

A prospective clinical pilot study comparing two post-operative dressings in the treatment of surgical incisions in volunteers

Objective: Surgical site infections (SSIs) are one of the leading causes of post-operative morbidity and mortality worldwide. The original post-operative dressing, gauze taped in place, did not protect the incision from contamination. A recent clinical trial demonstrated that transparent films were superior to gauze in reducing SSIs. Transparent films are semi-occlusive (semi-permeable, transparent). They protect the incision from contamination; however, one of the drawbacks of current films is that they may become dislodged during daily activities, such as showering. Patients may not realise that the integrity of the dressing has been compromised, leading to soiling of the incision and possible infection. DrySee (DrySee Inc., US) is a novel film dressing with a colorimetric indicator that alerts the patient when the dressing has been compromised.

Method: This trial compared the film dressing with the indicator (DSD) to a commonly used post-operative dressing comparator (Tegaderm + Pad; 3M, US). A 1.5cm incision was made in the volar forearm of volunteers. The incisions were randomly treated with the DSD or comparator dressing.

Results: A cohort of 20 volunteer patients was recruited. The DSD had a greater wear time and patients reported that the DSD dressing stayed in place better during activities compared to the comparator.

Conclusion: Overall, 75% of patients preferred DSD and 25% preferred the comparator.

Declaration of interest: This research was sponsored by an unrestricted grant from DrySee Inc., Houston, TX, US. The authors have no conflicts of interest to declare.

clinical trial • dressing indicators • surgical wounds • wound • wound care • wound dressing • wound healing

As many as 4% of patients worldwide suffer from wound complications following surgery, such as surgical site infections (SSIs) and dehisced wounds.¹ In addition to the personal suffering, the cost is crippling healthcare systems globally, particularly in low-to-middle-income countries.² In the US, the National Quality Forum (NQF) classified several SSIs as 'never events', refusing to reimburse hospitals for preventable SSIs.³ In an effort to improve identification and prevention of surgical wound complications (SWC) the International Surgical Wound Complication Advisory Panel (ISWCAP), in their 2018 consensus document, identified gaps in evidence in the field. ISWCAP suggested conducting further research into the use of advanced wound care dressings for surgical wounds.⁴

ISWCAP defines a surgical wound complication as disruption of normal wound healing following surgery.⁴ The most common source of bacteria in SWCs is skin flora;⁵ however, a key element in preventing SWCs, the post-operative dressing, has only recently received attention. The first surgical dressings consisted of gauze held in place with adhesive tape. These dressings did not protect the incision from external contamination.

The ideal post-operative dressing is semi-permeable and remains intact during normal activities, including showering. One of the improvements in surgical dressing technology, transparent films, are waterproof and allow patients to participate in their routine activities. Several studies suggest that transparent films are superior to gauze.⁶⁻⁸ In addition, ISWCAP recommends dressings that allow visual inspection of the incision for the first five post-operative days.⁴

One of the drawbacks of transparent films is that they can separate from the skin during activities such as showering. The patient is often unaware that the dressing integrity has been compromised. This trial evaluated a novel transparent film, DrySee (DSD; DrySee inc., US), as a surgical dressing. The DSD has a liquid indicator in the perimeter of the dressing that turns blue when moisture is present (Fig 1). It is indicated for wounds with low levels of exudate. Clinicians, patients and caregivers are alerted to the loss of dressing integrity and can replace the dressing when any portion of the perimeter changes to a blue colour. In addition, the dressing turns blue when the central pad is saturated with fluid, allowing the patient or provider to change the dressing.

Method

The clinical trial was conducted at a single research centre (SerenaGroup Advanced Wound, Hyperbaric and Research Center Monroeville, PA, US). The trial design was chosen to simulate a real-world setting that is not always achievable in animal studies. The forearm model

Kristy Breisinger,¹ Research Analyst; Kristina Harrell,¹ RN, Chief Nursing Officer; Laura Serena,¹ LPN, Chief Research Officer; Thomas E Serena,¹ MD, President and Trustee*

*Corresponding author email: serena@serenagroups.com

¹ SerenaGroup Research Foundation Cambridge, MA, US.

also involves the creation of low-exudate wounds consistent with the indications for both dressings studied. Each patient served as his or her own control. They received both dressings: one on each forearm. They were randomised with regards to which arm would receive a particular dressing. This ensured that one dressing was not applied more frequently to a given arm.

Volunteer subjects were recruited from the general population in Pittsburgh, PA, US, and they received a nominal stipend. The trial was approved by a central institutional review board (IRB) (Advarra, Inc. 6100 Merriweather Drive, Suite 600, Columbia, MD, US; Pro00053780), and the patients provided approved consent prior to enrolment, which included the use of photography.

Only subjects with a known allergy to the study agents were excluded from the trial. Patients with comorbidities were not excluded from this clinical trial, as is often the case in volunteer studies. The authors hoped to use a population that represented a typical post-operative group.

The skin on each forearm was prepared with chlorhexidine and the area of the incision anaesthetised with 2% xylocaine. A fluorescence image was obtained prior to creating the incision to ensure that the skin did not contain $>10^4$ colony forming units (CFU)/g using the validated MolecuLight device (MolecuLight, Canada). A single surgeon created a 1.5cm incision on the volar forearms of the volunteers, 5cm distal to the antebrachial fossa (Fig 2). The full-thickness incisions were closed with Steri-Strips (3M, US) once complete haemostasis was achieved. The subject's incisions were then randomised to receive either a Tegaderm + Pad (3M, US) transparent film dressing or a DrySee dressing with moisture detection. Both dressings are US Food and Drug Administration (FDA) cleared as non-significant risk devices. Patients were instructed to participate in normal daily activities, including showering.

The incisions were photographed three times per week using the MolecuLight device in non-fluorescence mode. The patients were followed for a total of 2 weeks post intervention. Data on dressing wear time, integrity and adverse events were collected every two days in the research centre. For this study, wear time was defined as the length of time the patient left the dressing in place before changing it. Dressing integrity was defined as the length of time that the dressing stayed in place. A survey was administered at the close of the study (details available on request).

Results

The average age of the volunteers was 52 years (range: 20–80 years). Among the cohort of 20 volunteers, 55% (11/20) reported no comorbidities; and 45% (9/10) reported at least one comorbid condition. The demographics for the volunteers is shown in Table 1.

During the study, the volunteers logged their wear

Fig 1. Liquid indicator in transparent dressing

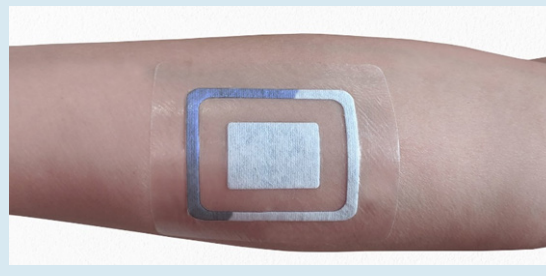


Fig 2. The study incision



Fig 3. Two weeks post wounding



time for the two comparative dressings. They were instructed to wear the dressing and continue their typical activities of daily living (ADLs). There were no differences in the wear time between the two transparent dressings. The average wear time across all subjects and treatments was 1.4 days. There was no difference in wear time based on the arm used for either dressing.

Among the participants, 95% (19/20) reported that

Table 1. Volunteer demographics

Subject	Age (years)	Gender	Comorbidities
1	70	Male	Coronary artery disease, valvular heart disease, cerebral vascular disease
2	60	Female	N/A
3	54	Male	Chronic venous insufficiency, venous leg ulceration
4	64	Female	N/A
5	42	Female	N/A
6	54	Female	Depression
7	52	Female	N/A
8	68	Female	Lymphoedema, chronic obstructive pulmonary disease, hypothyroid, hypertension, type 2 diabetes, anaemia, general body chronic pain, urinary retention, peripheral vascular disease, congestive heart failure
9	42	Male	Hypertension, gastroesophageal reflux disease, type 2 diabetes, diabetic neuropathy
10	63	Male	Hypertension, type 2 diabetes
11	60	Female	Anxiety, depression, psoriasis, insomnia, hyperlipidaemia, hypomagnesaemia, type 2 diabetes, gastroesophageal reflux disease, chronic venous insufficiency, chronic obstructive pulmonary disease, hypertension
12	72	Female	Fibromyalgia, lumbar fusion
13	80	Female	N/A
14	35	Male	N/A
15	32	Male	N/A
16	33	Female	N/A
17	32	Male	N/A
18	57	Female	N/A
19	59	Female	Diabetic neuropathy, type 2 diabetes, hyperlipidaemia, hypertension
20	20	Female	N/A
N/A—not available			

the DSD dressing maintained integrity during showering and typical ADLs (laundry, light exercise, use of technology) compared to 70% of the time for the comparator. In the post-trial survey, the subjects preferred the DSD dressing over the comparator in 75% of cases.

One patient had a mild allergic reaction to the adhesive in the comparator that resolved shortly after removal of the dressing. One patient had mild bleeding, requiring a dressing change, on the day of the procedure in the DSD arm. There were no infectious complications.

The volunteers denied having significant post procedure discomfort: only 20% of subjects experienced mild discomfort (2/10 on a numeric pain scale of 0–10, where 0 is no pain, and 10 is the worst pain imaginable) during the first two days. After two days the volunteers denied having pain greater than 2 on the numerical scale.

Discussion

Surgical wound complications are the most common wounds seen in the hospital and make up a growing percentage of patients in the outpatient wound clinic and home setting.⁹ The search for the ideal post-operative dressing continues in earnest. Most surgeons have abandoned gauze dressings in favour of surgical dressings that protect the wound from external contamination and allow visual inspection of the incision. Increasing in popularity, waterproof transparent films protect the incision and allow the patient to watch for signs of infection. The addition of a liquid colour indicator in the DSD dressing permits patients and clinicians to change the dressing when its integrity has been compromised.

This volunteer study reinforced the advantages of transparent dressings. The subjects were able to carry on their normal routine after the procedure. The majority reported that the DSD dressing held up during showering and other activities compared to the comparator. In addition, the subjects preferred the DSD dressing over the comparator. Several subjects reported that the indicator gave them a sense of security.

Limitations

The limitations of this study include the small sample size: the analysis is based on descriptive statistics. The trial was conducted at only one institution. Although having a single surgeon create all the incisions increased the standardisation in the trial, it limited the extrapolation of the data to all surgeons. Finally, incisions in volunteers are not equivalent to incisions in many surgical procedures.

The trial design allowed investigators to compare two different surgical dressings in a safe and controlled setting; there were no significant adverse events and minimal scarring at two weeks (Fig 3).

The limited inclusion and exclusion criteria and the inclusion of patients with comorbidities provided a real-world patient population. The trial design also permitted the study of surgical dressings prior to embarking on a larger clinical trial evaluating dressing efficacy in more extensive surgical procedures. Dressing manufacturers may wish to consider this design early in product development. There is little comparative effectiveness data on surgical dressings.¹⁰ Investigators could use this design or something similar to garner comparative effectiveness data.

Conclusion

Transparent films may be a good option for post-operative dressings. The addition of an indicator that

alerts the patient or clinician to a break in the integrity of the dressing may allow patients to remain active post procedure without fear of unknowingly disrupting the dressing. The forearm incision model may permit more robust comparative effectiveness studies in the future. **JWC**

References

- 1** Pearse RM, Moreno RP, Bauer P et al. Mortality after surgery in Europe: a 7 day cohort study. *Lancet* 2012; 380(9847):1059–1065. [https://doi.org/10.1016/S0140-6736\(12\)61148-9](https://doi.org/10.1016/S0140-6736(12)61148-9)
- 2** Nepogodiev D, Martin J, Biccard B et al. Global burden of postoperative death. *Lancet* 2019; 393(10170):401. [https://doi.org/10.1016/S0140-6736\(18\)33139-8](https://doi.org/10.1016/S0140-6736(18)33139-8)
- 3** Michaels RK, Makary MA, Dahab Y et al. Achieving the National Quality Forum's "Never Events": prevention of wrong site, wrong procedure, and wrong patient operations. *Ann Surg* 2007; 254(4):526–532. <https://doi.org/10.1097/01.sla.0000251573.52463.d2>
- 4** Sandy-Hodgetts K, Ousey K, Conway B et al. International best practice recommendations for the early identification and prevention of surgical wound complications. *Wounds International* 2020
- 5** Gould JM, Hennessey P, Kiernan A et al. A novel prevention bundle to reduce surgical site infections in pediatric spinal fusion patients. *Infect Control Hosp Epidemiol* 2016; 37(5):527–534. <https://doi.org/10.1017/ice.2015.350>
- 6** Hutchinson JJ, Lawrence JC. Wound infection under occlusive dressings. *J Hosp Infect* 1991; 17(2):83–94. [https://doi.org/10.1016/0195-6701\(91\)90172-5](https://doi.org/10.1016/0195-6701(91)90172-5)
- 7** Hutchinson JJ. A prospective clinical trial of wound dressings to investigate the rate of infection under occlusion. In: Harding K (ed). *Proceedings of the first European Conference on Advances in Wound Management*, London. Macmillan, 1993
- 8** Ubbink DT, Vermeulen H, van Hattem J. Comparison of homecare costs of local wound care in surgical patients randomized between occlusive and gauze dressings. *J Clin Nurs* 2008; 17(5):593–601. <https://doi.org/10.1111/j.1365-2702.2007.02032.x>
- 9** Lancet Commission on Global Surgery (2018). Number of surgical procedures (per 100,000 population). <http://www.data.worldbank.org/indicator/SH.SGR.PROC.P5> (accessed 23 August 2022)
- 10** Sood A, Granick MS, Tomaselli NL. Wound dressings and comparative effectiveness data. *Adv Wound Care (New Rochelle)* 2014; 3(8):511–529. <https://doi.org/10.1089/wound.2012.0401>

Reflective questions

- How might the incorporation of diagnostics into post-operative dressings improve patient adherence and satisfaction?
- How might volunteer studies supplement the literature on the prevention of surgical site infections?

Journal of Wound Care