

ORIGINAL ARTICLE

Open-label clinical trial comparing the clinical and economic effectiveness of using a polyurethane film surgical dressing with gauze surgical dressings in the care of post-operative surgical wounds

Ana Abejón Arroyo¹, Pablo López Casanova², José Verdú Soriano³ & Joan-Enric Torra i Bou⁴

¹ Supervisora de Enfermería COT, Hospital Clínico Universitario de Valladolid, Valladolid, Spain

² Unidad Integral de Heridas Crónicas, Departamento de Salud Elche-Hospital General, Agencia Valenciana de Salud, Elche, Alicante, Spain

³ Departamento de Enfermería Comunitaria, Medicina Preventiva y Salud Pública e Historia de la Ciencia, Universidad de Alicante, Alicante, Spain

⁴ Clinical manager Iberia Region, Smith & Nephew Advanced Wound Management, Sant Joan despi, Barcelona, Spain

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Correspondence to

J-E Torra i Bou, Bsc, Msc (Nursing)
Clinical Manager Iberia Region
Smith & Nephew Advanced Wound Management
Sant Joan despi, Barcelona, Spain
E-mail: Joanenric.torra@smith-nephew.com

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Abstract

Surgical site infection (SSI) is a common postoperative complication and can cause avoidable morbidity and excessive costs for the health service. Novel dressings, designed specifically for postoperative wounds, can help to reduce the risk of SSI and other complications such as blistering. This study compared the use of a new polyurethane film surgical dressing (Opsite Post-Op Visible, Smith & Nephew, Hull, UK) with gauze and tape in the management of postoperative wounds. The results show that the polyurethane film dressing results in a significant reduction in SSI (1.4% versus 6.6%, $P = 0.006$) as well as a reduction in other postoperative wound complications (e.g. blistering and erythema). Economic analysis conducted alongside the study suggests that these improved outcomes can be achieved at a lower treatment cost than gauze and tape dressings. The modest incremental cost of the polyurethane film surgical dressing is easily offset by the reduction in the costs related to treating SSI and other wound complications associated with gauze and tape dressings.

Introduction

According to the World Health Organization (WHO) (1), healthcare-associated infections (HAI), also known as nosocomial infections, are infections acquired in hospital settings, which were not present or incubating at the time of admission. They are the major cause of morbidity and mortality and a public health problem that is associated with a significant economic and human impact. The WHO suggests that the most common types of HAI are urinary tract and respiratory infections, followed by surgical site infections (SSIs). The latter are infections at the surgical site following an operation. These infections can present at three different levels: superficial, deep and organ/space wounds (2).

Rates of SSI vary significantly according to the type of surgery, the anatomical location and the type of

epidemiological follow-up performed. WHO research conducted in 55 hospitals across 14 countries, reported an SSI prevalence of 8.7% (1). According to information

Key Messages

- surgical site infections and blistering are common adverse outcomes of surgical procedures and their care, creating avoidable morbidity and excess financial costs for health services
- our study shows that the use of a polyurethane film surgical dressing can significantly reduce the rate of surgical site infections and other wound complications compared to gauze and tape dressings
- the modest incremental cost of polyurethane film surgical dressings is easily offset by the reduction in the costs associated with treating SSI, making this dressing regime both clinically as well as cost wise effective.

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released by the National Institute for Health and Clinical Excellence (NICE) in the UK, approximately 5% of the four million people who undergo a surgical procedure in the UK every year become infected with an SSI (3), while evidence from an audit study, comprising patients from 13 hospitals across Canada, identified an SSI rate of 6% (4). An important point to note is that many estimates of the rate of SSI are believed to under-report the true scale of the problem, as many infections occur following discharge from hospital.

Although the problem of wounds in the health system is often attributed mainly to chronic wounds (e.g. pressure, vascular and diabetic foot ulcers), a number of studies analysing wounds and their burden, show that surgical wounds represent a significant proportion of the total cost of wound management.

Drew *et al.* (5) conducted an audit of wounds managed in primary and secondary care as well as nursing homes in one region in the UK between 2005 and 2006. They concluded that 43% of patients presented with traumatic or surgical wounds, two thirds of these were treated in the community, and 15% showed signs of local infection. A second study from the UK (6), covering a different population, came to similar conclusions, estimating that just under 50% of wounds being managed across primary and secondary care were surgical/trauma in origin. A further audit study, conducted in Canada (7), found that the most common source of wounds managed in community settings was surgery, accounting for around a third of all wounds. This audit evidence suggests that a significant proportion of all wound care resources, including those in the community, are allocated to the management of surgical wounds.

The resources involved in managing surgical wounds increase dramatically as a result of infections. The cost of managing SSIs varies significantly depending on the nature of the health service and the type of infection. Guidelines from the UK (3) estimate that an infection can double the duration of a hospital stay, place additional burden on nursing staff and require medication, with a resultant cost to the health service of up to £6600. This takes no account of the impact of such infections on patients' quality of life and the indirect costs to society (absence from work, impact on carers, avoidable deaths, etc.) (8).

SSIs are largely avoidable through improved postoperative management of the wound. The use of sterile dressings on sutured surgical wounds is considered the routine conclusion to an aseptic process, the main purpose of which is to stop bacteria from entering the wound, thus preventing contamination and the increased risk of infection (9). Some authors (10) highlight the lack of scientific consensus regarding this type of measure and point to the need for comparative studies with alternative approaches to managing infection risk. As a result of the equivocality of the data, neither the North American Center for Disease Control (CDC) Guidelines for SSI prevention (11) nor the NICE guideline of 2008 (2) make specific conclusions about the choice of dressing to be used to manage the risk of postoperative infection.

As part of routine surgical wound care, healthcare professionals need to monitor wounds by visual inspection and in

Table 1 Ideal specifications of postsurgical dressing

It should allow gaseous exchange
It should act as a barrier against water and liquids but not against water vapour
It should allow monitoring of the wound (visualisation)
It should not adhere too strongly to the wound for easy, non-traumatic removal
It should act as a barrier against bacterial contamination

Source: Cosker *et al.* (14).

some cases direct manipulation is required to check for possible complications and take the necessary measures to resolve these early and quickly.

If wounds are covered with standard postoperative gauze dressing, these must be removed to allow a visual inspection of the wound. Every dressing change is another opportunity for an infection to take place, for healing to be delayed by other possible effects on the area (repeated adhesion of dressings) and, if local infection occurs, for treatment. Gauze surgical dressings carry a risk of other problems such as the development of blisters and erythema caused by the adhesives used to keep them in place (12). In this respect, it is interesting to note the work of Jester *et al.*, which describes an association between the appearance of blisters and orthopaedic surgical processes, with a blister rate of 13% in a convenience sample of 169 orthopaedic surgical patients (13).

Because of that clinical practice guidelines for local care of surgical wounds refer to prevention of SSIs as needing an *interactive dressing* after the operation that allows inspection of the wound, absorbs exudate, reduces pain on removal and the appearance of blisters as well as protecting newly formed tissue (2,12). Notwithstanding the lack of experimental evidence regarding which products to use, some authors, such as Tustanowski (12), stress the need to use moist environment-based dressings on orthopaedic surgical wounds, which offer advantages in the care of surgical wounds, exudate control and reduction in the risk of blistering and infection. Cosker *et al.* (14) list the ideal specifications of a postsurgical dressing (Table 1).

Although articles were published in the early 1990s regarding routine use of polyurethane film dressings to cover surgical wounds (15), such wounds have traditionally been covered with gauze surgical dressings fixed using an adhesive tape system. These dressings have a dual purpose, to cover the wound and absorb any exudate present in the wound area. Although widely used, this approach has a number of drawbacks in practice:

- The dressings are not waterproof (therefore the wound may become contaminated from outside).
- The dressings do not allow the wound to be viewed and must be removed for observation.
- The gauze may stick to the wound, causing trauma on removal.
- The dressing adhesives often cause skin problems such as erythema, blistering and pain on removal.

As a result of these limitations, the use of gauze and tape postoperatively is associated with four potential problems for the healthcare system:

- An increased risk of SSI because they do not serve as a barrier against external bacterial contamination.
- The need for frequent dressing changes to be able to inspect and evaluate the surgical wound. This increases the burden on nurses' time, consumes more supplies (pads, gauze, cleaning materials, sterile materials, etc.) and also increases the risk of SSI because of more frequent manipulation.
- An increased risk of skin infections around wounds due to skin breakage in areas with erythema and blisters.
- The patient also suffers discomfort which interferes with quality of life (inability to shower, pain when removing dressings, etc.).

With the intention of addressing the above problems, specific dressings have been designed for covering surgical wounds based on the moist wound healing environment technique which, as well as protecting the wound from external aggression, allows a degree of exudate management and the possibility of inspecting the wound without removing the dressing. OPSITE® Post-Op Visible (OPOV) is a dressing designed specifically for this purpose. It is a waterproof, bacterial-resistant dressing which is permeable to oxygen and water vapour, comprising a transparent polyurethane film and a lattice structure foam pad (16).

From a clinical standpoint, polyurethane films with absorbent pad offer several advantages over conventional gauze and adhesive dressings:

- It provides protection from bacteria as a result of the transparent polyurethane layer which is impermeable to bacteria, including multi-resistant bacteria.
- It avoids unnecessary dressing changes as the incision is visible through the material. The dressing can therefore be left in place for longer, thus avoiding possible exposure to infection. It also allows for indirect external manipulation of the wound through the polyurethane film, without directly touching the wound.
- The highly absorbent lattice pad maximises absorbency of low level exudate without affecting peri-wound skin.
- It helps to prevent maceration of peri-wound skin, thanks to the polyurethane film, which is highly permeable to water vapour.
- It helps to reduce the risk of blistering, thanks to the low allergy adhesive and the highly extensive film.
- The dressing conforms to the patients' skin and post-operative oedema without restricting limb movements.
- Patients are able to shower with the dressing in place and without compromising dressing performance due to the waterproof properties of the film.
- The surgical wound benefits from healing in a moist environment (17–19).

The above features make it possible to leave the dressing in place for longer time than conventional dressings which leads to savings in materials (gauze, products for

Table 2 SSI criteria according to the North American CDC

Diagnosis requires at least one of the following criteria:
Purulent drainage from the skin or subcutaneous tissue of the incision
Organisms isolated from an aseptically obtained culture
Diagnosis of superficial incisional SSI by the surgeon or attending physician
At least one of the following signs or symptoms of infection: pain or tenderness, localized swelling, redness
The superficial incision is deliberately opened by surgeon, unless the incision is culture-negative

Source: Horan *et al.* (21).

cleaning the wound, sterile material, pads) and healthcare staff hours.

Previous studies have suggested that polyurethane films with absorbent pad might provide both clinical and health economic benefits (16,20), including a reduced rate of infection; a reduction in other skin problems caused by adhesive dressings (e.g. blistering); a reduction in the number of dressing changes and improved quality of life.

This paper reports the findings of a comparative clinical study of the use of gauze and tape compared to a new polyurethane film with absorbent pad (OPOV). The study sought to assess the clinical and economic effectiveness of this dressing relative to gauze/tape dressings.

Patients, material and methods

Patients were recruited across 14 hospital sites in Spain. Patients were randomly allocated to gauze/tape or OPOV over two consecutive 15-days period (i.e. all patients presenting in the first 15 days were treated with one dressing, all patients in the second 15 days with a second dressing). This design of recruiting patients was chosen as a pragmatic means of randomising patients and in order to maximise the recruitment rate.

Patients who met the following criteria were eligible for inclusion in the study:

- over the age of 18 years;
- consented to take part in the study;
- had undergone scheduled surgery, resulting in a post-operative wound anticipated to heal by primary intent;
- had undergone operations leading to wounds with no or low to moderate levels of exudate;
- had undergone clean surgery (i.e. excluded surgical procedures with a known, high-risk of infection, such as colorectal surgery).

The primary endpoint of the study was the rate of superficial SSI identified during the initial hospitalisation. Superficial SSI was diagnosed according to the protocol for monitoring nosocomial infections at each site and the CDC criteria (21) (Table 2). Secondary endpoints included the rate of complications related to the surgical dressing used (specifically erythema and blistering) and the number of dressing changes during the patient's hospital stay.

In addition to these, a number of endpoints relating to dressing performance were also captured during the evaluation. These were measured on a simple Likert scale, scored from 0 (worst score) to 4 (best score) and included:

- ease of application;
- capacity to control exudate;
- adhesiveness;
- visibility of the wound;
- ease of removal;
- adherence during showering;
- overall evaluation by the professional;
- overall evaluation by the patient.

Sample size calculation and statistical analysis plan

Sample size calculations were based on the expected rate of SSI. Two preliminary patient series had found SSI rates of 13.3% in patients treated with gauze and tape. Sample size calculations were based on an alpha risk of 0.05 and a beta risk of 0.2. A total of 195 patients in each treatment group would be required to detect a relative risk of 0.33 or less. A loss-to-follow-up rate of 5% was estimated. Based on these calculations, a target recruitment of 200 patients in each arm was established. The Poisson approximation was used to calculate the sample size using version 7.10 of the Granmo statistical packet.

The information in the case report forms (CRF) was analysed using the SPSS (version 15.0). Descriptive statistics were calculated for group comparison and relative risk measurements, risk differences and number needed to treat to avoid an infection. A health economic analysis was also conducted alongside the trial. The economic analysis extrapolated the findings of the study (i.e. relative SSI rates) and applied these to a hypothetical cohort of 1000 patients, assumed to be treated either with polyurethane film or gauze and tape in a hospital setting. Unit costs were applied to the resource use identified in the study, with costs being derived from published Spanish sources (22) or local data held at investigator sites. Where unit costs were not readily available, assumptions reflecting local practice patterns were adopted.

Ethics and consent

The study protocol was drafted in accordance with the Helsinki protocol and was approved by the Ethics Committee at the Hospital de Elche. Participating patients signed the corresponding informed consent.

The products for evaluation were authorised for use in Spain by the health authorities. The confidentiality of the patients and of the information gathered was guaranteed at all times.

There was no direct compensation paid to investigators who participated in the study or to patients. Smith & Nephew supplied the polyurethane films with absorbent pad dressings for use in the study. No prior commitment to buy was required from the participating hospitals in the study.

Table 3 Patient characteristics at baseline

	Gauze/tape group	OPOV group	
Mean duration of hospital stay (days)	7.19 ± 3.23 (DE)	7.74 ± 3.56 (DE)	<i>P</i> = 0.107
Gender			
Men	85 (43.2%)	94 (43.5%)	
Women	111 (56.8%)	121 (56.5%)	
Specialty			
Orthopaedic	135 (68.9%)	151 (70.2%)	
Cardiac Surgery	16 (8.2%)	15 (7.2%)	
Urological-gynaecological surgery	15 (7.77%)	17 (7.9%)	
Oncological surgery	12 (6.1%)	12 (5.6%)	
Thoracic surgery	10 (5.1%)	11 (5.1%)	
General surgery	8 (4.1%)	9 (4.2%)	
Suture type			
Silk sutures	15.68%	16.92%	
Staples	84.32%	83.08%	
Wound length	16.7 ± 7.62 (DE) cm	16.81 ± 7.92 (DE) cm	<i>P</i> = 0.89
Level of exudate			
Nil	36%	41.6%	
Minimum	36%	38.8%	
Moderate	23.7%	14.4%	
Abundant	4.3%	5.3%	

List of hospitals: Hospital de Elche (Elche, Alicante), Hospital de la Marina Baixa (Villajoyosa, Alicante), Hospital Don Benito (Badajoz), Hospital Infanta Cristina (Badajoz), Hospital de Mérida (Mérida, Badajoz), Hospital Esperit Sant (Santa Coloma Gramanet, Barcelona), Hospital de Coria (Cáceres), Hospital de San Agustín (Linares, Jaén), Hospital MD Andrrsen (Madrid), Hospital de la Merced (Osuna, Seville), Hospital Victoria Eugenia (Sevilla), Hospital de Santa Tecla (Tarragona), Hospital la Fé (Valencia), Hospital Lluís Alcanyis (Xàtiva, Valencia), Hospital Clínico de Valladolid (Valladolid).

Results

A total of 416 patients were included in the study, 199 in the gauze/tape group and 217 in the polyurethane films with absorbent pad group, recruited from 15 hospitals. No patients abandoned the study as a result of the dressing used. A total of five patients were excluded from the analysis, three from the gauze/tape group and two from the polyurethane film with absorbent pad group because data was omitted from the questionnaires that made them non-evaluable. Therefore, data from 411 patients was analysed, 196 from the gauze/tape group and 215 from the polyurethane film with absorbent pad group. Table 3 sets out data for comparison of the two intervention groups.

Superficial SSI identified during the hospital stay is reported in Table 4. SSI was identified in 13 (6.6%) patients in the gauze/tape group and 3 (1.4%) in the polyurethane film with absorbent pad group. The difference between the groups was statistically significant.

Patients treated with the polyurethane film with absorbent pad had a relative risk of infection of 0.21 compared with patients treated with gauze/tape. The difference in the absolute

Table 4 Superficial SSI identified by type of dressing

	Infection of surgical wound	No infection	Total	Incidence of surgical wound
Gauze/tape group	13	183	196	6.6%
OPOV group	3	212	215	1.4%
$P = 0.006$				

Table 5 Non-infectious complications caused by the dressing by type of dressing

	Number of patients with blistering	Rate of blistering
Gauze/tape group	17	8.7%
OPOV group	5	2.3%
$P = 0.04$		
	Number of patients with erythema	Rate of erythema
Gauze/tape group	24	12.2%
OPOV group	6	2.8%
$P < 0.01$		

risk between the two treatment groups (0.066–0.014) was 0.052. The number of patients that would need to be treated with the polyurethane film with absorbent pad to avoid an additional superficial SSI was (1/risk difference) calculated as 21.

With regard to other complications such as blistering and the appearance of erythema, the results are set out in Table 5. Patients treated with the polyurethane film with absorbent pad were significantly less likely than those treated with gauze/tape to experience blistering or erythema.

Patients treated in the gauze/tape group required an average of 4.81 (± 2.29) (SD) dressing changes per week compared to 1.51 (± 0.87) (SD) changes per week in the polyurethane film with absorbent pad group ($P < 0.001$). During the hospitalised follow-up a total of 5.22 (± 3.12) (SD) dressing changes were needed in the gauze/tape group compared to 1.75 (± 1.10) (SD) changes in the polyurethane film with absorbent pad group ($P < 0.001$).

Table 6 sets out comparative information on the performance of the two dressings, based on the perception of their use by professionals and patients. Characteristics were scored on a Likert scale, with 0 as the lowest score and 4 as the maximum score.

The polyurethane film with absorbent pad dressing performance was rated as significantly better than gauze/tape in all domains. Of particular note, the significant difference relating to the visibility of the wound afforded by the polyurethane film and the permanence of the dressing during showering. The former offers significant clinical benefits while the latter can help to improve patient well-being.

An economic analysis was conducted based on the outcomes of the study. The analysis applies the infection rates reported in the study to a hypothetical cohort of 1000 surgical patients treated with either polyurethane film with absorbent

pad or gauze/tape dressing. The analysis considers how the additional costs of the new dressing compare to the potential savings that might have occurred due to improved dressing performance and fewer SSIs. Table 7 reports the costs associated with postoperative management of the surgical site. The unit costs of dressings, supplies and nurse time were derived from participating centres.

The unit cost of the polyurethane film dressing with absorbent pad is greater than gauze/tape, meaning that the use of this dressing postoperatively creates an incremental cost of €2900 (or €2.9 per patient). However, the polyurethane film dressing with absorbent pad is associated with fewer dressing changes, resulting in a reduction in auxiliary dressings (–€900) and a reduction in nurse time of approximately 500 h. Applying a monetary value to the nurse time results in a reduction in total postoperative treatment costs of €9610 in the polyurethane film arm compared to the gauze/tape arm.

Table 8 sets out the information on the costs of managing SSIs in each group. The rate of SSI is derived from the trial. The cost involved in managing an SSI considers only the cost of any additional hospital stay and antibiotics, a treatment approach widely used in Spain. Patients presenting with an SSI in the study were hospitalised for 9.5 (± 5.4) (SD) days and those who did not present with SSI for 7.4 (± 3.3) (SD) days ($P = 0.016$). On this basis, we assume that an SSI adds an incremental 2 days to hospital stay. All patients who experience an SSI are assumed to be treated with antibiotics.

Patients treated with the polyurethane film dressing are expected to experience 52 fewer superficial SSIs than the gauze/tape arm. This is expected to result in a saving of approximately 104 bed days. Savings on the avoidance of antibiotic treatment account were estimated to be in excess of €10,000. The total cost saving resulting from fewer infections is €37,000. Taking into account the total costs of managing the surgical site postoperatively and any SSIs, the incremental investment of €2900 in OPOV has the potential to result in savings of over €45,000.

Discussion

The two intervention groups are comparable in terms of the different demographic variables and the surgical procedures, and the a priori statistical assumptions were satisfied. On this basis, the study can be considered a reliable comparison of gauze/tape and OPOV in the treatment of postsurgical wounds.

Our findings suggest that the new polyurethane film dressing can result in dramatically reduced levels of superficial SSIs compared to conventional postoperative dressings. This is attributable to the features of OPOV which meet the ideal criteria for a postsurgical dressing designated by Cosker *et al.* (14). There is no doubt that the creation of a moist wound healing environment together with the barrier properties of the polyurethane film dressing and the possibility to view the wound from the outside reduces the risk of hospital-acquired infection through numerous mechanisms, including:

- efficient protection of the wound from the risk of external contamination;

Table 6 Dressing performance (according to the Likert Scale scoring from 0 = lowest score to a maximum score of 4)

	Gauze/tape group	OPOV group	
Ease of application	2.62 ± 1.01 (SD)	3.71 ± 0.45 (SD)	$P < 0.001$
Capacity to control exudate	1.99 ± 0.91 (SD)	3.51 ± 0.66 (SD)	$P < 0.001$
Adhesiveness	2.49 ± 0.77 (SD)	3.80 ± 0.47 (SD)	$P < 0.001$
Conformability to the wound	2.22 ± 0.88 (SD)	3.63 ± 0.51 (SD)	$P < 0.001$
Visibility of the wound	0.32 ± 0.61 (SD)	3.54 ± 0.77 (SD)	$P < 0.001$
Ease of removal	2.34 ± 0.84 (SD)	3.71 ± 0.47 (SD)	$P < 0.001$
Ability to shower with the dressing in place	0.59 ± 0.89 (SD)	3.71 ± 0.5 (SD)	$P < 0.001$
Overall evaluation by the professional	2.07 ± 0.72 (SD)	3.68 ± 0.49 (SD)	$P < 0.001$
Overall evaluation by the patient	2.52 ± 0.85 (SD)	3.61 ± 0.59 (SD)	$P < 0.001$

Table 7 Direct costs of postoperative management of the surgical site

	Gauze/tape treated patients	OPOV treated patients
Number of patients treated	1000	1000
Number of dressings/patient during hospitalisation*	5	2
Cost/dressing	€0.3	€2.2
Total cost of dressing materials	€1500	€4400
Cost of auxiliary dressings/supplies per patient per dressing change†	€0.3	€0.3
Total cost of auxiliary dressings/supplies	€1500	€600
Nursing time/dressing change (min)‡	10	10
Total nursing time (h)	833	333
Cost of nursing time/minute	€0.387	€0.387
Total nursing time costs	€19,350	€7740
Total treatment costs	€22,350	€12,740

*Trial results report 5.22 versus 1.75 dressing changes during hospitalisation. These are rounded off for the purposes of this analysis.

†Assumption based on information provided by investigator sites. This covers the cost of gloves, gauze, saline etc.

‡Assumption based on information provided by investigator sites.

- allowing the wound to be seen and manipulated externally without the risk of infection;
- extended periods between dressings and a smaller number of manipulations.

What in fact means also less dressing removal procedures and thus less infective problems related with the manipulation of the wounds.

The superficial SSI rates reported in this study corroborate those reported by other investigators who have compared conventional postoperative dressing with polyurethane film (15). For example, Roberts *et al.* reported an SSI rate of 6.4% in outpatient surgery patients treated with conventional dressings (Mepore, Mölnlycke Health Care, Gothenburg, Sweden) as opposed to 4.8% treated with OP SITE (Smith & Nephew, Hull, UK) (23). Some studies have questioned the use of advanced postoperative dressings on surgical patients and suggested that there is no difference in the rate of complications (including SSI) between advanced and traditional approaches

Table 8 Cost of managing superficial SSI

	Gauze/tape treated patients	OPOV treated patients
Number of patients treated	1000	1000
Predicted number of SSIs*	66	14
Incremental hospital stay as a result of SSIs (days)†	2	2
Cost per hospital day‡	€350	€350
Cost of hospital stays for SSI	€46,200	€19,600
Cost/patient of antibiotics for the treatment of SSI episode‡	€200	€200
Total cost of antibiotic treatment for SSIs	€13,200	€2800
Total cost of treating SSIs	€59,400	€22,400

*Based on results reported in the trial.

†Trial reported an incremental length of stay of 2.1 days associated with SSI.

‡Assumption based on information provided by investigator sites.

(9). While our study reports similar levels of SSI in patients treated with conventional dressings in these studies, the SSI rate in those treated with OPOV is significantly lower.

Our findings also suggest that other complications, such as blistering and the erythema related to adhesive tape, were also significantly less frequent in the polyurethane film with absorbent pad group. These complications can cause impaired patient well-being and can also be risk factors for infection. With regard to the appearance of blisters in surgical patients, this is an area analysed by a number of authors who agree that it is a recurrent and relatively overlooked problem, which they link directly to the use of non-elastic tape that forms blisters when swelling occurs in the wound area (12–14,24,25). A previous study of patients undergoing hysterectomy reported a blistering rate of 0% in patients treated with OP SITE Post-Op compared to 25% of the patients treated with Mepore (24). Some previous studies have reported higher rates of blistering with OPOV, for example, Jester (13) reported an incidence of 9% in patients treated with OPSITE Post-Op (the previous version of OPOV which did not allow for visibility of the wound) and 14.3% in patients treated with the conventional dressings (Mepore), while Cosker *et al.* reported rates of 6% with OPSITE Post-Op and of 16% with a polyurethane film with an absorbent conventional dressing approach (Tegaderm, 3M & Primapore, Smith & Nephew) (14). The differences

between studies may be due to different indications considered or underlying risk factors for infection in patients recruited. This study benefits from including patients recruited following a range of surgical procedures, although it should be noted that patients undergoing 'dirty' surgery were excluded from the analysis.

There are few reference studies focusing on variables related to the behaviour of surgical dressings and quality of life. The results of our study agree with those of another study on the behaviour of OPOV, highlighting the superiority of OPOV compared to the gauze/tape in all the dimensions described in Table 6 (16).

These results suggest that OPOV can lead to improved dressing performance and fewer complications than gauze/tape. Critically, the economic analysis suggests that these benefits can be attained with only a modest level of investment. This dressing is marginally more costly than gauze/tape (a difference of €1.9 per dressing), meaning the acquisition cost of postoperative dressings is expected to increase marginally when this is used. However, as a result of fewer dressing changes, the incremental costs of the dressing are more than offset by savings in the cost of auxiliary dressings and nurse time. Taking into account the costs associated with treating SSIs makes the potential savings even more dramatic. Even using a partial analysis, our findings suggest that for every €1 spent on OPOV, there is a potential saving of approximately €20. While it is recognised that some of these savings may not materialise as 'cash savings' (e.g. nurse time), releasing resources in this way allows them to be allocated to other activities. It should also be noted that any cost savings generated in the analysis might be considered to be conservative. The cost of a superficial SSI adopted in the study was significantly lower than estimates reported elsewhere (26), no account was taken of the cost of treating complications other than SSIs, nor have we attempted to capture the longer-term costs and consequences of SSIs which often occur following discharge. This could be one of the limitations of our study. On this basis, the true cost savings associated with the polyurethane film dressing may be even greater than reported here.

Health economics approaches are becoming crucial in the assessment of new wound care products, specially in austerity markets like the Spanish one, where economic resources for health care are being reduced.

Limitations of the study

The study adopted a pragmatic design, meaning there are a number of limitations which should be acknowledged. Gauze tape dressings are widely used in Spain and this is the reason they were selected as a comparative arm.

Patients were randomised by weeks of treatment although this is not believed to have introduced any systematic bias into the evaluation. Although a computer-generated random list is better than the system that we used, it allowed lesser interference in usual clinical practice in the participating centres. Blinding investigators and/or assessors were not possible, due to the visible differences in the dressings. This

may have affected self-reported perceptions of the dressings, but is unlikely to have affected the objectively reported outcomes, such as reported rates of superficial SSI or periwound complications. The two patient groups were reasonably well-matched at baseline and there do not appear to be any significant differences between the treatment arms. Finally, while the economic analysis was planned a priori, it should be noted that the analysis is only partial, as it quantifies treatment cost and selected consequences. This was a conscious decision to avoid over-burdening the data collection and to make the findings as relevant as possible to the hospital-based decision makers. However, the result is that the findings might be regarded as conservative.

Conclusion

The findings suggest that the routine use of polyurethane film surgical dressings can significantly reduce the rate of superficial SSI compared to traditional postoperative management. Clinicians rated the performance of OPOV dressings as superior to traditional dressings and there were fewer periwound complications reported. Economic analysis suggests that the incremental acquisition cost of OPOV dressings is marginal and can be entirely offset as a result of fewer dressing changes and improved outcomes. As a result, OPOV delivered improved outcomes at a lower treatment cost than conventional postoperative dressings.

Our findings try to answer some open questions in reviews about the choice of surgical dressings based on moist environment technique,

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