The role of prophylactic, single-use, negative pressure wound therapy dressings in wound management following breast surgery

Authors:
Shona Tormey, Helen Earley, Samantha Sloan, Helen Mathers, Manvydas Varzgalis, Sami Abd El Wahab, Brendan Skelly, Gareth Irwin, Nora Scally, Charlotte Cosgrove, Eimer McGeown, Tim Styche and Catherine Whittall

In breast surgery, surgical site infections and other surgical site complications are major issues. These can impact patients' morbidity, quality of life and treatment pathways, with economic implications for healthcare providers. Four centres in Ireland and Northern Ireland implemented prophylactic single-use negative pressure wound therapy (sNPWT) following breast surgery and captured data from patients at risk of surgical site complications. Analyses of complications, costings and estimated reduction in length of hospital stay with sNPWT were undertaken. The study demonstrated the efficacy and cost-effectiveness of sNPWT for reducing complications following breast surgery across a range of oncological and cosmetic indications in a real-world clinical setting.

Breast surgery represents an extensive and demanding interventional paradigm that encompasses a wide range of oncological and cosmetic indications. These include augmentation, reduction, mastectomy and mastopexy procedures and therapeutic mammoplasty for treatment of breast cancer. However, incidence of complications, particularly surgical site infections (SSIs), are a major problem for post-surgical care. According to previous literature reports, incidence of SSIs after breast surgery ranges between 0.8% and 26% (Nahabedian et al, 2003; Vilar-Compte et al, 2004; Prospero et al, 2006; Ruvalcaba-Limon et al, 2006; Neumayer et al, 2007; Edwards et al, 2009; Tanner et al, 2011; Degnim et al, 2012).

Surgical site complications (SSCs) can have a deleterious effect on patient morbidity and quality of life by prolonging wound healing, extending hospital stays and impacting delivery of post-surgical therapy, such as adjuvants for cancer treatment (Olsen et al, 2008; McIntosh and O'Donoghue 2011). The incidence of SSIs and SSCs can result in substantial economic and resource implications for healthcare providers, in terms of costs imposed by impeded perioperative treatment pathways and mitigatory interventions (Olsen et al, 2008; Jenks et al, 2014). Thus, interventional strategies for mitigating post-surgical complications must achieve both clinical efficacy and cost-effectiveness.

A number of strategies have been employed to reduce the risk of SSCs, including SSIs, such as administration of prophylactic antibiotics, use of various disinfectants and skin preparations, meticulous handling of the implant to reduce the risk of introduction of foreign material or bacteria into the breast pocket, and the application of negative pressure wound therapy (NPWT) dressings (Ploegmakers et al, 2017).

In particular, single-use NPWT (sNPWT) is gaining popularity in the management of complex wounds with unfavourable healing factors to aid healing by primary intention. A growing body of evidence supports sNPWT in the management of complex wounds across several surgical specialities, including obstetrics, gastrointestinal surgery and orthopaedics (Brem et al, 2014; Hyldig et al, 2016; Karlakki et al, 2016; Strugala et al, 2017; Sahebally et al, 2018; Yu et al, 2018). As well as reducing the risk of SSCs and SSIs, these provide increased portability and comfort for patients (World Union of Wound Healing Societies [WUWHS], 2016; National Institute for Health and Care Excellence [NICE], 2019). The application of NPWT to closed incisions deemed at high risk of SSC or

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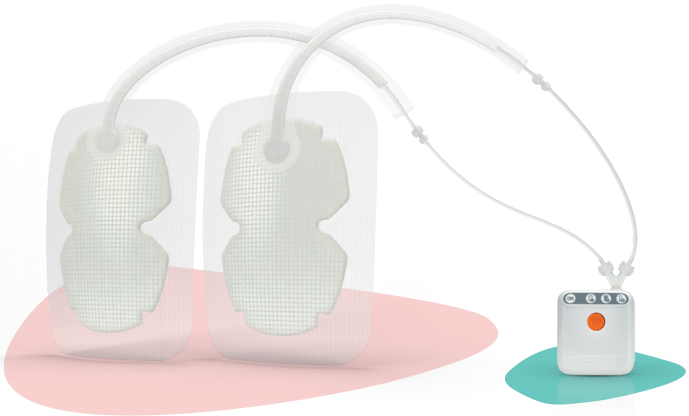
PICO◊ sNPWT was observed to reduce the incidence of wound dehiscence by 75%*, thus reducing the potential for delay in the commencement of adjuvant therapy[1]



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* In a breast surgery study, n=24; PICOsNPWT (4.2%) compared vs standard dressings (16.7%) **References: 1.** Holt R, Murphy J. PICO◊ incision closure in oncoplastic breast surgery: a case series. *British Journal of Hospital Medicine*. 2015;76(4). **2.** Saunders C, Nherera LM, Horner A, Trueman P. Single-use negative-pressure wound therapy versus conventional dressings for closed surgical incisions: systematic literature review and meta-analysis. BJS open. 2021 Jan;5(1):zraa00a3.

Table 1: Patient demographics.			
Age	**Standard care (%)**	**sNPWT (%)***	**Total (%)**
<30	4 (5.8)	2 (2.2)	6 (3.7)
30–39	6 (8.7)	11 (12.0)	17 (10.6)
40–49	16 (23.2)	18 (19.6)	34 (21.1)
50–59	22 (31.9)	33 (35.9)	55 (34.2)
60–69	8 (11.6)	16 (17.4)	24 (14.9)
70–79	9 (13.0)	9 (9.8)	18 (11.2)
80–89	4 (5.8)	2 (2.2)	6 (3.7)
90	0 (0)	1 (1.1)	1 (0.6)
Total	69 (100.0)	92 (100.0)	161 (100.0)
BMI	**Standard care (%)†**	**sNPWT (%)‡**	**Total (%)**
<18.5	1 (1.8)	1 (1.1)	2 (1.4)
18.5–24.9	10 (18.2)	32 (34.8)	42 (28.6)
25–29.9	14 (25.5)	26 (28.3)	40 (27.2)
30–34.9	17 (30.9)	18 (19.6)	35 (23.8)
>35	13 (23.6)	15 (16.3)	28 (19.1)
Total	55 (100.0)	92 (100.0)	147 (100.0)

Missing data: *1, †14, ‡1.
BMI = body mass index; sNPWT = single-use negative pressure wound therapy

Table 2: Procedures and incisions.		
Procedure	**Standard care (%)**	**sNPWT (%***
Augmentation	3 (4.3)	0 (0)
Axillary clearance	1 (1.4)	2 (2.2)
Delayed reconstruction	1 (1.4)	7 (7.5)
Mastectomy	13 (18.8)	17 (18.3)
Mastopexy	2 (2.9)	7 (7.5)
Reduction	7 (10.1)	11 (11.8)
Simple mastectomy	17 (24.6)	18 (19.4)
Therapeutic mammoplasty	5 (7.2)	6 (6.5)
Wide local excision	14 (20.3)	14 (15.1)
Other	6 (8.7)	11 (11.8)
Incision	**Standard care (%)**	**sNPWT (%)**
Circumareola	14 (21.9)	5 (5.4)
Transverse	33 (51.6)	60 (64.5)
Vertical	5 (7.8)	6 (6.5)
Wise pattern	12 (18.8)	22 (23.7)

sNPWT = single-use negative pressure wound therapy

in high-risk surgeries is supported by recent consensus recommendations (Willy et al, 2017).

The PICO™ sNPWT system (Smith + Nephew, Hull, UK) delivers an effective nominal pressure of –80 mmHg to the wound. One dressing can be used for up to 7 days and can manage up to 150 ml of exudate from the wound.

A number of studies have demonstrated the use of sNPWT in reducing the incidence of complications following breast surgery. A case series of patients who underwent mammoplasty (*n*=21) and Wise pattern skin-sparing mastectomy (*n*=3), with contralateral symmetrising surgery, found that the side treated with sNPWT had a reduced rate of wound breakdown (4.2%) versus the contralateral side managed with standard wound dressings (Holt et al, 2015).

More recently, an intra-patient, multicentre randomised controlled trial of sNPWT, used prophylactically on patients undergoing bilateral reduction mammoplasty, demonstrated significant reductions in wound complications, including dehiscence, when compared to standard care (Galiano et al, 2018).

Further evidence from a randomised control study of patients undergoing bilateral reduction mammoplasty showing significant reductions in wound healing complications and significant improvements in scar quality (at 42 and 90 days postoperatively) with sNPWT compared to standard care (Tanaydin et al, 2018).

To add to the current body of evidence, a post-market, observational, multicentre data collection study of prophylactic sNPWT in clinical practice was undertaken, investigating the impact of this dressing on the incidence of complications in complex breast wounds, across a range of incisional indications, when compared to the standard of care.

Method

Datasets from patients, considered to be at risk of SSC following breast surgery were obtained. Data were collected from four sites across Ireland and Northern Ireland that had implemented the use of PICO sNPWT following breast surgery, in overlapping time periods between 2017 and 2019. This comprised two cohorts of patients who received postoperative wound care after undergoing breast surgery. One cohort received sNPWT prophylactically following its implementation into the surgical service, and a historic comparator cohort (prior to the implementation of sNPWT) received standard care dressings (the standard of care). Clinicians reported any recognised complication post-surgical intervention, namely SSI, wound dehiscence, seroma, necrosis and haematoma.

Anonymised data were extracted using the SNAP Surveys tool with data analysed using SAS 9.4. It was not necessary to seek ethical approval or patient consent, due to the nature of data collection (observational service evaluation), as part of routine clinical practice. Clinicians from

Table 3: Risk factors.		
Risk factor	**Standard care (%)**	**sNPWT (%***
Steroids	2 (2.9)	0 (0)
Smoker	17 (24.6)	19 (20.4)
Nicotine replacement therapy	0 (0)	2 (2.2)
Diabetes	8 (11.6)	8 (8.6)
Neoadjunctive chemotherapy	2 (2.9)	14 (15.1)
Previous chemotherapy	3 (4.3)	6 (6.5)
Previous radiotherapy	1 (1.4)	6 (6.5)
Previous SSI	1 (1.4)	1 (1.1)
Other recent operation	5 (7.2)	19 (20.4)
High BMI (≥30)	30 (43.5)	33 (35.5)

BMI = body mass index; sNPWT = single-use negative pressure wound therapy; SSI = surgical site infection.

each participating centre sought all approvals required for inclusion of the data from their centre in the overall analysis. Due to the nature of the study and small sample sizes, no formal matching was undertaken.

Comparative frequency counts for demographic details, procedure numbers, risk factors and complications were conducted. Fisher's exact test for the difference in surgical complication rate was calculated and a simple costing analysis was undertaken to estimate the financial impact of implementing the sNPWT device in post-surgical care.

In this costing analysis, the cost of an SSI was estimated at £2,239.28 (€2,642.35). This was derived from a published analysis of the clinical and economic burden of SSIs undertaken by Jenks et al (2014), inflated using Personal Social Services Research Unit inflation indices and converted to local currency (conversion rate of €1.18:£1, as of December 2019). The sNPWT device, if used, was costed at an estimated £118.64 (€140) per device. Costs were modelled over a population of 100 patients to address the imbalance in patient numbers between the two cohorts. Based on the assumption that SSI results in an incrementally longer length of stay in hospital by 3 days (Jenks et al, 2014), a further analysis was conducted to estimate the impact of sNPWT on hospital length of stay.

Results

Data from 162 patients who underwent breast surgery were captured and used for the analysis; this included 69 patients who received standard care dressings and 93 patients who received sNPWT prophylactically. Patients undergoing surgeries prior to the site's implementation of the sNPWT device were treated with standard care dressings (the standard of care). Sutures were used in all patients in the standard care cohort (in combination with glue and/or staples as appropriate) and in 98.9% of patients in the sNPWT cohort. One patient in the sNPWT cohort was not sutured, and received steri-strips and glue, as clinically appropriate. Moreover, 89.9% of patients in the standard care cohort and 96.7% of patients in the sNPWT cohort were reported to have received antibiotics during their surgical episodes. It was reported that 91 of the 93 patients in the sNPWT cohort had the sNPWT device applied in the operating theatre, in line with recommendations, while the remaining two patients had the device applied on the ward within 24 hours of the surgery.

Demographic distributions of age and body mass index (BMI) groups are presented in *Table 1*. Patients in both cohorts were distributed across several age and BMI categories; distributions of both variables were similar in both cohorts *[Table 1]*. In both cohorts, the mean age was 54 years. The mean BMI in the standard care and sNPWT cohorts were similar, at 25.7 kg/m^2 and 24.9 kg/m^2, respectively.

Patients received standard care or sNPWT after having undergone various types of breast surgeries *[Table 2]*. For each represented indication, the frequencies of patients receiving standard care or sNPWT were similar. The majority of patients in both cohorts had transverse incisions. Circumareola incisions were more commonly observed in the standard care group than the sNPWT group, 21.9% and 5.4% respectively *[Table 2]*.

Frequencies of patients in both cohorts with risk factors for SSIs and other surgical complications are shown in *Table 3*. In patients who received either standard care dressings or the sNPWT device, the most common risk factor was reported to be a high BMI ≥30 kg/m^2. The mean numbers of risk factors in patients receiving standard care and sNPWT were 1 and 1.16, respectively.

Data relating to the incidence rates of complications are shown in *Table 4* and *Figure 1*. In the cohort that received standard dressings, 30.4% of patients experienced complications. Following the implementation of the sNPWT device, this halved to 15.1%, a significant reduction (P=0.01). Analysis of complications by type showed that, with the exception of organ space SSI, the incidence rates of patients experiencing each type of complication were reduced with the application of sNPWT versus standard care. Notably, implementation of sNPWT led to a decrease in the incidence of

Table 4: Incidence rates of complications.*			
Complications	**Standard care (%)**	**sNPWT (%)**	**Statistical significance**
Unknown	3 (4.3)	9 (9.7)	–
No	45 (65.2)	70 (75.3)	–
Yes	21 (30.4)	14 (15.1)	p=0.01

*Complication incidence rate is on the basis of the percentage of patients who reportedly experienced a complication (patients may have experienced more than one complication).BMI = body mass index; SSI = surgical site infection; sNPWT = single-use negative pressure wound therapy.

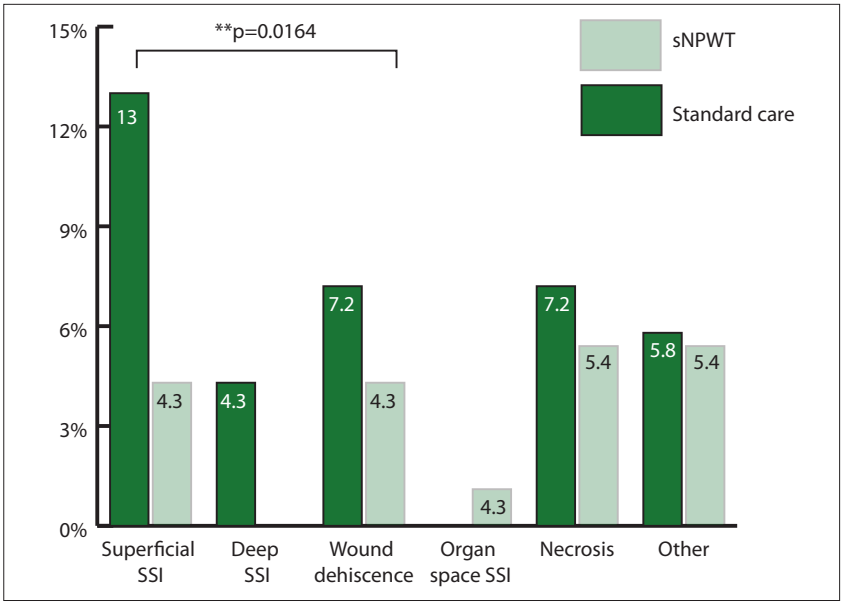

Figure 1. Complication rate by patients. The complication rate is on the basis of the percentage of patients who were reported to have the given complication. SSI = surgical site infection; sNPWT = single-use negative pressure wound therapy.

major complications (superficial SSI, deep SSI and wound dehiscence) from 24.6% (standard care; 13% + 4.3% + 7.2%, respectively) to 9.8% (sNPWT; 4.3% + 0% + 4.3%, respectively), a significant change (*P*=0.0164). Further analysis of the patients who developed wound complications revealed that in the standard care group 23.5% were smokers, compared to 15.8% of the sNPWT group.

The findings of the economic analysis, comparing the estimated costs of SSCs incurred with standard care versus with sNPWT (per 100 patients), are presented in *Figure 2*. It was estimated that with standard care dressings, the costs arising from SSCs would total £55,982 (€66,059) per 100 patients. Although application of sNPWT was estimated to cost approximately £11,864 (€14,000) per 100 patients, it is expected to reduce the costs directly attributed to incidence of SSCs to £22,393 (€26,424) per 100 patients. The total cost of using sNPWT is therefore expected to be £34,258 (€40,424) per 100 patients. Thus, the implementation of prophylactic postoperative sNPWT in the treatment of 100 patients undergoing breast surgery would be expected to lead to a cost reduction of £21,725 (€25,635; 38% reduction), a saving of £217 (€256) per patient treated (*Figure 2*).

Data from modelling analysis indicated a reduction of 15 major complications per 100 patients. As such, it is estimated that per 100 patients the introduction of prophylactic sNPWT could reduce total bed-day utilisation by 45 days.

Discussion

The use of sNPWT as a therapeutic adjunct to various types of surgeries has been widely studied (Brem et al, 2014; Kostaras et al, 2014; Payne et al, 2014; Hyldig et al, 2016; WUWHS 2016; Strugala and Martin 2017; NICE 2019). In particular, its effectiveness in postoperative healing following breast surgery is an emerging, promising therapeutic area, supported by a growing body of evidence (Murphy et al, 2015; Ferrando et al, 2018; Galiano et al, 2018; Tanaydin et al, 2018; Irwin et al, 2020). This observational data analysis is intended to complement current clinical evidence, as well as demonstrate cost-effectiveness in a real-world clinical setting.

Incisional breast surgery is necessary in a wide range of oncological, therapeutic and cosmetic indications; these were well-represented among patients in this study (*Table 2*). Sutures were used in virtually all patients for incision closure (primary intent), in both sNPWT and standard care cohorts. Moreover, this analysis demonstrates the versatile application of sNPWT to various incisional wound types (*Table 2*). Wise pattern incisions, mastectomies and breast conserving surgeries, which are surgical procedures that can lead to complex wounds, are represented in sNPWT cohort in this study. Notably, approximately 24% of the patients who received sNPWT had surgery involving a Wise pattern incision, a particularly challenging wound configuration for healing because it results in a T-junction.

The observation that sNPWT reduced incidence of incision-related complications (versus standard care) is consistent with previous studies (Murphy et al, 2015; Ferrando et al, 2018; Galiano et al, 2018; Tanaydin et al, 2018; Irwin et al, 2020). In particular, there was an observably steep decline in SSI risk. Notably, after sNPWT was implemented, there was a 67% reduction in the rate of superficial SSIs and no incidences of deep SSIs were reported.

A number of mechanisms have been proposed for the observed efficacy of sNPWT

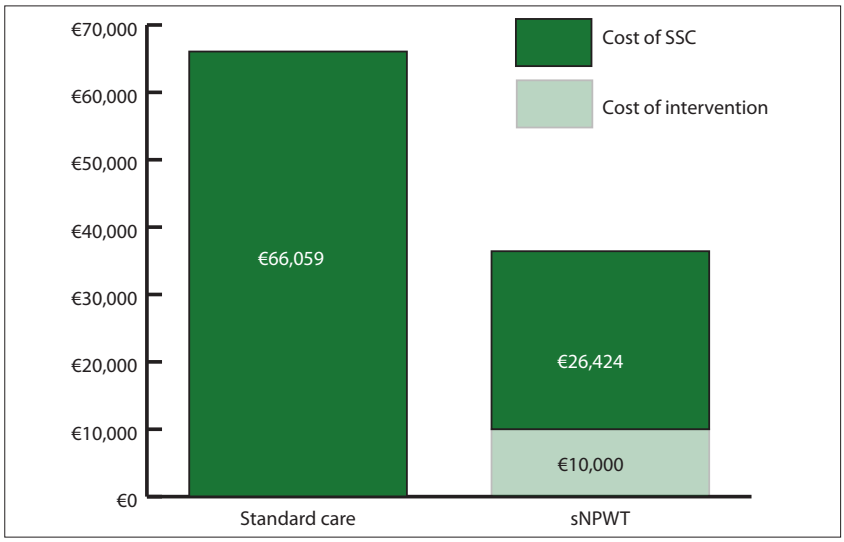

Figure 2. Estimated cost breakdown per 100 patients.
SSC = surgical site complication; sNPWT = single-use negative pressure wound therapy.

in wound healing and avoidance of SSCs. NPWT is thought to promote superior wound healing through promoting wound contraction (Borgquist et al, 2010), removal of excess fluid reducing seroma formation (Huang et al, 2014) and stimulating angiogenesis around the area (Hyldig et al, 2016; Strugala and Martin 2017; Sahebally et al, 2018; Yu et al, 2018).

The clinical and economic burdens of SSIs and other SSCs following a range of surgeries are well-established (Jenks et al, 2014). A single-hospital surveillance study of SSIs found that the median additional cost of SSIs, in patients who had breast surgery was £1,469 (Jenks et al, 2014). A surveillance study of patients undergoing primary breast surgery found that incidence of SSI was associated with an average additional cost of £1,443 per patient, with the greatest costs associated with length of stay and readmissions (Tanner et al, 2011). In a large US database study, it was found that of $69,781 (approximately £50,000), the total adjusted cost of lumpectomy with oncoplastic reconstruction and whole breast radiation, $2,242 (approximately £1600) was attributed to complications within 2 years of diagnosis (Hwang et al, 2017).

Given that treatment pathways for incisional surgery are typically resource-intensive and healthcare providers are under increasing financial constraint, there is growing interest in the cost-effectiveness of sNPWT. A 2016 international consensus recommended the application of NPWT to closed incisions in high-risk surgeries and patients deemed to be at high-risk of complications, recognising its potential cost benefits for healthcare providers (Willy et al, 2017).

A recent UK-based single-site prospective database study (Irwin et al, 2020) demonstrated that sNPWT in prepectoral implant reconstruction led to a reduction in wound breakdown and implant loss, leading to a cost saving of £426 per patient, compared with standard dressings. Consistent with this, the findings of our economic and modelling analyses suggest a saving of approximately £217 (€256) per patient, and a reduction in total bed-day utilisation by 45 days per 100 patients. This is the first published retrospective multicentre study to demonstrate both the clinical and economic benefit of sNPWT in reducing SSCs across a range of breast surgeries.

Complications that affect cosmetic appearance, treatment pathway progression or result in revision can be psychologically taxing for women, in what is often an already distressing situation (for example, in oncological cases). Although not formally investigated in this study, we speculate that application of sNPWT following breast surgery, could improve patients' self-esteem and quality of life. Previous studies lend support to this. Irwin et al (2020) previously reported that patients who received sNPWT following prepectoral breast reconstruction experienced reduced implant failure, a source of psychological distress, compared with those receiving standard dressings. Tanaydin et al (2018) demonstrated reduced complications and improvement in aesthetic quality of scarring with NPWT following reduction mammoplasty, versus fixation strips. Hyldig et al (2020) found that postpartum mothers who received incisional sNPWT for caesarean section were generally more satisfied with the cosmetic appearance of scarring than a control group receiving standard dressings.

In addition to the clinical and economic outcomes of sNPWT following breast surgery, the impact on patient outcomes pertaining to satisfaction and quality of life is also a significant consideration. It is anticipated that further studies will investigate this important component of patients' post-surgical treatment pathways.

This study has a number of strengths and limitations. The strengths lie in the multicentre nature of the study and the fact that it investigated both clinical and economic outcomes. Given that this was an observational, real-world study, randomisation and blinding were not necessary, although this meant that there was an imbalance in patient numbers between the sNPWT and standard care cohorts. However, the economic and modelling analyses

Acknowledgement

The authors would like to acknowledge Sherwin Barretto (Medical Writer, Smith+Nephew) for his support with drafting this manuscript.

Shona Tormey *is Consultant General and Breast Surgeon, University Hospital Limerick, Limerick, Ireland;* ***Helen Earley*** *is Specialist Registrar in General Surgery, Royal College of Surgeons, Dublin;* ***Samantha Sloan*** *is Consultant General and Breast Surgeon, Belfast City Hospital, Belfast, Northern Ireland;* ***Helen Mathers*** *is Consultant Breast Surgeon, Craigavon Area Hospital, Portadown, Northern Ireland;* ***Manvydas Varzgalis*** *is Consultant General and Breast Surgeon, Letterkenny University Hospital, Ulster, Ireland;* ***Sami Abd El Wahab*** *is Specialist Registrar General, Breast and Endocrine Surgery, Beaumont Hospital, Dublin, Ireland;* ***Brendan Skelly*** *is Consultant General and Oncoplastic Breast Surgeon, Altnagelvin Area Hospital, Waterside, Northern Ireland;* ***Gareth Irwin*** *is Consultant Breast Surgeon, Belfast City Hospital, Belfast, Northern Ireland;* ***Nora Scally*** *is Locum Consultant Breast Surgeon, Craigavon Area Hospital, Portadown, Northern Ireland;* ***Charlotte Cosgrove*** *is Specialist Registrar, Belfast Trust, Belfast, Northern Ireland;* ***Eimer McGeown*** *is Breast Care Nurse Specialist, Craigavon Area Hospital, Portadown, Northern Ireland;* ***Tim Styche*** *is Market Access and Health Economics Manager, Smith+Nephew;* ***Catherine Whittall*** *is Health Economics and Outcomes Research Manager, Smith+Nephew*

were conducted on a basis of 100 patients to mitigate against this imbalance.

Conclusion

In conclusion, this study demonstrates the efficacy and cost-effectiveness of sNPWT for reducing complications following breast surgery, across a range of oncological and cosmetic indications, in a real-world clinical setting. With healthcare providers being under increasing pressure to provide value-based justifications for choices of surgical wound intervention, the insights of this study will be important in informing decision-making. There is a need for further prospective RCTs to provide further evaluation of sNPWT within this surgical indication.

WINT

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