Uncertainties: Should dressings be used to cover primary surgical wounds?

Jane M Blazeby^{2,3} on behalf of the Bluebelle Study Group*

*Bluebelle grant co-applicants: Lazaros Andronis¹, Jane Blazeby^{2,3}**, Natalie Blencowe^{2,3}, Melanie Calvert¹, Joanna Coast¹, Tim Draycott⁴, Jenny Donovan², Rachael Gooberman-Hill⁵, Robert Longman³, Laura Magill⁶, Jonathan Mathers¹, Tom Pinkney^{1,6}, Barney Reeves⁷, Chris Rogers⁷, Andrew Torrance⁶, Trudie Young⁸, Mark Woodward³

*Other members of the Bluebelle Study Group: Gemma Clayton⁷, Jo Dumville⁹, Lucy Ellis⁶, Rhiannon Macefield², Christel McMullan¹, Thomas Milne², Helen van der Nelson⁴, Alexandra Nicholson², Leila Rooshenas², Dimitrios Siassakos⁴, Sean Strong², Daisy Townsend², Cathy Winter⁴

**Author for correspondence, Professor of Surgery & Honorary Consultant Surgeon, j.m.blazeby@bristol.ac.uk, Tel: 00 44 117 9287332

- 1. School of Health and Population Sciences, University of Birmingham, Birmingham UK
- 2. Centre for Surgical Research, School of Social and Community Medicine, University of Bristol,
- 3. Division of Surgery, Head and Neck, University Hospitals Bristol NHS Foundation Trust, Bristol, UK
- 4. North Bristol NHS Trust, Bristol
- 5. Musculo-Skeletal Research Unit, School of Clinical Sciences, University of Bristol
- 6. Academic Department of Surgery, Queen Elizabeth Hospital, University of Birmingham,
- 7. Clinical Trials and Evaluation Unit, School of Clinical Sciences, University of Bristol, Bristol
- 8. Welsh Wound Innovation Centre, Rhodfa Marics, Ynysmaerdy, Pontyclun, Rhondda Cynon Taf,
- School of Nursing, Midwifery & Social Work, University of Manchester
 Introduction (1200-1500 words)

Every week thousands of operations are performed worldwide. At the end of most procedures the skin incision is closed with sutures, clips, or adhesive strips. After skin closure it is common for a dressing to be applied over the wound, although in some areas of surgery the closed wounds are routinely left uncovered. Whether it is effective and cost effective to use dressings routinely, however, is uncertain.

Dressings placed over an already closed wound have several theoretical benefits, although evidence to support these claims is weak. Practical advantages are management of wound exudates and prevention of wound damage from inadvertent disturbance. Psychologically, patient anxiety may be reduced if the incision is covered and not able to be seen. Conversely, leaving a wound without a dressing avoids the need for painful dressing removal and enables the patient and health care professionals to see the wound. Easy visibility may reduce patient anxiety about the unknown beneath a dressing and allow for earlier diagnosis of an impending wound problem. In addition to the practical and psychological controversies that surround the use of wound dressings there is uncertainty about their role in the prevention of surgical site infection (SSI). Wound dressings may limit SSI by reducing external contamination with bacteria, or increase SSI by incubating contained bacteria in the local environment created by the dressing.

Another concern related to the generally widespread use of dressings is their cost and the resource implications for NHS staff required to change and remove dressings. Costs vary from about £0.10 for a basic gauze dressing, up to £0.50 for an adhesive transparent dressing, through to expensive "interactive" dressings with claimed therapeutic properties that may cost up to £20 or topical negative pressure therapy dressings (for use on an already closed primary wound) that can cost as much as £100 per week (ref BNF). Tissue adhesive "glue" may also be used "as-a-dressing" on an already closed primary wound (refs). A vial of tissue adhesive that will cover a 20cm closed wound costs between £6 and £20. There are therefore a variety of practical, psychological, clinical and cost-

related issues to be considered when using a dressing or not on a primary wound. It is, however, SSI risk that is most often the focus of research in this field.

SSI is a major concern following surgery. After high risk procedures (e.g. unplanned abdominal surgery) SSI rates may reach 20% although in elective clean surgery SSI rates are frequently less than 5% (<3% in hernia surgery and <1% in surgery involved prosthetic implants) (refs). Whilst many SSIs resolve with simple antibiotic treatment, the more serious ones cause pain, discomfort and inconvenience, and, after some operations, SSI will threaten the principal outcome of the procedure, the future health of the patient and may even be life threatening. Surgical site infection also has major costs for health services. Indeed it has been estimated that the NHS and societal cost of treating an SSI ranges from £5 to over £10K (Tanner/Jenks). Whilst it is often a main outcome of research in this area, SSI can be difficult to define and measure. The existing tools used in surveillance and research (the Centres for Disease Control and Prevention (CDC) criteria and ASEPSIS) have limited validation and patient input, and do not identify SSI consistently. In addition, as most SSIs occur after hospital discharge capturing real rates is challenging: surgical review of all wounds post-discharge is costly; measures such as receipt of antibiotics will not necessarily reflect the presence of a wound infection; and self-report may be inaccurate because tools have limited development and validation for patient use. There are also challenges in measuring other endpoints associated with wounds and dressings such as practical management of exudate, or patient and clinician experience of dressings; to date, there are no validated tools available for this purpose. These difficulties underline the need for methodological research in this field as well as the need to understand the clinical and cost-effectiveness of different dressing types or leaving closed primary wounds exposed without a dressing (referred to in the remainder of the paper as "no dressing").

What is the evidence of uncertainty?

A Cochrane systematic review summarising evidence for the use of dressings to prevent SSI was published in 2011 and updated in 2014(refs). Twenty randomised controlled trials (RCTs) were

included which examined types of dressing and "no dressing" on a closed primary wound to reduce SSI. The review did not include search terms of tissue adhesive "as-a-dressing". All trials were at an unclear or high risk of bias and included studies were underpowered to detect SSI events. Just two studies compared wound dressing application with leaving wounds exposed, and the remainder compared two types of dressing. No evidence was identified to suggest that any dressing significantly reduced the risk of developing an SSI compared with leaving wounds exposed; neither did the review show any SSI benefit associated with particular dressing types. In the studies, precision around the risk of SSI occurring was often very large and uncertainty great, meaning that a real difference between dressings or no dressing use could not be excluded. Given the very low levels of certainty around the impact of dressing approaches on SSI incidence, the review concluded that current decision-making around dressings may need to be informed (perhaps for pragmatic reasons) by costs of dressings and practical issues such as wound symptom management. It also recommended that, if deemed a priority area for research, the design of future trials should focus on surgical procedures at highest risk of an SSI, as well as evaluating the dressings or approaches that health professionals use most widely; importantly, the review emphasised that any such study should be adequately powered.

We have recently updated the above review with searches to include terms for tissue adhesive "as-a-dressing" to cover an already closed primary wound. We screened over 300 abstracts, retrieved 25 full papers and included four RCTs (Parvizi, Romero, Grauhan, Al-Belasy). Trials were small, single centre, only undertaken in clinical areas and all at a high or unclear risk of bias. Currently, evidence for the effectiveness of tissue adhesive "as-a-dressing" is very poor.

Is ongoing research likely to provide relevant evidence?

Searches in the WHO International Clinical Trials Registry have identified on-going trials comparing advanced 'interactive' dressings with standard simple dressings. We were unable to find new main

trials with a comparison group of "no dressing" and trials evaluating tissue adhesive "as-a-dressing". There is an on-going NIHR feasibility study (The Bluebelle Study HTA 12/200/04) which will establish whether a definitive trial of different dressing types and "no dressing" is possible and a worthwhile investment for the NHS⁵. The feasibility work includes in-depth qualitative case studies with patients, surgeons, nurses and midwives exploring views and current practice of dressings, methodological work to improve outcome measures to use in a trial, and a pilot RCT to establish whether it is possible to randomise patients to "no dressing" and whether adherence to treatment allocation of "no dressing" is possible.

What dressings should we use or not use in the light of the uncertainty?

In light of uncertainties in this area it is difficult to provide practical guidance for wound dressing use in surgery, and therefore, there is a clear need for further research (Box 1). Perhaps an important step for all health professionals who regularly place dressings on already closed wounds is to consider the practice of others in this field - where no dressings are used and wounds are left exposed to heal. Whether knowledge that a dressing will not be used will influence the quality of skin closure is unknown. It is quite possible that if no wound dressing is planned that the skin closure is performed more carefully to ensure that there is less exudate making immediate practical wound care management acceptable to staff and patients. We suggest that surgeons reflect on the reasons for applying wound dressings and retain an "open mind" about whether or not they are necessary. We also recommend collaborative research endeavours between surgeons to answer these questions of importance to patients, staff and the NHS (Box 1).

We have read and understood the BMJ policy on declaration of interests and do not have any interests to declare. Box 3 shows how patients have been involved in the development of ideas for this article.

References

- 1. Walter CJ, Dumville JC, Sharp CA, Page T. Systematic review and meta-analysis of wound dressings in the prevention of surgical-site infections in surgical wounds healing by primary intention. Br J Surg. 2012 Sep;99(9):1185-94. doi: 10.1002/bjs.8812.
- 2. Dumville JC, Gray TA, Walter CJ, Sharp CA, Page T. Dressings for the prevention of surgical site infection. Cochrane Database Syst Rev. 2014 1;9:CD003091. doi:10.1002/14651858.CD003091.pub3. 3(BNF Joint Formulary Committee. British National Formulary. 68th ed. London: BMJ Group and Pharmaceutical Press; 2014).
- 4 Tanner J, Khan D, Aplin C, et al. Post-discharge surveillance to identify colorectal surgical site infection rates and related costs. J Hosp Infect 2009;72(3):243-50
- Jenks PJ, Laurent M, McQuarry S, et al. Clinical and economic burden of surgical site infection (SSI) and predicted financial consequences of elimination of SSI from an English hospital. J Hosp Infect 2014;86(1):24-33
- 7. The Bluebelle study: FeasiBiLity stUdy of complEx, simple and aBsEnt wound dressings in eLective surgery http://www.nets.nihr.ac.uk/projects/hta/1220004

Box 1. Recommendations for future research

- Can valid, reliable and acceptable patient centred methods for measuring SSI be established?
- Is it possible to develop an accurate and easy to use tool to assess symptoms and experiences associated with the practical issues of wound management in the early postoperative setting?
- What is the effectiveness and cost-effectiveness of tissue adhesive 'as-a-dressing' compared
 to standard adhesive (and/or absorbent) dressings to reduce SSI and improve practical
 wound management after surgery with a closed primary wound?
- Can surgeons and nurses work together to undertake a very large scale randomised controlled trial to assess the effectiveness, cost effectiveness and patient acceptability of dressing types and 'no dressings' on closed primary wounds and is such a large trial a worthwhile investment for the NHS?

Box 2 The bottom line

- Surgeons! Consider leaving a carefully closed wound exposed without a dressing
- Clinical staff changing dressings. Consider leave a wound undressed to heal.

Box 3 How patients were involved in the creation of this article

We have consulted widely with patients undergoing surgery to understand their experience of dressings, views of not having a dressing and the practical issues associated with incisions and dressings (ref Bluebelle). We have talked to patients who have tissue adhesive "as-a-dressing". Patient views led us to understand the advantages and disadvantages of dressing use which are described in the article and they informed the need to develop better research for measuring practical wound management problems.