased post-operative morbidity and mortality, and longer hospital stays in adult and paediatric patients in a range of surgery types^[188-191] ■ Peri-operative nutritional support has been shown to improve clinical outcomes in patients undergoing major gastrointestinal surgery^[188]
Treatment of bacteriuria	<ul style="list-style-type: none"> ■ In a study of the pre-operative treatment of bacteriuria in patients undergoing posterior spinal fusion and instrumentation, significantly fewer patients in the group treated on the basis of urine culture results developed SSI than in the untreated group^[192]
Control of blood glucose	<ul style="list-style-type: none"> ■ Patients with diabetes are at higher risk of SSI than patients without diabetes^[71] ■ Blood glucose levels of diabetic patients should be monitored and controlled to <11mmol/l or 200mg/dl^[193]
Maintenance of normothermia (avoidance of hypothermia) unless otherwise indicated	<ul style="list-style-type: none"> ■ Pre-operative hypothermia occurs in about half of all surgical patients^[194] ■ Hypothermia may delay healing and predispose patients to SSI through effects on the immune system and vasoconstriction^[194,195] ■ Maintain normothermia (e.g. body temperature $\geq 35.5^{\circ}\text{C}$)^[30] ■ Active warming may reduce the incidence of SSI^[196]
Administration of appropriate prophylactic antibiotics as indicated according to local guidelines	<ul style="list-style-type: none"> ■ Ensure administration of prophylactic antibiotics within the optimal time (often one hour depending on the antibiotic in use) prior to incision ('blade to skin') to maximise tissue concentration^[30,71,193] ■ Adjust dose according to patient weight^[30] ■ Repeat dosing as indicated according to the antibiotic in use and duration/type of surgery
Patient showers or baths on the day of surgery	<ul style="list-style-type: none"> ■ Commonly practiced, using soap or an antiseptic agent, but the effect on the incidence of surgical site complications is not known^[131] ■ There is no clear evidence of superiority of any particular wash product in reducing incidence of SSI^[197]
Use of clippers to remove hair pre-operatively	<ul style="list-style-type: none"> ■ Clippers may be associated with fewer SSIs than razors^[198] ■ Only remove hair if necessary^[30]
Management of hydration/fluid levels appropriately	<ul style="list-style-type: none"> ■ Fluid overload may cause soft tissue oedema and impair tissue oxygenation, delay wound healing and increase risk of other post-operative complications^[199,200] ■ Ensure adequate hydration but not fluid overload
Management of bleeding/thrombotic risk in patients on oral anticoagulants	<ul style="list-style-type: none"> ■ Patients about to undergo surgery and who are receiving long-term anticoagulation should be assessed carefully for the risk of intra-operative and post-operative bleeding ■ Management will depend on the anticoagulant in use, reason for anticoagulation, risk of bleeding, procedure type and urgency, but may include cessation of the anticoagulant or replacement with a shorter acting agent such as heparin peri-operatively^[201]
Location of heparin injection sites away from operative site	<ul style="list-style-type: none"> ■ Haematoma is more common if the heparin injection site is relatively close to the incision^[202,203]
Use of antifibrinolytic agents	<ul style="list-style-type: none"> ■ Antifibrinolytic agents such as tranexamic acid and aprotinin have been found to significantly reduce the need for blood transfusion in a range of types of surgery^[204]
Use of an operative safety checklist	<ul style="list-style-type: none"> ■ WHO Surgical Safety Checklist^[71], for example ■ An initial international multicentre cohort study showed the checklist to reduce mortality, overall complications and rates of SSI^[120]. A systematic review and meta-analysis concluded that evidence is highly suggestive of a reduction in post-operative complications^[205]
Interventions for selected patients/procedures	
Nasal bacteriological evaluation for <i>Staphylococcus aureus</i>	<ul style="list-style-type: none"> ■ Nasal carriage of <i>S. aureus</i> increases the risk of SSI after major heart surgery, breast reconstruction and implant surgery and orthopaedic surgery^[104,206,207] ■ Test: <ul style="list-style-type: none"> - Patients undergoing cardiac surgery or surgery resulting in an implant (e.g. arthroplasty, breast implant surgery) - Paediatric patients - Patients who are healthcare workers or institutional residents ■ If positive, decolonise according to local protocol

Appendix 7 | Intra-operative interventions for reduction of surgical site complications

Intervention	Notes
All patients/procedures	
Compliance of operating room personnel with hygiene measures	<ul style="list-style-type: none"> ■ Although intuitively prudent, few controlled studies have examined the impact of these measures on incidence of surgical site complications ■ For example: covering hair, face masks, operating room suits, hand/forearm preparation, sterile gloves, sterile gowns, removal of hand jewellery, artificial nails and nail polish^[68,71,73]
Minimisation of operating room traffic	<ul style="list-style-type: none"> ■ SSI usually originates from the patient's own flora, but airborne microorganisms may be an issue also^[208] ■ The level of microbes in operating room air is directly proportional to the number of people^[208,209] ■ Minimising operating room traffic will decrease door opening and movement that will disturb airflow and distribute microorganisms
Maintenance of normothermia unless otherwise indicated	<ul style="list-style-type: none"> ■ See Appendix 6, page 25
Control of blood glucose	<ul style="list-style-type: none"> ■ See Appendix 6, page 25
Optimal oxygenation	<ul style="list-style-type: none"> ■ Supplemental oxygen may aid wound healing by preventing tissue hypoxia at cut tissue edges ■ Supplemental oxygen is widely used to achieve haemoglobin saturation of >95%^[73] ■ A meta-analysis of RCTs concluded that supplemental oxygen prevents SSI^[210] ■ Subgroups that appear to benefit include patients undergoing colorectal surgery^[210]
Use of antiseptic skin preparation	<ul style="list-style-type: none"> ■ Using an antiseptic to prepare the skin of the surgical site reduces skin microbiological load and reduces contamination of the surgical field by skin flora ■ Although aqueous or alcohol-based solutions of povidone-iodine or chlorhexidine are most widely used, it is not clear which is the most effective antiseptic^[211-214]
Use of a skin sealant	<ul style="list-style-type: none"> ■ Cyanoacrylate skin sealant has been investigated in cardiothoracic and orthopaedic surgery patients to reduce the risk of incision contamination during surgery ■ In studies, use of skin sealant was associated with a significant reduction in: <ul style="list-style-type: none"> - Colony forming units on sutures^[215] and sternal incision site^[216] - Incidence of SSI^[217,218]
Avoidance of excessive traction and tissue manipulation	<ul style="list-style-type: none"> ■ Good surgical technique, including gentle handling of tissues, is believed to reduce the risk of surgical site complications^[85]
Use of wound edge protectors/guards	<ul style="list-style-type: none"> ■ A wound edge protector is a device that usually comprises one or two semi-rigid rings with drapes attached; it is inserted into the incision during surgery to protect the wound edges from further trauma or microbial exposure and is removed before incision closure ■ Mainly used in colorectal surgery, although results of RCTs have been contradictory^[219,220]
Use of antifibrinolytic agents	<ul style="list-style-type: none"> ■ See Appendix 6, page 25 ■ A Cochrane review concluded that topical application of tranexamic acid reduces bleeding and blood transfusion^[220]
Use of triclosan-coated sutures	<ul style="list-style-type: none"> ■ A systematic literature review and meta-analysis concluded that triclosan-coated sutures significantly reduced the incidence of SSI after clean, clean-contaminated and contaminated surgery^[221]
Use of gentamicin-impregnated collagen sponges	<ul style="list-style-type: none"> ■ Gentamicin-impregnated collagen sponges are placed in surgical incisions to provide high local antibiotic concentrations; the sponge is resorbed and does not require removal ■ The sponges have been investigated in several different surgery types. Significant reductions in rates of SSI have been found in meta-analyses of studies in cardiac surgery and colorectal surgery, and in a cohort study of femoropopliteal bypass surgery^[222-225]
Covering of wound with an appropriate sterile dressing	<ul style="list-style-type: none"> ■ Although dressings have not been shown to reduce the incidence of SSI, they provide a barrier to external contamination, prevent the wound from catching on clothing, absorb any leakage and may reduce patient anxiety^[71,193] ■ Dressings should be applied under sterile conditions at the end of surgery before the patient leaves the operating room ■ Particularly in paediatric and elderly patients, the dressing selected should be unlikely to cause skin trauma ■ It is not yet clear whether the use of a dressing containing an antiseptic agent confers benefit in the prevention of SSI^[125] ■ Consider incisional NPWT for patients with closed incisions who are at high risk of surgical site complications (see pages 10-11)

Appendix 7 | Continued

Interventions for selected patients/procedures

Changing gloves during procedure and/or before closure of wound, and/or double gloving	<ul style="list-style-type: none"> ■ Although widely practiced, evidence of effect on SSI rates is inconclusive^[226] ■ May reduce incidence of SSI by reducing glove perforations^[227] ■ Often reserved for high risk/contaminated procedures
Cavity irrigation/intra-operative wound irrigation	<ul style="list-style-type: none"> ■ Washing out wound cavities with an antiseptic/antibiotic solution is performed to reduce bacterial load, and to remove blood clots and necrotic tissue^[228] ■ A meta-analysis of studies in abdominal surgery showed a reduction in SSI rates, with the most marked change in colorectal surgery^[228] ■ Antiseptics are used in preference to antibiotics in paediatric patients because of potential problems of antibiotic overdosing due to tissue absorption
Hyperoxygenation	<ul style="list-style-type: none"> ■ Hyperoxia has been suggested to reduce SSI by enhancing production of reactive oxygen species involved in killing pathogens and by reducing cytokine production^[230] ■ Studies have produced conflicting results^[230], but there may be a reduction in SSI in patients who have had colorectal surgery^[231] ■ However, there are concerns that the potential benefits of hyperoxia are outweighed by detrimental effects at the extremes of age^[232]

Appendix 8 | Post-operative interventions for reduction of surgical site complications

Intervention	Notes
All patients/procedures	
Maintain normothermia	<ul style="list-style-type: none"> ■ See Appendix 6, page 25
Control blood glucose	<ul style="list-style-type: none"> ■ See Appendix 6, page 25
Ensure optimal oxygenation	<ul style="list-style-type: none"> ■ See Appendix 7, pages 26–27
Locate heparin injection sites away from operative site	<ul style="list-style-type: none"> ■ See Appendix 6, page 25
Use of antifibrinolytic agents	<ul style="list-style-type: none"> ■ See Appendices 6 and 7, pages 25–27
Maintain dressing over wound for at least 48 hours	<ul style="list-style-type: none"> ■ Epithelialisation of a closed surgical incision starts within hours of surgery and is usually complete within 48 hours^[68,233,234] ■ Dressings should be inspected regularly and left in place for the first 48 hours post-operatively to reduce the risk of contamination^[71,193] ■ If dressing change is required before 48 hours, the dressing should be changed using aseptic technique ■ Consider incisional NPWT for high risk patients, see Tables 8–9 (pages 10–11)
Visitor restrictions and hygiene measures	<ul style="list-style-type: none"> ■ Where restrictions on visiting are in place and/or where hand cleansing/protective clothing is necessary, ensure these are clearly explained and demonstrated to visitors
Patient, family and carer education	<ul style="list-style-type: none"> ■ At discharge, explain/provide information on: <ul style="list-style-type: none"> – How to care for the wound and dressing – How to recognise problems and who to contact
Patient-reported outcomes/feedback questionnaire	<ul style="list-style-type: none"> ■ Patient-reported outcome measures are increasingly being used for surveillance and monitoring, and may influence reimbursement in some healthcare systems
Perform surveillance for SSI and compliance and feedback	<ul style="list-style-type: none"> ■ Active surveillance may decrease SSI rates^[235,236] ■ Collect data on surgical site complications and compliance with bundle measures^[71] ■ Supply feedback to individual surgeons and other surgical team members^[30] ■ Monitor trends

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Appendix 9 | Clinical studies of NPWT on closed surgical incisions

This summary is representative of published papers on NPWT for closed surgical incisions from 2011 onwards, but does not comprise the entire literature

Author/journal	Type	Purpose	Outcomes
Reviews			
Hyldeg N, et al. <i>Br J Surg</i> 2016; 103; 477-86 ^[10]	Meta-analysis	Evaluate whether NPWT reduces post-operative wound complications when applied to closed surgical incisions	<ul style="list-style-type: none"> ■ Included 10 RCTs: orthopaedic, cardiothoracic, trauma and plastic surgery ■ NPWT was associated with a significant reduction in wound infection (RR 0.54 (95% CI 0.33-0.89)) and seroma formation (RR 0.48 (95% CI 0.27-0.84)) vs standard care ■ Reduction in wound dehiscence was not significant vs standard care (RR 0.69 (95% CI 0.47-1.01))
Sandy-Hodgetts K, et al. <i>JBI Database System Rev Implement Rep</i> 2015; 13(1): 253-303 ^[136]	Systematic review	Evaluate NPWT in preventing surgical wound complications in closed surgical incisions	<ul style="list-style-type: none"> ■ Included 8 studies: trauma, cardiothoracic, orthopaedic, abdominal and vascular surgery ■ NPWT was associated with a statistically significant reduction in SSI vs standard care (p=0.001) ■ Conflicting results were found for wound dehiscence and seroma
Scalise A, et al. <i>Int Wound J</i> 2015 Oct 1. doi: 10.1111/iwj.12492 ^[20]	Systematic review	Evaluate the effect of NPWT on surgical sites healing by primary intention	<ul style="list-style-type: none"> ■ Included: 1 biomedical engineering study, 2 animal studies, 15 human studies, 6 RCTs, 5 prospective cohort studies, 7 retrospective analyses ■ Concluded that NPWT over closed surgical incisions decreases the incidence of infection, sero-haematoma formation and on the re-operation rates ■ Data on dehiscence was inconclusive
Semsarzadeh NN, et al. <i>Plast Reconstr Surg</i> 2015; 136(3): 592-602 ^[153]	Meta-analysis	Evaluate the effectiveness of closed-incision NPWT in lowering SSI incidence compared with standard dressings	<ul style="list-style-type: none"> ■ Overall weighted average rates of SSI in the NPWT and control groups were 6.61% and 9.36%, respectively ■ Across all studies, odds of SSI decreased 0.564 (p<0.00001) ■ Overall rates of dehiscence in NPWT and control groups were 5.32% and 10.68%, respectively, but study heterogeneity prevented true meta-analysis
Horch RE. <i>J Wound Care</i> 2014; 24(sup4b): 21-28 ^[237]	Review	Review scientific and clinical research relevant to incisional NPWT	<ul style="list-style-type: none"> ■ In healthy humans, NPWT increased saturated oxygen levels and blood flows to skin ■ Incisional NPWT -> reduction in seroma formation following abdominoplasty and dermolipidectomy -> earlier drain removal and decreased length of hospitalisation ■ In several clinical studies, NPWT over incisions was associated with lower rates of overall wound complications, wound dehiscence and seroma formation
Webster J, et al. <i>Cochrane Database Syst Rev</i> 2014; 10: CDO09261 ^[161]	Updated systematic review	Updated systematic review for the effects of NPWT on post-operative wounds expected to heal by primary intention	<ul style="list-style-type: none"> ■ Included 9 RCTs: 3 on skin grafts; 7 on closed incisions (4 orthopaedics; 2 general surgery/trauma) ■ NPWT compared with standard dressings: <ul style="list-style-type: none"> - SSI: 4 trials analysed — no differences in the rate of SSIs - Dehiscence: 2 studies analysed — no between group differences
Ingargiola MJ, et al. <i>ePlasty</i> 2013 Sep 20; 13: e49. eCollection 2013 ^[154]	Systematic review	Evaluate the effect of incisional NPWT on surgical sites healing by primary intention	<ul style="list-style-type: none"> ■ 5 RCTs, 5 observational studies ■ 6 studies compared NPWT with sterile dry dressings ■ Significant decrease in rates of infection when using NPWT ■ Decreased dehiscence rates with NPWT seen in some studies, but results were inconclusive ■ Data inconclusive for seroma, haematoma, skin necrosis
Karlakki S, et al. <i>Bone Joint Res</i> 2013;2(12):276-84 ^[8]	Literature review	Identify evidence within orthopaedic surgery and other surgical disciplines	<ul style="list-style-type: none"> ■ 33 publications were identified, including 9 clinical study reports from orthopaedic surgery; 4 from cardiothoracic surgery; and 12 from abdominal, plastic and vascular disciplines ■ 2 RCTs (orthopaedic and cardiothoracic) show evidence of reduced incidence of wound healing complications after 3-5 days of NPWT ■ Reduction in haematoma and seroma, accelerated wound healing and increased lymphatic clearance are significant mechanisms of action
Stannard JP, et al. <i>Int Wound J</i> 2012; 9(suppl 1): 32-39 ^[155]	Review	Review focusing on clinician experience and a literature review	<ul style="list-style-type: none"> ■ NPWT over clean surgical wounds following orthopaedic and cardiac surgery, including in morbidly obese patients, results in no or low rates of SSI and wound dehiscence ■ Precise indications to be determined: use for patients with a clean, closed post-operative incision that is at high risk for infection and/or wound dehiscence ■ High risk is associated with injury or fracture type; soft tissue injury or contusion; patient factors ■ The potential of NPWT to prevent SSI and dehiscence suggests cost savings

Appendix 9 continued

Clinical studies and reviews by surgical specialty

Abdominal surgery

Pellino G, et al. <i>Updates Surg</i> 2015; 67: 235-45 ^{[135]*}	Literature review	Assess the effects of NPWT on surgical wound healing by primary closure after colorectal surgery compared with conventional dressings	<ul style="list-style-type: none"> Main analysis involved 5 studies: 3 prospective and 2 retrospective NPWT was helpful in all studies: positive outcomes included reductions in wound complications (SSI/seroma) and length of stay Portable NPWT may increase patient adherence and is easy for the patient to manage at home At present there are no widely accepted algorithms to select patients for prophylactic NPWT In the authors' practice, NPWT is considered for patients with at least two accepted predictors of SSI or when there is breakdown in peri-operative prophylactic measures
Pellino G, et al. <i>Surg Innov</i> 2014; 21(2): 2014-12 ^{[171]*}	Prospective pilot study	Evaluate whether NPWT reduces SSI and other wound-related complications in patients with Crohn's disease undergoing surgery	<ul style="list-style-type: none"> In comparison with patients receiving standard dressings (n=17), patients receiving NPWT (n=13) experienced significantly fewer wound complications (p=0.001) and SSI (p=0.017) Patients who received NPWT also had significantly shorter hospital stays (p=0.0007) No significant differences in cosmetic results were found
Pellino G, et al. <i>Int J Surg</i> 2014; 12: S64-S68 ^{[238]*}	Open label, prospective, controlled	Assess the efficacy of NPWT in preventing surgical site complications in breast and colorectal surgery	<ul style="list-style-type: none"> NPWT vs standard dressings significantly reduced SSI in both breast and colorectal surgery (p<0.05) In colorectal surgery, NPWT significantly reduced seroma (p=0.02), but not in breast surgery No significant differences were observed according to age
Selvaggi F, et al. <i>Surg Technol Int</i> 2014; 24: 83-89 ^{[239]*}	Prospective, open-label, controlled	Compare the effects of portable NPWT with gauze dressings after elective surgery for Crohn's disease	<ul style="list-style-type: none"> Patients receiving NPWT (n=25) vs gauze dressings (n=25) had significantly fewer surgical site complications: <ul style="list-style-type: none"> seroma — NPWT 8% vs gauze 44% (p=0.008) SSI — NPWT 8% vs gauze 49% (p=0.004) All SSIs in the NPWT group were superficial; in the gauze group 50% of SSIs were superficial, 33% were deep and 17% were organ/space In patients on steroids, there was a significant reduction in SSI in patients who received NPWT (p=0.001)
Bonds AM, et al. <i>Dis Colon Rectum</i> 2013; 56(12): 1403-8 ^{[240]**}	Single-centre retrospective	Evaluate known risk factors and the use of incisional NPWT on SSI rates in colorectal surgery	<ul style="list-style-type: none"> 32 patients received NPWT; 222 standard care 4 (12.5%) SSIs were in NPWT patients and 65 (29.3%) in patients with standard care Multiple logistic regression revealed that diabetes mellitus increased the risk of SSI, and the use of NPWT decreased the risk of SSI Obesity was associated with a trend towards increasing SSI

Cardiothoracic surgery

Jennings S, et al. <i>Heart Lung Circ</i> 2016; 25: 89-93 ^{[241]***}	Retrospective audit	Evaluate the effect of incisional NPWT on surgical sites healing by primary intention	<ul style="list-style-type: none"> Of 62 patients identified as having received NPWT, only one developed a sternal wound infection Statistically significant reduction in sternal wound infections against the predicted rate for both high- and low-risk groups (both p<0.05)
Witt-Majchrzak A, et al. <i>Polish J Surg</i> 2015; 86(10): 456-65 ^{[158]*}	RCT	Identify evidence within orthopaedic surgery and other surgical disciplines	<ul style="list-style-type: none"> 40 patients in each group Uneventful healing was significantly more frequent in the NPWT group vs standard dressings (92.5% vs 75%; p<0.05) Superficial SSI was less frequent in the NPWT group vs standard dressings (2.5% vs 17.5%; p<0.05)
Dohmen PM, et al. <i>Med Sci Monit</i> 2014; 20: 1814-25 ^[92]	Conclusions of a consensus meeting	Review focusing on clinician experience and a literature review	<ul style="list-style-type: none"> NPWT appears to prevent wound complications when used over clean, closed surgical incisions, including median sternal incisions Patients with 1 major risk factor (BMI <18 or ≥40; insulin-dependent diabetes mellitus or dialysis) are strong candidates for NPWT Patients with ≥2 intermediate risk factors may also benefit from NPWT NPWT strongly recommended in heart, lung and heart-lung transplant patients

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Appendix 9 continued			
Cardiothoracic surgery continued			
Dohmen PM et al. <i>GMS Hygiene Inf Control</i> 2014; 9(3): 1-4 ^[242]	Systematic literature review	Analyse whether NPWT is able to prevent post-sternotomy mediastinitis	<ul style="list-style-type: none"> Three studies were included; each showed a reduction of mediastinitis in patients at high risk for SSI High risk factors for post-sternotomy mediastinitis included morbid obesity, insulin-dependent diabetes, chronic renal failure and bilateral mammary grafting
Grauhan O, et al. <i>Int Wound J</i> 2014; 11 Suppl 1: 6-9 ^{[243]**}	Prospective and retrospective audit	Evaluate incisional NPWT with respect to SSI after sternotomy	<ul style="list-style-type: none"> 237 patients treated with NPWT were analysed prospectively; 3,508 patients treated with conventional dressings were analysed retrospectively as controls NPWT group had a significantly lower SSI rate: 1.3% versus 3.4% in control group (p<0.05) After 6-7 days, incisions were closed in 234 of 237 NPWT patients
Grauhan O, et al. <i>J Thorac Cardiovasc Surg</i> 2013; 145:1387-92 ^{[157]**}	Prospective, open label (RCT)	Evaluate NPWT in the prevention of post-sternotomy wound infections in obese patients	<ul style="list-style-type: none"> Patients with BMI ≥30 received NPWT (n= 75) or standard dressings (n=75) Fewer patients in the NPWT group developed SSI (4% vs 16%; p=0.027) or dehiscence (p=ns)
Colli A. J <i>Cardiothorac Surg</i> 2011; Dec 6: 160 ^{[13]**}	Case series	Present an initial evaluation and clinical experience with NPWT for treating closed surgical incisions	<ul style="list-style-type: none"> 10 patients with a mean Fowler risk score of 15.1 (range 8-30) had NPWT immediately after surgery, left in place for 5 days After 5 days, wounds and surrounding skin showed complete healing, with the absence of skin lesions No device-related complications were observed 30 days after surgery, there were no wound complications
Obstetric/gynaecological surgery			
Bullough L, et al. <i>Clin Serv J</i> 2015; 2-6 ^{[244]*}	Retrospective audit	Evaluate the effect of incisional NPWT on surgical sites healing by primary intention	<ul style="list-style-type: none"> 239 patients received NPWT; 1,405 patients received a film dressing SSI rates: NPWT group (BMI >35) 0.4%; film dressing group (BMI <35) 3.6%
Hickson E, et al. <i>Surg Infect</i> 2015; 16(2): 174-77 ^{[108]*}	Retrospective audit	Compare SSI rates in women undergoing caesarean section before and after introduction of NPWT	<ul style="list-style-type: none"> Included the charts of 4,942 patients who underwent caesarean section over a 5-year period in which a range of interventions were introduced NPWT was used on patients at high risk of SSI High risk was defined as BMI>35 or ≥2 of diabetes mellitus, steroids or anticoagulants, autoimmune disease, blood disorder, immunosuppression, hypertension, history of wound infection/healing problems, pre-existing skin problems, emergency/urgent caesarean section After introduction of the high risk bundle (which included NPWT), overall SSI rate fell from 0.61% the previous year to 0.1% (p=ns)
Pappala S, et al. <i>Br J Obs Gynaecol</i> 2015; 122: 82 ^{[170]*}	Audit	Compare SSI rates in high risk women undergoing SSI before and after introduction of a bundle to reduce SSIs	<ul style="list-style-type: none"> 11 step bundle included NPWT High risk was defined as: BMI >35, diabetes and previous caesarean section SSI SSI rate in the general population before the bundle was 33.3% After introduction of the bundle, SSI rate in the high-risk women was 12.97% There were also reductions in return to theatre rates (3% to 0.5%) and readmission rate (3% to 0.54%)
Swift SH, et al. <i>J Reprod Med</i> 2015; 60(50): 211-18 ^{[245]**}	Cohort with historical control Pilot RCT	Evaluate the effect of single use NPWT on post-operative complications after caesarean delivery	<ul style="list-style-type: none"> 110 women with ≥1 risk factor for post-operative complications received NPWT after caesarean section Historical controls with ≥1 risk factor were selected NPWT group had a significantly lower rate of overall wound/infectious morbidity (21% vs 6.4%; p=-0.0007)
Chaboyer W, et al. <i>Healthcare</i> 2014; 2(4): 417-28 ^{[246]*}	Pilot RCT	Assess the effect of NPWT on SSI rates in obese women after elective caesarean section	<ul style="list-style-type: none"> 92 obese (pre-pregnancy BMI ≥30) were randomised: 46 received single-use NPWT and 46 received standard care SSI developed in 10/46 patients in the NPWT group and in 12/46 patients in the control group Relative SSI risk in the NPWT group was 0.81 (95% CI 0.38-1.68); for the number of complications excluding SSI, it was 0.98 (95% CI 0.34-2.79)

Appendix 9 continued

Orthopaedic surgery			
Gillespie B, et al. <i>Surg Innov</i> 2015; 22: 488-95 ^{[247]*}	Pilot RCT	To assess the use of NPWT to prevent infection and other wound complications in patients undergoing hip arthroplasty	<ul style="list-style-type: none"> Patients undergoing primary hip arthroplasty received NPWT (n=35) or standard hydrocolloid dressing (n=35) 2/35 patients in the NPWT group and 3/35 patients in the standard dressing group developed SSI (p=ns) The rate for overall complications (bleeding, bruising, haematoma, seroma, dehiscence) was significantly lower in the NPWT group (p=0.04)
Hudson D, et al. <i>Int Wound J</i> 2015; 12: 195-201 ^{[15]*}	Clinical evaluation	Evaluate a simplified disposable NPWT system	<ul style="list-style-type: none"> 20 patients received NPWT (16 closed surgical wounds, 2 traumatic wounds, 2 meshed split thickness skin grafts) 11/16 surgical incisions were closed by study end; of the 9 wounds not fully closed all but one wound were making progress to closure There was no evidence of increased risk of <i>de novo</i> infection during treatment with NPWT
Matsumoto T, et al. <i>Foot Ankle Int</i> 2015; 36(7): 787-94 ^{[248]*}	Retrospective cohort	Investigate the role of NPWT in decreasing wound healing problems after total ankle arthroplasty	<ul style="list-style-type: none"> Patients undergoing total ankle arthroplasty received NPWT (n=37) or standard hydrocolloid dressing (n=37) NPWT reduced wound healing problems with an odds ratio of 0.10 (95% CI 0.01-0.50; p=0.004) 3 patients in the control group and one in the NPWT group developed SSI (p=ns)
Adogwa O, et al. <i>The Spine Journal</i> 2014; 14: 2911-17 ^{[159]*}	Retrospective	Assess incidence of SSI and dehiscence in patients undergoing long-segment thoracolumbar fusion before and after the routine use of NPWT	<ul style="list-style-type: none"> 160 patients (NPWT n=46; non-NPWT n=114) There was a 50% decrease in wound dehiscence in the NPWT group in comparison with the non-NPWT group (6.38% vs 12.28%; p=0.02) SSI was also significantly decreased in the NPWT group in comparison with the non-NPWT group (10.63% vs 14.91%; p=0.04)
Brem MH, et al. <i>Int Wound J</i> 2014; 11 (suppl 1): 3-5 ^[133]	Literature review	Assess the effects of NPWT on closed orthopaedic surgical incisions	<ul style="list-style-type: none"> NPWT prevents haematoma and dehiscence after total ankle replacement or surgery for calcaneal fracture Reduced oedema, decreased pain and shorter healing time of the wounds were seen with NPWT Decreased infection rates and wound healing problems where NPWT was used on incisions after acetabular fracture Reduced incidence of seroma and improved wound healing where NPWT was used after total hip arthroplasty In patients with tibial plateau, pilon or calcaneus fractures requiring surgical stabilisation after blunt trauma, NPWT was associated with reduced risk of developing infection, and acute and chronic wound dehiscence
Pauser J, et al. <i>Int Wound J</i> 2014; doi:10.1111/iwj.12344 ^{[160]**}	RCT	Evaluate the use of NPWT on wound healing and seroma formation following hip hemiarthroplasty	<ul style="list-style-type: none"> 21 patients: n=11 NPWT (5 days); n=10 control Seroma developed in 36% of NPWT patients vs 80% of control patients Seroma volume at day 5: 0.26cm³ in NPWT patients vs 4.00cm³ in control patients
Pachowsky M, et al. <i>Int Orthop</i> 2012; 36: 719-22 ^{[149]**}	Prospective randomised evaluation	Evaluate the effect of incisional NPWT on wound healing and development of seromas after hip arthroplasty	<ul style="list-style-type: none"> Patients received NPWT (n=9) or a standard dressing (n=10) Seroma (assessed by ultrasound) developed in 90% of the dressing group and 44% of the NPWT group Average volume of seroma was significantly higher in the dressing group (5.08ml vs 1.97ml; p=0.021)
Orthopaedic trauma			
Stannard JP, et al. <i>J Orthop Trauma</i> 2012; 26(1): 37-42 ^{[156]***}	Multicentre RCT	Investigate the effect of NPWT on infection rate after surgical repair of lower limb fracture	<ul style="list-style-type: none"> After open reduction and internal fixation of fractures, 249 patients received either NPWT or standard dressings Significantly more infections were seen in the standard dressings group (23/122; 19%) than the NPWT group (14/141; 10%) (p=0.049) Dehiscence was significantly less common in the NPWT group than in the standard care group (8.6% vs 16.5%; p=0.044) Patients in the NPWT group were discharged 0.5 days earlier than those in the dressings group
Nordmeyer M, et al. <i>Int Wound J</i> 2015; doi: 10.1111/iwj.12436 ^{[49]*}	RCT	Evaluate clinical use/economic aspects of NPWT after stabilisation of spinal fractures	<ul style="list-style-type: none"> Patients received NPWT (n=10) or standard wound dressing (n=10) Seroma volume was significantly lower at days 5 and 10 in the NPWT group (p=0.05 NPWT vs control at both time points) Patients treated with NPWT needed fewer dressing changes and less time for wound care

Appendix 9 continued

Plastic/breast surgery			
Holt R, et al. <i>Br J Hosp Med</i> 2015; 76(4): 217-23 ^{[249]*}	Case series	Evaluate the use of NPWT on closed incision in patients undergoing oncoplastic surgery for breast cancer	<ul style="list-style-type: none"> ■ Patients (n=24) had oncoplastic surgery of the affected (therapeutic) breast and symmetrising surgery of the other breast ■ NPWT was applied to the affected breast; standard dressing to the other breast ■ Overall, wound breakdown occurred in 4.2% of therapeutic breasts and 16.7% in the contralateral breast
Galiano R, et al. Poster, 2014 ^{[134]*}	Randomised, intra-patient, multicentre	Assess the efficacy of single use NPWT in reducing complications after bilateral reduction mammoplasty and to assess aesthetic appearance and scar quality	<ul style="list-style-type: none"> ■ 200 patients received NPWT to one breast and standard care to the other ■ Scar quality was assessed using VAS and POSAS ■ NPWT vs standard care: <ul style="list-style-type: none"> - Significantly fewer healing complications overall (p=0.004) - Significant reduction in incidence of dehiscence (16.2% vs 26.4%; p<0.001) - No significant differences in delayed healing at 7 or 10 days, or in infection rates - Significantly better scar quality at 42 and 90 day assessment (VAS and POSAS: p<0.001)
Pellino G, et al. <i>Int J Surg</i> 2014; 12: S64-S68 ^{[237]*}	Open label, prospective, controlled	Assess the efficacy of NPWT in preventing surgical site complications in breast and colorectal surgery	<ul style="list-style-type: none"> ■ NPWT vs standard dressings significantly reduced SSI in both breast and colorectal surgery (p<0.05) ■ In colorectal surgery, NPWT significantly reduced seroma (p=0.02), but not in breast surgery ■ No significant differences were observed according to age
Vascular surgery			
Hasselmann J, et al. <i>World Congress Surg</i> 2015; 223.05 ^{[250]*}	RCT	Evaluate whether NPWT on primarily closed groin incisions may prevent SSI in vascular surgical patients	<ul style="list-style-type: none"> ■ NPWT vs standard dressings ■ N=81 patients: NPWT group included 64 groin incisions; control group included 63 ■ SSI in the NPWT group vs control was 4.7% vs 11.1% (p=0.18) ■ Overall wound complication rate was 12.5% (NPWT) vs 15.6% (control) (p=0.59)
Koetje JH, et al. <i>Surg Res Pract</i> 2015; 2015; 1-4 ^{[251]**}	Non-randomised comparison	Analyse the effect of NPWT on rate of post-operative wound infections following groin surgery	<ul style="list-style-type: none"> ■ 90 consecutive patients (n=40 NPWT) ■ No significant differences between the NPWT and control groups in rates of wound healing disturbances or SSI were detected
Weir G. <i>Int Wound J</i> 2014; 11 Suppl 1: 10-12 ^{[252]**}	Prospective case-control study	Assess wound complications in patients undergoing vascular bypass procedures	<ul style="list-style-type: none"> ■ NPWT vs standard wound dressing in 8 patients ■ No significant wound complications occurred in wounds treated with incisional NPWT, compared with 3 significant complications in control wounds ■ No observed increase in haemorrhage in high-risk patients with severe comorbidities ■ Data were suggestive of potential reduction in wound complications in closed vascular incisions
Matatov T, et al. <i>J Vasc Surg</i> 2013; 57(3): 791-95 ^{[16]**}	Retrospective review	Investigate whether NPWT could reduce the risk of groin wound infection after vascular surgery	<ul style="list-style-type: none"> ■ 90 patients with 115 groin incisions ■ 52 incisions were treated with NPWT; 63 incisions were controls and received standard care ■ Overall infection rates were significantly lower in the NPWT group: 6% vs 30% (p=0.0011)
ns=not significant; RCT=randomised controlled trial *PICO Single Use Negative Pressure Wound Therapy (Smith & Nephew) **Prevena Incision Management System (KCI) ***V.A.C (KCI)			

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CONSENSUS DOCUMENT

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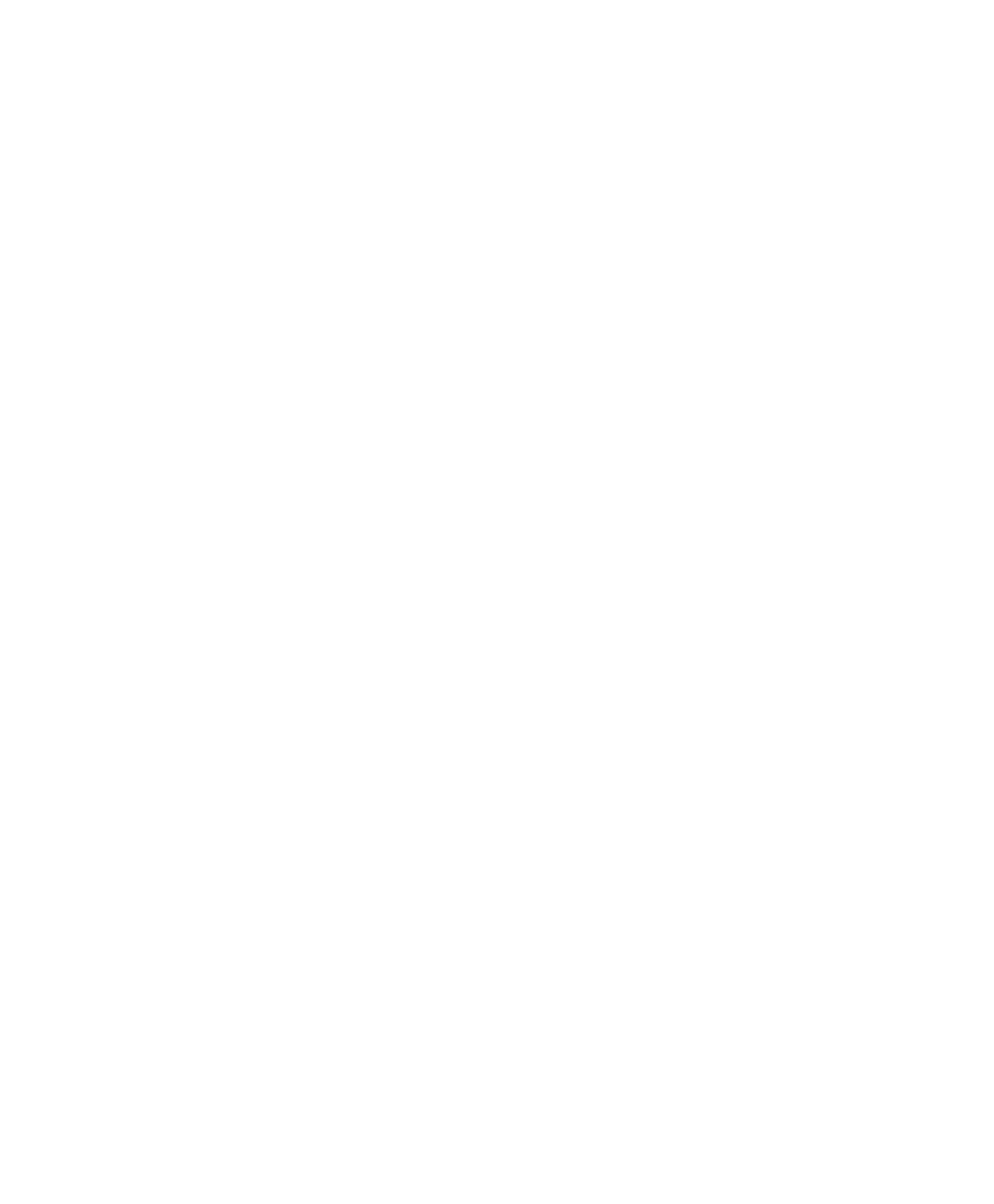
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